



European Monitoring Centre
for Drugs and Drug Addiction

EARLY WARNING SYSTEM

NATIONAL PROFILES



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EMCDDA project leaders
Ana Gallegos and Roumen Sedefov

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This publication is available in English.

Cataloguing data can be found at the end of this publication.

Luxembourg: Publications Office of the European Union, 2012

ISBN: 978-92-9168-500-4

doi: 10.2810/51894

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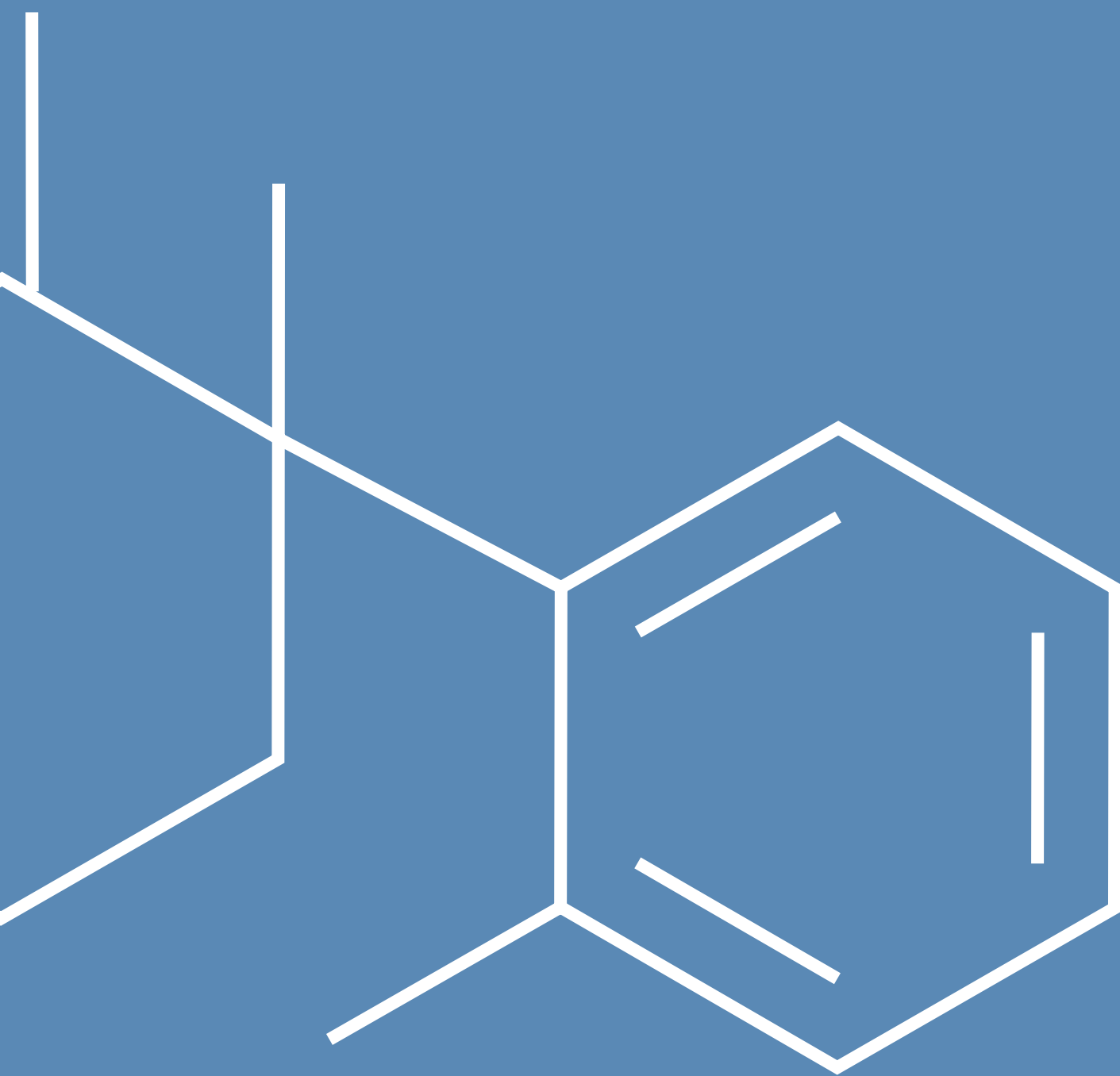


European Monitoring Centre
for Drugs and Drug Addiction

Cais do Sodré, 1249-289 Lisbon, Portugal
Tel. (351) 211 21 02 00 • Fax (351) 218 13 17 11
info@emcdda.europa.eu • www.emcdda.europa.eu

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Introduction

New psychoactive substances (NPAS) and 'legal highs' have become a global phenomenon which is developing at an unprecedented pace. In 2011, 49 new psychoactive substances were officially notified for the first time in the European Union. This represents the largest number of substances ever reported in a single year, considerably up from 2010 (41 substances) and 2009 (24 substances). The speed at which new drugs appear on the market — which is reflected not only in the sheer number of substances, but also in their diversity and in how they are produced, distributed and marketed — challenges the established procedures for monitoring and calls for a re-evaluation of the information sources used and the ways in which we disseminate information to inform policy, practice and the general public.

The EU mechanism to monitor new drugs — the early warning system (EWS) — as established by Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances ⁽¹⁾ has been one of the innovative, successful and highly visible activities carried out by the EMCDDA during the last years. It allows the European Union institutions and Member States to rapidly exchange information and to act on new narcotic and psychotropic substances that appear on the European Union drug scene. It also provides the possibility of a risk assessment to be conducted and, if merited, the control of specific new psychoactive substances.

The European EWS on new psychoactive substances is a multidisciplinary network of 30 national early warning mechanisms ⁽²⁾ which collect, appraise and rapidly disseminate information on new drugs and products that contain them. It is implemented primarily by the EMCDDA and its partners in the Member States (the Reitox network), in cooperation with Europol, and with the active contribution of the European Medicines Agency (EMA) and the European Commission. The EWS builds on a variety of information sources such as health and care providers, law enforcement organisations, sources closer to drug users, media, the Internet, etc.

The considerable added value of the EWS is that it not only fulfils the requirements of Council Decision 2005/387/JHA, but is also an important part of the overall EU drug information system. The EWS has been successful in fulfilling its role as a low-cost mechanism to share information on new threats, and as a catalyst for action, when this has been merited. In the last years, the EWS has established itself as a real-time vehicle for the exchange of multidisciplinary information which is now extensively used by forensic science community, health and law enforcement professionals throughout Europe. Furthermore, the EWS is highly recognised among professionals outside the EU who are increasingly relying on it as an alert system on new psychoactive substances and to remain up to date.

Responding to the need to remain vigilant and react rapidly to new substances and products identified, the EWS has increased its operational capacity and expanded to include not only new forensic science and toxicological laboratories, but also a range of health and law enforcement professionals as well as independent researchers. Investment to allow better detection of new drugs by improving the capacity for investigative forensic and toxicology analysis and to increase the capacity to identify and monitor patterns and trends in their use linked to the EWS are therefore essential.

Council Decision 2005/387/JHA provides legally binding definitions of the substances it covers; however, there are other terms in common usage in this area and confusion is possible. For example, historically, new psychoactive substances have been often referred to as 'designer drugs', although today the term 'legal highs' is more often used. Much overlap exists between these terms but for the purpose of the EWS, it is worth delineating the concepts.

Council Decision 2005/387/JHA takes the United Nations drug control conventions as a point of reference and defines a new psychoactive substance as '*a new narcotic drug or a new psychotropic drug in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs ⁽³⁾, and that may pose*

⁽¹⁾ Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances (Official Journal L 127, 20.5.2005).

⁽²⁾ The 27 EU Member States, candidate countries to the EU — Croatia and Turkey — and Norway.

⁽³⁾ Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, United Nations.

a threat to public health comparable to the substances listed in Schedule I, II or IV' (new narcotic drug) or 'under the 1971 United Nations Convention on Psychotropic Substances' (4), and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV' (new psychotropic drug).

It is not new to design a drug using the structure of a parent compound with known properties. The term 'designer drugs', however, emerged in the 1980s and became particularly popular with the emergence of the 'ecstasy' compounds (MDMA, MDA, MDE, etc.) on the illicit drug market. Designer drugs were typically manufactured from chemical precursors in a clandestine laboratory. They can be best defined as unregulated (new) psychoactive substances, intentionally designed to mimic the effects of controlled drugs by slightly altering their chemical structure in order to circumvent existing controls.

'Legal highs' (5) on the other hand is an umbrella term for unregulated (new) psychoactive substances or products claiming to contain them, which are specifically intended to mimic the effects controlled drugs. It encompasses a wide range of synthetic and/or plant-derived substances and products, which may be presented as 'legal highs' (emphasising 'legality'), 'research chemicals' (implying legitimate research use), 'party pills' (alternative to 'party drugs'), 'herbal highs' (stressing the plant origin), etc., which are usually sold via the Internet or in smart/head shops and in some cases intentionally mislabelled with purported ingredients differing from the actual composition. 'Legal highs' are usually manufactured in chemical laboratories outside of Europe and legally imported, either as chemicals or as already packaged products. The 'legal highs' market is distinguished by the speed at which suppliers circumvent drug controls by offering new alternatives to restricted

products and advertising them with aggressive and sophisticated marketing strategies (room odorisers, herbal incenses, bath salts, plant fertilisers, collectors' items, etc.).

The term 'new' is not intended to refer exclusively to newly invented/synthesised substances, but rather should be understood as 'newly available' or 'newly misused' substances.

This publication

This publication consists of 30 short chapters describing the different national EWS (N-EWS) in operation in 2011. It reflects not only on the current state but also on future plans for development. The objective is to present a compendium of the N-EWS in their diversity, while using a common format to provide a coherent structure and clarity. By doing so, the publication aims to promote best practices and to enhance the exchange of experiences between different N-EWS.

The European Commission (EC) is currently preparing a proposal for the revision of Council Decision 2005/387/JHA. It is expected that the Commission will propose stronger EU legislation on new psychoactive substances, taking into account the rapid developments in this field and scientific evidence concerning the risks posed by these substances (6). Therefore, the existing EWS networks and their reporting and monitoring tools and instruments may need to be adapted and subsequently implemented and operationalised.

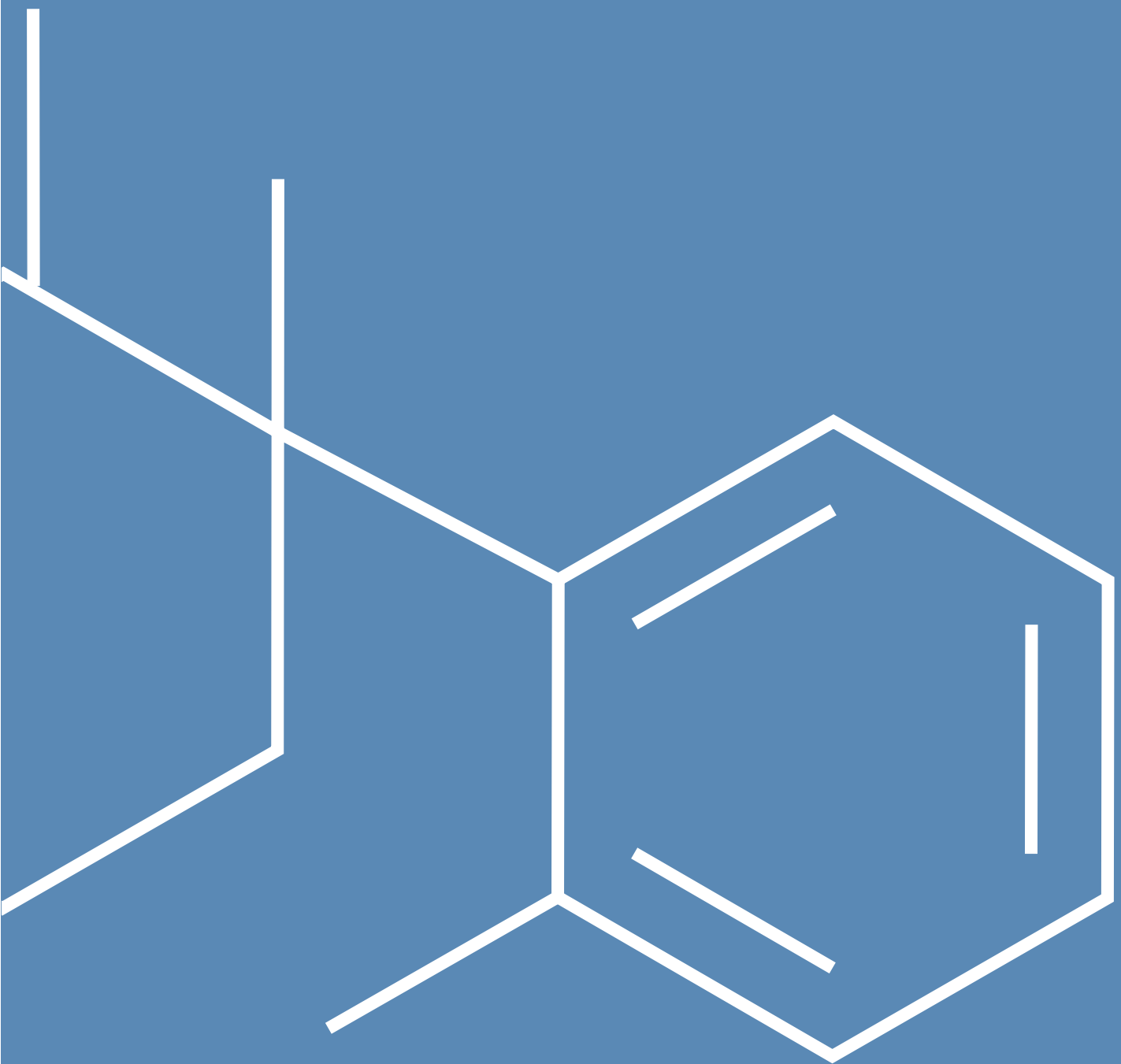
Acknowledgements

The EMCDDA would like to thank to the EWS correspondents of the Reitox national focal points.

(4) Convention on Psychotropic Substances, 1971, United Nations.

(5) The term 'legal highs' is used in inverted commas because describing these substances/products as 'legal' can be incorrect or misleading to customers as many of them can be covered by e.g. medicines or food safety laws. In addition, 'legal highs' products may contain substances controlled under drugs legislation.

(6) European Commission (2011), Communication from the Commission to the European Parliament and the Council 'Towards a stronger European response to drugs', Brussels, 25.10.11, COM(2011) 689/2.



Austria — early warning system

Marion Weigl and Alexander Grabenhofer-Eggerth

Introduction

The European early warning system (EWS) was implemented in Austria in 1997 and started with a simple mailing list, operated by the Austrian Reitox focal point. In 2002, 'Strychnine' was identified by the Forensic department of the Medical University of Vienna in some samples of heroin, which had been seized by the police in Vienna. Information surrounding this was spread by the media. This incident led to a meeting organised by the drug coordination of Vienna, where the reasons and possible health consequences of such impurities in heroin were discussed. It was also agreed that existing information systems should be improved, to gain new insights concerning impurities or other unexpected issues in context with drugs and to distribute this information via an official network instead of receiving information from the media. Subsequently, the Ministry of Health started a consultation process on the development of a specific Austrian EWS with an extended scope on the basis of the European EWS. This process was carried out in close cooperation with the Federal Drug Forum and the regional coordinators responsible for drug addiction. It was decided that the focus of this new Austrian system should be on new psychoactive substances but also on relevant health-related issues, such as unexpected high doses of psychoactive substances, unexpected impurities with dangerous substances or new risky consumption patterns. The new concept was adopted by the Federal Drug Forum in 2006 and *Gesundheit Österreich GmbH/Geschäftsbereich ÖBIG (GÖG/ÖBIG)* was commissioned by the Ministry of Health to implement this system. This new Austrian EWS started officially in June 2008.

Organisational issues

There is no legal basis or formal founding regulation for the Austrian EWS. It is based on a decision of the Federal Drug Forum, where the concept of the Austrian EWS was adopted, and the GÖG/ÖBIG is commissioned on a yearly basis to implement this system. This situation is going to change with a new law on new psychoactive substances, which should become effective in February 2012 and establish the legal basis for the Austrian EWS.

The objectives of the Austrian EWS are:

- to disseminate information received from the EMCDDA (the European EWS) to national partners and — if possible — to collect and provide feedback to the EMCDDA;
- to establish an official network for information about new psychoactive substances and unexpected issues in the context with drugs in Austria;
- to use existing structures and therefore the Reitox focal point, where the European EWS is located in Austria;
- to include all relevant institutions and experts;
- to provide information on health risks for prevention and treatment;
- to establish an early warning system in Austria;
- to establish an Advisory board with experts from different areas, who provide advice in critical situations but also on strategic issues.

The coordination and implementation of the Austrian EWS is done by GÖG/ÖBIG, where the Austrian Reitox focal point is also located. The persons responsible for the Austrian EWS are the Head of the Austrian focal point (an ecologist), a psychologist and a medical doctor.

A link to European institutions is given by the fact that the involved persons are also part of the team of the Reitox focal point, which enables a close cooperation with the EMCDDA and the European EWS. There is no direct link to Europol or other European information networks such as the one on infectious diseases, but through the Advisory board, there are persons from the Ministry of Health and the Ministry of Interior involved, who can act as communicator to these systems.

The communication runs mainly by e-mail and is defined clearly in the concept of the system. A meeting of the Advisory board is organised in June each year. In addition, there are meetings organised on demand (after consultation with the Ministry of Health), either to discuss specific urgent issues and to carry out a risk assessment (e.g. for 'Spice' in 2009) or to discuss strategic issues (e.g. how to handle 'research chemicals' in the future in 2010). Finally, in the

beginning of 2010, a web-based discussion forum was set up to stimulate the information exchange between emergency departments of hospitals.

The Austrian early warning system covers the whole country and is carried out in German language only. Due to limited resources, it was decided to provide a passive system which is not available around the clock. For severe emergency cases, however, there is cooperation with the Vergiftungsinformationszentrale (Poison Control Centre) which is also located at the GÖG.

To ensure scientific and political independence, an interdisciplinary Advisory board was established, where experts from different areas are involved. These 13 experts cover the following areas/expertise: administration (national and regional drug addiction coordination); addiction prevention; treatment; harm reduction; toxicology; forensic medicine; emergency medicine; and addiction research. Some additional experts, covering addiction prevention, pharmacy, youth psychiatry and forensic chemistry, are nominated for specific requests. The first and constituent meeting of the Advisory board took place in June 2007.

Core functions and information flow

GÖG/ÖBIG is the central interface of the Austrian EWS. All reports/alerts are sent to and validated by GÖG/ÖBIG (if necessary, in consultation with the Ministry of Health or experts). If relevant and useful/necessary, the information/warning is (sometimes together with additional useful information) disseminated to the network. There is a special e-mail address for the system (ews@goeg.at) and a special form for alerts/reports about new substances, etc. There are also rules on how to label and deal with these reports/alerts.

The network for the information exchange within the Austrian EWS is divided into two parts:

- Network A, on a federal level, which is informed directly by GÖG/ÖBIG, includes relevant ministries (e.g. Ministry of Health), the regional drug addiction coordinators, relevant institutions on a federal level (e.g. medical organisation, pharmaceutical organisation, social insurance), laboratories and addiction research as well as interfaces to the regional level (which is in some cases the regional drug addiction coordination):
- Network B, on a regional level, includes institutions/services of the drug help system (outreach, low-threshold services, treatment facilities, counselling

services, secondary prevention, etc.), emergency departments and organisations, institutions for forensic medicine and administration (public health sector). Depending on the case/situation, additional partners can be included and informed, such as, for example, the police, hospitals, general practitioners, youth institutions.

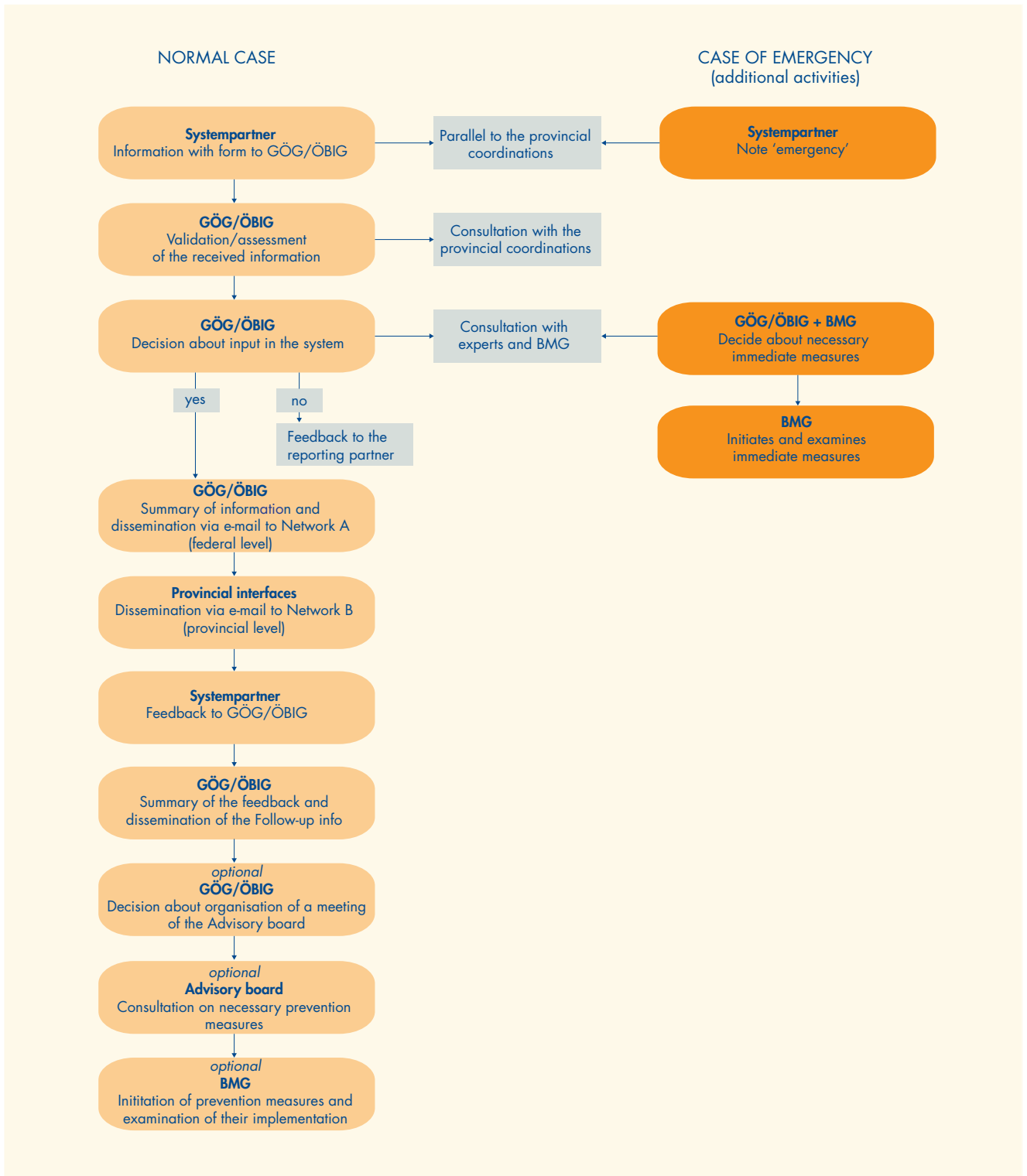
The process is clearly defined and distinguishes between 'normal case' and 'emergency case', as shown in the flow chart (Figure 1). There are no timelines defined for the separate steps of the process. But it is stated clearly in the concept that the Austrian EWS aims to exchange relevant information as quickly as possible to prevent any negative health consequences.

Information on new substances, impurities, especially high concentrations or new consumption patterns, etc. can be gathered and reported by different partners on a regional or federal level of the system. Usually, new substances and impurities are analysed and reported by three main partners: ChEck iT! (Viennese drug testing service); the OMCL (Official Medicines Control Laboratory) located in the AGES PharmMed (Austrian Medicines and Medical Devices Agency); and the Bundeskriminalamt (Federal Bureau of Criminal Investigation, BMI/.BK). ChEck iT! offers voluntary analysis of substances to young people at festivals and parties to reduce the risk of negative health consequences and to collect information on available psychoactive substances. The AGES PharmMed is responsible for the analysis of counterfeited pharmaceuticals and suspicious products, which could contain (illicit) active ingredients, to prevent negative health consequences for the general population. The BMI/.BK is responsible for the analysis of seizures of suspicious pharmaceuticals and substances to identify possible illegal activities.

Information on emergency cases is reported by different partners. To improve the involvement of emergency departments of hospitals, a special web-based discussion forum was set up in 2010.

There are no outputs such as annual reports foreseen within the Austrian EWS. But it provides the EMCDDA with progress and final reports each year. The new law on new psychoactive substances, which should become effective in February 2012, also establishes the basis for further monitoring of new substances in Austria. A tool, which enables better documentation and reporting, shall be developed during 2012.

Figure 1 — Flow chart of the Austrian EWS



Source: GÖG/ÖBIG.

There is no formal procedure for risk assessments in Austria. But the concept of the Austrian EWS also includes risk assessments as a major task of the Advisory board. Risk assessments are done on an ad-hoc basis and on behalf of the Ministry of Health. This is also going to change with the new law on new psychoactive substances, which should become effective in February 2012 and provides the basis for setting up a formal risk assessment procedure.

Case study

'Spice'

The example 'Spice' is chosen to show the process of the Austrian EWS.

ChEck iT! contacted GÖG/ÖBIG (also on behalf of the drug and addiction coordination of Vienna) with a question about possible analysis for 'Spice' products within, or financed by the EMCDDA. At that time, psychoactive effects of 'Spice' were reported by users once in a while. But the results of an analysis by a private laboratory about a year ago gave no hint of the existence of illicit substances in 'Spice' products. So it was unclear how to explain the psychoactive effects.

Step 1: The reliability of the information was regarded as high because the information came from experts. The EMCDDA was informed about the issue, together with a request for further information.

Step 2: Together with ChEck iT!, all available information on 'Spice' was collected and summarised. The findings were disseminated to the network in combination with a request for further information.

Step 3: GÖG/ÖBIG received feedback from experts in Upper Austria and Tyrol.

Step 4: In cooperation with ChEck iT! and after consultation with the Ministry of Health, a fact sheet on 'Spice' was prepared, which included information on counselling and prevention. This was again disseminated to the network.

Step 5: After consultations between several ministries and discussion at the Federal Drug Forum, an ad-hoc meeting of the Advisory board of the Austrian EWS was organised. As no severe incidences with 'Spice' were reported until that time and information on health consequences as well as

information on psychoactive ingredients was still missing, it was recommended to find a solution for the control of 'Spice' outside the Narcotic Substances Act. At the same time, the Ministry of Health commissioned AGES PharmMed to analyse 'Spice' samples.

Step 6: A German laboratory identified the psychoactive substance JWH-018 in 'Spice'. These results were confirmed in Austrian samples by the AGES PharmMed a few days later.

Step 7: After consultations of the Advisory board for the differentiation of pharmaceuticals and other products, the Ministry of Health decided to control 'Spice' on the basis of the pharmaceutical law. A short-term decree (valid only for two weeks) was issued on 22 December 2008, which prohibited the distribution of 'Spice' and similar products.

Step 8: A regular decree followed on 7 January 2009, which prohibited the import and distribution of all products containing JWH-018.

Step 9: After the identification of further synthetic cannabinoids in 'Spice' and similar herbal mixtures, the decree was replaced by another one on 3 March 2009. This decree prohibited the import and distribution of all incense mixtures containing cannabinomimetic substances. Those cannabinoids, which have been identified until March 2009, were listed in the amendment.

Step 10: Another meeting of the Advisory board was organised in March 2009, where the current situation was discussed. It was agreed that an expert group, which clusters synthetic cannabinoids with potential psychoactive effects, should be commissioned by the Ministry of Health. These clusters would avoid the need for changes of the law after identification of further new synthetic cannabinoids. It was also agreed that the control of these substances should remain on the basis of the pharmaceutical law.

Step 11: In October 2010, the amendment to the decree on incense mixtures was updated. It now contains the following substances: CP 47,497 and its C6-, C8- and C9-homologues, HU-210, JWH-018, JWH-015, JWH-019, JWH-073, JWH-081, JWH-200 and JWH-250 and o-desmethyltramadol.

Step 12: In January 2011, the fact sheet on 'Spice' was updated and disseminated again.

Strengths, limitations and the way forward

The strengths of the Austrian EWS are a good and comprehensive network, which involves all kinds of relevant experts and information providers, as well as a very well-structured information flow in the context of dissemination. The identification of new substances or impurities is also working well, especially in the context of festivals and parties where ChEck iT! is active. The interest in the Austrian EWS and the motivation to participate in the network are increasing among experts from different areas. During the process of setting up the Austrian EWS, a list was created with information on analytical methods, tasks and contact details of relevant laboratories to support the information exchange between them. This turned out to be a helpful basis for the implementation of the Austrian EWS, especially when it is necessary to gather additional information or to assess information on new substances.

Limitations are still observed in the context of gathering information on actual health consequences, such as emergencies. A crucial factor, which cannot be changed by the Austrian EWS, is the lack of analysis of substances within emergency departments of hospitals. Therefore, the reason for an emergency case and the contribution of a

psychoactive substance, as well as the type of substance, can often only be speculated (e. g. in the context with GHB/GBL). The information exchange with the laboratories is limited mainly due to contractual and financial issues.

The system started as a work in progress and is still improving. Further steps will be the further improvement of the information exchange, especially with hospitals but also with experts from counselling services. To do so, the web-based discussion forum will be adapted and opened to all members of the network of the Austrian EWS. The expert consensus on possible measures for analysis and prevention in the context of 'research chemicals' — which was finalised at the end of 2011 — shall be completed with possible measures for treatment during 2012. It is also planned to tackle the issue of media coverage, which is highly sensitive in terms of prevention.

Links and references

The concept of the Austrian EWS is published on the website of GÖG/ÖBIG (<http://www.goeg.at>) and in the web-based EWS-forum (<http://forum.goeg.at/ewsforum>).

Belgium — early warning system

Nathalie Deprez and Johan C.H. van Bussel

Introduction

The establishment of the Belgian early warning system (BEWS) by the Belgian government followed the adoption of the Joint Action on New Synthetic Drugs (Council of the European Union, 1997). The first steps in the development of this BEWS were taken at the end of 1997 by establishing the cooperation between the Ministry of Public Health and the Ministry of Justice. The initial aim of the BEWS was the collection and distribution of social, medical and cultural information on new synthetic drugs and (combinations of) high-risk psychoactive substances by the Belgian Monitoring Centre for Drugs and Drug Addiction (BMCDDA, the Belgian focal point) and the regional focal points (RFPs). From the onset, a decision was taken to collect information at laboratories' level. In February 1999, the BMCDDA performed a feasibility study to investigate whether a web-based database with all analytical results of analysed drugs would facilitate the monitoring tasks of the BEWS. This web-based database was operationalised in 2002 (Leus et al., 2001; Leus and Walckiers, 2002). Currently, a new version of this technical platform is under development.

Organisational issues

The BEWS is hosted by the BMCDDA which is embedded in the research program 'Substance use and Related Disorders' (SURD) of the service Surveys, Lifestyle and Chronic Diseases. This service is part of the Operational Directory 'Public Health and Surveillance' of the Scientific Institute of Public Health (WIV-ISP), situated in Brussels. The BMCDDA monitors, collects, analyses and disseminates drug-related information towards the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and towards its national stakeholders. The EMCDDA and the Federal Government Department of Public Health, Food Safety and the Environment co-finance the BMCDDA and its BEWS.

The main objectives of the BEWS are: (1) the rapid detection of new psychoactive substances in Belgium and; (2) the monitoring of the composition of known illicit substances and trends in the composition of these substances. In order to fulfil these objectives, the BEWS relies on the reporting of drug analyses by laboratories.

The reporting of the analysis results to the BEWS is regulated by two Royal Decrees (Federale Overheidsdienst Volksgezondheid, 2003; Federale Overheidsdienst Volksgezondheid, 2006; Service Public Federal Sante Publique, 2003; Service Public Federal Santé Publique, 2006). These Royal Decrees make the reporting of analytical results to the BEWS mandatory for the toxicological laboratories in Belgium, except for cannabis. The reporting of analytical results by clinical laboratories is only mandatory for new substances (see also Figure 2).

Complementary to the national BEWS, two regional focal points (Eurotox and the Vereniging voor Alcohol — en andere Drugproblemen, VAD) host a regional EWS. As the BEWS is responsible for the monitoring of trends in the compositions of analysed seized drugs, the regional EWSs focus on the prevention level. They therefore collaborate with services like 'De Druglijn', a telephone helpline for people (not only users) with questions about drugs. The three EWSs collaborate in the dissemination of 'alerts' when new or high-risk psychoactive substances are reported.

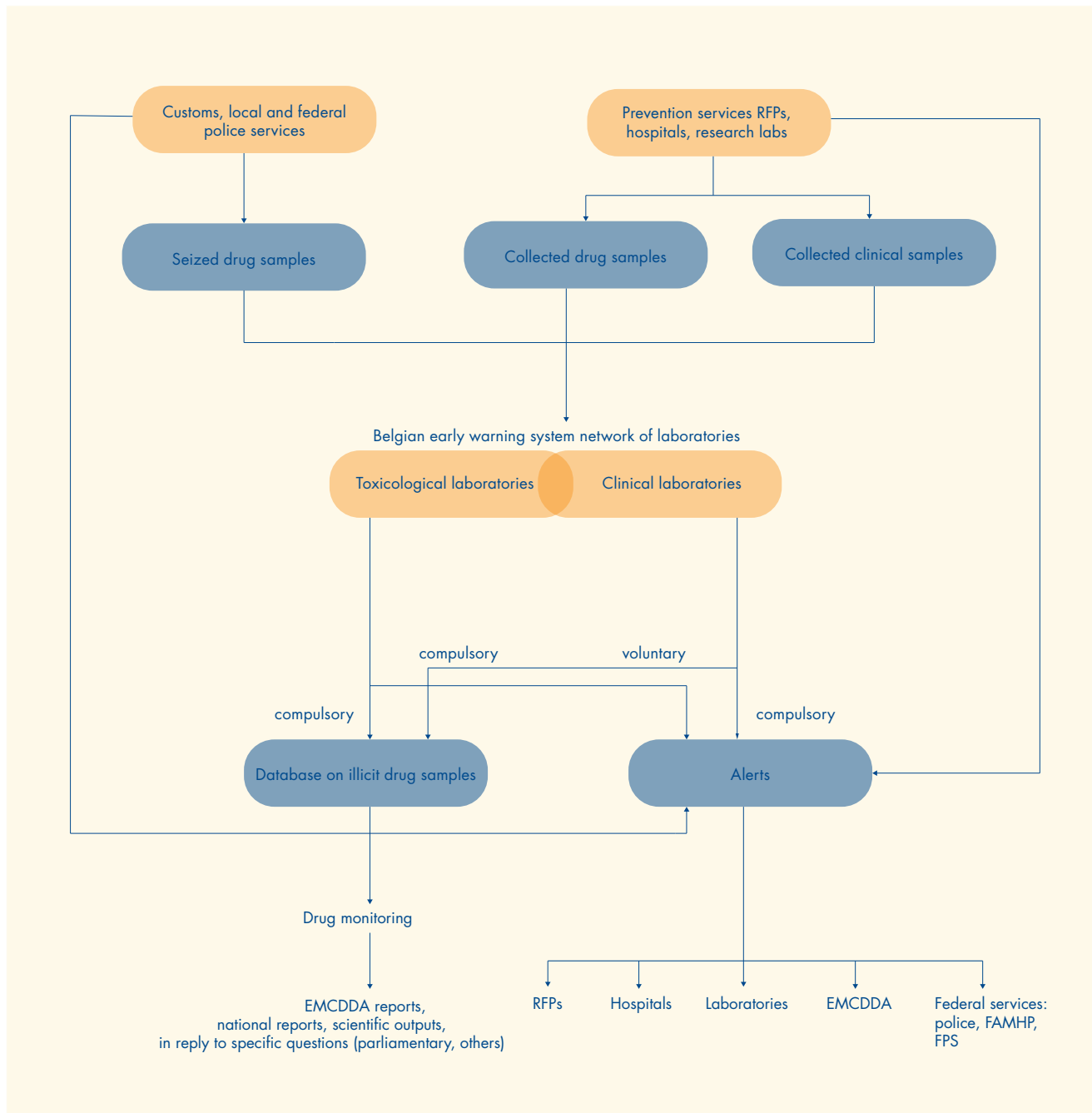
Core functions and information flow

The BEWS collects and disseminates information about the composition of drugs within a network including the RFPs, laboratories, hospitals, police services, the Federal Agency for Medicines and Health Products (FAMHP) and the Federal Government Department of Public Health, Food Safety and the Environment (FPS) (see Figure 2).

The data registered by the BEWS is mainly provided by the laboratories analysing the drug samples. Twenty-three laboratories (spread over Flanders, Wallonia and Brussels capital) are participating in the BEWS network, of which 18 laboratories reported results since 2002.

Most of the reported analyses concern drug seizures commissioned by the Director of Public Prosecutions. Although the samples come from all over Belgium, the number of samples sent by the different judicial districts may differ.

Figure 2 — Information flow in the framework of the Belgian EWS



Most laboratories submit their common analytical results (no new or high-risk substances) to the BEWS in the first months after the previous reporting year (from 1 January until 31 December). Some laboratories report their results on a more regular basis. When the results of one registration year are complete, the BEWS responsible processes these data for the output. The output includes Chapter 10 of the Belgian Annual report, Standard Tables 14 and 15 (European Monitoring Centre for Drugs and Drug

Addiction, 2011), specific EWS reports and reports on request (EMCDDA requests, parliamentary questions, etc.).

In the case where laboratories identify a new or high-risk psychoactive substance, the BEWS is immediately informed. In a small number of cases (mainly when unexpected effects or appearances of psychoactive substances are reported), information comes first from police services or prevention services and is then followed by an analysis. The available

information (analysis results, origin of the sample, appearance of the drug, and reported effects in humans) is collected by contacting the involved partners. The identification of new or high-risk psychoactive substances is first reported to the hierarchical line of the WIV-ISP, the communication services of the WIV-ISP, the FPS and the cabinet of the Minister of Public health. Secondly, the information is disseminated through 'alerts' (in the form of e-mails) to the BEWS network. The RFPs disseminate the information in their regional network of prevention services. Furthermore, a log book is created collecting all information provided by the partners of the BEWS network.

Every six months, the new substances are also reported in the EWS Progress and Final reports on new substances for the EMCDDA.

Case study

In January 2011, a local police service informed the BEWS about two serious intoxications in drug users (of which, one died). The incidents took place after the use of a yellow powder bought as 'yellow speed' from one and the same dealer. The police commissioner of the local police service sent the samples to a clinical laboratory, to investigate the powder and human samples.

The BEWS immediately informed the regional EWS of Eurotox and VAD. These regional EWSs informed the local prevention services of their network. The EMCDDA and the other BEWS partners were informed although: (a) the identification of the psychoactive substances in the powder was not available at the time; and (b) it was assumed that most of the powder would be off the market. Moreover, it was only after identification of the psychoactive substance that it could be concluded that the users' intoxications were related to the yellow powder.

The reach of the BEWS is illustrated by the fact that users came to low-threshold services with questions about their own yellow powder (when feeling bad after the use of a yellow powder, or after having bought yellow powder that was sold as 'heavy stuff'). None of these secondary samples were identified as parts of the same batch of the initial powder.

Strengths, limitations and way forward

In Belgium, the drug-related aspects (treatment, prevention, law enforcement, etc.) are divided over different political

levels (federal and federate). As a result of the collaboration with the RFPs, the BEWS reaches the different types of services related to drugs and drug use. The functioning and reach of the BEWS is continuously extended, and police services find their way to the BEWS (see section 'Case study').

Since 2002, the majority of the data is provided by four laboratories. Although no information of the representativeness is available, it is assumed that these four laboratories analyse most of the seized drug samples in Belgium. Other laboratories in the BEWS provide a smaller number of data. However, it is assumed that other smaller laboratories do not report their data to the BEWS. In 2011, surveys for laboratories and law enforcement services (courts and police) were conducted to improve the coverage of the BEWS and to estimate the representativeness of the current BEWS.

Currently, the BEWS dataflow is interrupted several times as there is no connection between the database of the police and the information from the judicial courts (circumstances and size of seizure, decision for analysis of the sample) on the one hand and the BEWS database (data collection based on lab results) on the other hand. The information on the context of the seizure is only obtained for new and high-risk drugs, and only by specific request of the BEWS responsible. As a consequence, for the regular drug monitoring, it is not clear whether this seizure took place at dealer or user level, which proportion of all the seizures is analysed, etc.

To improve the representativeness of the BEWS, the project 'Drugs in Circulation' was started in 2003 analysing all seized drugs (not only a selection of them) in specific judicial districts (Van Der Biest and Walkiers, 2004). However, due to funding and practical matters, this project diminished over the years, and has come to an end in 2010. Now, other steps are taken to improve the system: the creation of a 'unique sample identifier' used by the police, the directorates of public prosecutions, and the laboratories is under consideration. This identifier will facilitate the linking of the different databases, will make the dataflow more transparent, and will also result in a better estimation of the representativeness of the system.

The focus on seized drugs by the BEWS has both advantages and disadvantages. Some of the disadvantages could be minimised by investing in collecting samples at user level. Users might be more motivated to have their drugs tested after having had a bad or unusual experience, speeding

up the detection of new and dangerous drugs. Furthermore, users could provide information on the street names used for specific drugs, which could also make the alerts more specific.

Over the years, drug-testing projects at user-level were initialised by the RFPs: the RAPID-project — Risico Analyse Project voor het Identifieren van Drugstalen (Schrooten, 2010) — and the pill-testing project 'Modus Fiesta' (Modus Vivendi, 2005). However, due to legal, ethical and policy considerations and a lack of funding, these projects were not easy to maintain.

The BMCDDA currently develops a new technical platform facilitating the data submission by the laboratories. Specific attention will be paid to the automatic quality control of the data. In addition, generic feedback reports (with benchmarking) will be programmed for the participants and stakeholders of the BEWS. Furthermore, a multidisciplinary national Risk Assessment Expert group will be established.

Finally, a BEWS-SharePoint, facilitating the exchange and archiving of up-to-date information with the Belgian partners is developed.

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Links

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Bulgaria – early warning system

Momtchil Vassilev and Raina Ilieva

Introduction

The history of the early warning system (EWS) in Bulgaria started in 2004 with a visit of the EMCDDA, in the framework of the project 'Joint Action on new types of synthetic drugs' at that time. The visit was related to official meetings with representatives of the Bulgarian political power, dedicated to presenting the work and the nature of the EWS in general and the need for establishing such a mechanism for information exchange at national level.

The real action in building a working EWS in Bulgaria began in 2006 (13 April) with the formation of an expert working group of the national focal point (NFP) with the participation of representatives of governmental, non-governmental and local institutions and organisations related to the drug problem and dependence, whose first task was to identify key partners and outline key steps in organising activities for the exchange of information on new substances in the country. The group included experts from the Ministry of Health (Department of Emergency Medical Care), Ministry of Interior (General Directorate for Combating Organised Crime, Research Institute of Forensic Science and Criminology (RIFSC)), Ministry of Finance (Customs Agency), Alexandrovska Multi-Profile University Hospital for Active Treatment – Centre for Forensic Medicine and Deontology, Clinic of Toxicology, N.I. Pirogov Multi-Profile University Hospital for Active Treatment and Emergency Medicine – Department of Information, and partners from the Prevention and Information Centres for Addictions in Sofia and Varna.

The newly formed working group took the following fundamental decisions:

- the rules for the operation of the working group should be elaborated urgently;
- the process of formation of the working group was not completed. Extending the range of key partners remained a permanent objective of its operation. Whenever necessary, additional short-term external contributors/experts can be used to work on certain tasks and topics;
- regular meetings of the working group should be held twice a year.

In 2007, in accordance with one of these decisions, representatives of non-governmental organisations doing outreach work with users and the Clinic of Toxicology at the N.I. Pirogov Multi-Profile University Hospital for Active Treatment and Emergency Medicine in Sofia joined the group. In 2009, an invitation for cooperation on new substances was extended to the Bulgarian Drug Agency and the Clinic of Toxicology at the Military Medical Academy in Sofia.

The collection of information began by sending a query to the Prevention and Information Centres in the country for the existence of new psychoactive substances and new patterns of use of already established psychoactive substances in the drug markets at local level.

In its relatively short period of functioning, the EWS in Bulgaria has developed as an active European and national partner in the area of new drugs contributing to identify for the first time three new psychoactive substances, processing over 100 communications from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), proposing the supervision by the national legislation of six new substances and supporting by information and experts the procedure for the inclusion of another 25 new substances in the Law on Narcotic Substances and Precursors Control. The Head of the national focal point is a member of the Expert Committee of the National Drug Council, involved in the preparation of risk assessment for emerging substances and proposals for placing them under control as drugs. The NFP, through its representative in the Expert Committee of the National Drug Council, has actively participated in the preparation of a proposal for amending the Law on Narcotic Substances and Precursors Control, designed to allow for faster controls on emerging new (uncontrolled) psychoactive substances.

Organisational issues

The work of the EWS in Bulgaria is managed and coordinated entirely by the NFP on drugs and drug addictions through a manager and an authorised

coordinator in the team of the Centre (two full-time employees, but not working only with N-EWS). The NFP is based at the National Centre for Addictions, which is part of the EWS of the Ministry of Health. The total number of external experts working on the EWS is approximately 15, some of which are members of the working group. Freelancers (external experts) working with N-EWS are of a diverse educational background and professional qualifications — chemists, toxicologists, physicians, nurses, psychologists, operatives and experts in the field of law enforcement and in the law-enforcement authorities, outreach workers, addictions consultants. All members of the expert group formed are united by the voluntarily assumed responsibility to cooperate in the development and operation of the EWS at the national level — a conception enshrined in the internal operating draft document entitled ‘Consensus rules for the operation of the early warning system in Bulgaria’. The document is based on the decisions made at the first meeting of the working group in 2006 and its main purpose is to describe the relations within the EWS and the effective way of exchanging relevant information on monitoring and evaluation of new drugs detected in the Republic of Bulgaria, and new patterns of use of already known drugs. The maintenance and development of N-EWS were regulated normatively by a text included in the Law on Narcotic Substances and Precursors Control in 2010 reading as follows: *‘The Bulgarian national focal point builds and maintains a public information system on drugs and drug addictions as well as early warning information system about new narcotic substances as part of the European early warning system’*.

The status of the NFP as the basic advisory, expert and information unit on drugs in Bulgaria, as an official partner of the EMCDDA, as a participant in the European Information Network on Drug Addiction (Reitox), and the objective circumstances in the dynamic development of the problem of new drugs in the country identified the additional roles of N-EWS and forced the expansion of its activities. The work is organised in several directions, and parallel to the main one (participation in the European information network on new psychoactive substances with the provision of information on such substances identified in the territory of Bulgaria and new patterns of use), the capacity of the EWS for providing information on new substances at the national level, participation in legislative initiatives in the field of new drugs and for initiating research projects in this field has developed.

The EWS has the potential for national coverage through the Prevention and Information Centres on the problems of drug

addiction in 26 cities across the country and through the subsidiary laboratories for analysis of the Research Institute of Forensic Science and Criminology and the Customs Agency.

The working language in the National early warning system (N-EWS) is Bulgarian; the language of international communication is predominantly English.

Core functions and information flow

The exchange of information within the EWS for new drugs is done in pursuance of Council Decision 2005/387/JHA of 10 May 2005 and is conducted in cooperation with the European Monitoring Centre for Drugs and Drug Addiction.

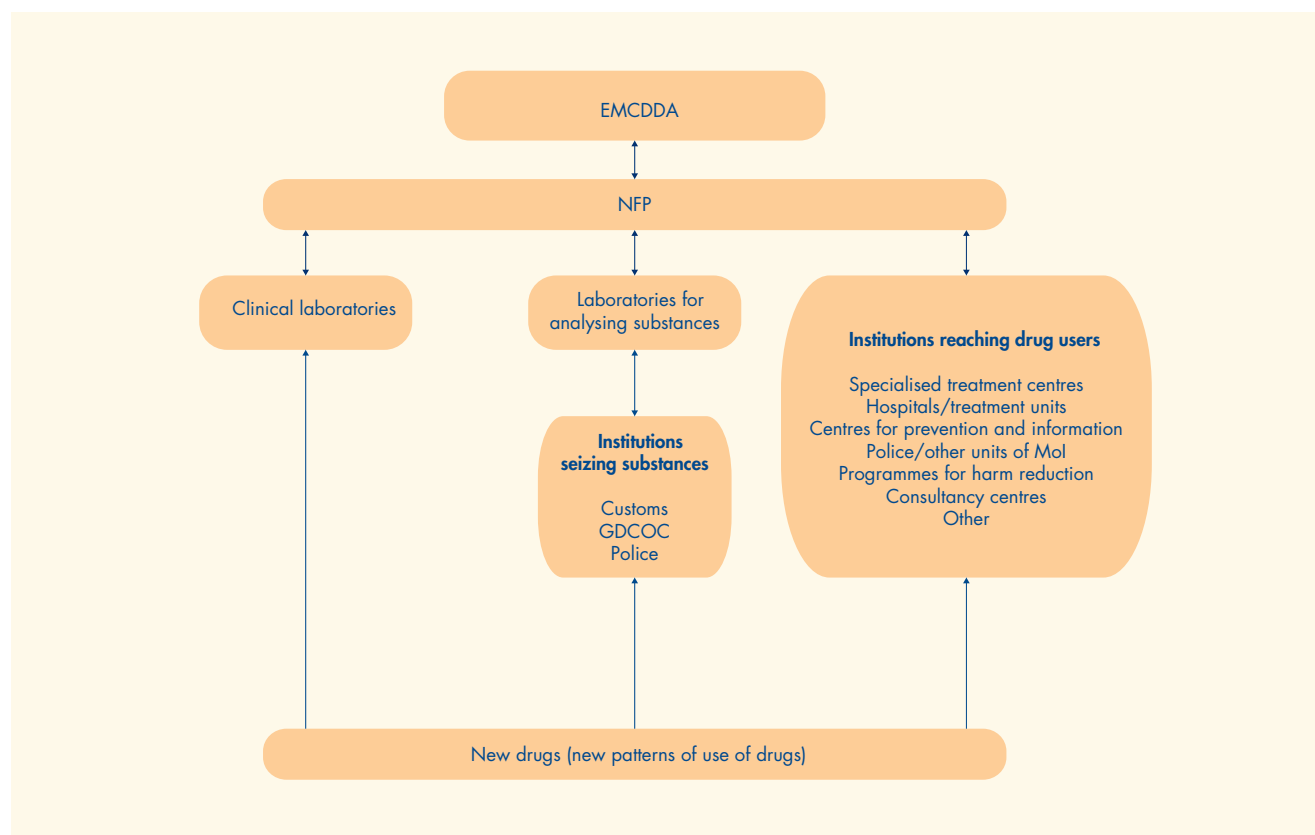
The very concept of the EWS implies simultaneous functioning of two major information flows (Figure 3):

- Outgoing — from Bulgarian sources (as an EU Member State) through NFP and the EMCDDA to the European institutions;
- Incoming — from sources in the EU Member States through the EMCDDA and NFP to the relevant Bulgarian institutions.

