

**THE  
MUTUAL RECOGNITION CO-ORDINATION GROUPS  
ESTABLISHED BY  
DIRECTIVES 2004/27/EC AND 2004/28/EC**

**Report prepared by**

**The Ad Hoc Working Group set up by HoA/HEVRA**

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Adopted by Heads of Medicines Agencies at their meeting of 26 May 2004, in Dublin, Ireland.

Confirmed by Heads of Medicines Agencies at their meeting of 8 September 2004, in Scheveningen, the Netherlands.

## **1. INTRODUCTION**

In their meeting of 8-9 July 2003 in Verona, Heads of Agencies (HoA) agreed to set up an *ad hoc* Working Group to consider the role of a new Co-ordination Group that is foreseen in legislation to assist procedures for authorisation of a medicinal product in more than one member state. At the Heads of Veterinary Agencies (HEVRA) meeting of November 2003 in Rome it was decided to create such an *ad-hoc* group also for the veterinary sector. At the January 2004 HEVRA meeting, the Heads of Veterinary Agencies gave mandate to VMRFG as a whole to evaluate the work already done by the human side in order to produce a document which should harmonise as much as possible the approach from both sides (human and veterinary Co-ordination Groups).

The successful operation of the current informal Mutual Recognition Facilitation Group (MRFG) and Veterinary Mutual Recognition Facilitation Group (VMRFG) will be recognised in the expanded role of these new formal groups. These new Groups have a legal basis for operation and have new responsibilities as detailed in the recently approved legislation. This paper outlines some of the most relevant features of the new groups. It should stand as a reference paper and should be periodically revised and updated according to the practical experience gained by the Co-ordination Groups, HoA, HEVRA and national competent authorities. Its contents should be reflected in the Rules of Procedures which will be formally adopted by each of the Co-ordination Groups once set up.

## **2. BACKGROUND**

The review of the pharmaceutical legislation<sup>1</sup> relating to human and veterinary medicinal products maintains a Mutual Recognition Procedure (MRP) for granting a national marketing authorisation (MA) for medicinal products in more than one member state (MS).

In the case where the medicinal product has not yet received any MA the review creates the decentralised procedure, whereby the evaluation of the application is

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<sup>1</sup> The review of the pharmaceutical legislation, for the purpose of this document, consists of Directive 2004/27/EC, amending Directive 2001/83/EC, and Directive 2004/28/EC, amending Directive 2001/82/EC. All references to Directives 2001/83/EC and 2001/82/EC integrate the newly adopted amendments.

undertaken by the Reference Member State (RMS) with the contribution from all Concerned Member States (CMS).

The new legislation sets up human and veterinary Co-ordination Groups (CGs) to examine any question related to the MA through MRP or the decentralised procedure<sup>2</sup>.

In the case of disagreement between MS on the grounds of “potential serious risk to public health” or “potential serious risk to human or animal health or the environment”, the application will be considered by the CG and MS will use their best endeavours to reach agreement on the action to be taken<sup>3</sup>.

In the case of an unsolved disagreement in a specific MR/decentralised procedure, the matter must be referred to the CHMP or the CVMP for arbitration<sup>4</sup>.

In addition, in order to promote harmonisation of MAs across the Community, the CGs will lay down a list of products where the SPC needs to be harmonised taking into account the proposals from MS<sup>5</sup>.

The CGs shall draw up their own Rules of Procedure for Commission approval<sup>6</sup>.

### **3. VISION**

The *ad hoc* working group and VMRFG considered and agreed their vision as to how the new CGs would function. Primarily, they will be groups of MS representatives responsible for the smooth functioning and good outcomes of MR and decentralised procedures, with a mix of regulatory and scientific work, building on the success of the procedural/regulatory activities of MRFG and VMRFG, and reinforcing their current scientific role. Their mission will be:

- to aim for consensus and avoid referrals to CHMP or CVMP other than in exceptional cases of disagreement on the grounds of “potential serious risk to public health” or of “potential serious risk to human or animal health or the environment”;

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<sup>2</sup> Arises from Article 27(1) of Directive 2001/83/EC and from Article 31(1) of Directive 2001/82/EC.

<sup>3</sup> Arises from Article 29(1) and (3) of Directive 2001/83/EC and from Article 33(1) and (3) of Directive 2001/82/EC.

<sup>4</sup> Arises from Article 29(4) of Directive 2001/83/EC and from Article 33(4) of Directive 2001/82/EC.

