

HMA-MG & -PS Best Practice Guide

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PERMANENT SECRETARIAT SUPPORT TO THE HMA MANAGEMENT GROUP

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1. MANDATE

HMA Management Group

The Heads of Medicines Agencies Management Group (HMA-MG) was established to co-ordinate and to facilitate the network of Heads of Medicines Agencies (HMA). The HMA-MG shall also manage and supervise the Heads of Medicines Agencies Permanent Secretariat (HMA-PS). Furthermore, the HMA-MG is contact point for issues that should be brought to the attention of the HMA.

- The HMA-MG shall only take decisions on behalf of the HMA where specifically mandated to do so by HMA.

HMA Permanent Secretariat

The Heads of Medicines Agencies Permanent Secretariat (HMA-PS) shall facilitate and support the work of HMA, HMA-MG and the EU Presidency by ensuring co-ordination, consistency and continuity of their work and activities and providing the collective memory of HMA in order to be an efficient and effective partner in the European network¹.

To this end the HMA-PS shall undertake, in particular, the following tasks:

- give executive and administrative support to HMA-MG and HMA through the HMA-MG,
- be central contact point,
- be responsible for co-ordinating and facilitating communication within HMA and to external interested parties,
- facilitate the integration of new Heads of Agency to the network by providing them with an induction package,
- provide collective memory by keeping updated records of agendas, minutes and decisions as well as items for strategic discussions for HMA-MG and HMA,
- report to the HMA-MG,
- other appropriate tasks agreed with the HMA-MG.

Working groups and projects

In relation to working groups and projects, the role and interaction of the HMA-PS with the HMA-MG was defined as follows: the HMA-PS shall bring possible problems and issues of relevant interest to the attention of the HMA-MG and will contribute thus to the agendas of the HMA meetings.

- **The HMA-PS does not provide organisational or administrative support to working groups or projects.**

¹ By Network it is meant the group of EU National Competent Authorities, the European Medicines Agency and the European Commission.

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General communication

After receiving an inquiry from any interested parties, the HMA-PS acknowledges receipt of the inquiry immediately upon receipt. A response will be issued by the HMA-PS after the inquiry has been discussed at the HMA-MG or at the next HMA meeting.

The response to an inquiry will be drafted by the members of the PS and will be sent for signature to the chair of the MG. After receiving the signature, the document will be transformed into a pdf file and will be sent out to the interested party via the official HMA-PS mailbox.

HMA-MG meetings

On a rotational basis, the HMA-PS members draft agenda, minutes and list of actions of the HMA-MG meetings. The HMA-PS member responsible for the agenda and minutes of a HMA-MG meeting is also responsible for ensuring the collection and circulation of relevant documents for the meeting.

HMA meetings

The HMA-MG will keep HMA updated on its regular activities at HMA meetings, through regular updates and reports.

If requested to do so, a HMA-PS member provides support to the HMA-MG when the latter is responsible for an agenda item at a HMA meeting. Support may encompass drafting of documents for the HMA meetings, presentations, etc.

The HMA-PS will keep an updated list of outstanding issues as well as strategic items that need further discussion at future HMA meetings. The updated list will be made available to all presidencies to aid the preparation of the agendas of HMA meetings.

Stakeholder's Information (press release following HMA meetings)

The Presidency will prepare a draft stakeholder's information for discussion at the HMA-MG meeting prior to a HMA meeting. The draft stakeholders' information will then be circulated to the Heads of Medicines Agencies as quickly as possible with a 24-hour comment time line. If no comments are received, it will be taken as an affirmative. The presidency should ensure that the document is posted on the HMA website 5 working days after the end of a HMA meeting.

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2. MEMBERS

<u>MG Permanent Members</u>	MS	E-mail address	Phone number
Chair: Aginus Kalis <i>Assistant / Secretary:</i> Marijke van IJzerloo	NL	aaw.kalis@cbg.meb.nl mc.v.ijzerloo@cbg-meb.nl	0031-70-356-74-48 0031-70-356-74-48
Martina Cvelbar <i>Assistant/ Secretary:</i>	SL	martina.cvelbar@jazmp.si	00386-8-2000-508
Xavier De Cuyper <i>Assistant/ Secretary:</i>	BE	xavier.decuyper@fagg.be	0032 2524 8005
Thomas Heberer <i>Assistant/ Secretary:</i>	DE	Thomas.heberer@bvl.bund.de	0049 30 18444 30000

<u>Permanent Secretariat</u>			
Central Contact Point: Nuala Harman (IMB)	IE	hma-ps@imb.ie nuala.harman@imb.ie	00353-1634-3453
Nuno Simões (INFARMED)	PT	nuno.simoese@infarmed.pt	00351-21-798-52-30
Birte van Elk (MEB)	NL	b.v.elk@cbg-meb.nl	0031-70-356-7482
Åsa Kumlin Howell (MPA)	SE	asa.kumlinhowell@mpa.se	0046-18-17-47-93