The purpose of the outgoing flow is to inform the European Union Member States and institutions about new substances and/or new patterns of use of known substances found in the territory of the Republic of Bulgaria. The purpose of the incoming flow is to provide the interested institutions and experts in Bulgaria with information on the new substances and/or new patterns of use of known substances found in the territory of other European countries.

Several types of national sources provide the outgoing data flow:

- laboratories in the field of forensic science (Research Institute of Forensic Science and Criminology — Laboratory Unit ‘Drugs’; Research Institute of Forensic Science and Criminology — Chemical and Toxicological Laboratory; Customs Agency Laboratory);
- laboratories in the field of forensic medicine (Centre for Forensic Medicine and Deontology, Alexandrovska Multi-Profile University Hospital for Active Treatment);
- clinical laboratories (Chemical and Toxicological Laboratory at the N.I. Pirogov Multi-Profile University Hospital for Active Treatment and Emergency Medicine; Chemical and Toxicological Laboratory at the Military Medical Academy);
- therapeutic, outreach and other units which have direct

Figure 3 — Functional scheme of the early warning system in Bulgaria

contacts with drug users (hospitals, treatment programmes, NGOs and others);

- law enforcement units, which in their activities have direct contacts with drug dealers (Main Directorate for Combating Organised Crime — Ministry of the Interior (Mol); Customs Agency — Ministry of Finance);
- units accumulating information in the field (National Focal Point, Prevention and Information Centres for Addictions, National Centre for Addictions, Ministry of Health and others).

The incoming flow is directed to several categories of recipients in Bulgaria with different levels of access to this information.

With unlimited access:

- laboratories in the field of forensic medicine;
- laboratories in the field of forensic science;
- clinical laboratories;
- law enforcement units;
- therapeutic and outreach units.

With limited access:

- media;
- users outside the professional community.

The entire information within the EWS for new drugs in Bulgaria is collected, coordinated and directed by the National Focal Point for Drugs and Drug Addiction which, where necessary, organises its further processing and analysis, seeking assistance from the national scientific and research units outside the working group or the European Partner Network. Each participant in the working group is committed to provide the NFP with data within the range of their competence on new types of psychoactive drugs found, new combinations and new patterns of use of already known ones, if possible, immediately after the acquisition of such information. The information is submitted to the NFP in a format consistent with the database of the institution. After processing, the data for new substances obtained from national partners is sent directly to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) by filling in an established form — Reporting Form. By forwarding the

EWS Progress Report and Final Report, full information about the condition and operation of N-EWS in the current calendar year is provided.

The information submitted through the EWS by the European partners of the NFP is timely distributed by the latter to the participants in the working group in three main ways — in the form of warnings, alerts and reports. Warnings disseminate primarily information on new psychoactive substances identified and reported through the EWS and communication is taking place over the Internet. Communication of incidents directly affecting the physical health of drug users (death cases, toxic combinations of substances, dangerous supplements found in known drugs) must be submitted as alerts, especially in private conversation on the phone with the relevant representative in the working group. Reports are basically used during the annual meetings of N-EWS, where experts of the working group are informed in detail about the situation with new substances in Europe and Bulgaria.

The communication between experts in the working group is arranged so that each member may request at any time to be provided with information by another member on any matter relating to the development and operation of the EWS in the country.

In connection with the need to build a complete mechanism for dealing with the new psychoactive substances at national level, in 2009 the NFP began to work on a proposal related to establishing a national system for assessing the risk of using such substances by creating a complete cycle of activities — from the identification of a new substance to placing it under control. The first step to this effect was compiling a list of laboratories and assessing their capacity (available equipment, library, staff, etc.) to work with the new substances. The laboratories were divided into four main groups depending on the needs of the N-EWS: laboratories for identification and analysis of unidentified substances; laboratories for identification and analysis of new chemical substances from biological samples; laboratories for testing the effects and toxicity of chemical substances; and laboratories for synthesis of scientific and practical purposes of chemical substances.

Case study

A good example of how the N-EWS works in practice is when the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) released information about deceased

heroin users infected with anthrax — a lot of information untypical for the nature of the EWS. Due to the fact that the working group includes representatives of institutions and organisations working in various fields of drugs and drug addiction, the EWS in Bulgaria did not face any obstacles to spread this message. The partners in the working group having access to drug users were informed immediately. Through them, the information reached their colleagues from similar organisations in other cities that were not part of the working group and feedback was obtained on whether, in the population of heroin users in Bulgaria, there were cases of individuals infected with anthrax.

On the other hand, the message was also sent to the relevant Directorate at the National Centre for Addictions, related to this serious case. The experts of the Directorate also responded immediately and contacted the National Centre for Infectious and Parasitic Diseases (NCIPD) asking for assistance. The NCIPD responded with data on the presence or absence of such cases and appropriate recommendations.

Strengths, limitations and way forward

The major strength of the EWS in Bulgaria is the diverse composition of the working group. It covers sources of information from all areas of drug addiction, which allows obtaining the necessary information on the functioning of the mechanism at national and European level. In addition, the N-EWS has the capacity to develop additional areas in the field of new drugs, going, at national level, well beyond its core activities related to the identification and provision of information on the availability of new substances in the country. It seeks to establish a comprehensive mechanism of concrete steps to work in a dynamic environment of the new psychoactive substances.

As to the difficulties faced by the EWS in Bulgaria, most of them are caused by circumstances beyond the control of and independent from the NFP as a coordinator. An outstanding problem is the lack of modern equipment for analysis of new substances, modern libraries and reference material. The non-realised scientific potential (due to lack of funding) in the field of new drugs and the lack of a complete national mechanism for a comprehensive risk assessment of the use of new psychoactive substances, are additional difficulties in the work of the N-EWS.

The weak connection with the population of drug users and mostly with those experimenting with drugs is a problem in

the state of the EWS at the moment. This is a field of activity on which the EWS in Bulgaria is now focusing its efforts, which undoubtedly is related to its future development.

The possible directions for the development of the N-EWS include several aspects:

- expansion of information services, including monitoring of the Internet;
- assistance in developing the national legislation on new psychoactive substances, including proposals for possible amendments to the Law on Control of Narcotic Substances and Precursors Control;
- conducting surveys of the popularity and use of new substances.

The focus in the current state of the N-EWS and most likely in its future development is to carefully assess the current situation in the drug market and bring in line with it the entire mechanism for monitoring and placing under control new, emerging substances. This is related to the need for reducing the time for assessment and possible controls on new substances. The market has become much more dynamic than it was 10 years ago and requires a new speed of responsiveness and perhaps a new organisation of work. In general, new substances become available with the status of legal ones; they are placed on the market aggressively and quickly and provoke strong public pressure to bring them under control as quickly as possible.

This pressure, accompanied by the pressure from law enforcement authorities through which quite a few legal packets containing such substances pass, which are known to feed the market of drugs, reduce the possibilities of conducting the process of research and risk assessment of a given substance in the 'classical' way. In fact, this could be a general challenge to the EU Member States.

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Croatia – early warning system

Lidija Vugrinec

Introduction

The use of designer drugs or other new psychoactive substances in Croatia represents a relatively recent phenomenon which is, to a large extent, connected with the new behavioural trends of young people during their leisure time. The emergence of new drugs in Croatia has been closely monitored since 2007, in the framework of the existing capacities. However, there are not much data available on the prevalence of their use, which is planned to be improved in the forthcoming period with the aim of creating appropriate responses of relevant institutions.

Even before installing the formal National early warning system (N-EWS) in 2007, Croatian relevant authorities have been actively cooperating in the exchange of information on new psychoactive substances that posed a significant threat to the Croatian society and had a clear legal possibility to place problematic new substances under legislative control. This practice proved to be successful in 2004 when five types of piperazine were listed at the national level, using available legal instruments. In accordance with the Law on Combating Drugs Abuse, the Minister of Health is in authority responsible for updating a List of drugs, psychotropic substances and plants that drugs can be produced from, as well as substances that can be used in order to produce drugs (precursors) [List]. The Forensic Science Centre (FSC) regularly conducts analyses of all drugs seized, including new psychoactive substances. In cases where the classic drugs and psychotropic substances are not an issue, new substances can be identified by using professional literature and a data bank. If a newly detected psychoactive substance poses a serious threat to public health and has a limited therapeutic value, the Minister of Health can specify this substance to be included in the List, upon the recommendation of an expert group. Each unauthorised possession and trade in substances that are on the List is considered a criminal offence.

Organisational issues

The National Strategy on Combating Drugs Abuse in the Republic of Croatia 2006–12 (National Strategy) foresees the creation of a system for rapid exchange of information

on production, trade, use and risks related to new psychoactive substances in order to prevent negative effects and to undertake on time-appropriate actions. Therefore, based on the National Strategy and the Protocol on National Drug Information System in the Republic of Croatia, there has been developed the Protocol on early warning System on New Psychoactive Substances in the Republic of Croatia (adopted by the Government of the Republic of Croatia, at its session held on 2 December 2007) as a basic document for setting up identification, communication and exchange mechanisms on new psychoactive substances at the national level and with EU agencies, which is fully compliant with the *acquis communautaire* in this domain. There has also been signed an agreement on institutional cooperation in the N-EWS between the Office for Combating Drugs Abuse (OCDA) and relevant authorities, which is going to be expanded with new stakeholders in 2011. Concrete tasks and activities are described in the National Action Plan on Drug Information System in the Republic of Croatia (2008–09 and 2010–11), which enables monitoring of activities and progress.

Besides identifying new psychoactive substances that may appear on the national drugs market and reporting according to the Council Decision (2005/387/JHA), the primary objective of the N-EWS in Croatia is to prevent (diminish) negative health and social consequences of new psychoactive substances and to stop the spread of new phenomena in the country. Legal control and decrease of the availability of those new psychoactive substances is another, equally important aspect of the system.

The OCDA is an expert service of the Government of the Republic of Croatia which is acting as a drugs policy coordinator. More specifically, the National Drugs Information Unit and International Relations Department is playing a key role within the OCDA structure in collecting drug-related information from respective institutions to monitor the drug situation in Croatia. As such, the OCDA is the Reitox national focal point and also coordinator of the N-EWS. The OCDA and the Europol National Unit at the Ministry of Interior are key institutions of the Croatian N-EWS in charge of rapid exchange of relevant information on new psychoactive substances at the national level, as well as for

direct communication with the top authorities of the EU EWS hierarchy, the EMCDDA and Europol.

In general, the N-EWS in Croatia is acting at the national level. However, an ongoing restructure of the system foresees stronger activities at the professional, grassroots level, which will also enable better coverage in the local communities. At the OCDA, tasks related to the operating of the N-EWS are shared by two persons. The Head of National Drugs Information Unit and International Relations Department (criminalist) is in charge of structuring and management of the N-EWS, planning of activities, initiating joint projects and direct communication with the EMCDDA and national experts, whilst one expert associate (social pedagogue) provides technical assistance, e.g. dissemination or collection of information, assistance in elaborating documents etc.

The Working Group on the N-EWS meets regularly two times per year and ad hoc upon the invitation of the OCDA (e.g. discussions on emerging trends). The core expert group meets on ad hoc basis, when a 'risk assessment' is required to make a decision on a necessity to place a specific new psychoactive substance under the legal control. After reconstruction of the N-EWS, there are foreseen also annual and ad hoc meetings of specific focus groups of professionals, which are in more detail described under the section Core functions and information flow. Besides meetings, there is almost daily communication (by phone, e-mail) between the OCDA as the N-EWS coordinator and relevant experts. Experts will soon also have a possibility to exchange information, knowledge and experience at the discussion forum (restricted area) which will operate on the website of the OCDA (online settings are already available).

The Croatian N-EWS operates in Croatian language, and only seldom some important or urgent information received from the EMCDDA is transmitted to national key experts in English language (as a prompt reaction).

The N-EWS, as well as the core expert group, has scientific and political independence to implement the national risk assessment procedure and to propose legal control for a specific new psychoactive substance. In all cases, the Minister of Health accepted the proposal and approved amendments to the List of controlled substances.

Core functions and information flow

The general principle of the N-EWS is committed collaboration between all relevant partners, on a regular and ad hoc basis, using a multidisciplinary approach and specific

expertise in identifying new substances and assessing their risks.

The Croatian N-EWS operates at four levels:

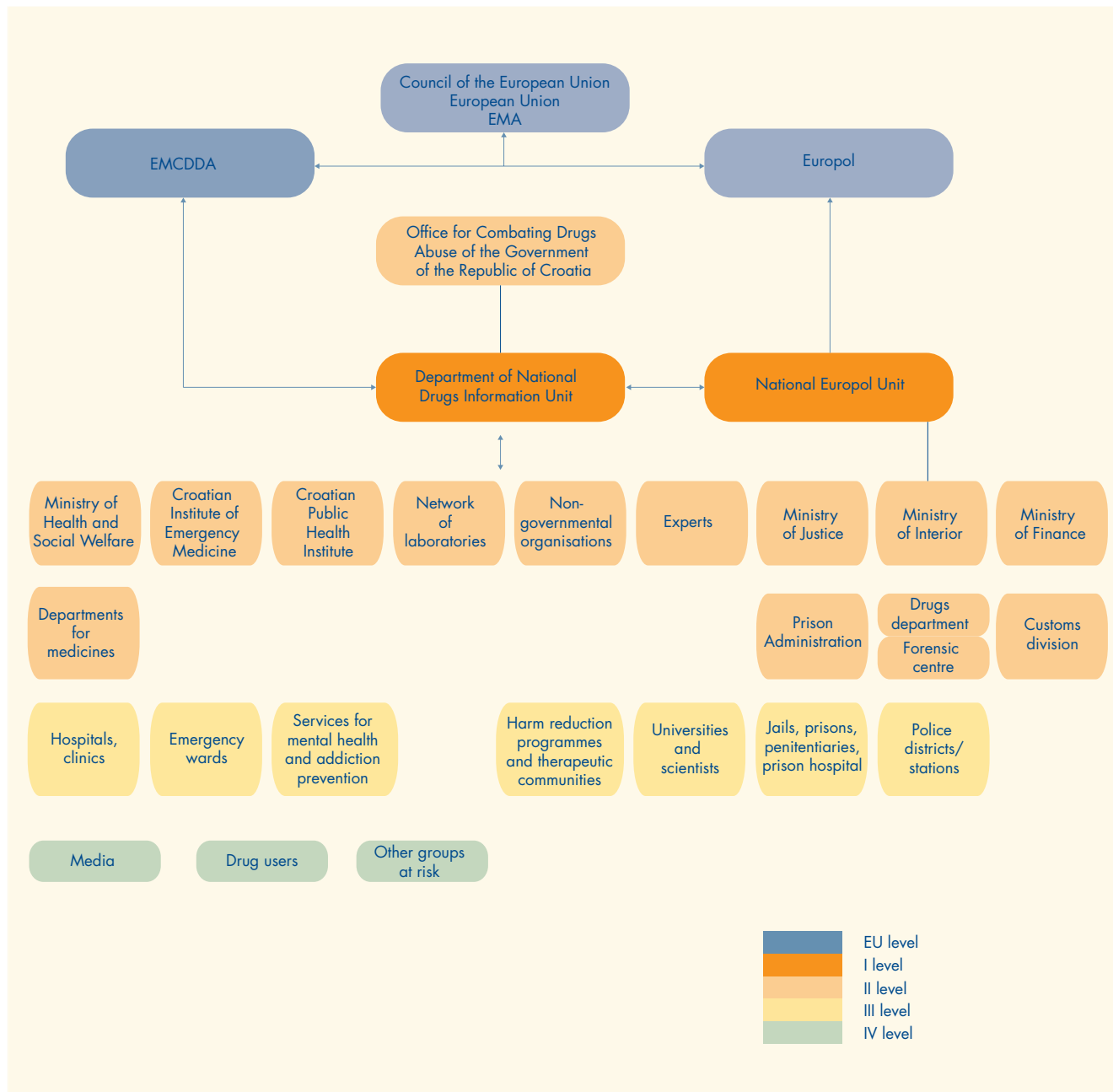
Level I — As a national coordinator of the N-EWS, OCDA is responsible for providing sound ground for cooperation with and between national partners, further development of the N-EWS, planning and supervision of implementing activities, collection and dissemination of information, reporting and direct communication with the EMCDDA. The National Europol Unit is in charge of reporting to the Europol Drugs Unit as described in the respective legal documents and at the national level, assists the OCDA in its coordinative function.

Level II — The advisory body to the OCDA is the Working Group on the early warning system (WG N-EWS), composed of representatives of key national institutions, non-governmental organisations and other acknowledged experts in the field. It advises the OCDA on general policy of the N-EWS, communication strategy, further development, discusses actual topics and emerging trends in the area, collects and disseminates, participates in production of work documents and expert literature. Selected experts from the WG N-EWS make a core expert group responsible for risk assessment.

Level III — Key public and scientific services/institutions as well as NGOs are organised as Focus Groups according to their professional/expert branches and each of them is being coordinated by the member of the of the WG N-EWS coming from their supervising authority (e.g. a representative of the Croatian Institute of Emergency Medicine will coordinate work of the focus group on emergency wards, etc.). As regular counterparts of the OCDA, they are obliged to continuously monitor emerging trends in their field, collect any information on new psychoactive substances and immediately report to the OCDA (directly or through their coordinators).

Level IV — This level is being activated only in cases when important warnings or alerts have to be transmitted to drug users, other groups at risk, services, experts and professionals concerned or even exceptionally to general population.

All information received from the EMCDDA or national authorities are kept in a simple database at the OCDA, translated, analysed and used for preparing information packages that are adjusted to the needs of specific target groups. Urgent warnings are immediately

Figure 4 — Organisational scheme of the early warning system on new psychoactive substances in the Republic of Croatia

Source: OCDA.

transmitted to all members of the WG N-EWS, who then decide (in consultation with the OCDA) whether information should be immediately forwarded to all or just some focus groups and potentially further to drug users or specific populations concerned and in which format. Other information received by the OCDA from EU or national counterparts are updated on a monthly basis and are disseminated to 2nd and 3rd level of the N-EWS as an

informative leaflet on new trends and developments in Croatia and the EU.

At the national level, data are collected in the standardised reporting form. When receiving a monthly information leaflet, all relevant stakeholders are reminded and encouraged to inform on new trends and developments observed in their field of work or in their environment/local

community. Since such practice was introduced only in the beginning of 2011, the main data provider on new psychoactive substances or dangerous impurities in traditional drugs is still the Forensic Sciences Centre at the Ministry of Interior. However, more and more information on emerging trends is received from the treatment services and harm reduction programmes. In the first half of 2011, a survey on distribution and prices of illicit drugs in Croatia was conducted among clients of harm-reduction services (N=622). Although there were also questions asked about the availability and prices of 'legal highs', there was not much information collected, probably due to the surveyed population which is more oriented on traditional drugs.

Risk assessment is carried out by a core expert group (pharmacologist, chemist, forensic expert, medical doctor, specialised police officer, and jurist). When a meeting is convened, each appointed expert is obliged to report on findings in his/her field of expertise, that could provide evidence of health and social risks posed by a specific psychoactive substance as a sound ground for proposing its legal control at the national level. However, there is no written risk assessment procedure with set scientific standards.

Besides aforementioned information packages for professionals, the OCDA also produces information leaflets, brochures, Internet articles etc. targeted at consumption population, especially youngsters. There are also regularly prepared updates and informative material for the media. Upon request, the OCDA prepares presentations and lecturers for professionals or specific populations (e.g. schools).

Case study

Mephedrone first appeared in Croatia in 2009. After several seizures of that substance and information on its availability obtained from the treatment services, the core expert group decided to put mephedrone under legal control, based on the national risk assessment procedure. After information received from the EMCDDA about the anthrax outbreak and fatalities among heroin users in the UK and Germany, the OCDA, in cooperation with relevant members of the WG N-EWS produced Instructions for protection of officials from possible exposure to anthrax spores during their work for police and health workers. The alert was also sent to treatment facilities and harm-reduction services with the aim to warn domestic drug users.

Strengths, limitations and way forward

The major obstacle in further development of N-EWS is of a financial nature. There is ongoing expansion of the N-EWS network. The major strength is a wide and well-structured network, as well as documents that clearly describe how the N-EWS should function.

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Cyprus — early warning system

Natasa Savvopoulou and Byron Gaist ^(?)

Introduction

The Cypriot early warning system (EWS) in the framework of the national focal point (NFP) began its formal operation on 17 June 2004, with the first meeting of the EWS network data providers, during which the communication procedures and other topics were discussed and arranged. At the time, the data was to be provided by the following organisations:

- State General Laboratory (SGL);
- IKAN — Cyprus Police Drugs Unit;
- KENTHEA — private sector NGO/therapeutic structures;
- Ministry of Health Pharmaceutical Services;
- Ministry of Health Mental Health Services.

Regular meetings of the working group, which would also act as an evaluation committee for the NSDs, were programmed for three-monthly intervals, with ad hoc meetings for special circumstances.

The Cypriot NFP, in collaboration with the Greek NFP, organised a training day for officers of the Cypriot NFP in June 2004 with the Greek EWS representative, followed by a training seminar with potential members of the EWS network, which was held in Nicosia with the Greek EWS representative and the Cypriot NFP in a training role. After this training, further contacts were made and the participation of the Cyprus EWS network partners/representatives was ensured.

Organisational issues

The need for the creation of an early warning system was prompted as a result of the establishment of the Cyprus NFP. Thus, the Cyprus EWS was established following the EMCDDA's recommendations and support. Although the National EWS was implemented to serve the Council Decision, it has come to take on a broader role and now it is the main source of information on which the responsible

parties rely in order to make new amendments to the drugs Law L 29/77. However, there is no formal founding regulation or decree for its establishment.

The National early warning system (N-EWS) is one of the main responsibilities and functions of the NFP, which is under the administrative management of the Cyprus Antidrug Council (CAC), although it is scientifically independent. It is located within the NFP's premises and is run by an NFP officer, assisted by the N-EWS working team and its operation covers the whole Republic of Cyprus (except for the occupied areas).

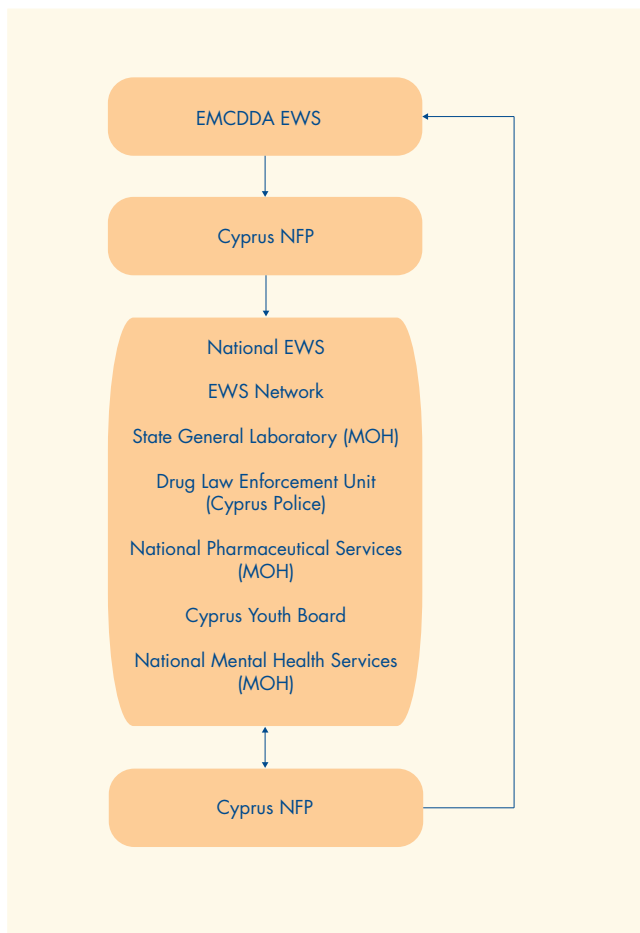
Most of the information exchange and dissemination takes place through e-mail as a way of speedy communication, as well as through regular mail or fax for a more formal level of exchange. This communication is usually in Greek language. The N-EWS is scientifically and politically independent. It is noted that according to the National Drug Strategy 2009–12, the Cyprus NFP is and will continue to be actively involved in an interdisciplinary committee aiming at the timely and effective recommendation to the Council of Ministers of substances needed to be added to the controlled substances Narcotic Drugs and Psychotropic Substances Law L 29/77.

Core functions and information flow

Once the information arrives at the NFP, the EWS officer reviews and translates the informational material accompanying the alert. The information is then disseminated to the N-EWS network which is comprised of the National Laboratory, the Drug Law Enforcement Unit (DLEU) of the Police, the Pharmaceutical Services of the Ministry of Health, the Cyprus Youth Board, the CAC and the National Mental Health Services of the Ministry of Health (MOH). The CAC developed an ad hoc committee aiming at studying and reviewing the Law L 29/77, thereby adding several new reported substances to its controlled lists.

^(?) With the assistance of Mrs Maria Avxentiou (State General Laboratory) and Mr John Kkolos (National Pharmaceutical Services).

Figure 5 — Information flow in the framework of the Cypriot EWS



Each mentioned partner has a contact person assigned for: (1) further in-house dissemination of the information; and (2) reporting back to the NFP if related information is available locally. If this is the case, the information reported is fed back to the EMCDDA EWS.

Data collection, information exchange and drug monitoring

The data collection and information exchange is mainly done through letters and e-mails, as well as EMCDDA reporting forms. Information deriving from general population surveys (GPS) or other surveys can also be reported, if available.

Timing/deadlines

EWS Final (annual) reports are submitted every January and EWS Progress reports every July.

Data appraisal and analysis

The Analysis of Drugs is done by the State General Laboratory of Cyprus. The main method used for the detection of drugs is Gas Chromatography with Mass Spectrometry (GC/MS). Several MS spectrum libraries (Willey, NIST, etc.) are used for the identification of drugs. A library from SWG ENFSI, with new designer drugs, is also available in the Lab. An in-house library has been built with the new drugs that are found in Cyprus.

Risk assessment

The ad hoc committee on L 29/77 essentially operates as a risk assessment body at national level.

Case study

Mephedrone

Once the EWS disseminated the reports on mephedrone, the N-EWS promptly forwarded the information to its network as mentioned above. On 21 April 2010, the CAC's ad hoc committee reviewed the information, and decided to prepare a decree suggesting the control of mephedrone and its derivatives. On 19 May 2010, the aforementioned committee presented the decree via the Ministry of Health, to the Ministerial Council. The Council approved the suggestion, and the decree for mephedrone's control was published in the Republic of Cyprus government gazette on 24 September. As of that date, mephedrone and its derivatives are Class B controlled substances. The operation of the EWS information system gives local experts the opportunity to be aware of new substances identified on the continent, and to apply their expertise and knowledge to the particular situation in Cyprus. In the case of mephedrone, this collaboration resulted in the control of the substance even prior to its control at European level.

Strengths, limitations and way forward

Strengths

Clearly the communication networked from other EU Member States is an advantage in alerting local experts to the new substances.

Limitations

It would be a desirable improvement to include contact persons from NGO therapeutic and preventive centres for a fuller picture of novel uses of familiar substances and new substances traced within the drug users' community. Further, it would be useful to include representatives of all hospital emergency units to the N-EWS so that when health-related alerts are reported, they are informed. The NFP requested the appointment of representatives, although there was no response.

Finally, the Cypriot NFP noted the need and proposed the development of a local EWS, which will be operating as a warning system, alerting all involved parties for the trafficking and use of new synthetic substances, as well as for

the existence of dangerous substance mixtures sold locally.

Links and references

EWS progress report to the EMCDDA (2004), 9 July.

Meeting minutes of CAC ad hoc committee on the 29/77 Law (2010), 21 April.

Meeting minutes of CAC ad hoc committee on the 29/77 Law (2010), 20 September.

Meeting minutes of CAC ad hoc committee on the 29/77 Law (2010), 26 October.

Czech Republic — early warning system

Roman Pesek and Viktor Mravcik

Introduction

The Czech national focal point (the Czech NFP, the National Monitoring Centre for Drugs and Drug Addiction) cooperates with the EMCDDA within the early warning system (EWS) since 2002, when information exchange on new synthetic drugs started. Within the period 2003–04, several meetings with experts and representatives of the Czech key authorities, as well as consultations with the EMCDDA, took place.

As a result of this consultation and inception phase, the document named ‘System včasneho varovani pred novymi drogami v Ceske republice’ (The early warning system for New Drugs in the Czech Republic) was adopted by the Council of the Government for Drug Policy Coordination on 15 July 2005, providing an official and formal framework for inter-institutional and inter-departmental cooperation within the EWS in the Czech Republic. This framework document defines objectives, principles and rules of the EWS cooperation based on the Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk assessment and control of new psychoactive substances (Council Decision). The EWS coordination working group (the Czech EWS WG) was established and the Czech EWS correspondent to the EMCDDA was officially assigned.

The objectives of the Czech EWS are based on those defined by the Council Decision, although similarly to the EU EWS, they are not limited just to new synthetic drugs or new psychoactive substances. The Czech EWS is also responsible for monitoring newly emerging or re-emerging (potential) risks and harms related to drugs and drug use in general (such as dangerous adulterants of ‘traditional’ drugs, e.g. levamisole in cocaine, contamination of drugs with infectious diseases agents, e.g. Bacillus Anthracis in heroin, or the outbreak of drug overdoses). The Czech EWS WG gathers significant Czech experts and the representatives of key authorities and works under coordination of the Czech NFP.

Organisational issues

The Czech EWS working group and the institutions involved

The Czech EWS WG is an expert apolitical body, the chairman of the group is a Czech NFP employee. The frequency of the Czech EWS WG meetings is biannually. The minutes are done for each meeting and are published in limited form on the website of the Czech NFP (see below, Links and references section).

Members of the Czech EWS WG are representatives of key institutions and authorities. The composition and the roles of the members are as follows:

- The Czech NFP — to coordinate the work of the Czech EWS WG, to collect, process and distribute the information coming from the EMCDDA’s level of the EWS, to conduct thematic surveys focused on the phenomenon of party drugs and new drugs, to initiate legislative and structural changes;
- The National Drug Headquarters of the Czech Police — to collect the law-enforcement data related to new drugs and emerging trends (e.g. monitoring the offer of ‘legal highs’, prosecution of trafficking related to new drugs, etc.);
- The Institute of Criminalistics Prague — to analyse the drugs seized by the police forces (mainly by the National Drug Headquarters) and by the General Directorate of Customs (the Customs Drug Unit), to implement research in this field, to identify new substances in the seized drugs;
- The General Directorate of Customs (the Customs Drug Unit) — to provide information on seized new drugs and trends in this regard;
- Europol National Unit of the Czech Police — liaison office with the Europol headquarters;
- The State Institute for Drug Control (the Medicine

Control Authority) — to provide information on the legislative framework of medical drugs control and information from the pharmacovigilance system related to the EWS;

- The Inspectorate for Narcotic and Psychotropic Substances of the Ministry of Health — an authority responsible for legal control of narcotic and psychotropic substances and for the legislative framework in this regard (mainly Act No 167/1998 Coll., on addictive substances);
- The General Directorate of the Prison Service — to provide information on new drugs and emerging trends among prisoners;
- The Institute of Forensic Medicine and Toxicology, 1st Faculty of Medicine, Charles University and General Teaching Hospital in Prague — to inform about results of toxicological analyses with respect to new drugs and emerging trends;
- The Department of Pharmacology, 3rd Faculty of Medicine, Charles University in Prague — to provide data resulting from analyses of new (party) drugs; the Czech EWS correspondent is an employee of this institution and is one of the main providers of informative and preventive website focusing on relevant information related to party drugs;
- The Prague Psychiatric Centre — monitoring the use of new (party) drugs and neurobiological research of new drugs;
- Non-governmental organisations (NGOs) — to monitor new drugs and emerging trends among drug users (e.g. 'party goers'), including distributing information on risks of new drugs and emerging trends at the national level (an NGO named 'Podane ruce' provides a website focused on prevention and counselling in the field of party drugs).

Communication with European partners

The Czech EWS correspondent and the Czech NFP (the chairman of the Czech EWS WG) are responsible for communication with the EMCDDA. Each year, the EWS Progress and Final Report is sent to the EMCDDA, as well as additional (ad-hoc) information on new drugs and emerging trends in the Czech Republic. Another institution responsible for communication with European partners is the Europol National Unit. Another formal or informal communication between members of the Czech EWS WG and European partners happens and is presented at the Czech EWS WG meetings.

Coverage of the Czech EWS

In general, the Czech EWS operates at national level. However, if the data on risks related to new drugs and emerging trends come from a specific region, the Czech EWS concentrates mainly on this region in order to spread appropriate preventive information and to ensure suitable preventive measures (for example, an outbreak of heroin overdoses in Prague in 2009).

Communication tools and main sources of information

The Czech EWS WG meets, at minimum, twice a year. E-mail communication is the standard way for information exchange. Each report coming from the EU-level of the EWS is sent to all working group members on a regular basis. The EWS national activity reports are, before their submission to the EMCDDA, communicated within all the members of the Czech EWS WG.

The Police Institute of Criminalistics in Prague and The Department of Pharmacology, 3rd Faculty of Medicine, Charles University in Prague are the main sources of information on identification of new synthetic drugs in the Czech Republic in seized or collected samples.

The Institute of Forensic Medicine and Toxicology, 1st Faculty of Medicine, Charles University and General Teaching Hospital in Prague provide information on the substances identified in clinical samples, including new synthetic drugs (see also the Case study below). NGOs are providers of (rare) reports on health-damage incidents among drug users, including incidents related to new synthetic drugs.

Core functions and information flow

There are two ways of information flow:

(a) Information on incidence and prevalence of new drugs and emerging trends at the national level — information provided through telephone and e-mail by a member of the Czech WS WG or by another person (e.g. informed provider of some drug service), information on new drugs and emerging trends found out in media monitoring, etc. These data are consulted by phone or e-mail within the Czech EWS WG. This way, a relevance of such data is assessed (assessment phase) and the WG is informed. If the assessment indicates the need for further action, the bodies responsible for implementation and coordination of

drug-policy measures are informed, according to extent and nature of the incident. In cases of public-health concern, the most relevant warning mechanism is chosen (ranging from direct e-mail to drug treatment and counselling services possibly with a request for additional information to press release, disseminated to the mass media).

(b) Information on incidence and prevalence of new drugs and emerging trends at the European level (information provided mainly by the EMCCDA). These data are distributed to the members of the Czech EWS WG via e-mail and the risk assessment with respect to the Czech Republic is conducted — in this respect, the feedback coming from the National Drug Headquarters, the Institute of Criminalistics Prague and NGOs is usually very important. If necessary, the most convenient instrument for distribution of appropriate information is selected.

Case study

In April 2004, severe intoxication of two individuals by 2,5-dimethoxy-4-bromamphetamine (brolamphetamine or 'DOB') occurred in Prague, Czech Republic (Balikova, 2005). Two men used white powder containing an unknown substance described as 'a new hallucinogenic LSD-like drug'. They used it orally. Subsequently, they experienced a rapid onset of intense hallucinations (within 15 minutes) followed by vomiting and unconsciousness. After an unknown period of time, both men were admitted to the hospital in a comatose state. The first man (28 years old) survived but experienced serious convulsions, was restless and had to be treated with strong sedation; the second man (29 years old) was in a deep coma without response to pain, with attacks of generalised convulsions, and metabolic acidosis — he died after six days. The results of toxicological screening from the gastric, blood, and urine specimens collected in admission were negative. Only thanks to information from an NGO working in the dance scene gathered from users, the Czech NFP was warned about the possible use and adverse effect of a new synthetic drug. An emergency unit and then toxicological laboratory were immediately contacted, specimens were re-analysed and DOB identified.

Without institutions cooperating within the Czech EWS, DOB would not be identified. The press releases were issued in the next few days and information about possible risk of intoxication with DOB was spread through newspapers,

radio and TV channels at the national level. Further cases of DOB intoxications within the same incident (outbreak) were not reported.

Strengths, limitations and way forward

Strengths

If necessary, an effective communication and information sharing among members of the Czech EWS WG is available.

Limitations

At present, the standard process of assessment of new substances with regard to their inclusion to the list of controlled narcotic and psychotropic substances is not defined. The Czech EWS and the Czech EWS WG supply this absent mechanism to a certain extent.

Another issue is an efficient dissemination of information on emerging trends and risks related to new drugs among drug services providers and implementation of appropriate measures into practise are not set up.

Links and references

Balikova, M. (2005), 'Non-fatal and fatal DOB (2,5-dimethoxy-4-bromamphetamine) overdose', *Forensic Science International* 153, pp. 85–91.

Other sources:

Official minutes coming from Czech EWS WG meetings (full version available only for members of Czech EWS WG meetings).

Standardised EWS reporting forms used for reporting to the EMCDDA.

The National Monitoring Centre for Drugs and Drug Addiction (the Czech national focal point).

The website on which contacts of members of the Czech EWS WG and limited forms of minutes coming from Czech EWS WG meetings can be found here: http://www.drogy-info.cz/index.php/o_nas/pracovni_skupiny/pracovni_skupina_system_vcasneho_varovani_pred_novymi_drogami

Denmark — early warning system

Kari Grasaasen

Introduction

In Denmark, monitoring of new drugs is included in the overall monitoring of the drugs problem in Denmark. The National Board of Health and the Danish police authorities (the National Commissioner) are jointly responsible for monitoring the emergence of new drugs and furthermore, the National Board of Health undertakes to assess the health-related consequences of the new drugs, including recommendations to the responsible minister that new drugs must be regulated on a current basis and banned.

From 2000, the EWS stepped up its monitoring of new drugs emerging in Denmark. The objective was: (1) to comply with a national wish to qualify and improve monitoring mechanisms in order to meet and 'capture' an increasing supply of new drugs traded on the market; and (2) to implement Council Decision 2005/387/JHA on information exchange, risk assessment and control of new psychoactive substances. Earlier on in 1997, this was referred to as the Joint Action on New Synthetic Drugs. The intensification of the national monitoring and the intervention against new drugs, combined with new trends surfacing, resulted in the establishment of new monitoring systems in Denmark and a national forum/working group for information sharing and collaboration. Furthermore, the authorities of the Nordic countries have joined together in collaboration/network teams in order to exchange information on drugs and the associated legislation — a Nordic network in extension of the European EWS. This chapter provides an outline of the Danish monitoring system, its players and network, and the process involved from the emergence of new drugs and to a possible regulation and ban.

Organisational issues

The responsibility for monitoring new synthetic drugs is divided by the National Board of Health (which is also the focal point in relation to the EMCDDA) and the National Commission (who also refers to Europol). Also, it has been agreed that the Danish focal point has the coordinating task of 'operating' the national EWS network, the primary reason being that information sharing in relation to international

collaboration is carried out under the auspices of the EMCDDA. The Danish focal point is thus responsible for the national coordination and therefore also responsible for recommending new drugs to be banned.

Monitoring of new drugs in Denmark is a national task and is based on reports on drugs seized by all 12 police districts. Apart from the drug samples collected on a routine basis by the police and submitted for forensic analysis, a so-called Ecstasy EWS monitoring system has been established to identify new drugs. The project is a collaboration network headed by the National Commissioner, the National Board of Health and the three institutes of forensic chemistry. The basic concept is that all substances which look like illicit drugs — pills/tablets, powders and liquids, etc. are submitted by the police districts to one of the three institutes of forensic chemistry for analysis.

The EWS network also consists of representatives from all the three institutes of forensic chemistry on the three Danish universities of Odense, Aarhus and in Copenhagen. The network also includes representatives from the Danish Medicines Agency, the Ministry of Justice, the Ministry for the Interior and Health and a number of medical professionals and experts. The expertise represented in the network vary a great deal and include pharmacists, forensic chemists, medico-legal forensic experts, assistant police prosecutors, sociologists, doctors and others holding university degrees.

An actual estimate on EWS network time consumption on monitoring and information sharing has not been made. However, an estimate on costs has been made, and it shows that forensic analyses made under the Ecstasy and EWS monitoring system run into approximately EUR 33 525 (the equivalent of DKK 250 000) on an annual basis. This amount is paid by the National Commissioner and the National Board of Health. In 2009, a total of 43 055 pills and objects were examined.

The purpose of the national EWS network is to inform each other immediately on the surfacing of new drugs detected nationally or internationally. Information on new drugs surfacing in other European countries and reported to the Danish EWS network is also used as an inspiration to be on

the outlook for such drugs on a national basis. Apart from using the network for information sharing and for collaboration on monitoring new drugs, the network is used during the hearing process on recommendations submitted on new drugs under bans consideration.

In order to capture new trends and user patterns, so-called regional hearings were made for a number of years in Denmark in the previous 15 counties. These hearings were based on qualitative and 'soft' information provided by local stakeholders such as the School, Social authorities and Police (SSP), local police, medical officers, drug use therapists, etc. However, the information obtained during the process did not provide significant revelations and when the counties were abolished during the structural reform in 2007, the National Board of Health/the Danish focal point decided to stop the hearings. The instruments and channels making up a source of information today include information about possible new behavioural patterns and drug user groupings and include qualitative surveys as well as routine statistics — primarily drug-related deaths (DRD), general population surveys (GPS) and treatment demand indicator (TDI).

Apart from the national EWS network, which is naturally linked to the European network of focal points in Europe, Denmark is part of the Nordic NADiS network (The Network for the Current Situation of Drugs in Nordic countries). This network includes countries such as Norway, Sweden, Finland and Denmark and Iceland and involves the sharing of information on new drugs and the associated legislation. Apart from the central Nordic authorities (the National Board of Health in Denmark), there are national Nordic NADiS networks. In Denmark, the NADiS network is more or less identical to the Danish EWS network. However, the Danish NADiS network has been expanded to include the national 'Giftlinje' (the Poison Control Hotline) and the Danish customs and tax authorities.

Core functions and information flow

The core of the monitoring and information on emerging drugs in Denmark is, as mentioned earlier, the chemical forensic analyses of the police routine drug samples and the analyses made in connection with the Ecstasy/early warning monitoring project. However, analyses made as a result of specific drug-related deaths or sporadic episodes resulting from poisonings treated in emergency rooms and hospitals in Denmark may also reveal information about emerging drugs. No other targeted monitoring projects and systematic reporting systems — for example, drug-user network groups

or NGOs — have been established. As mentioned earlier, special regional hearings have been held without this, providing crucial knowledge about new trends. However, the media have from time to time played a role when covering stories on individuals involved. This has been useful information for the authorities and has shed a light on new drugs emerging or new behavioural patterns gaining ground. An example of this is dextromethorphan (DXM), a cough medicine which, after having been an over-the-counter (OTC) medicine, was placed on the ban list when it was gleaned from stories in the media that young people were using DXM as a psychoactive substance. However, this is still the exception. Primarily, the EWS bases its conclusions on the forensic analyses of drugs seized by the police.

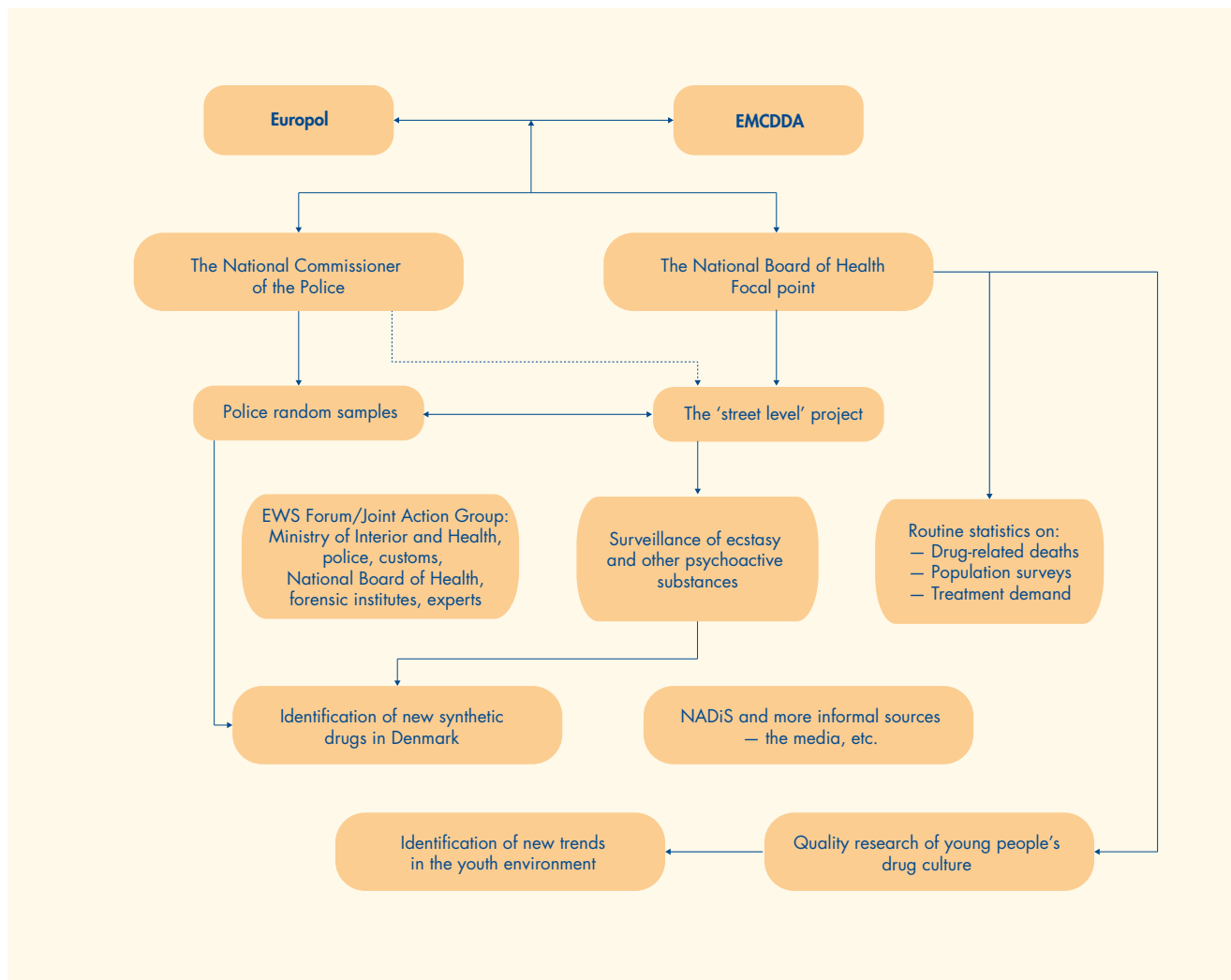
All chemical forensic analyses resulting from the ecstasy/EWS-monitoring system are compiled in a library database under the institutes of forensic chemistry and quarterly and annual reports are made and placed on the National Board of Health's website (see below, Links and references section). These reports provide an outline of the new drugs and show the development over time in terms of ingredients and concentration.

When new drugs are found in the forensic analyses — and this happens regularly — the National Board of Health/focal point is informed immediately. The information is also conveyed to the Danish EWS network and to the EMCDDA (by the focal point) and to Europol (by the National Commissioner). Following this, it is up to the National Board of Health to assess the need for a risk assessment procedure and to decide whether or not to recommend that the drug be banned nationally.

With regards to the banning of drugs, The National Board of Health plays a special role in submitting new drugs for legal regulation. The National Board of Health's role has been laid down in Section 1 and 2 of the Act on Psychoactive Substances, after which the minister for the Interior and Health shall be authorised to determine that drugs posing a particular risk (§1)/risk (§2) as a result of their psychoactive qualities as laid down by international resolutions or as set out by the National Board of Health shall not exist in Denmark (§1)/shall only be used for medical or scientific purposes (§2).

Thus, the ban of new drugs can either be made according to international resolutions — either under the auspices of the UN or the EU — or according to recommendations submitted by the National Board of Health. During recent

Figure 6 — Information flow in the framework of the Danish EWS



years, the latter approach has prevailed, as it has been possible to regulate on a speedy basis, and since an international risk assessment has not been imminent. There is a staff 'overlap' when it comes to carrying out risk assessments within the National Board of Health and the focal point coordination of the national EWS network. The national risk assessment of new drugs includes their hazardous potential — particularly in relation to risk of poisoning and psychosis (which may lead to accidents and violence). Another element of risk assessment involves dependency potential, prevalence and legislation in other countries. Also, factors such as the framework or practical problems (disadvantages) associated with a ban are assessed. As documentation on injuries and risk is often sparse in relation to emerging drugs, the basis for the risk assessment is often the similarity of the new drugs with drugs already known and provided for in the regulation.

Information provided both via the international collaboration between the EMCDDA and the Nordic NADiS is crucial to the national risk assessment. Another vital source is Internet searches on user sites. The final recommendation is sent via a hearing to the national EWS network.

The period from the new drug is identified via forensic analyses and until the drug has been subjected to risk assessment and finally listed in the executive order concerning the Act on Psychoactive Substances varies and may take from a total of 14 days to a few months. This relative 'speed' has meant that Denmark only very rarely awaits the European risk assessments when it comes to regulation of these new drugs.

The central health authorities in Denmark rarely issue actual 'warnings' on new drugs or particularly 'hazardous' drugs

on the market. However, when new drugs are regulated, the news of this is often issued very broadly and often the newly regulated drugs are described in press release material. Furthermore, the local police will issue letters of notification to users when particularly hazardous (and strong) drugs are being sold on the market.

Case study

Synthetic cannabinoids

There are many examples of the Danish EWS network in operation. The network operates on a daily basis and its work involves reporting, clarifications and communication of new drugs emerging nationally and internationally. Recently, the focus on synthetic cannabinoids has intensified, and the Danish EWS has taken action. Only a few of the synthetic cannabinoids have been observed on the Danish market so far, but a much higher number of synthetic cannabinoids have, however, been regulated in Denmark.

Immediately after the first reports had been issued on synthetic drugs emerging in Europe in 2008, the Danish EWS network was informed. The feedback from the EWS network was that the cannabinoids had not yet reached the Danish market — nor had ‘Spice’ products. In addition to the information and questions asked immediately after the first European reports were issued, the National Board of Health sent out information in February 2009 and a request for information on the use of cannabinoids and ‘Spice’ products to all the schools under the SSP (School, Social authorities and Police) collaboration network. Once again, this request did not give any information that ‘Spice’ or cannabinoids had yet been observed or found to be used. Following this, reports were received from the other EU countries via the EMCDDA on the surfacing of synthetic cannabinoids. However, not until in March 2009 was the first Danish seizure of cannabinoids (JWH-073) reported from an institute of forensic chemistry in Denmark. The information on JWH-073 in Denmark was immediately conveyed to the Danish network and informed to the EMCDDA as well as to the NADiS network. Since then, several cannabinoids have surfaced in Denmark and twice, the National Board of Health has recommended the prohibition of synthetic cannabinoids, following which the drugs have been regulated under the Danish drugs legislation.

As far as the cannabinoids are concerned, in Denmark reports on the current cannabinoids are regularly ‘compiled’ instead of recommending and regulating the cannabinoids one by one as they turned up. This means that a number of cannabinoids are already prohibited before they are observed on the Danish market. So far, Denmark has regulated a total of 32 synthetic cannabinoids in two rounds, where these cannabinoids have already been observed in one or several of the other member countries. Only five of the cannabinoids have been seen in Denmark so far.

Thanks to the European EWS, the Nordic NADiS and the Danish EWS network and to a speedy and flexible information-sharing process on the drugs — as well as the availability of the (however relatively sparse) documentation and knowledge to all relevant players — it has been possible to act relatively quickly on the prevalence of synthetic cannabinoids in Denmark.

