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PROPOSAL

from :	European Commission
dated :	8 October 2003
Subject:	Proposal for a Council Decision on information exchange, risk assessment and control on new narcotic drugs and new synthetic drugs

Delegations will find attached a Commission proposal submitted under a covering letter from Ms Patricia BUGNOT, Director, to Mr Javier SOLANA, Secretary-General/High Representative.

Encl.: COM(2003) 560 final

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 03.10.2003
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2003/0215 (CNS)

Proposal for a

COUNCIL DECISION

On the information exchange, risk-assessment and the control on new narcotic drugs and new synthetic drugs

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Introduction

This Council Decision aims at updating, re-enforcing and extending the *Joint Action on New Synthetic Drugs of June 16th 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs.* [1]

Since 1997 five synthetic drugs[2] have been examined using the provisions of the Joint Action on New Synthetic Drugs. Two of them (4-MTA and PMMA) have been made subject to control measures in the European Union. Council conclusions in relation to GHB and ketamine were also adopted, recommending that the European Police Office (Europol) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) closely monitor the misuse of both substances over a period of one year.

The European Union Action Plan on Drugs 2000-2004 asks the Commission to: *organise an assessment of the Joint Action on New Synthetic Drugs of June 1997 taking into account the evaluation by the EMCDDA of the early warning system.*[3] In order to execute this task an external evaluator was selected to carry out the evaluation. Based upon a series of interviews with stakeholders, the replies to an extensive questionnaire sent to the parties involved (Member States, Europol, the European Commission, the European Agency for the Evaluation of Medicinal Products (EMEA), and the EMCDDA) and desk research, a report has been produced, which was made available in November 2002.[4]

2. Outcome of the evaluation

The assessment of the external evaluator indicated that the Joint Action on New Synthetic Drugs plays a significant role in the combat against drugs. Nevertheless, the evaluation concluded that the Joint Action on New Synthetic Drugs is in need of a re-orientation with respect to its objective and scope. Furthermore, the evaluation made clear that clarification of the applicable procedures and enhancement of the transparency of its operation in practise is necessary.

By means of this Council Decision the mechanism as created by the Joint Action on New Synthetic Drugs is being adapted significantly, but incrementally, as its established basic structure remains unaffected. This Council Decision consists of the three consecutive but independent phases created by the Joint Action on New Synthetic Drugs:

- an early warning system (EWS) to exchange rapidly all information available on substances notified to Europol and the EMCDDA;

- a risk-assessment by a scientific committee in order to assess the social, health and other risks associated with a notified substance;

- an EU-level procedure for bringing notified substances under control in the Member States.

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1 OJ L 167, 25.06.1997, p.1-3.

2 MBDB, 4-MTA, GHB, Ketamine and PMMA.

3 COM (1999) 239 final; Action Point 2.2.5.

4 "Assessment of the Joint Action on New Synthetic Drugs 16th June 1997" by The Evaluation Partnership Limited, 26th October 2002.

3. Changes to the Joint Action

The changes to the Joint Action are directly related to the outcome of the external evaluation. Besides the redrafting of those definitions and procedures that have proven to be unclear, the most important innovation is that this Council Decision includes under its scope all new synthetic drugs and all new narcotic drugs alike, including those drugs that could be defined as medicinal products.

This extended scope, which will permit the notification of a wider range of substances than under the former Joint Action on New Synthetic Drugs, will not lead to an enhanced use of the risk-assessment and the control-measures (the second and third phase). The phases of risk-assessment and control are restricted to a small number of the substances that come within the scope of the Council Decision. Most notably, medicinal products and substances already under assessment by the United Nations are excluded from these phases. Thus, a sharper separation between the early warning system and the procedures of risk-assessment and control will be created. With these proposals the relevance of the instrument for the Member States will be enhanced, taking into account its use in practice.

