EMCDDA–Europol 2007 Annual Report on the implementation of Council Decision 2005/387/JHA

In accordance with Article 10 of Council Decision 2005/387/JHA on information exchange, risk assessment and control of new psychoactive substances

Overview

This is the third EMCDDA-Europol Annual Report on activities in support of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances (hereinafter the Decision) ([1]).

During 2007, fifteen new psychoactive substances were officially notified for the first time through the information exchange/Early-Warning System (EWS) set up by the Decision. Most of these were new psychotropic substances (i.e. synthetic drugs) similar to those listed in Schedules I and II of the 1971 United Nations Convention on Psychotropic Substances. However, the group of notified substances is rather diverse and, beside new synthetic drugs, includes medicinal products and naturally occurring substances.

This report describes in detail two important implementation developments which took place for the first time in 2007 – a risk assessment and an active monitoring report. Firstly, the EMCDDA and Europol submitted to the Council, the Commission and the European Medicines Agency (EMEA) a joint report on the new psychoactive substance 1-benzylpiperazine (BZP). Based on the joint report's recommendations, the Council formally requested a risk assessment of BZP. The risk assessment report was drawn up at a special session of the Extended Scientific Committee of the EMCDDA ([2]) and submitted to the Council and the Commission on 31 May 2007. Secondly, the EMCDDA and Europol prepared and submitted to the Commission a report on the findings of the active monitoring of the new psychoactive substance 1-(3-chlorophenyl)piperazine (mCPP). Both BZP and mCPP are dealt with in the relevant sections of the report.

The report also reiterates that challenges remain with respect to identifying comprehensive information sources and cost-effective mechanisms to allow a timely identification of the use of notified substances in the manufacture of medicinal products. Issues of a more general nature related to the identification of new substances, which the system has to face up to in the coming years should also be addressed, in order to maintain the operational nature of the EWS.

Finally, the lessons learnt from the process and outcome of the risk assessment of BZP provide insight into the mechanism's advantages and limitations in producing sound scientific evidence for decision-making within rigorous deadlines and at reasonable costs.

([1]) OJ L 127, 20.5.2005, p. 32.

([2]) This Committee consists of the regular EMCDDA Scientific Committee plus representatives from Europol, the EMEA and the Commission.

1. Introduction and background

Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances establishes 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. This allows European Union institutions and Member States to act on all new narcotic and psychotropic substances that appear on the European Union drug scene ([3]). The Decision also provides for an assessment of the risks associated with these new substances so that measures applicable in the Member States for the control of narcotic and psychotropic substances can also be applied to new psychoactive substances ([4]).

The EMCDDA and Europol, in close collaboration with their networks – the Reitox national focal points (NFPs) and Europol National Units (ENUs) respectively – are assigned a central role in detecting and reporting new psychoactive substances (Article 4). Furthermore, in cooperation with the EMEA, the two organisations may collect, analyse and present information on a new psychoactive substance in the form of a joint report (Article 5). The joint report provides evidence-based advice to the Council and the Commission on the need to request a risk assessment on a new psychoactive substance. Such a risk assessment examines the health and social risks posed by the use of, the manufacture of, and traffic in, a new psychoactive substance, the involvement of organised crime and the possible consequences of control measures. In order to carry out the risk assessment, the EMCDDA convenes a special meeting under the auspices of its Scientific Committee (Article 6).

To ensure transparency in the implementation of the Decision, Article 10 stipulates that: 'The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The report shall, in particular, include experience relating to coordination between the system set out in this Decision and the pharmacovigilance system.'

In compliance with the above provision, the EMCDDA and Europol herein present the third annual report on the implementation of the Decision for the period January to December 2007. The report outlines the results of the implementation and describes key issues arising from accumulated experiences. Thus, the report also serves as a monitoring tool which provides the Commission with information for its annual progress review on the implementation of the EU Drugs Action Plan (2005–2008).

The report is written as a stand-alone document with its annexes kept to a minimum, while extensive footnote referencing is provided to relevant official documents. The report frequently refers to articles of the Decision, therefore, to facilitate its reading the

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([3]) Under the definitions of the Council Decision 'new psychoactive substance' means a new narcotic drug or a new psychotropic drug in pure form or in a preparation; 'new narcotic drug' means a substance in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedules I, II or IV; 'new psychotropic drug' means a substance in pure form or in a preparation that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedules I, II, III or IV.

([4]) In compliance with the provisions of the 1961 UN Single Convention on Narcotic Drugs and the 1971 UN Convention on Psychotropic Substances.

full text of the Decision is annexed (Annex 1). When describing the notified new psychoactive substances the report presents sufficiently detailed information, whilst avoiding highly technical descriptions. However, more comprehensive information on new substances described in the report is available from the EMCDDA and Europol.

2. Implementation of the Decision and results

2.1 Specific implementation arrangements

2.1.1 EWS and risk assessment guidelines

To operationalise the implementation of the information exchange/early-warning mechanism set-up by the Decision, the EMCDDA and Europol have prepared, tested and are implementing *Operating guidelines of the Early-Warning System on new psychoactive substances*. In 2007, the guidelines were officially published by the two organisations ([5]) and distributed to all partners in the EU Institutions and the Member States.

Furthermore, the EMCDDA has undertaken to assist the Agency's Scientific Committee in modifying the conceptual framework for risk assessment of new psychoactive substances in line with the scope and mechanism set up by the Decision and in view of the experiences accumulated during the period 1999-2007. Adaptation of the existing *Guidelines for the risk assessment of new synthetic drugs* is underway and is expected to be finalised in 2008 by the newly elected EMCDDA Scientific Committee. To support this process, during its final meeting in December 2007, the outgoing Scientific Committee made a few specific recommendations (see section 3.2).