Strengths, limitations and the way forward

The Danish EWS is a quick and effective system for the monitoring of new drugs. This is probably attributable to a long tradition of cooperation across the participating players/institutions on drug analyses, coupled with the fact that the network’s tasks are well suited for the players’ professional work and fields of interest.

As mentioned earlier, no systematic reporting procedures are implemented in emergency rooms and hospitals under the EWS network. The information on injuries such as poisonings resulting from drugs is thus brought to the attention of the system more sporadically and often stem from stories in the media. In the future, it can be considered whether more systematic reporting procedures could be useful in relation to a qualification of EWS in Denmark.

Links and references

Danish Medicines Agency — <http://lms-lw.lovportaler.dk/ShowDoc.aspx?docId=bek20080749-b1>

Danish National Board of Health — <http://www.sst.dk>

Danish National Board of Health, content of illicit drugs — <http://www.sst.dk/Sundhed%20og%20forebyggelse/Narkotika/Indhold%20i%20illegale%20stoffer.aspx>

Estonia — early warning system

Katri Abel-Ollo

Introduction

The development of the early warning system (EWS) on new synthetic drugs in Estonia began in 2002. On 16 April 2002, the Minister of Social Affairs at that time officially appointed an employee at the Estonian Drug Monitoring Centre of the Institute of Experimental and Clinical Medicine, as the correspondent of the Joint Action on New Synthetic Drugs (JANSAD) in Estonia. This title would mean acting as a national contact person in everything related to the EWS, as well as a liaison officer at both international and local level.

The first step in developing the EWS was mapping potential cooperators and sources of information, as well as introducing the system. The first ascertained potential sources of information in 2002 were the State Agency of Medicines, Tallinn Emergency Medical Service, the Forensic Service Centre, the Estonian Bureau of Forensic Medicine, the Border Guard, the Police Board and Customs Board. The first introduction of the EWS took place at the Drugs Committee under the Estonian Ministry of the Interior. This advisory committee had been meeting since 2000 (established on the basis of Directive No 142 of the Minister of the Interior of 28 March 2000) and included representatives of the Police Board, Criminal Police, Border Guard, Customs Board, Prosecutor's Office, State Agency of Medicines, Ministry of Justice and Ministry of Social Affairs. A representative of the Estonian Drug Monitoring Centre under the area of administration of the Ministry of Social Affairs also participated in the committee's work.

The initial attitude of different agencies on the necessity of the EWS was somewhat limited as it was seen only to exist to achieve the objectives of an EU agency. Notwithstanding that from the very beginning, the potential local needs were included in the EWS — in addition to the needs of the EU — in order to motivate the local cooperators. The first local need considered was a Rapid Exchange System for a fast exchange, which would serve public-health purposes and inform relevant agencies and service providers dealing with drug users immediately of the appearance of a new psychoactive substance on the Estonian drug market. As an ideal, this kind of rapid exchange of information would have contributed to the prevention of overdoses and improved the reaction of other agencies to new narcotic substances.

However, the lack of necessary legislation which would have provided a legal basis for rapid information exchange of an often confidential nature between different institutions became a hindrance to the development of this kind of local information exchange. Initially, a suitable basis for exchange of information was being sought by the compilation of a Memorandum of Understanding.

Although this document was prepared with the help of a foreign expert, it was found at the moment of signing that there should be relevant legislation to supervise the exchange of information. Since 2003, the Narcotic Drugs and Psychotropic Substances Act was being amended, it was decided to try to include the EWS into the amendments. It was agreed with the Ministry of Social Affairs that the act would be supplemented with the following sentences to cover the field of the Estonian Drug Monitoring Centre:

- the Estonian Drug Monitoring Centre (hereinafter referred to as 'EDMC'), which operates under the National Institute for Health Development, shall occupy itself with collecting and analysing existing epidemiological and statistical data on the situation related to drugs and evaluating the spread of drug addiction.
- In the framework of the cooperation project 'Joint Action on New Synthetic Drugs' (JANSAD) of the EMCDDA and Europol, the EDMC shall be informed immediately about the appearance of any new synthetic drug in Estonia.
- In the framework of the JANSAD cooperation project, the EDMC shall have the obligation of forwarding the information related to new synthetic substances to the EMCDDA.

As can be seen from the draft clauses above, the initial intention was to separately bring out the EWS. However, the act was not passed in this wording in 2005, and it only gave the EDMC a role of collecting and analysing data on drug addiction in Estonia. The approved role of the EDMC as the collector of data regarding drug addiction was presented as the reason for omitting the EWS from the act, as it was found that there was no reason to include such single projects in the act. However, according to the passed act, agencies had an obligation to respond to the information inquiries of the

EDMC, but not to show initiative by immediately forwarding the received relevant information to the EDMC. Also, the act did not govern exchange of information between institutions in the way that would ensure retaining the confidentiality of the information. Since the necessary legislation was not established, the EWS worked for years and, at the time of writing this chapter, is still working — to a certain degree — at local level as a project of so-called passive exchange of information. In 2009, Estonian cooperations became interested again in developing the EWS at local level. Partly, it was due to the increasing number of narcotic substances on the Estonian market which had not been added to the lists of Estonian narcotic and psychotropic substances ('legal highs'), and on the other hand, Estonia already had experience with the fentanyl analogues which appeared on the Estonian drug market at the beginning of the 2000s, causing a number of overdose waves. Thanks to the rapid changes in the drug market, the cooperation between the Police and the Border Guard Board, the Ministry of Social Affairs, the State Agency of Medicines, the Estonian Tax and Customs Board and the Estonian Drug Monitoring Centre has become closer and more active during the last two years. Several meetings have taken place between different parties with the aim of developing the EWS system at local level, as well as getting new narcotic substances under control in a timely manner.

This exchange of information concerning new narcotic substances between institutions, with the aim of adding such substances to the list of narcotic and psychotropic substances as soon as possible, is one of the advantages of the local EWS. For collecting background information on new narcotic substances, the local EWS network has also successfully introduced the EMCDDA database EDND (the European database on new drugs). In order to facilitate the exchange of information, a relevant legislative base will be prepared by the Ministry of Social Affairs at the beginning of 2012; this legislative base will govern the exchange of confidential data between agencies — something that has been borne in mind for years. It has been agreed that the extranet attached to the website of the National Institute for Health Development is the environment through which the data is exchanged; experts can enter the extranet using a password, and exchange information about new narcotic substances and consequences thereof. Hopefully, after the legislative base is available for data exchange, information on new narcotic substances will be added from the health care sector, as well. At the moment, neither Tallinn Emergency Medical Service nor services of other regions are

active members of the EWS.

In summary, development of the EWS has been in progress for nearly 10 years. A common web environment for the EWS information exchange was created in 2011 and legislation is expected at the beginning of 2012. It was mostly the local need for a quick reaction and control over the new, potentially harmful narcotic and psychotropic substances to public health that motivated the development of the system.

Organisational issues

The EWS is a nationwide information system. Currently, the local EWS is functioning via e-mail correspondence between the partners and meetings. As already mentioned in the previous section, after establishing the legislation and with the use of a new web environment that enables the exchange of information, it will become possible to exchange information between the EWS partners in a more operational manner. However, before establishing the relevant legislation, the EWS is more like a passive system for distributing information. Most of the EWS' data movements are forwarding the information received by the Estonian Drug Monitoring Centre from the EMCDDA to the local information network. A majority of the information gathered within the framework of the EWS has been collected through the data inquiries made by the EDMC. The problem is that the current system actually reduces other institutions' initiative in distributing information their agencies have received. Gathering all of the information into one system, as well as the initiative of different institutions to share information, are the most positive features of the new system.

Currently, the EWS has the following local cooperators:

- State Agency of Medicines — according to the statutes of the State Agency of Medicines (RTL, 2005), its obligations include identifying substances or medicines as narcotic or psychotropic substances and participating in the preparation of legislation and explanatory reports regarding narcotic and psychotropic substances and precursors, as well as performing supervision over handling narcotic and psychotropic substances for medical and scientific purposes and issuing relevant permissions, supervision and reporting in respect of narcotic and psychotropic substances and precursors. The State Agency of Medicines belonging to the field of

administration of the Ministry of Social Affairs has the essential role in taking control over new narcotic substances.

- Emergency Medical Services — emergency calls for the overdoses related to narcotic and psychotropic substances. Estonia is lacking a common nationwide emergency medical services statistical system. Each regional emergency medical service has its own separate statistics for emergency calls.
- Estonian Forensic Science Institute (EFSI) was founded in 2008 as the result of the merger of two agencies, the Estonian Bureau of Forensic Medicine and the Forensic Service Centre, and is the legal successor of these institutions. EFSI performs forensic researches, technical investigations, participates in investigative actions and performs forensic medical examinations, forensic chemical and forensic biological examinations. In summary, all forfeited narcotic and psychotropic substances are identified in EFSI, as well as all identifications of drug-related deaths and detections of narcotic substances in the body of the casualty.
- Police and Border Guard Board commenced working on 1 January 2010 as the result of the merger of the two agencies, the Police Board and the Border Guard Board. As a source of information in the field of drug addiction, its major role is to provide initial information about confiscations of narcotic substances on the border

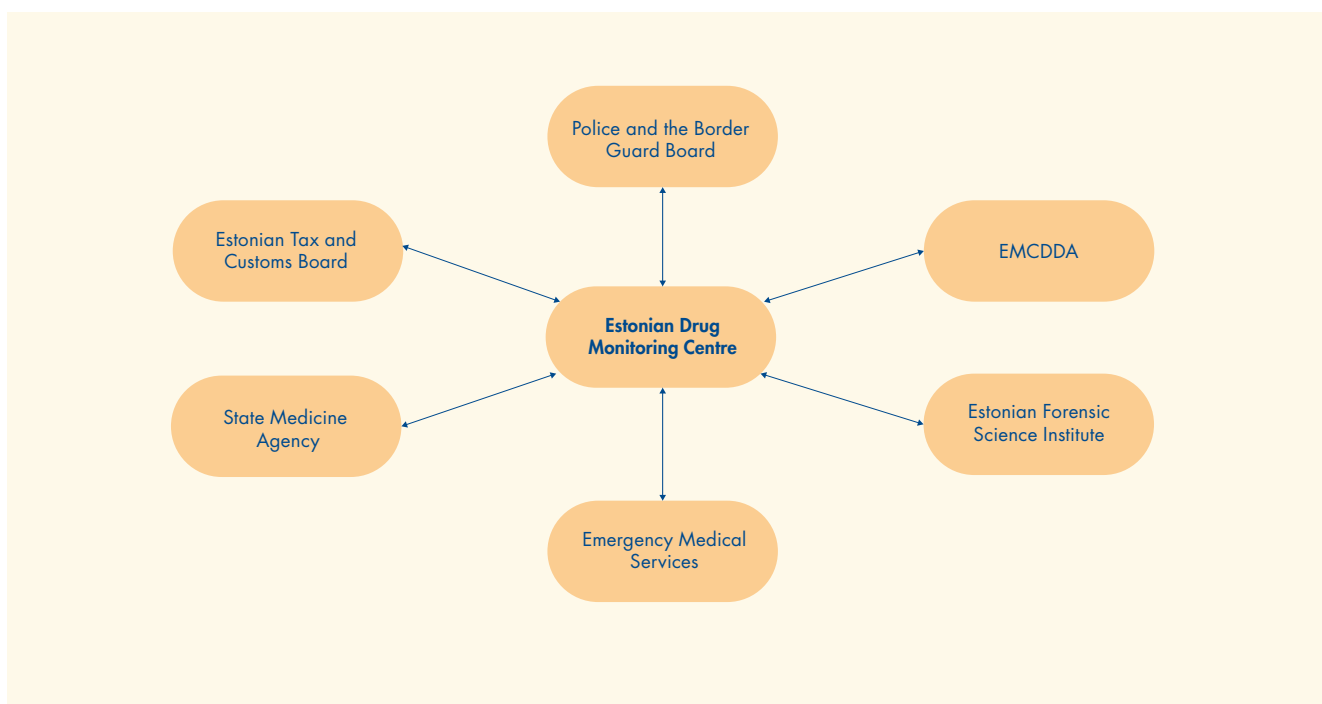
and information obtained by surveillance.

- Estonian Tax and Customs Board has been operating since 2004 and is the legal successor of the Tax Board and the Customs Board. As a source of information in the field of drug addiction, it provides information in the field of detecting crimes related to narcotic substances in the economic environment.

Core functions and information flow

In the Estonian EWS information system, the Estonian Drug Monitoring Centre (EDMC) has a central role and position. EDMC is the only one who communicates with the EMCDDA and forwards information from the EMCDDA to the local network of information. On the Figure 7, the arrows with two ends indicate the institutions with which the EMCDDA exchanges information. Although the initiative of EWS's partners to exchange information is limited for several reasons as already mentioned, information about narcotic substances moves without any particular problems when needed. In the future, when the EWS has its own legislative basis, better cooperation with the health-care sector is expected and if possible, also with the harm-reduction services. At the moment, components such as information from the users and information about the health consequences related to the use of drugs are insufficient.

Figure 7 — Information flow in the framework of the Estonian EWS



In Estonia, the harm-reduction services cannot be taken for a fully-fledged partner of the EWS with whom to share all of the information available in the system; it should rather be developed as a source of additional information and a necessary channel of information with an aim to reduce the risk behaviour of drug users.

Case study

The fentanyl situation is described under the case-study paragraph because it was the first substance that raised the importance of the development of the local EWS. As the fentanyl appearance determined the wide-scale overdoses wave, the rapid information exchange between the relevant institutions was crucial. When China White and White Persian appeared on the drug market, the Estonian Drug Monitoring Centre, Estonian Forensic Institute, Police Board along with services providing harm-reduction services, collected and exchanged the relevant information on the fentanyl situation. The appearance of fentanyl in Estonia was related to the shortage of heroin caused by the Afghanistan war period in 2001. Heroin was available only in small quantities with a high price and low purity level. Estonian opiate users began to find a substitute for their daily drug and used fentanyl as a replacement. Fentanyl has been widely on the Estonia market since 2002. When fentanyl first appeared, it was sold and used as heroin to IDUs. As fentanyl potency is much higher than that of heroin, the use of it created an overdose wave. According to Tallinn Medical Service, there were 401 drug-related overdose cases in 2001 and 971 in 2002. Between 1999 and 2010, there have been a total of 825 drug overdose related death cases, and 89 % of them have been males (a total of 736 cases). The average age of deceased individuals who died as a consequence of an accidental drug poisoning was 29 years and, according to the Estonian Forensic Science Institute, most of them are related to the use of fentanyl.

The fentanyl prevalent in Estonia is illicit fentanyl produced in clandestine laboratories, known by its street name as China White and 3-methylfentanyl known as White Persian. Fentanyl mainly originates from the Saint Petersburg region. Based on the IDUs risk behaviour and infectious diseases prevalence studies in the time period 2005–10, the fentanyl used as a main injected drug in the last four weeks varied from 13–64 % among IDUs in different Estonian towns.

Strengths, limitations and way forward

The strength of developing the EWS in Estonia is definitely the smallness of the country, where the statistics of an entire country are gathered, in most cases, into one central national institution. Also, before establishing the necessary legislative basis for exchanging information, the essential factor of fluent information flow in the framework of the EWS is close cooperation amongst the experts involved and good professional relationships. As already mentioned, the further development of the EWS is related to the establishment of the legislative basis for exchanging information, as well as developing the necessary online environment for experts. The new online environment enables the experts to exchange information in an interactive forum in a prompt manner and send rapid information requests to their collaborators. After establishing the new online environment, there is no need anymore for e-mailing the partners upon any new information received from the EMCDDA.

Links and references

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Finland – early warning system

Martta Forsell, Katja Pihlainen and Hannele Tanhua

Introduction

In Finland, there is a strong tradition of inter-agency cooperation. The N-EWS in Finland is built upon this tradition of both formal and informal cooperation, but the system is currently under transition to better face the new challenges posed by the new psychoactive substances.

Organisational issues

The home of the N-EWS has been with the focal point in the National Institute for Health and Welfare (THL). The EWS network consists of the Poison Information Centre, Finnish Customs Laboratory, Finnish Customs, National Bureau of Investigation, Forensic Laboratory, Finnish Medicines Agency (Fimea) and the Department of Forensic Medicine at the University of Helsinki.

Originally, the EWS network was formed to meet the demands of the EMCDDA's EWS-cooperation. It has been working on a relatively loose basis, mainly functioning via e-mail.

Starting from spring 2011 onwards, the duties are shared with the Finnish Medicines Agency (Fimea). This is due to a change to the Narcotics Act, which has enabled a national classification of new narcotic substances from 1 June 2011 onwards. Fimea is the leading agency in this process. It is stipulated in the 2011 legislation that only such emerging psychoactive substances which have been reported to the European early warning system can be classified nationally as narcotic drugs. However, this premise is not applicable to active pharmaceutical ingredients which may also now be nationally classified as narcotics. From 2011, the N-EWS serves also as an elemental part in the national classification efforts and will therefore be more formal by nature.

To prepare a legislative proposal and looking ahead to the foreseen changes, the key persons and agencies have met almost monthly. The collaboration has continued to be frequent in 2011, although lately in the inter-agency cooperation the main tool of communication is e-mail. The EDND database and the Nordic NADIS database (see Chapter on the Danish early warning system) are also widely

used by the experts of different fields in different agencies. The communication language within N-EWS is in Finnish, yet material originally in English (or in Swedish) is forwarded as such.

Core functions and information flow

Prior to 2011, the N-EWS has functioned mainly as an information exchanging tool. The information about new substances emerging in Europe has been distributed nationally to the national network. Since Finland has been very active in reporting new substances for the first time in the European level, the information exchange has been well motivated.

The N-EWS has been organised by the EMCDDA focal point until early 2011. It is planned that Fimea will take a more active role from 2011 onwards after the legislative changes and also of new personnel.

Much information provided through the N-EWS is nevertheless provided by the law enforcement agencies (the Finnish Customs, the National Bureau of Investigation (NBI) and the National Police Board) and their forensic laboratories. Other laboratories in the network include the forensic laboratory of the Department of Forensic Medicine in the Hjelt Institute, part of the University of Helsinki and the laboratory with the National Institute for Health and Welfare (THL).

Other partners in the N-EWS network but also on the foreseen national classification effort include the Poison Information Centre and the national drug policy coordination. The social aspects are looked after from the National Institute for Health and Welfare (THL).

Case study

MDPV

In 24 November 2008, Finnish Customs seized 2 x 1 g of MDPV from an incoming post and the new substance was

reported to the EWS in November 2008. The substance was simultaneously emerging for the first time in the UK, Sweden and Denmark. The Finnish Customs asked Fimea if the new substance in hand was a medicinal substance and the Agency classified MDPV as a medicinal product on 20 January 2009.

MDPV gained some popularity among drug users and received attention in the mainstream media. The first efforts to gain comprehensive knowledge on the substance were made during summer/autumn 2009. The N-EWS provided a good platform for finding laboratory-based information. Nevertheless, as it was established that MDPV was in fact circulated to a great extent, it became more important for the outreach workers, the health-care personnel and the law enforcement to learn more about the substance itself and about its properties. Gaining reliable knowledge on the substance was difficult and it took almost a year before a fact sheet about MDPV was published by the focal point. By summer 2010, the politicians were also taken by the MDPV phenomenon and the substance was controlled as a narcotic drug on 28 June 2010.

The lessons learned from the MDPV phenomenon were that the N-EWS was geared for formal cooperation of relatively rare substances. The reliable information on substances is hard to find even within the established cooperation and the spheres of communication have to be enlarged in case of exceptional substance and prevalence. The new legislation and national classification aims to prevent such a phenomenon but also to include more medical knowledge in the network and a clearer link to the other non-governmental forums.

Strengths, limitations and way forward

The strength of the Finnish N-EWS will in the future be the inter-agency trust and mostly straightforward and low-bureaucracy cooperation within the network. In the future, one of the main functions of the N-EWS will not only be the collection of data but also sharing this information more efficiently not only to the monitoring and law enforcement personnel but also to treatment facilities, health-care personnel — and possibly also to the public. The problems posed by the nature and increasing number of new psychoactive substances will nevertheless be best addressed through European cooperation, rather than national solutions only.

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Finnish Medicines Agency (Fimea) — <http://www.fimea.fi>

Forensic Laboratory — <http://www.enfsi.eu/page.php?uid=166>

National Bureau of Investigation — <http://www.poliisi.fi/poliisi/krp/home.nsf/pages/5A23874F6668B910C225702F0023A86E?Opendocument>

Poison Information Centre — <http://www.hus.fi/default.asp?path=59,403,19336,9739,9541>

France — early warning system

Emmanuel Lahaie and Agnès Cadet-Tairou

Introduction

The French early warning system (EWS) was created in 1999 within the context of the French national focal point (OFDT: Observatoire français des drogues et des toxicomanies — French Monitoring Centre for Drugs and Drug Addiction) at a time when the French public authorities were concerned about the arrival of new substances in France as a result of the growing popularity of the 'techno' movement. Focusing on the identification of emerging phenomena linked to drugs, it very quickly began to draw on a network of local partners before setting up a network of monitoring centres in 2001 covering the major cities in France. This network appeared to be necessary in order to be close to conditions in the field and drug users while at the same time ensuring the use of reliable information collection methods common to all sites. The system, focusing on identification of products in circulation and real-time transmission of information (SINTES, Système d'identification national des toxiques et substances — National detection system of drugs and toxic substances) is backed up by a surveillance system (TREND, Tendances récentes et nouvelles drogues — Recent trends and new drugs) for more in-depth observation of uses (description of users, substances used, practices, representations and, insofar as possible, consequences) in populations with a high prevalence of use; in addition, local markets and micro-trafficking (availability, accessibility, price, substances in circulation).

In 2006, the scope of the surveillance activities of the SINTES system, which had previously concerned only synthetic substances, was extended to include all illicit drugs. The zone monitored was also extended to include every region of the country. At the same time, the SINTES system was divided into two parts: an 'observation' part and a 'monitoring' part, based on two different collection approaches.

The system as a whole enables the OFDT to provide an innovative and reliable overview of populations that are generally difficult to access, as well as the substances in circulation, by getting as close as possible to users.

Organisational issues

The main objective of the French EWS is to provide the general public and the state authorities with reliable, real-time information on new trends concerning the composition of drugs and their uses. The system was validated in its current state of operation at an interministerial meeting on 1 February 2006. It is therefore in line with the decision of the Council of the European Union of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances.

Collection of information and products

The core of the French EWS information system is based on seven sites located in seven cities (Bordeaux, Lille, Marseille, Metz, Paris, Rennes and Toulouse). Each of these sites has a local coordinator responsible for leading ethnographic observers collecting continuous information on uses and substances in circulation. Local coordinators are generally health and welfare professionals — several are sociologists, one is a pharmacist and another, a youth worker — working within a healthcare and/or health information structure receiving drug users and with a 'historic' presence in the region.

This system conducts the annual 'observational' surveys of the SINTES system. These provide information on the composition of a substance in circulation on the basis of simultaneous collection of a drug sample (for laboratory analysis) and a questionnaire from drug users. They supplement data resulting from seizures by providing a snapshot of the composition of substances used or ready to be used. The most recent observational survey conducted in 2011 deals with heroin. It involves 108 collectors at the seven different sites. The number of collections is estimated to be 400.

Collectors carry cards bearing their names and authorising them to collect in accordance with the scheduled procedure (collection kits are specific and numbered). These cards also

mention the telephone number of the responsible coordinator and the address of a website giving access to all the official documents authorising the system and the list of people authorised to collect without a specific project order. Observation concerning illicit products is extended to other healthcare structures or professionals. They are encouraged to consult the national EWS in order to have a product that is novel in terms of its nature or one having caused unusual adverse effects in a user among their patients analysed or transmit an alert via the network.

This extended system represents the surveillance component of the SINTES system. It is part of a health-focused approach in that it enables quantitative analysis of substances that might represent a particular risk or that are novel in nature and/or the transmission of alerts concerning the same phenomena.

In particular, it is used to analyse new synthetic substances and substances suspected to be the source of overdose (OD) among one or more users. In 2009, the notion of 'active surveillance' was introduced, allowing the OFDT to have a substance actively investigated (for example, heroin in the event of the occurrence of several overdoses).

As part of this component, the person needing to make the collection must contact his local coordinating site if his zone is covered by part of the network or the national coordination system. If the collection is authorised, the person is supplied with a specific project order in his name by e-mail or fax in real time, authorising him to collect and store the product. He then receives a collection kit by post, along with the original of the project order.

All the products collected are transported to laboratories contracted by the national EWS for analysis.

Rapid exchange of information

The French EWS also helps ensure the rapid exchange of information between several external sources.

- Drug user reception and care structures. All the structures in France are linked to the NFP, which conducts annual national activity and assessment surveys.
- Data supplied by law-enforcement service seizures. The French EWS has signed partnership agreements with scientific laboratories dependent on the Customs Department (SCL), the police (INPS) and the National Gendarmerie. These agreements commit both parties to share information concerning the composition of drugs

and specific events (specific cutting agent, high purity, newly identified substance).

- Healthcare institutions. The French EWS is a major player in terms of transmission of alerts relative to psychoactive substances to the Cellule nationale d'alerte (CNA — National Alert Unit) for psychoactive substances. This unit is composed of the national EWS, the Narcotics Department of AFSSAPS (Agence française de sécurité sanitaire et des produits de santé, French Health Products Safety Agency), the Ministry of Health and the Department of Infectious Diseases of the InVS (Institut national de veille sanitaire, French National Health Monitoring Institute). The CNA's role is to assess, investigate and propose a healthcare response to any specific alerts linked to drug use that represent an immediate potential risk to public health. A regularly reviewed procedure determines the role of each party, the methods of information sharing within the unit and with the networks of each party and the decision-making methods. It also considers the various potential actions that can be implemented.

The role of the TREND system: contextual information

The OFDT monitoring system is a major transmitter of alert signals. It also provides feedback of grassroots information and draws a picture of drug use practices constantly updated, year on year. It therefore enables rapid evaluation of a signal (plausibility, unusual nature, cross-checking of information, etc.) and also enables sorting out of the numerous signals received. The TREND observer network can also be used to launch rapid investigations to shed light on an alert signal.

Publications aimed at partners (feedback)

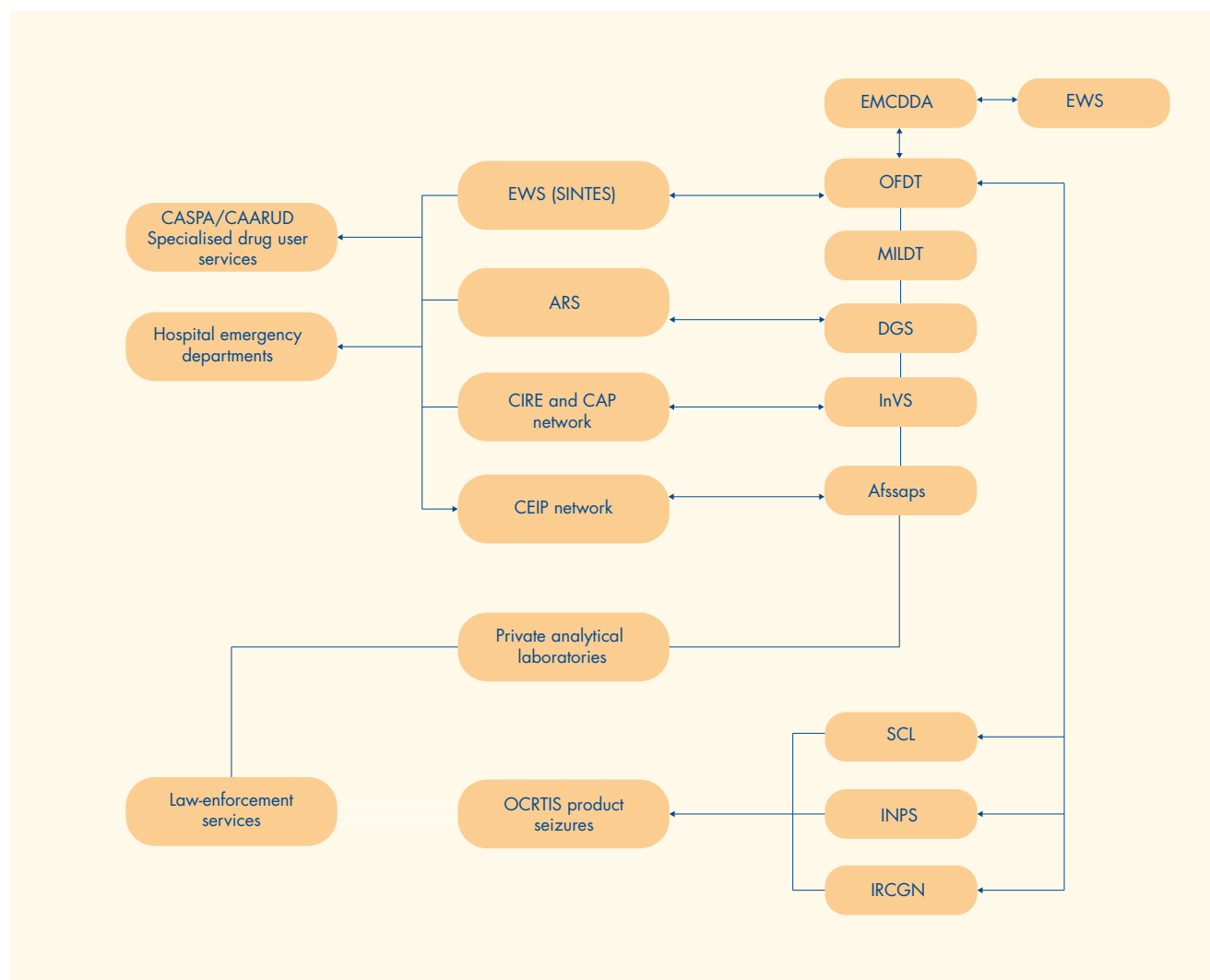
The provision of feedback to the players involved representing the core of the SINTES system and its partners can take several forms:

- SINTES information notes (online, freely accessible) — see Links and references section for more information;
- SINTES information bulletins (every four months — online, access limited to partners);
- SINTES observational survey report;
- e-mails;
- TREND annual report (qualitative observations on the basis of regional reports produced by each TREND site);
- updating of the www.ofdt.fr website.

In addition, the person supplying information or collecting a substance is systematically kept informed of the outcome of this alert or the results of sample analysis.

Core functions and information flow

Figure 8 — Bodies involved in the monitoring of psychoactive substances



Notes:

AFSSAPS: *Agence française de sécurité sanitaire des produits de santé* (French Agency for the Safety and Healthcare Products)

CAARUD: *Centre d'accueil et d'accompagnement à la réduction des risques des usagers de drogues* (Reception and Support Centre to Reduce Risks Among Drug Users)

CEIP: *Centre d'évaluation et d'information sur les pharmacodépendances* (Centre for Drug Addiction Evaluation and Information)

CSAPA: *Centre de soins d'accompagnement et de prévention en addictologie* (Centre for Supportive Care and Prevention of Addictions)

DGS: *Direction générale de la santé* (Government Department Health)

EMCDDA: European Monitoring Centre for Drugs and Drug Addiction (=OEDT)

EWS: early warning system – European network for information on new phenomena linked to drugs. The EWS is coordinated by the EMCDDA, which is responsible for circulating the information among the 27 Member States of the European Union. The French representative of the EWS is the SINTES system.

INPS: *Lyon Institut national de police scientifique* (Lyon National Forensic Police Institute) (incorporating all forensic police laboratories)

InVS: *Institut national de veille sanitaire* (French National Health Monitoring Institute)

IRCGN: *Institut de recherche criminelle de la gendarmerie nationale* (National Gendarmerie Institute for Criminal Research)

LPS: *Laboratoire de police scientifique* (Forensic police laboratory)

MILD: *Mission interministérielle de lutte contre la drogue et la toxicomanie* (Interministerial mission to control drugs and drug addictions)

OFDT: *Observatoire français des Drogues et des Toxicomanies* (French Monitoring Centre for Drugs and Drug Addiction)

OEDT: *Observatoire européen des drogues et des toxicomanies* (=EMCDDA)

OCRTIS: *Office central pour la répression du trafic illicite des stupéfiants* (Central Office for the Control of Illicit Drug Trafficking)

SINTES: *Système d'identification nationale des substances et toxiques* (National system for the identification of substances and intoxicants) (OFDT)

SCL: *Service commun des laboratoires* (Joint laboratory service) (Customs Department laboratories)

TREND: *Tendances récentes et nouvelles drogues* (Recent trends and new drugs) (OFDT).

Case study

Heroin overdoses

Between December 2007 and May 2008, 17 death cases linked to heroin use were recorded in the Metz area (eastern France). The health authorities at first suspected a batch of high-purity level heroin. But the different samples collected by the SINTES network along this time frame show no increase in the purity of the available heroin. The users interrogated by the TREND device also declared that they hadn't heard about high-purity heroin available in the area.

In June 2008, the OFDT and the local TREND/SINTES coordination investigated different health actors (low-threshold structures, toxicological laboratories etc.). This investigation concluded that a new type of consumption was being faced, rather than a simple purity issue:

- the victims were young (< 35 years);
- they showed no trace of injection in their arm(s);
- besides heroin, many other substances were found;
- the large majority of the victims were unknown to the low threshold structures in the area.

New evidence enlightened by the recent TREND observations confirmed the above-mentioned elements:

- greater availability of heroin;
- drug use among people socially inserted, notably young people who are used to snorting heroin;
- users unaware of/underestimating the related risks of snorting opiates;
- low transmission of harm-reduction practices toward these 'new' users, born after the 'HIV generation' and less aware of the risks (dose, effects, mix with others drugs).

A TREND/SINTES note to the public health institutions led to a press release considering the dangers of heroin, even if not injected and to recall the basics of harm reduction.

Lidocaine

In 2008, several reports of a new substance called COCA PEP were quoted by the local TREND/SINTES coordination of Metz. The substance seemed to have a good reputation among users, although they had no idea of the composition. The substance was presented as a powder with slight stimulant effects. It was finally collected from a person who had experimented this product several times.

- The analysis of the collected sample finally identified lidocaine.
- A second analysis on a new sample collected in 2009 under the same name confirmed the composition.
- This was the first time that lidocaine was used for its own properties and not only as cocaine cutting agent. It was also the first cocaine derivative analysed in France.

Strengths, limitations and way forward

The strength of the French EWS lies primarily in the implementation of a permanent network of healthcare players working with drug users. This continuity enables reactive feedback of information. The French EWS also leans on its permanent network to conduct more specific investigations (Cadet-Taïrou et al., 2006; Reynaud-Mauruptand Hoareau, 2010; Escots and Suderie, 2010). The collection methodology guarantees analysis in a laboratory of uncut samples actually intended for consumption by drug users.

The SINTES system launches initiatives designed to extend its network to structures located in regions where TREND is not yet implemented. Information in hospital emergency departments is also being studied in order to enable the analysis of samples of drugs directly related to overdoses. Since 2011, the observational scope has also been extended to include the Internet. Continuous observation and specific one-off surveys are currently being implemented on the subject of new synthetic substances.

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Germany – early warning system

Ingo Kipke, Alicia Casati, Lisa Jakob and Tim Pfeiffer-Gerschel

Introduction

The German early warning system (EWS) is an informal network consisting of relevant national, as well as selected, regional and local institutions. The main objective of this network is the exchange of information concerning new drugs and modified patterns of drug use. The information flows both from the EMCDDA via the German national focal point (NFP) to the participants of the national EWS and from the local or national institutions via the NFP to the EMCDDA. As the German NFP is co-funded by the Federal Ministry of Health (Bundesministerium für Gesundheit, BMG), the NFP also provides information to the BMG and the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) and acts as one of their advisors concerning new drugs.

The German EWS has been initiated in 1997 in line with the Joint Action of the European Council on New Synthetic Drugs (Council of the European Union, 1997). Similar to the EU-level cooperation between the EMCDDA and Europol, the German NFP initiated a cooperation with the Federal Criminal Police Office (Bundeskriminalamt, BKA) to cover the area of sentencing, as well as to receive chemical analyses of new, unknown substances and additionally established a network with key persons from important national, regional and local institutions covering the areas of epidemiology, prevention, treatment and harm reduction. With the adoption of Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, the focus has been expanded (medicine misuse and biogenic drugs have been included) and new partners (BfArM; Phar-Mon) have been recruited.

Organisational issues

The coordination of the EWS is located at the German NFP (staff: approximately 3.5 full-time jobs, one part-time employee is, beside other issues, responsible for the EWS) and has access to all its resources (e.g. the network of relevant national and local scientists, drug commissioners, workers in the drugs care system). Accordingly the NFP is responsible for information flow from the EMCDDA to

national level and from national level to the EMCDDA. Once a year, the German NFP organises a regular meeting of the national EWS. As German NFP has no formal mandate to obligate any institution to participate, the network on national level is informal – all partners participate on a voluntary basis and provision of information is voluntary as well.

The German EWS includes key persons from governmental and non-governmental organisations on national, regional and local level which represent in most cases networks with sub-units. The participating partners in the German EWS are (see also Figure 9):

- Federal Criminal Police Office (Bundeskriminalamt (BKA)): the BKA is responsible for reducing the supply of illicit drugs at federal level and, accordingly, is the German actor in the Europol framework. The BKA collects all information from police units on Länder level which, on their part, receive information from subordinate units. The BKA-laboratory is the most important source of analytical data in the framework of the German EWS.
- Robert Koch Institute (RKI): the Robert Koch Institute is one of the major institutions for monitoring infectious diseases and health protection in Germany. It serves as a central scientific institution in the field of biomedicine for the Federal Ministry of Health. The Institute combines risk research with political advice. Its most important tasks include protection against infectious diseases and the analysis of the health situation in Germany.
- The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)): the BfArM is an independent high federal authority within the portfolio of the Federal Ministry of Health. The aim of BfArM's work is preventing health risks by continuous improvement of the safety of medicinal products and by risk monitoring of medical devices as well as by monitoring the legal traffic in controlled substances scheduled in the UN-Conventions of 1961, 1971 and 1988.
- Phar-Mon: the Phar-Mon system monitors medicines misuse among clients of outpatient addiction treatment centres. The reference centres deliver data on medicines misuse three times per year. The main purpose of the

project is to serve as an early warning system for medicines misuse. In order to enhance the early warning nature of the Phar-Mon project, a pilot study on medicines misuse data gathered from external sources (e.g. police, pharmacies, hospitals, fitness studios) is under way. The Phar-Mon project is funded by the Federal Ministry of Health and works in close cooperation with the Federal Centre for Drugs and Medical Devices as well as with the German national focal point.

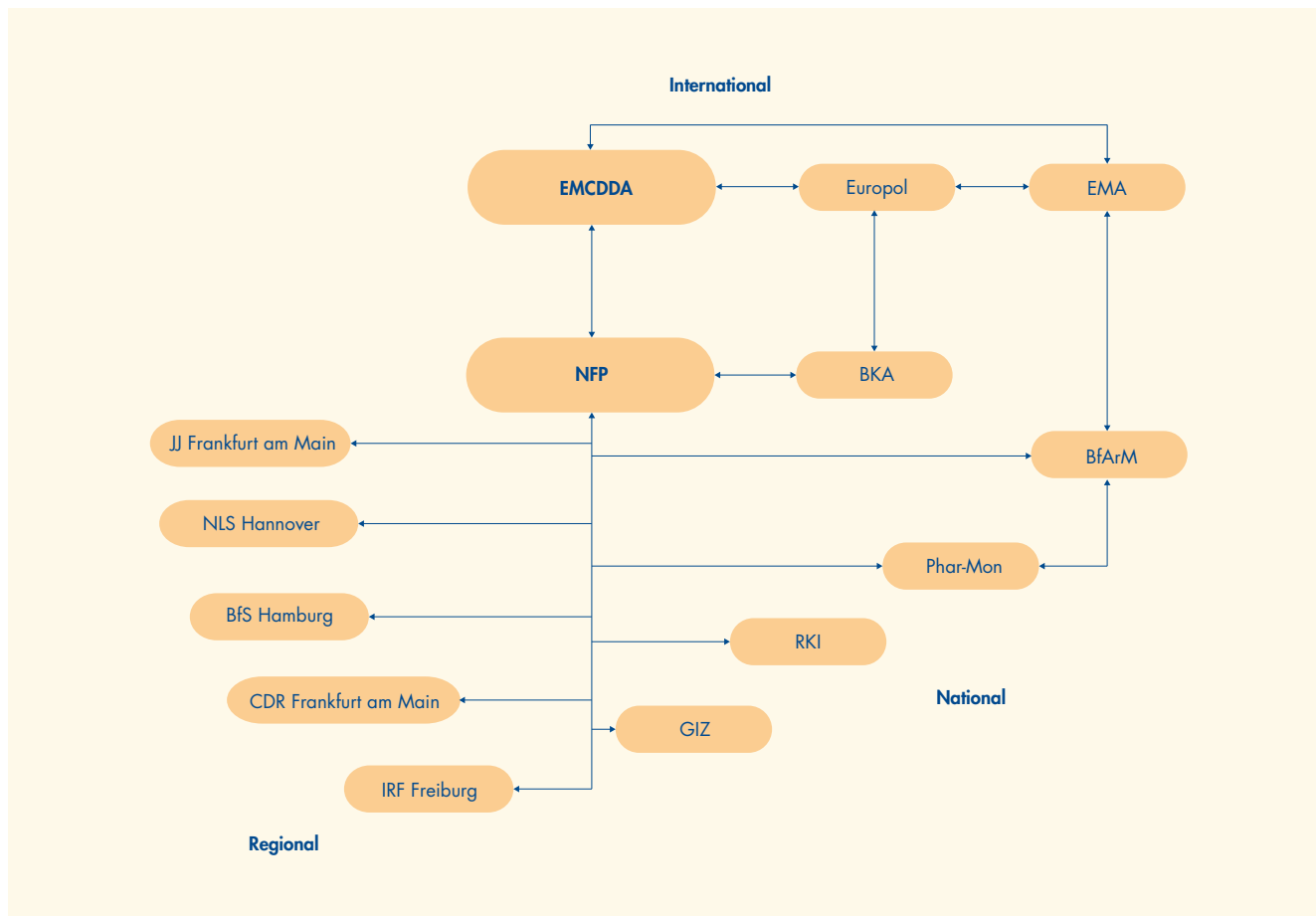
- Poison Control Centres (Gif tinformati onszentren (GIZ)): physicians and scientists who work in GIZs in Austria, Germany and Switzerland are organised in the Association of Clinical Toxicology (Gesellschaft für Klinische Toxikologie e.V.). The aim of the GIZs is fast and substantiated counselling of the population and of physicians in cases of intoxication. The GIZs are usually located at university hospitals in the capitals of the Federal Länder. They are documenting all cases of intoxication and have a broad data collection.
- Youth Counselling and Help Centre for Youth (Jugendberatung und Jugendhilfe, (JJ), Frankfurt am Main): this non-governmental organisation serves the EWS as a model of the drug help system at the local level and its employees are in close contact with users in the well-established drug scene of Frankfurt am Main. The JJ offers prevention programmes, centres for drug counselling, outpatient substitution centres, detoxification centres, inpatient drug treatment centres, facilities for assisted accommodation, schools for students with risks of drugs and former drug dependents, living and care facilities as well as help for children, adolescents and families.
- Lower Saxony Centre for Addiction Issues (Niedersächsische Landesstelle für Suchtfragen (NLS)): the NLS is the umbrella organisation of all addiction care facility centres and all self-help organisations of the non-statutory public welfare in Lower Saxony. The NLS represents the drug help system of the Federal Länder within the German EWS.
- Bureau for Prevention of Addiction (Büro für Suchtprävention (BfS), Hamburg): the BfS is located at the Hamburg Centre for Addiction Issues and its aims are the collection of practice-related data, the development and implementation of prevention concepts, as well as the evaluation and quality assurance of implemented measures. The offers concerning universal and selective prevention are primarily addressed to both individuals and institutions who play an active role in their work field or life environment, in order to implement addiction preventive measures.
- Centre for Drug Research Frankfurt am Main (CDR): the CDR is located at the University of Frankfurt am Main. The CDR is continuously conducting local school surveys and monitors the open drug scene, as well as other party scenes in Frankfurt am Main (local monitoring system). In 2011, the CDR started the EU project 'Spice and synthetic cannabinoids: Fast responses by means of forensic, toxicological and socio-scientific analyses with direct impact on prevention measures' in cooperation with the Institute for Forensic Medicine Freiburg (IRF) and the BKA.
- Institute for Forensic Medicine of the University Hospital of the city of Freiburg (Institut für Rechtsmedizin des Universitätsklinikums der Stadt Freiburg, IRF): the IRF represents forensic institutes within the German EWS. The laboratory of the IRF identified the synthetic cannabinoids CP-47,497 homologues in the herbal incense 'Spice' (Auwärter et al., 2009). As the IRF is a partner of the CDR in the aforementioned EU project, the laboratory searches for synthetic cannabinoids in herbal incenses. In this function, the IRF has identified several synthetic cannabinoids and provided reports via the NFP to the EMCDDA.

Core functions and information flow

As described in the previous section (see also Figure 9), the German NFP is responsible for the flow of information. Usually, information is provided via Internet or telephone, ad-hoc information is gathered from case to case by the NFP.

Like the EMCDDA, Europol and the European Medicines Agency (EMA) also have partners on a national level (in Germany, the BKA and the BfArM) and continuously exchange information from European to national level and vice-versa. As the BfArM and the BKA are also part of the EWS, a systematic link exists between the EWS and other European networks (Europol, EMA) exchanging information on new drugs.

All nationwide institutions (BKA, RKI, BfArM, Phar-Mon, GIZ) receive information from subordinate units on regional and local level and provide this information to the German EWS. As the monitoring of the drug scenes in Frankfurt am Main, Hannover and Hamburg is well established, local scientists and street-workers are well informed about new substances, trends and patterns of use and represented within the EWS.

Figure 9 — Information flow in the framework of the German EWS

Case study

The 'Spice' phenomenon

Already in December 2007, experts of the CDR Frankfurt am Main reported on 'Spice' to all participants of the national EWS meeting (BKA, BfArM, JJ, NLS, NFP, GIZ) for the very first time. This information was received from headshop staff within a 'trendscout' panel (the official report was published in July 2008). It was reported that 'Spice' is a herbal mixture with cannabis-like effects which is just a bit more expensive than cannabis products (approximately EUR 10 per gram).

The media hype started in August 2008, when newspapers reported on the abundance of a legal psycho-drug. After this, all relevant TV and radio stations as well as all nationwide and regional newspapers reported on herbal incenses. From the very beginning of the media hype in the summer of 2008, the German EWS acted as an advisor and provided information to the BMG and the EMCDDA

(e.g. at two meetings and the survey on 'Spice' among the NFPs in 2009) from its participants and from other European countries (information received from the EMCDDA or through bilateral contacts). Since August 2008, purchases and consumption (due to the extensive media reports) rapidly increased. In the autumn of 2008, the Drug Emergency Service in Berlin conducted a non-representative survey among approximately 250–300 new clients, of whom 10–15 reported at least an occasional use of 'Spice'. At this time, lab-tested knowledge of effects of ingredients still was insufficient and no common alkaloids had been found so far (only vitamin E) in several toxicological analyses in Federal State Laboratories and at Forensic Departments of Universities. Thus, legislative bodies had no clear concept how to deal with the matter (using the Narcotics Law, Tobacco Law, Pharmaceutical Act). The political answer was an invitation by the Federal Drug Commissioner to all relevant departments of the responsible ministries (health, youth, interior, agriculture, justice) and their subordinated

government agencies (BKA, BfArM, Federal Institute for Risk Assessment) on 2 December 2008, to discuss further suggestions to deal with the problem.

On 3 December 2008, the Federal Institute for Risk Assessment published a warning on the use of 'Spice' and similar products because of possible health risks. The Management Board of the EMCDDA was informed and the EMCDDA conducted a rapid survey among the NFPs (only the NFPs from Germany, Austria and Poland reported the phenomenon). Besides this, some drug service organisations published warnings for their clients, mostly young cannabis users, not to 'substitute' cannabis with 'Spice'. The media were informed by the Federal Drug Commissioner that the Government is investigating, with high pressure, possibilities of prevention and a subsequent ban on the purchase of these products. On 16 December 2008, the Drug Coordinator Office of the City of Frankfurt am Main, together with the research company THC Pharm (specialised in research of cannabinoids for pain treatment) published that the psychoactive ingredient of 'Spice' was the synthetic cannabinoid receptor agonist JWH-018. On 19 December 2008, the Federal Bureau of Criminal Investigation published a press release on new findings of further analytical results conducted by the IRF. The IRF joined the German EWS in January 2009 and continuously provides analytical data on new synthetic cannabinoids, as does the laboratory of the BKA. Analysed samples contained not only JWH-018, but also other synthetic cannabinoids.

The responsible department of the Federal Ministry of Health prepared a fast track regulation for the prohibition of producing and purchasing of 'Spice' containing the identified ingredients, which was ready on Christmas Eve. On 30 December 2008, the media had been informed by the Federal Drug Commissioner that 'Spice' would be banned as soon as possible. By adoption of the 22nd Amending Regulation on Narcotic Drugs (22 January 2009), certain synthetic cannabinoids were placed under schedule II of the German Narcotics Act (narcotics eligible for trade but not for medical prescription). Trafficking, production, acquisition, possession of herbal incenses which contain these active agents, became illegal. As this fast-track regulation was only valid for one year, the 24th Amending Regulation on Narcotic Drugs (January 2010) placed the aforementioned synthetic cannabinoids and additionally JWH-019 and JWH-073 permanently under schedule II of the German Narcotics Act. While some synthetic cannabinoids have been banned, many new, not controlled, cannabinoids have been synthesised and added to new herbal incenses. This poses

the question whether legal restrictions and bans could be the answer to this phenomenon and how to deal with new synthetic cannabinoids.

On behalf of the NFP, an item on the prevalence of herbal incenses like 'Spice, Smoke' etc. was added to the General Population Survey in Germany in 2009 (Epidemiological Survey of Substance Abuse, ESA) (Kraus et al., 2010). The results of the ESA 2009 (N=8,030; 18–64 years) show that the lifetime prevalence (ltp) of herbal incense consumption is 0.8 %, the last year prevalence (lyp) 0.4 % and the last month prevalence (lmp) <0.1 %. In contrast to the prevalence across all ages, the prevalence among young adults (especially ltp and lyp) is much higher (18–20 years: 2.5 % ltp, 1.9 % lyp, <0.1 % lmp; 21–24 years: 2.5 % ltp, 1.8 % lyp, 0.1 % lmp; 25–29 years: 2.1 % ltp, 1.0 % lyp, <0.1 % lmp).

The CDR conducted a study on consumption and motivation for consumption of herbal mixtures (Werse et al., 2010) and concluded that most of the users of herbal incenses are typical cannabis users, who are already in trouble with the law (e.g. those who have lost their driving license). Others have to take drug tests and therefore use 'Spice' products as substitutes for cannabis, so that drug consumption will remain unnoticed. The CDR is currently conducting a study in cooperation with the laboratories of the IRF and the BKA on 'Spice and synthetic cannabinoids: Fast responses by means of forensic, toxicological and socio-scientific analyses with direct impact on prevention measures' in order to answer the question: *How can we reach potential users with specific measures of prevention and treatment?*

Strengths, limitations and way forward

The information flow within the German EWS improved noticeably in the last years. Most of the relevant multipliers are included in the EWS, therefore making regular information flow and the exchange of ad-hoc information fast.