Other changes are the result of a more fundamental re-orientation of the established Joint Action's mode of operation. Originally, the Joint Action had been designed to operate as a quick response mechanism aimed at achieving a rapid exchange of information on a new synthetic substance and the quick synchronisation of its legal status in the Member States, in case of a sudden surge in the presence of this substance within the European Union. In practise, another important task has been added over time. Nowadays, the long term monitoring of a synthetic substance by a continuous exchange of information between Member States and Europol/ EMCDDA, possibly followed by a procedure aimed at controlling the substance, could be considered as prominent a function as its quick response-task. However, the fusion of both objectives in one instrument is not self-evident and might lead to confusion and to questions of legitimisation and legitimacy in case information collected for one goal would be used to support another. Therefore, in this Council Decision a choice between both uses had to be made. This Council Decision has been drafted from the perspective of a quick response mechanism, which indicates a return to the original intentions of the Joint Action as set out in its preamble. Even so a continuous flow of information on new drugs amongst the Member States is valuable and must not be hampered by unnecessary formalities. In order to reconcile both practises the Council Decision makes a distinction between notified substances that demand prompt measures at European Union level, and substances that do not demand prompt measures. This distinction has been made operational by the inclusion of two specific provisions:

– the inclusion of a deadline by which the Joint Report by Europol and the EMCDDA must be submitted to the Member States, the EMEA and the Commission. In case no Joint Report by Europol/EMCDDA has been submitted by this deadline the phases of risk-assessment and control remain closed.

– the provision of some discretion to Europol and the EMCDDA whether or not to draw up a Joint Report. Though in principle a notification of a new narcotic drug or a new synthetic drug under this Council Decision should be followed up by a Joint Report, it can be assumed that not all notifications would merit such a follow-up. As not all cases in which a deviation from the principle that a notification should be followed by a Joint report can be foreseen in advance, a certain flexibility is necessary. Therefore no explicit criteria have been included in this Council Decision. First and foremost, a prudent judgement is required to be exercised by both bodies,

but Europol and the EMCDDA are also invited to develop policy guidelines which could be used to select those notifications that would demand a risk-assessment. The choices made by Europol and the EMCDDA in this respect should be explained in the annual report on the operation of the Council Decision. This report is to be prepared annually by Europol and the EMCDDA in order to provide adequate feedback to those Member States that have notified substances to the early warning system, and insight into the working of the instrument in general.

The early warning system may therefore be used for the exchange of information on, and thus the monitoring of, new narcotic drugs and new synthetic drugs alike, including medicinal products. However, under this Council Decision a risk-assessment will only be allowed when specific conditions are fulfilled.

Another fundamental change will be the re-emphasis on the principle of subsidiarity with respect to the use of control measures. The Council Decision should address these issues, which cannot be effectively dealt with by Member States individually. In this Council Decision the necessary presence of such an overall interest is expressed by the introduction of a majority threshold with respect to the start of a risk-assessment on a notified substance. Only where more than half of the Member States of the European Union have indicated to be in favour of a risk-assessment on a notified new narcotic or new synthetic substance the risk-assessment will be carried out.

A final change concerns the EMCDDA-Scientific Committee, which, extended with experts from the Member States and representatives of the Commission, the EMEA and Europol, is responsible for the carrying out of the risk-assessment. At present, all Member States may, in addition to their representative on the EMCDDA-Scientific Committee, nominate an expert for the implementation of the risk-assessment. The Council Decision proposed here deviates from this policy line. After the completion of the enlargement process of the European Union the extended Scientific Committee might be of a size which would make it unmanageable. Instead, as a consequence of this Council Decision, the extended Scientific Committee will be composed of the members of the EMCDDA Scientific Committee and representatives from the Commission, the EMEA, and Europol. To this body will be added at most five experts from scientific fields not (sufficiently) represented in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the risks associated with the assessed substance, including health and social risks. The reference to experts from scientific fields not currently represented, or currently not sufficiently represented, on the Scientific Committee relates to the circumstance that a balanced risk-assessment, which takes into account different types of risks, demands the presence of experts in all relevant fields.

