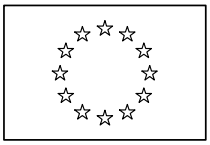

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COMMISSION STAFF WORKING DOCUMENT

on EU guidelines and mechanisms for detecting, monitoring and responding to emerging trends in drug use and drug markets

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CONTENTS

1. INTRODUCTION

One of the objectives set in the EU Action Plan on Drugs (2005–2008)[1] is to develop clear information on emerging trends and patterns of drug use and drug markets. The Plan calls for the Commission to work with the EMCDDA and Europol to develop EU guidelines and mechanisms for detecting, monitoring and responding to emerging trends. This objective is also reflected in objective 23 (action 69) of the current EU Action Plan on Drugs (2009-2012)[2] calling for an assessment of the functioning of Council Decision 2005/387/JHA[3] on the information exchange, risk assessment and control of new psychoactive substances, which is to be carried out in the course of 2009. This staff working paper describes the mechanisms for detecting, monitoring and responding to emerging trends currently in place in the EU and proposes some guidelines for future work. It does not provide detailed guidelines, since those can only be agreed upon among experts and relevant stakeholders, from the bottom up.

The identification of emerging trends requires a different approach from the common use of key indicators to estimate levels of drug use and associated problems in the EU. Methods to **detect** emerging trends rely largely on local information from drug users, outreach workers etc., in conjunction with information from the Internet, IRC galleries, etc. This information can then be used to develop local **responses** to emerging trends. The challenge of detecting and responding to emerging trends is far greater at EU level, because of the lack of available data and difficulties in interpreting the validity and relevance of local-level data from an EU perspective. A local emerging trend calls for a local response and **most often** does not develop into an EU-wide trend. EU-wide information collection is only relevant where similar trends are seen in different places in a short space of time. On the other hand, globalisation can mean that drug trends and user characteristics in different locations share common features and would benefit from a common response.

A joint model for early identification and response in the EU, building on the experience gained so far, would facilitate (1) the exchange of information on identified and assessed emerging drugs phenomena and (2) collection, analysis and dissemination techniques. New drugs, emerging patterns of use and emerging harms could be identified earlier than with a standard monitoring system, thus allowing earlier intervention in prevention, health and law enforcement. Detecting an emerging trend requires flexible, rapid assessment techniques. More robust epidemiological or cohort studies can only be implemented afterwards, if needed.

A number of Member States (e.g. France, the United Kingdom, Austria, and the Netherlands) have set up national systems for detecting, monitoring and responding to emerging trends. Experience gained outside Europe can also provide valuable input into guidelines and mechanisms — for example, the US Community Epidemiology Work Group (CEWG), a structured network of local researchers and professionals[4], and DAWN (the Drug Abuse Warning Network)[5] a monitoring system based on epidemiological indicators designed to identify trends early.

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1 Objective 41, see OJ C 168, 8.7.2005.

2 OJ C 326, 20.12.2008.

3 OJ L 127, 20.5.2005.

4 See Kozel, N.J., Robertson, E.B., Falkowski, C.L., (2002) The community epidemiology work group approach, in Substance Use and Misuse, Volume 37, Issue 5-7, pages 783–803.

5 http://dawninfo.samhsa.gov/.

There are also valuable lessons to be learned from an EU-wide surveillance system in a related field, namely HIV/AIDS, that effectively collects, collates and disseminates valid scientific information and allows for a rapid response to emerging threats.

2. DEFINITIONS[6]

For the purposes of this paper, the following definitions are used. Note that, as the work progresses, some terms may need to be redefined. In fact, there is no unanimously agreed definition of an emerging trend[7] and it may have different meanings at local, national and EU level.

A trend is a long movement in an order series (e.g. a time series). An essential feature is that even if the movement might be irregular in the short term, it shows movement consistently in the same direction over a long period. The term is also used loosely to refer to an association which is consistent in several samples of strata but is not statistically significant.

An emerging drug phenomenon is a drug-related change observed for the first time. It may be a new phenomenon or a pre-existing phenomenon perceived for the first time.

