

Outcome of the Consultation with HMA's Partners and Stakeholders

HMA-SIG Recommendations on Consultation Responses

Introduction

HMA-SIG was mandated to identify actions proposed by Partners and Stakeholders during the consultation exercise that could realistically be implemented by HMA in the framework defined by the HMA Strategy Paper, at this stage.

HMA-SIG has undertaken a revision of the HMA Strategy Paper Work Plan that includes recommendations for specific tasks on HMA-relevant working groups and timelines for those tasks. The revision was adopted by HMA at its February 2007 meeting in Dresden.

This document contains the general comments and actions proposed by Partners and Stakeholders that were selected by HMA-SIG for development by the Network as part of the implementation of the HMA Strategy Paper Work Plan.

Some of the selected actions are already addressed in the Revised Work Plan and others are not. Actions that were not selected at this point in time might be considered for a future revision of the Work Plan.

Under each of the proposed actions the relationship with actions in the Revised Work Plan, the concerned working groups that might be involved in implementation and sometimes comments for clarification are indicated in italics.

List of general comments

Role: Clarification of HMA role in the European Medicines Regulatory Network
Relates to action 10 of the Revised Work Plan. It should be considered by HMA-MG, HMA WGV, HMA-SIG.

Identity: Define HMA's voice in the Network
Relates to action 10 of the Revised Work Plan. It should be considered by HMA-MG, HMA WGV, HMA-SIG.

Timeframe: The HMA document should include a clearer vision of the HMA and EMRN strategy over the 3 to 10 years time frame.
No related action in the Revised Work Plan. The review of HMA Strategy Paper is a continuous process. Follow up of the Work Plan should occur on a regular basis e.g. annually. HMA might develop a long term strategic view, but the Strategy Paper addresses the current evolving situation of the regulation of medicinal products from the Network's point of view. It should be considered by HMA.

Scope: more emphasis on MRP/DCP operation, clinical trials directive implementation, alternative treatments, SMEs, pharmacovigilance inspections.
Relates to actions 1, 2, 7, 8 and 15 of the Revised Work Plan involving CMDs on improving decision and information flow in MRP/DCP operation. It was acknowledged in the Revision of the Work Plan that some areas were not sufficiently addressed by the strategy. In terms of Clinical Trials directive implementation the role and mandate of the CTFG need to be clarified and reviewed, where necessary. It should be considered by HMA for the next

version of HMA Strategy Paper.

Safety: improvements of tools to conduct good risk-benefit assessment
Relates to action 4 of the Revised Work Plan. It should be considered by ERMS-FG, PhVWPs, ESS WG.

Harmonisation: various suggestions (Re Outcome of the Consultation document)
Relates to 2, 7 and 8 of the Revised Work Plan involving harmonisation initiatives. It should be considered by HMA-relevant WG.

Efficiency/resources: avoid duplication of work and overlap, include reference to resources for implementation of the strategy
Relates to action 15 of the Revised Work Plan. It should be considered by all HMA-relevant WG.

Innovation: Support of innovation by the Network unclear
Relates to action 17 of the Revised Work Plan. The European Medicines Regulatory Network should support innovation ensuring the highest possible skills of its assessors/inspectors/analysts in order to support their regulatory activity. It should be considered by HMA-Resource Planning-WG, HMA-Training-PT, NCAs, EMEA, EDQM, EC.

Access: distribution and supply of medicines. Implementation of GDP.
No related action in the Revised Work Plan. When linked to anti-counterfeit activities, it should be considered by HMA, Enforcement Officers Group, EMEA-AHIG, EC.

Telematics: lack of reference to impact of international standards,
Relates to action 18 of the Revised Work Plan. It should be considered by HMA-Tandem Support Working Group.

Stakeholders: clarification of EMEA-HMA relationship, avoid overlap with EMEA role, clarify on role of Academy and EDQM
Relates to action 10 of the Revised Work Plan. It should be considered by HMA-MG, HMA-SIG, HMA WGV, HMA-NCP.