4. The choice of the legal instrument

Since the entering into force of the Amsterdam Treaty and the subsequent amendment of the Treaty on European Union the Joint Action is no longer available as a legal instrument, which made it necessary to choose a new legal instrument. The adaptation of the Joint Action has not lead to a significantly different approach than taken before as this Council Decision continues to ask from Member States to put control-measures on specific substances which have passed through the stages of notification and risk-assessment. These control-measures were not defined in detail in the 1997 Joint Action on New Synthetic Drugs, nor are they defined in detail in this Council Decision. As these are left to the discretion of the national legislator, the Member States are not asked to adapt their legislation, but to make effective use of the existing provisions in their legislation. These circumstances make a Council Decision the most appropriate legal instrument available to succeed the Joint Action.

5. Analysis per Article

This Council Decision consists of 13 Articles. Some of the Articles describe the procedure from notification to control-measures, while others are related to the scope of this instrument or contain definitions.

Article 1 describes the purpose of the Council Decision. It emphasises that the Council Decision does not envisage a duplication of the pharmacovigilance system as established by Directive 2001/83/EC of the European Parliament and of the Council, which has been created to report suspected adverse reactions to a medicinal product. As it might not be clear from the outset whether or not an incident involving a new narcotic drug or a new synthetic drug would fulfil the reporting criteria under the pharmacovigilance system, Article 11 of this Council Decision asks Member States to maintain a close link between the mechanism created by this Council Decision and the pharmacovigilance system.

Article 2 is concerned with the scope of the Council Decision. The Article defines under the scope of this legal instrument all substances, which have not been listed under either the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances.

Therefore substances listed under either the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances do not come within the scope of this Council Decision.

Article 3 contains the definitions used throughout the Council Decision.

Article 4 describes the notification procedure a Member State should follow after the discovery of a new narcotic drug or a new synthetic drug on its territory. Article 4 also sets out the work to be undertaken jointly by the EMCDDA and Europol as a follow-up to a notification by a Member State: the EMCDDA and Europol are asked to collect the information available on the notified substance. The Article contains a list of issues on which information should be collected. However, at the same time, Article 4 attributes a certain discretion to Europol and the EMCDDA to judge whether or not prompt measures, and thus the collection of information, would be desirable.

By means of Article 5 the EMCDDA and Europol are asked to collate a Joint Report from the information gathered under the provisions of Article 4.

Article 6 describes the procedure relevant to the assessment of risks associated with a notified substance. In order to fulfil the criterion of subsidiarity, more than half of the Member States of the European Union should agree on the risk-assessment by the extended EMCDDA Scientific Committee. During the period of thirty working days which is given to the Member States in order to come to a decision, they will have sufficient time to consult their experts and to assess their national situation with respect to the notified substance. Also, Article 6 contains a list of issues, which should be included in the risk-assessment report.

Article 7 lists the circumstances, which would disqualify a notified substance from being assessed on its risks as indicated in Article 6. Most importantly, Article 7 states that substances that would qualify as medicinal products as categorised under this Article, will not be assessed on their risks under this Council Decision. Measures to be taken to diminish the abuse of these medicinal products could be considered by the EMEA and the Council. The EMEA could, based upon a scientific assessment of the risks associated with a medicinal

product, submit advice on the classification of the medicinal product involved, while the Public Health Group of the Council could decide on proper public health related measures with respect to the substance.

Article 8 describes the procedure for applying control-measures to a new narcotic drug or a new synthetic drug.

Article 9 describes the responsibility of the Member States with respect to the substances that are placed under control as described in Article 8.

Article 10 demands that the EMCDDA and Europol prepare a report on the operation of the Council Decision. The main aim is to increase the transparency of the instrument.