The 'early information function' (EIF) is one of the purposes of a drug information system. It is intended to quickly identify, assess and categorise an emerging drug phenomenon in order to allow the production of relevant information and its timely dissemination to the target audience.

Early warning system (EWS) refers to a drug information system generally focusing on changes that have implications for policy, for interventions or other public concerns. It may also focus on one particular drug-related concern such as HIV infection.

One should also distinguish between detecting an emerging trend, monitoring/reporting on it and responding to it.

- Detecting an emerging trend is mostly the work of local or national stakeholders such as prevention and health services, who are confronted in their day-to-day work with changes in patterns and methods of drug use, for example. The stakeholders may include drug users themselves.
- Monitoring/reporting on it is a task both of local and/or national stakeholders and reporting structures, including National Focal Points, and of EU stakeholders and reporting structures such as the EMCDDA. The first group may exchange information and develop the necessary responses nationally, while EU-wide bodies may benefit from a formal reporting system to assess whether specific emerging trends are being seen in multiple regions or cities across the EU. However, systematic reporting of this kind is not available in most countries.
- Responding to emerging trends is primarily the task of local or national stakeholders. Responses may entail measures not only to avert the potential risks of using a specific substance, but also to address risky settings and unsafe practices in drug-taking more generally. Structures like the EMCDDA can function as an information resource on effective measures, once data has been collected and analysed.

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6 These definitions are mainly adapted from; National Drug Trend Monitoring System (DTMS), pilot study report, National Advisory Committee on Drugs, Ireland, 2007.

7 A working definition could be something like 'An emerging trend is a series of new drug-related phenomena that is detected over a relatively short period and seems to be expanding in one or more settings or geographical areas.'

3. DEVELOPING THE IDEA OF DETECTING EMERGING TRENDS

This staff working paper is underpinned by the Council conclusions[8] on networking information on emerging trends, which included the following:

- it is desirable to organise a system that will alert more quickly on emerging trends;
- it is neither necessary nor desirable to create new structures, new networks or new financial obligations for the Member States;
- as far as possible, use should be made of the Reitox network;
- Reitox network activities could be developed towards observation of emerging trends and rapid release of this information;
- national focal points of the Reitox network should be able to use data produced by other bodies or networks concerned;
- the EMCDDA and EMEA are encouraged to jointly define their cooperation in information exchange;
- a Community financed pilot project on emerging trends should be set up[9].

The role of the EMCDDA in monitoring emerging trends was made more explicit in the (recast) Regulation (EC) 1920/2006[10]. Under the Regulation, the Centre's data collection, analysis and dissemination tasks **also** cover data on emerging trends in poly-drug use, including the combined use of licit and illicit psychoactive substances[11]. Annex I to the Regulation lists one of its priority areas as monitoring the state of the drugs problem, in particular using epidemiological or other indicators, and monitoring emerging trends, in particular those involving poly-drug use.

The EMCDDA already collects a considerable amount of information e.g. through the five key epidemiological indicators. Taking into account the legislation on data protection and confidentiality[12], possibilities for conducting quick analysis and testing hypotheses on new developments at European level based on the existing national data sets could be further explored.

The EMCDDA has also drawn up a list of possible information sources for the preparation of future actions on emerging trends:

- existing structured drug indicators — of availability, consumption and consequences — though there is a need for timeliness and specific analysis for early detection;
- forensic and scientific sources, in particular for new substances;
- conclusions drawn from 'triangulation' — linking the analysis of data from different sources, including bringing data from law enforcement (the supply side) together with demand side data;

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8 Council conclusions on networking information on emerging trends and patterns in drug abuse and poly-drug use and the associated risks, OJ C 17, 19.1.2001, p. 2.

9 The results of this project are presented below in section 5.

10 See Article 2(a)(i) and (c)(iii), Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction, OJ L 376, 27.12.2006, p.1.

11 Article 1(e) requires the Centre, if it identifies new developments and changing trends, to inform the competent authorities of the Member States.

