European Medicines Agency

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Status Report on the Implementation of the EMEA Road Map

I Introduction

The Management Board, at its 16 December 2004 meeting, endorsed the EMEA Road Map document. Such document consists of two parts, (1) the EMEA Strategy (in terms of the Agency's vision to 2010, the objectives to be achieved and the prerequisites to be fulfilled in order to allow the EMEA to implement its vision) and (2) the EMEA Road Map Implementation Plan (in terms of the concrete actions the EMEA will undertake to reach the objectives, as well as the estimated timeframes for finalisation of these activities).

This document provides, as per the outcome of the discussions at Management Board level, the current status of implementation of the EMEA Road Map project. Information provided in this status report relates to initiatives which have been undertaken in 2005. In addition, where relevant, it is indicated for which initiatives an important delay in implementation has occurred, or where, taking into account the current situation, a delay in 2006 deliverables might be encountered. Rather than providing the current status for all actions described in the EMEA Road Map Implementation Plan, high-level information is given on the progress made in 2005. It needs to be stated that the most important achievements which could be noted last year have also been included in the 2005 EMEA Annual Report.

The Management Board noted at its 9 March 2006 meeting the Status Report on the Implementation of the EMEA Road Map.

II Current Status of the EMEA Road Map Implementation

Overall, very good progress has been achieved in 2005 on the implementation of the EMEA Road Map, and this in various fields.

Numerous actions have been undertaken in 2005, in line with the EMEA Road Map Implementation Plan and the 2005 EMEA Work Programme. Several of these actions have been finalised in 2005, whilst others are ongoing. In few areas, delays have occurred, or could be encountered by the end of 2006. Detailed information on the progress made is provided in annex.

II.1 Summary of 2005 Achievements

Important achievements in 2005 relate to the organisation of the EU Regulatory System. Initiatives taken targeted the four initially identified areas, i.e. an enhancement of the overall quality of the EU Regulatory System by ensuring the availability of an adequate Quality Assurance System, the further development of the EMEA Secretariat in line with the new legal provisions to successfully address the challenges stemming from new Community legislation, the further development and implementation of EU telematics systems in line with the agreed EU IT Strategy and the future funding of the EMEA networking model.

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Many processes managed by the EMEA have benefited from substantial progress made in relation to the implementation of the EMEA Road Map. The preparation for the implementation of various new legal tools to facilitate early access to medicines is entering its final phase and will allow the Agency to make an important contribution to the development of an EMEA Strategy on Fast Track. Furthermore, the Agency's support to the Innovation Platform also contributed to the stimulation of research and innovation. Support was provided by the EMEA to pharmaceutical industry in the development of new therapeutic technologies and approaches. The Agency's commitment to continuously monitor the efficiency of its processes resulted in revisions being made, on the basis of experience gained, to several aspects impacting on the Centralised Procedure. Work continued in 2005 to address specific needs for veterinary medicines in areas such as availability of veterinary medicines, antimicrobial resistance and environmental risk assessment. Specific aspects related to generic and non-prescription medicines were progressed in 2005 as scheduled through enhanced collaboration with the respective pharmaceutical industry associations. Finally, initiatives were taken to allow for the full operation of the HMPC in accordance with the legal provisions.

Particular attention was given in 2005 to the provision of support to Small and Medium-sized Enterprises (SMEs), through initiatives such as the implementation of financial incentives and the establishment of an EMEA SME Office.

Interaction with the Agency's stakeholders progressed very well and focussed on the implementation of new Community legislation (interaction with the pharmaceutical industry), finalisation and implementation of the recommendations stemming from the EMEA/CHMP Working Group with Patients and Consumers Organisations, and involvement of academia and learned societies in discussions on innovative approaches in order to facilitate drug development. International collaboration mainly focussed on the preparation for the further EU enlargement, a strengthened interaction with the FDA under the EU/FDA Confidentiality Arrangements' umbrella, and the availability of a process allowing for the scientific evaluation of human medicines for non-EU countries (Article 58 scientific evaluations).