Article 11 relates to the pharmacovigilance system, which has been established EU-wide as a post-marketing surveillance system for authorised medicinal products. Member States, health care practitioners and the pharmaceutical industry are permanently assessing the safety of marketed medicinal products by reporting the suspected adverse reaction to medicinal products they have encountered, or that were reported to them, to the pharmacovigilance system. The major public health interests concerned here are such that there should be no loss of time caused by an accidental reporting of information relevant for the pharmacovigilance system to the Early Warning System only. Therefore Member States and the EMEA are asked to link the Early Warning System closely with the pharmacovigilance system.

Article 12 deals with the repeal of the predecessor of this Council Decision, the Joint Action on New Synthetic Drugs of June 16th 1997.

Article 13 contains the provisions on publication and entry into force of the Council Decision.

6. Financial consequences

This Council Decision does not have financial implications.

2003/0215 (CNS)

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COUNCIL DECISION

On the information exchange, risk-assessment and control on new narcotic drugs and new synthetic drugs

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission[5],

Having regard to the opinion of the European Parliament[6],

Whereas:

(1) The particular dangers inherent in the development of synthetic drugs and narcotic drugs require rapid action by the Member States.

(2) When new narcotic drugs and new synthetic drugs are not brought within the scope of criminal law in all Member States, problems may arise in the co-operation between the judicial authorities and law enforcement agencies of the Member States owing to the fact that the offence or offences in question are not punishable under the laws of either the requesting or the requested State.

(3) The European Union Action Plan on Drugs 2000-2004 asks the Commission to organise an appropriate assessment of the Joint Action on New Synthetic Drugs of June 1997[7] taking into account the external evaluation commissioned by the EMCDDA of the early warning system. The assessment has shown that the Joint Action on New Synthetic Drugs has fulfilled its expectations. Nevertheless, the outcome of the assessment made clear that the Joint Action is in need of reinforcement and re-orientation. In particular, its main objective, the clarity of its procedures and definitions, the transparency of its operation, and the relevance of its scope should be redefined. The Communication from the Commission to the Council and the European Parliament on the mid-term evaluation of the EU Action Plan on Drugs (2000-2004) [8] has indicated that changes to the legislation will be introduced in order to enhance action against synthetic drugs. The mechanism as established by the Joint Action on New Synthetic Drugs of June 16th 1997 should therefore be adapted.

(4) New narcotic drugs can be as harmful to health as new synthetic drugs.

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5 OJ C […], […], p. […].
6 OJ C […], […], p. […].
7 OJ L 167, 25.06.1997, p.1-3
8 COM/2002/0599 final, page 18.

(5) The information exchange under the early warning system, established under the Joint Action on New Synthetic Drugs having proved to be a valuable asset to the Member States, this system may also be used to disseminate information on the occurrence of unanticipated public health threats associated with the use of illicit drugs.

(6) No infringement on the quality of either human or veterinary health care by means of this Decision could be allowed. Substances with an established and acknowledged medical value are therefore excluded from control-measures based on this Decision. For substances with an established and acknowledged medical value that are being misused suitable regulatory and public health related measures should be taken.

(7) The introduction of deadlines in every phase of the procedure established by this Decision should guarantee the speediness of the instrument and emphasises its character as a quick response mechanism.

(8) The Scientific Committee of the European Monitoring Centre on Drugs and Drug Addiction having a central role in the assessment of the risks associated with a new narcotic substance or a new synthetic substance, it will for the purpose of this Decision be extended to experts from the Commission, Europol and the European Agency for the Evaluation of Medicinal Product, and to experts from scientific fields not represented, or not sufficiently represented, in the Scientific Committee of the European Monitoring Centre on Drugs and Drug Addiction.

(9) The extended Scientific Committee that assesses the risks associated with new narcotic drugs or new synthetic drugs should remain a concise technical body of experts, capable of assessing effectively all risks associated with a new narcotic substance or a new synthetic substance. Therefore the size of the extended Scientific Committee should remain manageable.

(10) Since the objectives of the proposed action, namely 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 Community level, the Community 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, the Decision does not go beyond what is necessary to achieve those objectives.