12 Article 6(1) states that Member States and the national focal points are under no obligation to provide information classified as confidential under their national law.

- qualitative or ethno-epidemiology and complementary networks of key informants;
- the local/regional dimension of many phenomena and the need for appropriate measures and methods to take this into account and not create false alarms;[13]
- existing EMCDDA networks (Reitox NFP and Expert Networks, including EWS network) possibly used in conjunction with a sub-network of qualitative researchers and/or carefully selected key informants.

The EMCDDA is a key player in the implementation of Council Decision 2005/387/JHA on new psychoactive substances. The Decision replaces the previous Joint Action[14], keeping in place the Early Warning System[15] set up under the Joint Action. Under the Decision, the key players in information exchange are the Member States (through their national Reitox Focal Points and Europol National Units), Europol[16], the EMCDDA, the European Medicines Agency (EMEA[17]) and the Commission[18].

Strictly speaking, under the Council Decision the EWS is an instrument aimed at detecting and notifying new psychoactive **substances** appearing on the drug market with a view to possibly placing them under control in the EU. However, point seven of the recital states that 'nothing in this Decision should prevent Member States from exchanging information, within … the Reitox network …, on emerging trends in new uses of existing psychoactive substances which may pose a potential risk to public health, as well as information on possible public health related measures, in accordance with the mandate and procedures of the EMCDDA'.

The EMCDDA has published detailed and comprehensive operating guidelines explaining steps, procedures, roles, responsibilities and the sequencing of actions[19]. A substantial amount of this information derives from forensic laboratory networks and law enforcement sources.

The EMCDDA launched a project called E-POD[20] in 2006 with the objective of utilising drug information that is available through existing channels in the EU and of contributing to the development of clear information on emerging trends and patterns of drug use and drug markets. E-POD has produced two case studies, one on hallucinogenic mushrooms[21] and another on GHB/GBL[22]. Substance-based case studies (using the so-called[23] bottom-up approach) are meant to explore the current capacity of EU Member States to meet the task of detecting, tracking and understanding drug trends.

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13 Note the importance of geographical and social strata in analysis. New trends often appear in specific locations (hot spots) and among specific social sub-groups. This points to the value of focused studies that explore the potential for wider diffusion of any new pattern of use.

14 Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs, OJ L 167, 25.6.1997.

15 Note that the Joint Action does not contain an explicit reference to an Early Warning System but that the EWS is a system created for information exchange under the Joint Action (Article 3).

16 The role and mandate of Europol is not discussed further for lack of space.

17 The role and mandate of the EMEA and the pharmacovigilance (drug safety) system are not discussed further for lack of space.

18 Article 4.

19 http://www.emcdda.europa.eu/attachements.cfm/att_52451_EN_EWSguidelines2.pdf.

20 European Perspectives on Drugs.

21 Hallucinogenic mushrooms: the challenge of responding to naturally occurring substances in an electronic age, EMCDDA, Lisbon, January 2007.

22 GHB and its precursor GBL: an emerging trend case study, EMCDDA, Lisbon, March 2008, http://www.emcdda.europa.eu/publications/thematic-papers/ghb.

23 The approach is not clearly bottom-up, since the substance(s) to be studied are decided on beforehand.

4. SURVEILLANCE AND CONTROL OF INFECTIOUS DISEASES, E.G. HIV/AIDS[24]

Since the late 1980s, the EU has put a lot of effort into setting up a European network to monitor HIV/AIDS and other infectious diseases. Both HIV/AIDS and hepatitis surveillance are closely related to illicit drugs and therefore the system for the rapid collection, exchange and dissemination of authoritative scientific information in these diseases, which produces the journal *Eurosurveillance*, also serves here as an example of good practice[25].

Eurosurveillance developed from a number of surveillance networks funded by the EU through the Public Health Programme. The system was further formalised by Decision 2119/98/EC[26] on the network for infectious disease surveillance and Commission Decision 2000/57/EC[27] on the early warning and response system. Since March 2007, *Eurosurveillance* has been published by the European Centre for Disease Prevention and Control (ECDC) set up in 2005[28]. Under Article 3 of the Regulation, ECDC's mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases.