2.1.2 Cooperation with the United Nations system

The World Health Organisation (WHO) is the specialised United Nations Agency designated for the evaluation of the medical, scientific and public health aspects of psychoactive substances under the 1961 and 1971 United Nations drug control Conventions.

Article 5.2(e) of the Decision requires the EMCDDA-Europol joint reports and risk assessment reports to include information on 'whether or not a new substance is currently under assessment, or has been under assessment by the UN system'. To obtain such information, the EMCDDA has established a close collaboration with the Department of Medicines Policy and Standards at WHO headquarters. The cooperation is fully operational and the required information is obtained practically without delay. In 2007, the WHO answered a request concerning the assessment status of BZP, informing the EMCDDA and Europol that the substance is currently not under assessment and has not been under assessment by the UN system.

2.2 Cooperation with EMEA and the pharmacovigilance system

The EMEA is a key partner in the implementation of the system set up by the Decision. Article 1 which defines the subject matter of the Decision stipulates that the mechanism for a rapid exchange of information on new psychoactive substances takes note of information on suspected adverse reactions to be reported under the pharmacovigilance

([5]) See http://www.emcdda.europa.eu/index.cfm?fuseaction=public.Content&nnodeid=431&sLanguageiso=EN

system. In accordance with Article 4(3), EMEA submits to Europol and the EMCDDA information on the marketing authorisation status of a new psychoactive substance in the European Union or in any Member State. Furthermore, Article 6(2) of the Decision stipulates that EMEA takes part in the extended Scientific Committee for the risk assessment on new psychoactive substances. In 2007, two EMEA experts participated in the meeting on the risk assessment of BZP.

In the spirit of the Decision, to ensure that no deterioration of either human or veterinary health care is permitted, all possible precautions are taken by the EMCDDA and the EMEA to guarantee that substances of established and acknowledged medical value are excluded from risk assessment and control measures based on the Decision. In 2007, whilst preparing the joint report and the risk assessment on BZP, extensive information exchange took place between the two Agencies and their respective networks in order to determine clearly that BZP has no established and acknowledged medical value and that there are no licensed medicinal products containing BZP in the European Union. Moreover, in anticipation of Article 7(3) and for the preparation of the risk assessment, in relation to the manufacturing of medicinal products in the European Union, the EMEA, in consultation with the EMCDDA, established that BZP is not used as an intermediate for the synthesis of a medicinal product.

Article 10 of the Decision requires that the annual report on the implementation of the Decision includes experiences relating to coordination between the mechanism set-up by the Decision and the pharmacovigilance system. Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce risks and increase risk-benefits from medicines. It is a key public health function and comprises: collecting and managing data on the safety of medicines; looking at the data to detect 'signals' (any new or changing safety issue); evaluating the data and making decisions with regard to safety issues; acting to protect public health (including regulatory action); communicating with stakeholders; and audit, both of the outcomes of action taken and of the key processes involved. The main players directly involved in pharmacovigilance include: pharmaceutical companies; patients as the users of medicines; healthcare professionals working with medicines (physicians, pharmacists, nurses, etc); regulatory authorities including the EMEA and those in each Member State responsible for monitoring the safety of medicines.

At present, the EMCDDA and the EMEA are implementing on an *ad hoc* basis a bilateral information exchange of data available through the Reitox EWS and the European Union pharmacovigilance system. Formalising the scope and nature of the information exchange on misuse of substances with medical value (i.e. medicinal products authorised in the Community) is an area of collaboration which is under development. Steps currently being considered are that the EMCDDA could report on a regular basis to the EMEA on misused medicinal substances in order to complement the somewhat inherent 'under-reporting' on misuse in the pharmacovigilance system. In addition, the EMEA could provide the EMCDDA with information on misuse of marketed products under conditions of confidentiality that need to be defined. Further synergies could be identified, for example, on the risk management plans of selected medicinal products.

In a recent technical meeting between the two Agencies, it was agreed that preparation of a cooperation framework will be undertaken by the end of 2008. It was also recognised that any further formalisation of the EMCDDA-EMEA collaboration should evolve within the mandates of the two Agencies while taking into account the operational

priorities and resources available. The consultation currently carried out by the Commission (DG Enterprise and Industry) on legislative proposals to strengthen and rationalise the European Union pharmacovigilance system, could be an appropriate opportunity to strengthen the basis of EMCDDA-EMEA cooperation.

2.3 Active monitoring of mCPP

The joint report on 1-(3-chlorophenyl)piperazine (mCPP) was submitted to the Council, the Commission and the EMEA on 28 October 2005 ([6]). In accordance with the joint report's findings, the Council decided that no risk assessment should be carried out since mCPP is used in some Member States to manufacture a medicinal product and thus falls under the provisions of Article 7.3 of the Decision ([7]). However, given the concern mCPP is causing, the Commission asked the EMCDDA and Europol to carry out further work in accordance with their mandates and the resources available to assess the importance of mCPP in the European Union illicit drugs market. In compliance with this request, in 2006 and 2007 the two organisations collected further data on mCPP through their respective networks.

In March 2007, the EMCDDA organised a technical expert meeting to evaluate the scientific evidence on the potential threat of mCPP. The meeting involved input from Europol, Member States experts and the Commission, but did not have the mandate or the extent and depth of a risk assessment. As a result, the EMCDDA and Europol submitted a concise report to the Commission on their findings. The report was produced for information purposes and has no legal status under the Decision.