Clarification/editing:
No related action in the Revised Work Plan. It relates to amendments and clarification on the wording of the current version of the HMA Strategy Paper. It should be considered by HMA for the next version of HMA Strategy paper.

Selected actions

Impact on Public and Animal Health Protection

77	Implement a general education campaign for the public to explain the concept of risk/benefit and reverse the current global trend of risk aversion. All stakeholders - regulators, industry and healthcare professionals – at the EU and national level join forces to proactively reach out to the public. Such a campaign can trigger a positive and constructive dialogue and build the basis for further transparency measures related to regulatory assessments and decisions to ultimately regain the public's trust in the robust European regulatory system and also contribute to a better compliance with prescription information.
<i>Relates to action 9 of the Revised Work Plan. It should be considered by HMA-NCP.</i>	

<i>Rather than a “general education campaign” it seems more appropriate that each stakeholder e.g. regulators, industry, healthcare professionals, should strengthen their efforts with a view of promoting a sound vision of risk/benefit, without blurring the respective responsibility of each stakeholder.</i>	
79	HMA should indicate that they would take account of existing websites related to medicines regulation in deciding on the scope and content of their own portal. Extensive websites exist for the EMEA, DG Enterprise and the European Directorate for the Quality of Medicines, and consultation with these bodies would be important to ensure that “consumers of medicines information” are presented with complementary rather than competing websites.
<i>Relates to action 11 of the Revised Work Plan. It should be considered by HMA-WGV.</i>	
80	Update MRP Index regularly.
<i>No related action in the Revised Work Plan. It should be considered by NCAs. CMDs have facilitated implementation through a common procedure. Resource implications need also to be taken into account. HMA has a role in encouraging update of information on medicinal products available to the public.</i>	
83	Improve HMA website for sharing of information with concerned stakeholders, including patients and healthcare providers. Information targeted at patients (and healthcare professionals to a lesser extent) should be made available in all the official languages of the EU.
<i>Relates to action 11 of the Revised Work Plan. It should be considered by HMA-WGV.</i>	
84	A bilingual (local language plus English) website is very useful for industry. Although translation of all documents into English could be very difficult and costly, a brief summary or even a translation of the headings in English would be greatly appreciated.
<i>Relates to national web sites. No related action in the Revised Work Plan. This approach may prove difficult to implement for all national authorities in the Network on a systematic basis and for all documents, but it could probably be envisaged on a selective basis, with particular emphasis on key documents with European dimension.</i>	

Patient Safety

98	Put in place a mechanism to ensure that the risk management measures enacted by different NCAs following the risk assessment advice of the PhVWP are harmonised, i.e. to ensure that whether PhVWP advice relates to CP, MRP or DCP, Member States take harmonised measures to ensure public and animal health, notwithstanding the differences that exist at a national level in terms of different ways of implementing the same risk control measures.
<i>No related action in the Revised Work Plan. CMDs established a Best Practice Guide. It should be considered by NCAs, ERMS-FG, PhVWP. As a general principle, harmonisation of core risk management processes for CP, MRP, DCP authorised medicinal products can of course be addressed. Nevertheless it would be unwise to preclude any possibility of national adaptations, taking into account in particular the specificities of the prescription/ distribution chains and the high sensitivity of some issues.</i>	
102	Establish a public-private-partnership (PPP) with industry to progress the scientific knowledge for conducting proactive pharmacovigilance. The PPP should examine tools for better evaluating the collected data. For example, the validation of safety signals or data mining techniques to evaluate validity of the methods should be one of its goals.
<i>Relates to action 4 of the Revised Work Plan. It should be considered by ERMS-FG, PhVWPs, ESS-WG. Convergent efforts of all stakeholders to further improve the skills and the methodology in</i>	