<sup>5</sup> Arises from Article 30(2) of Directive 2001/83/EC and from Article 34(2) of Directive 2001/82/EC.

<sup>6</sup> Arises from Article 27(3) of Directive 2001/83/EC and from Article 31(3) of Directive 2001/82/EC.

- to ensure consistency of standards and good quality decision making across the EU in the interests of public health, animal health and the environment;
- to achieve the harmonisation of SPCs of nationally authorised products in particular cases that would benefit citizens and animal health of the Community;
- to present a harmonised view on the interpretation of Directives and Regulations in order to facilitate implementation and finding solutions.

**Recommendations:**

Heads of Agencies and Heads of Veterinary Agencies are invited to endorse the vision of the CGs.

#### **4. MANDATE**

The mandate of the CGs will be:

1. To address procedural, regulatory and scientific issues arising from the MR and decentralised procedures.
2. To consider points of disagreement raised by a MS in relation to the assessment report, SPC, labelling and package leaflet of a medicinal product on the grounds of “potential serious risk to public health” or of “potential serious risk to human or animal health or the environment” within an MR or decentralised procedure. In the case of unsolved disagreement, the CGs will refer the matter to the CHMP or CVMP for arbitration with a detailed reasoning for the disagreement.
- 3 To facilitate the establishment of dialogue between MS, through meetings and oral explanations and to provide a forum to discuss any difficulties in dialogue and seek to overcome such difficulties.

4. To control the practical application of a “potential serious risk to public health” and of a “potential serious risk to human or animal health or the environment” taking account of:

- guidelines to be adopted by the Commission that provide a definition;
- the legal grounds for refusal/suspension/revocation of an application/MA in accordance with Articles 26 and 116 of Directive 2001/83/EC and Articles 30 and 83 of Directive 2001/82/EC.

5. In order to promote harmonisation of MAs across the Community, to lay down a list of products where the SPC needs to be harmonised taking into account proposals from MS. In the case of the human CG, this will be done on an annual basis.

6. To facilitate the resolution of procedural, regulatory and scientific issues arising from variation and renewal procedures, with a view to maintaining harmonisation of an MA following MR or the completion of a decentralised procedure or following a referral.

7. To identify issues which will be referred to the Commission, the Pharmaceutical Committee, the Veterinary Pharmaceutical Committee, HoA, HEVRA or other appropriate bodies.

8. In close liaison with the Pharmacovigilance Working Parties (PhVWP) of CHMP and CVMP, to ensure best practice for risk management of MAs granted through the MR/decentralised procedure. Specifically, the CGs will have responsibility for the efficient processing of periodic safety update reports (PSURs) across MS, making provision for work sharing when applicable, and co-ordinating the synchronisation of birth dates if necessary.

9. To undertake tasks concerning the overall management of the MRP and decentralised procedure, maintaining close interaction with HoA and HEVRA.

10. To draw up their own Rules of Procedure for endorsement by HoA or HEVRA, as appropriate, and for Commission approval. For this purpose, a transitional period could be envisaged (see section 10); the members of the CGs should be identified at least 6 months before the formal date of birth of the groups allowing the drafting of the Rules of Procedure to start.

**Recommendations:**

Heads of Agencies and Heads of Veterinary Agencies are invited to endorse the mandate of the CG.

## **5. ROLE OF THE CO-ORDINATION GROUPS**

### **1. Procedural/regulatory**

- The CGs will develop regulatory SOPs, guidelines and recommendations for use by MS and applicants.
- The CGs will present a harmonised view on the interpretation and implementation of Directives and Regulations in order to facilitate handling and finding solutions.
- The CGs will discuss issues related to specific procedures in order to facilitate reaching an agreed position.
- The CGs will adopt recommendations of scientific break-out sessions held separately to the plenary meeting.

### **2. Scientific**

- The CGs will undertake the necessary discussions to resolve scientific problems related to specific procedures:
  - Within the CGs, MS will consider oral/written explanations from the applicant in cases of disagreement between MS, on the grounds of potential serious risk to public health, human or animal health or the environment.
  - The CGs will prepare a detailed reasoning in cases of unsolved disagreement.