As the German EWS acts as one of many advisors to the Ministry of Health and doesn't have any formal mandate for decision-making processes, the possibilities of the German EWS are restricted to the areas of information collection and exchange.

Furthermore, the German EWS is intended to stabilise the partnership within the network, to increase information flow

and to recruit new partners from the medical field and from party projects. Cooperation with party projects are aimed at improving drug-use prevention.

Links and references

Links

Bureau for Prevention of Addiction (Büro für Suchtprävention (BfS), Hamburg) — <http://www.sucht-hamburg.de>

Centre for Drug Research Frankfurt am Main (CDR) — <http://www.cdr-uni-frankfurt.de>

Federal Criminal Police Office (Bundeskriminalamt (BKA)) — <http://www.bka.de>

German Monitoring Centre for Drugs and Drug Addiction (Deutsche Beobachtungsstelle für Drogen und Drogensucht (DBDD)), German NFP — <http://www.dbdd.de>

Institute for Forensic Medicine of the University Hospital of the city of Freiburg (Institut für Rechtsmedizin des Universitätsklinikums der Stadt Freiburg (IRF)) — <http://www.uniklinik-freiburg.de>

Lower Saxony Centre for Addiction Issues (Niedersächsische Landesstelle für Suchtfragen (NLS)) — <http://www.nls-online.de>

Phar-Mon monitoring system — <http://ift.de/index.php?id=335&L=0>

Poison Control Centres (Gif tinformation zentren (GIZ)) — <http://www.klinitox.de>

Robert Koch Institute (RKI) — <http://www.rki.de>

The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) — <http://www.bfarm.de>

Youth Counselling and Help Centre for Youth (Jugendberatung und Jugendhilfe (JJ) Frankfurt am Main) — <http://www.drogenberatung-ji.de>

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Greece — early warning system

Ioanna Siamou

Introduction

The Greek early warning system (EWS) was established in 1998. In fact, a meeting was convened where the Greek Reitox focal point informed the representatives of the competent services on the objectives of the project and asked for their participation in the EWS network and providing the requested information.

The role of the partners was substantial during the establishment of the N-EWS. In fact, they contributed to the development of the tools addressing information sources (laboratories, law enforcement authorities, specialised drug users' oriented services) and some of them became members of the Committee of experts for the appraisal of the incoming data.

Organisational issues

There was an agreement between the Greek focal point and the representatives of the law enforcement authorities, forensic/toxicological laboratories and treatment agents for their participation in the EWS in 1998. In fact, the Greek focal point convened a meeting where the representatives of the competent services and the focal point discussed in detail the development of a EWS national network for the collection of information on new drug phenomena in Greece.

Following the decision on the development of the EWS network, the type of collected information and the collection procedure was discussed by a working group composing of professionals of the services participating in the network and of the members of the focal point. According to the working group decision, the Greek EWS monitors both new psychoactive substances and new ways of using already known substances and new combinations of substances. The collected information written in Greek and English language is exchanged at national and European level.

The N-EWS is located within the Greek focal point. A social scientist (sociologist) has been working part-time for it since 1998.

The N-EWS collaborates closely with the EMCDDA and provides information upon request on new psychoactive

substances to different international and European organisations (e.g. WHO, Pompidou Group, etc).

The exchange of information between the N-EWS and the data providers is done by e-mail. A national database was operating from 2001 to 2006 for the early exchange of information at national and European level (national data providers, collaborators from the EMCDDA and the focal points). During the annual meeting of the Committee of experts for the appraisal of the incoming information, the experts are informed on the main actions of the project.

There is scientific independence regarding the operation of the N-EWS.

Core functions and information flow

Data collection, information exchange and monitoring

National partners

- Forensic laboratories: General Chemical State Laboratory (seizures) (2nd Chemical Service of Thessaloniki, 3rd Chemical Service of Athens — Department of Narcotics), Medical School of Athens University, Medical School of Thessaloniki University.
- Law Enforcement Authorities: Central Anti-drug Coordination Unit and the competent services of the Ministries of Citizen Protection (police departments, coastguard services), and Finance (customs services).
- Specialised drug users' oriented services: Drug treatment programmes, low-threshold programmes, outreach services.

Training of the data providers

It aims at improving the quality of the incoming data and strengthening collaboration. Data providers are informed on the data collection procedure and other issues related to the EWS, such as the risk assessment, the role of Europol and so on.

Data collection tools

Three semi-structured questionnaires addressing the various sources of information (law enforcement authorities,

laboratories, specialised drug users' oriented services) were constructed. The information categories of the questionnaires are based on those provided by the Reporting Form.

Information categories of the questionnaires addressing law enforcement authorities and laboratories:

- New drugs: Name/street name, chemical description, chemical description on the biological material, description of the biological material, physical description, chemical precursors, extent of use, possible risks of using a new substance, circumstances of detection, country of origins/domestic production, price of unit, involvement in the organised crime, socio-demographic data of offenders.
- New ways of using already known substances/new combinations of substances: description data.

Information categories of the questionnaire addressing specialised drug users' oriented services:

- New drugs: Name and street name, physical description, route of administration, experience of using the new substance, extent of use, groups of users, side effects, sources of purchasing (online shops, head shops, open drug scenes, etc).
- New ways of using already known substances/new combinations of substances: Experience of use, extent of use, groups of users, side effects.

The tools have been revised at least once so that they have become more user-friendly for the data providers.

— National database: It was operating for six years aiming at strengthening the flow of information between the national partners and the Greek Reitox focal point; and facilitating the early information of the European EWS collaborators (EMCDDA, focal points) on the Greek data. Owing to the information included being confidential, the access to the database was restricted to the national partners and the European collaborators (password protected).

Data appraisal and analysis

Firstly, the N-EWS makes a qualitative check of the incoming information which it records in tables. Secondly, the Committee of experts is convened to appraise the data.

Committee of experts

The Committee, which represents all types of agents/services participating in the EWS network, is an inter-scientific group of experts with expertise at theoretical and practical level. In fact, the criteria for their recruitment were related to their having specialised knowledge (psychiatrists, toxicologists,

chemists, pharmacists, social scientists, officers of the law enforcement authorities) and being experienced in the drug field. The N-EWS facilitates their task through their early and systematic information regarding the actions of the European and national EWS. Beyond their main task related to the appraisal of the national data, they contribute to the updating of the questionnaires, the training of the data providers and so on.

The main reason for its not operating any more is considered to be its limited use.

Outputs, reporting, publications and dissemination

Annual Report: It includes information on new psychoactive substances, new drug phenomena and emerging trends which is collected through the national network during the reporting year. Chapters on the actions of the EWS are developed occasionally for the Annual reports of the focal point published into the Greek language.

ADAT (Adequacy in Drug Addiction Treatment and Care) Project (Swiss Research Institute on Drug Addiction in collaboration with the World Health Organization, European Union, 2000): A document describing the structure and the achievements of the Greek EWS was included in the report of the project due to the fact that it was regarded as a well-organised information system for the collection of information on emerging trends.

Standard table 17: The incoming data is used for the completion of the table.

EWS progress and final reports on the implementation of the Council Decision: The Greek data is presented in the EWS reports.

Translation of the information on NPS: The information received by the EMCDDA on new psychoactive substances is translated into the Greek language for the national participants.

Scientific articles on new psychoactive substances written by Greek scientists (see Links and references section).

Seminars and projects:

Twinning projects: Training of the staff and the data providers of the focal points of the candidate countries: Cyprus (2004) and Turkey (2005, 2006), on the EWS included the operation of the N-EWS.

Presentations on the N-EWS in the First Reitox Academy Foundation Course (Athens, February 2002) and in the

Reitox Academy Special Seminar on Joint Action on New Synthetic Drugs (Slovenia, April 2002). The seminars addressed scientists of national focal points of candidate countries to be incorporated in the European Union. Presentations on the N-EWS operation in seminars organised by Greek specialised organisations in the drug field. Euro-trend project: The scientists participating in the N-EWS network contribute to the implementation of the project. The N-EWS information system was considered to be the basis for the development of a model of an Early Information Function (EIF) for Emerging Drug Phenomena (EDP) in Greece (Alvarez et al., 2003).

Dissemination process: There is a constant feedback to the national partners through the dissemination of information on NPS, health alerts, relevant articles, books and reports.

Case study

The N-EWS responds to any request regarding the new psychoactive substances. In other words, it informs the competent services on any issue related to NPS and motivates them to provide the relevant information. Below, there are two paradigms related to the actions of the EWS at national level.

Quantitative analysis of Ecstasy tablets

Considering that several Member States sent information on Ecstasy pills with a high concentration of precursors, such as MDMA and other substances in 2003, the N-EWS took the initiative to discuss with the director of the General Chemical State Laboratory (Forensic Drugs Laboratory) the issue regarding the quantitative analysis of Ecstasy tablets. The decision taken during the meeting was that the Laboratory engaged to make the quantitative analysis on the majority of the samples of seized Ecstasy tablets.

Exchange of information on the circulation of a dangerous substance in open drug scenes in Athens

The N-EWS informed the competent services on a dangerous substance circulating in the open drug scenes in Athens in 2011. The responsible persons of the street work programmes of the Therapy Centre for Dependent Individuals (KETHEA) and the Organisation against Drugs (OKANA) informed on the issue. The Greek focal point asked them to collect information (user reports) and prepared a letter for the competent services (forensic laboratories and law enforcement authorities) for further action. According to drug user reports (N=40), the dangerous substance is called 'SISA' or 'SHISA' and it may contain, among others, 'battery

fluids'. In addition to this, it is in crystal or powder form and it is smoked/inhaled or it is used intravenously. Its effects were reported to be similar to those of methamphetamine, cocaine or methadone. The main side-effects of the substance are related to insomnia, hallucinations and aggression. Considering the aforementioned information, it was mentioned that 'SISA'/'SHISA' might be a methamphetamine-like substance.

Strengths, limitations and way forward

Strengths

- The N-EWS contributes to the submission of the new psychoactive substances under control at national level by informing directly the Drugs Committee on the misuse of new substances at European level.
- The EWS network is frequently expanded by the participation of new sources of information which have been developed or already exist, and which are found that they could provide the EWS network with data. This results in the constant flow of information on account of the fact that the proportion of information coming from the new sources is usually greater than this deriving from the old ones.
- The N-EWS has easy access to all relevant sources at national level.
- The collection of further information contributes to an extent to the identification of emerging trends in Greece.

Limitations

- The rather limited information on new psychoactive substances is mainly attributed to the fact that Greece is not a priority drug market. As a result, the new substances are imported long after they are used in other drug markets. This is confirmed by the fact that there have not been found clandestine laboratories and/or online drug markets in Greece.
- The short delay of the data from the laboratories is put down: (a) to practical issues, i.e. the great number of samples of drugs which have to be analysed and the long process of the analysis of synthetic drugs; and (b) to the inadequate number of the personnel working at the laboratories.
- The emergency wards of state hospitals and the informal data sources, i.e. nightlife settings, are unexploited due to the lack of a recording system in the public hospitals and the limited number of interventions in nightlife settings (Alvarez et al., 2003).

Conclusion

The structure and the function of the N-EWS are related to the specific needs and the social and cultural factors of the country.

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EWS progress and final reports

Hungary — early warning system

Anna Péterfi

Introduction

Hungary joined the European Union in 2004 and, as a consequence, set up its own Reitox national focal point to meet the EU requirements. The Hungarian national focal point (NFP) started its operation on 1 January 2004. Aside from the development of data collection and information flow on the fields of the key indicators, the NFP started to work on the establishment of a national early warning system (N-EWS). Since there were no similar initiatives earlier, bringing together experts from different fields related to new psychoactive substances, the NFP had to set up its own channels, identify and involve the relevant institutes, organisations and experts. As a first step, the EMCDDA guidance on implementation of the early warning system (EMCDDA, 1997) was translated to provide an overview on the goals and tools of the system for possible members of the network. By the second half of 2005, following an expert meeting organised in cooperation with the EMCDDA, the core of the network was set and the information exchange started. By the end of 2005, the network had 22 members. Currently, the network works with 53 members representing 30 organisations, institutes and authorities.

In 2007, the EMCDDA *early warning system on new psychoactive substances — Operating guidelines* was translated into Hungarian and published by the NFP.

In 2008, the NFP initiated the clarification of the legal background of scheduling substances, as a result of which in 2009, the government adopted a decree defining which ministries are responsible for initiating control measures regarding new psychoactive substances (*Government Decree 1196/2009 on the duties regarding the scheduling of new or already known substances that are hazardous concerning misuse*). The Decree also defined from which institutes, authorities and professional organisations (including the NFP) an expert opinion could be requested in order to provide a basis for the decision. After issuing the Decree, in 2010, the Committee on Controlled Substances was established with the aim of assisting the ministries (in charge of drug regulation) by providing an evidence base (by carrying out risk assessment) for their decisions. The Committee carried out the first risk assessment (of mephedrone) in 2010.

Organisational issues

To ensure data and information sources for the operation of the NFP the government issued '28/2004 Government decree about completing the tasks of the national focal point' (http://drogfokuszpont.hu/dfp_docs/?id=28_2004_gov_decree.pdf). It does not include tasks specially related to new psychoactive substances but it defines the data provision obligation concerning the five Key indicators of authorities and institutes which get in touch with these substances. The other legal background for the operation of the N-EWS is 'Government Regulation 142/2004 on the activities allowed to be done with illegal drugs and psychotropic substances' which defines the reporting obligations in case of the appearance of new psychoactive substances and it also includes the Hungarian version of the EMCDDA Reporting form on new psychoactive drugs.

The responsible body for N-EWS is the NFP which operates under the National Public Health and Medical Officer Service, in the National Centre for Epidemiology. Tasks related to the N-EWS are coordinated by one staff member of the NFP. The N-EWS was set up to serve the Council Decision; therefore its objectives, tools and members were shaped according to the goals defined in the Decision.

The N-EWS consists of the representatives of relevant ministries, centres of national institutes, authorities and NGOs, providing harm-reduction services in a recreational setting. In theory, these representatives disseminate and collect information in/from their sub- or regional organisations. However, the Institute for Forensic Sciences delegates a representative from each of its regional laboratories. The N-EWS is in direct contact with the Europol National Unit (ENU) as its representative is a member of the professional network in the national system. All in all, it can be stated that the Hungarian EWS has a national coverage.

The NFP developed several tools in order to disseminate information and to enhance information exchange among professionals. The main element of the N-EWS is a mailing list where the NFP can share all the relevant information arriving from the EMCDDA with members, while members can also inform the NFP and other members about issues

related to new psychoactive substances. To improve knowledge concerning psychoactive substances, the NFP publishes information on its website about the activity of the N-EWS, the legal background, key facts and figures and shares the relevant links related to the topic. To discuss current trends and issues, the NFP organises an expert meeting for the members of the N-EWS annually. Due to the growing interest of the professional scene and the media, in 2011 — for the first time — the NFP organised a conference on new psychoactive substances for a wider audience, to introduce the N-EWS to those who work on the related fields but are not in touch with the system and to provide reliable information on the phenomena. Besides, information on current events, publications, etc. related to the N-EWS is included in the monthly newsletter of the NFP.

Core functions and information flow

Information on new psychoactive substances might be requested from the N-EWS by the EMCDDA, by the Committee on Controlled Substances (or the Coordination Committee on Drug Affairs) — the NFP is a permanent member of the Committee on Controlled Substances and provides European and national information on new drugs for the Committee on request — or professionals and organisations operating in the related fields. In all cases, information is requested via the NFP. The standardised tools for data collection are the 'Progress and Final Reporting form' of the EMCDDA and the so-called '142/2004 EWS Reporting form on new synthetic drug' which was developed alongside the 'Europol-EMCDDA Reporting form on new psychoactive drug', in accordance with the Council Decision (Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk assessment and control of new psychoactive substances). As mentioned above, a specific reporting obligation exists only in case of the latter Reporting form. In theory, all authorities, official bodies, functionaries, drug analytical laboratories, toxicological laboratories, healthcare service providers, research institutes and detention facilities are obliged to report to the ENU and NFP when new drugs or new forms of use appear and drug use (including production, trafficking or use) is detected. However, in practice only drug analytical laboratories had reported new substances or new forms of use by the '142/2004 EWS Reporting form' until now. Besides formal routine reporting, all members of the N-EWS can take part in a general information exchange on the mailing list and at

expert meetings and sometimes are asked to reply to *ad hoc* requests.

An important initiative in the field — although not directly related to the N-EWS — is the monitoring project of the Institute for Forensic Sciences named 'Increased monitoring of the active substance content of hazardous drugs' aiming to follow the change of the drug market (principally of heroin and amphetamine) to prevent overdose cases. The launched system monitors the change of dangerous components, street-level purity, other characteristics of these drugs and new psychoactive substances. The results of the analysis are published quarterly to provide reliable information on trends. An immediate alarm is released in cases of extreme rates and the appearance of hazardous compounds.

Recognising the role of the Internet in the trade of new psychoactive substances, the NFP conducted an Internet snapshot in January and February 2011 to explore the online market of 'legal high' substances in Hungary and to collect information on its main characteristics. The snapshot focused on the trade of four popular 'legal highs' (GBL, MDPV, JWH-018 and mefildronon) and identified 19 online shops selling at least one of these products.

As it has already been mentioned above, following the 'Government Decree 1196/2009 on the duties regarding the scheduling of new or already known substances that are hazardous concerning misuse', the Committee on Controlled Substances was established to prepare proposals on changing drug schedules for ministries in charge. The first proposal was prepared on mephedrone following a procedure of risk assessment of the substance. The risk assessment procedure was based on the EMCDDA risk assessment procedure.

Case study

At the end of May 2010, a notification arrived from the EMCDDA that a new synthetic cannabinoid receptor agonist, RCS-4, had been identified in Belarus. No notification on this compound had arrived from European countries before this case. The e-mail had been sent out to the members of the N-EWS and soon afterwards, the NFP received an inquiry from the Institute for Forensic Sciences if analytical data on the substance is available in a digital format. The EMCDDA managed to obtain the mass spectrum of the RCS-4 and

forwarded it to the Hungarian NFP shortly. It was sent out to drug analytical and toxicological laboratories in the country. Some weeks later the Hungarian Customs and Finance Guard seized a substance which, thanks to the information received from Belarus via the EMCDDA, could be identified as RCS-4.

Strengths, limitations and way forward

Following the first five years operation of the N-EWS its gap-filling role is unambiguous. Experts, organisations and authorities whose activity is related to new psychoactive substances would not meet, exchange information otherwise. Since the second half of 2010, the treatment and harm reduction services also faced the increased appearance of cathinones at the market. According to the information received from these services and the outcome of small local snapshots in their clientele the injecting use of cathinones became prevalent in 2011. Due to these changes of the

market and the patterns of use, service providers face new problems that should be addressed, but to do so they need more information on new substances. To address their needs, the NFP wants to improve and extend the current system of the N-EWS to involve these service providers.

The development of the N-EWS also aims to improve the horizontal information exchange within the system and the revision of current reporting practices.

Links and references

Hungarian national focal point — <http://drogfokuszpont.hu>

Hungarian Institute for Forensic Sciences — alerts and newsletters of their monitoring system <http://bszki.hu/page.php?532>

28/2004 Government decree about completing the tasks of the national focal point (http://drogfokuszpont.hu/dfp_docs/?id=28_2004_gov_decree.pdf)

Ireland — early warning system

Jean Long and Des Corrigan

Introduction

This early warning and emerging trends sub-committee was originally set up in September 1997 by the Department of Health as the ad-hoc early warning Committee on New Synthetic Drugs to consider national issues arising from the 1997 Joint Action on New Synthetic Drugs by the Council of the European Union concerning information exchange, risk assessment and control of new synthetic drugs where each Member State had to set up a system of early warning to monitor the emergence of this phenomenon. In 2001, the committee was placed on a formal basis within the National Advisory Committee on Drugs (NACD) and its remit extended to include the monitoring of emerging trends. The National Advisory Committee on Drugs (NACD) was established in July 2000 under the auspices of the Department of Tourism, Sport and Recreation. Between June 2002 and May 2011, the NACD was under the auspices of the Department of Community, Rural and Gaeltacht Affairs, later known as Community Equality and Gaeltacht Affairs. In May 2011, following a general election, the government relocated the NACD to the Department of Health. The objectives of the NACD are to:

- conduct, commission and analyse research on issues relating to drugs and;
- advise the government on policy development in the area.

The NACD advises the government in relation to monitor emerging drug trends, prevalence, prevention, treatment, rehabilitation and consequences of problem drug use in Ireland using high-quality research.

Organisational issues

The NACD's early warning and emerging trends sub-committee advises the Irish government on emerging drug trends or practices as well as the consequences of such drug use. This is a national committee and is set up under an administrative rather than legal basis. The committee meets each quarter and each of the members report on trends in drug use or consequences of drug use noted during the preceding quarter. In addition, members of the committee

communicate with each other by e-mail in order to report a new drug, a new trend in drug use, serious consequences of drug use, in particular, those consequences seen in emergency departments, acute hospitals or drug treatment services. The members of the early warning committee cover a wide range of government departments, professional disciplines and services which include: police and customs, human, chemical and forensic toxicology, pharmacology and pharmaceutical science, emergency medicine, drug treatment, harm reduction, public information and research, including the EMCDDA's focal point (the Irish national focal point for the EMCDDA is located in the Health Research Board, which is the lead agency in Ireland supporting and funding health research). Each member of the committee represents a wider body from whom they receive information and to whom they disseminate information. There are no full-time staff allocated to early warning and all staff incorporate this function into their other work.

The members of the current early warning and emerging trends sub-committee belong to the following institutions: Department of Health; Department of Justice and Law Reform; Health Services Executive; Emergency Department, Adelaide and Meath Hospital, incorporating the National Children's Hospital, Tallaght representing emergency department consultants; Customs and Excise at the Revenue Commissioners; Garda National Drugs Unit; Drug Treatment Centre Board Forensic Science Laboratory; Irish Medicines Board; Medical Bureau of Road Safety; State Laboratory; Toxicology Department, Beaumont Hospital; School of Pharmacy and Pharmaceutical Sciences, Trinity College, Dublin; Pharmacology and Therapeutics, Trinity Centre for Health Sciences; National Voluntary Drug Sector represented by the Ana Liffey Drug Project; Health Research Board (EMCDDA focal point); and the NACD.

Core functions and information flow

The functions of the early warning system for Ireland are to: identify new drugs; describe new trends in drug use, and report the serious and unusual consequences of drug use. The function of the system for Europe is to identify the emergence of new synthetic drugs in line with the

aforementioned Joint Action. The information flow is presented in Figure 10. There is no routine surveillance system although the members have been considering the possibility of developing such a system over the past 12 months. At present, members write short quarterly reports covering trends in drug use over the preceding quarter, any new or unusual substances encountered and any unusual negative consequences experienced. In addition, members report urgent situations by e-mail.

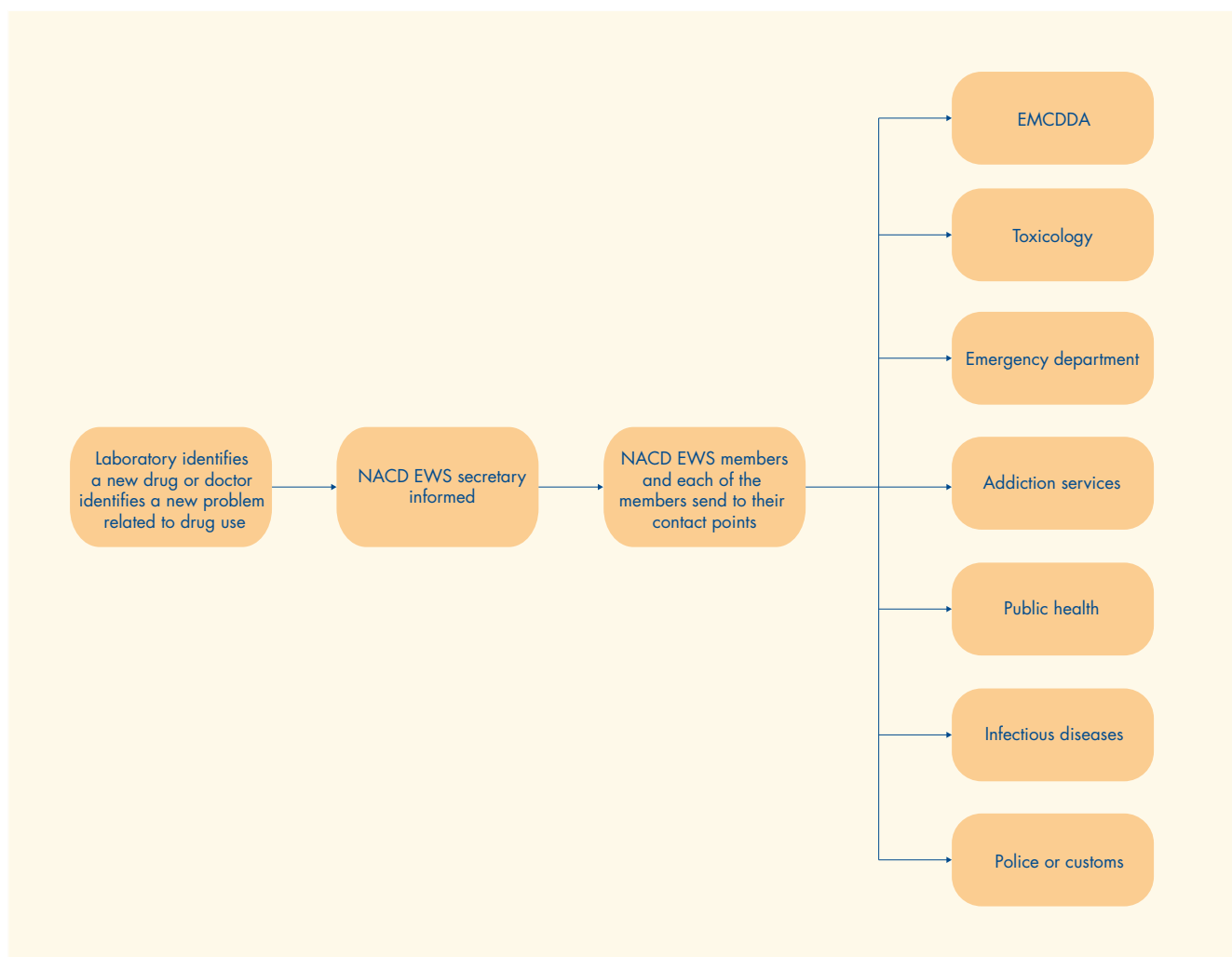
The Committee is currently in the preliminary stages of developing a national protocol for notifying drug use emergencies. The purpose of the protocol will be to facilitate the identification of significant public health issues associated with drug use requiring a rapid and coordinated response and disseminate appropriate public health messages and information.

The committee has completed two formal pieces of research to inform its work:

1. National drug trend monitoring system pilot (2007). The NACD developed and tested three new indicators for use in a Drug Trend Monitoring System (DTMS). The three indicators piloted were:

- a media monitoring system to monitor current drug seizures, drug-related court cases, and local drug issues around the country;
- a network of trend monitors consisting of frontline workers from around the country to complete a twice-yearly trend questionnaire on the drug situation in their area, and notify the DTMS when new trends arise;
- a series of focus groups with drug users to assess latest drug trends.

Figure 10 — Information flow in the framework of the Irish EWS



The results of the pilot indicate that, apart from media monitoring, the other tools could be useful methods for identifying new drugs and new methods of drug use.

2. An overview of psychoactive substances and outlets supplying them (2011). This overview presents the available knowledge on new psychoactive substances within the Irish context, and provides new insights into this multifaceted phenomenon. Specifically, the overview sought to assess the availability and accessibility of new psychoactive substances in retail outlets throughout Ireland and online, and to identify and describe the products, and where possible, identify their specific contents. A range of new psychoactive substances were purchased or acquired and were subjected to Gas Chromatography-Mass Spectrometry (GC-MS) chemical analysis in order to identify active constituents. The availability of reference standards for the analysis of new psychoactive substances was also determined. In addition, an online survey was completed to describe the nature and extent of new psychoactive substance use.

Case study

There are two case studies of note for the Irish early warning system:

Irish government bans sale of 'magic' mushrooms

Magic mushrooms are hallucinogens that grow wild in autumn or they can be cultivated for commercial sale. Their use in Ireland largely began in the mid-1970s when they emerged as an alternative to LSD. In 2005, the National Advisory Committee on Drugs (NACD) and the Drugs and Alcohol Information and Research Unit (DAIRU) of the Department of Health, Social Services and Public Safety in Northern Ireland published jointly the first results from an all-Ireland general population drug prevalence survey, which revealed that 5.9 % of young adults had tried these mushrooms at some point in their life.

A man in his thirties, from Dublin, died in 2005 after he jumped from a balcony at his apartment. He had consumed magic mushrooms, along with alcohol and cannabis, while entertaining a group of friends. The man's family believes that the hallucinogenic effects of the mushrooms contributed to the actions that led to his death. The man's family subsequently lobbied the Irish government to ban the sale or possession of fresh psilocybin-containing mushrooms.

As of 31 January 2006, the Irish government, in the exercise of powers conferred on them by section 2(2) of the Misuse of

Drugs Act, 1977, has ordered that 'any substance, product or preparation (whether natural or not), including a fungus of any kind or description, which contains psilocin or an ester of psilocin is a controlled drug for the purposes of the Act'. The effect of this order is to render the possession or sale of so-called 'magic' mushrooms criminal offences under the Act.

Irish government ban the sale of psychoactive substances in head shops and other outlets

In January 2010, at the request of the Minister with responsibility for the National Drugs Strategy, an expert and multi-disciplinary Research Advisory Group (RAG) was established by the NACD's early warning and Emerging Trends Sub-Committee to carry out a review of new psychoactive substances and the outlets supplying them. The multidisciplinary Research Advisory Group (RAG) comprised representatives from Citywide Drug Crisis Campaign, Customs Drug Law Enforcement, Department of Health and Children, Department of Community, Equality and Gaeltacht Affairs, Department of Justice and Law Reform, Food Safety Authority of Ireland, Forensic Science Laboratory, Garda Síochána, Health and Safety Authority, Health Research Board, Health Service Executive, Irish Medicines Board, and the NACD itself.

In addition to designing and commissioning the research, each representative examined what action they could take in their respective area. For example, the Garda Síochána enumerated and mapped the location of each head shop. They updated their map on a regular basis between January and August 2010. At their peak in early 2010, there were 113 head shops in the country, with at least one in every county. The Gardaí, along with their colleagues in customs seized substances when suspected controlled under the Misuse of Drugs Act, 1977. The Forensic Science Laboratory tested all substances seized by the Gardaí and customs. The academic and clinical laboratories worked closely with the Forensic Science Laboratory to maximise resources and share knowledge. Together, all of the laboratories identified a number of new substances. The Irish Medicines Board took action using its legislation when a substance contained a legal drug while the Food Safety Authority of Ireland expressed a willingness to do likewise if a substance contained a food. The Food Safety Authority also examined the issue of misleading labelling and the possibility of taking action against retailers for misleading their customers. The Department of Health and other relevant members worked on legislation to control the sale or possession of: specific synthetic cannabinoids; benzylpiperazine (BZP) and piperazine derivatives; specific

cathinones; gamma butyrolactone (GBL) and 1,4-butanediol; ketamine; and tapentadol. On 11 May 2010, the government ban or controlled the aforementioned head shop products and on this day there were 102 shops opened, 11 having closed for a variety of reasons. On 12 May, the Gardaí visited all head shops and warehouses and seized all banned products. By 13 May, there were 34 head shops selling psychoactive substances and in early August, the number increased to 39 shops. The Department of Health and other relevant members continued to examine the need to control other drugs and the Forensic Science Laboratory and other laboratories continued to identify new psychoactive products. On 16 August 2010, the Department of Justice and Law Reform introduced The Criminal Justice (Psychoactive Substances) Act 2010. This legislation was enacted to introduce more general control by way of criminal justice legislation to deal with head shop products as they emerged. The Act also gives appropriate powers to the Gardaí and to the courts to intervene quickly, by way of prohibition notices and prohibition orders, to prevent the sale of psychoactive substances. Following the introduction of this Act, the Gardaí visited head shops in early September 2010; only 19 were open and none were selling psychoactive substances (An Garda Síochána, personal communication, 2010). On 4 October 2010, the number of head shops open had decreased to 10.

Strengths, limitations and way forward

Strengths

This is a national network, with representation from a broad range of sectors which have collaborative relationships and can detect problems quickly. Each member of the network represents a wider audience and can exchange information quickly and easily.

Limitations and way forward

The committee need to develop a formal data collection system through formal submissions from forensic science,

police, ambulance services, emergency departments and harm-reduction services. However, some of these services need to put such information systems in place.

The availability and cost of chemical standards seriously limit the laboratories ability to confirm the identity of new substances.

A more structured process for the conduct of formal risk assessments is needed in order to identify and classify the harm caused by new drugs and make proposals for the imposition of regulatory controls on these new drugs.

The NACD Report on New Psychoactive Substances and the outlets supplying them suggested that legislation that permits a temporary ban on substances that are deemed dangerous would be highly desirable.

Links and references

National drug trend monitoring system pilot (2007).

Available at: http://www.nacd.ie/publications/DTMSReport_Final.pdf

An overview of psychoactive substances and outlets supplying them (2011). Available at: http://www.nacd.ie/publications/Head_Report2011_overview.pdf

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Long, J. (2010), 'Further update on psychoactive substances sold in head shops and on line', *Drugnet Ireland* 35, pp. 15–16. <http://www.drugsandalcohol.ie/13971>

Italy – early warning system

Giovanni Serpelloni, Elisabetta Simeoni, Silvia Zanone, Teodora Macchia, Carlo Locatelli, Claudia Rimondo and Catia Seri

Introduction

According to what is indicated by Council Decision 2005/387/JHA, in order to strengthen the functioning of a national early warning systems network in support of the national focal point (NFP), an early warning system (EWS) project, sponsored by the Ministry of Health, was assigned to the Veneto Region (Verona Addiction Department, ULSS 20) in 2007. In the framework of this project, the procedure for real-time collection of information and alerts activation was developed and described in a theoretical model.

In June 2008, the coordination of national policies on drugs was assigned to the Presidency of the Council of Ministers. The new Department for Anti-drug Policies was designated as the coordination office. The Italian focal point was based within the Department.

The new Department for Anti-drug Policies capitalised network and experiences gained by the national EWS project held by the National Institute of Health and the abovementioned Verona Addiction Department to make a new national EWS project at institutional level.

As a number of national experts had already been involved, as procedures for notifications and alerts had been highlighted and since results gained had been significant, on March 2009 the Department for Anti-drug Policies institutionalised and promoted the new national early warning system (N-EWS).

Organisational issues

The N-EWS has a double goal: on one side, it is aimed at early identification of phenomena potentially dangerous for public health and related to the appearance of new drugs and/or new patterns of consumption, new formulations and mixes of 'traditional' substances, new peculiarities at toxicological, clinical, behavioural and control level. On the other side, the N-EWS is aimed at promptly activating alert notifications involving all those organisations responsible for public health and for setting off suitable actions. The N-EWS acts with national coverage.

The N-EWS is characterised by a rapid management of notifications, shortening the time between notification and a possible alert starting up. Moreover, the system circulates specific and validated information (specificity), such as information coming from analytical laboratories. It is also able to catch no explicit symptoms and signs (sensitivity) thanks to its direct connection with drug users. That allows a high degree of efficacy and a real capability of reducing or preventing drug-related risks.

The N-EWS operates through working groups. These are organised in four functional levels, according to the responsibility criteria coming from the institutional role and responsibility covered by each single group's member.

First level – decision: The first level is directed by the Department for Anti-drug Policies. Deployed within the department, the national focal point represents the sole institutional interface between the N-EWS and the EMCDDA. It rules the informative flow between national and European levels.

Second level – coordination: The N-EWS direction avails itself of the advice and cooperation of three organisations, each one expert and responsible for a specific area:

- National coordination of bio-toxicological aspects – National Institute of Health, Therapeutic Research and Medicines Evaluation Department, Rome;
- National coordination of clinical-toxicological aspects – Pavia Poison Control Centre 'Salvatore Maugeri' Foundation IRCCS;
- National coordination of operational aspects – Addiction Department, ULSS 20 Verona.

The three organisations work according to the Chief Department's indications; they concur to alert decisions, enrolment of new collaborative units, analysis/assessment of incoming data/information, preparation of reporting forms and outputs communication, field research.

Third level – consultancy: The third level has the purpose of study and support for the decisional level in the

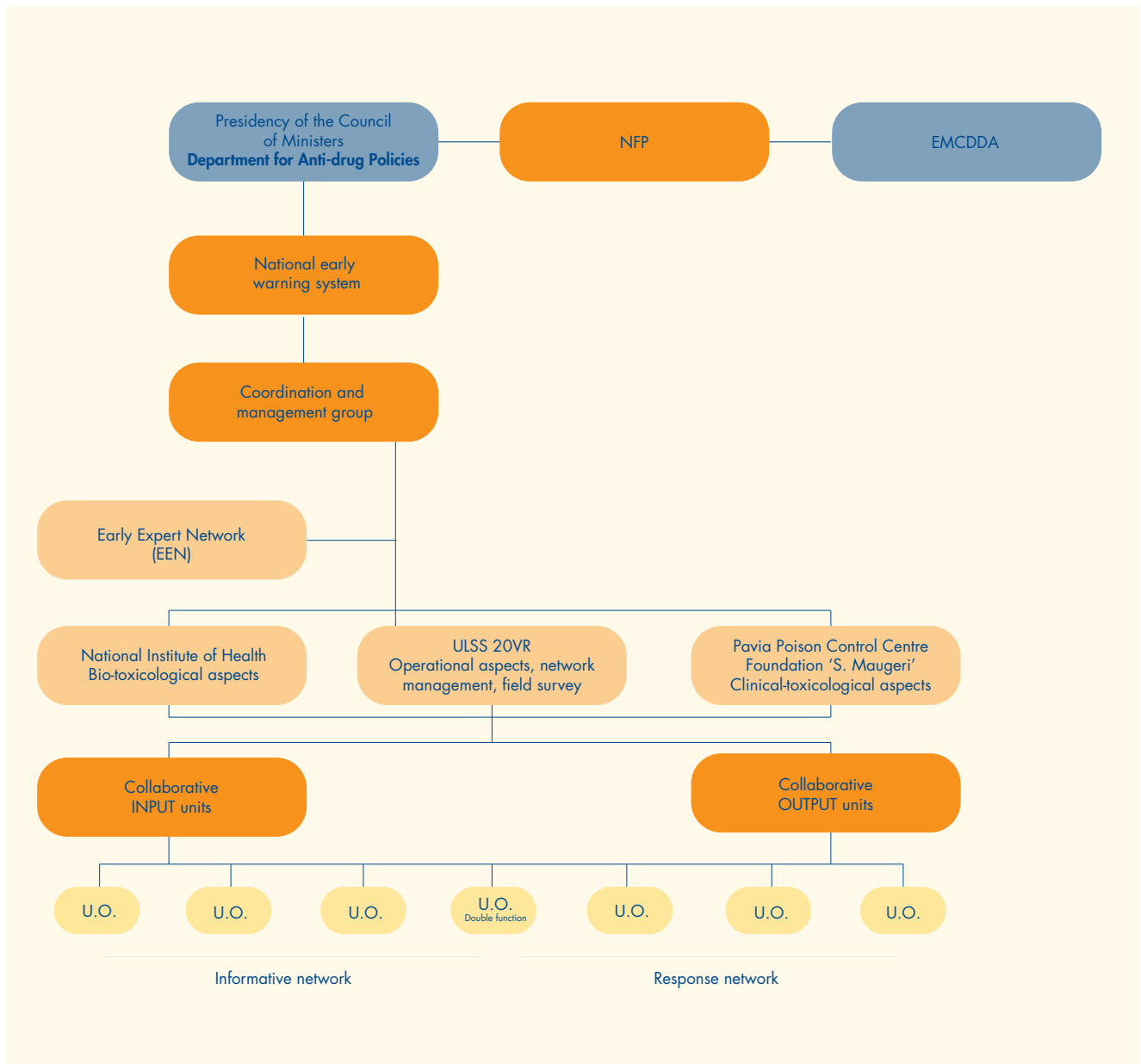
technical-scientific field. It is composed of consultants setting up the Early expert network, a network of 59 experts for early consultancy. It gives opinions about incoming notifications and activation of possible alerts.

Fourth level — practicality: The fourth level is made up of collaborative operative units feeding data, information and notification flow (input units) directed towards the N-EWS. They are responsible for the activation of response actions when they receive warning and alert communications (output units). Collaborative units are located all over the national territory.

National early warning system collaborative centres

Istituto Superiore di Sanità Dipartimento del Farmaco, Centro Antiveleni Pavia Centro Nazionale di Informazione Tossicologica IRCSS Fondazione Salvatore Maugeri, Dipartimento delle Dipendenze ULSS 20 Verona, Ministero dell'Interno UTG Trieste Nucleo Operativo Tossicodipendenze, Ministero della Salute, Centro Antiveleni Az Osp Universtaria Careggi Firenze, Centro Antiveleni Bergamo Az Ospedali Riuniti, Centro Antiveleni Milano Az Osp Ospedale Niguarda Cà Granda, Centro Antiveleni Policlinico Umberto I Roma, Centro Antiveleni Policlinico Gemelli Roma, Centro Antiveleni Ospedale Cardarelli

Figure 11 — Organisational chart of the Italian early warning system



Napoli, Centro Antiveneni Ospedale Gaslini Genova, Centro Antiveneni Foggia, Laboratorio Tossicologia Analitica IRCCS Policlinico San Matteo di Pavia, TF Università degli studi di Firenze, TF Università degli studi di Bologna, TF Università degli studi di Napoli, TF Università degli studi di Bari, TF Università Cattolica del Sacro Cuore Roma, TF Università degli studi di Padova, TF Università 'La Sapienza' Roma, TF Università degli studi di Verona, TF Università degli studi di Perugia, Laboratorio di Tossicologia Azienda sanitaria provinciale di Catanzaro, Laboratorio Generale Azienda Ospedaliera Universitaria Careggi, Dipartimento di Scienze Farmaceutiche Università degli studi di Pisa, Dipartimento di Scienze Farmaceutiche 'P. Pratesi' Università degli studi di Milano, University of Hertfordshire Department of Pharmacy, Dipartimento di Scienze anatomiche istologiche medico-legali e dell'apparato locomotore Università 'La Sapienza' Roma, Direzione Centrale Servizi Antidroga III Servizio, Direzione Centrale Anticrimine Polizia di Stato Servizio Polizia Scientifica, Servizio Polizia Scientifica Sez Indagini sulle droghe d'abuso Polizia di Stato, Arma dei Carabinieri Reparto Investigazioni Scientifiche, Reparto Carabinieri Investigazioni Scientifiche di Parma, Agenzia delle Dogane Laboratorio chimico di Roma, Agenzia Delle Dogane Laboratorio e Servizi Chimici Napoli, Polizia di Stato Squadra Mobile di Bologna, Presidenza del Consiglio dei Ministri, Tossicologo Consulente per il Tribunale di Busto Arsizio, Laboratorio Analisi Doping Torino, ARPAC Dipartimento tecnico di Benevento, AIFA Agenzia Italiana del Farmaco Ufficio Valutazioni e Autorizzazioni, UO Biochimica clinica e tossicologia Az Sanitaria USL2 Lucca, Laboratorio di Sanità Pubblica Area Vasta Toscana Centro Azienda Sanitaria di Firenze, Laboratorio di Igiene Ambientale e Tossicologia Forense Dipartimento di Prevenzione ULSS12 Veneziana Regione Veneto, Azienda Ospedaliera 'Ospedale S. Anna' di Como, Sezione Medicina Legale Dipartimento Neuroscienze Università Politecnica Marche, Procura della Repubblica di Torino, Direzione Politiche Sociali Servizio promozione e inclusione sociale Comune di Venezia, Università degli Studi di Modena e Reggio Emilia Tossicologo Forense, UO Chimica e Clinica Tossicologica ASP Catania Regione Sicilia, Laboratorio di Sanità Pubblica — Area Vasta Toscana Centro — Azienda Sanitaria di Firenze, Laboratorio di Igiene Ambientale e Tossicologia Forense — Dipartimento di Prevenzione ULSS12 Veneziana — Regione Veneto, Laboratorio Ospedale 'S. Anna' — Como, Laboratori di Ricerche di appartenenza Analitiche e Tecnologiche su Alimenti e Ambiente — Università degli Studi di Milano, Istituto di Medicina Legale — Dipartimento Neuroscienze Università Politecnica Marche, Direzione Politiche Sociali Servizio promozione e inclusione sociale — Comune di Venezia.

Core functions and information flow

Management of notifications and alerts at European and international level is the competence of the national focal point. That is the only channel through which the information flow between Italy, Europe and other foreign countries gets fed. The EMCDDA sends notifications and alerts concerning foreign states to the Italian focal point. In turn, the Italian focal point acts as the collector of Italian alerts: it forwards them to the EMCDDA and from the EMCDDA, the information reaches other Member States.

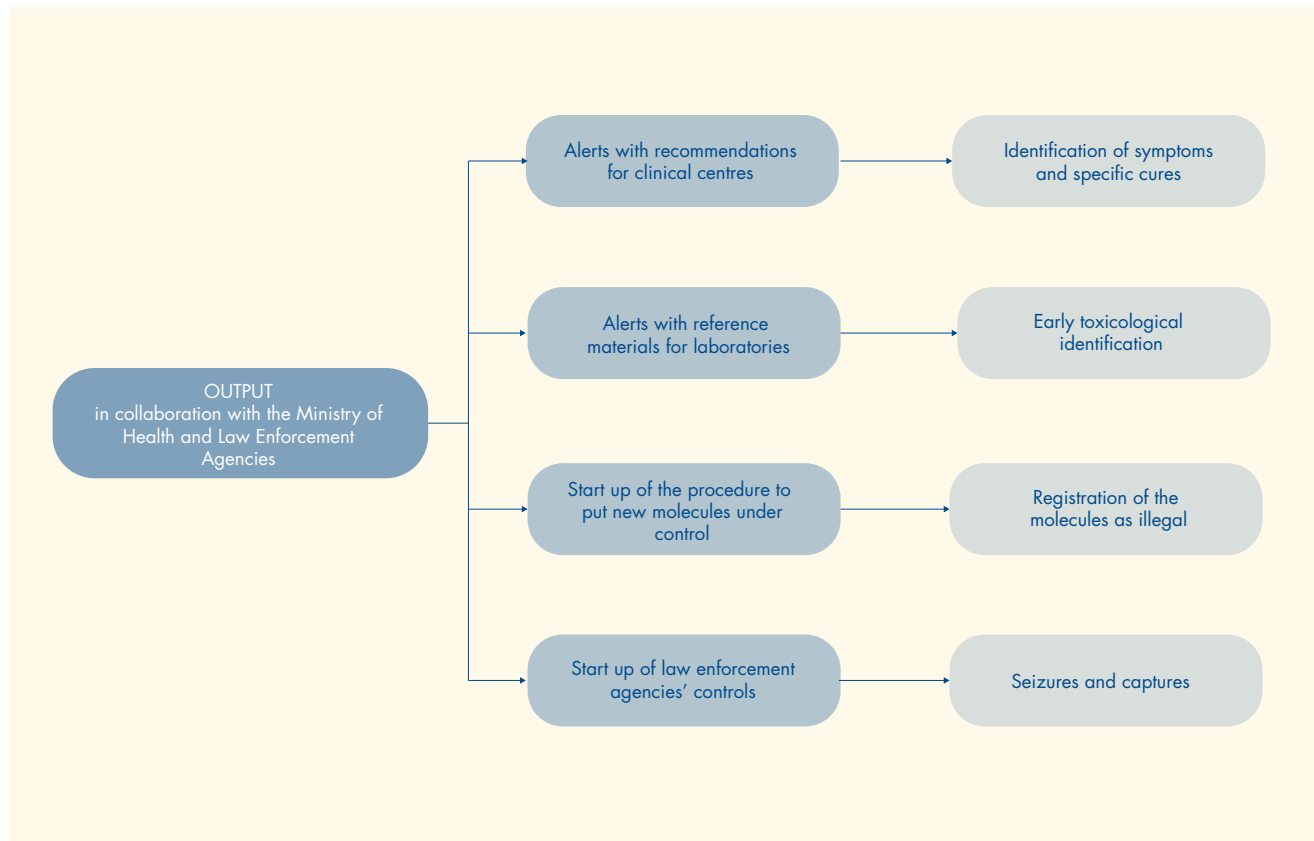
At national level, in order to gather information, the N-EWS avails itself of an articulated input network involving different kinds of units: health units, public facilities, poison control centres, forensic, clinical, research, law enforcement and custom laboratories, law enforcement agencies, emergency departments, outreach mobile units, schools, no profit associations, media and entertainment settings (see Figure 11).

Once the N-EWS receives a notification, according to its content it is possible to activate alerts, in collaboration with the Ministry of Health and law enforcement agencies, with recommendations for clinical centres and/or with reference materials for laboratories. In the first case, the system allows the early identification of symptoms and specific cures for intoxicated patients; in the second one, the system eases laboratories to early identify the new substances. It is also possible to start up the procedure to put new molecules under control and, once a molecule has been registered as illegal, to boost law enforcement agencies' controls all over the country. That usually ends up in seizures of illicit substances and captures of traffickers and drug dealers (Figure 12).

On the Italian territory, notifications and alerts are operatively managed by the Addiction Department, ULSS 20 Verona. The management gets supported by a 2.0 web software called 'N-EWS' (www.allertadroga.it). That is a groundbreaking technology allowing to geo-locate input notifications and to address alerts (output) towards well defined geographical areas. The System can receive notifications through different communication channels (telephone, e-mail, fax, sms, mms, web) and is able to reach every kind of organisation through a contemporary and multichannel transmission.

The macro-functioning of the N-EWS information flow may be described as follows. Notifications coming from operative units stream into the N-EWS following seizures, observations, admissions to emergency departments by drug intoxications,

Figure 12 — Output and concrete actions following notifications to the Italian National early warning system



news referred by users, etc. Therefore, the information does not reach the System on a regular basis but on the occurrence. Notifications are assessed by the N-EWS direction and, if necessary, the information gets detailed through field research and contacts with technical-scientific consultants. Notifications may generate different kinds of communication: the System can elaborate and send simple Informatives, Warnings or Alerts. Alerts may be differentiated in level 1, 2 or 3 according to the severity of the notified event and health risks. For the recipients' sake and for a more effective fruition, the System also supplies communication with specific technical reports, pictures and information coming from the scientific literature, when available. The System selects case by case the geographical areas and the output units to send the alert to, when that is not of national relevance. Output units are responsible for the activation-implementation of rapid response actions in order to face the notified event and to avoid, or at least reduce, users' and general population's health risks.

Case study

Since 2010, the N-EWS recorded 227 notifications coming both from the EMCDDA and from the national units (106 in 2010 and 121 in 2011). 30 alerts were produced, most of them related to the appearance of new high-risk substances or adulterated 'traditional' drugs. Synthetic cannabinoids found in herbal blends, as well as the related intoxications, were the main matter of the alerts.

