

26 January 2012

Memorandum of understanding on working arrangements

between

the European Medicines Agency and
the European Food Safety Authority

THE EUROPEAN MEDICINES AGENCY AND THE EUROPEAN FOOD SAFETY AUTHORITY,

Having regard to the respective mandates — under 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 Agency¹ and under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing a European Food Safety Authority and laying down procedures in matters of food safety², and in particular Article 23 thereof,

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, and in particular the reference to the remit of EFSA as contained in Article 85 of Regulation (EC) No 726/2004,

Recalling the remit of the European Food Safety Authority (hereinafter referred to as 'EFSA'), and in particular its duty to identify and handle at early stage potential contentious scientific issues in accordance with Article 31 of Regulation (EC) No 178/2002 and the reference to the remit of EMA as contained in Article 63 of Regulation (EC) No 178/2002,

Recalling that in relation to food-producing animals and to foodstuff of animal origin it is, as a result of scientific and technical progress, possible to detect the presence of residues of veterinary medicinal products in foodstuffs at ever lower levels and that consequently Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 31, 1.2.2002, p. 1.

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the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council³, and in particular Articles 1 and 2, Article 4(2) and Article 18 of Regulation (EC) No 470/2009 take account of related remits and mandates of EMA and EFSA,

Recalling that it is nevertheless important to avoid confusion between the missions of EMA and EFSA,

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,

HAVE AGREED AS FOLLOWS:

1. Purpose of the Memorandum of Understanding: Enhanced cooperation and avoiding of duplication

EMA and EFSA as Parties of the present Memorandum of Understanding commit to fostering cooperation between the two agencies in the field of activities identified below based on the principles of appropriateness, common interest, reciprocity and complementarity.

The implementation of this Memorandum of Understanding aims in particular at avoiding duplication, at further developing the scientific excellence and the other core values of the two agencies involved, at optimising of the use of risk assessment capacity across the European Union, at developing and harmonising methodologies and approaches to assessing risks associated with the remit of the agencies involved, and at strengthening the evidence basis for risk assessment and risk monitoring.

2. Areas of cooperation

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

- exchange of information and cooperation to ensure early identification of potential sources of conflict between scientific opinions between committees, panels and other groups of the two Parties;
- exchange of information on areas of mutual interest, such as zoonoses, antimicrobial resistance, consumption of veterinary antimicrobial agents, residues in foodstuff of animal origin, maximum residue limits and scientific approach to safe limits for residues, methodologies for risks assessment of substances, genetically modified organisms, indications/health claims for products containing herbal ingredients, and food supplements and additives;
- exchange of views and coordination as to the handling of scientific questions of common interest and e.g. related to antibiotics in food-producing animals, residues in foodstuffs of animal origin or borderline products (herbal medicinal products and food supplements);
- mutual invitations to attend meetings 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;

³ OJ L 152, 16.6.2009, P. 11.

- implementation of specific joint work projects, e.g. in relation to surveillance and monitoring activities, epidemiological investigations etc., 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;
- development of scientific guidance on the above topics
- cooperation in risks communication;
- exchange of information with a view to greater cooperation in areas such information technology, public procurement, legal matters, and policies and best practice regarding independence and handling conflicts of interest, openness and transparency policies and mechanisms.

3. Mutual consultation

The parties undertake to, where possible and appropriate:

- 3.1. Consult each other regularly and endeavour to keep each other informed on matters of common interest in order to coordinate activities and to avoid contradicting messages;
- 3.2. 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 agencies have an interest;
- 3.3. Have ad hoc consultations on new emerging situations where urgent cooperation would be necessary to avoid potential conflicting scientific opinions.

4. Coordination

Each party shall 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 working arrangement. These coordinators shall keep and update as necessary, a list of contact persons for the main areas of cooperation.

When necessary the coordinators shall convene meetings at the required level between representatives of the two parties.

In case of conflicting internal rules of the two agencies, the internal rules of the agency, in which the activity takes place, shall apply.

5. Further implementation

Further aspects and details of the cooperation between EMA and EFSA 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.

6. Confidentiality of information

- 6.1. Exchange of information between EMA and EFSA shall only take place for the purpose of, and in accordance with, the provisions of this working arrangement, and may not include data related to identified or identifiable individuals. Exchange of information contained in particular databases at EFSA shall be in accordance with their respective agreements on data sharing.

- 6.2. 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 indicate to each other such restrictions at a later stage.
- 6.3. 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.
- 6.4. Each Party shall ensure that information received from the other Party receives a level of protection which is equivalent to the level of protection offered by the measures applied to that information by the other Party. 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.
- 6.5. In accordance with the principle of proportionality, confidentiality levels shall be attributed at the lowest possible level by each Party and amended accordingly wherever possible.
- 6.6. The Party supplying the information shall be responsible for the choice of the appropriate confidentiality level for information supplied, and shall ensure that the level is clearly indicated.
- 6.7. 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.

7. Divergences of Interpretation or Implementation

The Parties undertake to cooperate with a view to resolving any divergence that may arise in the interpretation or implementation of the present Memorandum of Understanding in accordance with the provisions of Article 59 of Regulation (EC) No 726/2004 and Article 30 of Regulation (EC) No 178/2002.

8. Amendments

The present Memorandum of Understanding may be amended by mutual consent in writing between EMA and EFSA at any time, in accordance with their respective statutory requirements.

The present Memorandum of Understanding shall be implemented through technical procedures annexed to this document after mutual written agreement.

9. Termination of the Memorandum of Understanding

The present Memorandum of Understanding may be terminated by each of the two Parties giving at least three months' written notice or by both Parties via mutual written agreement. Both Parties shall take appropriate measures to ensure minimal damage to ongoing technical collaboration that could result from decision to terminate these working arrangements.

The present memorandum of understanding shall enter into force on the day following the date of signature by both Parties.

For the European Medicines Agency:

For the European Food Safety Authority:

Guido Rasi
Executive Director

Catherine Geslain-Lanéelle
Executive Director

Signature: On file

Signature: On file

Done at: London

Done at: London

Date: 27 January 2012

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In duplicate, in English.