

The Heads of Medicines Agencies Strategy Paper on the European Medicines Regulatory Network

Revised HMA Strategy Paper Work Plan

HMA-SIG undertook the task of analysing the recommendations for action by the Network in the HMA Strategy Paper Work Plan, in line with HMA mandate given to the HMA-SIG. The revised HMA Strategy Paper Work Plan that resulted from this work was adopted by HMA on 8 February 2007 during the meeting they held in Dresden.

Cooperation of the members of the Network in terms of visibility, information and work sharing, learning of best practice from one another and harmonisation of the interpretation of European legislation are at the heart of the work plan, with a view to improving the operation of the Network and the quality of its regulatory activity making the best possible use of available resources.

HMA-relevant working groups were identified for each action involving working groups with HMA mandate and European Working Groups that include guidance for medicinal products under the remit of MRP/DCP.

The creation of two new groups is proposed (the HMA National Communication Professionals and the HMA Training Project Team). Implementation timelines for actions range between Q1-2007 and Q2-2008.

HMA acknowledges that actions on some important areas such as the implementation of the clinical trials directive, distribution activity, and some specific aspects of innovation are not sufficiently addressed by the work plan and should be included in future updates.

No	Recommendation	Groups involved	Timeline
1	HMA should be more involved in the operation of the scientific/regulatory European groups with responsibilities for both national and European issues (e.g. CMDs, Ad hoc Inspectors Groups, PhVWP) as well as groups directly reporting to HMA. It should receive regular updates from relevant bodies that include national medicinal products/activities within their remit, so it can keep abreast of developments and reinforce decision making. The mandates of relevant working groups should explicitly include the reporting procedure to HMA.	HMA-MG/PS, HMA-relevant WG	Q2-2007
2	HMA should ask CMD(h) and CMD(v) to consider the optimum ways of ensuring that high quality robust assessment and European consensus are maintained in MRP and DCP with the view to promoting adequate functioning of the system, including overall satisfactory involvement of NCAs.	HMA-MG/PS, CMDs	Q2-2007

3	In addition to mechanisms already set out in the legislation, HMA and EMEA should consider ways of strengthening cooperation between NCAs in the pre-submission phase and once a procedure has started. A report should be prepared for consideration by the HMA.	NCAs, EMEA, CMDs	Q2-2008
4	HMA should get regular feedback and closely monitor progress in the implementation of the recommendations set by the HMA Strategy Paper in the field of pharmacovigilance in both human and veterinary sectors, based on the close cooperation between NCAs and EMEA.	ERMS FG, PhVWP, ESS Group, HMA-PS	Q2-2007
5	A veterinary group should be established which will survey the resource available to veterinary pharmacovigilance and address potential weaknesses in the system. It should learn from the experience of the ERMS FG.	HMA(v)	Completed
6	Enforcement issues (e.g. in the areas of clinical trials fraud, counterfeiting and internet sales of prescription only medicines) should be given a higher profile at HMA level, operating through and with the Enforcement Officers network and in consultation with the EMEA-AHIG and with the OMCLs. There should be regular reporting to HMA by relevant groups.	NCAs, EMEA-AHIG, EDQM, HMA-MG/PS, HMA-WGEO	Q1-2007
7	CMD(h) and CMD(v) should be asked to consider how, within the current legal framework, steps can be taken at European level to ensure that the quality of the SPC, leaflet and label all meet a high quality standard and are useful and relevant to patients, carers, animal owners and food producers and Health Care Professionals/veterinary surgeons, taking into account the work done by the QRD group in cooperation with CMDs. There should be a report back to HMA.	CMDs, EMEA-QRD, HMA-PS	Q1-2007
8	A procedure must be established to ensure that there are common outcomes in the application of the legal requirement to produce National Public Assessment Reports, even if the approach is different from one NCA to another.	NCAs, CMDs, HMA-PS	Q1-2008
9	HMA must formally recognise the Communications Group which has met informally under the Dutch presidency and ask it to consider and implement the solutions paper prepared by the Communications and Information Drafting Group.	NCAs, HMA-MG, EMEA	Q1-2007
10	The vision and mission of the HMA is to be re-assessed and given greater publicity to ensure it is seen as a viable and effective body within the Network	HMA-SIG, HMA-WGV, HMA-MG	Q2-2007
11	Arrangements in place for, and the functions of, the HMA website should be reviewed. This should be a gateway to information about the HMA role, the network itself and medicinal products available.	HMA-WGV, (BfArM, ANMV)	Q1-2007
12	A project team should be established to consider in greater detail the proposals made by the Drafting Groups for enhancing cooperation on the training of NCA staff, taking account of the EU Competence Development Strategy outlined in EMEA's Roadmap. This includes the possibility of establishing a European assessors' academy.	HMA-MG, NCAs, EMEA	Q2-2007
13	The BEMA SG should be asked to ensure that its Report into the 1st Benchmarking Cycle provides an analysis of best practice in key areas across the Network, so that the aim of the benchmarking exercise, i.e. raising performance levels and learning from one another, can be met.	BEMA SG, HMA-MG/PS	Completed
14	Sharing experience through specific benchmarking activities on particular topics, complementary to	NCAs, EMEA, EDQM,	Q1-2008