Between 2010 and 2011, the N-EWS registered in Italy 29 cases of acute intoxication by synthetic cannabinoids with admissions to emergency departments. Almost all of them (28) occurred in the north of Italy; one in Naples. Patients (15–55 years old) smoked herbal blends labelled as Njoy (n=6), Jungle Mystic Incense (n=5), Bonzai (n=8), Forest Green (n=3), Bonzai Summer Boost (n=2), Spice Arctic Synergy (n=1), Orange Alesya New (n=1), Atomic Bomb (n=1) and non-labelled products (n=2). LC-MS/MS analysis on samples available detected the following molecules: JWH-018 (11 intoxications), JWH-122 (9), JWH-081 (2),

JWH-250 (3), JWH-122 (1), JWH-018 + JWH-073 (1), unknown (2).

The first intoxication cases were recorded in February 2010: patients reached the emergency department after consuming 'Njoy'. Following the identification of substances responsible for the intoxications, the Department for Anti-drug Policies, in collaboration with the Ministry of Health, activated a procedure to put them under control according to Italian Law (D.P.R. 309/90). In three months, it was possible to include JWH-018 and JWH-073 in the list of illicit substances, together with the synthetic cathinone mephedrone.

After that, the Department notified all the Public Prosecutor's Offices and Prefects' Police Offices in order to foster active controls of shops still selling herbal blends that might be a danger for the users' health. In 21 Italian cities, law enforcement agencies carried out seizures and closed down shops selling illicit products. In Milan, an international agency distributing illicit herbal blends was shut down. Controls were carried out in 78 other cities but no irregularities were detected.

Thanks to the several controls performed, more than 80 different brands of herbal mixtures were analysed and the related results were communicated to the N-EWS. New abovementioned synthetic cannabinoids were identified, besides JWH-018 and JWH-073. The Department for Antidrug Policy has put under control JWH-122 and JWH-250, as well as derivatives of 3-phenylacetylindole and 3-(1-naphthoyl)indole.

Strengths, limitations and way forward

The new control measures on 'smart' drugs, previously freely sold, has allowed the Department for Anti-drug Policies to act against smart shops and to reduce the opportunities for buying these products. The decreased availability of such products may have contributed to the reduction of intoxication cases.

In order to allow a fast detection of new molecules in seized, collected and biological samples, the System purchased and supplied the collaborative laboratories network with analytical standards of several synthetic cannabinoids and other new molecules. That made detection of analytical compounds easier and increased the data flow to the System.

Information like that had been very useful to the N-EWS emergency units network. Knowing rapidly the substance by which a person got intoxicated, although negative to the usual screening drug test, allows a diagnosis without delay, as well as an appropriate and prompt patients' treatment and care. Emergency units and Poison Control Centres are very important elements in the N-EWS network because they allow the collection of clinical information about new psychoactive substances, otherwise impossible to gain from labs and law enforcement agencies.

Since 2010, the N-EWS registered a 59 % increase of adhesion to the input/output network. At the present time, collaborative centres of the N-EWS early expert network are 59. That has contributed to increased system visibility and effectiveness, to enlarge the national coverage and to boost the number of notifications coming from input units. According to the positive results gained in the last three years, it is possible to argue that the working method so far adopted is valid, reliable and effective. Therefore, it is suitable to proceed along the traced way. However, there are still a few aspects deserving attention the N-EWS intends to focus on in the next months.

The first aspect is the need to systematise clinical and analytical information on new substances detected through the N-EWS activity. According to that, the system is building a database for the collection of data, notifications and any other information on new identified substances. The database will be fed by the whole collaborative centres which will have an additional opportunity to share knowledge and tools in order to facilitate their work.

The second aspect is the Internet sales of illicit substances. This phenomenon has been known for at least five years. The N-EWS has created a monitoring unit aimed at periodically checking the web and trying to identify which sites are used for illicit traffic. The work is being conducted in collaboration with the Central Directorate for Anti-drug Services and with the Italian Communication Police. However, several difficulties emerged in identifying the real commerce on the Internet and the criminal organisations hiding behind those web sites. Therefore, further work is needed to tackle this issue.

Finally, a working group for activation and management of sewage analysis has been established within the N-EWS, in order to measure the consumption of new psychoactive

substances in the general population in Italy. The study is meant to be carried out in collaboration with a laboratory network and research centres.

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Latvia — early warning system

Agnese Zile-Veisberga

Introduction

The National early warning system on new psychoactive substances (N-EWS) was founded within the Reitox national focal point in 2004 (two partners in the local network — State police and State Medicine Agency) but, practically, development of the system began in 2007 when several institutions e.g. the Ministry of Health, the Health Inspectorate, Latvian Border Guard, the State Revenue Service Customs, Latvia State Centre for Forensic Medical Examination and others joined the local network of the early warning system (EWS). Due to 2008 and 2009, the local network of the N-EWS continued to enlarge and at the beginning of 2011, the network involved slightly more than 40 experts from various government institutions, law enforcement agencies, hospitals, treatment centres and NGOs.

Institutionally, the Latvian Reitox unit and the N-EWS have been hosted by several institutions. Until 2007, it was hosted by the State Addiction Agency, from 2007 until 2009, it was under the Public Health Agency, from 2009 until November 2011 by the Centre of Health Economics and finally now — the Reitox unit and the N-EWS is located under new organisation — the National Health Service (NHS). The NHS was developed by merging two institutions — the Centre of Health Economics and Health Payment Centre.

Organisational issues

The Latvian N-EWS formally serves mainly the Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk-assessment and control of new psychoactive substances without a wider role. At national level, the existence of the Latvian N-EWS is not regulated. Functions are regulated at institutional level by the Reitox national focal point and are developed according to EMCDDA guidelines (EMCDDA, 2007).

The aim and objectives of the Latvian EWS are directly related to the Council Decision 2005/387/JHA of 10 May 2005 and define the establishment of a mechanism for the rapid exchange of information on new psychoactive substances that may pose public health and social threats, including the involvement of organised crime.

Objectives:

- information collection on new psychoactive substances that are notified in Latvia (identification, use patterns, trafficking, etc.);
- regular and on-request reporting to a national network of experts on new psychoactive substances notification, usage, health risks, trafficking in Latvia and Europe;
- coordination of the risk assessment procedure and collection of necessary information in order to promote controlling measures of new psychoactive substances;
- regular and on-request reporting to the EMCDDA on the situation in Latvia (progress and final reports on the new psychoactive, notifications, legal measures, etc.).

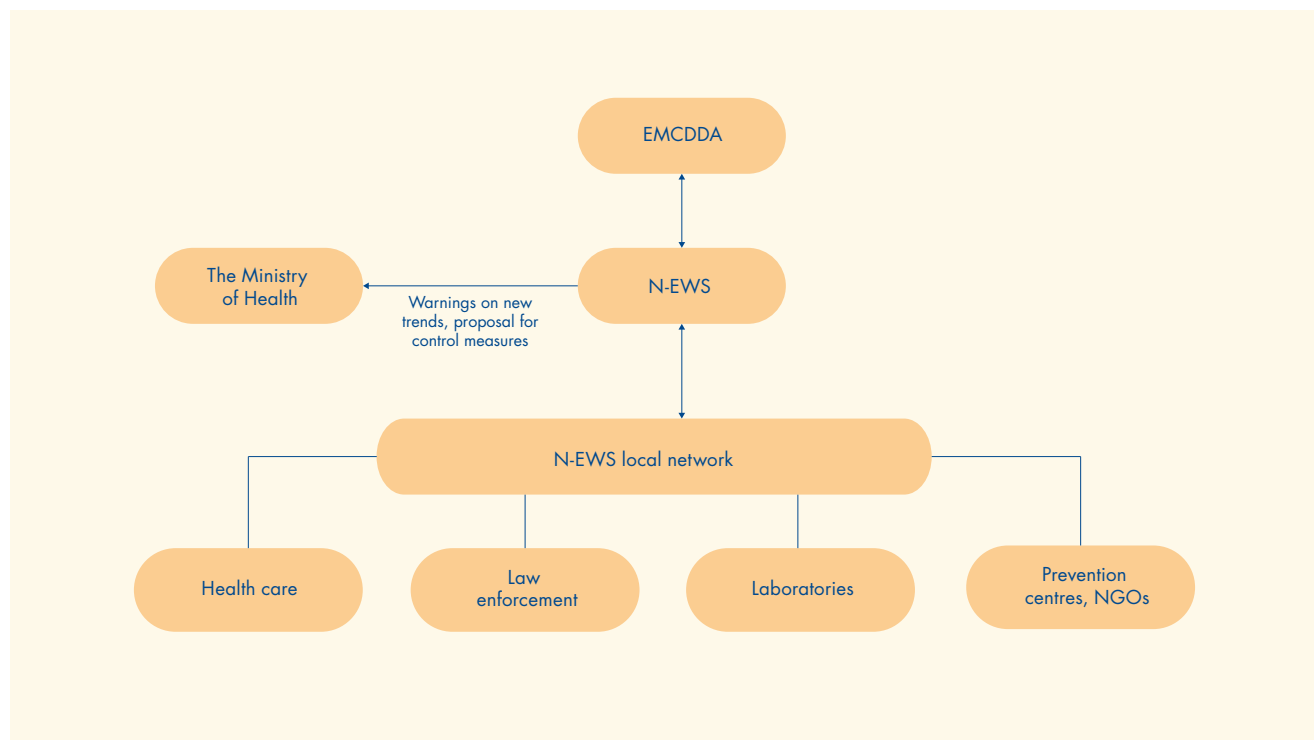
Core functions and information flow

In order to maintain the aim and objectives, the N-EWS has developed network at national level that includes experts from ministries, law enforcement agencies, health and care institutions, laboratories and prevention centres (see Figure 13).

Information on the situation in Latvia is derived from several sources. The N-EWS mainly cooperate with the State Police which, twice a year, reports official data (EWS official Reporting form) on seized and notified new psychoactive substances. On request, the State Police or in some cases the State Revenue Service provide additional information on the detection conditions. Other law enforcement authorities (Latvian Border Guard, Organised Crime Bureau, etc.) provide information on request.

Healthcare institutions (hospitals, Centre of Toxicology, etc.) typically provide data in cases of intoxication. Officially recorded cases are very rare and hospitals provide data rarely and in most of the cases on request.

The Latvia State Centre for Forensic Medical Examination and toxicological laboratories provide data on identified substances and their chemical analysis profile. Until now, four new psychoactive substances have been notified for the first time in Latvia (JWH-081, JWH-122, JWH-203 and AM-2201) by the Latvian Institute of Organic Synthesis.

Figure 13 — Information flow in the framework of the Latvian EWS

Of all the network partners least likely to information obtained from healthcare, prevention centres, and NGOs where information on new substance is obtained when the prevalence of the substance is essential and visible. In addition, in some cases, information is obtained from other sources, such as the media and various surveys like ECAD (Rīgas Domes labklājības departaments, 2010). The flow of information is mostly based on a local network and institutions responsible for the framework. The early warning system avoids the diffusion of information to the public as information on new substances may promote the circulation and visibility, and that may higher the risk of use. So far, the information on new psychoactive substances in the media was disseminated only in the case of 'Spice' product distribution in 2009, in order to inform about possible health risks.

The most frequently used communication tools for rapid and efficient flow of information is electronic correspondence and telecommunications. An effective tool for rapid and timely information exchange as well as the identification of key challenges is biannual meetings of the national network. In addition, seminars serve as a feedback for the N-EWS maintainers to continue maintenance and development of the system.

Outputs:

Core functions and output of the N-EWS is information exchange, risk assessment and proposals for changes in control measures of new psychoactive substances. The system's routine mode is reporting collected information on the situation in Latvia to the EMCDDA (reports, warnings, alerts). To local partners, the N-EWS mainly disseminate formal notifications, alerts and warnings and information on request about new psychoactive substances in Latvia and Europe, e.g., notifications in other EU countries, health risks, trafficking, etc.

The N-EWS has been the main initiators of the proposals to the Ministry of Health for amendments in legal measures of new psychoactive substances in 2009. The system usually collects necessary information to justify amendments. Also, the N-EWS is the main initiator to develop the risk assessment procedure at national level.

In addition, the N-EWS is publishing information on thematic issues about the EWS, notified new psychoactive substances and related health and social risks (e.g. Sīle, L., 2010 and Zīle, A., 2010).

Risk assessment:

Due to the increase of identification of new psychoactive substances in Europe, the list of controlled narcotics and psychotropic substances needed to be updated.

In the existing situation, a specific mechanism of listing new psychoactive substances was not created and the procedure was long and complicated. Aware of the situation and under the proposal of the N-EWS, the involved institutions agreed on a specific risk assessment procedure at national level which would be the basis for legal measures. Development of the risk assessment procedure at the national level is included in the National Drug Program 2011–17. Risk assessment guidelines are developed in accordance with the Council Decision of 10 May 2005 and the EMCDDA guidelines (EMCDDA, 2010) which will be adapted to the national situation. The Latvian EWS participates in the development of guidelines and is going to be the coordinator of the risk assessment procedure.

Case study

The benefit of the N-EWS was visible when it significantly increased prevalence of various ‘legal highs’, especially ‘Spice’ products in late 2008 and 2009. Riga City Welfare department reported there was a rousing interest in *Salvia Divinorum* among adolescents. Almost simultaneously with the distribution of *Salvia Divinorum*, an even greater resonance was caused by the smoking blend ‘Spice’, which could be purchased in small shops in the capital, and other Latvian cities. Several intoxication cases were reported by hospitals and Riga Psychiatry and the State Addiction Centre. The N-EWS collected available information on health risks and disseminated it to hospitals, healthcare centres and main prevention centres. Based on available information on usage, trafficking patterns, health risks that were known in Europe, the N-EWS prepared a proposal to the Ministry of Health with a request to put under control certain synthetic cannabinoids. In November 2009, the list of controlled substances (Regulations N 847 regarding Narcotic Substances, Psychotropic Substances and Precursors to be Controlled in Latvia, 2005) was amended with a number of synthetic cannabinoids — HU-210, JWH-018, JWH-073, JWH-250, JWH-398, CP 47.497 and three of its homologues C6, C8 and C9. Due to another proposal of the N-EWS in 2010, ‘Law on tobacco product marketing and advertising, limited use’ was amended with paragraph 8 ‘shall be forbidden to carry out a mixture of vegetable products with smoking, sniffing, chewing or inhaled as a result are secreted or ingested substances that cause severe substance similar psychiatric disorders to the user, and the

use of which can be addictive’ (Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products, 2010). A significantly decreased number of shops which sold smoking mixtures and most commercial sites on the Internet were also closed. The situation with the ‘Spice’ products raised the issue of the identification of new psychoactive substances, which promoted improvement of identification of new psychoactive substances.

Strengths, limitations and way forward

Practically, the N-EWS has been running a couple of years and the development of the system and optimisations are still in progress. The system’s strengths are the direct link to the EMCDDA, as well as support at national level of the Ministry of Health and the Drug Addiction Restriction Coordination Council. Similarly, the assessment of new psychoactive substances spread in Europe, at the national level the EWS is a significant institution that allows to quickly identify hazardous substances in order to put them under control.

System limitations are mainly related to the external factors, e.g. the current capacity delay rapid notification (technical equipment, reference materials, lack of knowledge) of new psychoactive substances, so that at the national level it is difficult to gather data on spread of new psychoactive substances. If the law enforcement agencies in the last year raised the capacity, clinical data from medical institutions and treatment centres are very poor. Internal factors are related to a lack of cooperation with certain local partners, like hospital and psychiatric centres, and a lack of necessary skills and knowledge in chemistry within the N-EWS.

Future activities mainly related to development of the system and improvement of information flow and quality of data. The main objectives to improve the N-EWS include:

- development of the risk assessment procedure together with other stakeholders and coordination of the system after the approval of the guidelines;
- improve cooperation with healthcare institutions, improving the flow of information and data quality. Currently, information from treatment centres on the new drug or other poisoning cases, the use of consequences is reported only in exceptional cases. The system should encourage the reporting of information on a regular basis, both of those cases where the use of a substance shown in clinical investigations and the self-reporting;
- enlarge capacity and quality in research and publications on issues, the new psychoactive substance

use among young people, spread of certain synthetic substances, Internet monitoring, etc.

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Lithuania — early warning system

Povilas Radzevicius, Maura Olechnovic, Audronė Astrauskienė and Jovilė Vingraitė

Introduction

In order to improve and coordinate better the activities of state and municipal institutions in the field of prevention of drug addiction and drug control, to ensure international cooperation and implementation of legal acts of the European Union, the Lithuanian Government on 1 January 2004 established the state-financed organisation, the Drug Control Department under the Government of the Republic of Lithuania (from 1 April 2011 — Drug, Tobacco and Alcohol Control Department), which was nominated as the focal point according to the requirements of the EMCDDA.

Director of the Drug Control Department under the Government of the Republic of Lithuania approved the Rules of Procedure of Information Exchange Concerning Occurrence of New Psychoactive Substances in 2005 (revised by the Director of the Drug, Tobacco and Alcohol Control Department in 2011). Under these rules, responsible state institutions are obligated to exchange information about the occurrence of new psychoactive substances in a timely fashion. These Rules of Procedure were developed according to the Joint Action of 16 June 1997 concerning the Information Exchange, Risk-Assessment and the Control of New Synthetic Drugs and amended based on Council Decision 2005/387/JHA of 10 May 2005 on the Information Exchange, Risk-Assessment and Control of New Psychoactive Substances. In order to assess the risk of new psychoactive substances and to implement control measures, an Inter-agency Commission of the Assessment of New Psychoactive Substances including representatives of competent authorities was established in 2009 (revised by the Director of the Drug, Tobacco and Alcohol Control Department in 2011).

Organisational issues

In Lithuania, the Drug, Tobacco and Alcohol Control Department is responsible for the organisation and coordination of the exchange of information concerning new psychoactive substances and preparations and important questions associated with narcotic drugs and psychotropic substances.

The following are institutions, the competencies of which include the collection of information about the occurrence of

new psychoactive substances and providing it to the Drug, Tobacco and Alcohol Control Department according to the template approved in the Procedure of Information Exchange Concerning Occurrence of New Psychoactive Substances (early warning system (EWS)):

- Prisons Department under the Ministry of Justice of the Republic of Lithuania;
- State Forensic Medicine Service under the Ministry of Justice of the Republic of Lithuania;
- Customs Department under the Ministry of Finance of the Republic of Lithuania;
- Health Emergency Situations Centre of the Ministry of Health;
- State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania;
- State Mental Health Center;
- State Non-Food Products Inspectorate under the Ministry of Economy of the Republic of Lithuania;
- State Public Health Service under the Ministry of Health of the Republic of Lithuania;
- State Food and Veterinary Service of the Republic of Lithuania.

The early warning system covers the entire territory of Lithuania. There has been no information about poisoning caused by new psychoactive substances and related deaths in Lithuania. This could be associated with difficulties in diagnostics.

In accordance with the established procedure, the Drug, Tobacco and Alcohol Control Department provides summarised information to the European Monitoring Centre for Drugs and Drug Addiction. Important information that should be known to the public is presented to the media. The Police Department under the Ministry of the Interior of the Republic of Lithuania collects data concerning the occurrence of new psychoactive substances and preparations and, in accordance with its competency, shares this information with the Drug, Tobacco and Alcohol Control Department and Europol.

The Drug, Tobacco and Alcohol Control Department was appointed a National Center of the European Information Network on Drugs and Drug Addiction (Reitox) by the Resolution of the Government of the Republic of Lithuania

No 244 of 23 February 2011. The Drug, Tobacco and Alcohol Control Department provides the abovementioned institutions with information concerning new psychoactive substances and other relevant information obtained from the EMCDDA. Information exchange takes place on a feedback basis. Analytical data are directly sent to laboratories of the authorised state institutions: the Lithuanian Police Forensic Science Centre, Forensic Science Centre of Lithuania, State Forensic Medicine Service under the Ministry of Justice of the Republic of Lithuania, Customs Laboratory at the Customs Department under the Ministry of Finance of the Republic of Lithuania.

The Drug, Tobacco and Alcohol Control Department continually collects information concerning possibly psychoactive products that are distributed through online stores and Lithuanian shops. In case of suspicion that marketed products may have a psychoactive effect, the Drug, Tobacco and Alcohol Control Department will put in a request with the Police Department under the Ministry of the Interior of the Republic of Lithuania, the State Non-Food Products Inspectorate under the Ministry of Economy of the Republic of Lithuania, the State Food and Veterinary Service of the Republic of Lithuania to check if the requirements of legal acts have not been violated during distribution of abovementioned products.

An Inter-institutional Commission for the assessment of risk of psychoactive substances was established at the Drug Control Department at the beginning of 2009 (from 2011 under the Drug, Tobacco and Alcohol Control Department). The Inter-institutional commission was established on an individual basis, its activities and Rules of Procedure were approved by the Order No T1-15 of 28 January 2009 of the Director of the Drug Control Department under the Government of the Republic of Lithuania. Below is the list of institutions, which have delegated their specialists to work at the Inter-institutional commission:

- Drug, Tobacco and Alcohol Control Department;
- Ministry of Health of the Republic of Lithuania;
- State Forensic Medicine Service under the Ministry of Justice of the Republic of Lithuania;
- State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania;
- Lithuanian Police Forensic Science Centre;
- Customs Department under the Ministry of Finance of the Republic of Lithuania;
- Lithuanian Forensic Medicine Centre;
- National Food and Veterinary Risk Assessment Institute;
- National Public Health Surveillance Laboratory;
- Faculty of Pharmaceutics of the Lithuanian University of Health Sciences;

- Faculty of Philosophy of Vilnius University;
- Faculty of Natural Sciences of Vilnius University;
- Institute of Botany of Nature Research Centre.

The Inter-institutional Commission analyses and assesses information concerning new psychoactive substances as well as other relevant information obtained from Lithuanian state authorities, EMCDDA and other sources in the event when substances may potentially endanger human health, as well as other information concerning important issues associated with narcotic drugs and psychotropic substances.

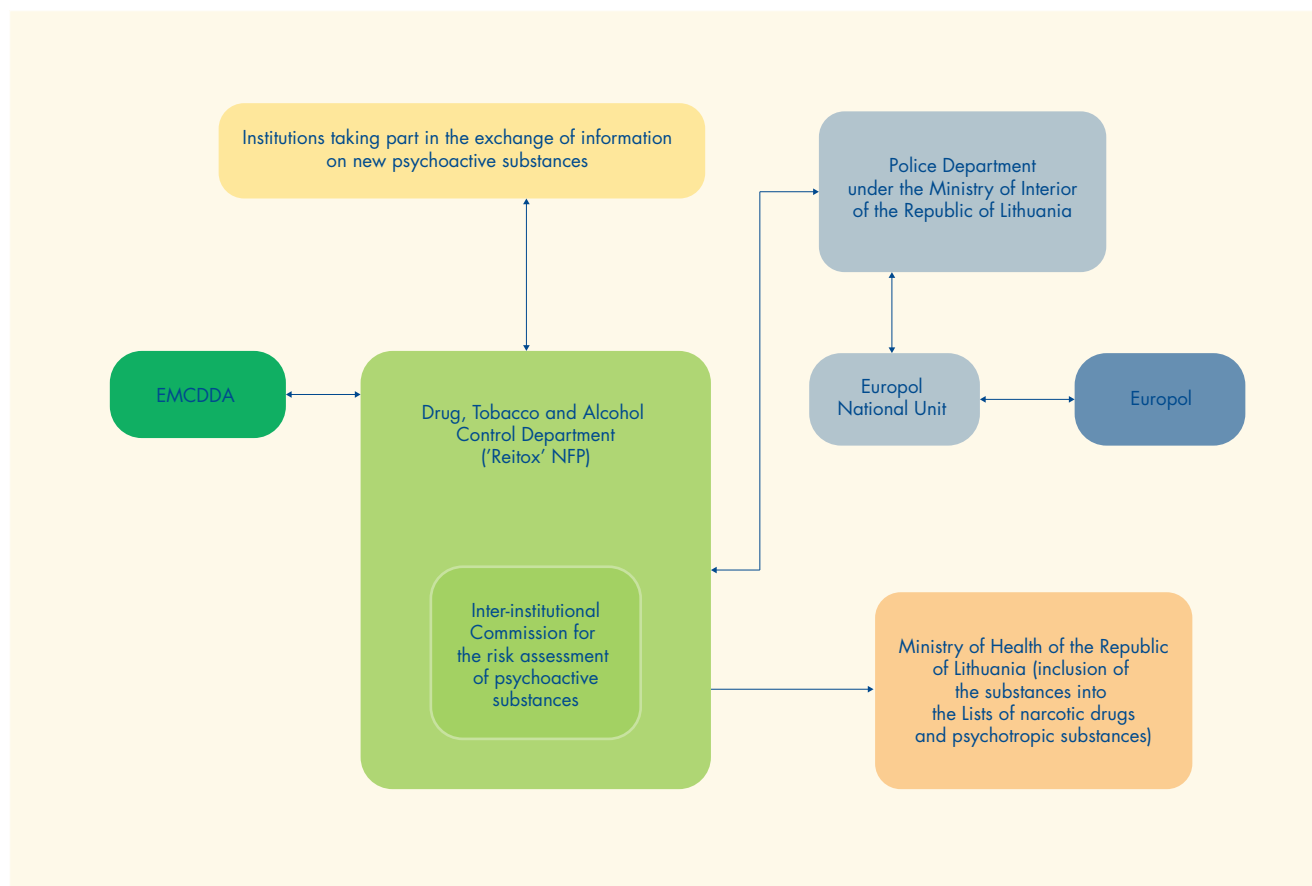
The EMCDDA European Database on New Drugs is used as a basis for the collection, analysis and assessment of information concerning new psychoactive substances. Sessions of the Inter-institutional Commission are held when necessary (no schedule of sessions has been established). Following information analysis and assessment, the Inter-institutional Commission develops (approves) proposals for restriction and control measures for the market of psychoactive substances and control and submits them to the Drug, Tobacco and Alcohol Control Department. In the event that the Inter-institutional Commission decides that a certain substance should be included in the Lists of narcotic drugs and psychotropic substances, the Drug, Tobacco and Alcohol Control Department shall issue a proposal of the Inter-institutional Commission to the Ministry of Health in an official letter. Substances shall be included in the Lists of narcotic drugs and psychotropic substances per Order of the Ministry of Health of the Republic of Lithuania.

In 2004–10, 42 new narcotic drugs, psychotropic substances and plants were included in Lists I and II of narcotic drugs and psychotropic substances approved by the Order of the Minister of Health of the Republic of Lithuania No 5 of 6 January 2000 (6). Furthermore, in 2011, generic definitions for cathinone derivatives and for six groups of synthetic cannabinoid receptor agonists were also added to List I. Amyl nitrite and cyclohexyl nitrite are included in the List of Toxic Substances according to their toxicity, approved by the Order of the Minister of Health of the Republic of Lithuania No V-975 of 30 December 2004.

List I: substances, the use of which is prohibited for medicinal purposes (includes substances included in Schedule IV of the United Nations Single Convention on Narcotic Drugs of 1961, substances included in Schedule I of the United Nations Convention on Psychotropic Substances of 1971, and some substances included in Schedules II, III and IV of the United Nations Convention on Psychotropic Substances of 1971).

Core functions and information flow

Figure 14 — Exchange of information on new psychoactive substances, their assessment and application of control measures



List II: substances, the use of which is allowed for medicinal purposes (includes substances from Schedules I and II of the United Nations Single Convention on Narcotic Drugs of 1961, and remaining substances in Schedule II of the United Nations Convention on Psychotropic Substances of 1971).

List III: substances, the use of which is allowed for medicinal purposes (includes remaining substances from the Schedules III and IV of the United Nations Convention on Psychotropic Substances of 1971).

An amendment to the Republic of Lithuania Law on the Control of Narcotic Drugs and Psychotropic Substances was adopted in 2010, by which control of not only individual narcotic drugs and psychotropic substances, but also derivatives of narcotic drugs and psychotropic substances was approved.

Case study

After information was obtained by the Drug, Tobacco and Alcohol Control Department that distribution of various herbal mixtures called 'Spice' with psychoactive effects has been launched in Lithuania, it immediately appealed to state regulatory authorities (Police Department under the Ministry of the Interior of the Republic of Lithuania, State Non-Food Products Inspectorate under the Ministry of Economy of the Republic of Lithuania, State Food and Veterinary Service of the Republic of Lithuania) with the request to find out if distribution of these products does not violate the requirements of applicable legal acts. Within one month, the State Non-Food Products Inspectorate under the Ministry of Economy of the Republic of Lithuania inspected shops and based on the Lithuanian Law on Product Safety, adopted a decision to prohibit pro tempore business units to provide to the market, offer to provide to the market and demonstrate eleven products: incense 'Smoke', incense 'Spice Gold',

'Tagetes Lucida', 'Wild Dagga 20X', 'Snow blow', 'Blow out', 'Snowberry', incense 'African Wild', incense 'Oaxacan High blend', incense 'Pink lotus', incense 'Marahuanila'. When information was obtained from the EMCDDA that synthetic cannabinoids are being added to 'Spice' products, the Drug, Tobacco and Alcohol Control Department appealed to the Ministry of Health of the Republic of Lithuania with the proposal to include synthetic cannabinoids in the Lists of narcotic drugs and psychotropic substances. In May 2009, synthetic cannabinoids JWH-018, JWH-073, CP-47,497, CP-47,497-C6, CP-47,497-C8, CP-47,497-C9 and HU-210 were added to the Lists of narcotic drugs and psychotropic substances.

Strengths, limitations and way forward

The legal basis for the inclusion of new psychoactive substances in the Lists of narcotic drugs and psychotropic substances is functioning well, accredited laboratories equipped with modern equipment and experts are present. However, due to lack of information concerning methods of identification of new substances and limited possibilities to obtain new standards, identification of new psychoactive substances is complicated and often impossible.

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Lietuvos Respublikos narkotinių ir psichotropinių medžiagų įstatymas (Žin., 1998, Nr. 8-161); Lietuvos Respublikos narkotinių ir psichotropinių medžiagų kontrolės įstatymo 2, 3, 10 straipsnių, penktojo skirsnio pavadinimo pakeitimo ir papildymo ir įstatymo papildymo 211 straipsniu įstatymas Nr. XI-1073 (Žin., 2010, Nr. 132-6718). [Republic of Lithuania Law on the Control of Narcotic Drugs and Psychotropic Substances; Republic of Lithuania Law No XI-1073 on the Amendment of the Articles 2, 3, 10 and the Name of the Fifth Section of the Republic of Lithuania Law on the Control of Narcotic Drugs and Psychotropic Substances and on the Addition of the Article 211].

Luxembourg – early warning system

Alain Origer

Introduction

The basic national drug law from 19 February 1973 (last modified in 2001), under Article 7, defines categories of substances to be controlled by means of Grand-ducal decrees. Currently, four Grand-ducal decrees list psychoactive substances controlled at the national level: Toxic substances 4 March 1974, psychotropic substances 20 April 1974 and 6 February 1997, narcotics 26 March 1974. Precursors are addressed by specific regulations 8 May 1993 and 2 February 1995. The annexes of the referred Grand-ducal decrees list the substances, common names if available, and individual chemical formulae, as appropriate.

The implementation of the national early warning system on drugs and patterns of use (hereinafter referred to as N-EWS) was implemented in 1997 following the Joint Action on the information exchange, risk assessment and the control of new synthetic drugs subsequently replaced by the Council Decision 2005/387/JHA of May 2005 on the information exchange, risk assessment and control of new psychoactive substances. The N-EWS developed progressively, including an increasing number of data providers. Over the last five years, the number of involved stakeholders has been stable and the N-EWS networks currently include the following partners:

- national EMCDDA focal point (NFP);
- specialised drug unit of the Judicial Police (also national Europol Drug Unit);
- Anti-drugs division of Customs;
- National Laboratory of Health (centralisation of toxicological analysis of suspect substances and the National Centre for Forensic Medicine);
- National Drug Addiction Prevention Centre;
- all specialised drug agencies (NGOs) (12);
- a series of General Practitioners.

Organisational issues

The legal basis of the N-EWS is enshrined in the ministerial decree establishing the national Inter-ministerial Committee on Drug Addiction (ICD), which includes representatives from the Ministry of Health, Ministry of Justice, Prosecution

Authority, Ministry of Interior, Police, Customs Administration, Ministry of Foreign Affairs, Ministry of Family, Ministry of Education and National Service of Youth, Ministry of Transport and determining its mandate. Thus, the ICD is officially mandated to maintain, develop and coordinate the N-EWS and related measures. The EWS information sharing is addressed as a permanent item on the agenda of ICD meetings.

The Luxembourgish EWS network relies on a nationwide coverage. Its primary objectives are the earliest possible detection of:

- the emergence of new psychoactive substances or products (including 'legal' highs);
- new patterns of use, including new types of use of already known or controlled substances or products;
- psychoactive products containing potentially dangerous adulterants or cutting agents;
- relevant information provided by forensic evidence (e.g. toxicological analysis/autopsies).

Furthermore, the N-EWS is designed to guarantee multilateral, top-down and bottom-up information exchange. It plays a crucial role in the process, which may lead to adopt national control measures on non-controlled substances as the ICD directly reports to the Minister of Health and recommends actions to be taken in terms of new regulations or public alerts. The ICD is currently chaired by the National Drug Coordinator, who is also the head of the national EMCDDA focal point. Also, the head of the national Europol Drug Unit is a member of the ICD and the Minister of Health mostly attends personally ICD meetings. The rapidity of the EWS-related information flow benefits largely from this constellation.

Luxembourg is also actively promoting the set-up of trans-border information exchange mechanisms on new psychoactive substances or products and new drug use patterns in the framework of the Benelux cooperation schemes. Trans-border interregional data are deemed crucial when it comes to the early detection of potentially dangerous substances and use trends.

In terms of financial resources, no specific state budget line is currently attributed to N-EWS activities. This is partly explained by the fact that the vast majority of the N-EWS partners (including the national EMCDDA focal point, that disposes of a EWS dedicated budget line) are in one or the other way financed or co-financed by the State and that EWS-related tasks are included, whether directly or indirectly in their mission framework.

Communication means that the N-EWS is based upon, are various and their respective use depends on the observed situation and the rapidity of a required response. Urgent notifications are most frequently made by phone and backed-up by e-mail. The flow of information received via international partners are generally distributed electronically to N-EWS partners, as are the EWS implementation progress reports to the EMCDDA due on a biannual basis. Meetings of the ICD are held three to four times a year, although competent members of the ICD may convene to address urgent matters if the situation requires so. Meetings with competent ministers are held ad hoc if the situation asks for rapid and/or important decisions.

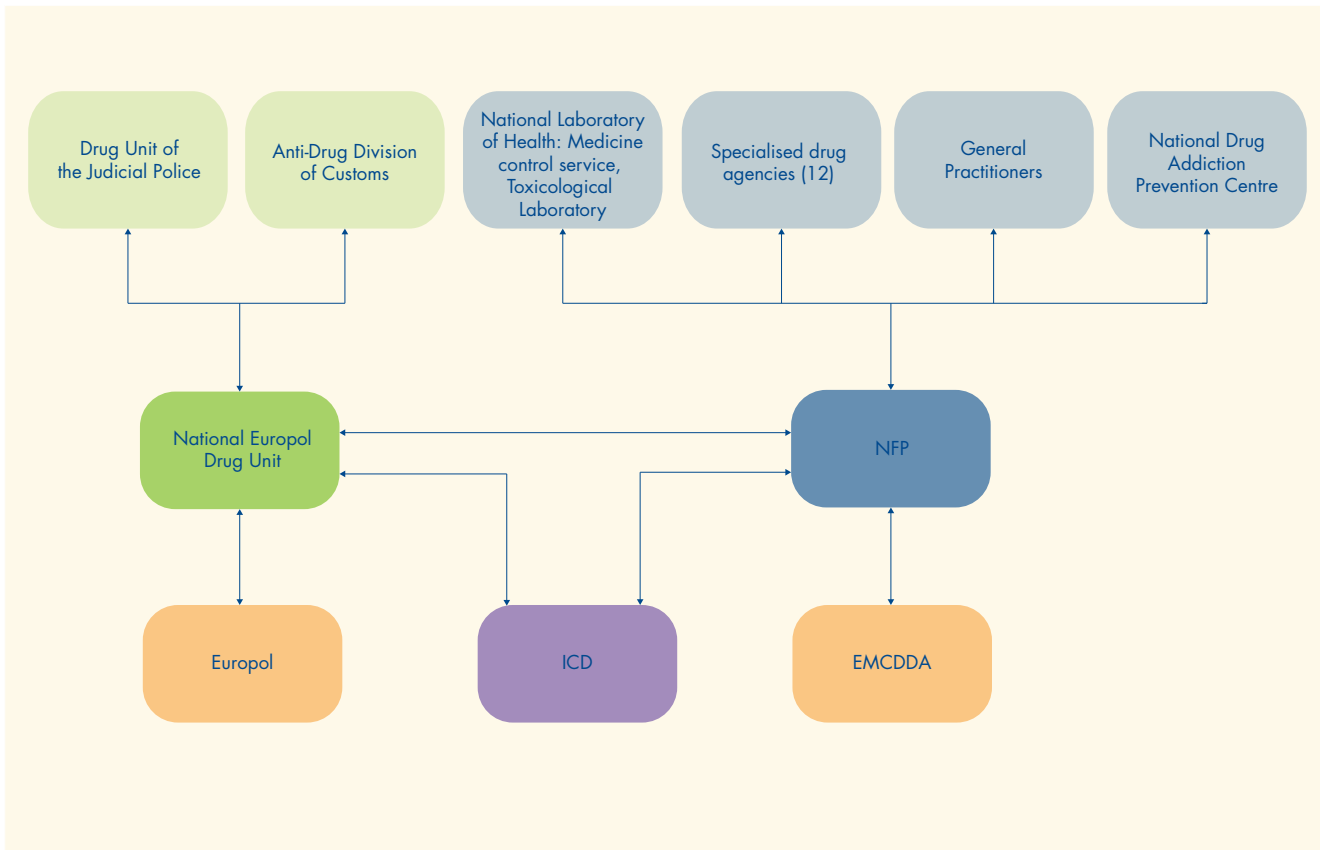
The fact that a majority of EWS stakeholders are multilingual (LU, DE, EN, FR) largely facilitates communication and especially the gathering of information on new drugs or patterns of use (e.g. web search, scientific publications, grey literature).

Core functions and information flow

N-EWS data may be provided via seizures, voluntary drug profiling demands, forensic evidence, (online) headshops' offer screenings, drug treatment agencies or the National Drug Prevention Centre (CePT). The latter also performs ad hoc rapid assessment studies on specific topics (e.g. inhalants). International incoming data are mostly channelled via the NFP and the national Europol Drug Unit to the ICD and the N-EWS network.

Most commonly, N-EWS network partners listed above notify new substances/products or new patterns of use in an informal way first, whether to the NFP or the national Europol Drug Unit. The NFP in collaboration with the

Figure 15 — Information flow in the framework of the Luxembourgish EWS



national Europol Drug Unit and, where appropriate, with other national experts, assesses the pertinence and relevance of the provided information and if required, assists data providers in the completion of the notification form to be transmitted to the EMCDDA. Simultaneously, the ICD is informed on any relevant issue. All EWS data are processed confidentially to avoid any iatrogenic effects, unless public warning is deemed necessary by the ICD and the competent minister.

Case study

The utility and reactivity of the N-EWS has been proven on numerous occasions, by providing the NFP and the ICD with valuable information on drugs via national or international channels or by contributing to general public warnings. It also has contributed significantly to adopt rapid control measures on 4-MTA, PMMA, 2C-I, 2C-T-2, 2C-T-7, TMA-2, GHB, BZP, in the context of the so-called 'Spice' and 'legal highs' phenomena on the whole range of synthetic agonists of cannabinoid receptors and most recently on mephedrone (cathinone), which use and seizure was notified in 2010 by police forces to the NFP and ICD through the EWS network and subsequently to the EMCDDA via the NFP.

As far as delays between Council decisions and effective control measures at the national level are concerned, the following has been observed:

- 4-MTA: 3 months;
- PMMA: 2 months;
- 2C-I, 2C-T-2, 2C-T-7 and TMA-2: 11 months;
- BZP: 2 months;
- Mephedrone: put under control in Luxembourg before the actual Council decision in December 2011 on an EU-wide control.

Up to 2011, two public alerts by the Ministry of Health, based on data gathered via the EWS occurred; a first one in 2007 concerning the possible presence of glass beads in herbal cannabis and the second in 2009, informing on the risks of heroin contaminated with anthrax.

Strengths, limitations and way forward

The national reference laboratory disposes of the required resources to perform high-quality toxicological analysis, even though most 'unknown' substances are currently profiled in other countries before they arrive on the national market. The toxicological department of the National Laboratory of Health is currently working on new methods to detect and

profile uncommon psychoactive substances by using high-performance gas chromatography in association to mass spectrometry.

Also worth mentioning are the relatively short delays between the risk assessment results, mostly provided by the EMCDDA, or the respective Council decision and the change of the national legislation allowing to control a given substance. These changes occur via Grand-ducal decrees modifying the annexes (lists) of respective regulations previously described.

Although the N-EWS is highly operational, there is obviously space for improvement, particularly as far as supplementary data sources are concerned. Thus, non-fatal drug-related emergencies requiring medical intervention are not reported systematically. Moreover, emergency services do not index drug-related interventions separately, which means that no valid monitoring of those cases can be performed. The referred situation is not likely to change and thus, the inclusion of emergency services in the N-EWS still appears to be unfeasible at the present stage.

National drug legislation does not expressively foresee a legal framework for on-site testing, profiling of illicit drugs (e.g. night clubs, public events or rave parties) or amnesty bins which could provide valuable first-line data. Also, new challenges are ahead as far as the surveillance of 'legal highs' products are concerned, since the marketing of these products obviously exploits the constraints of legal procedures substance control measures are generally based on. Furthermore, the acquisition of the products mainly occur via the Internet and new psychoactive molecules possibly included in these products are firstly difficult to detect and secondly, risk assessments are difficult to perform since long-term studies on adverse effects are generally not available.

Links and references

Links

Centre de Prévention des Toxicomanies:
<http://www.cept.lu>

Centre de Recherche Public de la Santé:
<http://crp-sante.lu>

Laboratoire national de santé, Grand-Duché de Luxembourg:
<http://www.lns.public.lu/index.html>

Ministère de la Santé, Direction de la Santé Grand-Duché de Luxembourg: <http://www.ms.etat.lu>

Portail Santé, Grand-Duché de Luxembourg:
<http://www.sante.public.lu>

Réseau Luxembourgeois d'Information sur les Stupéfiants et les toxicomanies, RELIS (Luxembourg Information Network on Drugs and Drug Addiction): <http://www.relis.lu>

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Malta — early warning system

Manuel Gellel and Richard Muscat

Introduction

The early warning system was originally set up in Malta in 2004/5. This was done in compliance with the Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk assessment and control of new psychoactive substances, early warning system of the EU Joint Action Plan on New Synthetic Drugs. The project was initiated by the Maltese national focal point (NFP), and brought together the Malta Police Drug Squad, the Europol Liaison Officer, the Malta Forensic Laboratory and the Toxicology Laboratory, with the aim to establish a means of exchanging information among Member States of the EU regarding the detection, risk and control of new synthetic drugs.

Organisational issues

The purpose of the EWS system in Malta is to establish a network of communication among stakeholders within the country, as well as to actively contribute and share information regarding the emergence of new synthetic drugs on an international level.

The members of the EWS in Malta come from different governmental departments and incorporate professionals within law enforcement, forensic toxicology, health and medical entities.

In line with its international obligations the Maltese EWS also communicates with Europol (Europol National Unit (ENU) and Europol Liaison Bureau) and the EMCDDA. The EWS in Malta covers the whole geographical area of the country.

Core functions and information flow

The functions of the Maltese EWS network are to identify new synthetic drugs and to notify all local entities involved in the network as well as the EMCDDA.

The Local EWS network comprises of:

- The Malta Police Drug Squad;
- Malta Customs;
- National Hospital — Toxicology and Data Department;

- Malta Medicine Authority;
- Malta National Forensic Laboratory.

In the case of the Local detection of a new synthetic drug, the notification is received by the NFP, either from the National Forensic Laboratory or the Malta Police Drug Squad. The NFP in turn disseminates the information to the rest of the local network and to the EMCDDA.

The NFP is also responsible for notification to the local network regarding reporting by other Member States which is received through the EMCDDA.

The following communication system for an early warning system for new synthetic drugs has now been put in place to be able to deal better with the expected following scenarios. In cooperation between the NFP and the Europol National Unit of Malta a communication network for the reporting of new synthetic drugs in order to be able to handle the following three scenarios.

Scenario 1: A new drug is detected by the Malta Police Force The Drug Squad Unit (DSU) informs the ENU who informs other law enforcement agencies (Les). The ENU informs NFP who in turn informs the EMCDDA and care agencies (CAs). The ENU also informs the European liaison officer (ELO) who then informs Europol.

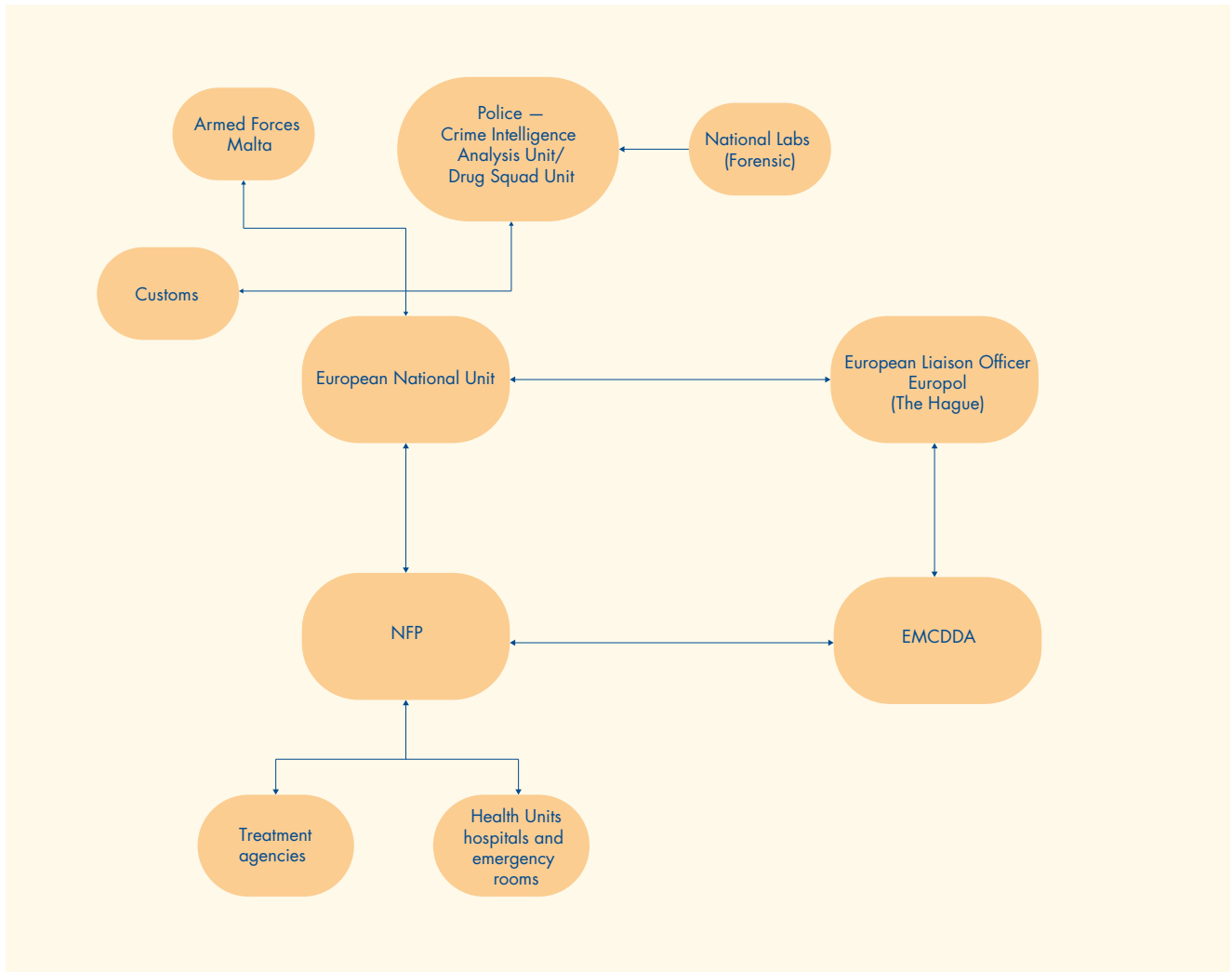
Scenario 2: A new drug is detected by a Care Agency in Malta
The CA informs the NFP who informs the ENU/DSU and the EMCDDA. The ENU informs the ELO, who informs Europol.

Scenario 3: A new drug is detected by another Member State.

Case study

The network of experts involved in the EWS come from the different sectors. This contributes to assuring that all areas directly affected by changes in drug use trends and by the emergence of new synthetic drugs have such important

Figure 16 — Communication network for the reporting of new synthetic drugs



information made available to them through the collaboration that this network supports. Contributions by the Maltese EWS network, together with information sharing with other Member States and the EMCDDA have resulted in the scheduling of a number of new synthetic drugs which emerged in recent years. A typical example in the local context was the addition of mephedrone to the list of drugs scheduled under Maltese laws in September of 2010. The Forensic Laboratory is responsible for the analysis of all the illicit drugs that are seized in Malta by the Police Drug Squad and hence all new synthetic drugs are reported by this laboratory. Although as a laboratory it is part of the local EWS network, though no official appointment as yet has been made. Since 2005, a number of synthetic compounds have been reported to the NFP (Table 1) who then reported on to the EMCDDA.

Though there is a good working relationship between the Forensic Laboratory and the NFP, there is no official so-called appointment and hence the network that links together the other members of the local EWS network is based on the good will of those that make up the relevant bodies of the said network.

This in turn could be remedied by the provision of an official appointment. At present, any general sharing of information about new synthetic substances between members of the network is done on an individual basis and then the NFP informs the relevant bodies.

In addition, when in 2010 a batch of bad heroin, found to be cut with Alprazolam was identified, the Forensic Laboratory also informed Sedqa, Malta’s National Agency

Table 1 — Reports to the EWS from 2005 until 2011

Chemical	Year/s	Number of reports
GBL	2011 (still not included on the EDND)	1
Desoxy-D2PM	2011	1
MDPV	2011	1
JWH-210	2011 (still not included on the EDND)	1
JWH-018	2011 (09-2011 still not included on 2011)	2
Mephedrone	2011 and 2010	6 (4 reports in 2010 and 2 reports in 2011)
GHB	2010	1 — overdose
BZP	2006	5 (3 reports on tablets and 2 reports urine samples)
mCPP	2006 (one of the biggest seizures in Europe – > 50 000 tablets)	1
DPIA	2005	3

Against Drug and Alcohol Abuse, to be able to better inform its clients.

Strengths, limitations and way forward

The National network is composed of forensic experts from the National Laboratory, law enforcement personnel from police, customs, hospital and the medicines authority. The network has a good level of communication which contributes to the swift communication regarding any new substances or emerging trends. Malta is represented in the annual EWS meeting held by the EMCDDA and the national focal point is kept informed of any developments. Early detection of new psychoactive drugs has contributed to the inclusion of new substances in the list of scheduled drugs in Maltese Law. Members of the Maltese EWS network were instrumental in Malta's decision to schedule mephedrone in September of 2010.

