European Medicines Agency

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EMEA ROAD MAP: 2008 – 2009 IMPLEMENTATION PHASE

I INTRODUCTION

The EMEA Road Map to 2010, which was launched in March 2005, is part of the Agency's longer term strategy. Its aim, as agreed in 2005 with the EMEA partners and stakeholders, is to contribute to better protection and promotion of public and animal health, to improve the regulatory environment for medicinal products, and to help stimulate innovation, research and development in the European Union (EU). This should be achieved within the context of the EU Regulatory System Network, hereafter called the "Network", through a close collaboration between the EMEA, the European Commission and the National Competent Authorities (NCAs) of the Member States.

Various initiatives have been undertaken since 2005 and progress made with the implementation of the EMEA Road Map has been described in two Status Reports which have been made publicly available, in May 2006 and October 2007 respectively (http://www.emea.europa.eu/htms/general/direct/roadmap/roadmapstatus.htm)

II SCOPE OF THE 2008 – 2009 EMEA ROAD MAP IMPLEMENTATION PLAN

The current EMEA Road Map Implementation Plan includes actions to be undertaken up to the end of 2007. Although excellent progress has been made (as shown in the aforementioned Status Reports), it should be noted that in some areas delays have been encountered. Such delays relate to certain aspects aiming at further strengthening the networking model, increasing the transparency of the EMEA activities, reinforcing the interaction with the Agency's stakeholders, and further improving the safety of medicines for veterinary use[1].

There are also a number of environmental changes which will impact on the operation of the EMEA and the Network over the next few years. The most important factors of a change relate to either the implementation of new Community legislation (advanced therapies) or the preparation for future Community legislation (in the fields of variations, pharmacovigilance, provision of information to patients, maximum residue limits). Alongside these legislative developments other factors which will affect the EMEA concern various initiatives undertaken by the European Commission to provide for better regulation and to reduce administrative burden, as well as new areas of EMEA activities which have emerged since 2005, notably in the field of paediatric and biosimilar medicines.

In addition, since the launch of the EMEA Road Map, Heads of Medicines Agencies (HMA) have developed an "HMA Strategy for the European Medicines Regulatory Network" (http://www.hma.eu/74.html) which will allow achieving a further strengthening

[1] For further details, please consult the document "Second Status Report on the Implementation of the EMEA Road Map" (http://www.emea.europa.eu/htms/general/direct/roadmap/roadmapstatus.htm).

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of the Network. Any initiatives as part of the further implementation of the EMEA Road Map to 2010 addressing networking aspects will have to be complementary to the actions identified in the context of the HMA Strategy Paper Work Plan.

The working methodology which has been applied for the elaboration of the next EMEA Road Map implementation phase takes due account of the aforementioned aspects, i.e. to (1) address not yet started / not yet completed initiatives identified in 2005, (2) complement, where relevant, actions undertaken within the frame of the HMA Strategy Paper Work Plan to strengthen the EU Regulatory System, and (3) cope with environmental changes which will impact on the EMEA over the next years.

III KEY INITIATIVES FOR THE 2008 – 2009 EMEA ROAD MAP IMPLEMENTATION PLAN

The key initiatives that are envisaged for the 2008 – 2009 implementation phase are described below. They have been presented as rather high-level initiatives and have been classified as per the EMEA priorities for the next two years.

Operation of the EU Regulatory System Network

An efficient operation of the Network is a prerequisite to ensure a successful implementation of the EMEA Road Map. Initiatives over the next years will be targeted to a further strengthening of various aspects of the networking model which should lead to a reinforcement of the already existing firm partnership between all EU Regulatory Authorities, ultimately resulting in a network of excellence.

