

# HMA-MG &-PS

Status: Version 2.0

Revision: January 09

Version: 100109

## CONTACT DETAILS HMA AND HMA WGS

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## ADDRESS LIST: HMA-HUMAN

<b>HEADS OF MEDICINES AGENCIES Human</b>	
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## PROFILES OF COMMITTEES AND WORKING GROUPS

### CMD(h)

#### Mandate:

The main task of the group is the co-ordination and facilitation of the operation of the mutual recognition and decentralised procedures and to consider points of disagreement raised by Member States during Mutual recognition or Decentralised procedures, in relation to the assessment report, Summary of Product Characteristics, labelling and package leaflet of a medicinal product.

#### Members:

all MS

#### Meeting Cycle:

monthly

#### Agendas:

Circulation prior to each meeting to members

#### Minutes:

Prepared by the chair with assistance of the EMEA secretariat. Circulated by EMEA secretariat via CMD(h) mailbox.

#### Chair general:

#### Chair current:

Truus Janse-de-Hoog (NL), Tel.: +31 703 567408, Fax.: +31 70 3567515,  
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#### Contact point:

Sonia Ribeiro, CMD(h) Secretary (EMEA), Tel.: +44 20 75237231, Fax.: +44 20 74188614,  
e-mail: sonia.ribeiro@emea.europa.eu

#### Other:

The Vice-Chairperson shall be appointed from among the members for the CMD(h) by the Member State which has the presidency of the Council of EU for the duration of the term of the presidency.

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### CMD(v)

#### Mandate:

The main purpose of the group is the coordination and facilitation of the operation of the mutual recognition and decentralised procedures.

#### Members:

All MSs and EFTA states

#### Meeting Cycle:

Monthly

#### Agendas:

Circulation prior to each meeting to each member

#### Minutes:

Prepared by the chair with assistance from EMEA secretariat. Circulated by EMEA secretariat via VMRFV [CMD(v)] mailbox

#### Press release

Published on [www.hma.eu](http://www.hma.eu)

#### Chair general:

#### Chair current:

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#### Contact point:

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#### Other:

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### TSC

(Telematics Steering Committee)

#### Mandate:

Deals with strategic IT issues.

#### Members:

EMEA, EU-Commission, HMA Management Group, EU Presidency

#### Meeting Cycle:

Once every EU-presidency in conjunction with HMA meeting

#### Agendas:

Circulation prior to each meeting to members

#### Minutes:

Circulated before meeting

#### Chair general:

EU-Commission

#### Chair current:

Georgette Lalis (EU-Commission), Tel. :0032- 2 298n79 30, Fax. : 0032- 2 299 80 10,  
e-mail : georgette.lalis@cec.eu.int

#### Contact point:

see current Chair

#### Other:

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### TMC

(Telematics Management Committee)

#### Mandate:

The group has the supervision over the TIGs and makes recommendations on IT strategy issues to the TSC.

#### Members:

EU-Commission, Chair of CMD(h), Chair of CMD(v), Chairs of TIGs, Head of EMEA IT unit, one member of HMA Management Group

#### Meeting Cycle:

twice per year in addition to 4 -6 teleconferences per year

#### Agendas:

Drafted by EMEA (see Contact point below), circulation prior to each meeting to members

#### Minutes:

Drafted by EMEA (see Contact point below), circulation before meeting and publication on EudraPortal

#### Chair general:

EU-Commission

#### Chair current:

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#### Contact point:

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#### Other:

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### PhVWP(h)

#### Mandate:

The group is primarily concerned with providing advice on the safety of medicinal products and the investigation of adverse drug reactions to enable identification, assessment and management of risk.

#### Members:

all MS, EMEA

#### Meeting Cycle:

monthly in parallel to CHMP

#### Agendas:

#### Minutes:

#### Chair general:

#### Chair current:

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#### Contact point:

[phvwp@emea.europa.eu](mailto:phvwp@emea.europa.eu)

#### Other:

## **PhVWP(v)**

### **Mandate:**

The Pharmacovigilance Working Party provides advice to the CVMP on the coordination and supervision of pharmacovigilance of centrally authorised veterinary medicinal products, as well as to the Member States for nationally authorised products or products authorised through the mutual recognition and decentralised procedure.