The report states that in 2006-2007, mCPP seems to be more widely available on the illicit drugs market than in 2004-2005. This is evidenced by the significant increase both in the number of seizures and the amount of seized material reported to Europol and the EMCDDA. mCPP has been encountered in all 27 Member States ([8]) and Norway. Geographically and quantity-wise, mCPP is the most widely encountered new psychoactive substance ever since the monitoring of new drugs started through the establishment of the European early warning system in 1997. This is all the more noteworthy since mCPP seizures may be under reported as in most Member States it is a non-controlled substance. Currently, eight Member States control mCPP under drug control or equivalent legislation as follows: Belgium, Denmark, Germany ([9]), Greece, Hungary, Lithuania, Malta and Slovakia. In three Member States – Finland, the Netherlands and Spain – mCPP is controlled under medicines-related legislation.

The report, however, concluded that mCPP seems unlikely to establish itself as a recreational drug in its own right. Since mCPP has no particular appeal to users, it seems that the mCPP market in the European Union is driven by a supply push rather than a demand pull. On the other hand, the Member States still face the question on how to deal with a substance, which based on the available scientific evidence, appears not to pose a substantial threat to individual health, but is being largely distributed via the

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([6]) 14409/05 CORDROGUE 73
([7]) 15832/05 CORDROGUE 88
([8]) In the last days of 2007, Cyprus reported its first mCPP encounter, thus the substance has now been found in all 27 Member States.
([9]) Emergency decree 20 BtMÄndV, 14.02.2007, published 23.02.2007; the amendment is limited for 12 months and became effective on 1 March 2007.

illegal drugs market, thus creating certain risks related to manufacture, trafficking, organised crime, etc.

2.4 Risk assessment of benzylpiperazine (BZP)

In compliance with the provisions of Article 5 of the Decision, the EMCDDA and Europol submitted on 23 February 2007 to the Council, the Commission and the EMEA a joint report on the new psychoactive substance 1-benzylpiperazine (BZP) ([10]). Based on the joint report's recommendations, and in accordance with Article 6(1) of the Decision, on 23 March 2007, the Council formally requested that 'the risks, including the health and social risks, caused by the use of, the manufacture of, and traffic in, a new psychoactive substance, the involvement of organised crime and possible consequences of control measures, be assessed' for BZP.

In accordance with Article 6(2), the meeting to assess the risks of BZP was convened under the auspices of the EMCDDA Scientific Committee with the participation of experts from the Commission, Europol and the EMEA. The meeting took place on 30 May 2007 at the EMCDDA in Lisbon. The risk assessment was carried out on the basis of information provided to the Scientific Committee by the Member States, the EMCDDA, Europol and the EMEA.

In compliance with Article 6.4, on completion of the risk assessment, a risk assessment report was drawn up by the Extended Scientific Committee ([11]). It presented an analysis of the scientific and law enforcement information available, and reflected all opinions held by the members of the Committee. The risk assessment report was submitted to the Commission and the Council, within the stipulated period of twelve weeks from the date of notification by the General Secretariat of the Council.

The overall conclusion of the risk assessment report was that: 'due to its stimulant properties, risk to health and lack of medical benefits, there is a need to control BZP ([12]). However, the Committee felt that the control measures should be appropriate to the relatively low risks of the substance.'

Further deliberations of the Committee were that: 'there is no evidence that the substance is safe for human consumption. As consumers are not protected then an argument must exist that drug control legislation may be appropriate. Such control would avoid problems in international law enforcement and judicial cooperation. However, it should also be noted that the evidence for harms arising from this drug are not strong and control measures could lead to increasing criminal involvement and possible replacement with other substances.'

The Committee also recommended that if a decision is made to place BZP under control, this should not inhibit the gathering and dissemination of accurate information on BZP to users and to relevant professionals. Furthermore, it was recognised that many of the questions posed by the lack of evidence on the health and social risks of BZP could be answered through relatively simple research. A strong conclusion of the Committee

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([10]) 6645/07 CORDROGUE 17
([11]) 10458/07 CORDROGUE 35
([12]) At the time of preparation of this report (Jan-Feb 2008), eight Member States control BZP under drug control or equivalent legislation, as follows: Belgium, Denmark, Estonia, Greece, Italy, Lithuania, Malta and Sweden; two further Member States – the Netherlands and Spain – control BZP under medicines-related legislation.

was that further studies are needed, especially in respect to potential neurotoxicity and social consequences.

The Chairman of the Scientific Committee presented the risk assessment report before the Horizontal Working Party on Drugs at its meeting on 5 September 2007. Following the recommendations of the risk assessment report, the Commission submitted a proposal for a Council Decision on defining 1-benzylpiperazine (BZP) as a new psychoactive drug which is to be made subject to control measures and criminal provisions ([13]). Subsequently, the Horizontal Working Party on Drugs agreed on the Commission's proposal and, after the consultation with the European Parliament, invited COREPER to agree on the text and ask the Council to adopt the decision ([14]).

2.5 New psychoactive substances notified in 2007

During 2007, a total of fifteen new psychoactive substances were officially notified for the first time through the EWS to the EMCDDA and/or Europol (see Annex 2). Subsequently, all new compounds were entered into the EMCDDA database on new drugs (EDND) and added to the list of substances monitored by the two Institutions. The number of new substances notified in 2007 is higher than those notified in 2006 when seven new psychotropic substances were reported for the first time. It is, however, comparable with the number of new substances (fourteen) reported in 2005. The group of newly notified substances is rather diverse and, beside new synthetic drugs *per se*, includes medicinal products, a metabolite/derivative of a medicinal product and naturally occurring substances.