In the various areas of EMEA activity the overall progress made was also very important. The area of scientific advice saw the preparation for the implementation of a revised scientific advice procedure, including external consultation, further to the establishment of the new Scientific Advice Working Party in 2004. In the field of scientific assessment a strengthening of the quality assurance was undertaken through the introduction of a procedure for pilot peer reviews during the initial assessment phase of marketing authorisation applications for human medicines. Initiatives in the area of monitoring of medicinal products for human use followed the Action Plan to further progress the European Risk Management Strategy (ERMS) and the rolling 2-year Work Programme, hence contributing to the development of a more intensive drug monitoring system. The Agency further strengthened its transparency and communication with respect to product related issues (primarily in the post-authorisation phase) and started to work on improving its transparency on non-product related information, e.g. by organising open workshops to discuss general scientific issues. Improved provision of information on human medicines to patients was high on the EMEA agenda through the work undertaken at the level of the EMEA/CHMP Working Group with Patients and Consumers Organisations. In the area of GXP, the focus was on the implementation of the new legal provisions. In addition, work progressed on a strengthening of the coordination of inspections in the context of the PMF and VAMF certification schemes.

II.2 Delayed/Possibly Delayed Activities

There are few areas where delays have occurred in 2005, or could be encountered by the end of 2006:

- The establishment of an EU-wide up-to-date inventory of the available scientific expertise for all aspects of human and veterinary medicines regulation, including the identification of missing/insufficient expertise at EU level and subsequently

complementing such missing/insufficient expertise, envisaged to be completed in 2006, will most probably only be completed in 2007.

- The strengthening of the competence development at EU level by developing an EU Competence Development Strategy, originally scheduled for the end of the 1st half of 2006 will probably be postponed to 2007.
- The interaction with healthcare professionals in the field of human medicines did not progress as originally scheduled. The planned dedicated workshop with healthcare professionals will now take place in March 2006.
- A formal review of the experience gained with the implementation of the EU/FDA Confidentiality Arrangements could not be done in 2005. This will be undertaken in March 2006. At such moment opportunities for further improvement will also be discussed.
- Some initiatives in the field of transparency and communication have been delayed, such as discussions with all involved parties on the most adequate balance between the provision of earlier information and the need to respect commercial confidentiality of proprietary information. These discussions will take place in 2006.

Annex 1

Details on the Progress Made in 2005 on the EMEA Road Map Implementation

As stated in Section II, the EMEA Road Map implementation progressed very well in 2005. Details on the current status of implementation of the EMEA Road Map in the various areas are described below.

I Organisation of the EU Regulatory System

The EMEA networking model

- The establishment of a network of excellence at EU level has progressed in 2005. Workload and resource planning is taken up at EU level through regular discussions at the Heads of Medicines Agencies (HMA) forum. The establishment of an EU-wide up-to-date inventory of the available scientific expertise, as well as the development of an EU Competence Development Strategy, both envisaged to be completed in 2006, might be delayed.
- Heads of Medicines Agencies (including EEA Countries) in collaboration with the EMEA have implemented an EU benchmarking system (BEMA) across the EU. The 1st benchmarking cycle is being performed.
- The quality assurance of the scientific assessment processes has been strengthened through the introduction at CHMP level of a peer review system in the pre-authorisation phase for the Day 120 assessment reports and the Lists of Questions. The outcome of this pilot phase is currently being reviewed. The decision on a further extension of the peer review concept will be taken on the basis of the outcome of such pilot phase.
- Discussions on the preferred evolution of the EU Regulatory System are currently ongoing at 2 levels: (1) at HMA level in the context of the discussions on the HMA Strategy Paper on the European Medicines Regulatory Network and (2) at the level of the EMEA Scientific Committees in the context of discussions on the criteria for selection of (Co)-Rapporteurs.