On request of the CVMP or the member states, the PhVWP-V prepares, revises and updates pharmacovigilance guidelines and provides recommendations on international agreements in the field of pharmacovigilance (particularly through the VICH forum).

For further information see <http://www.emea.europa.eu/pdfs/vet/phvwp/PhVWP-VMandate.pdf>

### **Members:**

all Member States, observers from EEA-EFTA states

### **Meeting Cycle:**

Usually 6 meetings a year

### **Agendas:**

Prepared and circulated before each meeting

### **Minutes:**

Circulated after each meeting

### **Chair general:**

Elected by the CVMP

### **Chair current:**

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e-mail: [cornelia.ibrahim@bvl.bund.de](mailto:cornelia.ibrahim@bvl.bund.de)

### **Contact point:**

see current chair

### **Other:**

## WGEO

(Working Group of Enforcement Officers)

### Mandate:

The working group shall contribute to the protection of public health and animal health and welfare through ensuring adherence to the regulation of the manufacturing and distribution chains of medicinal products, the disruption of illegal activities and the sharing information.

### Members:

Representatives from Member States including EEA States with EMEA, EU-Commission and Switzerland as observers.

### Meeting Cycle:

2 per annum (1 per Presidency)

### Agendas:

Prepared by the Secretariat: Michael Deats

### Minutes:

Prepared by the Secretariat: Michael Deats

### Chair general:

Permanent Chair by election

### Chair current:

Hugo Bonar (IE), Tel.: +353 1 676 4971, Fax.: +353 1 661 4764,  
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### Contact point:

Michael Deats (UK), Tel.: +44 207 084 3375, Fax.: - ,  
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### Other:

**Homeopathic Medicinal Products WG****Mandate:**

- To create a forum for exchange of regulatory and scientific expertise regarding the assessment of the quality and safety of homeopathic medicinal products in the Member States;
- On request from Competent Authorities, to provide guidance on the assessment of homeopathic medicinal products;
- To provide guidance for applicants on the registration of homeopathic medicinal products;
- To establish one common dossier template for applications for the registration (Art 14 of CD 2001/83/EC) of homeopathic medicinal products in the EU, in co-operation with the Notice to Applicants Group;
- To provide advice and expertise, on request of the Coordination Group on procedural, regulatory and scientific issues arising from the mutual recognition and decentralised procedures applicable to homeopathic medicinal products;
- To facilitate the resolution of procedural, regulatory and scientific issues arising from variation procedures pertaining to homeopathic medicinal products;
- To support the drafting of a list of safe dilution grades for homeopathic products referred to in article 14 (1) of Directive 2001/83/EC
- To address regulatory and scientific issues concerning homeopathic medicinal products on request by the European Commission, the Coordination Group, the HoA and the EDQM;
- The WG shall draft rules of procedure for approval by HoA;
- Guidance documents, prepared by the Working Group, will be presented to the HoA Group for approval and publication on the HoA website;

**Members:**

all MS, EDQM, EU-Commission, EMEA, Observers (EFTA, WHO)

**Meeting Cycle:**

two times per year (once per EU-presidency)

**Agendas:**

available to meeting participants only; sent to all members with the invitation

**Minutes:**

available to meeting participants only, prepared by the current chair

**Chair general:****Chair current:**

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**Contact point:**

see current Chair

**Other:**

## CTFG

(Clinical Trial Facilitation Group)

### Mandate:

In support of the efforts of the European Medicines Regulatory Network (EMRN) with regard to public health, the CTFG shall foster a common approach to the regulation of clinical trials conducted in the EU. To this end, the CTFG will establish and improve adequate communication channels within the EMRN and develop and promote common processes and procedures relating to clinical trials within the scope of the duties of the NCAs.

### Members:

MS, EMEA, EU Commission

### Meeting Cycle:

6 times per year

### Agendas:

Prepared by Anne Lenaers (BE)  
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### Minutes:

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### Chair general:

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### Contact point:

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## EMACOLEX

### Mandate:

In support of the efforts of the European Medicines Regulatory Network (EMRN) with regard to public and animal health the European Medicines Agencies Co-operation on Legal and Legislative Issues (EMACOLEX) will by dialogue and co-operation enhance knowledge, trust and confidence between legal staff and others involved in legal matters to ensure the best legal assistance to the EMRN and the individual national competent authorities.