The majority of the newly reported compounds (nine) were psychotropic substances, i.e. synthetic drugs, similar to those listed in Schedules I and II of the 1971 United Nations Convention on Psychotropic Substances. They included substances from better known chemical groups such as phenethylamines, tryptamines and piperazines, as well as substances with a less common chemical make-up. The group is equally divided between substances that have pronounced hallucinogenic effects and those that exhibit predominantly stimulant properties (cf Annex 2 – substances 1 to 9).

The group of reported substances which have (or may have) medicinal value includes a medicinal product (Glaucine) that is nationally authorised in some Member States ([15]), as well as a benzodiazepine derivative, which is not nationally or centrally authorised in the European Union, but is used as medicinal product in other parts of the world. This group also includes a metabolite/derivative of a medicinal product (cf Annex 2 – substances 10 to 13).

For the first time in 2007, three naturally occurring psychotropic substances have been reported through the information exchange mechanism; among them a plant – *salvia divinorum*. All three are known from literature and do not seem to represent a substantial new challenge at present. However, further vigilance with regard to *salvia divinorum* will be exercised since in the last years, at least three Member States (Belgium, Denmark and Italy) have already undertaken to control under their drug laws both the whole plant and its main active ingredient salvinorine A, or only the latter (Sweden) (cf Annex 2 – substances 14 to 16).

([13]) 11974/07 CORDROGUE 56
([14]) 12970/07 CORDROGUE 68 SAN 168
([15]) Glaucine is used in Bulgaria, Romania as well as in Iceland and Russia.

The 2006 Annual Report on the implementation of the Decision ([16]) singled out two potent hallucinogens ([17]) as exhibiting characteristics suggesting that they were particularly appropriate for further vigilance. None of them appears to have gained popularity in 2007, but bromo-dragonfly continues to cause specific concern in terms of its potency and toxicity. In 2008, the EWS will continue to monitor this compound closely.

2.6 Information exchange beyond the immediate scope of the Decision

The early-warning system on new psychoactive substances has a proven capacity to provide value beyond the immediate scope of the Decision. For example, on a few occasions in 2007, the EMCDDA issued public health-relevant warnings to the Reitox network partners concerning unusual hazards related to controlled substances. In particular on: cannabis contaminated with glass beads found in France, the United Kingdom, the Netherlands and Belgium; intoxications due to cocaine adulterated with atropine which occurred in Italy, Austria and the Netherlands; and lead poisonings possibly due to consumption of contaminated cannabis in Germany. However, the lack of scientifically verified information in most of these cases makes the definition and follow-up of such actions difficult.

Furthermore, information on various other controlled or non-controlled substances, with or without psychoactive properties, is occasionally exchanged through the information exchange mechanism set up by the Decision. However, the appraisal of such information did not warrant further action.

The Council Decision stimulates the identification, monitoring and exchange of information on emerging trends in new uses of existing substances and on possible public health-related measures. The EWS is therefore a valuable asset and an active player in implementing the EMCDDA's tool for detecting, tracking and understanding emerging drug trends called the European Perspective on Drugs (E-POD). The EWS contributes through delivering and analysing information from various sources, such as forensic science, toxicology, law enforcement, etc.

In the framework of E-POD, a thematic paper on gamma-hydroxybutyrate (GHB) and its precursor gamma-butyrolactone (GBL) was prepared in 2007 ([18]). GHB was risk assessed (2000) under the 1997 Joint action on new synthetic drugs ([19]). In March 2001, it was added to Schedule IV of the 1971 United Nations Convention, thus all European Union Member States were bound to control it under their legislation addressing psychotropic substances. The thematic paper states that the new controls rapidly curtailed the previously open sale of GHB. However, there is increased concern on the use of its precursor chemicals, GBL and 1,4-butanediol, that are rapidly converted to GHB when ingested and which are not covered by international drug control laws. Recently, direct consumption of GBL has been reported.

([16]) 5923/07 CORDROGUE 13

([17]) DOI (2,5-dimethoxy-4-iodoamphetamine) and bromo-dragonfly (bromo-benzodifuranyl-isoprophylamine).

([18]) See http://www.emcdda.europa.eu/html.cfm/index7079EN.html

([19]) OJ L 167, 25.6.1997, p. 1.

3. Issues arising from the implementation experiences

3.1 The information exchange/early warning system

In 2007, the range of substances notified by the Member States to the EMCDDA and/or Europol via the information exchange mechanism broadened to include not only new psychotropic substances (i.e. new synthetic drugs), but also medicinal products and naturally occurring substances and a plant. Some of the reported substances that might have medical value pose a challenge in terms of interpreting the scope of the Decision and, consequently, on possible decisions for further action. For example, careful consideration should be given before deciding whether or not to act on substances which are not authorised as medicinal products in the European Union, but are used as medicines in other parts of the world. Such a decision requires a broader consultation involving the EMCDDA, the EMEA, Europol and the Commission. Furthermore, notifying and monitoring psychoactive plants via the EWS may require different reporting approaches since issues related to the presence of more than one psychoactive ingredient, potency, cultivating, etc., should be appropriately addressed.

To add to this complexity, some of the new substances that appeared on the recreational drugs market in 2007 present an interesting new phenomenon, as pharmacologically they may act on the central nervous system, but their psychoactive properties are indistinct or unspecific. Such substances include, for example, some of the new piperazines, but also the medicinal product Glaucine which has been marketed as a 'piperazine-free' product.

The list of monitored substances is continuously growing and diversifying and some of the newly identified substances are from uncommon chemical groups, rarely or never reported before via the EWS since its establishment in 1997. This creates difficulties for forensic identification and brings up persistently the question of the availability of reference materials, especially where limited scientific literature or analytical details are available.