Key Initiatives
• To further enhance the overall quality of the EU Regulatory System in the context of the work undertaken at EMEA level by - ensuring the availability of top quality scientific expertise (e.g. by strengthening the competence development and by formalising the process for workload and resource planning, both in collaboration with HMA), - strengthening and, where relevant, extending current peer review systems at the EMEA, - exploring within the context of the EMEA Process Improvement Exercise which areas could benefit from further process efficiency gains, - improving the current operation of an increasingly complex set of procedures interlinking the EMEA Scientific Committees and the Working Parties, and - exploring alternative practical ways to provide the EMEA Scientific Committees and the Working Parties with the necessary specialist input. • To provide for a high-quality EMEA Secretariat professional workforce by - in accordance with the new legal provisions, further clarifying the respective roles and responsibilities of the EMEA Secretariat and the EMEA Scientific Committees' members and experts, - further improving the operation of the Agency (including a reinforcement of corporate Information Technology (IT) tools) and implementing any necessary organisational changes, and - developing and implementing an EMEA Competence Development Strategy. • To deliver a high-quality IT infrastructure by progressing the implementation of the EU Telematics Master Plan and by addressing specific needs in the field of electronic submissions and inter-operability, in close collaboration with HMA.

Key Initiatives
• To provide for an appropriate funding of the Network in the context of the work undertaken at EMEA level by - implementing generally accepted international costing methods, - proposing to the EMEA Management Board alternative options for establishing a new remuneration scheme for services provided by the NCAs, and - subsequently liaising with the NCAs as regards the implementation of the approach agreed at Management Board level. • To progress work in the field of GXP[2] by - following-up on the 2007 Clinical Trials Conference and continuing to facilitate the implementation of the Clinical Trials legislation through support to the NCAs, and - developing and strengthening policies and procedures on pharmacovigilance inspections.

Safety of medicines

Further improving the safety of medicines by enhancing the management of risks continues to be a top priority for the next years. Activities will be undertaken by the EMEA in close collaboration with HMA within the context of the European Risk Management Strategy (ERMS) (for medicines for human use) and the European Surveillance Strategy (ESS) (for medicines for veterinary use). Although a further improvement of the operation of the EU Pharmacovigilance System will remain high on the agenda, there will also be particular focus on a strengthening of the science and the methodology that underpins the safety monitoring. This should enable to move-up the evidence in accordance with the principles of the best evidence concept.

Key Initiatives
• To progress the ERMS in accordance with the ERMS rolling two-year Work Programme[3]. • To progress the ESS in particular by - further developing EudraVigilance Veterinary through the introduction of additional functionalities (e.g. data analysis tools), - establishing the concept of risk management plans, adapted to the needs of veterinary medicines, - facilitating work-sharing initiatives, and - strengthening communication on product safety to the professional community.

Research and innovation

The EMEA will continue to provide support to the European Commission's efforts to stimulate research and innovation in the EU. This primarily will be undertaken in the context of the Innovative Medicines Initiative (IMI) and the 7th Framework Programme. In addition, a number of complementary initiatives carried out by the Agency should help addressing bottlenecks in the area of drug development. Such initiatives also come

[2] GXP refers to Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices.

[3] Please consult the document "Implementation of the Action Plan to Further Progress the European Risk Management Strategy: Rolling Two-Year Work Programme (2008-2009)" for further information.

within the frame of the discussions held in the EMEA/CHMP Think-Tank group on innovative drug development.

Key Initiatives
• To implement the Action Plan resulting from the EMEA/CHMP Think-Tank group report on innovative drug development. • To further progress the Small and Medium-sized Enterprise (SME) concept by - introducing measures to tailor assistance to SMEs in the critical period between scientific advice and the marketing authorisation application, - collecting information on technologies/therapies under development by SMEs to better forecast the need for specific knowledge based expertise, and - developing and implementing the concept of SMEs within the Network.

Availability of medicines

Bringing medicines fast to the market will continue to be a key target for the EMEA. Although experience with the centralised procedure has shown the Agency's capability of delivering fast reviews, particular emphasis will have to be put on the monitoring of the implemented legal tools and the introduction of new legislative provisions in the field of Advanced Therapies. The Agency will also continue its efforts to introduce further improvements in the current regulatory licensing process for medicines for human use within the context of the EMEA Process Improvement exercise. In the field of veterinary medicines, the EMEA will respond to regulatory reform proposals expected from pharmaceutical industry.

