Memorandum of Understanding on Working Arrangements between

the European Medicines Agency (EMA)

and

the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

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

Having regard to the respective mandates, as laid down in Regulation (EC) No 1920/2006 on the European Monitoring Centre for Drugs and Drug Addiction, and in Regulation (EC) No 726/2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency),

Recalling the cooperation of EMA with other European Union bodies for early identification and management of potential conflicts over scientific opinions in accordance with Article 59 of Regulation (EC) No 726/2004,

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, in particular in the area of new psychoactive substances, while avoiding duplication of efforts and overlaps in their respective activities and ensuring the best use of available resources,

HAVE AGREED AS FOLLOWS:

1. Purpose of the working arrangements: Enhanced cooperation

In this Memorandum of Understanding 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 arrangements apply

1. Exchange of information on new psychoactive substances in accordance with their respective mandates and the requirements of Article 5b of Regulation (EC) No 1920/2006 as amended:

   - EMCDDA shall exchange information with EMA about new psychoactive substances.

   - Upon request, and within four weeks from the receipt of the request, EMA shall provide EMCDDA with the detailed information that has been requested under Article 5b(5) of Regulation (EC) No 1920/2006.

2. Exchange of information on abuse of medicinal products in accordance with their respective mandates and the requirements of Article 28c (2) of Regulation (EC) No 726/2004:

   - EMCDDA and EMA shall exchange relevant information about abuse of medicinal products.

   - EMA shall inform EMCDDA about confirmed signals related to abuse of medicinal products and provide EMCDDA with EudraVigilance data where relevant.

3. EMA may also consider ad hoc consultations with the EMCDDA on risk management plans of selected medicinal products.

4. In addition, consultations between the two agencies may be carried out to avoid potential conflicts over scientific opinions in areas not related to risk assessment of new psychoactive substances.

5. The EMA and EMCDDA may undertake additional cooperation projects on an ad hoc basis which shall take in consideration the work programme of each agency, following approval of the work programmes by the decision-making bodies and taking into account availability of adequate resources.

6. The EMA and the EMCDDA may invite each other to attend meetings convened under their respective auspices on matters in which the other agency has an interest or technical competence. Each agency shall cover its own expenses for participation in such meetings.

3. Mutual consultation and coordination

Where appropriate and feasible, the EMA and the EMCDDA undertake to:

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

4. Further implementation

Further aspects and details of the cooperation between EMA and EMCDDA may be developed in the framework of the present Memorandum of Understanding, including the respective roles and responsibilities of involved members of staff and participation as observer to relevant meetings, where needed.

5. 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 Memorandum of Understanding, and in accordance with the provisions of Regulation (EC) No 45/2001 in what regards the processing of personal data.

2. The exchanged information may include information of a non-public confidential and/or proprietary nature (“non-public information”). Both EMA and EMCDDA therefore accept to keep the exchanged information confidential, to the extent permitted by their respective applicable legislation (including, but not limited to Regulation (EC) No 1049/2001), and as set forth in this Memorandum of Understanding. EMA and EMCDDA agree that it is an essential element of this working arrangement that non-public information emanating from the other agency is treated as confidential, and is used only for the purposes of this Memorandum of Understanding.

3. The agencies 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, each agency may also inform each other of such restrictions at a later stage.

4. Each agency 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.

5. Each agency will ensure that information received from the other agency is granted a level of protection which is equivalent to the level of protection offered by the measures applied to that information by the other agency. Each agency shall also ensure that any conditions which apply to the exchanged information are complied with. In case the implementation of the present point does lead to conflicts with a relevant policy of one of the agencies, the other agency shall be informed in advance before the exchange of information take place.

6. For the purposes of this Memorandum of Understanding, information may be shared by EMA and EMCDDA with persons within their respective organisations who are bound by obligations of confidentiality and professional secrecy, as defined in their respective applicable legislation and in accordance with the restrictions on use as contained in this Memorandum of Understanding.

6. Amendments

This Memorandum of Understanding on Working Arrangements may be amended by mutual consent between the EMA and the EMCDDA at any time, in accordance with their respective statutory requirements.

This Memorandum of Understanding repeals and replaces the current working arrangement and will enter into force when signed by both agencies:

For the EMA,
Guido Rasi, Executive Director

[Signature on file]

Done in London, 7 December 2018

For the EMCDDA,
Alexis Goosdeel, Director

[Signature on file]

Done in London, 7 December 2018

In duplicate in English