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**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**

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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 (EMA) 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 EMA 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

⁽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-EMA 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 EMA 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

⁽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

⁽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-isopropylamine).

⁽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