	<i>the field of pharmacovigilance are indeed required. However, it should be reminded that initiatives in this area are being implemented, in particular by ERMS FG.</i>
103	Monitor the Commission's public consultation of the Community System of Pharmacovigilance and its results to enrich what is already stated in the HMA document.
	<i>No related action in the Revised Work Plan. It should be considered by HMA, and HMA-relevant WG, while taking due account of the consequences that the Commission itself may draw from the consultation.</i>
104	Examine tools for better evaluating the collected data. For example, the validation of safety signals or data mining techniques to evaluate false positives.
	<i>Relates to action 4 of the Revised Work Plan. Relates to action 102 of the Outcome of the consultation. It should be considered by ERMS-FG, PhVWPs, ESS WG.</i>
105	Include pharmacies and wholesalers in the list of stakeholders to be involved in communications strategies. In particular, in the case of rapid alert or recall, there should be an efficient communication system in place to inform wholesalers about the necessity to initiate a recall.
	<i>Relates to action 9 of the Revised Work Plan. Pharmacies and wholesalers are already involved in the recall processes. The current communication system between stakeholders should be looked into and more information in this area could be provided to the public. It should be considered by NCAs, EMEA-AHIG, HMA-NCP.</i>

Operation of the European Medicines Regulatory Network

182	Assist in the revision and harmonised implementation of a new Variations Regulation focused on risk based principles that classifies the approval of changes in a way that more self responsibility and less administrative work is needed by the industry, thereby reducing the workload of the Agencies.
	<i>No related action in the Revised Work Plan. It should be considered by HMA, CMDs. Such a process has to be implemented at an appropriate pace, consistent with the follow up of ICH activity, where the need for further work has been identified. It should also take account of the diversity of the situation and position of the pharmaceutical industry with regard to the move to a more risk-based approach and of the need to secure a smooth adaptation of the regulatory skills and methods that is looming.</i>
185	Agree on a "robust definition" of serious potential risk and provide direct guidance within NCAs to ensure that the serious risk guideline is adhered to. Only questions of serious potential risk should be asked by the CMS during an MRP/DCP.
	<i>No related action in the Revised Work Plan. It should be considered by HMA, CMD(h). This issue, already discussed by HMA and currently being reassessed by CMD(h) has to be dealt with in a balanced way: NCA should refrain from referring to the concept of serious potential risk for minor issues that are not significant in terms of public health, but on the other hand, each NCA remain entitled to ask for a collective appraisal of selected issues that it deems, in good faith, to raise a public health concern.</i>
188	Encourage competent authorities of EEA Member States, which are not participating in PIC/S, to apply for PIC/S membership.
	<i>No related action in the Revised Work Plan. It should be considered by NCAs.</i>
189	Facilitate the sharing of GMP information within PICS, notably with participating authorities from non-EEA/MRA member states to foster the international harmonisation of GMP under PIC/S.
	<i>Relates to proposed action 188 and the role of PIC/S. It should be considered by NCAs, EMEA-AHIG, PIC/S secretariat.</i>
191	Put in place measures to "pool" and harmonise scientific advice, perhaps by means of the scientific memory database.
	<i>Relates to action 3 and 18 of the Revised Work Plan. It should be considered by EMEA,</i>