Key Initiatives
• To implement new Community legislation on Advanced Therapies (e.g. by setting-up the new Committee on Advanced Therapies and by preparing the necessary guidance documents for regulators and pharmaceutical industry). • To progress work at the level of the CHMP/CVMP on a strengthening of the methodology for benefit/risk analysis to improve consistency of opinion-making at Committee level. • To extend the existing scientific advice procedure for human medicines to include biomarkers. • To progress work in the field of paediatrics by - monitoring the implementation of the new legal provisions and taking remedial action, whenever needed, - agreeing the strategy and establishing the EMEA network of paediatric research, and - establishing the inventory of paediatric needs based on the survey of off-label paediatric use at the level of the Member States.

Specific needs for veterinary medicines

The specificities of the veterinary sector will require efforts to be continued in 2008 and 2009 in order to address specific needs of medicines for veterinary use. Lack of availability of veterinary medicines especially for minor species and limited markets, concerns as regards the development of antimicrobial resistance in man and animals, as well as the environmental safety of medicines necessitate targeted actions over the next years.

Key Initiatives
• To progress the actions outlined in the HMA Action Plan on the availability of medicines for veterinary use[4]. • To work with relevant organisations in developing science based policies for the use of antimicrobials. • To continue and, if possible, extend the current pilot scheme for free scientific advice for veterinary medicines for minor species and limited markets. • To optimise good pharmacovigilance practice. • To balance, in the context of the implementation of Community legislation on environmental risks, the legislative requirements versus the impact on the availability of medicines for veterinary use.

Needs for specific classes of medicines

Specific classes of medicines (biosimilar and generic medicines, non-prescription medicines, herbal medicines) will require targeted actions to improve their management through the centralised licensing route. These actions come on top of initiatives undertaken in the context of the aforementioned EMEA Process Improvement exercise.

Key Initiatives
• To address specific needs for certain classes of medicines by - introducing the necessary measures to maintain consistency for opinions taken for centrally authorised biosimilar and generic medicines, - implementing in the case of non-prescription medicines a formal platform for regular interaction with non-prescription pharmaceutical industry to address potential hurdles in the submission of applications processed through the centralised licensing route, and - exploring for herbal medicinal products the possibility of complementary initiatives to progress the establishment of monographs and list entries, such as the involvement of academia alongside the resources made available by the Network.

Transparency

Openness of operation has since the start of the EMEA been an important feature. This has resulted in numerous initiatives to improve transparency of EMEA activities. Efforts over the next years will be directed to both transparency on product and non-product related issues. The Agency's partners and stakeholders will be involved in discussions on how to meet the increasing demands of patients/users of medicines and healthcare professionals on earlier information whilst respecting commercial confidentiality of proprietary information.

Key Initiatives
• To fully implement all outstanding transparency initiatives, such as the 2003 EMEA Transparency Policy measures (e.g. the revision of the EMEA website, publication of safety bulletins for medicines for human use), not yet completed initiatives stemming from the 2005 EMEA Road Map in the field of non-product related issues (e.g. publication of agendas and minutes/meeting summaries of EMEA fora), and access to the various Eudra databases.

[4] For further information, please consul the document "Report of the Task Force on Availability of Veterinary Medicines 2007" (http://www.hma.eu/203.html).

Key Initiatives
• To explore, through a debate with the Agency's partners and stakeholders, how to further improve transparency on product related issues. • To increase the transparency on the Agency's opinion-making, including the rationale for such opinion-making. • To also initiate a debate with the EMEA stakeholders on the draft EMEA Policy on access to EMEA documents.

Communication and provision of information

Communication and provision of information has been expanded and strengthened over the past years, resulting in an improved transparency of the Agency's work, more patient friendly information, as well as the launch of new tools for acquiring information on medicines (such as the EudraPharm database). In order to further progress in this field, there is a need to ensure an appropriate coherence and coordination in relation to the different types of information the EMEA provides, and the tools with which this information is communicated.