The EMEA Secretariat

- Discussions on the further development of the EMEA Secretariat, to take into account its extended tasks as per the new legal provisions, have started and will, once finalised, result in clearer roles and responsibilities for the EMEA Secretariat and the Scientific Committees members and experts (including the interaction with pharmaceutical industry).
- Work has started on adapting the EMEA competence development programme to the changing needs stemming from both new Community legislation and the EMEA Road Map.
- Although priority has been given in 2005 to the preparation for the timely implementation of new Community legislation, organisational and operational changes at the level of the Human and Veterinary Units are being introduced in order to strengthen the quality and the scientific and regulatory consistency of the EMEA processes.

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The EU IT Strategy

- The implementation of all EU telematics systems is currently on track, but possible budget issues for 2007 need to be considered.

The funding of the EMEA networking model

- Discussions at the level of the costing group and the reflection group on the long-term financing have been completed and their reports are currently under discussion at Management Board level. Taking into account the conclusions of these reports, proposals on how to progress the financial compensation for the National Competent Authorities (NCAs) have been provided to the Management Board for discussion.

II The EMEA Processes

Innovative medicines

- Work on the development of an EMEA Strategy on Fast Track progressed in 2005. The preparation for the implementation of the new legal tools (accelerated assessment, conditional marketing authorisations and compassionate use) to facilitate early access to medicines is entering its final phase. Four new Scientific Advisory Groups (SAGs) were created in 2005; three SAGs were established to cover the remaining three therapeutic areas for which the centralised procedure is mandatory (diabetes/endocrinology, neurodegenerative diseases/other central nervous system conditions, HIV/viral diseases). Preparations were also made for a new group with expertise on cardiovascular diseases.
- An important contribution to the stimulation of research and innovation was made through a range of activities: support was provided to the Innovation Platform of the European Commission's Directorate-General Research within the context of the 7th Framework Programme; a "think-thank" group on innovation, involving pharmaceutical industry, was established to consider innovative methods of drug development and assess potential hurdles encountered by pharmaceutical companies who have innovative approaches included in their research and development portfolio; an external website of the Innovation Task Force was created; a workshop on biomarkers was held at the end of 2005.
- Other process improvements related to the centralised procedure were also introduced by revising the Guideline on the acceptability of invented names for human medicines and by finalising a revised procedure for the handling of translations of product related information for human and veterinary medicines. Furthermore, the EMEA Policy and Procedure on the handling of conflicts of interests of EMEA Scientific Committees Members and Experts was revised, taking into account a one-year experience.

Specific needs for new technologies

- The EMEA took a number of initiatives in the human medicines field to support applicants in the development of new therapeutic approaches and technologies: a pilot procedure was established to facilitate the evaluation whether emerging approaches can be considered as medicinal products and have thus access to the Centralised Procedure; consultation with pharmaceutical industry started on challenges related to new technologies in the context of the "think-thank" group on innovation (in the next phase academia and learned societies will be involved in these discussions). Furthermore, information on new technologies and therapies is available on a dedicated web page on the external website.

Specific needs for veterinary medicines

- Work in the field of availability of veterinary medicines and the establishment of a priority list of agreed essential veterinary medicines for minor uses/minor species continued in 2005. This resulted in the availability of a CVMP proposal for a list of essential substances for horses as a basis for a new legislative list, an extension of the free scientific advice for minor uses/minor species and the creation of an HMA-V Task Force on availability of veterinary medicines, with active participation by the EMEA.

- In the field of antimicrobial resistance also good progress was made. The CVMP, with support provided by the SAG on Antimicrobials, developed several documents, which should result in the development of a new strategy on risk management and risk assessment for antimicrobials. Furthermore, there is now a systematic involvement of the SAG on Antimicrobials in the risk assessment of centralised marketing authorisation applications for new antimicrobials. Work on a pre-authorisation risk assessment guideline is ongoing.
- In order to ensure the adequacy of environmental risk assessment, the CVMP and its dedicated Working Party (the Environmental Risk Assessment Working Party) developed guidance to assist pharmaceutical companies in the preparation for the environmental risk assessment which is a new legal requirement in the context of veterinary marketing authorisation applications.