<i>CMDs, HMA Tandem support WG.</i>	
192	Use of European Public Assessment Reports for CAPs as a model for MRPs and DCPs.
<i>Relates to action 8 of the Revised Work Plan. This has already been implemented in CMDs best practice guide</i>	
194	International collaboration should be further developed and streamlined to reduce unnecessary duplication of work and increase efficiency of the processes for marketing approval and monitoring of medicines and support a stronger share of responsibilities between national and international agencies including trans-national bodies as WHO and FAO.
<i>No related action in the Revised Work Plan. It refers to interaction of the Network with international partners and should be considered by HMA, EMEA, HMA-NCP.</i>	
196	The role of the OMCL in the monitoring of the MRP/ CMD products should be increased, as is currently the case with CP products. This will avoid a great deal of repetition of tests and will allow a better and more efficient use of resources.
<i>Relates to action 16 of the Revised Work Plan. The HMA has agreed to establish a HMA Product Testing Task Force to begin the development of a Product Testing Strategy. OMCLs will be involved in the coordination at a later stage. OMCLs, EMEA and EDQM will be involved in the process.</i>	
197	Based on the current discussions and the control of IVMPs for implementing article 81 and 82 establish optimal cooperation at the level of control and testing centres (OMCLs and NCAs) aimed at cost saving through work sharing and mutual recognition.
<i>Relates to action 16 of the Revised Work Plan and to proposed action 196 on the outcome of the consultation. It should be considered by NCAs, HMA-relevant WG, EMEA, EDQM.</i>	
199	The current benchmarking exercise (BEMA) and inventory of scientific expertise across the NCAs, should be discussed in the context of how these initiatives may help to identify duplication and facilitate the optimal use of resources at the EU level.
<i>Relates to action 13 of the Revised Work Plan. It should be considered by BEMA SG.</i>	
200	Optimise the provision of scientific advice throughout development, as a means of increasing predictability of outcome in the authorisation procedure.
<i>Relates to action 3 of the Revised Work Plan. It should be considered by NCA, EMEA, CMDs</i>	
204	Develop a network of centres of expertise with relevant terms of reference to support enforcement activities, including confirmatory testing at skilled OMCLs of the Network.
<i>Relates to actions 6 and 16 of the Revised Work Plan. It should be considered by NCAs, EMEA-AHIG, EDQM, EO-WG.</i>	
206	The lecturers participating in a European Assessors Academy should not only come from Agencies but also from industry. Many companies' staff has in-depth knowledge in their respective therapeutic area and their contribution would be invaluable training for assessors.
<i>Relates to action 12 of the Revised Work Plan. It should be considered by HMA Training Project Team. HMA should carefully consider whether a full joint training scheme is appropriate as opposed to a selective approach where industry staff may participate in specific topics within the programme of NCA staff training scheme.</i>	
208	Consider the support and development of already existing training tools for GMP inspectors within PIC/S such as Expert Circles and Training Seminars.
<i>Relates to action 12 of the Revised Work Plan. It should be considered by HMA-MG, NCAs, EMEA, HMA Training Project Team.</i>	
210	Consider involving non EU/EEA agencies in common trainings and other initiatives in order to ensure that the outcome of regulatory decision making is robust and

	effective.
	<i>Relates to action 12 of the Revised Work Plan. It should be considered by HMA-MG, NCAs, EMEA, HMA Training Project Team.</i>
212	Establish a video-conferencing network that would allow the participation of national experts when necessary, in order to facilitate decision making at CMD meetings.
	<i>Relates to action 18 of the Revised Work Plan. It should be considered by HMA-Tandem Support Working Group, EMEA, EC.</i>
215	A central repository for eCTD should be established for the Centralised Procedure and also for the Mutual Recognition and Decentralised Procedures. In this way a single location can be established for the submission of information which can then be accessed by all NCAs.
	<i>Relates to action 18 of the Revised Work Plan. It should be considered by HMA-Tandem Support Working Group, EMEA, EC. The feasibility from an NCA's technical and legal point of view of such a centralised approach for electronic submissions should be assessed in depth.</i>
216	Integrate and give access to CAP/MRP databases
	<i>Relates to action 18 of the Revised Work Plan. Within the current move towards greater transparency HMA will consider to increase access to HMA-relevant information appropriately, taking into consideration confidentiality aspects. It should be considered by HMA-MG, EMEA, EC, HMA-Tandem Support Working Group.</i>
217	Develop transparent performance measures for the operation of the European Medicines Regulatory Network, in order to identify issues and drive improved performance.
	<i>No related action in the Revised Work Plan. It should be considered by HMA</i>
219	HMA should, in partnership with its key stakeholders, discuss the objectives of the enhanced communication proposals and develop an EU Communication & Transparency Policy together with EMEA. This should be an overarching strategy and should consider what needs to be communicated, why the information is being communicated, who the target audience for the information is and what the most appropriate manner of release is to ensure maximal effect. In addition, in order to maximise effect of any communication, the HMA needs to ensure that there is a consistent message from across the EMRN.
	<i>Relates to action 9 of the Revised Work Plan. It should be considered by HMA-MG, EMEA, HMA-NCP. The need for consistency of the messages across the Network is widely recognised. However, the way they are released may have to be adjusted to national contexts.</i>
221	Develop confidentiality agreements and pre-action information sharing with non-EU/EEA agencies for international networking of regulatory agencies.
	<i>Linked to proposed action 194. No related action in the Revised Work Plan. It refers to interaction of the Network with international partners and should be considered by HMA, EMEA, HMA-NCP.</i>
222	Integrate EDQM in the European communication network. EDQM is willing to annually report its activities to HMA.
	<i>No related action in the Revised Work Plan. EDQM is involved as a contact point in all actions where there is OMCLs participation and HMA will request EDQM to report on their activities as appropriate.</i>

