POLICY/0009
EMA/124704/2005 Rev.1

EMEA POLICY ON APPROPRIATE COORDINATION BETWEEN THE SCIENTIFIC COMMITTEES OF THE AGENCY

1. Introduction and purpose

Regulation (EC) No 726/2004 as amended[1] states that the EMEA Executive Director shall be responsible for ensuring appropriate coordination between the EMEA scientific committees[2] (CHMP, CVMP, COMP, HMPC, PDCO). With Regulation (EC) No 1901/2006[3] as amended that establishes the Paediatric Committee, the Executive Director holds a further specific coordination responsibility as he shall ensure appropriate coordination between the PDCO, the CHMP, the COMP, and their working parties and any other scientific advisory groups as regards the provisions of that Regulation. Coordination between the Committee for Advanced Therapies and other committees as provided for by Regulation (EC) No 1394/2007 will be addressed at a later stage.

The purpose of this policy is to lay down the principles that shall be adhered to by the committees, their respective working parties (WPs), scientific advisory groups (SAGs) and secretariats in order to achieve the sought coordination.

From this policy, procedures will be developed for each committee to describe the practical arrangements in place to implement the principles set out in the present document.

2. Scope

Scope of the coordination

The EMEA committees have well defined and distinct scientific competence. It is expected that coordination will primarily concern scientific topics of overlapping responsibilities/common interest between one or more committees. Coordination aims at maintaining consistent scientific standards throughout the Agency and avoiding conflicts between scientific opinions and views expressed by the committees. Coordination may also be applicable for some organisational issues.

Coordination with the GCP and GMDP Inspectors working groups and with the Coordination Groups for Mutual Recognition and Decentralised Procedures [4] (Human and Veterinary) is outside the scope of this policy and will be considered separately.

Where coordination relates to scientific issues of common concern[5] with other bodies established under Community law, specific guidelines/recommendations on the cooperation with other bodies in

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council; article 64.2(d)
[2] CHMP: Committee for Medicinal Products for Human Use
CVMP: Committee for Medicinal Products for Veterinary Use
COMP: Committee on Orphan Medicinal Products
HMPC: Committee on Herbal Medicinal Products
PDCO: Paediatric Committee
[3] Regulation (EC) 1901/2006 of the European Parliament and of the Council; article 3(3)
[4] Directive 2001/83/EC of the European Parliament and of the Council as amended; article 27.1
Directive 2001/82/EC of the European Parliament and of the Council as amended; article 31.1
[5] Regulation (EC) No 726/2004 of the European Parliament and of the Council; article 59

the European Union for the identification and management of potential conflict over scientific opinions shall be followed as soon as available. Such coordination is outside the scope of this policy.

Partners involved in the coordination

The coordination is guaranteed by the contribution of different partners involved in the work of the scientific committees under the responsibility of the EMEA Executive Director.

Together with the committee members, the following partners will play an essential role in the coordination exercise as set out in the committees' rules[6] of procedure, and described in section 4.2 of this document:

1. the chair and vice-chair of the committees
2. the members holding joint committee/WP membership and observers
3. Executive Support and the EMEA Senior Medical Officer
4. the secretariats of the committees

3. Definitions, abbreviations

CHMP: Committee for Medicinal Products for Human Use
CVMP: Committee for Medicinal Products for Veterinary Use
COMP: Committee on Orphan Medicinal Products
GCP: Good Clinical Practice
GDP: Good Distribution Practice
GMP: Good Manufacturing Practice
GMDP IWG: GMP/GDP Inspectors Working Group
HMPC: Committee on Herbal Medicinal Products
PDCO: Paediatric Committee
SAG: Scientific Advisory Group
WP: Working Party

4. Policy statement

4.1 Principles governing appropriate coordination

The following key principles have been identified to achieve effective coordination:

- Areas of overlapping responsibilities/common interest between two or more committees, their WPs and/or their SAGs shall be identified and flagged up by the respective secretariats and agreed by the respective committees so as to predefine the framework for future interactions.

  For example following a mutual review of the annual work programmes of their working parties two committees will establish a joint list of the scientific domains where they share common interest.

- For topics identified as being of overlapping responsibilities/common interest, it is the responsibility of the originating committee to care for the coordination with the other committee(s) concerned.

- Coordination on draft scientific opinions will be managed in full respect of the relevant legal provisions, at the initiative of the committee that shall adopt the opinion.

- A committee must bring to the attention of other committee(s) guidance documents[7] that pertain to the agreed areas of overlapping responsibilities/common interest at an early stage and in any

[6] EMEA/CHMP/111481/2004 Rev.1, EMEA/CVMP/422/04 Rev.1, EMEA/COMP/821200 Rev.3, EMEA/HMPC/139800/2004 Rev.1, EMEA/PDCO/358340/2007

case before the document is released for public consultation, unless urgent communication is needed.

- The committee submitting a document to other committee(s) for coordination purposes should propose a timetable that gives sufficient time to the receiving committee to prepare the input. Timelines, in particular those laid down in the legislation, must be highlighted to and respected by the receiving committee. Timetables will further take into account the committees meetings' frequency and allow consultation by written procedure if necessary. Committees, WPs and SAGs must respect agreed timetables.

- Divergences identified, which could not be resolved through coordination between two or more committees will be referred to the Executive Director for resolution. The time period for resolution will be determined by the urgency of the matter. In order to achieve resolution, the Executive Director may convene meetings with representatives from Executive Support, the Senior Medical Officer, the chair(s), vice-chair(s) and secretariat(s) of one or more committee(s).