Key Initiatives
• To review the current EMEA communication tools, taking due account of a stakeholder analysis, and to subsequently implement the revised tools. • To develop a coherent communication platform at the EMEA, combining all communication tools, with primary focus on the revision of the EMEA website. • To maintain and further develop the various Eudra databases which provide input into the EMEA communication platform. • To initiate a debate with the NCAs on how the EMEA can better assist the NCAs in the provision of information as per current Community legislation (i.e. information about centrally authorised products to the public and healthcare professionals, and information concerning pharmacovigilance to healthcare professionals). • To develop a communication structure for dissemination of information through the Network.

Interaction with stakeholders

Since its establishment the EMEA has initiated interaction with its stakeholders (patients, consumers and users of medicines, healthcare professionals, pharmaceutical industry, academia and learned societies). It has to be recognised that such interaction has evolved over time. Over the next years the Agency will strive for a more homogenous approach, both in terms of the level of interaction with each stakeholder as well as the involvement of the stakeholders in the various fields of EMEA activity.

Key Initiatives
• To streamline the interaction between the EMEA (i.e. the EMEA Secretariat as well as the various EMEA Scientific Committees) and pharmaceutical industry by progressing the development of a Best Practice Guide and subsequently implementing it. • To strengthen, in the field of medicines for human use, the interaction with patients by identifying additional EMEA activities which could benefit from patients' involvement, and by monitoring the yearly "satisfaction survey" and introducing improvements, whenever necessary.

Key Initiatives
• To reinforce, in the field of medicines for human use, the interaction with healthcare professionals by establishing a dedicated EMEA Scientific Committees' Working Party with Healthcare Professionals' Organisations, building on the achievements made at the level of the current Working Group, by finalising and implementing a formal framework of interaction and by taking forward recommendations for action proposed by the Working Party.
• To strengthen the interaction with academia and learned societies by including them in the provision of high-quality specialist training as per the joint EMEA/HMA Competence Development Strategy and by collaborating with these organisations in the field of outcome assessment in accordance with the EMEA Outcome Assessment Agenda.
• To communicate with Health Technology Assessment Bodies on how to increase transparency with respect to the Agency's rationale for opinion-making.

International collaboration

Over the years the EMEA has been confronted with an increasing demand for collaboration with non-EU Regulatory Authorities, irrespective if this was undertaken within the context of formal Confidentiality Arrangements concluded between the EU and such Authorities, or through a less formal route of interaction. This phenomenon comes on top of an already existing international collaboration in the frame of fora such as the (V)-International Conference on Harmonisation (ICH), the Food and Agricultural Organisation (FAO), the Codex Alimentarius, the Office International des Epizooties (OIE) and Mutual Recognition Agreements (MRAs). It is envisaged for these international activities to become more important over the next years, alongside initiatives to further facilitate accession to the EU in the frame of pharmaceutical regulation. The EMEA, therefore, will focus its efforts on a strengthening of its involvement on the international scene with due respect of the Network in which it operates.

Key Initiatives
• To develop a framework for managing the Agency's international relationships and commitments.
• To promote a greater visibility and involvement of the Network in international activities.
• To progress activities on Confidentiality Arrangements with non-EU Regulatory Authorities in coordination with the European Commission.
• To facilitate involvement of Accession and Candidate Countries in EMEA activities.
• To identify, in cooperation with the World Health Organisation (WHO), possible measures to assist developing Countries on regulatory matters in the context of Article 58 provisions.
• To strengthen the oversight of clinical trials (including ethical principles) performed outside the EU by developing links with local regulators.
• To provide support in the areas of avoidance of duplication of inspections and prevention of double standards, and prevention of counterfeit medicines.

Forthcoming regulatory initiatives

In addition to the aforementioned actions, the EMEA will contribute to forthcoming regulatory initiatives such as the preparation and subsequent implementation of new Community legislation (e.g. in the fields of variations, information to patients, maximum

residue limits, pharmacovigilance). The Agency will also provide support to policy initiatives undertaken by the European Commission (e.g. the Transatlantic Administrative Simplification exercise).

IV PLANNING AND REPORTING

The same methodology for planning and reporting as adhered to so far will apply during the next two year period. The aforementioned key initiatives will be included, where applicable, in the 2008 and 2009 EMEA Work Programme respectively. Information on the follow-up to all initiatives undertaken within a specific year will be provided in a yearly Status Report which will be made publicly available.