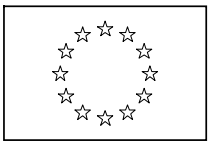

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.11.2000
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REPORT FROM THE COMMISSION TO THE COUNCIL

called for by the Joint Action on New Synthetic Drugs (97/396/JAI) concerning Ketamine

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Commission Report on Ketamine

1. On 17 October 2000, the European Commission received from the EMCDDA the report of the risk assessment of ketamine (2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone). The risk assessment report was established following a meeting on 25-26 September 2000 of the Scientific Committee of the EMCDDA and experts nominated by the Member States, representatives of the Commission, Europol and the EMEA. The risk assessment was requested by the Horizontal Drugs Group in April 2000, in the framework of the Joint Action on New Synthetic Drugs of 16 June 1997.

2. Article 5 of the Joint Action states that following the establishment of the report there can either be an initiative presented to the Council within a month to make the new synthetic drug subject to measures of control, or "if the Commission deems it not necessary to present an initiative … it shall present a report to the Council explaining its views".

3. Article 2 of the Joint Action states that the Joint Action "concerns new synthetic drugs which are not currently listed in any of the Schedules to the 1971 United Nations Convention on Psychotropic Substances, and which pose a comparable serious threat to public health as the substances listed in Schedules I or II thereto and which have a limited therapeutic value."

4. The Commission has considered the conclusions of the report and notes the following:

   4.1. Ketamine was first synthesised in 1962 and patented in 1963.

   4.2. Ketamine is used as an anaesthetic and analgesic and it has a unique therapeutic value in veterinary practice and value also in human medicine.

   4.3. Ketamine is used as a medicine in nearly all Member States and is subject to the medicine legislation. It can legally be sold only to authorised people (eg pharmacists).

   4.4. Ketamine is also used in recreational settings. In illicit use, an important factor of health risk is the lack of reliable indication of dose and the mixture with other substances accompanying sales of ketamine at street level. In some Member States, ketamine tablets are sold as ecstasy.

4.5. Ketamine has been associated with four deaths in the EU since 1996, in none of them ketamine was considered the main cause of death. There is a lack of information about hospital emergencies.

4.6. The main effects of ketamine are anxiety, agitation, changes in perception and the analgesic effects. In such condition, the user may be at risk of injury. Ketamine is contraindicated in patients with significant ischaemic heart disease and is to be avoided in those with a history of high blood pressure or cerebrovascular disorders.

4.7. There is no evidence that ketamine causes an abstinence syndrome in human beings.

4.8. The manufacturing process of ketamine is complicated. The precursors and numerous solvents and reagents needed for the manufacture of ketamine are difficult to obtain and the supply for illicit recreational use comes mostly from diversion from licit market. Seizure data suggests mostly low levels of availability of ketamine for illicit use.

5. Basing itself solely on the risk assessment report on ketamine and the principle of proportionality, the Commission concludes that it is not appropriate to present an initiative to the Council to propose that ketamine be submitted to control measures at the EU level, as provided for by Article 5(1) of the Joint Action on New Synthetic Drugs. But the Commission will:

5.1. Suggest that possible improvements in the control of diversion be discussed with the chemical and pharmaceutical industry, bearing in mind the importance of ensuring the continued availability of ketamine for medical and veterinary use.

5.2. Encourage EMCDDA and Europol to continue monitoring the trends in recreational ketamine use as part of the early warning system provided for by the Joint Action.

5.3. Welcome proposals for research on the effects of ketamine use to be considered by the Fifth Framework Program for Research and Development.

5.4. Take into account the outcome of the risk assessment of ketamine when it organises the assessment of the Joint Action on New Synthetic Drugs called for in point 2.2.5 of the EU Action Plan on Drugs (2000-2004).

Commission Report on GHB

1. On 17 October 2000, the European Commission received from the EMCDDA the report of the risk assessment of GHB (gammahydroxybutyrat). The risk assessment report was established following a meeting on 25-26 September 2000 of the Scientific Committee of the EMCDDA and experts nominated by the Member States, representatives of the Commission, Europol and the EMEA. The risk assessment was requested by the Horizontal Drugs Group in April 2000, in the framework of the Joint Action on New Synthetic Drugs of 16 June 1997.