The EMEA and the EMCDDA successfully implemented the requirements of Article 7(3) and were able to establish that BZP is not used as an intermediate for the synthesis of a medicinal product. However, in the absence of a European Union database on the synthetic routes of all registered medicinal products, the collection of information could not be exhaustive when drafting the joint report and even the risk assessment. The request to search if a substance is used for the synthesis of a medicinal product is difficult, time-consuming, often incomplete and under time constraint for the EMEA and the Member States.

3.2 The risk assessment procedure

In 2007, risk assessment was implemented for the first time under the terms of the Decision. In preparing the risk assessment, the responsible Institutions and their partners in the Member States demonstrated that the system set up in the Decision is operational and able to abide by the strict deadlines as stipulated by the Decision. Furthermore, given the complexity of the work, the risk assessment report presented unambiguous and, as far as possible, evidence-based advice to the Council and the Commission. However, the risk assessment report concludes by noting that many of the questions posed by the lack of evidence on the health and social risks of BZP could be answered through relatively simple research. Furthermore, a clear conclusion of the

Scientific Committee was that further studies are needed, especially in respect to potential neurotoxicity and social consequences.

The Decision does not provide for a range of options for control of new psychoactive substances to be considered. Under Article 9(1) of the Decision, the option for control that is available at European Union level is for the Member States to submit the new psychotropic drug BZP to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances. Therefore, even though the Committee unanimously agreed that there is a need to control BZP, it was aware that such a measure could have contradictory effects. On one hand, it could limit the potential for expansion of the supply and use of BZP by facilitating the capacity for the detection and monitoring of illegal manufacturing of and trafficking in BZP and international law enforcement cooperation. On the other hand, it could create an illegal market in BZP with an increased risk of criminal activity, or even lead to its replacement with other psychoactive substances which may also have public health consequences.

To address some of the current data limitations in the risk assessment process, the outgoing Scientific Committee made a number of specific recommendations as to the future conceptualisation and implementation of risk assessments. In particular, it stressed the need to review the risk assessment items related to the involvement of organised crime with an input from Europol so as to better reflect the increased emphasis on this domain within the Decision. Furthermore, the Committee recognised that a numerical scoring system could be a useful working tool in the preparation of the actual risk assessment, but it should not constitute a formal part of the risk assessment report. Such a system could be used as a trigger to focus the discussion on relevant items. It was proposed that only items where severe or moderate risk ratings are presented by individual Committee members should be put forward and discussed by the full risk assessment Committee. Finally, to increase the operational nature of the Committee, the risk assessment meetings could explore the viability of using small working groups and rapporteurs for each assessed domain.

4. Conclusion

The EMCDDA, Europol and their respective networks, with the active participation of the EMEA, have developed and are implementing at European Union level the necessary organisational framework and monitoring tools for the dynamic functioning of the information exchange mechanism as set up by the Decision. In addition, the early-warning system is a valuable asset and an active player in detecting and responding proactively to new phenomena beyond the immediate scope of the Decision.

In preparing and carrying out the risk assessment of BZP, the Institutions involved, Member State partners and the EMCDDA Extended Scientific Committee demonstrated that the system is operational and able to abide by the strict deadlines as stipulated by the Decision. The decision-making process both at the level of the information exchange and the risk assessment is transparent and, as far as possible, evidence-based. However, taking into account the nature of the new drugs phenomenon, any risk assessment on a substance at an early stage of knowledge and scientific evidence would inevitably have an element of inconclusiveness. If additional time and resources are available, some of the data limitations for the risk assessment exercise could be partly addressed through initial research.

In line with the extended scope of the Decision, the reported new psychoactive substances in 2007 have diversified to include medicinal products, naturally-occurring substances and a plant. Some of the newly identified substances are from uncommon chemical groups, never reported before via the early-warning system, which may create difficulties for their forensic identification. Furthermore, some of the reported medicinal products and substances that might have medical value pose a challenge in terms of interpreting the scope of the Decision and, consequently, on possible decisions for further action. Deepening the cooperation with the European Medicines Agency and its pharmacovigilance system will be crucial in dealing with such substances.

In 2007, adequate evidence has been accumulated which allows for a better understanding of key aspects required for an assessment of the efficacy and achievements of the system created by the Decision, both regarding the information collection phase of the mechanism and the risk assessment procedure. Nonetheless, if a fully-fledged assessment of the mechanism is to be undertaken, the 2005 and 2006 annual implementation reports should also be taken into consideration as they collectively provide useful and comprehensive information.

Annexes

Annex 1 – COUNCIL DECISION 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances

Annex 2 – New psychoactive substances reported to the EMCDDA and Europol for the first time in 2007 under the terms of Council Decision 2005/387/JHA

(Acts adopted under Title VI of the Treaty on European Union)

COUNCIL DECISION 2005/387/JHA

of 10 May 2005

on the information exchange, risk-assessment and control of new psychoactive substances

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 29, 31(1)(e) and 34 (2)(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) The particular dangers inherent in the development of psychoactive substances require rapid action by the Member States.

(2) When new psychoactive substances are not brought within the scope of criminal law in all Member States, problems may arise in cooperation between the judicial authorities and law enforcement agencies of Member States owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State.

(3) The European Union Action Plan on Drugs 2000-2004 provided for the Commission to organise an appropriate assessment of the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs [2] (herineafter 'the Joint Action') taking into account the external evaluation commissioned by the European Monitoring Centre on Drugs and Drug Addiction (hereinafter 'the EMCDDA') of the early warning system. The assessment showed that the Joint Action had fulfilled its expectations. Nevertheless, the outcome of the assessment made it clear that the Joint Action was in need of reinforcement and reorientation. In particular, its main objective, the clarity of its procedures and definitions, the transparency of its operation, and the relevance of its scope had to be redefined. The Communication from the Commission to the European Parliament and the Council on the mid-term evaluation of the EU Action Plan on Drugs (2000-2004) indicated that changes to the legislation would be introduced in order to enhance action against synthetic drugs. The mechanism as established by the Joint Action should therefore be adapted.

