European Monitoring Centre
for Drugs and Drug Addiction

**Note to Dr Peter Arlett, DG Enterprise and Industry**

**Subject:** Strategy to better protect health by strengthening and rationalising EU pharmacovigilance: public consultation on legislative proposal

## 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, thus allowing European Union institutions and Member States to act on all new narcotic and psychotropic substances that appear on the European Union drug scene ([1]). 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.

The EMCDDA and Europol, in close collaboration with their networks are assigned a central role in detecting and reporting new psychoactive substances (the early warning system). The European Medicines Agency (EMEA) is a key partner in the implementation of the system set up by the Decision. 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 system'. The EMEA submits to EMCDDA information on the marketing authorisation status of a new psychoactive substance in the European Union or in any Member State. Furthermore, the Decision allows the EMEA to take part in the EMCDDA's Scientific Committee for the risk assessment on new psychoactive substances.

The EMCDDA and Europol report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. It is stipulated that the annual report should include experiences relating to coordination between the mechanism set out by the Decision and the pharmacovigilance system.

## Current state of the EMCDDA-EMEA cooperation

At present, EMCDDA and EMEA are implementing on an *ad hoc* basis a bilateral information exchange of data available through the early warning system on new psychoactive substances and the pharmacovigilance system. Formalising the scope and modality 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 in developed. Steps currently being considered are that 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. On the other hand, EMEA could provide to

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

the EMCDDA 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 EU system of pharmacovigilance, is seen as an appropriate opportunity to strengthen the basis of EMCDDA-EMEA cooperation.

**Proposal for inclusion of new text in the legislation**

In the context of the above and in order to mirror what is implicitly included in the Council Decision 2005/387/JHA, the EMCDDA wishes to propose that you consider inserting the following text in the new pharmacovigilance legislation:

*Information on abuse of medicinal products in conjunction with illicit drugs shall be exchanged between the European Medicines Agency and the European Monitoring Centre for Drugs and Drug Addiction, where appropriate and within the framework of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances.*

If you were to take this action we would suggest that the amendment might best sit in *Chapter 4 Article 101d* of the new legislation.