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3. RESOURCES / TASKS

<u>HMA-Permanent Secretariat</u>	
Nuno Simões (INFARMED)	Resource planning WG, ESS WG, Training Project Team, ERMS Facilitation Group
Birte van Elk (MEB)	CMDh, PhVWP(v), Product Testing WG; Emacolex
Nuala Harman (IMB)	WGEO, CTFG, WGCP, WGQM, BEMA WG; HMA website, HMA DMS
Åsa Kumlin Howell (MPA)	CMDv, PhVWP(h), TSC/TMC, Homeopathics/Herbals, HMA Telematics Support Group

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4. COOPERATION, COMMUNICATION

HMA MG meetings, secretariat support

The HMA-MG will meet according to a yearly meeting plan agreed by the HMA-MG but at least in conjunction with the HMA meetings. Additional meetings can also take place by tele- or videoconference. HMA-MG meetings by tele- or videoconference are arranged by the central contact point.

At each HMA-MG meeting, the members of the HMA-PS will be present to take the minutes of the meeting and present possible issues on behalf of the HMA-PS. The list of actions of these HMA-MG meetings will be sent out to the MG together with the agenda and meeting minutes. The adopted agenda and minutes will be sent to all HMA MG after each MG meeting.

The full HMA-PS should attend all HMA meetings to ensure continuity and improve support by the HMA-PS. **Agencies of the Members of the Secretariat will pay travel costs while the Presidency pays accommodation for the Members of the Secretariat.**

HMA PS meetings

As a general rule, the HMA-PS meets every fortnight by videoconference or teleconference arranged by the central contact point. Points for discussion and possible accompanying documents are sent before the meeting to the central contact point who circulates an agenda and documents before the videoconference/ teleconference.

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5. PROCEDURES

Publication of HMA-WG documents on the HMA website

a) Documents for consultation

(Please also refer to B: Annex 1 'Policy on Working Group consultation on the website')

1. Draft document from WG to HMA-PS for attention of HMA/ HMA-MG.
2. HMA-MG discussion on which documents can be accepted for website consultation and approval for publication at regular HMA-MG meetings. HMA-MG may refer the decision on publication to HMA.
3. Publication on the website for public consultation after approval by HMA-MG.
4. Discussion of comments and finalisation at WG level.

b) Finalised Documents

(Please also refer to B: Annex 2 'Website procedures')

1. Finalised document from WG to HMA-PS for attention of HMA-MG.
2. Approval of publication by HMA at regular HMA meeting.
3. Document will be sent to the responsible website editor (Human, Veterinary and Joint) for a final check (e.g. editorial style, quality).
4. Publication of finalised document on HMA web-site after approval by HMA.

List of responsible website editors

Sections HMA Website	Website Editors
HMA Joint / Human Medicines	Nuala Harman (IMB, IE) E-mail: nuala.harman@imb.ie
Veterinary Medicines	Vivienne Saville (VMD, UK) E-mail: v.saville@vmd.defra.gsi.gov.uk

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6. DOCUMENTS & ARCHIVING

1. Correspondence, Agendas, Minutes, Meeting documents, Table of decisions, Lists of Actions, Presentations, and Stakeholders' Information.
2. Templates for documents and correspondence/corporate identity.
3. Induction package (regularly updated by PS).