Generic and non-prescription medicines

- Interaction with the generic medicines pharmaceutical industry was strengthened in 2005. The framework for the handling of generic applications was implemented in terms of the procedure to be followed and the templates to be applied. The first generic application for a veterinary medicinal product, received in 2004, was processed in 2005, resulting in a positive Opinion at the January 2006 CVMP meeting.
- In relation to non-prescription medicines, the criteria for switching the legal status for centrally authorised products were revised in the context of the update of the Guideline on changing the classification for the supply of medicinal products for human use. Furthermore, discussions on the need for special criteria to be applied for invented names for non-prescription medicines were initiated in 2005.

Herbal medicines

- The framework for the operation of the HMPC to take account of the full implementation of new Community legislation was implemented in 2005. A permanent Working Party on Community Monographs and Community List was established. Work undertaken by the Committee focussed on the establishment of the necessary procedures for conducting its business.
- The HMPC also released for public consultation its first Community herbal monographs (covering well-established and/or traditional use) and entries into the Community List.

III Provision of Incentives for Small and Medium-sized Enterprises

- Building on the initiatives which have already been undertaken by the EMEA in the field of support to SMEs, i.e. in the field of orphan drugs and EudraVigilance, the EMEA further strengthened this support in 2005 in line with the new legal provisions. Actions initiated relate to the implementation of financial incentives for SMEs, the establishment of a dedicated SME Office at EMEA level and the publication of all relevant information on a dedicated web page on the external website. The preparation of additional guidance is currently in progress.
- Further to a first meeting with SME stakeholder organisations (covering human and veterinary medicines) on 17 November 2005, several veterinary companies have contacted the SME Office to clarify their SME status.

IV Interaction with the Agency's Stakeholders

Interaction with the pharmaceutical industry

- Interaction with the pharmaceutical industry throughout 2005 concentrated on the preparation for the implementation of new Community legislation. Several meetings with the pharmaceutical industry associations were held to facilitate such preparation.
- In addition to the interaction, already described in Section II "The EMEA Processes, Generic and non-prescription medicines", discussions with generic and non-prescription

medicines pharmaceutical industry also took place in the context of the Business Pipeline project. Furthermore the generic medicines pharmaceutical industry was involved in discussions on similar biological medicinal products related issues.

- In the field of veterinary medicines, the interaction with pharmaceutical industry was reinforced, building on the procedure established in October 2004 to facilitate communication and dialogue between the CVMP and interested parties.

Interaction with patients

- The recommendations stemming from the EMEA/CHMP Working Group with Patients and Consumers Organisations were finalised in 2005, further to an external consultation exercise, and subsequently published. Most of the recommendations impacting on the EMEA have already been implemented in 2005.
- A specific framework for interaction between the EMEA and Patients and Consumers Organisations was adopted by the Management Board in December 2005.

Interaction with healthcare professionals

- Interaction with healthcare professionals in the field of human medicines was limited in 2005. The planned dedicated workshop between the EMEA and healthcare professionals to discuss the provision of adequate information to healthcare professionals and to strengthen their participation in the pharmacovigilance network had to be postponed due to lack of human resources. Such workshop will now be held on 28 March 2006.

Interaction with academia and learned societies

- A list of learned societies has been established.
- Academia and learned societies have been involved throughout 2005 in discussions on innovative approaches in order to facilitate drug development. Meetings were held with various learned societies, in the fields of urology, oncology, diabetes, cell therapy treatment, etc. Regular contacts are also taking place between the Paediatrics Working Party and learned societies.

V International Collaboration

- The preparation for the accession of countries to the EU continued in 2005, mainly through initiatives such as Bulgaria and Romania participating as observers in scientific meetings, and the implementation of a Pre-Accession Linguistic Check (PALC-II) project. The nCADREAC procedure applies to both countries as from 10 January 2006.
- Preparatory work for the accession of Croatia and Turkey has also been initiated. The nCADREAC procedure applies to Croatia as from 10 January 2006.
- An important contribution to the scientific evaluation of human medicines for non-EU countries was made through the availability on the EMEA website of a Guideline on Article 58 scientific evaluations. The first 2 CHMP Opinions for these products were given by the end of 2005.
- The interaction between the EMEA and the FDA in the context of the EU/FDA Confidentiality Arrangements made good progress in 2005. A discussion on the experiences obtained after 1 year of implementation and on the opportunities for further improvement could not take place in 2005 due to the fact that the EU/FDA bilateral meeting had to be postponed. Such meeting will now take place on 13 March 2006.

