

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

| HEADS OF MEDICINES AGENCIES Human | |
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| <p>Cyprus Acting Director Pantelista Koupepidou Ministry of Health (Cyprus) 7 Lamakas Avenue; Lefkosia 1475; Cyprus + 357 22 40 71 03 + 357 22 40 71 49 pkoupepidou@pms.moh.gov.cy</p> | <p>Luxembourg Pharm. Mariette Backes-Lies Ministère de la Santé Villa Louvigny - 1er étage Parc de la Ville - Allée Marconi - 2120; Luxembourg + 352 478 55 90 + 352 26 20 01 47 mariette.backer-lies@ms.etat.lu</p> |
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| <p>Estonia Dr Kristin Raudsepp Ravimiamet 1 Nooruse Str; Tartu - 50411; Estonia + 372 7 37 41 40 + 372 7 37 41 42 kristin.raudsepp@sam.ee</p> | <p>Poland Prof. Leszek Borkowski Urząd Rejestracji Produktów Leczniczych 41 Zabkowska Street – Warszawa - 03-736; Poland + 48 22 851 43 81 + 48 22 851 52 43 justyna.madejska@urpl.gov.pl</p> |

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| <p>Ireland Mr Pat O'Mahony Irish Medicines Board (Bord Leigheasra na hÉireann) The Earlsfort Centre Earlsfort Terrace - Dublin 2; Ireland + 353 1 676 49 71 + 353 1 661 47 64 pat.omahony@imb.ie</p> | <p>United Kingdom Prof Kent Woods Medicines and Healthcare products Regulatory Agency Market Towers - 1 Nine Elms Lane - London SW8 5NQ - GB + 44 20 70 84 25 46 + 44 20 70 84 25 48 kent.woods@mhra.gsi.gov.uk</p> |
| <p>Italy Prof. Guido Rasi Agenzia Italiana del Farmaco Via della Sierra Nevada 60 - Roma 00144 + 39 06 59 78 44 75 + 39 06 59 78 42 48 g.rasi@aifa.gov.it</p> | |

ADDRESS LIST: HMA-VETERINARY

HEADS OF MEDICINES AGENCIES

Veterinary

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| <p>Cyprus Dr Charalambos Kakoyiannis Director of Veterinary Services Ministry of Agriculture, Natural Resources and Environment 1417 Athalassas Street; Nicosia 1417 - Cyprus + 357 22 80 52 01 + 357 22 33 28 03 director@vs.moa.gov.cy</p> | <p>Luxembourg Pharm. Mariette Backes-Lies Ministère de la Santé Villa Louvigny - 1er étage; Parc de la Ville - Allée Marconi; Luxembourg 2120; Luxembourg + 352 478 55 90 + 352 26 20 01 40 luxdpm@ms.etat.lu</p> |
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| <p>Iceland Mrs Rannveig Gunnarsdottir Director, Lyftasjofnun Box 180; IS - 172 Seltjarnarnes; Iceland + 354 520 21 00 + 354 561 21 70 rannveig.gunnarsdottir@lyftastofnun.is</p> | <p>The Netherlands Dr Aginus Kalis College Ter Beoordeling van Geneesmiddelen Kalvermarkt 53; Den Haag 2511 CB; The Netherlands + 31 70 356 74 50 + 31 70 356 75 15 aaw.kalis@cbg-meb.nl / f.verheijen@cbg-meb.nl</p> |
| <p>Ireland Mr Pat O'Mahony Irish Medicines Board (Bord Leigheasra na hÉireann) The Earlsfort Centre Earlsfort Terrace; Dublin 2; Ireland + 353 1 676 49 71 + 353 1 676 78 36 pat.omahony@imb.ie</p> | <p>United Kingdom Mr Steve Dean Veterinary Medicines Directorate Woodham Lane New Haw; Addlestone KT15 3LS; United Kingdom + 44 1932 33 83 01 + 44 1932 33 66 18 s.dean@vmd.defra.gsi.gov.uk</p> |

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Italy

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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,
e-mail: gm.janse@cbg-meb.nl

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.

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 VMRFG [CMD(v)] mailbox

Press release

Published on www.hma.eu

Chair general:

Chair current:

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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:

Hans-Georg Wagner (EMEA), Tel.: +44 20 75237119, Fax.: -
e-mail: hans-georg.Wagner@emea.europa.eu

Contact point:

Gloria Terceiro (EMEA), Tel.:0044-20 7523 7079, Fax.:0044-20 7418 8670,
e-mail: gloria.terceiro@emea.europa.eu

Other:

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:

June Raine (UK), Tel.: +44 207 0842400, Fax.: 44 2070842765,
e-mail: june.raine@mhra.gsi.gov.uk

Contact point:

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:

Cornelia Ibrahim, Tel.: +49 1888 444 30400, Fax.: +49 1888 444 30009,
e-mail: 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:

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e-mail: Hugo.Bonar@imb.ie

Contact point:

Michael Deats (UK), Tel.: +44 207 084 3375, Fax.: - ,
e-mail: Mick.Deats@mhra.gsi.gov.uk

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:**

Emiel van Galen (NL), Tel.: +31 70-356 7486, Fax +,
e-mail: e.v.galen@cbg-meb.nl

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)

e-mail: Anne.Lenaers@fagg-afmps.be

Minutes:

Prepared by Anne Lenaers (BE)

e-mail: Anne.Lenaers@fagg-afmps.be

Chair general:

see current Chair

Chair current:

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Co-chair: Chantal Belorgey (FR) Tel : +(33) 1 55 87 36 75, Fax.:Fax : +(33) 1 55 87 36 72,

e-mail: Chantal.BELORGEY@afssaps.sante.fr

Contact point:

see current chair

Other:

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:

-

Minutes:

-

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

Chair current:

Permanent Chair

Contact point:

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Other:

MHRA provides the secretariat for the FG.

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:

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

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 PTF 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
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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