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A. ANNEX 1

ADDRESS LIST: HMA-HUMAN

HEADS OF MEDICINES AGENCIES

Human

<p>Austria Dr. Marcus Müllner Agentur für Gesundheit und Ernährungssicherheit GmbH Schnirchgasse 9; 1030 Wien; Austria + 43 50555 36001 + 43 1 427 07 100 marcus.muellner@ages.at</p>	<p>Latvia Dr. Inguna Adovica Valsts zāļu aģentūra Jersikas iela 15; Rīga 1003; Latvia + 371 70 784 24 + 371 70 784 28 info@vza.gov.lv</p>
<p>Belgium Mr. Xavier De Cuyper Federal Agency for Medicines and Healthcare Products (FAMHP) Place Victor Horta 40/40; Bruxelles - 1060; Belgium + 32 2 524 80 05 + 32 2 524 80 03 xavier.decuyper@fagg.be</p>	<p>Liechtenstein Mr. Peter Gstöhl Amt für Gesundheit Aeulestrasse 51 9490 Vaduz Liechtenstein + 423 236 7325 + 423 236 7350 brigitte.batliner@ag.llv.li</p>
<p>Bulgaria Dr. Alexander Yankov Bulgarian Drug Agency 8 Damyan Gruev str.; 1303 Sofia; Bulgaria +359 2890 3434 alexander.yankov@bda.bg</p>	<p>Lithuania Mr. Gintautas Barcys State Medicines Control Agency Traku 9/1 – Vilnius - 01132; Lithuania +370 5 263 92 64 +370 5 263 9265 gintautasbarcys@vkt.lt</p>
<p>Cyprus George Antoniou Ministry of Health (Cyprus) 7 Larnakas Avenue; Lefkosia 1475; Cyprus + 357 22 40 71 03 + 357 22 40 71 49 gantoniou@phs.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>
<p>Czech Republic Dr. Martin Beneš Státní ústav pro kontrolu léčiv Šrobárova 48 - Praha 10; 100 41; Czech Republic + 420 272 185 834 + 420 272 73 99 95 Martin.Benes@sukl.cz</p>	<p>Malta Dr. Patricia Vella Bonanno Medicines Authority 198 Rue D'Argens - Gzira GZR 003; Malta + 356 23 43 90 00 + 356 23 43 91 61 patricia.vella@gov.mt</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 Dr. Grzegorz Cessak Urząd Rejestracji Produktów Leczniczych 41 Zabkowska Street – Warszawa - 03-736; Poland + 48 22 851 43 81 + 48 22 851 52 43 grzegorz.cessak@urpl.gov.pl</p>
<p>Finland Ms. Sinikka Rajaniemi Lääkealan turvallisuus- ja kehittämiskeskusMannerheimintie 103b; Helsinki - 00300; Finland + 358 9 47 33 42 00 + 358 9 47 33 43 45 sinikka.rajaniemi@fimea.fi</p>	<p>Portugal Dr. Jorge Torgal Autoridade Nacional do Medicamento e Produtos de Saúde, INFARMED, I.P. Parque de Saúde de Lisboa Avenida do Brasil, 53 - Lisboa 1749-004; Portugal + 351 21 798 71 09 + 351 21 798 71 20 jorgetorgal@infarmed.pt</p>
<p>France Mr. Dominique Maraninchi Agence Française de Sécurité Sanitaire des Produits de Santé - 143-147 boulevard Anatole France Saint-Denis Cedex 93285; France + 33 1 55 87 30 14 + 33 1 55 87 30 12 dominique.maraninchi@afssaps.sante.fr</p>	<p>Romania Dr. Daniel Boda Agentia Nationala a Medicamentului Str. Aviator Sanatescu Nr.48; Sector 1; 011478 Bucuresti; Romania + 40 21 316 08 36 + 40 21 316 34 97 daniel.boda@anm.ro</p>
<p>Germany Prof. Dr. Klaus Cichutek Paul-Ehrlich-Institut Paul-Ehrlich Straße 51-59; Langen 63225; Germany + 49 6103 77 10 00 + 49 6103 77 12 40 director@pei.de</p>	<p>Slovak Republic Dr. Jan Mazag Štátny ústav pre kontrolu liečiv Kvetná 11; Bratislava - 825 08; Slovak Republic + 421 2 55 56 50 81 + 421 2 55 56 41 27 sukl@sukl.sk</p>
<p>Germany Prof. Dr. Walter Bundesinstitut für Arzneimittel und Medizinprodukte Kurt-Georg-Kiesinger-Allee 3; Bonn 53175; Germany + 49 228 207 32 03 + 49 228 207 55 14 Walter.Schwerdtfeger@bfarm.de</p>	<p>Slovenia Dr. Martina Cvelbar Javna agencija Republike Slovenije za zdravila in medicinske pripomočke Einspielerjeva ulica 6- Ljubljana 1000; Slovenia + 386 8 2000 508 + 386 8 2000 510 martina.cvelbar@jazmp.si</p>

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<p>Hungary Dr. Hilda Koszeginé Szalai Országos Gyógyszer Intézet; Hungary Zrínyi U. 3 - Budapest 1051 + 36 1 88 69 320 + 36 1 88 69 480 hszalai@ogyi.hu</p>	<p>Sweden Dr. Christina Rångemark Åkerman Läkemedelsverket Dag Hammarskjölds väg 42; Uppsala 751 83; Sweden + 46 18 17 46 00 + 46 18 54 85 66 christina.akerman@mpa.se</p>
<p>Iceland Mrs. Rannveig Gunnarsdottir Director, Lyftastofnun 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</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 1 661 47 64 pat.omahony@imb.ie</p>	<p>United Kingdom Prof. Kent Woods Medicines and Healthcare products Regulatory Agency 151 Buckingham Palace Road London SW1W 9SZ United Kingdom + 44 20 70 84 25 46 + 44 20 70 84 25 48 kent.woods@mhra.gsi.gov.uk</p>
<p>Italy Luca Pani Agenzia Italiana del Farmaco Via del Tritone,181 00187 Roma + 39 06 59 78 44 75 + 39 06 59 78 42 48 l.pani@aifa.it</p>	