### Members:

Lawyers of MS Medicines Agencies (human and veterinary), EMEA and EC

### Meeting Cycle:

Once every EU Presidency

### Agendas:

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### Minutes:

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### Chair general:

Changing with EU Presidency

### Chair current:

Mette Aaboe Hansen (DK), Tel.: , Fax.:  
e-mail: mah@dkma.dk

### Contact point:

see current Chair

### Other:

## **ERMS FG**

(European Risk Management Strategy Facilitation Group)

### **Mandate:**

To develop a European Strategy for Risk Management which builds on the Competent Agencies' resources and expertise and incorporates the EMEA's role in the co-ordination of the supervision of products authorised through the Community.

### **Members:**

DK, UK, FR, DE, ES, SE, NL, EMEA, European Commission

### **Meeting Cycle:**

As required

### **Agendas:**

Agenda available to meeting participants, drafted by the secretariat.

### **Minutes:**

Available to meeting participants, drafted by the secretariat.

### **Chair general:**

Jytte Lyngvig (DK), Tel.: +45 4488 9555, Fax.: -  
e-mail: [jyl@dkma.dk](mailto:jyl@dkma.dk)

### **Chair current:**

Permanent Chair

### **Contact point:**

Amanda Bryan (Secretariat to FG), Tel.: +44 020 7084 2366, Fax.: +44 020 7084 2765  
e-mail: [Amanda.bryan@mhra.gsi.gov.uk](mailto:Amanda.bryan@mhra.gsi.gov.uk)

### **Other:**

MHRA provides the secretariat for the FG.

# HMA-MG &-PS

Status: Version 2.0

Revision: January 09

Version: 100109

## HMA Telematics Support Working Group

### Mandate:

The mission of this group is to facilitate communication between European and national IT systems (e.g. NCA/EMEA, NCA/NCA, NCA/European Commission) and give advice on other IT activities undertaken by the European Medicines Regulatory Network (EMRN).

The key responsibilities of the WG are the provision of support to the chair for his/her contributions concerning policy building and decision making at HMA, tandem group and European Telematics level; communicating with the HMA-MG and Permanent Secretariat on the contributions of the WG; addressing of technical and financial aspects of all IT projects of the EMRN; formulating of proposals of action in order to facilitate planning, development and implementation of regulatory IT systems by the EMRN and providing advice on identification of priorities, recognising the efficiency of systems and building of standards for IT solutions in the regulatory area.

The group will follow the strategic orientations provided by the IT segment of the HMA strategy paper.

The HMA Tandem support WG is furthermore a permanent group that will follow up on the continuous development of information technology implementation within the EMRN.

### Members:

FR, DE, BE, DK, UK, PT, SE, NL, IS, NO, AT, EE, ES

### Meeting Cycle:

Two times per year minimum

### Agendas:

Prepared by the chair and circulated prior to each meeting to each member

### Minutes:

### Chair general:

### Chair current:

Steve Dean (UK), Tel: +44 1932 33 83 01, Fax: -,  
e-mail: s.dean@vmd.defra.gsi.gov.uk

### Contact point:

Vivienne Saville (UK), Tel: +44 1932 338438, Fax: ,  
e-mail: v.saville@vmd.defra.gsi.gov.uk

### Other:

# HMA-MG &-PS

Status: Version 2.0

Revision: January 09

Version: 100109

## WG on Resource Planning

### Mandate:

At its meeting in Vienna in February 2006, the HMA decided to establish a small working group on resource planning, including both HMA and EMEA, to bring forward work on resource planning.

### Members:

2 UK (VMD + MHRA), NL, EMEA

### Meeting Cycle:

As and when required.

### Agendas:

Circulation prior to each meeting to each member.

### Minutes:

Circulated before each meeting.

### Chair general:

### Chair current:

Steve Dean (UK), Tel.: +44 1932 338301, Fax.: +44 1932 336618,  
e-mail: s.dean@vmd.defra.gsi.gov.uk

### Contact point:

See Chair

### Other:

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## ESS WG

(European Surveillance Strategy Working Group)

### Mandate:

The ESS group is the initiative for a closer cooperation of EU member states and EMEA in a pro-active approach to veterinary pharmacovigilance. This includes to set up strategies for continuous monitoring of products, further development of harmonised risk management strategies and risk communication. ESS should recommend to HMA-V how to make effective use of resources in member states, including work-sharing and achieve better harmonisation.