- The CGs will solve the majority of issues, and avoid arbitrations; every effort should be made to refer to CHMP or CVMP in exceptional cases only.
- The CGs will identify and communicate to the EMEA when necessary the need for the modification or development of new guidelines with proposals for the consideration by the appropriate scientific committees.
- The CGs will reach a common understanding of the Commission guideline on serious risks to public health, animal health or the environment, which members should communicate within their agencies. This agreed understanding should form the basis for referring a product application to arbitration.
- The CGs may constitute temporary working parties for issues specific to medicinal products in the MR and decentralised procedures, which shall not overlap with already existing ones.
- One of these working parties shall be dealing with homeopathic medicinal products, ensuring the continuity of the currently existing informal group.
- Joint working parties for human and veterinary medicinal products may be envisaged.
- General scientific issues that relate more broadly to medicinal products may be referred to the CHMP or CVMP and its working parties for advice needed to reach a timely decision.
- The expertise of the new Committee on Herbal Medicinal Products may also be used by the CGs; early involvement of the Committee shall be envisaged when herbal medicinal products are at stake

### **3. Harmonisation of SPCs**

- A list of medicinal products for harmonisation of SPCs will be proposed to the Commission as prescribed in the legislation.
- In preparing the list the CGs will take due account of MS proposals, priority in terms of benefit for the Community, and resource implications.
- The competence of the Committee on Herbal Medicinal Products regarding the establishment of monographs shall also be taken in due account.

#### **4. Risk Management**

- The CGs will take forward HoA and HEVRA recommendations in relation to risk management strategies for nationally authorised medicinal products such as best practice for liaison with PhVWP and arrangements for work sharing of PSURs.

#### **5. Outcome of discussions**

- The CGs will try to reach agreement on an individual MR or decentralised procedure by unanimity between the MS involved in the procedure.
- The CGs will adopt recommendations and provide advice on matters arising from issues considered. This shall be achieved by agreement of the majority of all MS in accordance with its Rules of Procedure.

#### **Recommendations**

Heads of Agencies and Heads of Veterinary Agencies are invited to endorse the role of the CG.

#### **6. MEMBERSHIP**

According to the new legislation (article 27.2 of Directive 2001/83/EC and article 31.2 of Directive 2001/82/EC), the membership of the groups will be comprised of one representative per Member State. The primary role of the groups is to examine any question on national MAs authorised by the MR or decentralised procedures. Therefore, each representative needs to have knowledge and understanding of the authorisation of medicines in their Member State, namely adequate regulatory skills in the management of European MR procedures.

Membership of the group should reflect both the regulatory and scientific functions envisaged by the proposed mandate. To adequately discharge these functions, additional expertise may be required by the group or by individual representatives. The expertise of the CHMP/CVMP and their working parties should be utilised for general scientific issues, in order not to duplicate work and to ensure a harmonised approach. A formal procedure for these requests should address the need for timely advice.

The CG must try to reach agreement on issues arising during MRPs; therefore the members will need to have sufficient authority to take decisions on behalf of their MS. Members will need to reach a clear and common understanding of serious risks to public health, animal health or the environment, in order to ensure that only those risks are the subject of any arbitration.

**Recommendations:**

Members shall be from national agencies and have adequate regulatory expertise to discharge their functions. Members may be accompanied by the necessary experts in order to guarantee the discussion of any relevant issue and the elaboration of related opinions.

The members shall have sufficient delegated authority from their agencies to express final opinions and confirm their agencies' intention to implement the final outcome.

Members should bring back to their agency the background for decisions in the CG. Such feedback is important in order to reach a harmonised interpretation of directives, guidelines etc.

## **7. ORGANISATIONAL ASPECTS**

### **1. Meetings**

- The plenary of the CGs will be held once monthly at the EMEA;
- Break-out sessions and expert groups meetings will be set up and their outcome will be reported to the plenary meeting.
- Videoconference facilities should ideally be available at the level of Member States and EMEA, to ensure participation of all Member States.

### **2. Secretariat**

The secretariat will be provided by the EMEA, to ensure consistency. However, the participation of national detached experts in the secretariat should be envisaged.

The members of the secretariat will be primarily dedicated to the support of the CGs activities. The number of people involved will depend on the scheme of meetings foreseen.