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A. ANNEX 2

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<p>Bulgaria Dr. Yordan Voynov Institute for Control of Veterinary Medicinal Products 7, Shose Bankya Str.; 1331 Sofia; Bulgaria + 359 2 915 9820 cvo@nvms.government.bg</p>	<p>Lithuania Dr. Jonas Milius National Food and Veterinary Risk Assessment Institute Kairiūkščio st.10, LT – 08409 Vilnius; Lithuania + 370 5 278 04 70 + 370 5 278 04 71 jmilius@vet.lt</p>
<p>Cyprus Ioanna Talioti 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 italioti@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 - 2120; Luxembourg + 352 478 55 90 + 352 26 20 01 47 mariette.backer-lies@ms.etat.lu</p>
<p>Czech Republic Prof. Alfred Hera Institute for State Control of Veterinary Biologicals and Medicaments Hudcova 56a; Medlánky 621 00 Brno - Czech Republic + 420 541 518 201 + 420 541 21 26 07 hera@uskvbl.cz</p>	<p>Malta Dr. Anthony Gruppeta Ministry for Food, Agriculture and Fisheries (Malta) Albertown; Marsa CMR 02 - Malta + 356 21 22 59 30 + 356 21 23 81 05 anthony.s.gruppeta@gov.mt</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 Dr. Grzegorz Cessak Urząd Rejestracji Produktów Leczniczych 41 Zabkowska Street – Warszawa - 03-736; Poland + 48 22 851 43 81 + 48 22 851 52 43 grzegorz.cessak@urpl.gov.pl</p>
<p>Finland Ms. Sinikka Rajaniemi Lääkealan turvallisuus- ja kehittämiskeskusMannerheimintie 103b; Helsinki - 00300; Finland + 358 9 47 33 42 00 + 358 9 47 33 43 45 sinikka.rajaniemi@fimea.fi</p>	<p>Portugal Dr. Susana Guedes Pombo Direcção Geral de Veterinária - DGV Lago da Academia Nacional de Belas Artes 2 1294-105 Lisboa; Portugal + 351 21 323 8554 + 351 21 323 9652 dirgeral@dgv.min-agricultura.pt</p>
<p>France Dr. Jean Pierre Orand ANSES BP 90 203 Javené; Fougères Cedex 35302; France + 33 299 947870 + 33 299 947899 Jean-pierre.orand@anses.fr</p>	<p>Romania Dr. Ileana Musan Institutul pentru Controlul Produselor Biologice si Medicamentelor de Uz Veterinar 37 Dudului Street; Sector 6; 060603 Bucuresti; Romania Tel: +40 21 220 2112 Fax: +40 21 221 0820/ 3171 ileana.musan@icbmv.ro</p>
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<p>Hungary Dr. Gabor Kulscarg Central Agricultural Office Directorate of Veterinary Medicinal Products Keleti Károly u. 24; Budapest 1024 - Hungary + 36 1 433 03 45 + 36 1 262 28 39 kulscarg@oai.hu</p>	<p>Sweden Dr. Christina Rångemark Åkerman Läkemedelsverket Dag Hammarskjölds väg 42; Uppsala 751 83; Sweden + 46 18 17 46 00 + 46 18 54 85 66 christina.akerman@mpa.se</p>
<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</p>
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A. ANNEX 3

PROFILE OF COMMITTEES AND WORKING GROUPS

Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)	
<u>Mandate:</u>	The main purpose of the group is the coordination 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 Products characteristics, labelling and package leaflet of a veterinary medicinal product related to new applications, variations and renewals. The group shall provide recommendations on the classification of unforeseen variations and shall perform and support worksharing between Member States where appropriate.
<u>Members:</u>	All European Economic Area Members States.
<u>Meeting cycle:</u>	Monthly.
<u>Agendas:</u>	Circulation prior to each meeting to CMDh members.
<u>Minutes:</u>	Prepared by the CMDh Secretariat with assistance of the chair. Circulated by CMDh secretariat via CMDh mailbox.
<u>Press release:</u>	Published on www.hma.eu .
<u>Chair:</u>	Peter Backman (DE) Tel.: +49-228-207-4163 Fax: +49-228-207-3452 E-mail: peter.backman@bfarm.de
<u>Contact point:</u>	CMDh Secretary (EMA) Tel.: +44 207 523 7128 E-mail: H-CMDhSecretariat@ema.europa.eu
<u>Other:</u>	The Vice-Chairperson shall be appointed from among the members for the CMDh 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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Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv)	
<u>Mandate:</u>	The main purpose of the group is the coordination 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 Products Characteristics, labelling and package leaflet of a veterinary medicinal product related to new applications, variations and renewals. The group shall provide recommendations on the classification of unforeseen variations and shall perform and support worksharing between Member States where appropriate.
<u>Members:</u>	All European Economic Area Members States.
<u>Meeting cycle:</u>	Monthly.
<u>Agendas:</u>	Circulation prior to each meeting to CMDh members.
<u>Minutes:</u>	Prepared by the CMDv secretariat with assistance from the Chair. Circulated by CMDh secretariat via CMDh mailbox.
<u>Press release:</u>	Published on www.hma.eu .
<u>Chair:</u>	Esther Werner (DE) Tel.: + 49 6103 777401 Fax.: +49 6103 771254 E-mail: weres@pei.de
<u>Contact point:</u>	Emily Drury (EMA) Tel.: +44 207 523 7403 Fax.: +44 207 418 8447 E-mail: emily.drury@ema.europa.eu
<u>Other:</u>	The Vice-Chair shall be appointed from among the members for the CMDv 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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Pharmacovigilance Working Party - Human (PhVWP(h))	
<u>Mandate:</u>	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.
<u>Members:</u>	All Member States and EMA.
<u>Meeting cycle:</u>	Monthly, in parallel to CHMP.
<u>Agendas:</u>	Circulation prior to each meeting to PhVWP(h) members.
<u>Minutes:</u>	Prepared by the PhVWP(h) secretariat
<u>Press release:</u>	A press release is post at HMA and EMA websites after the meeting and a monthly report is also release on both websites.
<u>Chair:</u>	June Raine (UK) Tel.: +44 207 0842400 Fax.: 44 2070842765 E-mail: june.raine@mhra.gsi.gov.uk
<u>Contact point:</u>	phvwp@ema.europa.eu
<u>Other:</u>	