- In addition to coordination between the WPs and between WPs and SAGs of a given committee (intra-committee), coordination between WPs and SAGs of different committees (inter-committee) shall be organised. However, coordination shall always be initiated at committee level and the outcome of a given coordination process shall be reported to all concerned committees. Via the respective committees, WPs and SAGs must bring to the attention of other WPs/SAGs guidance documents[7] that pertain to the agreed areas of overlapping responsibilities/common interest at an early stage and in any case before the document is released for public consultation.

- Coordination should be focused primarily on issues and documents for which input from other committee(s), in the form of an opinion or comments, is being sought. For issues of overlapping responsibilities/common interest where input is not requested, circulation of documents for information may be sufficient.

- Coordination may also be initiated on new topics arising that could not have been anticipated at the time the list of topics of overlapping responsibilities/common interest was established.

4.2 Roles of the different partners for coordination purpose

The partners mentioned above play different roles in the implementation of the policy as outlined below:

4.2.1 Chair and vice-chair of the committees

The chair is responsible for the efficient conduct of the business of the committee that he/she chairs. He/she shall actively seek coordination, together with the secretariat, of the work of the committee with that of the other committees of the Agency. He/she may seek assistance in his coordination duties from the committee vice-chair.

He/she shall regularly remind committee members, chairs of WPs and/or SAGs, and in particular Rapporteurs for scientific opinions and guidance documents, of the principles agreed upon to ensure appropriate coordination.

He/she may contact the chair(s) of other committee(s) about a topic for which coordination is sought when the need arises given the sensitivity, complexity or controversy of the matter and in particular

[7] This encompasses not only guidelines but various types of documents referred to in the 'EMEA Procedure for EU guidelines and related documents within the pharmaceutical legislative framework' such as public statements and Questions & Answers documents

when conflicting views are emerging. Meetings to discuss coordination issues may be convened between chairs as necessary.

The chair shall take the opportunity of his/her bilateral meeting with the EMEA Executive Director (arranged at least on an annual basis) to propose possible improvements in coordination.

4.2.2 Members holding joint committee/WP membership and observers

Coordination will be facilitated when some members hold joint membership. Such joint membership may for example result from the nominations by national competent authorities or derive from legal provisions as regards a committee's composition. When several members hold a joint membership, some or all of these members may be given a coordination role with a clear mandate by the concerned committees.
A committee may admit observers from other committees or WPs for the purpose of strengthening coordination activities. Observers at working party level may also be admitted upon agreement by the respective committees.

Such members holding joint committee/WP membership and observers will play a key role in identifying at an early stage scientific opinions and guidance documents that fall within the scope of the planned coordination or that trigger a new coordination channel. They will also contribute to the exchange of comments and understanding of any recommendations raised by a committee, a WP or a SAG on behalf of a committee.

4.2.3 Executive Support & EMEA Senior Medical Officer

Within the EMEA, the 'Executive Support' sector monitors general coordination between the committees from a general policy, regulatory and procedural perspective in its support role for the Executive Director.

The Senior Medical Officer advises the Executive Director on a range of matters relating to the Agency's mission. The role of the Senior Medical Officer involves coordinating activities between the Agency's scientific committees. Based on experience gained with cross-committee interactions on coordination, he shall propose solutions and stimulate further coordination with the objective to improve quality and consistency of scientific decisions. The Senior Medical Officer will liaise with Executive Support in the exercise of his role for coordination of scientific issues between the committees.

4.2.4 Secretariats of the committees

Within the EMEA Secretariat, direct responsibilities for the practical aspects of coordination between two or more committees shall fall upon the concerned committees' secretariats, in line with procedures to be prepared by these secretariats. The secretariats provide scientific, technical, legal, regulatory and administrative support to the committees, WPs and SAGs with a view to the performance of their duties.

The secretariat of a given committee, WP or SAG shall in particular:

- support the chair in his/her coordination duties
- initiate the identification of areas of overlapping responsibilities/common interest with one or more committee(s)
- flag topics on the agenda that may be relevant for coordination and ensure appropriate coordination
- interact with members holding joint committee membership and observers on coordination matters
- liaise with the EMEA Senior Medical Officer as appropriate
- coordinate the review of documents that are subject to coordination with one or more committee(s)

- convene meetings with the secretariats of other committees when necessary
- ensure that timelines are respected
- communicate to the committee the outcome of the coordination with other committees

4.3 Monitoring the policy's implementation

For the purpose of monitoring the implementation of this policy, each committee secretariat shall record coordination activities. Meetings between the secretariats of the committees will be organised to discuss coordination processes and agreed monitoring indicators at least once a year.
All secretariats shall document the scope and extent of the coordination taking place between committees (each secretariat shall focus on the coordination undertaken at the initiative of their committee). Relevant elements of coordination may be reflected in the annual report[8] submitted by the Executive Director to the EMEA Management Board on the activities of the Agency.

A review of the coordination objectives and achievements will take place every 5 years and shall be led by the Senior Medical Officer. Such review may result in the revision of the present policy.

5. Related documents

Not applicable.

6. Changes since last revision

The revision of the policy was triggered in the summer 2007 by the need to reflect the establishment of the PDCO and the role of the Senior Medical Officer and Executive Support sector. The revised policy brings clarification about the coordination between working parties and the concept that a special coordination mandate may be given to those experts, who are members of two groups (committees and/or working parties) is introduced.

London, 31 October 2008

On file

Thomas Lönngren
Executive Director

[8] Article 64(3) of Regulation (EC) No 726/2004 as amended