Supporting Innovation

248	Work on harmonisation of standards (e.g. between EU and US) that have a significant role to play in providing support to innovation.
	<i>No related action in the Revised Work Plan. Harmonisation work has a broad scope (e.g.</i>

<i>ICH) and HMA is committed to it in various areas. It should be considered by HMA</i>	
249	Ensure that innovation is encouraged and the administrative work is made efficient by avoiding duplication and unnecessary delays.
<i>Relates to action 17 of the Revised Work Plan. The Network should support innovation ensuring the highest possible skills of its assessors/inspectors/analysts in order to support their regulatory activity, without giving up their regulatory mandate and their duty to optimise risk/benefit assessment. It should be considered by HMA-Resource Planning-WG, HMA-Training Project Team, NCAs, EMEA.</i>	
251	Develop a clear communication plan for SMEs. Improved communication and partnership would remove unnecessary regulatory burden on young innovative biotechnology companies.
<i>No related action in the Revised Work Plan. It should be considered by HMA, EMEA, HMA-NCP.</i>	
252	Foster the building of links with academia so as to ensure more involvement of academia in medicine assessment so that regulatory provisions closely follow emerging science.
<i>Relates to action 12 of the Work Plan It should be considered by NCAs, EMEA, HMA Training Project Team</i>	

Conclusion

HMA-SIG selected a number actions proposed by partners and stakeholders during the consultation of the HMA Strategy Paper.

The proposed actions were related to the actions in HMA's Revised Work Plan. Consequently, HMA-relevant working groups and other involved parties where necessary, should look into the selected stakeholder's proposals when implementing the Work Plan.

Follow up of the implementation of the Work Plan will occur at HMA meetings on a regular basis and communication with Partners and Stakeholders will take place to keep them involved in the evolution of the European Medicines Regulatory Network activities.

The next version of the HMA Strategy Paper will be done following a HMA update process, taking into consideration Stakeholder's input.

Partners and Stakeholders requested HMA for increased access to information, in particular, the availability of information on HMA and HMA working groups' activities. The Network will clearly take part in the general move towards transparency and overall visibility of HMA activity should improve significantly with the rolling out of the new HMA website. HMA should ensure that the website is kept up to date.

Glossary

ACRONYM	DESCRIPTION
AHIG	Ad Hoc Inspectors Groups
BEMA	Benchmarking of Medicines Agencies
CAP	Centrally Authorised Products
CMD(h)	Coordination Group for Mutual-Recognition and Decentralised Procedure (human products)
CMDs	Coordination Groups for Mutual-Recognition and Decentralised Procedure
CP	Centralised Procedure
CTFG	Clinical Trials Facilitation Group
DCP	Decentralised Procedure
DG	Directorate General
EC	European Commission
eCTD	Electronic Common Technical Document
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EO	Enforcement Officers
ERMS	European Risk Management System
ESS	European Surveillance Strategy
EU	European Union
FAO	Food and Agriculture Organization
FG	Facilitation Group
GDP	Good Distribution Practices
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
ICH	International Conference on Harmonization
IVMPs	Immunological Veterinary Medicinal Products
MG	Management Group
MRA	Mutual Recognition Agreement
MRP	Mutual Recognition Procedure
NCA s	National Competent Authorities
NCP	National Communication Professionals
OMCLs	Official Medicines Control Laboratories
PhVWP	Pharmacovigilance Working Party
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PT	Project Team
SIG	Strategy Implementation Group
SMEs	Small and Medium Enterprises
WG	Working Group
WGs	Working Groups
WGV	Working Group on Visibility
WHO	World Health Organization