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Pharmacovigilance Working Party - Veterinary (PhVWP(v))	
<u>Mandate:</u>	<p>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.</p> <p>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).</p> <p>For further information see http://www.emea.europa.eu/pdfs/vet/phwvp/PhVWP-VMandate.pdf and on the HMA website.</p>
<u>Members:</u>	All Member States, observers from EEA-EFTA states.
<u>Meeting cycle:</u>	Usually 6 meetings a year.
<u>Agendas:</u>	Prepared and circulated before each meeting.
<u>Minutes:</u>	Prepared by the PhVWP(v) secretariat.
<u>Press release:</u>	
<u>Chair:</u>	Cornelia Ibrahim Tel.: +49 1888 444 30400 Fax.: +49 1888 444 30009 E-mail: cornelia.ibrahim@bvl.bund.de
<u>Contact point:</u>	cornelia.ibrahim@bvl.bund.de
<u>Other:</u>	

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HMA Clinical Trial Facilitation Group (CTFG)	
<u>Mandate:</u>	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.
<u>Members:</u>	All member States, EMA and EU Commission.
<u>Meeting cycle:</u>	5 to 6 meetings a year.
<u>Agendas:</u>	Prepared and circulated before each meeting.
<u>Minutes:</u>	Prepared by Kristof Bonnarens. E-mail: kristof.bonnarens@fagg.be
<u>Press release:</u>	
<u>Chair:</u>	Chantal Belorgey (FR) Tel.: (33) 1 55 87 36 75 Fax.: (33) 1 55 87 36 72 E-mail: chantal.belorgey@afssaps.sante.fr
<u>Co-chair:</u>	Harmut Krafft (DE) Tel. +49 156 103 771 811 E-mail: kraha@pei.de
<u>Contact point:</u>	See current Chair.
<u>Other:</u>	

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HMA Benchmarking of European Medicines Agencies Steering Group (BEMA SG)			
<u>Terms of Reference:</u>	<ul style="list-style-type: none"> • 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. 		
<u>Members:</u>	HU, DE, PT, UK, FI and EMA.		
<u>Meeting cycle:</u>	Quarterly.		
<u>Agendas:</u>	Prepared and circulated to members prior to meetings.		
<u>Minutes:</u>	Circulated prior to and agreed at each meeting.		
<u>Press release:</u>			
<u>Co-Chairs:</u>	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> Pat O'Mahony (IE) Tel.: +353 1 676 4971 Fax.: +353 1 661 4764 E-mail: pat.omahony@imb.ie </td> <td style="width: 50%; vertical-align: top;"> Klaus Cichutek (DE) Tel.: +49 6103 77 1000 Fax.: +49 6103 77 1240 E-mail: director@pei.de </td> </tr> </table>	Pat O'Mahony (IE) Tel.: +353 1 676 4971 Fax.: +353 1 661 4764 E-mail: pat.omahony@imb.ie	Klaus Cichutek (DE) Tel.: +49 6103 77 1000 Fax.: +49 6103 77 1240 E-mail: director@pei.de
Pat O'Mahony (IE) Tel.: +353 1 676 4971 Fax.: +353 1 661 4764 E-mail: pat.omahony@imb.ie	Klaus Cichutek (DE) Tel.: +49 6103 77 1000 Fax.: +49 6103 77 1240 E-mail: director@pei.de		
<u>Contact point:</u>	See current co-Chairs.		
<u>Other:</u>			