The major limitation as highlighted above is the fact that the network has no formal status and thus depends entirely on

the good will of the actors within each of the relevant entities. This in itself — the good relations between the relevant entities — is not the limiting factor but, to the contrary, is the major reason why the network has functioned so well so far. However, this needs to be strengthened so that in times when there may be a change in personnel that may lead to less communication, this does not disturb the overall functioning of the network. Thus, in the future to prevent such a situation, the introduction of formal ties such as MoUs between the relevant bodies should provide the means through which the network continues to function as foreseen.

Links and references

Malta national focal point (2007), 2007 National report — Malta Drug Situation, ISBN-978-99932-688-6-4.

Ministry for the Family and Social Solidarity (2008), National Drugs Policy 2008.

Ministry for the Family and Social Solidarity, Malta.

Netherlands – early warning system

Leon Van Aerts and Raymond J.M. Niesink

Introduction

In practice, the daily monitoring, surveillance and the acute assessment of risks of new psychoactive substances is done by the Drugs Information and Monitoring System (DIMS). The DIMS was originally started as a local initiative in Amsterdam to give drug users the opportunity to determine the composition of their drugs. In 1992, it was decided to expand this system nationwide. This offered the possibility to gain insight into the various new drug markets. The monitoring task of the DIMS has become increasingly important in the course of the 1990s and forms the basis of the Dutch early warning system (EWS). The base is still the same: exchanging information. Drug users have their drugs analysed in order to know the exact composition and, in return, give information about observed effects, use and market.

Signals pointing to the appearance of new drugs on the market could be picked up by the DIMS. But other organisations, e.g. law enforcement or customs could also detect such signals. However, there was no exchange of information between these organisations. In fact, the lack of cooperation fuelled an attitude of distrust and when new information was gathered, each organisation assessed the need for further action in their own way. For example, the detection of a large amount of 2C-B by customs led to the use of a rapid procedure provided by the Netherlands drugs law ('Opiumwet'), resulting in a decree prohibiting this substance (Borst-Eilers and Sorgdrager, 1998). Yet the Minister of Health, Welfare and Sport, who is leading where the prohibition of drugs is concerned, did not have the possibility to assess the need for prohibition from a public-health perspective. Thus, it was felt that there was a need for a coordinated assessment at national level.

This coincided with the need to nationally implement the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs (Council of the European Union, 1997). This resulted in 1999 in the foundation of the Coordination Centre for Assessment and Monitoring of New Drugs (CAM) (Borst-Eilers, 2000a).

Concomitantly, the Committee for Risk Assessment of New Drugs (CRAND) was installed (Borst-Eilers, 2000b). The principal tasks of this committee are to exchange information on drugs and drug use and to assess the risks of new drugs decisively, independently and multidisciplinary. By exchanging information and assessing the risks, CRAND supports CAM in its task to inform and advise the minister of Health, Welfare and Sport on the new trends in drugs and drug use and the associated potential risks.

Initially, CAM was placed at the Health Care Inspectorate, but in 2006 it was moved to the National Institute of Public Health and the Environment.

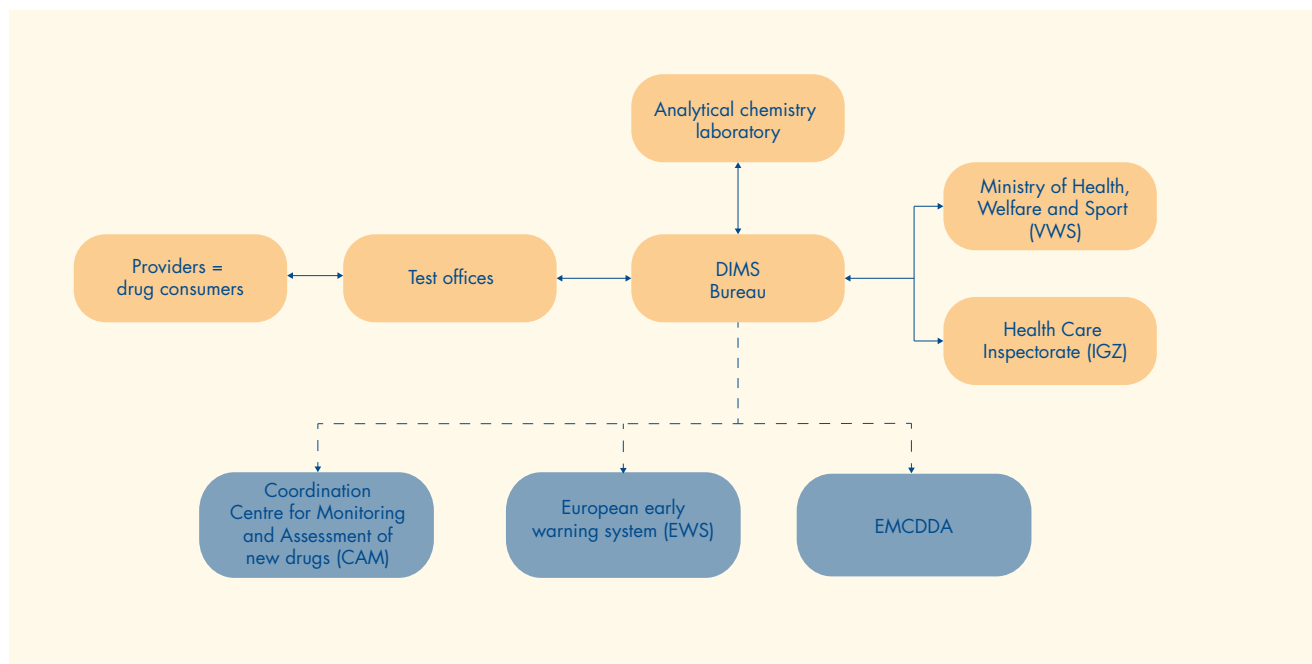
Organisational issues

DIMS

Since the start of the DIMS in 1992, the Ministry of Health, Welfare and Sport has financially supported the national activities of the DIMS. During the 1990s, the DIMS has been embedded in the official Dutch drug policy. In 1998, the Minister established an independent supervisory commission, the Begeleidingscommissie DIMS (Borst-Eilers, 1998a). The members of this commission are appointed by the Minister (Borst-Eilers, 1998b; Hoogervorst, 2004b; Klink, 2008). Since 1999, the DIMS is part of the National Drug Monitor (Borst-Eilers, 1999).

The main focus of the DIMS is to identify the compounds of (synthetic) drugs, to describe prevalence of drugs in the market and trends in drug use, and to identify health risks for drug-users (Keijsers et al., 2008; Vogels et al., 2009; Brunt and Niesink, 2011). Apart from its monitoring function, DIMS also has an important surveillance task. When a drug with extraordinary health risks appears on the market, the DIMS-bureau starts and coordinates a national warning campaign (i.e. Red Alert) to prevent and reduce health risks.

The DIMS functions under the authority of the Dutch Ministry of Health, Welfare and Sport and is supervised by the

Figure 17 — Organisation chart of the Drug Information and Monitoring System (DIMS)

Netherlands Health Care Inspectorate. An organisation chart of DIMS is shown in Figure 17.

DIMS is a network of cooperating institutions which consists of the coordinating and steering centre at the Trimbos Institute, which is the Dutch Research Institute for Mental Health and Addiction, 30 'test-offices', and numerous anonymous drug users. Most of the offices are part of the prevention departments of facilities for outpatient addiction care situated all over the Netherlands. Field workers (i.e. prevention professionals) working at these facilities subsequently inform the substance-user about the compounds of the provided drugs, based on laboratory analyses. The drug testing system enables scientists at the central DIMS office to monitor synthetic drug markets by gathering and interpreting the information from the offices.

About six people are working at the DIMS-Bureau. The head of the bureau is a toxicologist. The Begeleidingscommissie DIMS represents different disciplines.

The DIMS network is organised around a closed website. The DIMS website is used both for rapid exchange of information on new drugs, for internal warnings, but also for the identification of drugs.

Every year there is a refreshment course and meeting with the partners. Three times a year there is a meeting with the

representatives of the member institutions. The Begeleidingscommissie DIMS meets three times a year. The staff of the DIMS Bureau meets weekly on current affairs. The DIMS Bureau also organises courses for new testers of the member institutions. Communication within these bodies is in Dutch. Twice a year, the DIMS publishes an update on the monitoring results and once a year, a more glossy folder is published to inform the general public, both are in Dutch. The DIMS provides data to the National Drug Monitor, CAM, the European EWS and to the EMCDDA. Results of the DIMS are also published in international scientific journals.

CAM

CAM became operative in 1999. It was formally founded by a ministerial decree (Borst-Eilers, 2000a). Later, the managerial structure of CAM was adapted to secure the separation of independent assessment and advice from subsequent policy making (Klink, 2009a). It is the task of CAM to see that new drugs are subjected to a risk assessment, following established procedures and criteria. Based on the results of a risk assessment, CAM advises the Minister of Health, Welfare and Sport regarding appropriate measures. Furthermore, CAM has a coordinating task regarding the early signalling of new drugs, making use of already existing monitoring systems. In these matters, CAM reports to the relevant directorate of the ministry of Health, Welfare and Sport. When new psychoactive substances are involved, CAM will, on the basis

of a risk assessment, also report to the EMCDDA via the national focal point and to Europol.

CAM consists of a coordinator, his deputy and administrative support. The coordinator should have knowledge and experience in the field of drugs and drug use. Currently, CAM is located at the National Institute of Public Health and the Environment (RIVM), further securing the scientific independent performance of the risk assessments.

CAM organises at least three meetings of CRAND each year, to facilitate the broad exchange of information on new drugs and drug use. When there is a need for a risk assessment, additional meetings might be necessary. Minutes of the regular meetings are reported internally and to the Ministry of Public Health, Welfare and Sports. When a risk assessment has been performed, a risk assessment report is written, which is made public on the website of the RIVM after the Minister of Health, Welfare and Sport has sent his reaction to the Parliament. All communications are in Dutch, but when a risk assessment report is written, an English summary is included.

CRAND

CRAND was installed concomitantly with the foundation of CAM in 1999 (Borst-Eilers, 2000b). Originally, two separate committees were installed, one for the exchange of information and one for the risk assessments. Yet, the members appointed were almost the same. This was changed in 2003 when both committees were replaced by a single one, executing both tasks (Hoogervorst, 2004a; Hoogervorst, 2007; Klink, 2009b). Later on, the managerial structure of CAM and CRAND was criticised in the Parliament, as the head of the department from the Ministry of Health, Welfare and Sport, who is responsible for developing and executing drugs policy was also the chair of CRAND and member of the board of CAM. This was changed in 2008 by appointing an independent chair of CRAND and abolishing the board of CAM (Klink, 2009a).

The tasks of CRAND are:

- to support CAM in its task to inform and advise the minister of Health, Welfare and Sport;
- to broadly exchange information on drugs and drug trends;
- to assess the risks of new drugs decisively, independently and multidisciplinary;
- to examine and evaluate the risk assessment procedure.

CRAND consists of an independent chair and a maximum of 20 members. The members are appointed by the minister of

Health, Welfare and Sport and represent organisations having expertise in the field of drugs, drug use and addiction. The organisations currently represented in CRAND are the National Drug Monitor (also chair), DIMS, the Public Health Service of Amsterdam, the National Poisoning Information Center, the Health Care Inspectorate, the Food and Consumer Product Safety Authority, SolutionS Center (clinic for addiction care), Tactus group (addiction care), the Bongor Institute for Criminology from the University of Amsterdam, the Netherlands Forensic Institute, the Netherlands' Police Agency and the Public Prosecutor. Next to the expert members, representatives from the Ministry of Health, Welfare and Sport and the ministry of Security and Justice are appointed. The coordinator of CAM is the secretary of CRAND. When a risk assessment is performed, the representatives from the ministries may take part in the discussions, but do not actually assess the risks. The representatives from the other organisations base their judgment on their own expertise, without the need for consultation with the organisations they represent.

Focal point

The national focal point is hosted by the Trimbos Institute. In practice, DIMS also functions as the Dutch contact for the European EWS on behalf of the Dutch NFP.

Core functions and information flow

The N-EWS in the Netherlands is a network of organisations with each having their specific expertise and role. The involvement of each of them may vary depending on the process/function of the N-EWS that is at hand. Basically, three main N-EWS-related functions/processes can be discerned: Monitoring, Red Alert System and Risk Assessment. Each of these processes will be described here and it will be indicated which organisations are involved in each of them.

Monitoring

In the Netherlands, multiple monitoring instruments are present, which may provide relevant information for the early signalling of new drugs or new drug trends. Many of these are represented in CRAND. Meetings of CRAND are organised by CAM. Thus, the organisations involved are often referred to as the CAM network (Table 2).

In principle, information on all kinds of drugs is exchanged within the CAM network. However, in view of the monitoring task of CAM and CRAND, there is a focus on new drugs. Information is exchanged on a regular basis in CRAND

Table 2 – Sources providing relevant information for the National early warning system incorporated in the CAM network

Monitor	Location	Coverage	Drugs market	Principal methods
National Drug Monitor (NDM)	Trimbos Institute	National	all	Gathers and compiles information from all available sources
Reitox/EWS	EMCDDA	Europe	New psychoactive substances	Depends on Member States, mostly seizures
Drugs Information and Monitoring System (DIMS)	Trimbos Institute	National	New psychoactive substances, ecstasy, amphetamine, cocaine, opiates	Sample analysis at user level
Monitor Drug Incidents (MDI)	Trimbos Institute	National	all	Information from healthcare professionals (ED-hospitals, ambulance, police)
National Poisoning Information Centre	National Institute of Public Health and the Environment	National	all	Information requests from professionals
Addiction care	SolutionS Centre, Tactus group	National, Utrecht	all	Information from addicts, anecdotal
Antenne	Bonger Institute for Criminology	Amsterdam	all	Urban anthropologic surveillance
	National Forensic Institute	National	all	Sample analysis of seized drugs; Toxicology of drugs or road traffic victims
	Netherlands' Police Agency	National	all	Seizures, anecdotal
	Health Care Inspectorate	National	all	Drugs law-related inspections, anecdotal
	Food and Consumer Product Safety Authority	National	'legal highs'	Analyses of samples, inspections of smartshops, anecdotal
	Public Health Service of Amsterdam	Amsterdam	all	Ambulance reports, anecdotal
	Public Prosecutor	National	all	Seizures

meetings organised by CAM. However, when there is a need for immediate exchange of information, information is shared through the CAM network using e-mail communication. A need for immediate exchange of information is only felt when there is concern regarding public health or an issue seriously affecting public order would arise. Also, information is disseminated through the national focal point to the EMCDDA when, after first assessment, a public health issue relevant for other Member States is at hand. Information gathered in this way can be used by the Ministry of Health, Welfare and Sport as a basis for a decision to request CAM to start a risk assessment. If the information is insufficient to make a decision, CAM can initiate a so-called quick scan to retrieve and compile the available information from the CAM network.

Starting in January 2012, the DIMS will also operate as the national reporting centre for new drugs. By more actively and systematically sharing information on new psychoactive substances found by Netherlands Forensic Institute (NFI), customs and police labs it is tried to get more quickly

reliable information about 'legal highs' and other new drugs on the Dutch drug market.

Red alert system

Substance use implies health risks. Dutch drug policy aims to discourage substance use and to reduce the harm involved (De Kort and Cramer, 1999). Sometimes, additional health risks emerge when drugs are contaminated with other substances, or when drugs do not contain what they pretend. If such additional risks are noted, a warning campaign is conducted by the DIMS to reduce the number of hospitalisations and to prevent fatal drug incidents. The campaigns aim to timely inform (potential) substance users about these additional health risks. To determine acute risks for the Red Alert procedure a network of different experts can be consulted; e.g. toxicologists, the National Poison Centre, the National Forensic Institute. Several actors, namely field workers (i.e., prevention professionals), policymakers and scientists participate in these campaigns (Keijzers et al., 2008).

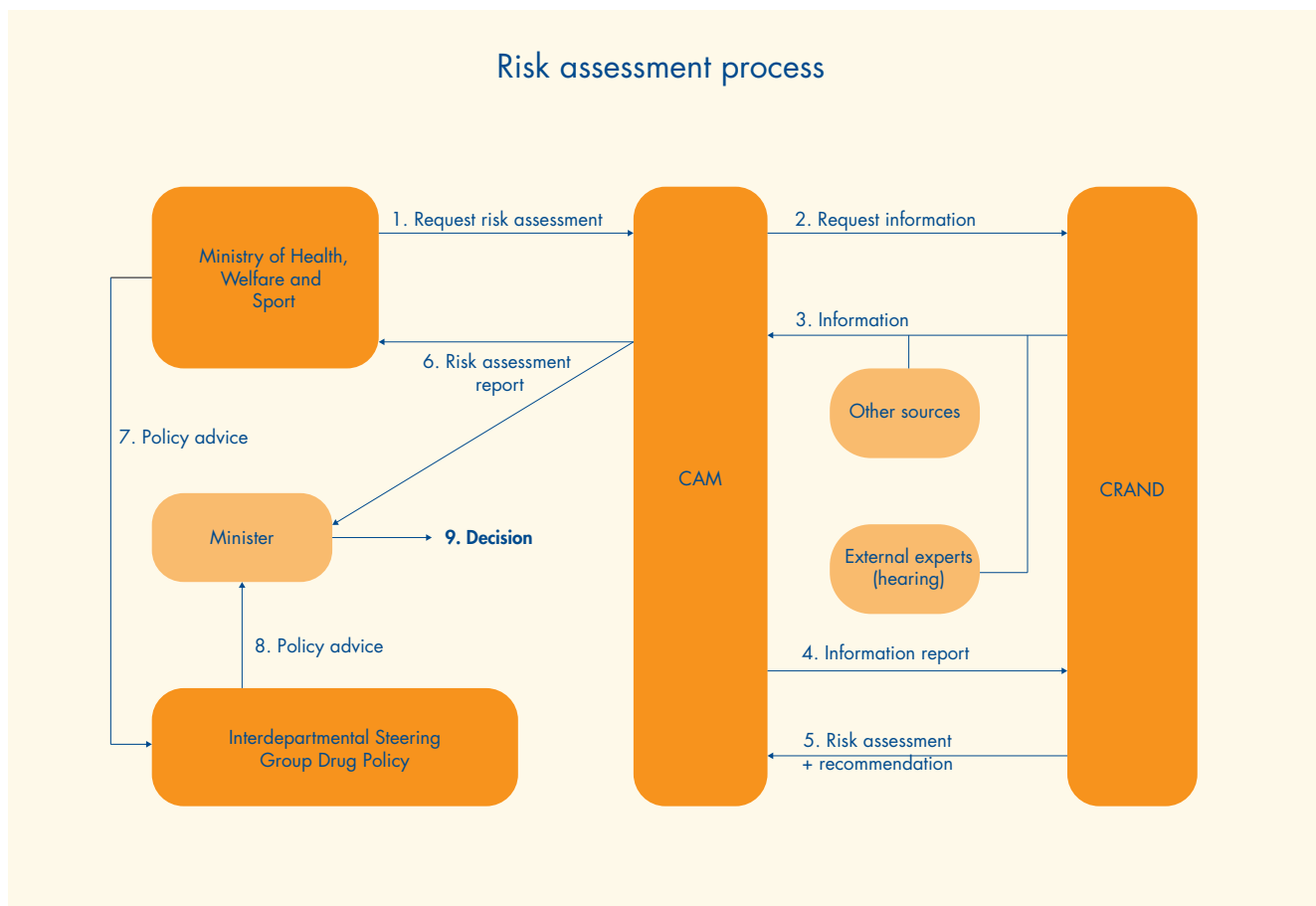
A quick and adequate response to a contaminated drug on the market is of vital importance for drug users. To anticipate this, required actions of those involved has been laid down in a protocol based on past practical experiences. This protocol includes the aims of a warning campaign, background of the organisational structure, list of professionals involved and their contact information, responsibilities and tasks of policy employees, and a decision tree. The protocol also contains a checklist to make it possible to control whether all activities have been executed and all authorities have been informed. A Red Alert is closely watched and steered by policy employees of the Ministry of Health, Welfare and Sport and the Netherlands Health Care Inspectorate. Scientists at the DIMS-Bureau communicate with both these policy officials, the field workers at the test-offices and the press. The protocol also describes how the Red Alert campaign should be evaluated.

Risk assessment

On the basis of serious signals indicating public health or public order may be affected, the Ministry of Health, Welfare

and Sport can request CAM to initiate a formal risk assessment [1] (numbers in square parentheses refer to numbers in Figure 18). CAM requests the members of CRAND to gather and send relevant information to CAM [2]. CRAND members send the relevant information to CAM. CAM gathers information from the literature and other relevant sources. Also, when there is a need, external experts can be involved, who may be invited for a special meeting of CRAND [3]. Based on all information that has been gathered, CAM compiles an information report and sends it to CRAND members [4]. The expert members of CRAND assess the risks individually and send the scoring forms with remarks back to the CAM. CAM compiles the risk scores and a risk assessment meeting of CRAND is convened where the results of the initial individual risk assessment are discussed. In a second scoring round during this meeting CRAND members can adjust their scores when there is a need. Subsequently, measures for further action are discussed including the consequences of these measures. On the basis of the risk assessment and the discussions during the meeting recommendations are made [5]. CAM now

Figure 18 — Risk assessment process of the Coordination Centre for Assessment and Monitoring of New Drugs (CAM)



produces a draft risk assessment report, which is commented by CRAND members (by e-mail) and subsequently, a final risk assessment report, which is sent to the Minister of Health, Welfare and Sport and the relevant department at the same ministry [6]. A policy advice is prepared by this ministry [7] which is discussed in the Interdepartmental Steering Group Drugs Policy. In this group, representatives from other ministries are present as well, including those from the Ministry of Security and Justice, the Ministry of Interior and Kingdom Relations, the Ministry of Foreign Affairs and the Ministry of Economic Affairs, Agriculture and Innovation. The comments from this group are sent to the Minister of Health, Welfare and Sport [8], who finally decides which further action will be taken [9].

Once the minister has sent his decision to the Parliament, the risk assessment report is released by placing it on the website of the National Institute of Public Health and the Environment. The report is written in Dutch. When the risk assessment concerns a new psychoactive substance, an English summary is sent to the EMCDDA and Europol.

Case study

PMMA warning on 11 November 2010

On 10 November 2010, the DIMS Bureau at the Trimbos Institute was informed by the NFI about ecstasy ('XTC') pills containing dangerously high amounts of PMMA. The pills were obtained from a police case in which a young man died after ingestion of these pills and some other drugs. The pills had been found in the surroundings of the victim. Because it was suspected that these pills might also be around in other places in the Netherlands, it was decided to make a general warning for these specific pills. The DIMS partners were informed and instructions were given which information should be given and in what way.

In addition, other Member States were informed through the EWS at the EMCDDA. Via the public relations official of the Trimbos Institute, a press communication was released and information was put on the website of the Trimbos Institute and on websites for drug users. Other relevant agencies were informed via specific e-mails and via the website of the Monitor Drug Incidents. The information was quickly received by national newspapers, radio and television. The news from the Trimbos website was also quickly spread via Twitter.

Strengths, limitations and way forward

Strengths

The network structure of the national EWS in the Netherlands ensures a flexible approach, where the relevant participants take action. Implicitly, responsibilities are decentralised to ensure a rapid response. Yet, feedback to other partners and the Ministry of Health, Welfare and Sport ensures accountability. Weighing the relevance of new findings for public health and public order prevents premature actions, which would generate an unnecessary workload and — in the case of public warnings — a desensitisation of the public. Embedding in a network structure with DIMS and CAM as coordination centres supports the broad exchange of information. The regular meetings and exchange of information has created an atmosphere of trust. The use of a standardised risk assessment procedure ensures that risks from new drugs are assessed in a comparable way. The results from risk assessments provide a basis for a rational decision-making process.

Limitations

The participants in the national EWS have fixed budgets and therefore are constrained in their activities. For example the CRAND may have the opinion that research on a specific substance is needed, but does not have the opportunity to initiate independent research. Yet, it should be said that the ministry of Health, Welfare and Sport always considers recommendations from CRAND, CAM, or other partners seriously.

In drug-related incidents, usually little toxicological data are gathered. Often, analyses are limited to confiscated drugs. When toxicology is performed in the hospital, case-related data are not released due to medical confidentiality constraints. Consequently, it is not always possible to confirm the contribution of a specific drug in an allegedly drug-related incident by toxicology data.

Way forward

Currently, no major changes to the structure of the N-EWS in the Netherlands are foreseen.

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Norway – early warning system

Marit Edland-Gryt and Odd Hordvin

Introduction

Norway has been part of the European early warning system (EWS) since it became a member of the EMCDDA in 2001. At the beginning of 2002, with a view to establishing a National early warning system (N-EWS), the Norwegian focal point embarked on a collaboration with the two most important players with regards to discovering new drugs in Norway, namely the National Criminal Investigation Service (Kripos) and the Norwegian Institute of Public Health (NIPH). The collaboration with these two institutions has been formalised. Initially, meetings were held every six months, but it was later decided that communication should primarily take place via e-mail. Since then, collaboration with other key players and individuals who are interested in the discovery of new drugs has also been established. This is described under the section Core functions and information flow. The first early warning report on the identification of new drugs in Norway was submitted in December 2001 for the year 2001.

In 2004, Norway joined the network for the current drug situation in Scandinavia (NADiS). The network, which was originally established as a Swedish network in 2000, became a Scandinavian collaboration when Norway and Denmark joined. In 2006, Finland became a member, as well as Iceland in 2011. NADiS is a closed network that largely involves institutions that analyse new drugs. The Norwegian Institute for Alcohol and Drug Research (SIRUS) is the administrator for the Norwegian part of NADiS. The Norwegian NADiS network consists more or less of the same agencies as the Norwegian EWS.

Organisational issues

The Norwegian EWS has no formal remit or regulation. It is based on voluntary participation and on Council Decision 2005/387/JHA, even though Norway is not formally bound by this decision. The Norwegian EWS is part of the Norwegian focal point and it is based at SIRUS. It has no links to EU institutions. The Norwegian EWS is a national system, with agencies in big Norwegian towns and cities. One person (a sociologist) works part-time as a national correspondent, and the head of the focal point is also

involved in the work. Most of the communication takes place via e-mail. The language used in the national network is Norwegian, and information about new drugs is translated into English before it is sent to the EMCDDA EWS. The work of the Norwegian EWS is both scientifically and politically independent.

Core functions and information flow

The Norwegian EWS comprises 15 agencies, but the core of the work is the collaboration with Kripos, the NIPH and the Norwegian Medicines Agency. As a matter of routine, e-mails from the EMCDDA about new drugs that have been identified in Europe are sent to all members of the Norwegian EWS, and information that is submitted to the EMCDDA by other Member States is received in return.

We also submit forms for drugs that have been discovered in Norway for the first time. It is mainly the Drugs Analyses Section at Kripos that fills out these forms when new drugs are seized, but the national customs laboratory has also identified drugs for the first time in Norway and submitted forms. SIRUS is responsible for maintaining a system whereby partners in the collaboration fill in forms when new drugs are identified, since this information is usually not available. The collaboration is often dependent on individuals. Norway has not established a separate database for the identification of new drugs, but uses the European database on new drugs (EDND).

In addition to persons from Kripos, NIPH, the Norwegian Medicines Agency and SIRUS, the network consists of people from two sections at the Directorate of Customs and Excise (the national customs laboratory and the section for border controls), the 'Føre Var' (early warning) project at the Bergen Clinics Foundation, the Directorate of Health's Poisons Information Department, the National Police Directorate, St. Olav's Hospital's Department of Clinical Pharmacology, Ullevål University Hospital's Department of Clinical Pharmacology and Toxicology, the Institute of Forensic Medicine at the University of Oslo, Oslo Police District, the Health and Overdose Team in Trondheim and City of Oslo Alcohol and Drug Addiction Service. At present, the

Norwegian network comprises of 21 persons. There have been four meetings held in the Norwegian network. Since 2010, the intention is to hold meetings once a year for members of the Norwegian network.

In addition to meetings of the Norwegian network organised by the focal point, other forums are also organised. Amongst other matters, collaborative meetings for analyses of drugs are organised by Kripos and SIRUS, and a collaboration group appointed by the Norwegian Medicines Agency for the continuous assessment of new drugs that should be included on the Norwegian list of narcotic substances is organised. The focal point is responsible for sending regular reports from the Norwegian EWS. The reports primarily contain information from the three main partners. For practical reasons, the reporting is limited to an annual EWS report. The Norwegian focal point and the EWS do not carry out risk assessments at the national level.

Case study

Example of PMMA and fatalities in Norway

As a case study, the process concerning the incidence of PMMA in Norway during 2010/2011, and fatalities connected to the drug in the period is described. From summer to September 2010, the NIPH found PMMA (para-methoxymethylamphetamine) in blood in four autopsies. This information was communicated to Nordic contacts through the Nordic network on 27 September 2010. At the same time, Kripos reported a number of seizures of PMMA in the preceding weeks.

On 6 October, the NIPH published a warning on its website (www.fhi.no) about fatalities relating to the use of PMMA in combination with amphetamine/methamphetamine in Norway. The number of fatalities had now risen to six. In addition, the drug was found in several persons suspected of driving under the influence, which showed that PMMA was in circulation.

The EMCDDA asked for more information with a view to issuing an alert to the Member States. The focal point contacted the NIPH, which wrote an updated text the same day. This was used in an alert about PMA and PMMA issued by the EMCDDA on 29 October.

On 12 November, following a very short consultation procedure, the Norwegian Medicines Agency included PMMA on the Norwegian list of narcotic substances that are

prohibited pursuant to section 4 of the Regulations on narcotics.

On 16 November, the EMCDDA sent an e-mail to Europol and the European Commission (the Directorate-General for Justice), in which it was pointed out that major seizures of the precursor 4-methoxy-BMK had been made, especially in Lithuania. It also stated that lack of control of the precursor, which is used to manufacture PMMA, can lead to increased amounts of PMMA and possibly also PMA on the illegal market in the time ahead. The concerned report originally came from the Technical Department at Kripos. It was forwarded to the EMCDDA by the focal point.

On 12 January 2011, the NIPH informed the Nordic network of a total of 11 fatalities in Norway. Most had high concentrations of PMMA in their blood. On 31 January, a new warning was issued on the NIPH website about the fatal consequences of using PMMA. The number of fatalities had now risen to 12. In addition, PMMA had been found in the blood of 22 persons suspected of, among other things, driving under the influence. Furthermore, the police had made more than 80 seizures of PMMA since summer 2010, in the form of powder, either alone or mixed with amphetamines. The number of deaths was also reported to the Nordic network.

The example primarily shows that the NIPH has provided good and up-to-date information, both on its own website and through the Nordic network. Kripos also used the Nordic network actively as a distribution channel. From the focal point's point of view, the collaboration with the two key analysis agencies worked well. The information and warning about the fatal consequences of taking PMMA were quickly communicated to Norwegian and Scandinavian partners, although it took more time before the EMCDDA was informed.

Strengths, limitations and way forward

The Norwegian EWS has both strengths and weaknesses. One limitation of the system is that it often depends on individuals and personal relations, which means that changes in the agencies that cooperate with the system can lead to changes in the collaboration. Another challenge is that it has been difficult to decide how often a meeting should be convened. One strength of the Norwegian EWS is that the network is relatively small and transparent. This makes it easier to establish new relations in the network.

It is a continuous challenge to get more agencies and people involved in the work on early warning in Norway. It is also a challenge to ensure that the system works satisfactorily. In 2010, a small-scale questionnaire survey was carried out in the Norwegian network, among other things about what can be done to increase activity in the network. It emerged that, for several of the participants in the network, pressure of time is a challenge in relation to giving priority to work on the EWS. It also emerged that more regular meetings were desirable.

Flexible and non-bureaucratic good cooperation exists with Kripos and the NIPH for many years. It could also be an option to extend the collaboration to include more agencies, although most of the relevant ones are already part of the Norwegian network. This is a continuous process. The goal

is to monitor developments closely and have as many and as good sources of information as possible about new drugs in circulation in Norway.

Links and references

Norwegian Institute for Alcohol and Drug Research —
<http://www.sirus.no>

Norwegian Institute of Public Health (NIPH) —
<http://www.fhi.no>

National Criminal Investigation Service (Kripos) —
<http://www.kripos.no>

Norwegian Medicines Agency (NoMA) —
<http://www.slv.no>

Poland — early warning system

Michał Kidawa and Dawid Chojecki

Introduction

Before Poland acceded to the European Union (in May 2005), the Polish early warning system (EWS) was quite different from the present one. The flow of information was limited and the number of institutions within the system was restricted. Over the years, partners and the whole idea of the system changed. After 2005, the implementation of the EWS became an obligation, not only a recommendation.

At the beginning, the system focused only on identifying new drugs on the market. There were, and still are, many limitations for active monitoring of new substances present on the Polish drug market. At present, an equally important factor is active identification of available information and alerts concerning new substances which may pose a serious threat to public health, especially to drug users.

From the beginning, there was a need to extend the network of laboratories capable of identifying new drugs. In 2005, the Central Forensic Laboratory of Police Headquarters (CLK) was included in the network as a major partner. Other institutions that have been playing a very important role in the system include the Institute of Forensic Research with which a written cooperation agreement was signed in 2005. In late 2005, a decision was made to extend the network and start cooperation with toxicological wards. The cooperation started and has been developing until today. In 2007, the cooperation with Central Laboratory of the Agency of Internal Security has started. In 2010, the cooperation with the National Medicines Institute (NIL) was started, as the leading scientific facility specialised in analysing contaminated medicines. It was caused by the fact that the NIL started analysing new drugs present on the 'licit' market.

Since the launch of the system, a number of meetings have taken place. One of the most important was the conference organised in Autumn 2005, during which the whole idea of the EWS was presented and new partners (such as representatives of the Ministry of the Interior and Administration, NGOs and toxicological wards) were invited to cooperate. The cooperation with outreach programmes was initiated as they are very important partners in the network and the main actors in the development of the Polish

EWS, i.e. active and precise dissemination of information. The outreach programmes with time started to play an equally important role as key informants concerning changes and new developments at the Polish drug scene in major Polish cities. The contact with outreach workers has also become a powerful tool to obtain in-depth information on new trends on the drug scene which is now becoming an important part of the Polish EWS.

Organisational issues

Development and implementation of the EWS is generally provided for in the *Act of Law of 29 July 2005 on Counteracting Drug Addiction* with the following tasks of the National Bureau for Drug Prevention (Kidawa, 2007):

- cooperating with international organisations concerned with counteracting and repairing damage caused by drug addiction;
- operating the national system of information on drugs and drug addiction as well as monitoring actions of counteracting drug addiction at national and international level, including:
 - (a) acting as the national focal point of the EMCDDA;
 - (b) participating in the reporting activities for the benefit of the national organisations;
 - (c) cooperating with the EMCDDA and the European Reitox Network on Drugs and Drug Addiction.

The obligation of creating and further improving of a national EWS is also present in action 1.3 of the *Ordinance of Council of Ministers of 22 March 2011 on the National Programme for Counteracting Drug Addictions 2011–16* under the section devoted to supply reduction. The programme serves the role of the national action plan and the national drug strategy.

The basic aim of the Polish EWS is to fulfil the obligation imposed by the Council Decision. Polish EWS plays a wider role than only fulfilling those obligations. The system is based on 3 pillars: (1) substance identification; (2) collection and

dissemination of information on possible health threats; and (3) identification of new trends and phenomena on the drug scene.

At the national level, one of the main challenges is to warn drug users against the potential danger connected with using new, not well-known substances or combinations of several substances. Furthermore, the N-EWS focuses also on contaminants/adulterants of known psychoactive substances (e.g. cannabis with glass, cocaine with atropine, heroin with anthrax) as well as some medicinal substances (e.g. drugs containing benzydamine, dextrometorphane, ephedrine/pseudo-ephedrine). Additionally, the Polish EWS collects qualitative data on drug scene in the framework of periodical meetings with outreach workers in order to have in-depth information on current drug scene developments.

Since the beginning the Polish EWS has been installed in the national focal point — a department of the National Bureau for Drug Prevention (NBDP), which operates as an agency of the Ministry of Health. Two employees of the National Bureau for Drug Prevention with the background in political and social sciences work part-time on the EWS. Other duties are connected to regular activities of the NFP and the Prevention Unit of the NBDP. Technical support is provided by scientific laboratories (mainly NIL, IES), which provide sound knowledge in that field and consult the remaining partners. The NFP plays a central role in the system. It is responsible for data collection and dissemination as well as coordination and further development of the EWS.

The coverage of the EWS is strictly dependent on sources of information. Almost all laboratories cooperating in the framework of the EWS operate as central laboratories collecting results from provincial laboratories (e.g. CLK) and/or analyse samples from all over the country (e.g. NIL, ABW, IES). The toxicology department serves the role of Poisonings Information Centres for different regions, so they also collect data and information from other institutions. The outreach programmes are located in big cities simply because there is a concentration of clients seeking this form of help. So the coverage can be considered nationwide, but the number of partners is limited and therefore it is hard to precisely estimate the coverage.

There are no meetings of all the network partners. The meetings are organised with smaller groups for particular 'categories', e.g. NGOs and laboratories. There are regular meetings with harm/risk reduction programmes providers. The meetings are organised annually. The meetings with

partners from laboratories are organised more often there are some urgent issues to discuss.

Core functions and information flow

At present, data are collected from the following partner institutions:

- *Central Forensic Laboratory of the Police Headquarters (CLK)* — responsible for forensic analyses for the Police. The CLK analyses more complicated samples (including samples of drugs) and collects data from 16 provincial police laboratories.
- *Institute of Forensic Research (IES)* — responsible for conducting research within forensic science, as well as preparing expert reports for courts and prosecutor's offices in criminal and civil cases. They conduct analyses of both body fluids and drugs seized. As a leading forensic institute in Poland they collect samples from all over the country.
- *National Medicines Institute* — responsible for the quality, safety and efficacy of medicinal products and medical devices available on the Polish market. The Institute specialises in analysing contaminated drugs. Recently it has also been involved in analyses of new drugs on the legal market (legal highs).
- *Central Laboratory of the Agency of Internal Security* — responsible for conducting forensic analyses (including drugs) in the course of the Agency's investigations.
- *Six toxicological departments — Poisoning Information Centres* — responsible for providing toxicological information for doctors and hospitals. In all cases, the centres are located in toxicological wards.
- NGOs providing harm reduction and risk reduction (outreach) programmes.

All communication within the system is done via e-mail. There is no special communication platform or database within the system. All partners from laboratories, who conduct analyses, have access to the EMCDDA (EDND) database. Substances are reported on EMCDDA reporting forms as all partners are fluent in English. The cooperating institutions fill out these forms with analysis results on an ad hoc basis. They send the information to the N-EWS. The information is verified and forwarded to the EMCDDA as well as the Polish network partners. Not all information is sent to outreach programmes. They receive information on new substances where there is more evidence of possible threat to users. They also receive information concerning all alerts received both from the Reitox network and the Polish network.

Additionally, outreach programmes serve the role of insiders and key informants in gathering information on the current situation and the latest developments on the drug scene. In the regular meetings with outreach programmes a focus group interview or a structured discussion is organised in order to get information on the current situation on the drug scene. The topic guide is similar on each with slight differences in emphasis on certain issues regarding recent developments. Data collection in this manner has started just recently (in 2008) but such simple analyses are planned every two years as they have proved effective.

As for substance identification, different techniques and approaches are used in different laboratories for identification of new substances.

The following identification techniques are used:

- Gas Chromatography–Mass Spectrometry (GC-MS)
- Liquid Chromatography–Quadruple Time-Of-Flight Mass Spectrometry (LC-Q-TOFMS)
- Nuclear Magnetic Resonance spectroscopy (NMR)
- X-Ray Powder Diffraction (XRPD)
- High-Performance Liquid Chromatography with Charged Aerosol Detector (HPLC-CAD)
- High-Performance Liquid Chromatography with Electrochemical Detection (HPLC-EC).

For quantitative analysis, the following techniques are used:

- High-Performance Liquid Chromatography with Diode-Array Detector (HPLC-DAD)
- High-Performance Liquid Chromatography with Charged Aerosol Detector Corona (HPLC-CAD).

To identify conformation, the following techniques are used:

- Near Infrared Spectroscopy (NIR)
- Fourier-Transformed Mid-Infrared Spectroscopy (FT-IR)
- X-Ray Powder Diffraction (XRPD).

Data on new substances analysed are reported to the EMCDDA and then to the Reitox network. Additionally, all information concerning new substances is disseminated to the national network of laboratories. If a possible threat connected to the use of a substance has been identified, outreach programmes are informed. Warnings and alerts are also sent to outreach workers. In cases of alerts going beyond the capacity of the EWS network, the alerts are sent to other institutions and organisations. For example, the information concerning anthrax in heroin was translated, filled with additional information concerning anthrax and sent to substitution treatment programmes, as well as

detoxification units, both of which are in close contact with heroin users.

There are no national guidelines and risk assessment procedures currently present in the national legislation. Work on national guidelines and the concept of restructuring the whole system, along with providing a clearly defined basis for the system has just started.

Case study

Since 2008, the EWS activities have been dominated by 'legal highs' (dopalacze — 'boosters' in literal translation). Especially the years 2009 and 2010 were the 'years of legal highs' (in 2008: about 40 shops all over the country, in October 2010: over 1 300 shops over the country were operating). The presence of the EWS and the possibility to exchange information both of new drugs and legal solutions concerning new drugs not only within the National network, but also with the EMCDDA and the Reitox network proved to be very effective to address this phenomenon. Analytical data available within the network facilitate the process of identifying new drugs present on the market. On the other hand, available knowledge of the existence of different legal solutions in other countries helped to prepare a basis for possible options for changes to the Polish law for the government, in order to respond to that phenomenon.

Strengths, limitations and way forward

The strong point of the Polish EWS is the establishment of cooperation with most institutions and laboratories capable of identifying new drugs. Also, the precise distribution of information gathered by the EWS seems to work. Good cooperation with outreach programmes and toxicology departments and the likely use of these partners as data sources on health threats and new trends seems to be an optimistic sign of the further extension of the system's application.

A major task for the future is to create a more integrated system. A vital thing here is the development of national guidelines and building strong legal grounds for the EWS. The concept of such procedures, along with draft guidelines and legislative solutions is currently being prepared. To achieve that, there is also a need to secure sustainable financing for the analyses of new drugs in general and make legal changes.

The main downside of the Polish EWS system is many legal procedures to be followed in order to place new substances under legal control and the lack of risk assessment procedures foreseen by law, which would include a scientific risk assessment of substances by interdisciplinary teams of experts. In the long term, legal solutions are planned to establish a Committee comprised of interdisciplinary scientists who would conduct risk assessment and would recommend control measures for the government. Before that, it is planned to create an advisory body of such sort within the Council of Counteracting Drug Addiction. The Council of Counteracting Drug Addiction operates at the Prime Minister's office and functions as a coordination and advisory body for counteracting drug addiction. Its main duties are to monitor and coordinate the actions within state policy in the field of narcotic drugs, psychotropic substances and drug precursors.

Another problem within the system is limited information concerning both the number of cases and the substance identified in body fluids coming from the toxicology branch. Additionally, the limitation is the lack of laboratories in poisoning centres capable of identifying new substances. In the long term, there are plans to create three or four laboratories nationwide, which would provide analyses of poisoning cases where there is no clear evidence what caused the condition. Those laboratories would serve the role of analytical base for hospitals from regions allocated to them. They would also be responsible for collecting data from hospitals. The system would be connected with the development of toxicological information exchange and the

monitoring system of toxicology and toxicity of products and goods. The draft concept of the whole system has been prepared by the National Consultant in Clinical Toxicology and presented to the Minister of Health.

Further development of the EWS should also include a scientific approach to new phenomena emerging on the drug scene the monitoring of new trends. The case of 'legal highs' in Poland showed that in-depth information concerning the population of users of new substances, along with their characteristics is equally important in identifying new substances in order to provide effective measures to address the threat that these new substances might cause to the public health.

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Portugal — early warning system

Ana Sofia Santos, Ana Rita de Castro, Óscar Duarte and Elsa Maia

Introduction

In Portugal, the main law on control, use and traffic of narcotic drugs, psychotropic substances and precursors is the Decree Law 15/93 of 22 January (republished as Law 18/2009 of 11 May), which regulates aspects regarding penalties, medical prescriptions, authorisations, certification and control activities, as well as governmental responsibilities concerning treatment, prevention, criminal investigation and money laundering. In the annexed tables of the mentioned Decree Law are included the list of controlled substances in Portugal, following a national decision, a World Health Organization recommendation, a Commission on Narcotic Drugs decision or an EU Council Decision.

On 16 June 1997, the European Union Council approved the Joint Action related to exchange of information, risk assessment and control of new synthetic drugs. In the following up of this initiative, the European Monitoring Centre for Drug and Drug Addiction (EMCDDA) and the Unit Drug of Europol (UDE), established their respective mandate and action fields in the context of new synthetic drugs and approach forms to start as early as 1997. The information collected and analysed by the UDE is mainly from forensic structures and law enforcement agencies, while data collected and analysed by the EMCDDA covers demand reduction area and is provided by the national focal points of each Member State.

In Portugal, the General Direction of Communitarian Affaires of the Ministry of Foreign Affairs organised a meeting with all the partners in this area, on 6 November 1997, to delineate the national implementation of the referred Joint Action. The meeting conclusions permitted the establishment of an exchange of information between the different institutions involved. The national system was created to ensure the fast gathering and analysis of information, feasible and relevant, on new synthetic drugs to contribute with relevant recommendations for legislative instruments and disseminate information for interventions in prevention and public health.

In 2003, the Portuguese Institute on Drugs and Drug Addiction (IPDT) was merged with the Service for Drug and Addiction Prevention and Treatment (SPTT), resulting in the Institute on Drugs and Drug Addiction (IDT). In Portugal,

as the Portuguese focal point is located within the Institute on Drugs and Drug Addiction (IDT, I.P.), being the focal point tasks carried out by International Relations Unit of the Institute, the transmission of relevant information of the EWS is done by the IDT, I.P. to the EMCDDA and by the National Unit of Europol to the UDE. This double procedure allows the collection of information from different sources and partners working in the drugs field and its regular transmission to the European agencies. Since the implementation of this mechanism, the IPDT responded, in cooperation with its national partners, to EMCDDA official requests and to punctual requests, namely from other Member States.

In December 2000, three years after the entry into force of the Joint Action, a national meeting of the early warning system was organised with the participation of all relevant partners, to promote a reflection on the work done and make suggestions for the future.

The main conclusion on the work undertaken indicated a positive evaluation of the articulation and exchange of information between national partners, improving each one's work quality, in the context of the EWS, as in other projects and collaborations involving different bodies and the NGOs. With the purpose of guaranteeing a higher normalisation of this mechanism at European level, the National Network of Alert Mechanism proposed the EMCDDA to prepare and disseminate implementation guidelines, as the solutions founded by the Member States to reply to this Joint Action differ, in this moment, in the ambit and results. Also, a clear definition of new synthetic drugs was needed, as well as the definition of common procedures to use in the context of this mechanism.

In 2005, after the entry into force of Council Decision 2005/387/JHA, another meeting of the National early warning system (N-EWS) was held, under the patronage of IDT, I.P., which gathered all the national partners of this network and also representatives from the European Commission and the EMCDDA. This was an opportunity to strengthen the debate on new synthetic drugs and the achievements of the network under the Joint Action. The new mandate on new psychoactive drugs, the procedure and deadlines established by the Council Decision were also discussed, especially the ways to adapt to the N-EWS to the European objectives.

Organisational issues

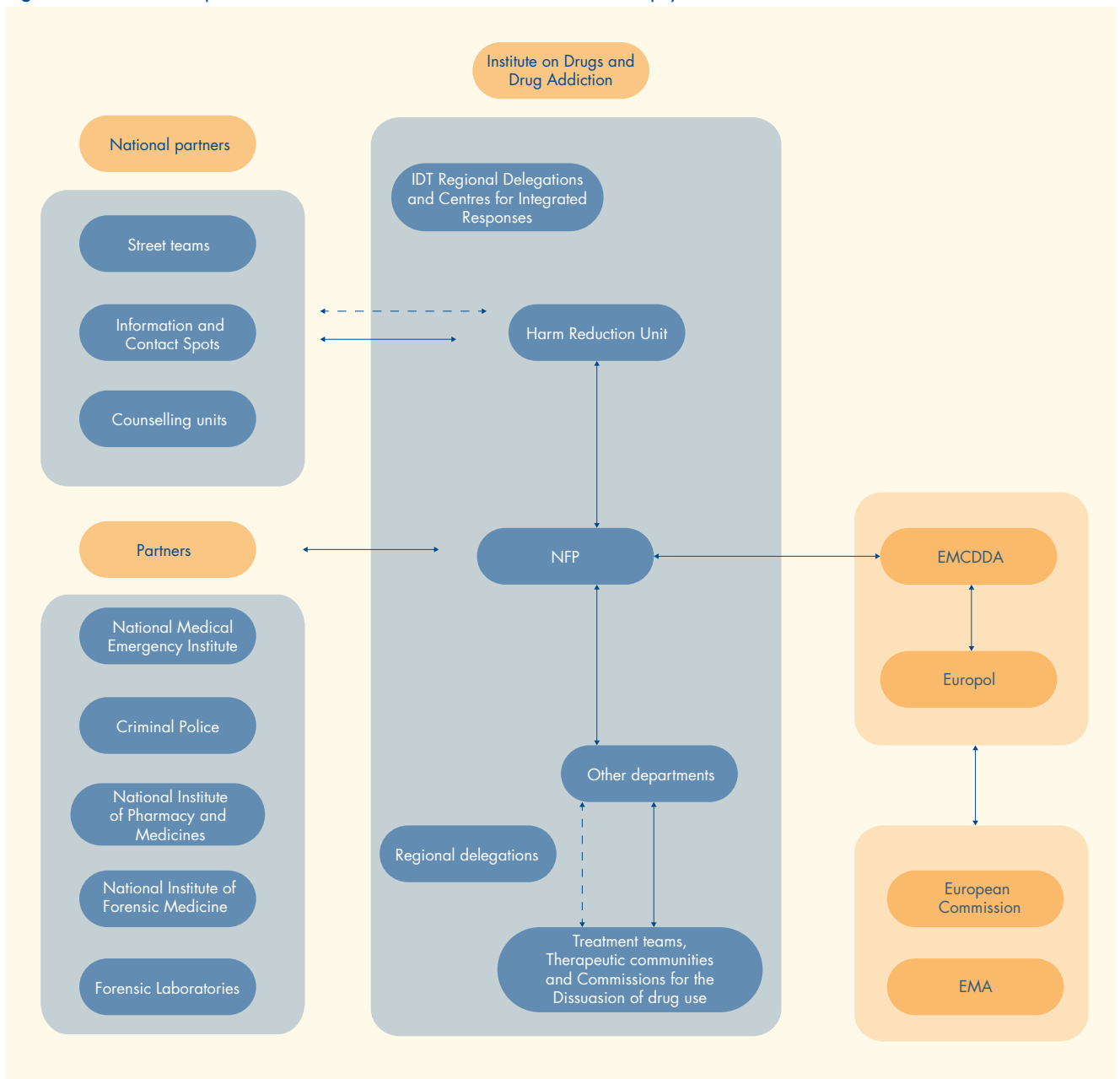
- The N-EWS is an informal network that gathers representatives of IDT, I.P. national structure (prevention, treatment units and help line representatives), law enforcement agencies, forensic laboratories, national emergency help line, among others, coordinated by IDT, I.P. staff members. Along with these professionals, researchers that work closely with drug addicts, in the field can be pointed out;
- its main objective is to disseminate at national level all relevant information regarding the new psychoactive substances and patterns of use;

- the coverage of the N-EWS is national and guaranteed by the sharing of information by the several IDT, I.P. regional delegations;
- the staff involved in this structure belongs to the national focal point;
- this network communicates basically by e-mail and telephone; using both Portuguese and English.