Since January 2008, *Eurosurveillance* has been a weekly, peer-reviewed[29] online publication, with both rapid communications and news and longer in-depth research articles and surveillance and outbreak reports. In addition, e-alerts are sometimes released on events that need to be urgently communicated to readers for rapid public health action.

Under Article 10 of the ECDC Regulation, some of the Centre's tasks as part of its Epidemic Intelligence[30] activities are to:

- establish, in cooperation with the Member States, procedures for systematically searching for, collecting, collating and analysing information and data with a view to identifying emerging health threats which may have mental as well as physical health consequences and which could affect the Community;
- forward to the European Parliament, the Council and the Commission an annual evaluation of the current and emerging threats to health in the Community; and
- inform the Commission and Member States as soon as possible about findings which require their immediate attention.
- identify and assess emerging threats to human health from communicable diseases, as well as to

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24 Infectious diseases and emerging drug trends differ in that an infectious outbreak has a biological agent with its own dynamics, while an emerging drug phenomenon is either a new substance produced and marketed and/or a cultural innovation happening in a social context. However, many basic principles of the Eurosurveillance system (e.g. national 'gatekeepers' who validate the data) are highly relevant to this paper.

25 'Eurosurveillance comes of age and moves to ECDC', Editorial, Eurosurveillance, Vol 12 (1), 1.2.2007, http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=681.

26 OJ L 268, 3.10.1998, p. 1.

27 OJ L 21, 6.1.2000, pp. 32-35.

28 Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control, OJ L 142, 30.4.2004, p. 1.

29 The editorial board is made up of 'national gatekeepers' from each of the European national public health institutes.

30 **Epidemic intelligence** can be defined as the process of detecting, verifying, analysing, assessing and investigating public health events that may represent a threat to public health. It encompasses not only activities related to early warning but also signal assessment and outbreak investigation. Providing early warning signals is a main objective of public health surveillance systems.

The sources of epidemic intelligence information include several websites and a large number of web pages retrieved through specialised search-engines. Additional information is gathered through direct contact with epidemiologists and health authorities in the EU and abroad.

5. KEY RESULTS SO FAR

The Community-funded project 'Development of a European early identification (EIF) function for emerging drug phenomena (EDP)'[31] (also referred to as the **TREND** project) produced a European manual on the topic[32]. The manual states that the early information function is needed to quickly identify, assess and categorise emerging drug phenomena in order to allow the production of relevant information and its timely dissemination to the target audience. It gives practical examples of national solutions for an EIF and a detailed overview on the sources and methods for data collection and dissemination.

The manual goes through five operational steps that emphasise that EIF is a continuous process:

- Data collection requires a variety of information sources (e.g. drug users, low threshold services, criminal justice, population surveys) and instruments (e.g. questionnaires). Pre-existing data collection tools should be included and optimised to make them functional for EIF purposes.
- Identification uses various analyses of existing indicators to discover any significant changes.
- Assessment describes EDP in as much detail as possible. EDP requiring special attention are chosen according to four criteria; diffusion potential, health, social consequences, and economic consequences[33].
- Dissemination strategy needs to be defined; purposes, target audiences, and dissemination methods. Dissemination should permit early reduction of potentially harmful phenomena.
- Feedback and follow-up should be sent to all those participating in data collection, and a follow-up process should be carried out for all topics that merit this.

Use of this model complements the traditional monitoring indicators. Seven[34] EU Member States participated in the project and the mix of national drug information systems involved suggests, to some extent, that the model proposed in the manual could be sufficiently adaptable to cope with different national systems. Available information sources and resources vary from one country to another but implementing common EU-level indicators should make adaptation less complex. Sensitivity towards emerging trends should also be a key issue in developing new EU-wide indicators, especially in drug supply reduction.