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HMA Working Group of Quality Managers (WGQM)	
<u>Mandate:</u>	<p>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.</p> <p>The Working Group</p> <ul style="list-style-type: none"> - will act as a forum for discussion to agree on common principles to be applied throughout the EMRN, - will operate to improve the exchange of quality management expertise and to contribute towards the development of best practices for quality management, - and will report to HMA on all cases where consistent practices are considered to be in the interest of the Community.
<u>Members:</u>	The HMA WGQM is composed of a representative of each NCA, EMA and EC.
<u>Meeting cycle:</u>	The WG should meet at least twice a year.
<u>Agendas:</u>	Prepared and circulated to members prior to meetings.
<u>Minutes:</u>	Circulated prior to and agreed at each meeting.
<u>Press release:</u>	
<u>Chair:</u>	<p>Brigitte Mauel-Walbröl (DE) Tel: +49-(0)228-207-3808 Fax: +49-(0)228-99-307-3808 E-mail: mauel@bfarm.de</p>
<u>Contact point:</u>	<p>Maria Chiara Barbera (IT) Tel: +39 065 978 4753 Fax: +39 065 978 4554 E-mail: mc.barbera@aifa.gov.it</p>
<u>Other:</u>	

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HMA Working Group of Communication Professionals (WGCP)	
<u>Mandate:</u>	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.
<u>Members:</u>	FR, PT, UK, DK, SE, NL, DE, HU, CZ, FI, EE, NO, RO, IS, IT, CY, IE and the EMA. The members are drawn from experts within the NCAs and EMA.
<u>Meeting cycle:</u>	Twice a year (1 meeting per Presidency).
<u>Agendas:</u>	Prepared and circulated to members prior to meetings.
<u>Minutes:</u>	Prepared by the Presidency of the day and agreed within the group.
<u>Press release:</u>	
<u>Chair:</u>	Interim chair: Diane Leakey (UK) E-mail: Diane.Leakey@mhra.gsi.gov.uk
<u>Contact point:</u>	See current Chair.
<u>Other:</u>	

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HMA Working Group on Product Testing (WGPT)	
<u>Mandate:</u>	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.
<u>Members:</u>	AT, CZ, DE, DK, FI, FR, GR, NO, PT, SE, SI, UK. Experts from Official Medicines Controls Laboratories (OMCLs), the Quality Working Party at the EMA and representatives of the European Directorate for the Quality of Medicines (EDQM) and the EMA Inspectors Working Group.
<u>Meeting cycle:</u>	At least twice a year, ideally four meetings a year.
<u>Agendas:</u>	Prepared and circulated to members prior to meetings.
<u>Minutes:</u>	Prepared by the Chair and agreed within the group.
<u>Press release:</u>	
<u>Chair:</u>	To be appointed Tel.: + Fax.: + E-mail:
<u>Contact point:</u>	See current Chair.
<u>Other:</u>	

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HMA Working Group of Enforcement Officers (WGEO)	
<u>Mandate:</u>	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.
<u>Members:</u>	Representatives from Member States including EEA States with EMA, EU-Commission and Switzerland as observers.
<u>Meeting cycle:</u>	Twice a year (1 meeting per Presidency).
<u>Agendas:</u>	Prepared by the Secretariat: Michael Deats
<u>Minutes:</u>	Prepared by the Secretariat: Michael Deats
<u>Press release:</u>	
<u>Chair:</u>	Kim Helleberg Madsen (DK) Tel.: +45 44 88 93 99 E-mail: khm@dkma.dk
<u>Contact point:</u>	Michael Deats (UK) Tel.: +44 207 084 3375 Fax.: - E-mail: Mick.Deats@mhra.gsi.gov.uk
<u>Other:</u>	

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HMA Homeopathic Medicinal Products Working Group (HMPWG)	
<u>Mandate:</u>	<ul style="list-style-type: none"> - 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 CD2001/83/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 HMA and the EDQM; - The WG drafted rules of procedure approved by HMA; - Guidance documents, prepared by the Working Group, will be presented to the HMA Group for approval and publication on the HMA website.
<u>Members:</u>	All MS, EDQM, EU-Commission, EMA, Observers (EFTA, WHO).
<u>Meeting cycle:</u>	Twice a year (1 meeting per Presidency).
<u>Agendas:</u>	Available to meeting participants only; sent to all members with the invitation
<u>Minutes:</u>	Available to meeting participants only, prepared by the current chair.
<u>Press release:</u>	
<u>Chair:</u>	Laurence Girod Tel.: +31 70 356 7486 Fax +,31 70 356 7515 e-mail: Laurence.GIROD@affsaps.sante.fr
<u>Contact point:</u>	See current Chair.
<u>Other:</u>	The representative of the Member State that holds the EU presidency acts as vice-chair every 6 months.