Role of the Secretariat:

- To propose an agenda for each meeting to the chairperson; to circulate the agenda;
- To circulate the relevant documents for each meeting;
- To produce the minutes and table of decisions for each meeting;
- To prepare for each meeting, taking into account the proposed agenda, a list of decisions taken on similar issues;
- To maintain a database for all regulatory and scientific decisions (memory). The outcome of decisions regarding a specific MR procedure should be included in the CTS, linked to that MRP;
- To facilitate liaison with other scientific working groups and with interested parties;
- Support the CG on drafting agreements reached at meetings and of other texts related to the role of the CG;
- Assistance in specific activities committed to the CGs under their work programmes, such as SPC harmonisation;
- To assist the chair in the preparation of the annual report on MRP and decentralised procedure.

### **3. Regulatory and Legal Support**

- Regulatory and legal support to the group's activities should be provided by EMEA staff with experience in the MRP.
- Advice from EMACOLEX on more general matters may be envisaged.
- Legal advice on the interpretation of Community legislation should be sought from the European Commission.

#### **Recommendations:**

In order to optimise national resources, CG meetings should take place preferably sequentially within the same week as the CHMP and CVMP meetings.

## 8. LEGAL QUESTIONS

### 1. Timing of the entry into force of the new MRP and decentralised procedure and CG

- Article 2 of Directives 2004/28/EC and 2004/27/EC states that “*Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 18 months after the entry into force of this Directive*”;
- according to article 3 the period of 18 months shall start on the day of publication in the Official Journal of the European Union, ie, 30th April 2004;
- timing of transposition may therefore be different in the various Member States, which will have impact on the start of the functioning of the new MR procedure, the new decentralised procedure and the Coordination Groups;
- examples of problems that will arise with different starting dates of the new legislation are:
  - a) a mutual recognition procedure including MSs with different implementation dates would be processed according to two different acts of legislation which is not feasible;
  - b) the new decentralised procedure could be in force in one CMS but not in the other;
  - c) a prerequisite for the new CG is that all MSs are involved and represented; this could not be done without new legislation in force in all MSs.
- because of the different legal frameworks and methods of law making processes in the MSs it would be very difficult to find a common date, which would be earlier than 18 months after publication.

#### **Recommendations:**

Member States shall include, in the national act by which they transpose the Directives, a disposition stating that the new procedures and the CG shall start functioning on a precise date, namely: the end of the 18 months period – 30 October 2005. The HoA and HEVRA should explain to governments the potential for confusion and barriers if this recommendation is not followed.

It is also very important that by that time there is an adopted guideline concerning the definition of *potential serious public health concerns* and of *potential serious risk to human or animal health or the environment*.

## **2. Role of the CG regarding variations, renewals and PSUR's**

- article 27(1) of Directive 2001/83/EC and article 31(1) of Directive 2001/82/EC, state that “A *coordination group shall be set up for the examination of any question relating to marketing authorisation of a medicinal product in two or more Member States in accordance with the procedures laid down in this Chapter.*”;
- “this Chapter” means “Chapter 4 – Mutual recognition procedure and decentralised procedure” and encompasses article 27 to 39 (in Directive 2001/83) and articles 31 to 37 (in Directive 2001/82), which refer to the two procedures for obtaining a marketing authorisation (MR and decentralised) and to the referrals;
- the provision can be interpreted either in a very strict sense (the CG shall only deal with the initial MA applications and arbitration procedures) or in a more broader sense (the CG shall deal with **any question** relating to these type of MAs).

### **Recommendations:**

The competence of the CGs shall be construed in a broader sense, allowing the Groups to take an active part in the life cycle of a medicinal product authorised by mutual recognition procedure or decentralised procedure.

## **3. Implications of the use of the word “agreement” and not “decision” or “opinion” regarding the outcome of the future CG discussions concerning applications for marketing authorisations, variations or renewals**

- both in articles 28 (4) and 29 (3) and (4) of the Directive 2001/83/EC and in articles 32 (4) and 33 (3) and (4) of Directive 2001/82/EC the rule is that the CG shall try to reach “agreement” and instructions on what to do if the CG fail to “reach an agreement”; the words “decision” or “opinion” are never used in this context;

- in article 28 (5) of Directive 2001/83/EC and in article 32 (5) of Directive 2001/82/EC it is mentioned that MSs shall adopt “a decision” if certain conditions are fulfilled;
- the distinction between the two terms could be justified in that the CG could “approve” or reach an “agreement” but it is always up to the competence of the MSs to conclude the procedures in a formal binding decision;
- the agreement in the CG is supposed to be made by representatives from the MSs with a proper mandate which then would be executed by the different competent authorities; there is the need to clearly recognise the responsibilities of the members of the CG in the decision making process and distinguish them from the responsibilities related to the formal decision taken by the national authorities. In particular, any divergence between the two decisions should be avoided and the agreement reached during the CG meetings should be accepted by the national authorities, unless serious grounds for divergence are put forward; it is therefore very important that the members of the CGs are invested with a proper mandate;
- an agreement to approve the AR, SPC, etc within the CG shall be by consensus between the MS involved in the procedure.