(4) New psychoactive substances can be harmful to health.

(5) The new psychoactive substances covered by this Decision may include medicinal products as defined in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products [3] and in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use [4].

(6) The information exchange under the early warning system, established under the Joint Action, has proved to be a valuable asset to the Member States.

(7) Nothing in this Decision should prevent Member States from exchanging information, within the European Information Network on Drugs and Drug Addiction (hereinafter '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.

(8) No deterioration of either human or veterinary health care as a result of this Decision will be permitted. Substances of established and acknowledged medical value are therefore excluded from control measures based on this Decision. Suitable regulatory and public health related measures should be taken for substances of established and acknowledged medical value that are being misused.

[1] Opinion delivered on 13 January 2004 (not yet published in the Official Journal).

[2] OJ L 167, 25.6.1997, p. 1.

[3] OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(9) In addition to what is provided for under the pharmacovigilance systems as defined in Directive 2001/82/EC and in Directive 2001/83/EC, the exchange of information on abused or misused psychoactive substances needs to be reinforced and appropriate cooperation with the European Medicines Agency (hereinafter 'EMEA') ensured. The United Nations Commission on Narcotic Drugs (hereinafter 'CND') Resolution 46/7 'Measures to promote the exchange of information on new patterns of drug use and on psychoactive substances consumed', provides a useful framework for action by the Member States.

(10) The introduction of deadlines into every phase of the procedure established by this Decision should guarantee that the instrument can react swiftly and enhances its ability to provide a quick-response mechanism.

(11) The Scientific Committee of the EMCDDA has a central role in the assessment of the risks associated with a new psychoactive substance, it will for the purpose of this Decision be extended to include experts from the Commission, Europol and the EMEA, and experts from scientific fields not represented, or not sufficiently represented, in the Scientific Committee of the EMCDDA.

(12) The extended Scientific Committee that assesses the risks associated with new psychoactive substances should remain a concise technical body of experts, capable of assessing effectively all risks associated with a new psychoactive substance. Therefore the extended Scientific Committee should be kept to a manageable size.

(13) Since the objectives of the proposed action, namely to bring about an exchange of information, a risk-assessment by a scientific committee and an EU-level procedure for bringing notified substances under control, cannot be sufficiently achieved by the Member States and can therefore, by reason of the effects of the envisaged action, be better achieved at European Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Decision does not go what is beyond what is necessary in order to achieve those objectives

(14) In conformity with Article 34(2)(c) of the Treaty, measures based upon this Decision can be taken by qualified majority as these measures are necessary to implement this Decision.

(15) This Decision respects fundamental rights and observes the principles recognised by Article 6 of the Treaty and reflected in the Charter of Fundamental Rights of the European Union,

HAS DECIDED AS FOLLOWS:

Article 1

Subject matter

This Decision establishes a mechanism for a rapid exchange of information on new psychoactive substances. It takes note of information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC.

This Decision also provides for an assessment of the risks associated with these new psychoactive substances in order to permit the measures applicable in the Member States for control of narcotic and psychotropic substances to be applied also to new psychoactive substances.

Article 2

Scope

This Decision applies to substances not currently listed in any of the schedules to:

(a) the 1961 United Nations Single Convention on Narcotic Drugs, that may pose a comparable threat to public health as the substances listed in Schedule I or II or IV thereof, and

(b) the 1971 United Nations Convention on Psychotropic Substances, that may pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV thereof.

This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [1], and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors [2] provide for a Community regime.

Article 3

Definitions

For the purpose of this Decision the following definitions shall apply:

(a) 'new psychoactive substance' means a new narcotic drug or a new psychotropic drug in pure form or in a preparation;

[1] OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).
[2] OJ L 47, 18.2.2004, p. 1.

(b) 'new narcotic drug' means a substance in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV;

(c) 'new psychotropic drug' means a substance in pure form or in a preparation that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV;

(d) 'marketing authorisation' means a permission to place a medicinal product on the market, granted by the competent authority of a Member State, as required by Title III of Directive 2001/83/EC (in the case of medicinal products for human use) or Title III of Directive 2001/82/EC (in the case of veterinary medicinal products) or a marketing authorisation granted by the European Commission under Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([1]);

(e) 'United Nations system' means the World Health Organisation (WHO), the Commission on Narcotic Drugs (CND) and/or the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances;

(f) 'preparation' means a mixture containing a new psychoactive substance;

(g) 'Reporting Form' means a structured form for notification of a new psychoactive substance and/or of a preparation containing a new psychoactive substance agreed between the EMCDDA/Europol and their respective networks in the Member States' Reitox and the Europol National Units.

Article 4

Exchange of information

1. Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the manufacture, traffic and use, including supplementary information on possible medical use, of new psychoactive substances and of preparations containing new psychoactive substances, to Europol and the EMCDDA, taking into account the respective mandates of these two bodies.

([1]) OJ L 136, 30.4.2004, p. 1.

Europol and the EMCDDA shall collect the information received from Member States through a Reporting Form and communicate this information immediately to each other and to the Europol National Units and the representatives of the Reitox network of the Member States, the Commission, and to the EMEA.

2. Should Europol and the EMCDDA consider that the information provided by a Member State on a new psychoactive substance does not merit the communication of information as described in paragraph 1, they shall inform the notifying Member State immediately thereof. Europol and the EMCDDA shall justify their decision to the Council within six weeks.