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HMA EMACOLEX	
<u>Mandate:</u>	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.
<u>Members:</u>	Lawyers of MS Medicines Agencies (human and veterinary), EMA and EC.
<u>Meeting cycle:</u>	Twice a year (1 meeting per Presidency).
<u>Agendas:</u>	Prepared and circulated prior to each meeting.
<u>Minutes:</u>	Prepared by the Presidency and agreed at each meeting.
<u>Press release:</u>	
<u>Chair:</u>	Current Presidency.
<u>Contact point:</u>	See current Chair.
<u>Other:</u>	

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HMA/HMA European Risk Management Strategy Facilitation Group (ERMS FG)	
<u>Mandate:</u>	To develop a European Strategy for Risk Management which builds on the Competent Agencies' resources and expertise and incorporates the EMA's role in the co-ordination of the supervision of products authorised through the Community.
<u>Members:</u>	DK, UK, FR, DE, ES, SE, NL, EMA, European Commission.
<u>Meeting cycle:</u>	As required.
<u>Agendas:</u>	Agenda available to meeting participants, drafted by the secretariat.
<u>Minutes:</u>	Available to meeting participants, drafted by the secretariat.
<u>Press release:</u>	
<u>Chair:</u>	Jytte Lyngvig (DK) Tel.: +45 4488 9555 Fax.: - E-mail: jyl@dkma.dk
<u>Contact point:</u>	Amanda Bryan (Secretariat to the FG) Tel.: +44 020 7084 2366 Fax.: +44 020 7084 2765 E-mail: amanda.bryan@mhra.gsi.gov.uk
<u>Other:</u>	MHRA provides the secretariat for the FG.

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HMA European Surveillance Strategy Working Group (ESS WG)	
<u>Mandate:</u>	The ESS group is the initiative for a closer cooperation of EU member states and EMA in a pro-active approach to veterinary pharmacovigilance. This includes setting 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.
<u>Members:</u>	Jytte Lyngvig (DK), Patrick Dehaumont (FR), Jiri Bures (CZ), Ton Kamphuis (NL), Anja Holm (DK), Fabia Dyer (UK), Fia Westerholm (EMA), Esther Werner (chair CMDv), Michelle Dagorn (FR), Cornelia Ibrahim (DE).
<u>Meeting cycle:</u>	4 times a year.
<u>Agendas:</u>	Circulation prior to each meeting to members.
<u>Minutes:</u>	Circulated before each meeting.
<u>Press release:</u>	
<u>Chair:</u>	Cornelia Ibrahim (DE) Tel.: +49 1888 444 30400 Fax.: +49 1888 444 30009 E-mail: cornelia.ibrahim@bvl.bund.de
<u>Contact point:</u>	See current Chair.
<u>Other:</u>	

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HMA Telematics Support Group (TSG)	
<u>Mandate:</u>	<p>The mission of this group is to facilitate communication between European and national IT systems (e.g. NCA/EMA, 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.</p> <p>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.</p>
<u>Members:</u>	
<u>Meeting cycle:</u>	Minimum twice a year by teleconference, as necessary, and one face-to-face meeting per annum.
<u>Agendas:</u>	Prepared by the chair and circulated prior to each meeting to all members.
<u>Minutes:</u>	Prepared by the chair and circulated prior to each meeting to all members.
<u>Press release:</u>	
<u>Chair:</u>	<p>Marcus Muellner (A) Tel.: +44 1932 33 83 01 Fax.: - E-mail: marcus.muellner@ages.au</p>
<u>Contact point:</u>	<p>Vivienne Saville (UK) Tel.: +44 1932 338438 Fax.: - E-mail: v.saville@vmd.defra.gsi.gov.uk</p>
<u>Other:</u>	

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B. ANNEX 1

LIST OF MENTORS OF HMA WORKING GROUPS

Names of HMA Working Groups	HoA as Chair or Member	Mentor
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)	No sponsor required Report to HMA on a regular basis	N/A
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv)	No sponsor required Report to HMA on a regular basis	N/A
Clinical Trial Facilitation Group (CTFG)		Xavier de Cuyper
Working Group of Quality Managers (WGQM)		Kristin Raudsepp
Homeopathic Medicinal Products WG (HMPWG)		Pending
Emacolex		Aginus Kalis
Telematics Support Group	Marcus Muellner	N/A
Working Group of Communication Professionals (WGCP)		Jytte Lyngvig
Working Group of Enforcement Officers (HMAWGEO)		Kent Woods
Benchmarking Steering Group (BEMA SG)	Pat O'Mahony/Klaus Cichutek	N/A
European Risk Management Strategy Facilitation Group (ERMS FG)	Jytte Lyngvig	N/A

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Names of HMA Working Groups	HoA as Chair or Member	Mentor
European Surveillance Strategy WG (ESSWG)	Jytte Lyngvig	N/A
HMA/EMA Training Project Team (HMA/EMA TPT)	Gro Wesenberg	N/A
Product Testing Task Force	Vacant	N/A
WG of Resource Planning????	Vacant	N/A
Pharmacovigilance Working Group – Human (PhVWG-h)		Jorge Torgal
Pharmacovigilance Working Group – Veterinary (PhVWG-v)		Jean-Pierre Orand

Responsibilities of a mentor for a HMA Working Group

The main responsibility of a mentor is to act as a link between the HMA Working Group (WG) and the HMA. The mentor can facilitate communication between HMA and a HMA WG and be an advisory partner to a WG. The mentor receives all agendas and minutes for the HMA WG he/she is sponsoring and in addition other documents, if required. A close liaison between the mentor and chair of their WG is expected.