Core functions and information flow

Information exchange is mainly based on the alerts sent by the EMCDDA that IDT, I.P. disseminates within the N-EWS,

Figure 19 — National partners and information flow of the EWS for new psychoactive substances



within a maximum delay of 48 hours, as shown above. The national mechanism envisages the coordination and exchange of information between both demand and supply sides of drug phenomena. One of the core functions of the N-EWS is to ensure the recollection and analysis of fast, reliable and relevant information concerning the new psychoactive drugs and the new patterns of use. This includes sharing this kind of reliable information with professionals, experts, policymakers, media and general population.

The information gathered through this mechanism is mainly focused to field interventions and public health protection.

Case study

As mentioned above, each time a new psychoactive substance is submitted to control measures, it is added to the annexed tables of the Decree Law 15/93. The lists annexed to this Decree Law have been amended several times as follows:

- 4-MTA through decree-law 214/2000, 2 September 2000, included under list II-A, annexed to decree-law 15/93, 22 January 1993;
- PMMA through Law 47/2003, 22 August 2003, list II-A annexed to decree-law 15/93, 22 January 1993;
- GHB through Law 17/2004, 11 May 2004, list II-A, annexed to decree-law 15/93, 22 January 1993;
- 2C-I, 2C-T-2, 2C-T-7, and TMA-2 14/2005, 26 January 2005;
- Oripavina and BZP through Law 18/2009, 11 May 2009.

Strengths, limitations and way forward

The N-EWS is an informal network within an institutional framework granted by the IDT, I.P. One of the strengths of the N-EWS is that since it is a rather small network it is very easy and fast to disseminate the information periodically sent by the EMCDDA. At a distance of an e-mail or a phone call, the alert is sent to all national partners.

One of the limitations of the system is that not all the seizures of all substances can be tested at the scientific laboratories with the desirable rapidity needed for the complete functioning of the N-EWS.

The way forward is to strengthen the national capacity of gathering data regarding the new patterns of using new substances and disseminating validated and evidence-based knowledge through, e.g., street teams.

In 2010, following the need to create rapid responses to a new reality in the streets, an information network was created involving IDT, institutional partners and the NGO in the field. This informal and very flexible mechanism has the purpose of monitoring the evolution of the drugs phenomena, collecting information on three main priorities: use of new psychoactive substances, new patterns of consumption and over use. A field assessment, namely including the notification of new substances and/or new patterns of use is gathered by the street teams' NGO and sent to IDT, I.P. — Harm Reduction Unit. This unit sends the collected information to the national focal point of the EWS which disseminates the relevant information among the network partners.

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Romania — early warning system

Andrei Botescu

Introduction

National drug policy

Shortly after 1991, most illicit known drugs have emerged on the Romanian black market and the number of drug trafficking offences increased considerably, as did the number of drug users and mainly injecting drug users (IDUs). In line with the European drug strategy, the national policy has tried to strike a balance between drug demand and drug supply reduction. Because of the missing links in the assistance chain and the alarming level of problem drug use that called for substitution treatment, higher emphasis was placed on demand reduction, which included preventive interventions and integrated care for addicted drug users.

The national drug policy was managed from 2001 by an Inter-ministerial Commission composed of eight ministries instrumental in the field of drugs. A preventive touch was added, once the Inter-ministry Commission for Drug Use Prevention joined the health, public administration, youth and education approaches in one body. These early models of coordination ended with the setup of the National Anti-drug Agency (NAA) in 2002, in which the Spanish model of coordination in the field of drugs was transferred in Romania. With the creation of the NAA, it has become possible to tackle drugs in a systemic, integrated, coherent and continuous manner, from the perspective of inter- and multidisciplinary teamwork.

Organisational issues

The organisation and functioning of the national early warning system (EWS)

The establishment of the Agency also meant the institutionalisation of the national focal point (NFP) in charge of monitoring the drug phenomenon. Thus, drug demand reduction, drug supply reduction, drug monitoring and training became the pillars of the national policy on drugs in Romania, implemented in a centralised manner. The 'philosophy, main actors, general actions and initiatives of the Government in the field of drugs' have been translated into practical terms into instruments following the main

European guidelines and recommendations. The Romanian national focal point is a member of the European Reitox network coordinated by the EMCDDA. The Romanian EWS is coordinated by the NFP at national level.

Objectives of the early warning system:

- to provide primary data on new psychoactive substances
- to provide public-health related information.

The Romanian EWS acts both at European and national level.

One of the Romanian EWS' main activities is the participation to the European early warning system coordinated by the EMCDDA, where it collects and disseminates the information available regarding new psychoactive substances and supports the assessment procedures available at EU level.

At national level, the Romanian EWS is entitled to support the response interventions elaborated by the drug demand reduction structure of the Romanian National Anti-drug Agency. Also, it supports the legislative and informative initiatives elaborated by the staff of NAA and submitted to the different parliamentary and governmental structures, working groups, etc. involved in drug demand and supply reduction legislation and regulation endeavours.

The organisation and functioning of the EWS at national level is a national responsibility. The national EWS is coordinated by NFP. The national network is comprised of one national coordinator, members of the NFP (all 11 members) and National Anti-drug Agency (drug demand and supply reduction departments), Romanian Europol National Unit, Forensic Science and Toxicology Laboratories from the Police, main hospitals and emergency units, University of Pharmacy, Institute for Legal Medicine and National Medicine Agency, NGOs involved in drug-related harm reduction programmes, public and private treatment centres. The coverage of the EWS is ensured at national level. The exchange of information is ensured by e-mail networking and information exchange, written institutional reports, and two annual workshops on new emerging psychoactive substances.

Outcomes example

In the 2011 workshop of the National early warning network of experts, a bureaucratic barrier in identifying drug-related deaths and emergencies was identified and surmounted. Accordingly, the paraphernalia often is taken by the police and there is lack of communication between the Forensic Medicine Institute (IML) and police.

The Romanian EWS has owned its scientific and political independence. The assessment performed with the help of the members of the network are carried out with participation of a wide range of experts: sociologists, toxicologists, chemists, psychologists, social workers and criminal police specialists. The reports are written at a high level of expertise and objectivity.

Core functions and information flow

The main sources of information are:

Healthcare system — specialised and non-specialised treatment centres, hospitals’ emergency rooms, poisoning centres, psychiatric departments, outreach and street work

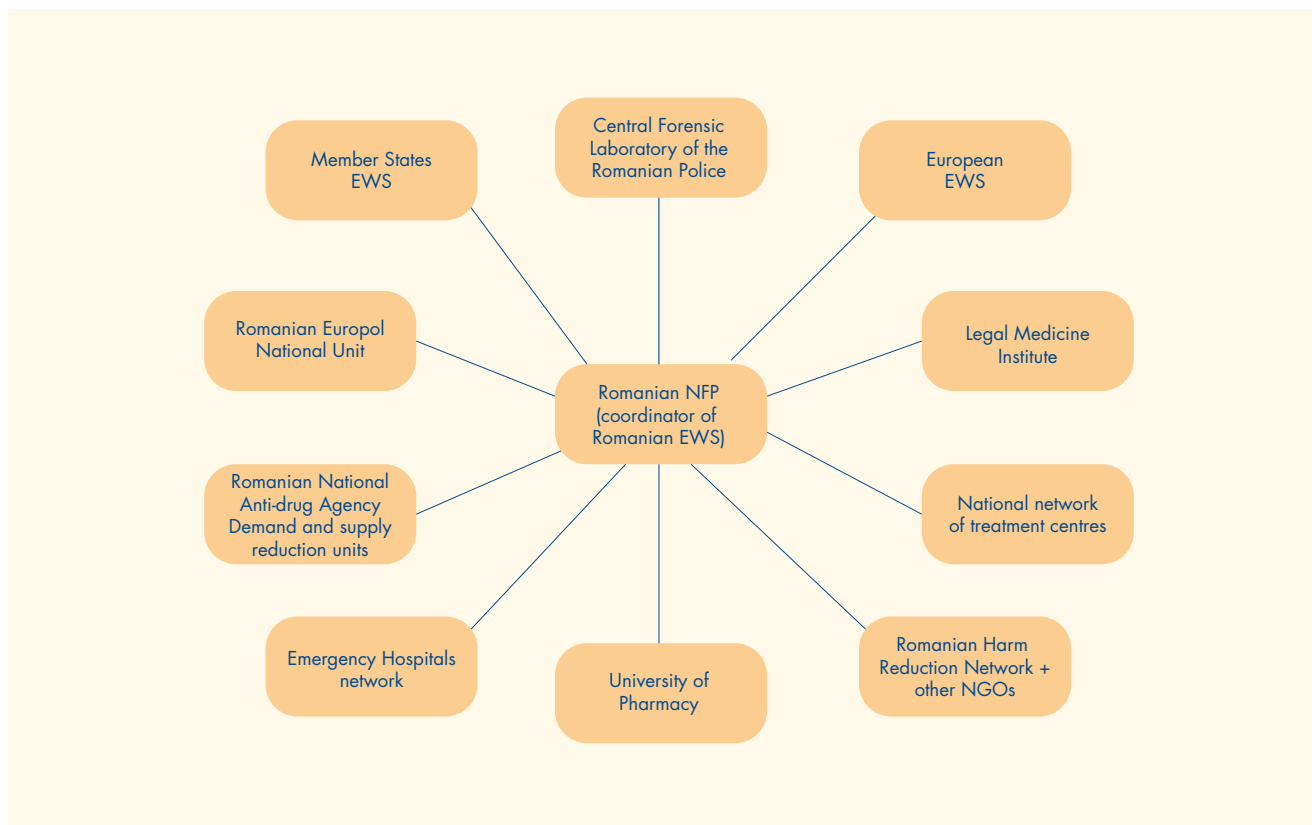
agencies, drug prevention and harm reduction establishments, low threshold services, drug helplines, general practitioners, etc., as well as the laboratory networks of the various healthcare establishments (toxicological analyses of specimens from deceased or living individuals, etc.);

Law enforcement agencies — police, specialised drug units, customs, border guards, prosecutors’ offices, etc. and their laboratory networks (forensic analysis of seized drugs);

Legal Medicine Institute:

- national medicines agencies and the national pharmacovigilance systems;
- universities and research establishments;
- scientific publications and grey literature in national languages;
- key informants — users (including discussion groups and forums), organisers of youth events (festivals, concerts, raves, etc.), owners and staff of clubs, etc.;
- media sources — printed and electronic media, the Internet, etc.

Figure 20 — Information flow in the framework of the Romanian EWS



Methodological diversity and triangulation of different approaches — the tools used in data collection of new emerging trends in substance use are diversified and most of them are having a low degree of standardisation.

Qualitative tools — Internet websites forums, social networks and media monitoring, interviews with key informants, drug users, etc.

Quantitative instruments:

- online surveys;
- Behavioural Surveillance Survey among Injecting Drug Users using Respondent driven sample (RDS);
- risk assessments (for assessing the scale of the emerging trend, market, the medical, social, and crime involved associated risks for new substances);
- emergency cases monitoring.

Case study

Pilot survey on drug-related medical emergencies

The Romanian national focal point conducted a pilot survey on drug related medical emergencies which is largely described in the National report on drugs 2010.

This study presents an efficient way of assessing new trends in psychoactive substances use together with the data from drug-related deaths. Data was required from 56 emergency hospitals from the administrative territorial units of Romania, of which 41 are located in counties and 15 in the Municipality of Bucharest. Of these, 45 medical units have responded to the request: 34 at county level and 11 in the Municipality of Bucharest. Toxicological analyses were conducted to determine the presence of a licit or illicit substance in body fluids and a direct cause was established between the cause of the emergency and drug use for 275 patients.

Online survey on drug use in recreational settings in 2008

Research project focusing on the lifestyle, attitudes, knowledge and practices referring to the use of licit and illicit substance use among young people in recreational setting activities in Bucharest. The study was carried out from 20 September to 5 December 2008 in partnership with a group of websites and online social networks usually involved in promoting recreational events.

Methodology of the online survey

- The target population was made up of Bucharest-based young people aged 15 to 34 who attend recreational settings;
- online questionnaire applied in websites and online social networks that promote recreational events e.g. afterhours.ro, nights.ro, clubbingradio.ro, metropotam.ro, beatfactor.ro, pubbing.ro, anyplace.ro, hi5.com on a self-nominated sample of 1 511 subjects;
- online portals in the study were chosen by representativeness criteria according to promoted music style, popularity/notoriousness among night life goers in Bucharest;
- recreational drug use in the online sample (1 511 respondents).

Results: Bucharest recreational setting is a complex picture, well segmented by criteria such as age, price, and musical/cultural options. Recreational drug use has become a reality at all levels categories participating in pastime activities, marked by psychotropic content substance use in a large variety: marijuana, ecstasy, amphetamines, cocaine, LSD, magic mushrooms, ketamine, bromomescaline, etc.

The subjects reported the use of several substances not usually in the previous surveys. The prevalence rate of these substances use is as follows:

- 1 % of the respondents reported lifetime ketamine use;
- 0.4 % bromomescaline (2cb)-phenethylamine;
- 0.3 % salvia divinorum — plant inductive of hallucinogenic effects, usually sold in ethno-botanical plant shops.

Other substances mentioned less frequently: DMT (dimethyltryptamine), DXM (dextrometorfanul, substance found in the pharmaceutical product Tusin), ice — crystal meth, datura — garden plant containing very toxic alkaloids for humans, ethnobotanical plants, medicines such as Regenor, Romparkin.

Specificities of synthetic drug use

Respondents of the survey were asked to provide details on the commercial names used for ecstasy pills/synthetic drugs on the market. Following database analysis, it was noticed these names are sub-types of pills with different concentration and prescription belonging to the designer drugs category — synthetic drugs (ecstasy/MDMA/amphetamine or

bromomescaline, etc.) As noticed also within the qualitative component of the research, names come from logos printed on the pills and usually rely on the notoriousness of brands known to young people (for cars, clothing etc). The most frequently mentioned names were: 'Armani', 'Rolex', 'Puma', 'Mitsubishi', 'Heart', 'Butterfly', 'Dollar', and 'Smiley'.

Risk assessment on new psychoactive substances sold as 'legal highs'

The Romanian national focal point, together with UNICEF Romania and Romanian Harm Reduction Network, started at the beginning of 2011 a qualitative research and evaluation project: 'Risk assessment on the use and abuse of psychoactive substances sold as legal highs', in order to assess the risk posed by this new drug use phenomenon and to make recommendations for building up of a harm reduction network of services addressing this specific category of addiction. The conceptual framework of data collection and analysis followed the published EWS Operating guidelines on Risk assessment of new psychoactive substances and the following key variables:

- dose and frequency of use
- short-term and especially long-term effects
- interactions with other substances (including alcohol and medicines)
- individual characteristics (e.g. genetic susceptibility, presence of interacting risk factors)
- characteristics of the social and cultural environment
- involvement of organised crime.

The methods of data collection involved online monitoring, focus groups and interviews conducted on key informants and questionnaires conducted on heavy 'legal highs' users and persons involved in 'legal highs' retail commerce activities.

Physical, chemical and pharmacological content

This component included searches of substance mixtures that have proved to be most searched for and used among children and young people included in searches, and testimonials detected on-line, on different forums that tackle these specific topics.

Mixtures of plants and chemical substances intended for smoking

The 'spice'-type substances are the most common categories of psychoactive substances sold as 'legal highs'. A large number of products designed for inhaling/smoking branded as 'spice' was detected such as 'Spice Silver', 'Spice Gold', 'Spice Diamond', 'Spice Arctic Synergy', 'Spice Tropical

Synergy', 'Spice Egypt', 'Spice Maraciuca', 'Ganja', 'M6', 'Diesel', 'Katana'.

Spice mixtures started to be searched for in the last 4–5 months of 2008, with a rapid increase in 2009, followed by a decrease once the Emergency ordinance appeared and placed 36 plants and psychoactive substances under national control. Soon after the effect of the ordinance, a new type of 'Spice' emerged fast on the market, namely 'Spice Maraciuca' that might not have contained a synthetic cannabinoid incriminated by Romania law. Additionally, the term 'spice' has been used for psychoactive plants before the term 'ethno-botanicals' became largely accepted. Another category is made up of plants such as Kratom and *Salvia Divinorum*, defining a category of plant mixtures destined for smoking. These substances were banned and the current information does not reveal any demands. *Salvia Divinorum* is probably the first psychoactive substance included among 'ethno-botanicals'. Online interrogations in Romania show the interest for this plant at the end of 2006 and beginning of 2007.

Mixtures of energising chemical powders (amphetamine type stimulants)

Mixtures of chemical powders that are synthetic psychoactive substances, have energising or hallucination effects, and are traded under different names and mixed with known energisers: caffeine, creatine, etc. Most psychoactive compounds detected in these mixtures fall within the category of cathinones and piperazines. The data of the Central Analysis Laboratory within IGRP referring to the time period from January 2009 to February 2010 showed they generally contained cathinones. The most popular products were sold under the brands 'Special Gold' and 'Magic'. A similar content has products such as 'Flower Magic Powder', 'Flower Magic Powder+', 'Charge+', 'Flower Power', 'Crush', 'Crystal bath', 'Dark+', 'Special Diamond', 'Special Original'. Other products with a similar content are mephedrone and some of its derivatives partially vanished from the 'legal highs' shops once the first ordinance took effect and placed legal highs under national control.

A product sold as 'White Sensation' and promoted as a substitute for 'Special Gold' became the most popular drug in the second half of 2010, after the ban on MDPV and 5-MeO-DALT, according to the forum 'droguri101.ro'. There is no accurate information on the active substance but according to the online forum, this product contains the cathinone 4-MEC.

Another mixture of energising substances called 'Pure by Magic' was probably more popular among drug users after the effect of the two legal documents. No accurate information is available for the active substance, but empirical evaluations make it similar to a relatively new product NRG1, that might, according to the mentioned source, consist of naphyrone. The product gained in popularity in the second half of 2010, peaked at the end of the year, after which it declined, showing a trend similar to 'ethno-botanical plants'.

The psychoactive substances described in the study are just a part of those present on the market. These products are changing from one day to another as does the concentration and ingredients that compose the sold brand. In addition, the trade name changes rapidly, which make the association between a substance and a certain brand difficult. Some of the most relevant findings of the Risk assessment of the use of new psychoactive substances among children and young people in Romania illustrated the following.

Strengths, limitations and way forward

The Romanian early warning system continues to develop by enlarging its network and strengthening its research capabilities. The main advantages of the Romanian EWS are related to the fact that the EWS involves a multidisciplinary network of professionals, involved in drug demand and supply reduction but also in treatment, harm reduction, etc. Because sometimes the data regarding new substances is received in isolated spots and many times ignored, the emergence of the network provided a very efficient tool of data integration and dissemination of the most efficient means of coping with emerging trends on new substances use, a way of providing evidence-based information to legal stakeholders and intervention-focused professionals.

Also, the network is constructed to work in a fast pace of information exchange, mainly by e-mail, telephone and expert meetings information exchange and debate and less based on bureaucratic institutional dialogue (such as written official requests, etc.).

The disadvantages are mainly related to the economic dimension. There is a lack of existing infrastructure for testing the biological samples in the toxicological units of emergency hospitals; a general problem with the new substances library

updates for all the units involved in testing activity (including the Police laboratory and the Forensic institute laboratory). For example, according to the Institute of Legal Medicine representative 'we do not have a toxicological confirmation of drug-related deaths for mephedrone (the 5th cases mentioned in media), but there are problems with acquiring standard samples used for analysis of such substances.' Also, there is a strong need for professional training in order to be able to obtain accurate empirical information about drug-related emergencies at national level. There is also a strong need for professional training in order to be able to obtain accurate empirical information about drug-related emergencies at national level.

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Slovakia – early warning system

Eleonora Kara ⁽⁸⁾

Introduction

The early warning system on new psychoactive substances was implemented in Slovakia in 2005 on the basis of EU Council Decision 2005/387/JHA on information exchange, risks assessment and control of new psychoactive substances in order to create an effective tool which could flexibly react and resolve issues of new psychoactive substances and provide early exchange of information regarding their appearance in all EU Member States.

In the Slovak Republic (SR), the EWS functions at national level. Its activities are organised by the Government Office of the Slovak Republic who is manager for addressing drug issues. Administratively and technically, EWS activities are provided by the General Secretariat of BMDADC (since November, the Department for Drug Strategy Coordination), via the NMCD department.

At national level, the EWS was established under the NMCD (NFP) by the establishment of the EWS working group which imply experts acting in various fields of drug phenomena (law enforcement, healthcare authorities, toxicology, forensic laboratory as well as the NGO and ENU. At present, the EWS group has 15 members who act in institutions and leading departments of the Ministry of Health, Interior, Justice, Economy, in low-threshold agencies (NGOs), NTIC and also specialists in the area of toxicology, forensic medicine and the provision of healthcare.

Organisational issues

Functioning of N-EWS

The EWS group regularly meets once in a year (in November or December). In practice, they mainly address and discuss measures leading to reducing the demand for new psychoactive substances and, if necessary, recommendations for their control under the relevant drug laws. An initiative for legal restriction of new drugs most often arises from the police via their special units which act in the area of reducing

the availability of drugs (National Drug Service), or from the Europol national centre. Before the EWS group recommends listing a new psychoactive substance in the list of controlled substances, they collect and verify all available data regarding the new substance (physical-chemical description of the substance, seizures, identification of a new substance and its admixtures, cases of intoxication and mortality in SR, its use in human and veterinary medicine, its distribution and methods of use and the involvement of organised crime). Key information sources are EMCDDA–Europol Joint Report as well as EMCDDA reports on Risk assessment. A very useful and prompt source of information is also the European Database of New Drugs (EDND) which provides updated information on new psychoactive substances.

Core functions and information flow

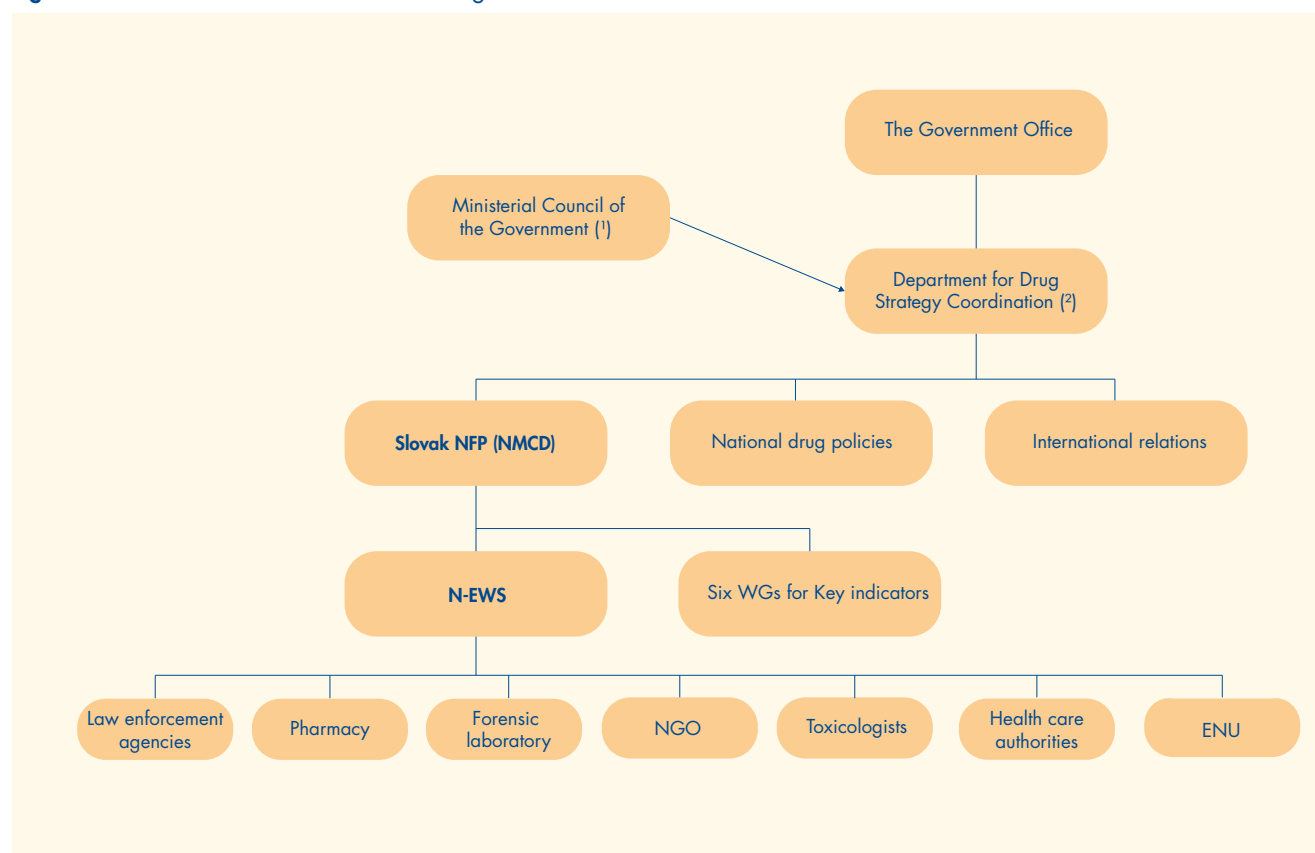
Information exchange

At national level, information related to new psychoactive substances is most frequently exchanged via NFP Internet portal www.infodrogy.sk which allows the exchange of sensitive EWS data (e.g. regarding analytical data and mass spectra of NPAS) via a closed section of specialists, accessible only by N-EWS members. The public has access to information of a warning and official nature (e.g. adopted NPAS control measures and warning reports of their harmfulness) via publicly accessible and open sections. Mass communication means (printed media and mass media) are used for the distribution of publicly accessible information.

Key EWS partners

A key EWS partner in the area of detection and discovery of new trends in the use of psychoactive substances at national level is the NDS BFOC PFH. Qualitative analysis and identification of seized new psychoactive substances is carried out by the IFS PF who is the second key partner in the EWS national network.

⁽⁸⁾ With collaboration of Andrej Bolf, specialist of the drug expertise, and Ivana Bučková, officer of the National drug service.

Figure 21 — Scheme of the basic N-EWS organisational structure

Notes: (!) Before 2 March 2011, the Board of Ministers for Drug Addictions and Drug Control (BMDADC).
 (?) Before 1 January 2011 the General Secretariat of BMDADC.

Source: DDSC, 2011.

Cooperation between National Drugs Service and N-EWS
 Within the Ministry of Interior and the Presidium of Police Force, the fight against drugs is addressed by the Bureau of the Fight Against Organised Crime (hereinafter 'BFOC'), mainly via the section of the National Drugs Service and the West, Middle and East anti-drug departments. The National Drugs Service within the BFOC structure is a department addressing the fight against organised crime activities at national level whilst its activities are also orientated towards international cooperation in the combat against drugs. Within the BFOC structure, the West, Middle and East anti-drug departments focus upon the detection of drug crime in the appropriate regions of eastern (Košice and Prešov regions), central (Žilina and Banská Bystrica regions) or western (Bratislava, Trnava, Trenčín and Nitra regions) Slovakia.

The National Drugs Service has cooperated within the EWS national network since 2005, mainly in the form of mutual exchange of information regarding the occurrence of new

psychoactive substances in the Slovak Republic and EU Member States. Since 2007, the National Drugs Service has cooperated within the national EWS, not only in the provision of information about new trends in drug use, but also in initiating the inclusion of new psychoactive substances (which are increasingly being used in Slovakia) in the list of controlled substances.

The National Drugs Service will provide the N-EWS coordinator with the following data structure:

- number of cases in which the substance was seized (data and time of seizure);
- persons who possessed, smuggled or traded the substance;
- the seized amount, form and name under which the substance is sold;
- the origin, method of production, distribution and sale of this substance;
- method of further processing, packaging of the substance in the area, its price if known (mainly in the

case of Internet sales);

- participation of criminal groups, characteristics of dealers, sellers or cooperation with international criminal groups.

Cooperation between IFS PF and N-EWS

The Institute of the Forensic Science of Police Force was established in 1991 within the Ministry of Interior as an organisation for providing criminal-technical and expertise activities for the needs of the Slovak Republic Police Force, bodies acting in criminal proceedings and the courts, as well as for providing scientific-technical development in this area. They most frequently carry out investigation in cases where prosecution (most frequently for drug possession or trafficking) is commenced and samples are seized by bodies acting in criminal proceedings (the police) or for the needs of criminal police or customs administration (where a sample is seized by a unit of the Bureau of the Fight against Organised Crime and the Customs Criminal Office).

From a structural viewpoint, the IFS PF is under the authority of the Police Force Headquarters as an independent part and performs its activities via three departments:

- (1) off shores in Bratislava — analyses samples seized in the area of Western Slovakia (Bratislava, Trnava, Trenčín and Nitra regions);
- (2) off shores in Slovenská Ľupča — analyses samples seized in the area of Central Slovakia (BanskáBystrica and Žilina regions);
- (3) off shores in Košice — analyses samples seized in the area of Eastern Slovakia (Košice and Prešov regions).

The department in Bratislava maintains a central database of all seizures including new psychoactive substances which are not in the list of controlled narcotic and psychotropic substances in Slovakia (Act 139/1998 Coll. on narcotic substances, psychotropic substances and preparations). Data is compiled at annual intervals and processed for the purposes of statistics of the Ministry of Interior and further distributed at national level (for the needs of the NFP — Annual report on drugs, ad hoc reports and studies) at an international level for the UN and EU.

Most frequently, powdered or crystalline materials are submitted for expert analysis if there is a suspicion of a presence of narcotic or psychotropic substances. Within forensic analysis, the IFS PF states the precise content of seized substances (active compounds + admixtures). Gas chromatography with mass spectrometry (GC-MS) detection and infrared spectroscopy (FTIR) are the standard methods

used for identification of these substances. If new narcotic or psychotropic substances are discovered using these methods, definite identification depends upon the availability of referential spectra of these substances, which in most cases is a problem since many times these are substances which have not yet been 'scientifically assessed'. Referential spectra are from specialist literature or via international cooperation within the European Network of Forensic Science Institutes (ENFSI), or from accessible EWS information (analytical data) from the EMCDDA or from information obtained via Europol.

In cases of new psychoactive substances, the IFS PF does not perform determination of the concentration of the active compound as standard, since they do not primarily have official standards of such compounds at their disposal and do not have the capacity for the preparation of such standards (IFS PF) are able to determine the concentration of new psychoactive substances (e.g. in case of mCPP).

In case of testing biological material (urine, blood) for the presence of narcotic or psychotropic substances and their metabolites, determination of the presence of new narcotic and psychotropic substances in samples is not routinely carried out (drugs are identified in cooperation with Toxicological Laboratory).

The main N-EWS outputs include:

- '*Reporting form on NPAS*' — via the mentioned standard form, a summary of information regarding any NPAS seized and identified in the Slovak Republic is provided. Reports are sent by the IFS PF. Most frequently, the period for sending an official report is around 30 days. If a new psychoactive substance is definitely identified, a report is sent to the EWS within one week.
- '*Questionnaire on NPAS*' — more detailed information about an NPAS (their users, effects, production, distribution, etc.) which is provided to the EMCDDA upon request (e.g. in case of a discovery of 'Spice phenomenon' and mephedrone).
- '*Final report*' (covering 12 months), '*Progress report*' (covering the first six months of the year).
- '*NPAS Central database*' — at national level, includes basic data about seizures of new narcotic and psychotropic substances since 2005. Seizures are recorded in individual years and in practice, they include all NPAS reports via 'Reporting forms'.
- '*Presentations and minutes from EWS meetings*' — the N-EWS coordinator prepares a report from each EWS

meeting which contains the main conclusions, tasks and measures taken at the meeting and via the section of specialists, gives access to all presentations and materials from the meeting (by 10 working days from the date of the meeting).

- *Official suggestions for including NPAS in the list of controlled substances:* to date, three suggestions were prepared for inclusion of new substances: mCPP, ketamine, synthetic cannabinoids identified in 'Spice' products (JWH-018, JWH-073, CP47,497, HU-210) into the act on narcotic substances, psychotropic substances and preparations.
- Official statements to control measures issued by the EU Council in relation to NPAS (e.g. BZP, mephedrone).

Case study

Trends in terms of NPAS

Via the N-EWS, for the period (2005–10), a total of 23 new psychoactive substances were seized and identified in Slovakia: mCPP, BZP, TFMPP, phenylpiperazine, diphenylpiperazine, dibenzylpiperazine, pFPP, 2-CB, 4-fluoroamphetamine, ketamine, JWH-018, CP 47-497, JWH-250, JWH-073, JWH-122, mephedrone, butylone (bk-MBDB), methylone, diphenylprolinol, N-ethylcathinone, dimethylcathinone, MDPV, and Salvia Divinorum. For the mentioned six-year period, the police, in cooperation with customs officers, reported 98 seizures of new psychoactive substances in the EWS, from which more than half were represented by seizures of piperazines (mainly mCPP). The most frequently seized new psychoactive substance in the Slovak Republic (2005–10) is mCPP with 44 seizures, followed by mephedrone (11), JWH-250 (8) and ketamine (8). The order remained unchanged in the proportion of most frequently seized groups of new psychoactive substances: piperazines (53 %), cathinones (23 %), synthetic cannabinoids (12 %) and other substances (12 %).

Strengths, limitations and way forward

The expansion of the network of certificated toxicological laboratories which provide information about the objective effects and health risks would be a great contribution to the functioning of the N-EWS in the area of exchange of information of serious intoxications, due to experimentation with NPAS.

The low number of IFS workplaces and their employees who carry out analysis of all seized psychoactive substances in the Slovak Republic causes delays and significantly increase the time of expert examination and provision of timely reports about an NPAS notification via a Reporting form.

The method for adopting control measures and including NPAS in drug law is also complicated and complex. Amendments to law must undertake inter-departmental discussion proceedings by the MH SR, the government, departments of the Parliament of the Slovak Republic and Parliament itself (which usually takes several months to a year). Since in the Slovak Republic the Act regarding narcotic substances, psychotropic substances and preparations is under the auspices of the Ministry of Health of the Slovak Republic, the main criteria for including such substances in the list are mainly their affect upon health and potential to induce drug addiction. However, in practice, substances are more often included in this list due to their social risks (their frequent seizure, use, production and trade). In the majority of cases, these are seizures of new substances, the effects of which there is very little valid information. Since application of legal consequences and measures is only possible if the substance has the status of a controlled substance, in accordance with the Drug Act No 139/1998 coll., the initiative for inclusion of an NPAS in the mentioned Act in the majority of cases came from law-enforcement authorities. At present, within the N-EWS, new options of how to effectively prosecute persons who use NPAS (mainly producers and traffickers) using other measures than an amendment to the law on narcotic substances, psychotropic substances and preparations are sought.

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Slovenia – early warning system

Milan Krek, Andreja Drev, Mina Paš and Jože Hren (*)

Introduction

The problem of illicit drugs in Slovenia became a topic of discussion especially during the 1990s, when the epidemic of using illicit drugs started to rise. Initially, the epidemic of using heroin was in the foreground but later on, other synthetic drugs also gained importance. With the development of electronic music and the accompanying youth culture, the use of synthetic drugs also came to be in full swing in Slovenia.

Slovenia has taken a number of measures to effectively carry out a holistic and multi-disciplinary approach towards getting illicit drugs under control. In 2002, the system for early detection of new psychoactive substances (NPAS) began to establish itself with the help of the European Union, along with the information system on NPAS. Carefully following the legal orders and the European Union guidelines, an integrated system has been established in Slovenia, connecting the key institutions and non-governmental organisations, which can have an important influence on the early detection and monitoring of NPAS, as well as on informing the experts and the general public about the appearance of NPAS and which can also offer suggestions for NPAS to be included on the list of illicit drugs. All this contributes to lesser risk for the health of drug users and it also gives the legislative and repressive bodies a chance to take appropriate measures in this domain.

The beginnings of the preparation of the project of the early warning system (EWS) in Slovenia go back to the year 2002 when a professional educational workshop was organised in Slovenia under the guard of the EMCDDA, in which representatives of the candidate countries for the EU have gathered, i.e. those who were supposed to cooperate in the EWS in the future. In the same year, the national unit of the European Police Directorate (the Europol section at the General Police Directorate) began to operate, which represented the basis for the functioning and upgrading of the EWS in Slovenia, along with the other units of the police. In 2003, the national correspondent of the EWS was appointed and he started to take part in the meetings of the

European specialist in this field and he also made a draft of the Slovene model of the EWS.

At first, only two partners took part in the model of the EWS, which were the National Institute of Public Health (NIPH) and the Europol Section at the Criminal Police Directorate. They exchanged information using two information paths. The first was through the European Information Network for Drugs and Drug Addiction (Reitox) and the other one through Europol. The other key partners joined the existing model in 2004 and also the network of those receiving alerts from the EWS has been spreading since then.

By adopting the Council Decision 2005/387/JHA from 10 May 2005, Slovenia also regulated this domain in accordance with this document and appointed an inter-ministerial working group in July 2007, which has been observing the appearance of NPAS on a regular basis and proposed appropriate measures to the Ministry of Health. In September 2009, a new enlarged inter-ministerial working group was appointed by a decision of the Health Minister.

Organisational issues

Legal-legislative context for establishment of the early warning system

The legal basis for the organisation of the EWS in Slovenia is represented by the legislation in the domain of illicit drugs; the Production of and Trade in Illicit Drugs Act, the Penal Code of the Republic of Slovenia, the Act Regulating the Prevention of the Use of Illicit Drugs and the Treatment of Drug Users, the Resolution on the 2004–09 National programme on drugs control and also EU legislation, respectively, the Council Resolution 2005/387/JHA from 10 May 2005.

Regulation and tasks of the early warning system

In Slovenia, the Minister of Health appointed an inter-ministerial expert group of the EWS with a resolution.

(*) Technical review: Aleksander Pučko, Rajko Kozmelj, Tomo Hasovič.

This group includes: the National Institute of Public Health, the Ministry of Health, The Europol Section at the General Police Directorate, the Section for Illicit Drugs at the General Police Directorate, the National Forensic Laboratory at the General Police Directorate, the Institute for Forensic Medicine at the Faculty of Medicine in Ljubljana, the Centre for Poisoning at the University Clinical Centre Ljubljana and the non-governmental organisations DrogArt and Stigma. The inter-ministerial working group has following tasks:

- to prepare expert guidelines and recommendation for the work of the EWS;
- define the conditions and procedures for the analysis of new psychoactive substances;
- make suggestions to the Ministry of Health for including NPAS into the Regulation of the Illicit Drug Classification;
- actively cooperates in the European EWS;
- ensures appropriate exchange of information from the European EWS into the national territory.

The inter-ministerial working group assembles in sessions if necessary; the sessions are organised by the group leader once or twice a year, especially if it is necessary to discuss more serious problems and if any measures need to be taken.

There are also other institutes that cooperate with the EWS on a regional and local level: regional institutes for public health, community health centres, non-governmental organisations from the field of illicit drugs, emergency help services and a network of centres for prevention and treatment of illicit drug addiction.

The Slovenian EWS is designed more widely than the European model, which gives it an added value. It also exchanges information about the appearance of illicit drugs with a high concentration of psychoactive substances, as well as illicit drugs with dangerous adulterants.

The Slovenian EWS also includes experts who have been in contact with the field of drugs in their field of work and are familiar with the problematic of drugs, have valuable experiences and appropriate knowledge and are also professionally and politically independent at their work. The mutual communication is enabled by e-mails and by phone in both Slovenian and English language. The expert public is informed about the appearance of the NPAS in the form of notifications, which they receive by e-mail, while the general public and the media get the information from the notices for the public and the media, which are published on the Internet pages of the National Institute of Public Health and in mass media.

Core functions and information flow

Core functions of partners of the early warning system on the NPAS

- the Ministry of Health in the Republic of Slovenia is competent for legislation in the domain of drugs, which also includes the Regulation on the Illicit Drugs Classification. This document is regularly complemented with new psychoactive substances based on relevant documents and suggestions, which are forwarded by competent institutions. The ministry also appointed an inter-ministerial working group of the EWS.
- the National Institute of Public Health has the role of the coordinator within the EWS. It receives information from the EMCDDA and sends this information into the national system, it also takes care for the flow of different information between the members of the inter-ministerial working group within the system and also takes care of informing the wider group of participants. When a new or dangerous NPAS emerges, the Institute gathers information and takes care of its flow, when the information is received by the system's partners and participants. Then the experts from the Toxicology Section at the Institute prepare an estimation of risk for drug users, the experts from public relations form a notification for the media and the general public. The Institute also needs to forward the relevant information to the European EWS.
- the Europol Section at the General Police Directorate receives information from the European Police Directorate about the appearance of NPAS and forwards them to the national EWS. The information about the appearance of NPAS in Slovenia is forwarded to the European Police Directorate.
- the Illicit Drug Section at the General Police Directorate gathers information about NPAS, which occur in the Slovene territory and also gathers samples of these NPAS. The information is then forwarded to the EWS.
- the National Forensic Laboratory at the General Police Directorate, within which there are five operating laboratories (biology, chemistry, physics, dactiloscopic laboratory and a laboratory for document research) carries out also analyses of the confiscated NPAS, especial in the chemistry laboratory, which uses different analytical instrumental methods. The laboratory is equipped with four gas chromatographs, connected to mass spectrometers (GC/MS), with liquid chromatograph (HPLC), infrared spectrophotometer with a microscope (FTIR) and an ionic chromatograph (IC). The existing instruments are used to analyse and define

the sort of the drugs, the additives, active additions, the drugs are also profiled and the percentage of active components is also defined. The chemistry laboratory is also used to analyse a wide spectrum of substances, from colours, varnishes, explosives, to poisons, illicit and other (e.g. designer) drugs, which occur on the black market and also medicines.

- The Toxicology laboratory of the Institute for Forensic Medicine at the Faculty of Medicine carries out toxicological analyses of mostly biological samples. The basic fields of work of this laboratory are forensic toxicology, clinical toxicology, determining drugged driving, therapeutical monitoring of less frequent and analytically challenging medicines. Within the 24-hour duty service, the toxicologists carry out urgent toxicological examinations as a support to the Centre for poisoning and other health institutes around Slovenia. The laboratory mainly carries out instrumental chromatographic analyses GC-MS. The laboratory forwards the information about the appearance of a NPAS in the samples of body fluids of its users to the EWS.
- The Centre for Poisoning at the University Clinical Centre Ljubljana is treating all kinds of acute poisonings, including illicit drug poisonings and at the same time offers a 24-hour information consultant service from the field of clinical toxicology to all the doctors in Slovenia. The Centre also has a Register of poisoning of the Republic of Slovenia, which includes poisonings with illicit drugs. The centre forwards information about poisonings with NPAS to the EWS.
- The non-governmental organisation DrogArt operates in the field of lessening the damage caused by stimulant drugs and alcohol, among other activities they carry out a field action of informing and giving first aid to the users of stimulant drugs at electronic music events, they also administrate a web forum, where users can exchange experiences about drugs, currently on the market. They forward information about the appearance of NPAS and their spreading to the EWS. They are often the first to detect the appearance of a NPAS and also get a sample of this substance for the analysis.
- The non-governmental organisation Stigma also operates in the field of lessening the damage caused because of the consequences after using illicit drugs. The work is done in two drop-in centres, on field and in prisons. Among other activities they ensure free sterile set and replacement of needles, consultation concerning drug problems, help with social matters, employment and health services, information about the programmes of

treatment. They forward the information about the appearance of NPAS to the EWS and also to the network of low-threshold programmes.

Information flow

The National Institute of Public Health, the Europol Section and the Illicit Drug Section get information about NPAS and then forward this information to the inter-ministerial working group. Within this group the information is exchanged about the appearance of NPAS, about the confiscated samples, analyses results, trafficking, use and risks for the users. Within the group, some confidential information is also exchanged. To be constantly updated, the information is exchanged using e-mail.

After exchanging all available information, the inter-ministerial working group appraises the risks for the users and makes a decision whether it is necessary to inform the wider group of participants and also the general public and the media in the future and which information these notifications should contain. If the group estimates that the risks of the psychoactive substance are very high, a press conference can also be made.

The wider group of participants includes centres for prevention and treatment of illicit drug addiction, non-governmental organisations operating in the domain of drugs, community health centres, emergency help services, institutes for health care and some centres for social work. When this group receives a notification about the appearance of a NPAS, it returns the information about this substance back to the EWS, i.e. the information concerning the appearance of this substance, the forms of the substance, the reported dangerous effects when using it, the price, etc.

The feedback is also being gathered by the National Institute of Public Health, which forwards it to the members of the inter-ministerial working group. Based on all gathered information, which have been forwarded to the System from the members of the inter-ministerial working group as well as from the wider group of participants, joint information is formed for the EMCDDA. Some suggestions for necessary measures for the Ministry of Health are also prepared and the Ministry can then carry out the procedure of adding the NPAS on the list of illicit drugs.

The national EWS gets the information about the NPAS also from the European EWS. The EMCDDA and Europol forward this information to the National Institute of Public Health or to the Europol Section at the General Police Directorate. The

received information is then forwarded to the members of the inter-ministerial working group to study and estimate. The members of the group then forward feedback to the network, each member for their field of expertise. This is followed by a consultation of the members, which is done by e-mails, where they discuss the level of risks of the new substance for the health of its users, about the appearance or the possibility of appearance in Slovenia, about availability of the substance etc. If the members estimate that the substance could have any risks, a notification for the expert public is made, including negative effects when using the substance, instructions for taking measures and other important information. This notification is then sent using e-mails to all the receivers of the notifications of the EWS.

The time frame: When the information about the appearance of a NPAS gets into the EWS NPAS, a notification, along with the estimation about the danger for its users is sent to the wider group of participants, to the general public and media as soon as possible. This mostly means that this happens within a few hours, any other time delays occur when it is necessary to wait for the analyses results.

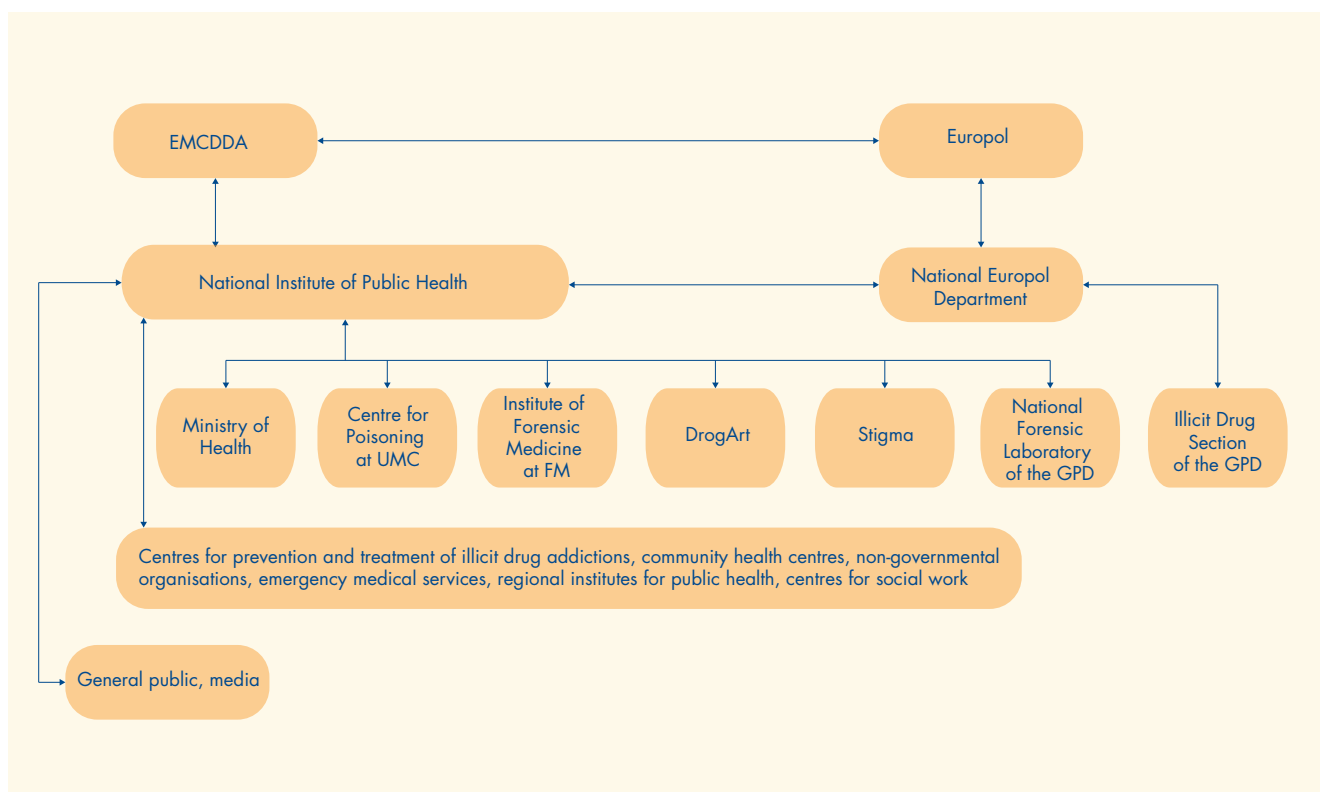
Case study

Mixture of atropine and cocaine in Slovenia

In November 2005, the EMCDDA forwarded a notification about the appearance of a mixture of atropine and cocaine in several European countries to the National Institute of Public Health. The mixture first emerged in France, Belgium, Germany and Italy. The Institute forwarded the information to the members of the inter-ministerial working group of the EWS NPAS, who decided that it is necessary to inform other members of the system due to the immediate proximity of Italy and all other risks for the drug users in Slovenia connected to this fact. DrogArt was also among those who received the notification and therefore notified its users on their web page and on the web forum about the appearance of the new substance.

On 2 February 2006, DrogArt received a call at their duty service about cocaine users, who reported eye sight problems after consuming cocaine. One of the users also wrote the same message on the web forum. Since eyesight

Figure 22 — Information flow in the framework of the Slovenian EWS



problems are a common symptom of atropine poisoning, DrogArt immediately considered the possibility whether it is possible that the substance is actually a mixture of cocaine and atropine, about which they had received a notification from the EWS NPAS a few months earlier. This is why they asked the user to bring a sample of the suspicious cocaine to the Organisation DrogArt. The user brought the sample and the employees at DrogArt immediately gave the sample to the National Forensic Laboratory at the General Police Directorate, in cooperation with the National Institute of Public Health.

On 16 February 2006 the National Forensic Laboratory confirmed that the substance is a mixture of atropine and cocaine. The inter-ministerial working group of the EWS NPAS decided that it is necessary to immediately inform other participants in the system and the general public about this because of the risks this substance presents to the potential users. The National Institute of Public Health prepared a report for the public which was also forwarded to other participants in the system and to the media and the report was also published on the Institute's website. The organisation DrogArt informed its users (mostly visitors of electronic music events) about the new mixture on their website and on the web forum.

Strengths, limitations and way forward

Strengths

The Slovenian EWS has a number of strengths, including covering the territory of the whole country, it is extremely fast and useful and serves to the public good. It is known for its extremely good cooperation between the key carriers of the system, which are the health sector and the police.