Article 5

Joint Report

1. Where Europol and the EMCDDA, or the Council, acting by a majority of its members, consider that the information provided by the Member State on a new psychoactive substance merits the collection of further information, this information shall be collated and presented by Europol and the EMCDDA in the form of a Joint Report (hereinafter the 'Joint Report'). The Joint Report shall be submitted to the Council, the EMEA and the Commission.

2. The Joint Report shall contain:

(a) a chemical and physical description, including the name under which the new psychoactive substance is known, including, if available, the scientific name (International Non-proprietary Name);

(b) information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered, and information on the means and methods of manufacture of the new psychoactive substance;

(c) information on the involvement of organised crime in the manufacture or trafficking of the new psychoactive substance;

(d) a first indication of the risks associated with the new psychoactive substance, including the health and social risks, and the characteristics of users;

(e) information on whether or not the new substance is currently under assessment, or has been under assessment, by the UN system;

(f) the date of notification on the Reporting Form of the new psychoactive substance to the EMCDDA or to Europol;

(g) information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State;

(h) as far as possible, information will be made available on:

(i) the chemical precursors that are known to have been used for the manufacture of the substance,

(ii) the mode and scope of the established or expected use of the new substance,

(iii) any other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks.

3. The EMEA shall submit to Europol and the EMCDDA the following information on whether in the European Union or in any Member State:

(a) the new psychoactive substance has obtained a marketing authorisation;

(b) the new psychoactive substance is the subject of an application for a marketing authorisation;

(c) a marketing authorisation that had been granted in respect of the new psychoactive substance has been suspended.

Where this information relates to marketing authorisations granted by Member States, these Member States shall provide the EMEA with this information if so requested by it.

4. Member States shall provide the details referred to under paragraph 2 within six weeks from the date of notification on the Reporting Form as set out in Article 4(1).

5. The Joint Report shall be submitted no more than four weeks after the date of receipt of the information from Member States and the EMEA. The Report shall be submitted by Europol or the EMCDDA, as appropriate, in accordance with Article 5(1) and (2).

Article 6

Risk assessment

1. The Council, taking into account the advice of Europol and the EMCDDA, and acting by a majority of its members, may request that the risks, including the health and social risks, caused by the use of, the manufacture of, and traffic in, a new psychoactive substance, the involvement of organised crime and possible consequences of control measures, be assessed in accordance with the procedure set out in paragraphs 2 to 4, provided that at least a quarter of its members or the Commission have informed the Council in writing that they are in favour of such an assessment. The Member States or the Commission shall inform the Council thereof as soon as possible, but in any case within four weeks of receipt of the Joint Report. The General Secretariat of the Council shall notify this information to the EMCDDA without delay.

2. In order to carry out the assessment, the EMCDDA shall convene a special meeting under the auspices of its Scientific Committee. In addition, for the purpose of this meeting the Scientific Committee may be extended by a further five experts at most, to be designated by the Director of the EMCDDA, acting on the advice of the Chairperson of the Scientific Committee, chosen from a panel of experts proposed by Member States and approved every three years by the Management Board of the EMCDDA. Such experts will be from scientific fields that are not represented, or not sufficiently represented, in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the possible risks, including health and social risks. Furthermore, the Commission, Europol and the EMEA shall each be invited to send a maximum of two experts.

3. The risk assessment shall be carried out on the basis of information to be provided to the scientific Committee by the Member States, the EMCDDA, Europol, the EMEA, taking into account all factors which, according to the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances, would warrant the placing of a substance under international control.

4. On completion of the risk assessment, a report (hereinafter the 'Risk Assessment Report') shall be drawn up by the Scientific Committee. The Risk Assessment Report shall consist of an analysis of the scientific and law enforcement information available, and shall reflect all opinions held by the members of the Committee. The Risk Assessment Report shall be submitted to the Commission and Council by the chairperson of the Committee, on its behalf, within a period of twelve weeks from the date of the notification by the General Secretariat of the Council to the EMCDDA referred to in paragraph 1.

The Risk Assessment Report shall include:

(a) the physical and chemical description of the new psychoactive substance and its mechanisms of action, including its medical value;

(b) the health risks associated with the new psychoactive substance;

(c) the social risks associated with the new psychoactive substance;

(d) information on the level of involvement of organised crime and information on seizures and/or detections by the authorities, and the manufacture of the new psychoactive substance;

(e) information on any assessment of the new psychoactive substance in the United Nations system;

(f) where appropriate, a description of the control measures that are applicable to the new psychoactive substance in the Member States;

(g) options for control and the possible consequences of the control measures, and

(h) the chemical precursors that are used for the manufacture of the substance.

Article 7

Circumstances where no risk assessment is carried out

1. No risk assessment shall be carried out in the absence of a Europol/EMCDDA Joint Report. Nor shall a risk assessment be carried out where the new psychoactive substance concerned is at an advanced stage of assessment within the United Nations system, namely once the WHO expert committee on drug dependence has published its critical review together with a written recommendation, except where there is significant new information that is relevant in the framework of this Decision.

2. Where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule the new psychoactive substance under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, a risk assessment shall be carried out only if there is significant new information that is relevant in the framework of this Decision.

3. No risk assessment shall be carried out on a new psychoactive substance if:

(a) the new psychoactive substance is used to manufacture a medicinal product which has been granted a marketing authorisation; or,

(b) the new psychoactive substance is used to manufacture a medicinal product for which an application has been made for a marketing authorisation or,

(c) the new psychoactive substance is used to manufacture a medicinal product for which a marketing authorisation has been suspended by a competent authority.