**Recommendations:**

The HoA and HEVRA should commit to give an adequate mandate to the representatives of the CG.

**4. Article 29 vis-à-vis Article 26 and Article 116 of Directive 2001/83/EC and Article 33 vis-à-vis Article 30 and Article 83 of Directive 2001/82/EC**

The task for the CG is to make efforts to solve disagreements concerning serious risk to public health and serious risk to human or animal health or the environment. This is explicitly mentioned in article 29 of Directive 2001/83/EC and in article 33 of Directive 2001/82/EC.

The grounds for refusal of a marketing authorisation application<sup>7</sup> and the grounds for suspension/revocation of a marketing authorisation<sup>8</sup> shall be taken into account when drafting the guideline on potential serious risk to public health and on serious potential risk to human or animal health or the environment.

**Recommendations:**

These criteria shall be taken into account when drafting the Guideline on potential serious risk to public health and on serious potential risk to human or animal health or the environment.

## **9. IMPACT – RESOURCES**

Both in the meeting of the HoA of 8-9 July 2003, in Verona, and in the meeting of the Heads of Veterinary Agencies of January 2004, in Dublin, the EMEA expressed its wish to be informed as to the possible impact that the creation of the CGs might have on the organisation of the EMEA and on its budget. The presumable impact of new tasks and competences as currently outlined in this paper, both for National Competent Authorities and for the EMEA, have been considered.

### **Points for consideration**

- The CGs are formally set up in legislation and should be endowed with the same status and same support enjoyed by the other committees and working groups.
- Their role as a forum of first instance for the settling of disagreements between MS over the MR or decentralised procedures should act as a filter to minimise the involvement of CHMP and CVMP in referral activities and should as such be granted the greatest possible support by all parties involved.
- The responsibilities of the Chairperson of the CGs should rest with the same elected person for a timeframe which could be envisaged as lasting three years, in analogy to other committees and working groups. The workload of the Chairmanship should fully rest on the Competent Authority of provenance with additional support from the CG secretariat.

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<sup>7</sup> Article 26 of Directive 2001/83/EC and article 30 of Directive 2001/82/EC.

<sup>8</sup> Article 116 of Directive 2001/83/EC and article 83 of Directive 2001/82/EC.

- Taking into account the accession of new MS it is foreseeable that the number of issues arising from MR and decentralised procedures that have to be dealt with by the CGs will increase significantly.

**Table on impact – resources (for each CG)**

<b>Provisions</b>	<b>Resources by National Authorities</b>	<b>Resources by EMEA</b>
Monthly 2 day meeting at EMEA	28 members for 3 days 1 chairperson for 3 days 1 vice-chairperson for 3 days Experts for <i>ad-hoc</i> expert group meetings and break-out sessions Travel and accommodations for experts.	Meeting room for 50-60 persons Rooms for <i>ad-hoc</i> expert group meetings and break-out sessions Booking service
Secretariat and technical support		Meeting support (reprographics, distribution of papers, etc) <b>Human CG:</b> 1 scientific administrator full time and 1 administrator (including support to database needs) 1 administrative assistant full time; 1 secretary full time <b>Vet CG:</b> 1 scientific administrator full time; 1 administrative assistant full time; 1 secretary full time
Communication and Information Technologies	Videoconference	Videoconference Creation and maintenance of scientific and regulatory memory (database)

**Recommendations:**

The CG shall be given the same status and support as other groups foreseen in community legislation.

The existence of videoconference facilities in the EMEA and in all the national authorities is considered fundamental to assure effective participation of relevant experts in the discussion of the procedures.

HoA and HEVRA are invited to seek clarification from Commission and EMEA about the reimbursement of expenses to CG members. It should be straight forward that these groups, as any other formal group, should not be financed by the single MS.

## **10. TRANSITIONAL PERIOD**

In order to guarantee the smooth starting of the functioning of the CGs and the new procedures, a transitional period of 6 months before the formal birth date of the CGs could be envisaged. This period would allow minimising the time needed for the formally constituted CGs to organise their functioning.