There is a formally founded inter-ministerial working group, which has been appointed by the minister, which gives legitimacy to the operation of the system and at the same time enables quicker, faster and more effective operation.

The strength of the system is also the fact that it includes non-governmental organisations operating in the field of illicit drugs, which have good connections with the drug users and are often the first ones to detect the appearance of a NPAS, what contributes greatly to the effectiveness and fast operation of the system.

The system includes all those key institutions and those in connection with illicit drug users on a regional and local

level. This way, it is ensured that the workers in these institutions get the necessary information needed for working with drug users. On the other hand, these institutions also ensure a faster information flow to the end users — the illicit drug users.

Limitations

Although the EWS has been operating for several years, the protocol of operation still hasn't been formally written down, there are also no written guidelines and procedures of informing when a new or/and dangerous NPAS appears, there are also no instructions of which information should or could a notifications for the expert public, for the general public and the media include and there are also no standardised forms. The operation of the system is therefore often based on verbal contracts and previous experiences.

Further development

Since the General Police Directorate (Europol Section, Illicit Drug Section, National Forensic Laboratory) and the National Institute of Public Health are still the bodies who carry the largest part of responsibility for proper operation of the EWS, it will be necessary to ensure bigger incorporation of other partners.

It will be necessary to establish a common database about the NPAS on a national level, to which all the experts included into the system will be able to access.

It will also be necessary to think about enlarging and upgrading the system, in the sense of including new receivers of the notifications as well as cooperating with the other early warning systems. The usefulness of such cooperation of the EWS has already been shown in the past in the field of infectious diseases.

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Sklep sveta 2005/387/PNZ- o izmenjavi podatkov, oceni tveganja in nadzoru nad novimi psihoaktivnimi snovmi. U. l. EU L 127/32. 2005.

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Spain — early warning system

Rosario Sendino Gómez, Elena Álvarez Martín, David Navarro Pérez and Julia Gonzalez Alonso

Introduction

The EU Council Decision 2005/387/JHA required every EU country to rely on a national exchange and collection data system on new substances to report to the EMCDDA and thus comply with the objective of the Decision.

As it was not an EU Directive but an EU Decision, the Spanish Government did not need to set up a new regulation on this subject. Instead, a specific Spanish applicable regulation stemmed from the 1961 UN Single Convention on Narcotic Drugs and 1971 UN Convention on Psychotropic Substances was used as a legal framework for the EWS development: *Ley 17/1.967, de 8 de abril, de normas reguladoras por las que se actualizan las normas vigentes sobre estupefacientes adaptándolas a lo establecido en el Convenio de 1.961 de Naciones Unidas and Real Decreto 2829/1.977, de 6 de octubre, por el que se regulan las sustancias y preparados medicinales psicotrópicos, así como la fiscalización e inspección de su fabricación, prescripción y dispensación.*

National regulation on illicit drugs allowed the Spanish Ministry of Health, Social Services and Equality and several other ministerial departments to apply the necessary measures in compliance with the EU Decision.

Nonetheless, the Spanish Government Delegation for the National Plan on Drugs (national focal point) has been regularly sending official reports on new drugs to the EMCDDA since 2001, although reports were mostly sent on the EMCDDA's request during 1997–2001. Gradually, the Spanish NFP started devising specific protocols involving all the EWS partners to ensure data flow reached the appropriate target.

Organisational issues

Administrative/legal basis/mandate:

As stated above, the Spanish Government Delegation for the National Plan on Drugs (Ministry of Health, Social Services and Equality) is responsible for complying with the EU Decision on the EWS. Spain relies on the necessary generic

legal framework to carry out the EU Decision mandate, even though there is not a specific or detailed legislation on the EWS.

Recently, a new national regulation establishing the protocol by which new narcotic drugs can be subjected to control measures, in accordance with *Ley 17/1.967*, has been approved (*Real Decreto 1194/2011, de 19 de agosto, por el que se establece el procedimiento para que una sustancia sea considerada estupefaciente en el ámbito nacional*).

Objectives

The Spanish EWS definitely serves the Council Decision. Moreover, it has turned out to be very useful to improve the drug reporting system and to speed up information flow with the 19 Spanish Autonomous Communities and Cities and with other agencies and entities (National Institute of Toxicology and Forensic Sciences, Spanish Drug Agency, etc.). Theoretically, EWS protocols could also be used to channel different types of drug-related information (data on epidemiological indicators, mortality, seizures, etc.)

Institutional basis

The Spanish Governmental Delegation for the National Plan on Drugs (DGPNSD) is responsible for the EWS-Unit right functioning. DGPNSD is located within the Spanish Ministry of Health, Social Services and Equality. The EWS unit comprises:

1. Agencies located within the Spanish Ministry of Health, Social Services and Equality:
 - Governmental Delegation for the National Plan on Drugs (DGPNSD) — Spanish Observatory on Drugs, responsible for epidemiological data on drugs: surveys and drug-related problems key indicators (admission to treatment, emergencies and mortality);
 - Spanish Agency on Drugs (Agencia Española de Medicamentos y Productos Sanitarios);
 - Drug Analysing Labs network (which is mostly responsible for seized derived samples) (Public Health Department);
 - Secretariat of National AIDS Strategy;
 - Public Health Alert System (Public Health Department).

2. Agencies located in several other departments:
 - Intelligence Centre against Organised Crime/CICO, (Ministry of Interior); The Spanish Cuerpo Nacional de Policía and Guardia Civil are responsible for drug seizures throughout the whole country, control measures, etc.
 - National Institute of Toxicology and Forensic Sciences (Ministry of Justice) which is mostly responsible for biological samples of drug analysis. Seized derived samples are subject to analysis at the INTCF only if cases are under the Law 38/2002, de 24 de octubre regulating express trials;
 - Customs (Ministry of Treasury and Public Administrations).
3. Autonomous Communities and Cities (19)
 - Autonomic drug-specialised treatment network (outpatient, inpatient and emergency premises which are the data source of the drug-related problems key indicators);
 - Autonomic Police Force in some specific Autonomous Communities (working in collaboration with the Spanish Cuerpo Nacional de Policía and Guardia Civil).

Links to EU institutions

Contact with EU institutions is made through the Spanish NFP (DGPNSD). Although reports are almost exclusively sent to the EMCDDA, there is a Spanish NFP for Europol which is contacted occasionally for specific purposes and the Spanish Drug Agency maintains close contact with the EMA (European Medicines Agency).

Coverage

The Spanish EWS unit has national coverage.

Administrative/legal basis/mandate

It is very difficult to figure out the exact size of the EWS unit in terms of staff. The EWS relies on a basic structure within the DGPNSD and CICO, which is made up of five people from different backgrounds (civil servants, lawyers, medical doctors, members of the Spanish Cuerpo Nacional de Policía/Guardia Civil, etc.) in charge of EWS-related issues, among many other tasks. Besides, there are many other people throughout the country whose work is devoted to the EWS correct functioning (drug-treatment professionals, laboratory technicians, Cuerpo Nacional de Policía, Guardia Civil and autonomous police staff, etc.)

Communication tools (information technology, meetings, periodicity of meetings)

Communication among the different actors and levels of the EWS process is based on e-mails, fax and phone calls. The SENDA (Sistema Estadístico de Análisis y Evaluación sobre Crimen Organizado y Drogas) database in CICO and the Drug-related problems Key indicators information system in the Spanish Observatory on Drugs (DGPNSD) are used as the main sources of information for reporting. However, the Spanish Observatory on Drugs is currently working on a web-based drug problems indicators system that will facilitate the reception of timely and updated information.

Lately, the Internet has demonstrated to be a good information source to detect new drugs and new drug consumption patterns. The possibility of conducting web-based monitoring activities on a regular basis has been considered. Meetings of the involved departments are convened at the request of any of them when necessary, but with no fixed periodicity.

Language

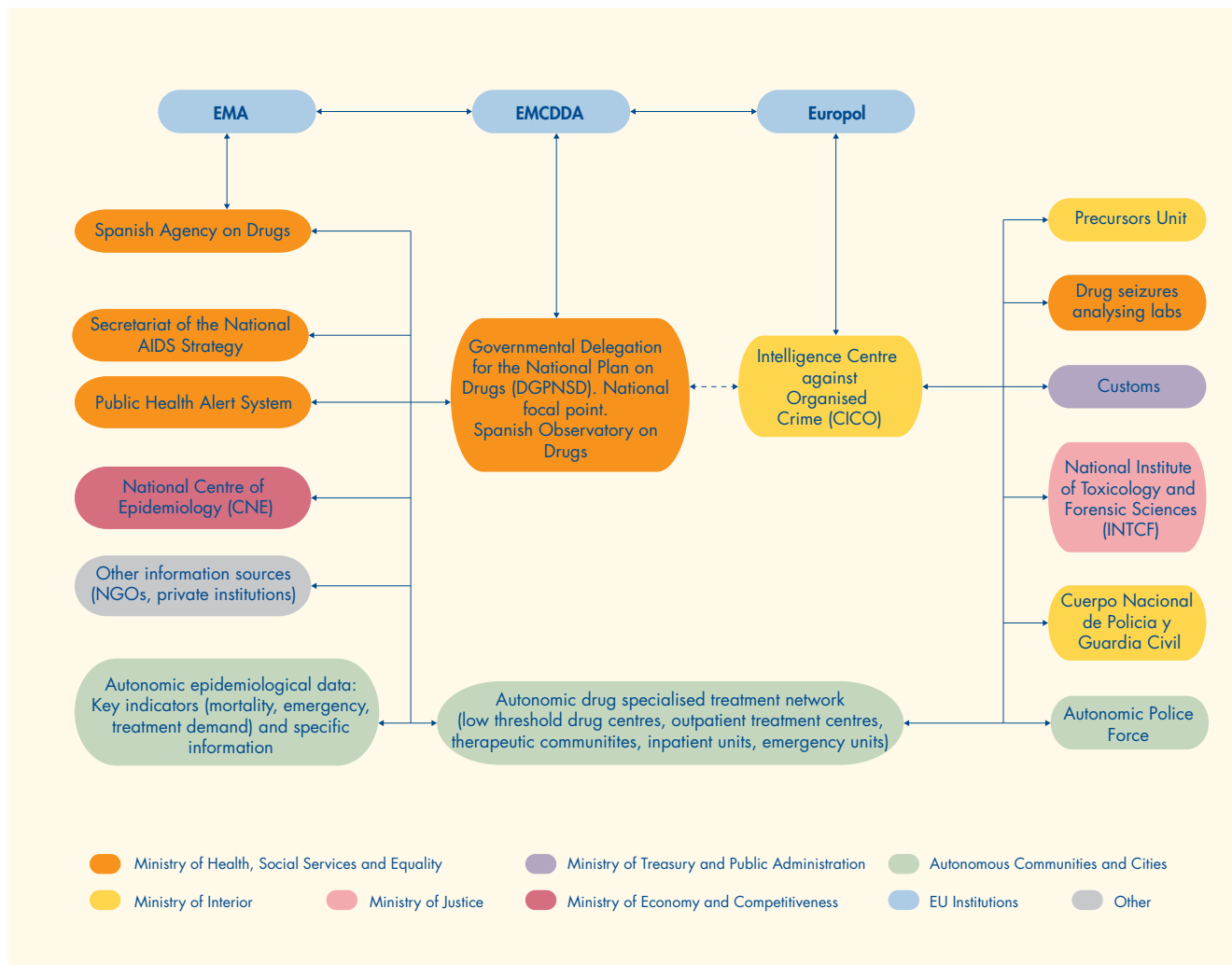
The official working and reporting language is Spanish, except for reporting activities to the European institutions, for which English is used.

Scientific/political independence

The EWS unit reports and opinions serve no political purposes, since the EWS works as a national new drug (or a new pattern of drug use) surveillance national system. EWS reports are entirely based on technical expertise and therefore political independence is guaranteed.

Core functions and information flow

On one hand, the Intelligence Centre against Organised Crime (CICO) starts collecting data on the controlled substances seizures on a regular and standardised basis from the Police and Guardia Civil forces and from the Customs Corps. This information is loaded up in a computerised information and communication system called SENDA (see 'Communication tools'). Information is then analysed and assessed to produce reports on the actual and current situation of drug supply and on new trends, which is regularly sent to the Spanish national focal point.

Figure 23 — Information flow in the framework of the Spanish EWS

On the other hand, and regarding both controlled and non-controlled substances, there is a nationwide net-like laboratory system which has the mandate to analyse and report to CICO on the exact composition of drug seizures. Information on those identified controlled and non-controlled substances is regularly sent to CICO.

If the alert is referred not to seizures but to a new pattern of drug use or to the detection of contaminants within drugs, etc., the responsibility of reporting to the DGPNSD falls on the correspondent autonomous communities authorities who will establish the necessary control measures and responses.

There is no standardised procedure to carry out a risk assessment of a new drug but decisions to set up control measures on a specific substance may be proposed by any

of the agencies involved in the EWS, provided that a justified and well-reasoned request is made and an agreement among them is reached. Ad-hoc committees are convened when necessary.

The DGPNSD regularly allocates public funds to several types of drug programmes (prevention, treatment, rehabilitation, etc.) to be developed by the autonomous communities, local entities, research institutions and NGOs. Some of the NGOs are running prevention and harm-reduction programmes offering drug users the possibility to analyse (field testing) purity or composition of illicit drug pills they will be abusing soon after. The number and composition of the analysed pills are not systematically reported to the Spanish EWS. Only occasionally, the Spanish EWS becomes aware of the results of these interventions through the EMCDDA or the press.

Case study

Cases follow the above included diagram.

Strengths, limitations and way forward

Strengths

- The Spanish EWS belongs to the Spanish Public Administration and has a nationwide structure with a fairly good coverage.
- Drug-related problems information system (Spanish Key indicators: Admission to drug treatment, Drug-related mortality, Drug-related emergency episodes). The well functioning of this information system ensures a correct surveillance of drug-related clinical issues.
- In relation to the drug analysing laboratories network:
- the fact of counting on a network of drug seizures analysing laboratories (Ministry of Health, Social Services and Equality) throughout the country and that they draw on the same common guidelines promotes and ensures homogeneity of analysis results and reports;
- the fact that these laboratories are widely distributed throughout the country and that they take care of almost 100 % of the seized drugs in Spain, places an added value and significance to the results and reports;
- every drug seizures analysing laboratory works with and follows the United Nations best practice drug-analysis recommendations. However, technical resources, well-trained staff and burden of work are not distributed evenly.

Limitations

- Since several Ministerial Departments as well as the autonomous communities are involved in the EWS, a very close collaboration among them is required to make further progress. Thus, coordination efforts are necessary.
- Risk assessment protocols and procedures are neither well established nor standardised yet, thus affecting decisions' timing and deadlines, if those are to be made.
- The lack of EWS-specifically devoted staff makes work less efficient.
- In Spain, the large number of seizures and the amount of seized drugs pose a considerable burden on drug analysing laboratories and makes analysis and reporting a rather difficult and time-consuming process.
- Storage, custody and destruction of such an amount of seized drugs often entails difficulties, and delays analysing and reporting, thus preventing the NFP to report on time.
- Laboratories complain about technical problems to

identify new not-well-known, non-controlled substances without having previously been provided with technical guidance or at least some information on them.

- It is the policy of the Spanish EWS that national data should be reported to European institutions only by the NFP.

Way forward

- Promote a better coordination among the different departments and actors involved in the EWS.
- Setting up a standing committee, made up by representatives of every involved sector to meet on a regular basis.
- Strengthen coordination and work relations between the EWS and the Public Health Alert System (Ministry of Health, Social Services and Equality).
- Devise a specific procedure for the risk assessment of new substances, including flow information and decision-making protocols, scientific workgroup and standing committee composition and timing/deadlines of the whole process.
- As stated above, it would be advisable to provide drug analysing laboratories with updated information and new drugs identifying patterns to allow them to be proactive in looking for new substances before intoxications or deaths have occurred, or big amounts of those new drugs have been seized.
- The use of the Internet as an additional source of information for new drugs and drug consumption trends surveillance purposes should be promoted. The possibility to use it as a means to counteract new drugs marketing and promoting activities should be explored.

Links and references

Ministerio de Sanidad, Política Social e Igualdad — <http://www.mspsi.es>

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<http://www.pnsd.msc.es/Categoria2/legisla/pdf/26.pdf>

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Sweden — early warning system

Sara Wall and Anders Persson

Introduction

The Swedish National Institute of Public Health (SNIPH) is a focal point of the Reitox network and accordingly has the responsibility of reporting to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) on the drug situation.

The Swedish Government has commissioned SNIPH and the Medical Product Agency (MPA) to collect and assess information on new drugs and consider if there is a need to regulate them as narcotic substances at a national level. The mission is divided between the two authorities, whereby the MPA investigates medicinal substances/substances with potential medical value and SNIPH investigates other psychoactive substances with a potential for misuse. The SNIPH also has the task of guarding and investigating whether there is a need for a substance to be regulated under the Act on the Prohibition of Certain Goods Dangerous to Health. The easiest way to explain this act is to say that it focuses on health issues, but does not criminalise personal use.

This joint effort provides for the establishment of an early warning system (EWS) to identify new synthetic drugs as they appear on the European market. It also incorporates a mechanism for assessing the risks of these drugs and comprises a decision-making process, through which these products may be placed under control in the EU Member States.

Swedish Customs, the National Criminal Investigation Department of the National Police Board, social services and the healthcare services are required by Swedish law to report to SNIPH without delay if in their work they notice anything that indicates that a new psychoactive substance is unsuitable or if there is a change in patterns of use. Other involved organisations are the National Laboratory of Forensic Science which carries out analyses on seizures made by the Swedish Police. For the seizures made by Customs, the majority is analysed by Customs' own laboratory, although in exceptional cases, some are analysed with help from the National Laboratory of Forensic Science. The Department of Forensic Chemistry of the National Board of Forensic Medicine provides information about drugs detected in

bodily fluids or specimens, performs toxicological analyses of specimens collected post-mortem and analyses blood and urine samples from individuals suspected of driving under the influence of drugs. The department also analyses samples from correctional care, the Police, healthcare services and social services to verify suspected use of narcotics.

The Swedish Council for Information on Alcohol and Other Drugs (CAN) is an independent organisation that delivers statistics on 'Drug trends in Sweden', CAN's annual report and the widest statistical resource within the drug field.

There is also a collaboration called STRIDA (Collaborative project concerning toxicity assessment and risk assessment of Internet drugs based on laboratory analysis). The Swedish Customs laboratory, the National Board of Forensic Medicine, the National Laboratory of Forensic Science and the MPA are the members of the network. This is a national activity focused on Internet drugs which aims to provide current information on the drugs in use, addiction potential, how they are metabolised in the body and how to develop new analysis techniques. STRIDA also interacts with, and distributes information to the healthcare sector and relevant authorities. STRIDA is partly financed by SNIPH.

The Network for the Current Situation of Drugs (NADiS) was formed in Sweden when the Act on the Prohibition of Certain Goods Dangerous to Health (SFS 1999:42) entered into effect. The law applies to goods that, due to their inherent characteristics, entail a danger to human life or health and are used or can be assumed to be used with the aim of achieving intoxication or other effects. The NADiS was founded by the SNIPH in 2000. Contributing bodies are the MPA, Swedish Customs, National Criminal Investigation Department of the National Police Board, the Department of Forensic Chemistry, the National Board of Forensic Medicine, the National Laboratory of Forensic Science, the Swedish Poisons Information Centre, CAN, the Swedish Prosecution Authority, Karolinska Institutet and representatives from the social services and healthcare services.

In 2003/2004, the Danish National Board of Health and the Norwegian Institute for Alcohol and Drug Research (SIRUS) joined in the network. After a couple of years, Finland de-

cided to follow suit in 2006. Iceland joined this year. The purpose of the network is to increase knowledge and gather information about new substances with the aim of possible regulation at the national level. This extended network is known as the Network for the Current Situation of Drugs in Nordic countries (Nordic-NADiS).

These networks are the providers of the EWS, which makes it possible to identify new synthetic drugs as they appear on the European and Nordic market and incorporates a mechanism for assessing the risks of these drugs. The EWS also comprises a decision-making process through which these products may be placed under control in Sweden and the other Nordic countries.

Organisational issues

The Swedish National Institute of Public Health was established by the Swedish Government.

The goal of drug policy work is a drug-free society. SNIPH has three specific duties related to this goal:

- monitor and investigate the need for drug classification and the need for inspection of goods under the Act on the Prohibition of Certain Goods Dangerous to Health (1999:42);
- promote access to quality statistics;
- serve as the national unit in the cooperation with EMCDDA.

A Government decision regarding proposed classifications led to regulation according to the Act on Penal Law on Narcotics (1968:64), the Act on the Control of Narcotic Drugs (1992:860) or to the Act on the Control of Narcotic Drugs (1999:42). In Sweden, a control system is applied which classifies substances individually, i.e. substance by substance. On 1 April 2011, The Destruction of Certain Hazardous Abuse Substances Act (2011:111) entered into force. According to this Act, it is possible to seize and destroy a substance that is likely to be regulated at the national level, following a decision by a public prosecutor. From April to December 2011, approximately 100 decisions to destroy a psychotropic substance from a seizure were taken due to the new legislation.

Objectives

The National early warning system (N-EWS) does not only serve the Council Decision. It has a wider role as its objective is to stay alert and aware of the current situation of drug use and create conditions under which a more scientific

approach to classifications can develop. The collaboration within NADiS and Nordic-NADiS is an important tool to increase knowledge on new drugs and the way they are used/misused and their interaction with pharmaceuticals. At the same time, the collaboration also minimises the risk of countries doing the same work when experiences can be used across borders. Finally, Nordic-NADiS facilitates the Nordic countries' obligation as a focal point in the EWS.

Institutional basis

The SNIPH is the responsible institution, the national focal point for EMCDDA and an agency under the Ministry of Social Affairs.

Link to EU institutions

The SNIPH is obliged to report to the EMCDDA on the drug situation. The National Criminal Investigation Department of the National Police Board collaborates with Europol.

Coverage

The N-EWS operates on a national level, but collaboration with the other Nordic countries takes place on a regular basis.

Staff

Currently, two persons at the SNIPH are working with the N-EWS and classifications and their scientific backgrounds are within pharmacology (PhD) and biology (Master of Science).

Approximately 25 people in Sweden are active within NADiS. The SNIPH, MPA, Swedish Customs, the National Criminal Investigation Department of the National Police Board, the Department of Forensic Chemistry, the National Board of Forensic Medicine, the National Laboratory of Forensic Science, the Swedish Poisons Information Centre, CAN, the Swedish Prosecution Authority, the social services and the healthcare services have representatives in this group. Nordic-NADiS has approximately 100 members, but not everyone is active.

Communication tools

As a base for the EWS work, the European database on new drugs (EDND) is used. A Nordic website called the NADiS web, where information can be exchanged between the Nordic countries and their various participant areas, i.e. police, medical care, health institutes etc., is also available. This is a fast and simple tool for information exchange. The website is encrypted. There are one or two persons from each country who have the ability to do editorial work on

the website, such as writing on the information page, adding fact sheets and issuing members' passwords. In the forum, all Nordic-NADiS members can read and write posts. Each national administrator is responsible for the website in their country. The SNIPH in Sweden has the overall responsibility and the right to the website tool. The administrators of the system are regularly in contact with each other. The thought behind the web page is that it will be self-serving with a minimal contribution from the administrators. Information and data that is posted in forums and fact sheets is used in the daily work on classifications.

The information posted on fact sheets for a specific substance should be as scientific as possible with references to the source.

Within the Swedish group meetings are held three to four times a year. The meetings are held by the SNIPH who convene the meetings, serve as the meeting chair and takes

notes. The meeting is hosted each time by one of the bodies that participate in the group. Discussion around new substances and possible classifications is on the agenda and a summary of latest news by each of the members.

Within the Nordic-NADiS group, an administrator meeting is held at least once a year. Practical questions regarding the national groups, Internet functions and theoretical questions are reviewed. The current situation in each country is discussed and information is exchanged.

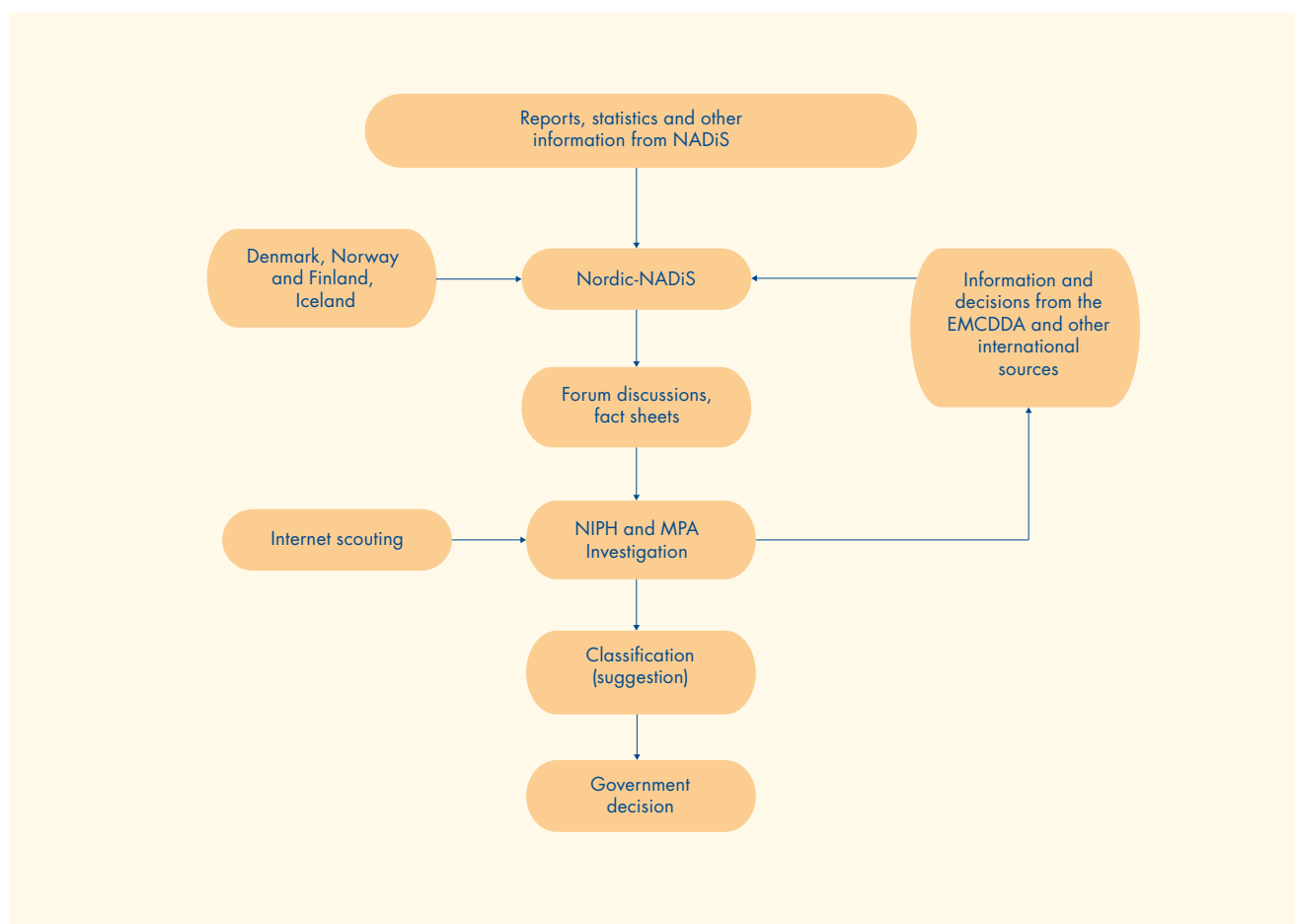
Language

The spoken language within the Nordic-NADiS is Swedish, Norwegian and Danish.

Scientific/political independence

The mission for the SNIPH is controlled by the Government. But the SNIPH is scientifically independent.

Figure 24 — Information flow in the framework of the Swedish EWS



Core functions and information flow

Data and information from different authorities' own observations are reported on the common web page. This is followed by discussions and guidance towards a classification. The SNIPH or MPA prepares a classification based on the discussions by the group, scientific data, statistics, the EDND and other web information. The classification is executed by a Government decision.

Data collection tools — Other methods and information collection used in the classification work are:

- surveys
- seizures
- drug analyses
- controlled purchases
- Internet scouting
- official reports from international organisations and governmental institutions.

Data appraisal and analysis

The National Laboratory of Forensic Science carries out analyses on seizures made by the Swedish Police. For the seizures made by Customs, the majority is analysed by the Customs' own laboratory, some exceptional cases are analysed with help from the National Laboratory of Forensic Science. The Department of Forensic Chemistry of the National Board of Forensic Medicine provides information about drugs detected in bodily fluid/specimens. The Department of Forensic Chemistry performs toxicological analyses of specimens from deceased persons and analyses blood and urine samples from individuals suspected of driving under the influence of drugs. They also analysed samples from the correctional care, the police, healthcare and social services to verify suspected use of narcotics. This statistical report is to be turned in every half year.

Outputs, reporting, publications and distribution — alerts, databases, confidentiality levels

Regular meetings with expert groups, information exchange within the NADiS-website, where an e-mail is sent to the entire group each time someone adds a fact sheet or comment on something in the forum. Presentations at conferences and scientific publications are also information tools.

Risk assessment at national level

In principle, the operating guidelines of risk assessment are followed.

Case study

Mephedrone

- 1 January 2008, first police seizure in Sweden
- 25 April 2008, analysis and identification by the Department of Forensic Chemistry
- Spring 2008, discussion at the Network for the Current Situation of Drugs in Sweden
- 17 October 2008, first application for regulation under the Act on Prohibition of Certain Goods Dangerous to Health (1999:42)
- 15 December 2008, regulated according to 1999:42
- March 2009, application for the substance to be regulated under the Penal Law on Narcotics
- 23 April 2009, Government decision, regulated under the Penal Law on Narcotics
- 25 May 2009, officially regulated under the Penal Law on Narcotics.

Strengths, limitations and way forward

Strengths: Broad network, collaboration

Limitations: Software, resources

Way forward:

- increase knowledge and commitment
- use of sewage epidemiology and information
- Nordic collaboration also includes Iceland
- continue to develop the NADiS website for a wider range of use
- purchase of legal drugs for forensic and chemical laboratories to accelerate the possibility for forensic data regarding new drugs
- Swedish Chemicals Agency should be assigned to apply Regulation (EC) No 1272/2008 more extensively with the purpose of reducing Internet sales
- clarify the role of SNIPH regarding risk assessment
- use of techniques such as Quantitative Structure-Activity Relationships (QSAR)
- biological mechanism/investigations.

Links and references

Links

Swedish National Institute of Public Health (SNIPH) — <http://www.fhi.se>

Medical Product Agency (MPA) —
<http://www.lakemedelsverket.se>

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Turkey – early warning system

Bülent Demirci and Ali Bertan

Introduction

The early warning system (EWS) Working Group in Turkey was established in 2006 as one of the national working groups within the framework of the PHARE project launched between the EMCDDA (European Monitoring Centre for Drugs and Drug Addiction) and TUBİM (Turkish Monitoring Centre for Drugs and Drug Addiction) and has been carrying out its activities since then.

Organisational issues

In the Turkish National action plan, it is stated that the EWS Working Group established within TUBİM convenes at least twice annually under the chairmanship of a national expert. The EWS Working Group can be convened under the coordination of TUBİM whenever deemed necessary.

There is extensive communication between the EWS Working Group in Turkey and the EMCDDA. The information about the new substances encountered in the Member States is shared with all Member States and other information about the substance is demanded by the EMCDDA. Likewise, a new psychoactive substance found in Turkey is reported to the EMCDDA by TUBİM. Turkey also reports to the EMCDDA about the new substances recently taken under legal control.

The EWS Working Group was established on a national basis. There are 20 officials chosen from different institutions dealing with drugs and drug addiction in the Working Group. The Working Group comprises the representatives of the institutions below:

- 1) Ministry of Justice:
 - Council of Forensic Medicine
- 2) Ministry of Health:
 - General Directorate of Pharmaceuticals and Pharmacies
 - Refik Saydam National Public Health Agency
 - General Directorate of Curative Services
- 3) Ministry of Customs and Trade:
 - General Directorate of Customs Enforcement
 - Counter-Narcotics Trafficking Department
- 4) Turkish National Police:

- Department of Anti-smuggling and Organised Crime
 - Division of Counteracting Narcotic Crimes
 - TUBİM (Turkish Monitoring Centre for Drugs and Drug Addiction)
 - Department of Police Criminal Laboratories:
 - Ankara Criminal Police Laboratory
 - İstanbul Criminal Police Laboratory
- 5) General Command of Gendarmerie:
 - Department of Anti-smuggling and Organised Crime
 - Department of Criminal Laboratory
 - 6) Turkish Coast Guard Command:
 - Intelligence Department
 - Intelligence Division – Anti-Smuggling Office
 - 7) Marmara University:
 - School of Medicine – Department of Medical Pharmacology.

The group communicates via e-mails, official letters and meetings. A new report, information and meeting reports submitted via the EWS system are shared with all the group members.

Turkey believes that the EWS works concerning the new psychoactive substances should be conducted on an effective, fast-paced and scientific basis. There are both scientists and people from the field in the EWS Working Group. The new substances in the EWS are evaluated scientifically and the necessary decisions are taken.

Core functions and information flow

Narcotic units affiliated with the Turkish National Police, General Command of Gendarmerie, General Directorate of Customs Enforcement and Turkish Coast Guard Command send the substances they seize to police and Gendarmerie Criminal Laboratories and the Council of Forensic Medicine. If a new psychoactive substance is identified at the laboratory analysis, the 'EMCDDA–Europol Reporting Form on New Psychoactive Drugs' developed by the EMCDDA and Europol is filled in by those institutions and then sent to TUBİM. The new substance reported is then e-mailed to the EMCDDA and information about the substance is demanded

while other related information, such as the seizure data throughout the country, is gathered by TUBİM.

The information gathered is reported to the EWS Working Group and their knowledge, ideas and suggestions are received. The TUBİM EWS Working Group convenes in accordance with the data. In the meetings concerning those substances, the following are assessed:

- the new substances’ chemical composition and effects;
- the possibility of addiction and the gravity of the possible addiction;
- the social risks for the drug user;
- the harm it may cause in the society and its relation to violence.

If the psychoactive substance(s) are considered by the experts at the meetings to be a risk to society, a recommendation is prepared to legally control the substance. The recommendation is sent to the Ministry of Health as an official letter by TUBİM.

The necessary processes to include a new psychoactive substance in the banned substances list is defined in the 19th article of Law No 2313 ‘Law on Controlling Drugs’.

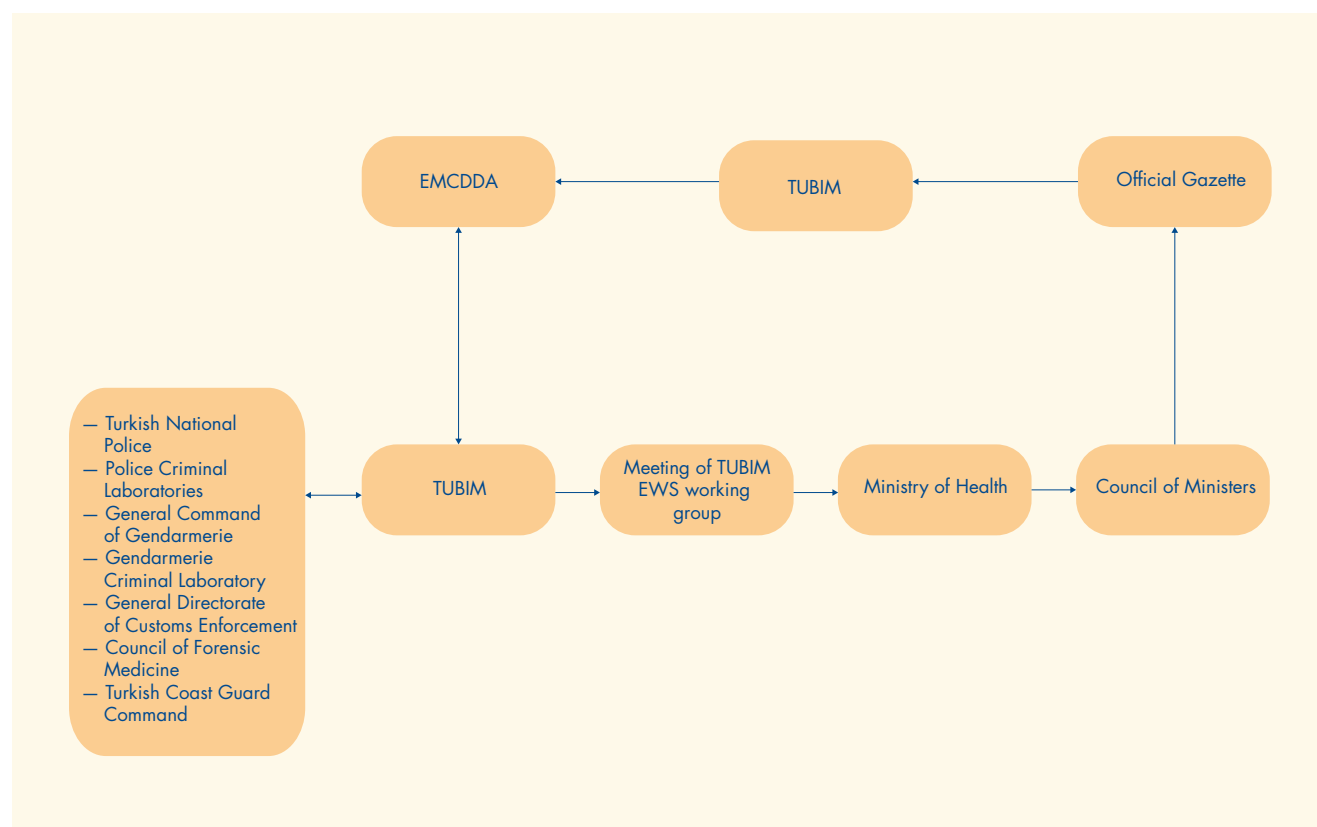
According to this article, substances not listed in the Law as illicit drugs and identified as having the effects of a drug, are brought under legal control with the recommendation of the Ministry of Health and with the decision of the Council of Ministers. The Ministry of Health evaluates the substance’s chemical structure, its psychoactive effects, its health consequences like death and disease and possible social risks about its use and trade, by taking into account the views of the scientists and commissions, when necessary.

The substances published in the official gazette and included in the legal restrictions are reported to the EMCDDA and all the relevant authorities by TUBİM.

Case study

The Officials of Antalya Security Directorate Anti-Smuggling and Organised Crime (KOM) Division informed TUBİM of the recent appearance of a new substance consisting of herbal mixtures in Antalya. TUBİM demanded that a sample of the said substance be procured and sent to Antalya Criminal Police Laboratory and the resulting analysis report to TUBİM.

Figure 25 — Functioning of the early warning system in Turkey and information flow



In the meantime, TUBİM was informed of a substance named 'bonsai' consisting of herbal mixtures by Isparta and Eskisehir KOM Divisions. As a result of the analysis of these plant mixtures in the Criminal Police Laboratories, a new psychoactive synthetic cannabinoid substance called JWH-018 was identified in it. It was understood to be the same substance which had been identified in Antalya.

On the other hand, the General Directorate of Customs Enforcement reported to TUBİM a new substance seized by İstanbul Customs Enforcement Office of the General Director Units. It was Catha Edulis (khat) which involves the active ingredients of cathinone and cathine.

The Council of Forensic Medicine and Police Criminal Laboratories notified TUBİM of the increasing seizures of 2C-B and 2C-P substances of the phenethylamine group.

In the meantime, 'Reporting form on new psychoactive drugs' was filled out about the substances identified for the first time in Turkey and sent to the EMCDDA. The EMCDDA was notified of this development and the present information about the said substances has been demanded by Turkey.

By means of the information received from the relevant institutions, TUBİM collected data about the substances' chemical properties, nationwide seizure data, whether it was previously seen in any European country and its legal status in those countries. The resulting data of these researches and the data from the EMCDDA were first shared with TUBİM EWS Working Group Members and then the group was convened outside of its meeting routine.

In this context, as a result of the TUBİM early warning System (EWS) Risk Assessment Committee, a decision of recommendation concerning the above-mentioned substances was taken to include them under the Law No 2313, Article 19.

This decision was officially written to the Ministry of Health to start the legislation process. These articles also sent to the Council of Ministers by the Ministry of Health were subjected to the provisions of Law on Drug Control No 2313.

Strengths, limitations and way forward

Thanks to TUBİM's structuring, called 'provincial focal points' operating within KOM (Anti-Smuggling and Organised Crime) divisions in 81 provinces, new

psychoactive substances and related information reaches TUBİM in a very short time.

The fact that there are officials in the EWS Working Group both from the field and scientific community makes it strong. The group can get reliable and up-to-date information about the substances it examines and evaluates thus, taking independent decisions on a scientific basis.

All the relevant institutions have a high level of awareness about reporting the new psychoactive substances to TUBİM so TUBİM can smoothly get the information as stated above.

In Turkey, one of the most important problems faced in the operation of the EWS system is the Forensic laboratories' difficulty in obtaining the 'reference substances' to carry out the analysis of the new substance. This difficulty may be due to the commercial unavailability of the reference substance yet, or it may be due to the long amount of time needed for the procurement to be completed for those substances that are commercially available. Moreover, even though the reference substance is obtained, since the analysis cannot be conducted outside the Forensic laboratories, there is the difficulty of processing the biological samples taken from the user.

Another problem is the possible delays in getting such substances under the scope of the law due to bureaucratic processes. Although the fact that implementation can be carried out directly by the Decree of Council of Ministers without any requirement for a parliamentary decision in Turkey may seem to be a facilitating factor, the lapse of approximately 1.5 to 2.5 years for the relevant items in the last two Decree of Council of Ministers to be adopted after their notification to the Ministry of Health indicates the need for remedial measures.

In conclusion, the EWS is one of the most important fields for Turkey in the fight against drugs and drug addiction. Turkey believes that this fight will be more successful with international information/expertise sharing.

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United Kingdom – early warning system

Leslie A. King

Introduction

In the UK, an informal early warning system (EWS) had been in operation during the mid-1990s and was managed from a base in the Forensic Science Service (FSS). The network consisted of representatives from forensic science laboratories in Europe. The primary function was to circulate information and analytical data on the many new synthetic substances that had started to appear in drug seizures in the early 1990s. This network was superseded by the introduction of the Joint Action on New Synthetic Drugs in the EU in 1997 with national focal points taking responsibility at Member State level. From 1997 to 2002, the UK national focal point (NFP) was managed by DrugScope, but from 2003, it has been based within the Department of Health, London. In 2005, the Joint Action was superseded by Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances.

Organisational issues

Apart from agreements with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the EWS has no other statutory basis. Its primary role since 1997 has been to provide information to the EMCDDA, which in recent years has been carried out under Council Decision 2005/387/JHA (above). The EWS is also occasionally used at EU level as a convenient mechanism for the distribution of information on certain related topics (e.g. contaminants in drugs, health alerts, and unusual cases). At national level, a number of systems are used for collecting and distributing information on a wider range of substances and drug-related activities including established drugs of misuse; these include the National Programme on Substance Abuse Deaths (np-SAD), alerts from the Health Protection Agency (HPA), amnesty bin analyses and law enforcement intelligence initiatives. In the context of concerns about so-called 'legal highs' and the Government's introduction of temporary class drug orders (TCDOs), the new Drug Strategy published in December 2010 included a commitment to improve analytical capabilities for new psychoactive substances and to establish an effective Forensic early warning system (FEWS). Consideration is currently being given to the UK focal point

assuming a more central role as a de facto 'information hub' in providing information to support the assessment of new psychoactive substances that may be subject to a TCDO.

The membership of the EWS was originally limited to government departments, police, Customs, the Europol national unit and forensic science laboratories, but it has expanded greatly in recent years. This is a reflection of the increased public and official interest in what are often informally known as 'legal highs'. From the outset, the EWS represented all four countries of the UK. There are currently around 50 members of the EWS. In addition to research workers in academic establishments, the organisations represented include: Department of Health (in which the UK focal point on drugs is based); Medicines and Healthcare products Regulatory Agency (MHRA); Scottish Crime and Drug Enforcement Agency (SCDEA); Serious and Organised Crime Agency (SOCA); Forensic Science Service, (FSS); LGC Forensics; Forensic Science Agency of Northern Ireland (FSNI); Guy's and St Thomas' NHS Foundation Trust; ROAR Forensics; Key Forensics; Environmental Scientifics Group; National Poisons Information Service; Home Office (Drugs Policy); Advisory Council on the Misuse of Drugs (ACMD); Public Health Wales; International Centre for Drug Policy at St. George's Hospital Medical School, London; TICTAC Communications, St. George's Hospital Medical School, London. Although not formally part of the UK, the network also includes members from the Channel Islands (Official Analyst's Laboratory, Guernsey; Customs and Excise, Guernsey; Official Analyst's Laboratory, Jersey).

From mid-2011, the EWS has been coordinated by two staff (around 0.2 FTE), one of whom specialises in substance use epidemiology and emerging drug issues, while the other is an analytical chemist specialising in psychoactive substances (previously, it was supported by a chemist with a background in forensic science and drug analysis). They are assisted by other staff in the NFP when organising the annual meeting. Apart from the annual meeting, members of the EWS maintain regular contact by e-mail and telephone and occasional ad hoc meetings. The working language is English. The EWS operates as an independent information provider and is not directly involved in policy matters.

Core functions and information flow

Apart from the EMCDDA, outputs of the EWS are available for use by all members of the network including those developing policy, but almost all input comes from forensic science laboratories and to a lesser extent, forensic and clinical toxicology laboratories. Formal data collection is carried out twice-yearly to produce the Progress and Final reports for the EMCDDA, and on those occasions when information is required by the EMCDDA for other purposes such as compilation of Joint reports and EU-wide risk assessments under the Council Decision. No national database of new substances is maintained, since this function is well-provided at EU level by the European Information system and European database on new drugs (EDND).

The EWS acts as the national (UK) contact for the EMCDDA, receiving information from it and disseminating this within the UK as appropriate. Its staff maintain an overview of the scientific and grey literature, including Internet sources, as well as legislative developments in the UK and elsewhere, primarily to keep abreast of developments with new substances. They also engage in other academic and professional activities relevant to these substances.

Risk assessment at UK level is not the function of the EWS. However, the ACMD assess the harms of drugs, as appropriate in the context of the Misuse of Drugs Act 1971.

Case study

The main strength of the EWS from a UK perspective has been the information-sharing phase. The EU-wide control decisions taken before 2008 were of limited value to the UK since the various phenethylamines examined by earlier risk-assessments (i.e. MBDB, 4-MTA, PMMA, 2C-T-2, 2C-T-7 and TMA-2) were already controlled in the UK, mostly by generic legislation. It was also the case that mephedrone (4-methylmethcathinone) had already been brought under control in the UK in early 2010 before a risk assessment was carried out by the scientific committee of the EMCDDA in mid-2010.

In the case of 1-benzylpiperazine (BZP), the EMCDDA risk assessment was of special benefit to the UK. Although the question of controlling BZP first arose in discussions in the ACMD in late 2006, it was clear at that time that the substance was being considered by the EMCDDA. It was therefore agreed that the ACMD process would wait for a decision to be made at EU-level. Following a risk assessment

carried out in mid-2007, a decision was subsequently made to recommend control of BZP in all Member States. Although the exact classification of BZP under the Misuse of Drugs Act 1971 still had to be determined, the need for a detailed domestic assessment of the harms posed by the drug was avoided.

Strengths, limitations and way forward

The major strength of the EWS is that forensic drug analysis in the UK is well-managed and well-equipped, and staffed by individuals with great enthusiasm for reporting new substances. In late 2010, the UK Government announced that the Forensic Science Service (FSS) would be winding down its services. Robust arrangements have been put in place to ensure continuity of service once the FSS has ceased operational business.

Although the collection of information on new substances for the purposes of the 2005 Council Decision is not intended to be an exercise in precise epidemiology, a further difficulty arises because of the way in which some drug types (especially piperazine derivatives such as BZP, CPP, TFMPP, mCPP and DBZP) are normally found as mixtures with one another and with established drugs such as amphetamine, cocaine, heroin, ketamine and MDMA. Another limitation on information about new substances arises from the fact that, at least initially, they are not controlled by drug legislation. Since the primary role of forensic science laboratories is to provide a service to law enforcement and prosecution agencies, the analysis of non-controlled substances may be treated as a low priority.

Some information is received from clinical and forensic toxicology laboratories, but this is more ad hoc and partly reflects the wider variations of such analyses between different hospital trusts, as well as the limited chemical analysis that is justified in non-fatal cases. Scope exists for obtaining far more clinical information from poisoned patients that would benefit the EWS. The UK focal point, part of which is the EWS, is currently working with a number of national stakeholders including the National Poisons Information Service, a service commissioned by the Health Protection Agency on behalf of the Department of Health across the UK to obtain such information directly and on regular basis.

Although the UK is fortunate in that some laboratories have access to analytical techniques such as nuclear magnetic resonance spectroscopy (NMR), which provides absolute

chemical-structural information, the limited availability of pure reference materials remains a problem in the identification of new substances. In early 2011, the Home Office started a project to test-purchase 'legal highs' and to commission syntheses of selected substances as reference materials. This is largely intended to support the TCDOs on certain substances, but should be of general assistance to the EWS. It should also be mentioned that the rapid proliferation of new substances and their chemical complexity in the past three years has placed increased demands on all of those involved in the EWS.

Some of the EWS members are part of academic establishments, which host a variety of activities dedicated to researching new psychoactive substances. The resulting output informs a variety of stakeholders operating on both national and international levels. For example, the two current coordinators maintain an interdisciplinary research programme designed to address the issues of psychoactive drugs in the context of chemistry, pharmacology and public health. Examples included the implementation of test purchases, development of improved organic synthesis procedures and increasing involvement in the determination of pharmacological investigations.

Apart from laboratory data, currently little useful information on new substances is derived from other sources. It has remained the case that, in the absence of precise laboratory analysis, qualitative data from users or drug agencies is of limited value in assessing trends with new substances.

Links and references

Links

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Forensic Science Agency of Northern Ireland (FSNI) — <http://www.fsni.gov.uk>

Guy's and St Thomas' NHS Foundation Trust — <http://www.guysandstthomas.nhs.uk>

Home Office — <http://www.homeoffice.gov.uk>

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National Programme on Substance Abuse Deaths (np-SAD) — <http://www.sgul.ac.uk/research/projects/icdp/our-work->

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European Monitoring Centre for Drugs and Drug Addiction

Early warning system — national profiles

Lisbon: European Monitoring Centre for Drugs and Drug Addiction

2010 — 165 pp. — 21 x 29.7 cm

ISBN: 978-92-9168-500-4

About the EMCDDA

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is one of the European Union's decentralised agencies. Established in 1993 and based in Lisbon, it is the central source of comprehensive information on drugs and drug addiction in Europe.

The EMCDDA collects, analyses and disseminates factual, objective, reliable and comparable information on drugs and drug addiction. In doing so, it provides its audiences with an evidence-based picture of the drug phenomenon at European level.

The Centre's publications are a prime source of information for a wide range of audiences including policymakers and their advisers, professionals and researchers working in the field of drugs, and, more broadly, the media and general public.