

10 December 2010
EMA/MB/520678/2010
Directorate

Working arrangement

Between the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC)

The European Medicines Agency, hereinafter referred to as 'the EMA', and the European Centre for Disease Prevention and Control, hereinafter referred to as 'ECDC';

Recalling 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 851/2004 of the European Parliament and of the Council of 21 March 2004 establishing a European Centre for Disease Prevention and Control;

Recalling the EMA's 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 ECDC 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.

2. Areas to which the working arrangement applies

Cooperation between the two agencies will relate to following areas in accordance with their respective mandates:

European Medicines Agency

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Centre for Disease Prevention and Control

Postal address 171 83 • Stockholm • Sweden

Visiting address Tomtebodavägen 11a • Solna • Sweden

Telephone +46 (0)8 58 60 1000 **Facsimile** +46 (0)8 58 60 1001

E-mail info@ecdc.europa.eu **Website** www.ecdc.europa.eu

- Exchange of information on areas of mutual interest such as vaccines (effectiveness and safety, schedules), antimicrobial agents and resistance, antivirals, including pandemic aspects;
- Benefit/risk monitoring of vaccines with focus on post-authorisation phase;
- EU level activities on the area of substances of human origin (SoHO);
- Invitations to each other 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;
- The implementation of specific joint work projects 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.

Practical aspects of the cooperation between the EMA and ECDC will be developed in the framework of this working arrangement, including a document on the respective roles and responsibilities of each agency within the scope of the legislation, as well as an implementation plan, where needed.

3. Mutual consultation

The parties undertake to, where possible and appropriate:

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;
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. Have ad hoc consultations on new emerging situations in the area of communicable diseases where urgent cooperation would be necessary to avoid potential conflicting scientific opinions.

4. Coordination

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

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

5. Confidentiality of information

1. Exchange of information between the EMA and ECDC 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. Exchange of information contained in particular databases at ECDC should be in accordance with their respective agreements on data sharing.
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.

6. Amendments

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

This working arrangement will be implemented through technical procedures annexed to this document after mutual agreement.

7. Termination of the working arrangement

This arrangement may be terminated by both Parties giving at least three months' written notice or by mutual written agreement. Both Parties will take appropriate measures to ensure minimal damage to ongoing technical collaboration that could result from decision to terminate these working arrangements.

This working arrangement will enter into force when signed by both Parties:

For the European Medicines Agency,

For the European Centre for Disease Prevention
and Control,

Thomas Lönngren, Executive Director

Marc Sprenger, Director

Signature: _____

Signature: _____

Done at: _____

Done at: _____

SIGNATURE ON FILE

SIGNATURE ON FILE

Date: _____

Date: _____

In duplicate,