(11) In conformity with Art 34 (2) (c) Treaty on European Union, measures based upon this Decision can be taken by qualified majority as these measures are necessary to implement this Decision.

(12) This Decision respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the Union.

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

This Decision establishes a mechanism for a rapid exchange of information on new narcotic drugs and new synthetic drugs that are being used illicitly or misused. It does not cover information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC of the European Parliament and of the Council.[9]

This Decision also provides for an assessment of the risks associated with these new narcotic drugs and new synthetic drugs in order to permit the application of the measures of control on narcotic and psychotropic substances, applicable in the Member States equally to new narcotic drugs or to new synthetic drugs.

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 pose a comparable threat to public health as the substances listed in Schedule I or II or IV; and

b) the 1971 United Nations Convention on Psychotropic Substances,

that pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV;

This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90[10], and Council Directive 92/109/EEC[11] provide for a Community regime.

Article 3

Definitions

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

a) 'new narcotic drug': a substance, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that poses a threat to public health comparable to the substances listed in Schedule I, II or IV.

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9 OJ L 311 of 28.11.2001, p. 67, as last amended by Directive 2002/98/EC (OJ L 33, 8.2.2003, p.30-40

10 OJ L 357, 20.12.1990, p.1, as last amended by Regulation (EC) No 1116/2001(OJ L 153, 8.6.2001, p.4) and Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p.5).

11 OJ L 370, 19.12.1992, p.76.

b) ‘new synthetic drug': a substance that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that poses a threat to public health comparable to the substances listed in Schedule I, II, III or IV;

c) ‘marketing authorisation’: the permission to place on the market of a Member State either a medicinal product for human use as indicated in Title III of Directive 2001/83/EC of the European Parliament and of the Council, or a veterinary medicinal product as indicated in Title III of Directive 2001/82/EC of the European Parliament and of the Council.

d) ‘United Nations-system’: the World Health Organisation (WHO), the Commission on Narcotic Drugs (CND) and/or the Economic and Social Committee (Ecosoc) acting in accordance within 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.

e) ‘preparation’: a mixture containing either a new narcotic drug or a new synthetic drug.

Article 4

Exchange of information

1. Each Member State shall ensure that its Europol National Unit of the European Police Office ("Europol") and its representative in the Reitox network provide information on the production, traffic and use, including medical use, of new narcotic drugs and of new synthetic drugs and of preparations containing new narcotic drugs or new synthetic drugs, to Europol and the European Monitoring Centre on Drugs and Drug Addiction ("EMCDDA"), taking into account the respective mandates of these two bodies. Europol and the EMCDDA shall collect the information received 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 European Agency for the Evaluation of Medicinal Products ("EMEA").

2. Europol and the EMCDDA shall supplement the information on a new narcotic drug or a new synthetic drug or on a preparation containing a new narcotic drug or a new synthetic drug obtained from a Member State to the extend that the information available shall entail:

   (a) a chemical and physical description, including the name under which the new narcotic drug or the new synthetic drug is known,

   (b) information on the frequency, circumstances and/or quantities in which a new narcotic drug or new synthetic drug is encountered, and information on the means and methods of production of the new narcotic drug or the new synthetic drug,

   (c) information on the involvement of organised crime in the production or trafficking of the new narcotic drug or the new synthetic drug,

(d) a first indication of the risks associated with the new narcotic drug or new synthetic drug, including health and the social risks,

(e) information on whether or not the new narcotic drug or the new synthetic drug is currently under assessment, or has been under assessment by the UN-system,

(f) the moment of notification of the new narcotic drug or the new synthetic drug to the EMCDDA or to Europol,

(g) information on whether or not the new narcotic drug or the new synthetic drug 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,

(ii) the mode and scope of the established or expected use of the new synthetic drug or the new narcotic drug,

(iii) other use of the new narcotic drug or new synthetic drug and the extent of such use, the risks associated with this use of the new narcotic drug or new synthetic drug, including the health and the social risks;

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

(a) the new narcotic drug or new synthetic drug has obtained a marketing authorisation;

(b) the new narcotic drug or new synthetic drug is in the process of obtaining a marketing authorisation;

(c) a provided marketing authorisation has been suspended.