Where the new psychoactive substance falls into one of the categories listed under the first subparagraph, the Commission, on the basis of data collected by EMCDDA and Europol, shall assess with the EMEA the need for further action, in close cooperation with the EMCDDA and in accordance with the mandate and procedures of the EMEA.

The Commission shall report to the Council on the outcome.

Article 8

Procedure for bringing specific new psychoactive substances under control

1. Within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present to the Council an initiative to have the new psychoactive substance subjected to control measures. If the Commission deems it is not necessary to present an initiative on submitting the new psychoactive substance to control measures, within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present a report to the Council explaining its views.

2. Should the Commission deem it not necessary to present an initiative on submitting the new psychoactive substance to control measures, such an initiative may be presented to the Council by one or more Member States, preferably not later than six weeks from the date on which the Commission presented its report to the Council.

3. The Council shall decide, by qualified majority and acting on an initiative presented pursuant to paragraph 1 or 2, on the basis of Article 34(2) (c) of the Treaty, whether to submit the new psychoactive substance to control measures.

Article 9

Control measures taken by Member States

1. If the Council decides to submit a new psychoactive substance to control measures, Member States shall endeavour to take, as soon as possible, but no later than one year from the date of that decision, the necessary measures in accordance with their national law to submit:

(a) the new psychotropic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances;

(b) the new narcotic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1961 United Nations Single Convention on Narcotic Drugs.

2. Member States shall report the measures taken to both the Council and the Commission as soon as possible after the relevant decision has been taken. Thereafter this information shall be communicated to the EMCDDA, Europol, the EMEA, and the European Parliament.

3. Nothing in this Decision shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified by a Member State.

Article 10

Annual report

The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The Report shall, in particular, include experience relating to coordination between the system set out in this Decision and the pharmacovigilance system.

Article 11

Pharmacovigilance system

Member States and the EMEA shall ensure an appropriate exchange of information between the mechanism set up by means of this Decision and the pharmacovigilance systems as defined and established under Title VII of Directive 2001/82/EC and Title IX of Directive 2001/83/EC.

Article 12

Repeal

The Joint Action on New Synthetic Drugs of 16 June 1997 is hereby repealed. Decisions taken by the Council based on Article 5 of that Joint Action shall continue to be legally valid.

Article 13

Publication and taking effect

This Decision shall take effect on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 10 May 2005.

For the Council
The President
J. KRECKÉ

European Monitoring Centre for Drugs and Drug Addiction

EUROPOL

EMCDDA–Europol 2007 Annual Report on the implementation of Council Decision 2005/387/JHA

Annex 2: New psychoactive substances reported for the first time in 2007

1. 2C-B-Fly
(8-bromo-2,3,6,7-benzo-dihydro-difuran-ethylamine) – reported on 15 February 2007 by Finland ([1])

2. 5-MeO-Dalt
(N,N-diallyl-5-methoxytryptamine) – reported on 15 February 2007 by Finland

3. N-ethyl-2C-B
(N-ethyl- 4-Bromo-2,5-dimethoxybenzeneethanamine) – reported on 22 February 2007 by Finland

4. Vanoxerine
(1-[2-[bis(4-fluorophenyl)methoxy]ethyl]-4-(3-phenylpropyl)piperazine) – reported on 3 May 2007 by Belgium

5. D2PM (proposed code name)
((S)-(-)-α,α-Diphenyl-2-pyrrolidinylmethanol) – reported on 11 May 2007 by the United Kingdom

6. N-Acetyl-DOB
(N-Acetyl-4-bromo-2,5-dimethoxyamphetamine) – reported on 11 June 2007 by the United Kingdom

7. 1-PEA
(1-Phenylethylamine) – reported in the 1st half of 2007 by the United Kingdom

8. Gelbes (working name)
(1-(3-chlorophenyl)-4-(3Chloropropyl)piperazine hydrochloride) – reported on 24 September 2007 by Austria

9. NMPEA (proposed code name)
(N methyl Phenylethylamine) – reported on 6 December 2007 by France

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([1]) 1-9 are psychotropic substances similar to those listed in Schedules I and II of the 1971 UN Convention on Psychotropic Substances

10. Glaucine (International non-proprietary name)
((6aS)-1,2,9,10-tetramethoxyaporphine) – reported on 2 July 2007 by the United Kingdom ([2])

11. Fenazepam
(7-brom-5/o-chlorphenyl/1,2-dihydro-3H-1,4-benzodiazepin-2-on) – reported in the 1st half of 2007 by Finland

12. Nimetazepam
(2-methyl-9-nitro-6-phenyl-2,5-diazabicyclo[5.4.0]undeca-5,8,10,12-tetraen-3-one) – reported in the 1st half of 2007 – United Kingdom

13. N-desmethylsibutramine – reported on 14 December 2007 by Poland

14. Bufotenine
(3-(2-dimethylaminoethyl)-1H-indol-5-ol) – reported in the 1st half of 2007 by the United Kingdom ([3])

15. Harmine
(7-Methoxy-1-methyl-9H-pyrido[3,4-b]indole) – reported in the 1st half of 2007 by Finland

16. Salvia Divinorum – reported in the1st half of 2007 by the United Kingdom

([2]) 10-13 are substances which have (or may have) medicinal value; 12 is internationally controlled (listed in Schedule IV of the 1971 United Nations Convention on Psychotropic Substances) but rarely encountered in Europe, it is included in this list as it was never before reported via the EWS; 13 is a metabolite/derivative of a medicinal product Sibutramine (prescription anorectic).

([3]) 14-15 are naturally occurring psychotropic substances; 16 is a plant which contains psychotropic substances.