One of the main drawbacks of the Trend project was that there is usually a need for more resources to implement it and it is doubtful that such a system can be set up Europe-wide with

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31 Final report available at: http://ec.europa.eu/health/ph_projects/2001/drug/drug_project_2001_full_en.htm#16.

32 The executive summary of the manual is available at; http://www.ofdt.fr/BDD/publications/docs/m_et_an.pdf.

33 There are no criteria for supply reduction/law enforcement/public order.

34 France, Germany, Greece, the Netherland, Portugal, Spain, and Sweden.

existing resources. Whilst a Trend system has been implemented e.g. in France with resources invested specifically for that purpose, such resources are unlikely to be available in other countries.

Nevertheless, Member States may consider a number of options at national level to enhance the flow of information on drug phenomena allowing active detection of, reporting on and response to emerging trends. Some of these options may include:

– investing further in coordination of different information flows from and between services working at local, regional and national level, enabling such services to meet on a regular basis and/or exchange information through a dedicated website and/or set up an information dissemination mechanism to alert stakeholders to emerging trends; national Focal Points may be at the forefront of this information structure;

– developing a 'social map' of support services, including law enforcement and emergency services, and clarifying roles and tasks and by providing contact details, as one way of improving coordination;

– encouraging further investment in and increased visibility of services that are in direct contact with potential target groups; Action 15 of the EU Drugs Action Plan 2009–2012 calls for a publicly available register of support services;

– possibly providing funding - subject to the priorities established in the relevant annual work programmes - through Community programmes such as the Drug Prevention and Information Programme and the Public Health Programme to further encourage network building at national and EU level and the exchange of best practice on detecting and responding to emerging trends, e.g. through exchanges between information operators such as drug help lines, etc.;

– Member States examining further the development of scenarios and response strategies for emerging phenomena and trends that may be a cause for concern but that are still unsettled, are marginally present in very specific sub-cultures and might even disappear over time; too much focus on such emerging trends may cause overexposure in the media and possibly in the policy arena, which may in some cases strengthen a trend rather than reduce or suppress it.

The E-POD pilot project was developed to address some of the shortcomings of the Trend project. The focus of E-POD has been on recreational drug trends emerging among socially integrated groups rather than on more marginalised and problem drug user groups.

The main features of **E-POD** are:

- timely, informed and objective publications and/or information feedback to specially concerned networks;
- low-cost data collection using information already available through existing networks;
- triangulation to determine the veracity of information using routine indicators, qualitative research and a wide range of other information sources (e.g. Internet).

After the first case study under E-POD, an expert meeting agreed a set of criteria for the selection of future case studies on emerging trends:

- potential for spread
- potential for harm
- reported changes in Member States about levels of use or seizures
- evidence of conflicting (mis)information
- media interest and coverage.

The method used to analyse information from different sources is called triangulation, a term commonly referring to the application and combination of several research methodologies to increase validity and provide deeper and broader understanding of the subject matter. There is usually only a limited amount of quantitative data available on emerging trends, highlighting the importance of qualitative data, which again may give rise to many methodological problems (e.g. conflicting findings). One way of dealing with some of the issues is to set up a multidisciplinary team to oversee the exercise; this was done both in TREND and in E-POD.

E-POD has identified some key areas for the short-term development of EIF.

- A standardised method for searching the Internet and assessing the validity of information. Even if English is a predominant language in the Internet, special attention should be paid to information in other Community languages.
- Data collection tools, and particularly a reporting template for one-off information requests need to be harmonised and streamlined to avoid overlapping with existing tools and information already available on a routine basis in the EMCDDA or elsewhere.
- Practical experience with triangulation will provide opportunities for grounded reflection about methods of detecting, monitoring and responding to emerging trends, and active cooperation between the EMCDDA and Member States should be encouraged.

According to the EMCDDA, the main strength of the E-POD approach has been that it is relatively easy and does not require investment in new data collection mechanisms. The work uses a focused and grounded (case study) approach that can produce useful outputs. The outputs are available faster because the information was collected and analysed centrally at the EMCDDA by a small team with a specific skill mix.