Where this supplementary information relates to marketing authorisations granted by Member States, these Member States shall provide this information to the EMEA on request from the EMEA.

4. Member States are requested to deliver the information referred to under paragraphs (2) and (3) without unnecessary delay.

5. In case Europol and the EMCDDA consider that the information provided by a Member State on a new narcotic drug or a new synthetic drug would not merit the further collection of information as described in paragraph (1), they will inform the notifying Member State instantly hereof, and the risk assessment procedure referred to in Article 6 will not apply. Europol and the EMCDDA will explain the decision taken in the annual report as referred to in Article 10.

Article 5

Joint Report

1. The information collected shall be collated and presented by Europol and the EMCDDA in the form of a Joint Report (hereinafter the "Joint Report"), which shall be submitted directly to the Member States, the EMEA and the Commission

2. The Joint Report shall be submitted no more than thirty working days after the date of reception of information from Member States by Europol or the EMCDDA in accordance with paragraph (1) of Article 4.

Article 6

Risk assessment

1. The risks, including the health and social risks, caused by the use of, the production of, and traffic in, a new narcotic drug or a new synthetic drug, the involvement of organised crime and possible consequences of prohibition shall be assessed in accordance with the procedure set out in paragraphs 2 to 5, provided that more than half of the Member States have informed the Council in writing to be in favour of such an assessment. The Member States shall inform the Council as soon as possible, but in any case within thirty working days after the date of reception of the Joint Report.

2. As soon as more than half of the Member States have informed the Council in writing to be in favour of a risk-assessment on a new narcotic drug or a new synthetic drug as indicated in paragraph (1), the Council shall alert the EMCDDA and Europol.

3. 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 shall be extended with at most five experts, who are specialists in scientific fields 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 be invited to send a maximum of two experts each to this meeting.

4. The risk-assessment shall be carried out on the basis of information to be provided to the Committee as described in paragraph 3 (hereinafter "the 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.

5. On completion of the risk-assessment, a report (hereinafter the "Risk-Assessment Report") will be drawn up. The risk-assessment shall consist of an analysis of the scientific information available, and will include possible dissenting scientific opinions held by the members of the Committee. The Risk-Assessment Report shall

be submitted to the Commission by the chairman of the Committee within a period of ninety working days, as from the date of the information from the Council to the EMCDDA and Europol referred to in paragraph (2).

The Risk-Assessment report shall include:

(a) the physical and chemical description of the new narcotic drug or the new synthetic drug and its working, including its medical value,

(b) the health risk associated with the new narcotic drug or the new synthetic drug,

(c) the social risks associated with the new narcotic drug or the new synthetic drug,

(d) information on the level of involvement of organised crime and information on seizures, and production of the new narcotic drug or the new synthetic drug,

(e) information on the assessment of the new narcotic drug or the new synthetic drug in the United Nations-system,

(f) a description of the control-measures to which the new narcotic drug or the new synthetic drug is submitted in the Member States, when applicable,

(g) options for control and the possible consequences of prohibition.

Article 7

Circumstances where no risk assessment shall be carried out

1. No risk-assessment shall be carried out in case the new narcotic drug or the new synthetic drug concerned is currently under assessment within the United Nations-system.

2. In case the new narcotic drug or the new synthetic drug has been under assessment within the United Nations system without the decision having been taken to schedule the new narcotic drug or the new synthetic drug under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances a risk-assessment shall only be carried out when there is significant new information relevant in the framework of this Decision.

