European Monitoring Centre for Drugs and Drug Addiction

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/248916/2010

Working arrangement

between the

European Medicines Agency (EMA)

and the

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

The European Medicines Agency, hereinafter referred to as the EMA, and the European Monitoring Centre for Drugs and Drug Addiction, hereinafter referred to as the EMCDDA;

Recalling Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances which is implemented within their respective mandates under the 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 and under the Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast);

Recalling the EMA's initiative on cooperation with other European Union bodies for early identification and management of potential conflicts over scientific opinions;

Taking note with satisfaction of the progress achieved so far in the exchange of information and expertise and considering that it is within their common interest to enhance further their cooperation while avoiding duplication of efforts and overlaps in their respective activities and ensuring the best use of available resources;

The Parties have agreed on the following Principles:

1. Enhanced cooperation

The EMA and the EMCDDA commit to foster cooperation between the two agencies in the field of activities identified below based on the principles of appropriateness, common interest, reciprocity and complementarity.

2. Areas to which the working arrangement applies

1. Cooperation between the two agencies shall relate to exchange of information on new psychoactive substances in accordance with their respective mandates and the requirements of Council Decision 2005/387/JHA.
2. The above information exchange may include reports on a regular basis through a Reporting Form from EMCDDA to EMA as well as *ad hoc* reports on misused medicinal products in order to complement the reporting via the EU pharmacovigilance system.
3. EMA may provide to the EMCDDA on an *ad hoc* basis information on misuse of marketed products under conditions of confidentiality specified in Principle 4.
4. EMA may consider *ad hoc* consultation with the EMCDDA on the definition of risk management plans of selected medicinal products.
5. Cooperation between EMCDDA to EMA on risk assessment of new psychoactive substances under the Council Decision 2005/387/JHA shall pay particular attention to ensure that no deterioration of either human or veterinary health care as a result of this Decision will be permitted and that potential conflicts over scientific opinions will be identified and managed at an early stage.

6. In addition, consultations between the two agencies may be carried out to avoid potential conflicts over scientific opinions not related to risk assessment of new psychoactive substances.
7. Implementation of any additional cooperation projects shall take in consideration each agencies' annual work programmes, following approval of the work programmes by the decision-making bodies and taking into account the availability of adequate resources.
8. Specific projects which require additional resources should be jointly agreed by both agencies and included in a document to be annexed to the present working arrangement.
9. The EMA and the EMCDDA may invite each other within their regulations to attend meetings convened under their respective auspices and which consider matters in which the other organisation has an interest or technical competence. Each organisation shall cover its own expenses for participation in such meetings.
10. Practical aspects of the cooperation between the EMA and EMCDDA will be developed in the framework of this working arrangement.

3. Mutual consultation

Where appropriate and feasible, the EMA and the EMCDDA:

(a) should consult each other and keep each other informed on matters of common interest, for the purpose of achieving their respective objectives, implementing their respective mandates and coordinating their respective activities;

(b) should consult each other to ensure the greatest possible degree of coordination with regard to the organisation of meetings and missions of technical experts concerning questions in which both agencies have an interest

(c) should each designate one or more staff members for the maintenance of close, direct and continuing contacts with a view to ensuring the implementation of the provisions of the present working arrangement;

(d) should convene coordination meetings at the required level between representatives of the two agencies. Where necessary, decisions shall be referred to the Director of the EMA and the Director of the EMCDDA.

4. Confidentiality of information

1. Exchange of information between the EMA and the EMCDDA shall only take place for the purpose of and in accordance with the provisions of this working arrangement, and will not include data related to identified or identifiable individuals.

2. The Parties may inform each other, at the moment of the information exchange or before, of the purpose for which the information is intended to be used and of any restriction on its use, deletion or destruction, including possible access restrictions in general or specific terms. Where the need for such restrictions becomes apparent after the supply, the parties may also inform each other of such restrictions at a later stage.

3. Each Party shall ensure that information received on the basis of this working arrangement will be subject to its confidentiality and security standards for the processing of information.

4. Each Party will ensure that information received from the other Party will receive a level of protection which is equivalent to the level of protection offered by the measures applied to that information by the other Party.

5. In accordance with the principle of proportionality, confidentiality levels will be attributed at the lowest possible level by each Party and amended accordingly wherever possible.

6. The Party supplying the information will be responsible for the choice of the appropriate confidentiality level for information supplied and shall ensure that the level is clearly indicated.

7. Both Parties may at any time request an amendment of the chosen confidentiality level for information supplied, including the possible removal of such a level. The receiving Party shall be obliged to amend the confidentiality level accordingly.

5. Amendments

This working arrangement may be amended by mutual consent between the EMA and the EMCDDA at any time, in accordance with their respective statutory requirements.

This working arrangement will be considered operative when signed by:

For the European Medicines Agency,
Thomas Lönngren, Executive Director

signature: _____

Done at [place], [date] 10/0 10

For the European Monitoring Centre for Drugs and Drug Addiction,
Wolfgang Götz, Executive Director

signature: _____

Done at [place], [date]

In duplicate in English