However, a case study approach has the weakness of being largely a reactive tool in the sense that the focus is on the analysis of existing data rather than on detecting new signals (early warning) and generating ongoing data sets that may be sensitive to changes.

6. CONCLUSIONS

These conclusions should be read in conjunction with Action 69 of the EU Drugs Action Plan (2009-2012), which calls for the Commission to assess the functioning of Council Decision 2005/387/JHA and propose amendments if needed. The conclusions from this staff working paper will be taken into account in the assessment.

The EMCDDA, ECDC, EMEA and Europol have worked on and continue to work on different aspects of emerging trends within their respective mandates and cooperation, e.g. through ad hoc meetings, is seen as very useful. Emerging trends involve a number of Commission Directorate-Generals, most directly Health and Consumers, Enterprise and Industry, and Justice, Freedom and Security. Cooperation between them is crucial. The main

emphasis here will be on trying to link public health monitoring of emerging trends and monitoring for the purpose of placing new psychoactive substances under control.

Work already carried out under the Early Warning System has resulted in clear, detailed operating guidelines on the roles of different actors, reporting forms etc. This work should be continued, following two strands.

(1) early identification and analysis of new substances on drug markets with a view to possible risk assessment and EU-wide control;

(2) early identification of emerging trends in the drug scene and drug markets, including poly-drug use, to allow rapid response to protect users' health and safety, reduce associated harm and ensure public health, public order and safety without necessarily aiming to add to the list of controlled substances.

The two strands distinguish between trends as such (e.g. poly-drug use), which by definition cannot be brought under legislative control in most Member States because the legislation on illicit drugs is substance-based, and the emergence of new substances which may then be brought under control. The current EWS may be used for this with some minor changes in the roles of those involved. As the producer of the most up-to-date information on communicable diseases, the ECDC has to be fully incorporated in the system.

The approach developed in the E-POD project will need to be considered in the light of the assessment of and/or possible amendment of Council Decision 2005/387/JHA. The strengths of E-POD have to do with its rapid system for information collection, analysis and dissemination. These should be converted from a case study approach into a system of monitoring, detecting, analysing and disseminating information on emerging trends on a continuous basis. The Reitox focal points, of course, play a key role but information from other sources should continue to be incorporated. The EMCDDA E-POD team should be the key facilitator and similar teams should be set up at national level. Further practical arrangements need to be discussed by the EMCDDA and the Reitox focal points under the Cooperation Agreements or Memorandums of Understanding between the EMCDDA, ECDC, EMEA, Europol and other relevant actors.

As far as information collection, exchange and analysis are concerned, this can be done under the legal framework provided by the Council Decision. However, it may be necessary to consider widening the legal base of the Decision to cover Article 152 of the EU Treaty (public health). This will be further explored in the assessment to be launched by the Commission in 2009.

There is also a need for a new type of risk assessment procedure based on information collected from different sources, which should be wider than the current system under Decision 2005/387/JHA. It should not only be on a particular substance but on, e.g.:

- new types of use, including poly-drug or combined use of licit and illicit substances, where expanding a substance-based control mechanism is not a realistic option;
- outbreaks of epidemics among the drug-using population (e.g. hepatitis and botulism among intravenous drug users).

The EMCDDA, ECDC and EMEA should be the primary producers of data under their respective remits and close, systematic cooperation between all of them is needed at all stages of the process. The detailed rules of procedure will need to be agreed but no legislative changes are envisaged for the time being.

Objective 23 of the EU Action Plan on Drugs calls for further development of instruments to monitor the drug situation and the effectiveness of responses to it. It covers the existing five key indicators of the EMCDDA, and identification of key indicators on supply reduction, drug markets, etc. (Action 67). The ability to identify emerging trends — and information collection, exchange and dissemination on them — should be a key consideration in developing new indicators and fine tuning existing ones, since an effective mechanism on emerging trends is only feasible as part as the overall monitoring mechanisms, not as a separate approach.