Memorandum of Understanding on Working Arrangements

Between the European Medicines Agency (EMA) and the European Chemicals Agency (ECHA)

THE EUROPEAN MEDICINES AGENCY AND THE EUROPEAN CHEMICALS AGENCY,

Having regard to the respective mandates as defined in their founding legal act 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 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, and afterwards supplemented by sector specific Union legislation;

Recalling the cooperation of the European Medicines Agency (hereinafter referred to as '"EMA") with other European Union bodies for early identification and management of potential conflicts over scientific opinions in accordance with Article 59 of Regulation No 726/2004;

Recalling the remit of the European Chemicals Agency (hereinafter referred to as '"ECHA"), and in particular its duty to ensure early identification and handling of potential sources of conflict between its opinions and those of other bodies established under Community law in accordance with Article 95 of Regulation (EC) No 1907/2006 and the reference to the remit of EMA as contained in Article 110 of Regulation (EC) No 1907/2006;

Recalling that it is nevertheless important to avoid confusion between the missions of EMA and ECHA;

Having regards to the common guidelines on practical arrangements for the sharing of scientific data between the Scientific Committees and panels of the European Agencies and the Scientific Committees of the Commission of 10 November 2008;

Taking note with satisfaction of the progress achieved so far in the exchange of information and expertise, and considering that it is within the common interest of both Parties to enhance further their cooperation, 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 Memorandum of Understanding: Enhanced cooperation

In this Memorandum of Understanding ("MoU") EMA and ECHA (referred to herein each as a "Party" or together as the "Parties") commit to foster cooperation between the two agencies in particular in the

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field of activities identified below based on the principles of appropriateness, common interest, reciprocity and complementarity.

The implementation of this MoU aims in particular at ensuring coherence in scientific opinions, in accordance with the principles set out in the agencies' respective founding Regulations[1], through active information exchange.

2. Areas of cooperation to which the MoU applies

Cooperation between the two agencies encompasses the following indicative areas, in accordance with the respective mandates of the agencies:

1. Exchange of information on areas of mutual interest;
2. Exchange of information regarding evaluation and authorisation/restriction of chemicals under Regulation (EC) No 1907/2006, as relevant for the activities of EMA;
3. Exchange of information and cooperation concerning risk management through classification of substances under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ("classification") and possible future changes in the classification of substances;
4. Exchange of information concerning excipients (e.g. labelling, possible adverse reactions);
5. Exchange of information on toxicological assessment by predictive methods (such as read-across/chemical categories) & new-approach methodologies (-omics, HTS etc);
6. Exchange of information and cooperation related to biocides in particular the establishment of MRLs for pharmacologically active substances contained in biocidal products used in animal husbandry and obtain a better understanding of the differences between the classification of some biocides and of some veterinary products;
7. Exchange of information and cooperation regarding Environmental Risk Assessment (for both human and veterinary medicinal products) and ecotoxicology, in particular between the Environmental Risk Assessment Working Party ("ERAWP") of the Committee for Medicinal Products for Veterinary Use ("CVMP") and the Safety Working Party (SWP) of the Committee for Medicinal Products for Human Use (CHMP) in EMA and ECHA;
8. Invitations between the Parties to attend meetings, videoconferences or teleconferences convened under their respective auspices or participate in relevant working groups established by either of them in matters in which the other Party has an interest or technical competence. Co-operation on other matters such as public procurement or recruitment exercises, training, staff exchange, joint communication activities on issues of common interest, best practice exchanges on access to information and documents etc.;
9. The implementation of specific joint work projects between the Parties shall be undertaken with reference to each Party's annual work programme, following approval of the work programmes by the decision-making bodies and taking into account availability of adequate resources.

3. Mutual consultation

The Parties undertake to, where possible and appropriate:

[1] In particular Article 59 of Regulation No 726/2004 and Article 95 of Regulation (EC) No 1907/2006

1. Consult each other regularly and endeavour to keep each other informed on matters of common interest in order to coordinate their activities and to avoid that they give contradicting messages;
2. 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 Parties have an interest;
3. Have ad hoc consultations on new emerging situations where urgent cooperation would be necessary to avoid potentially divergent scientific opinions.

4. Coordination

1. Each Part will designate one staff member as coordinator for the maintenance of close, direct and continuing contacts with the view to ensuring the application of the provisions of the present MoU. These coordinators will keep and update as necessary, a list of contact persons as well as a working list of specific activities for each area of cooperation;
2. When necessary the coordinators will convene meetings at the required level between representatives of the Parties.

5. Further implementation

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

6. Confidentiality of information

1. Exchange of information between the Parties for the purpose of this MoU, shall only take place in accordance with the provisions of this MoU, and in accordance with the applicable laws and regulations governing the processing and release of information in particular the provisions of Regulation (EC) No 45/2001. Sharing of information shall safeguard the legitimate rights of third parties, including their intellectual property rights. Exchange of information held by the Parties may only take place in accordance with its mandate;
2. The Parties shall inform each other, before the information exchange, of the purpose for which the information is intended to be used. Any conditions which apply to the use of the information exchanged for example with regard to its deletion or destruction, including possible access restrictions in general or specific terms shall be clearly communicated at the time the information is exchanged at the latest. Where the need for such conditions becomes apparent after the exchange of information takes place, such conditions as are considered necessary shall be notified to the receiving Agency as soon as possible;
3. Each Party shall ensure that data or other information received on the basis of this working arrangement shall be subject to its confidentiality and security standards for the processing of information;
4. Each Party shall ensure that information received from the other Party 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 Party. Each Party 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 Parties, the other Party shall be informed in advance before the exchange of information take place.

7. Divergences of Interpretation or Implementation

The Parties undertake to make the best efforts to cooperate with a view to resolving any divergence that may arise in the interpretation or implementation of the present MoU, in accordance with the provisions of Article 59 of Regulation (EC) No 726/2004 and Article 95 of Regulation (EC) No 1907/2006.

8. Amendments

The present MoU may be amended by mutual consent in writing between the Parties at any time, in accordance with their respective statutory requirements.

9. Termination of the Memorandum of Understanding

The present MoU may be terminated by each of the Parties giving at least three months' written notice to the other Party, or via a mutual written agreement.

The Parties shall take appropriate measures to ensure minimal damage to ongoing technical collaboration that could results from decision to terminate this MoU.

This MoU will enter into force when signed by both Parties:

For the European Medicines Agency,	For the European Chemicals Agency,
Guido Rasi, Executive Director	Geert Dancet, Executive Director
Signature: On file	Signature: On file
Done at: Helsinki,	Done at: Helsinki,
Date: 14 May 2014	Date: 14 May 2014

In duplicate, in English.