2. Article 5 of the Joint Action states that following the establishment of the report there can either be an initiative presented to the Council within a month to make the new synthetic drug subject to measures of control, or "if the Commission deems it not necessary to present an initiative … it shall present a report to the Council explaining its views".

3. Article 2 of the Joint Action states that the Joint Action "concerns new synthetic drugs which are not currently listed in any of the Schedules to the 1971 United Nations Convention on Psychotropic Substances, and which pose a comparable serious threat to public health as the substances listed in Schedules I or II thereto and which have a limited therapeutic value."

4. The Commission has considered the conclusions of the report and notes the following:

   4.1. GHB has been used therapeutically in anaesthesia since the early 1960's, later in the treatment of alcohol withdrawal and in long term sedation. It is being investigated for the treatment of narcolepsy associated cataplexy. Products containing GHB have a marketing authorisation in four Member States.

   4.2. In recent years GHB has been used recreationally. When used for such purposes, the effects of GHB are much closer to those produced by alcohol, cannabis and benzodiazepines (Schedule IV of the 1971 UN Convention) than they are to MDMA (Schedule I of the 1971 UN Convention) and other stimulant drugs.

   4.3. There have been some media and police reports of GHB use in drug assisted sexual assaults, but the extent of this involvement is unclear.

   4.4. Illicit use of GHB poses risks to health, given the narrow dose margin between the desired and the serious adverse effects. These risks increase when GHB is combined with other substances particularly alcohol. GHB has been associated with 11 deaths in the EU between September 1995 and January 2000. Deaths involving solely GHB appear to be rare. At least 200 non-fatal cases of GHB overdose have been admitted to hospital in the EU and Norway. No information is available on the health consequences for the general population.

   4.5. Throughout the EU GHB is subject to the medicines legislation. It can only be legally sold to authorised people. In addition, six Member States have controls on GHB under their legislation on illicit drugs.

4.6. The 32nd WHO Expert Committee on Drug Dependence recommended to the UN Commission on Narcotic Drugs (CND) that GHB be listed in Schedule IV of the 1971 UN Convention on Psychotropic Substances.

4.7. There is no information on large-scale production, trafficking and distribution of GHB, and seizures in the EU are very small when compared to seizures of regular synthetic drugs such as amphetamine, MDMA and MDA.

4.8. GHB can be relatively easily produced from one of two precursors: GBL (Gamma Butyrolactone) or 1,4 butanediol. Neither is included in the list of chemical precursors in the UN Convention of 1988. GBL is included in the Voluntary Monitoring List under the EC Precursors legislation, but 1,4 butanediol is not.

4.9. Biological samples can apparently contain levels of GHB in circumstances where there is no evidence of GHB consumption.

5. Basing itself solely on the risk assessment report on GHB and the principle of proportionality, the Commission concludes that it is not appropriate to present an initiative to the Council to propose that GHB be submitted to control measures at the EU level, as provided for by Article 5(1) of the Joint Action on New Synthetic Drugs. But the Commission will:

5.1. Encourage the EMCDDA and Europol to continue monitoring trends in recreational use of GHB as part of the early warning system provided for in the Joint Action, and to inform the Horizontal Drugs Group should they find new elements, particularly evidence of a threat to public health;

5.2. Pass the report on the risk assessment of GHB to the "Drug Precursors" Committee set up under Article 10 of Regulation 3677/90 and Directive 92/109/EEC, and ask the Committee whether or not 1,4 Butanediol should be included in the Voluntary Monitoring List;

5.3. Welcome research proposals on GHB, in particular with a view to establish guidance for best practice in handling and analysis of biological samples containing GHB, under the 5th Framework Programme for Research; and

5.4. Take into account the outcome of the risk assessment of GHB when it organises the assessment of the Joint Action on New Synthetic Drugs called for in point 2.2.5 of the EU Action Plan on Drugs (2000-2004).