Regarding communication between the WG and the HMA, the mentor has the responsibility to make sure that all decisions and/or specific orientations taken by the HMA during HMA meetings are reported back to the WG chair and implemented accordingly. The mentor is also responsible for keeping the HMA informed and updated on relevant subjects discussed by the WG. The mentor should also identify possible issues to be addressed by HMA, keep track of the objectives to be achieved by the WG and to consider if any additional resources need to be involved.

B. ANNEX 2

POLICY ON WORKING GROUP CONSULTATION ON THE WEBSITE

Following a query from the Homeopathic Medicinal Products Working Group, the HMA Management Group has developed principles for Working Group (WG) consultation on the website which are applicable to all Working Groups (WG).

The general principle is that documents for publication on the website should be adopted by HMA (see procedure in Best Practice Guide for Permanent Secretariat to the HMA Management Group):

1. Draft document from WG to HMA-PS for attention of HMA/MG;
2. Approval for publication by HMA at regular meeting;
3. Publication on website for public consultation after approval by HMA (3 months public consultation period);
4. Discussion of comment and finalisation at WG level;
5. Approval of (updated) document for publication by HMA at regular meeting;
6. Publication of finalised document on HMA website.

However, for consultations of WG documents on the website, a smoother, faster and more efficient procedure is necessary. On the one hand, the HMA should have control of what is published on the website; and on the other hand, the HMA should not be overloaded with documents and should not act as a delaying filter.

To take into consideration the different needs, the following procedure is set out as follows:

- WGs send draft documents that they would like to publish on the website for consultation to the HMA-PS for the attention of the HMA-MG;
- HMA-MG decides if publication of the notification of consultation on website is acceptable or if the matter should be referred to HMA either as written procedure or at a HMA meeting;
- Once publication of the notification of consultation is accepted, HMA-PS sends the documents to the webmaster;
- Comments on documents are sent directly to the contact person appointed by WG;
- If the final document is to be published on website, then this needs to be approved by HMA either by written procedure or at a HMA meeting.

The MG will inform HMA of WG consultations that are accepted for publication on the website.

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B. ANNEX 3

WEBSITE PROCEDURES

Procedure for publishing documents on the HMA website

Scope

This document sets out the procedure to follow for publishing information on the HMA website.

General principles / How it would work

All documents for publication on the website should be approved by the HMA. For this to happen, a three tier filter system should operate involving the HMA-PS, HMA-MG and the HMA. The exception to this process would concern consultations, where a faster process is required (see below).

The procedure for posting documents on the website to be followed is:

- Draft document from WG to HMA-PS for attention of HMA-MG;
- Approval for publication by HMA at regular meeting;
- Publication on website for public consultation after approval by HMA (3-month public consultation period)
- Discussion of comment and finalisation at WG level;
- Approval of (updated) document for publication by HMA at regular meeting;
- Publication of finalised document on HMA website.

Consultations

In case of consultations of WG documents on the website, a smoother, faster and more efficient procedure is necessary. While the HMA should have control of what is published on the website, it should not be overloaded with documents. Moreover, it should not act as a delaying filter.

To take into consideration the different needs, the following procedure is set out:

- WGs send draft documents that they would like to publish on the website for consultation to the HMA-PS for the attention of the HMA-MG;
- HMA-MG decides if the publication of the notification of consultation on website is acceptable or if the matter should be referred to HMA either as written procedure or at a HMA meeting; Once publication of the notification of consultation is accepted, HMA-PS sends the documents to the webmaster;
- Comments on documents are sent directly to the contact person appointed by WG
- If the final document is to be published on website, then this needs to be approved by HMA either by written procedure or at a HMA meeting.
- Once publication is accepted, HMA-PS sends documents to the webmaster

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	Version: 15102010

The MG will inform HMA of WG consultations that are accepted for publication on the website.

How to submit a document to the HMA website

All requests must be submitted to the HMA-PS at hma-ps@imb.ie for the attention of the HMA-MG.

Documents should be sent in one of the following formats:

- Word
- Adobe PDF
- PowerPoint
- Excel
- JPEGs or GIFs for images

Only the **final version** of documents should be submitted for publication. All track changes must be accepted and comments and drafting notes removed.

The website editors (Human, Veterinary and Joint) will check that the content adheres to editorial style and is of suitable quality for publication on the website; minor editorial/stylistic changes will be made where appropriate. If major changes are required or there are queries about factual accuracy, the content will be returned to the author for modification. The responsibility for the accuracy of information remains with the originating author.

Quarantine period

Documents that are due to be posted on the HMA website will be held for seven days in quarantine prior to their publication. This quarantine period will give members of the Management Group additional time to delay the publication of a document, should new information come to their attention.