HoA and HEVRA should, therefore, identify the members of the CGs at least 6 months before 30th October 2005, which is the end of the transposition period envisaged for the newly approved Directives. This period could be used for:

1. Drafting of the Rules of Procedure, in order to allow formal adoption by the CG immediately after the formal birth date and subsequent approval by the Commission;
2. Analysing practical implications of the new procedures;
3. Maintaining activities carried out currently by MRFG and VMRFG.

Nomination of the members of the CGs should, however, be envisaged as soon as possible.

### **Recommendations**

HoA and HEVRA are invited to nominate members of the CGs at least 6 months before its legal implementation.

## RECOMMENDATIONS<sup>9</sup>

1. Heads of Agencies and HEVRA are invited to endorse the vision of the CG.
2. The Heads of Agency and HEVRA are invited to endorse the mandate of the CG.
3. The Heads of Agency and HEVRA are invited to endorse the role of the CG.
4. Members of the CG shall be from national agencies and have adequate regulatory expertise to discharge their functions. They shall have sufficient delegated authority from their agencies to express final opinions and confirm their agencies' intention to implement the final outcome.
5. Members may be accompanied by the necessary experts in order to guarantee the discussion of any relevant issue and elaboration of related opinions.
6. Members should bring back to their agency the background for decisions in the CG. Such feedback is important in order to reach a harmonised interpretation of directives, guidelines etc.
7. In order to optimise national resources, CG meetings should take place preferably sequentially within the same week as the CHMP and CVMP meetings.
8. Member States shall include, in the national act by which they transpose the Directives, a disposition stating that the new procedures and the CG shall start functioning on a precise date, namely, the end of the 18 months transposition period (ie, 30 October 2005). The HoA and HEVRA should explain to governments the potential for confusion and barriers if this recommendation is not followed.

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<sup>9</sup> Adopted by Heads of Medicines Agencies at their meeting of 26 May 2004, in Dublin, Ireland. Confirmed by Heads of Medicines Agencies at their meeting of 8 September 2004, in Scheveningen, the Netherlands.

9. By the end of the transposition period there must be a final adopted guideline concerning the definition of *potential serious risk to public health* and *potential serious risk to human or animal health or the environment*.

10. The competence of the CG shall be construed in a broader sense, allowing the Group to take an active part in the life cycle of a medicinal product authorised by mutual recognition procedure or decentralised procedure.

11. The HoA/HEVRA should commit to give an adequate mandate to the representatives of the CG.

12. The criteria for refusal of an MA application and for suspension/revocation of a MA shall be taken into account when drafting the Guideline on potential serious risk to public health and on serious concerns to human or animal health or the environment.

13. The CGs shall be given the same status and support as other groups foreseen in community legislation.

14. The existence of videoconference facilities in the EMEA and in all the national authorities is considered fundamental to assure effective participation of relevant experts in the discussion of the procedures.

15. HoA and HEVRA are invited to seek clarification from Commission and EMEA about the reimbursement of expenses to CG members.

16. HoA and HEVRA are invited to nominate members of the CGs at least 6 months before its legal implementation.

## Appendix

### 1. Composition of the Ad Hoc Working Group\*

Rui Santos Ivo, INFARMED, Portugal (chairman)

António Faria Vaz, INFARMED, Portugal

Caitriona Fisher, Irish Medicines Board, Ireland

Christer Backman, Medical Products Agency, Sweden

Dina Lopes, INFARMED, Portugal

Julia Yotaki, National Organization for Medicines, Greece

Per Helboe, Danish Medicines Agency, Denmark

Sara Macedo, INFARMED, Portugal

Shirley Norton, Medicines and Healthcare Products Regulatory Agency, United Kingdom

Silvia Fabiani, Ministero della Salute, Italy

2. In the veterinary sector discussions were held in the frame of VMRFG. An ad hoc group was constituted to prepare discussions:

Virgilio Donnini, Ministero della Salute, Italy (Chairman)

Inge Sandberg, Medicines Evaluation Board, The Netherlands

Maggie Gething, Irish Medicines Board, Ireland

Margarida Alves, INFARMED, Portugal

Paula Kajaste, The National Agency for Medicines, Finland

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\* Set up by HoA at the Meeting held under the Italian Presidency, in July 2003, in Verona.