	BEMA, should be considered as a way to promote best practice within the Network and its working groups, e.g. sharing of information on outcomes of laboratories of control activity through OMCLs, on experience gained through twinning projects, on Joint Audit Programme (JAP) of GMP inspectors activity, etc.	HMA-PS	
15	Subject to legal requirements and operational concerns, efforts to implement work sharing across the operational areas of medicines regulation in the veterinary and human sectors should be encouraged.	HMA-relevant WG, EMEA, HMA-MG/PS	Q1-2007
16	The link between evaluation, inspection and laboratory controls must be reinforced. Scoping exercises and recommendations should be carried out.	NCA's, HMA-relevant WG, EMEA, EDQM	Q4-2007
17	HMA should ensure that there are sufficient skills in place across the Network to deal with new technologies. A survey of resource, horizon scanning, establishment of learning sets and a timetable for the production of guidelines and standards could be considered, taking into account the work already undertaken by EMEA and in association with the Commission.	HMA-Training-PT, HMA-Resource Planning WG, NCA's, EMEA, EDQM, EC	Q2-2008
18	The EU telematics strategy should be reviewed, to ensure that the strategy continues to meet the wider needs of the Network, supporting more collaborative working and fostering innovation.	HMA Tandem Support WG, EMEA, EC	Q2-2007

Glossary

ACRONYM	DESCRIPTION
AHIG	Ad Hoc Inspectors Groups (equivalent to Inspectors Services Groups)
ANMV	Agence Nationale du Médicament Vétérinaire
BEMA	Benchmarking of Medicines Agencies
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
CMD(h)	Coordination Group for Mutual-Recognition and Decentralised Procedure (human products)
CMD(v)	Coordination Group for Mutual-Recognition and Decentralised Procedure (veterinary products)
CMDs	Coordination Groups for Mutual-Recognition and Decentralised Procedure
DCP	Decentralised Procedure
EC	European Commission
EDQM	European Directorate for the Quality of Medicines
EMEA	European Medicines Agency
EMEO	European Medicines Enforcement Officers
EO	Enforcement Officers
ERMS	European Risk Management System
ESS	European Surveillance Strategy

EU	European Union
FG	Facilitation Group
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
HMA(h)	Heads of Medicines Agencies (human sector)
HMA(v)	Heads of Medicines Agencies (veterinary sector)
MG	Management Group
MRP	Mutual Recognition Procedure
NCA s	National Competent Authorities
OMCL s	Official Medicines Control Laboratories
PhVWP	Pharmacovigilance Working Party
PS	Permanent Secretariat
PT	Project Team
QRD	Quality Review of Documents
SG	Steering Group
SIG	Strategy Implementation Group
WG	Working Group
WGV	Working Group on Visibility