### Members:

DK, FR, CZ, NL, UK, DE, EMEA, chair CMDv.

### Meeting Cycle:

4 times per year

### Agendas:

Circulation prior to each meeting to members

### Minutes:

Circulated before each meeting

### Chair general:

### Chair current:

Cornelia Ibrahim (DE), Tel.: +49 1888 444 30400, Fax.: +49 1888 444 30009,  
e-mail: cornelia.ibrahim@bvl.bund.de

### Contact point:

see Current Chair

### Other:

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## **BEMA SG**

(Benchmarking of European Medicines Agencies Steering Group)

Mandate: (is in the process of being redrafted)

BEMA-SG's Terms of Reference are as follows:

- To develop and agree on a number of high level indicators supported by specific performance indicators to achieve the best practice standards
- To define procedures and methodology for self assessment and assessment
- To co-ordinate information gathering activity
- To validate outcomes through peer review
- To interpret information gathered
- To make recommendations to Heads of Agencies for an approach to continuous quality improvement, and EU wide improvement for the future

### Members:

IE and FR are joint rapporteurs. The BEMA-SG comprises HU, DE, PT, SE, UK, FI and the EMEA.

### Meeting Cycle:

Quarterly

### Agendas:

Circulated to members prior to SG meetings

### Minutes:

Circulated prior to and agreed at each meeting

### Chair general:

#### Chair current:

Pat O'Mahony (IE), Tel.: +353 1 676 4971, Fax.: +353 1 661 4764,  
e-mail: pat.omahony@imb.ie

Patrick Dehaumont (FR), Tel.: + 33 2 99 94 78 71, Fax.: + 33 2 99 94 78 99,  
e-mail: p.dehaumont@anmv.afssa.fr

### Contact point:

see Chairs

### Other:

## WGCP

(Working Group of Communication Professionals)

### Mandate:

In support of the efforts of the European Regulatory Medicines Network (ERMN) with regard to public health and animal health and welfare, the HMA Working Group of Communication Professionals (HMA WGCP) shall foster the professional communication between ERMN, its stakeholders (e.g. patients, doctors, veterinarians, pharmaceutical industry) and the general public (including the media). To this end, the HMA WGCP will establish and improve adequate communication channels within the ERMN.

### Members:

FR, PT, UK, DK, SE, NL, DE, HU, CZ, FI, EE, NO, RO, IS, IT, CY, IE and the EMEA

### Meeting Cycle:

One meeting per Presidency normally hosted by the presidency of the day

### Agendas:

### Minutes:

### Chair general:

Simon Gregor (UK) e-mail: [simon.gregor@mhra.gsi.gov.uk](mailto:simon.gregor@mhra.gsi.gov.uk)

### Chair current:

### Contact point:

to be determined

### Other:

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## WGQM

(Working Group of Quality Managers)

### Mandate:

In support of the efforts of the European Medicines Regulatory Network (EMRN) with regard to public and animal health, the HMA Working Group of Quality Managers (WGQM) shall provide guidance relating to quality management and best practice benchmarking.

### Members:

The HMA WGQM is composed of a representative of each NCA, EMEA and EC.

### Meeting Cycle:

The WG should meet at least twice a year.

### Agendas:

### Minutes:

### Chair general:

Silvia Fabiani (IT) e-mail: s.fabiani@aifa.gov.it

### Chair current:

### Contact point:

to be determined

### Other:

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## WGPT

(Working Group on Product Testing)

### Mandate:

In support of the efforts of the EMRN with regard to public and animal health, the “HMA working group on product testing” is given the mandate by the HMA to implement the recommendations of the PTTF for the quality control of MRP and DCP products. Major elements of its endeavours will be a rational use of resources and a risk based approach in defining which medicinal products should be tested for the benefit of patients.

### Members:

Experts from NCAs, from Official Medicines Controls Laboratories (OMCLs) and representatives of the European Directorate for the Quality of Medicines (EDQM) and the EMEA.

### Meeting Cycle:

At least twice per year, ideally four per year

### Agendas:

### Minutes:

### Chair general:

Jean Marimbert (FR) e-mail: [jean.marimbert@afssaps.sante.fr](mailto:jean.marimbert@afssaps.sante.fr)  
Tel. : + 33 1 55 87 30 14, Fax. : + 33 1 55 87 30 12

### Chair current:

### Contact point:

to be determined

### Other:

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