3. No risk-assessment shall be carried out on a new narcotic drug or a new synthetic drug in case it falls within one of the following categories:

(a) The new narcotic drug or the new synthetic drug is an ‘authorised medicinal product’ which is either a medicinal product intended for human use, that has been granted a marketing authorisation in one or more Member States or in the European Union in accordance with the provisions of Title III of Directive 2001/83/EC[12], or a veterinary medicinal product that has been granted a marketing authorisation in one or more Member States or in the European

[12] OJ L 311, 28.11.2001, p. 67

Union in accordance with the provisions of Title III of Directive 2001/82/EC[13]; or,

(b) The new narcotic drug or the new synthetic drug is a 'medicinal product under review', which is either a medicinal product intended for human use that is under examination in order to be granted a marketing authorisation in one or more Member States or in the European Union in accordance with the provisions of Title III of Directive 2001/83/EC, or a veterinary medicinal product that is under examination in order to be granted a marketing authorisation in one or more Member States or in the European Union in accordance with the provisions of Title III of Directive 2001/82/EC; or,

(c) The new narcotic drug or the new synthetic drug is a 'suspended medicinal product', which is either a medicinal product intended for human use for which the marketing authorisation is suspended in one or more Member States or in the European Union, or a veterinary medicinal product for which the marketing authorisation is suspended in one or more Member States or in the European Union; or,

(d) The new narcotic drug or the new synthetic drug is an 'exempted medicinal product', which is either a medicinal product for human use, which is exempted from having a marketing authorisation as specified under Article 7 of Directive 2001/83/EC, or a veterinary medicinal product; which is exempted from having a marketing authorisation as specified in Article 8 of Directive 2001/82/EC.

In the case the new narcotic drug or the new synthetic drug falls into one of the categories listed under this paragraph, it will be referred to the EMEA for a scientific evaluation of the risks associated with the new narcotic drug or the new synthetic drug and to the Council in order to discuss public health related measures.

Article 8

Procedure for bringing specific new narcotic and new synthetic drugs under control

1. Within thirty working days from the date on which the Risk-Assessment Report has been received, the Commission shall present to the Council an initiative to have the new narcotic drug or new synthetic drug subjected to control measures.

   If the Commission deems it not necessary to present an initiative to have the new narcotic drug or the new synthetic drug submitted to control measures, it shall within thirty working days from the date on which the Risk-Assessment Report has been received present a report to the Council explaining its views.

2. When the Commission presents the Council with an initiative, the Council shall decide by qualified majority, on the basis of the said initiative and acting in accordance with Article 34 (2) (c) of the Treaty, whether to submit the new narcotic drug or the new synthetic drug to measures of control.

[13] OJ L 311, 28.11.2001, p. 1

3. The procedure provided for by this Article shall take no longer than ninety working days from the date of reception by the Council of the initiative by the Commission to the date of adoption by the Council of the initiative by the Commission as referred to in paragraph (2).

Article 9

Control measures taken by Member States

1. If the Council decides to submit a new narcotic drug or a new synthetic drug to measures of control, Member States shall take within one year the necessary measures in accordance with their national law to submit:

   (a) the new synthetic drug to control measures and criminal penalties as provided under their legislation complying with 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 complying with 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.

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 this Member State has identified a new narcotic drug or a new synthetic drug.

Article 10

Annual report

The EMCDDA and Europol shall report annually to the Council on the operation of this Decision. The report will take into account all aspects relevant to judge the efficacy and achievements of the system created by this Decision.

Article 11

Pharmacovigilance-system

Member States and the EMEA shall secure 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[14] and Title IX of Directive 2001/83/EC[15].

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[14] OJ L 311 of 28.11.2001, p. 0001–0066, Directive 2001/82/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

[15] OJ L 311 of 28.11.2001, p. 0067–0128, Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use

Article 12

Repeal

The Joint Action on New Synthetic Drugs of June 16th 1997 is hereby repealed.

Article 13

Publication and entry into force

This Decision shall be published in the Official Journal of the European Union. It shall take effect the day following that of its publication.

This Decision is addressed to the Member States.

Done at Brussels, […]

For the Council
The President
[…]