VI The EMEA Areas of Activity

Area of scientific advice

- The new Scientific Advice Working Party was established in 2004. The implementation of the revised scientific advice procedure is ongoing following external consultation.

- Due to the postponement of the 2005 EU/FDA bilateral meeting no formal discussion could take place on the experience obtained with the parallel scientific advice procedure and the opportunities for further improvement. Such discussion will now take place on 13 March 2006.

Area of scientific assessment

- As already mentioned in Section I, "Organisation of the EU Regulatory System, The EMEA networking model", the revision of the scientific assessment procedure for human medicines has been initiated through the introduction, as a pilot phase, of a procedure for peer review. The outcome of the pilot phase is currently under review.

Area of monitoring of medicinal products

- Initiatives in the area of monitoring of medicinal products for human use largely have been progressed in the context of the ERMS. Good progress was made in 2005 in this field. The EMEA and HMA-H published an Action Plan to further progress the ERMS, as well as a rolling 2-year Work Programme (mid 2005-mid 2007).
- Progress made in relation to the ERMS project related in first instance to the implementation of new Community legislation. Guidance both for pharmaceutical industry and EU Regulatory authorities (e.g. the CHMP) has been made available in relation to several new legal tools to further strengthen the safety monitoring of medicinal products (e.g. risk management plans).
- Furthermore, complementary initiatives were undertaken under the ERMS umbrella relating to the following areas:
    - Speeding-up the electronic reporting of adverse drug reactions through EudraVigilance: progress in this field has been important since 24 NCAs are now in production (EVPM) and the number of MAHs/sponsors of clinical trials is also further increasing. In addition, substantial work has been undertaken at the level of both the EudraVigilance Steering Committee and the EudraVigilance Expert Working Group on the further facilitation of the electronic reporting.
    - Input has been provided in relation to the Innovative Medicines Initiative (7^{th} Framework Programme) in relation to the development of the Strategic Research Agenda in the field of pharmacovigilance.
    - A Concept Paper on the use of academic centres for intensive drug monitoring is currently being discussed at CHMP and PhVWP level.
    - The scientific expertise at PhVWP level has been reinforced. Further to the re-establishment of the PhVWP in September 2005, a gap-analysis of the available scientific expertise has been performed and the identified missing / insufficient expertise has been complemented through the co-optation of 8 additional PhVWP members. Discussions on how to best involve such additional expertise for the benefit of the whole EU Regulatory System are currently ongoing.
    - A Concept Paper on the conduct of pharmacovigilance for vaccines and a Guideline on paediatric pharmacovigilance have been drafted and are currently subject to public consultation.
- In the field of veterinary medicines, the implementation of risk management has partly been initiated within the frame of the European Surveillance Strategy. Full risk management strategies for veterinary medicinal products, including a definition of the scope and the development of guidance, are yet to be planned. Furthermore, initiatives have been taken within various fora to increase and facilitate reporting of adverse reactions within the EU. The first results of these initiatives, in the form of guidelines and the development of specific electronic tools, should become visible by the end of 2006.

Area of transparency and communication

- The further implementation of the EMEA Transparency Policy Measures adopted by the Management Board in October 2003 continued in 2005 with publication of Summaries of Opinions for certain post-authorisation opinions (mainly extensions of indication and the addition of new contra-indications or warnings) and the systematic release of Q&A documents for all major safety issues involving centrally authorised products.
- In order to further improve the Agency's transparency in the field of non-product related issues, a pilot has been initiated on the publication of Management Board agendas, minutes and relevant supporting documentation. Publication of meeting summaries on non-product related information is currently already done at the level of the HMPC through the HMPC reports which are publicly available.
- Open workshops to discuss general scientific issues have been organised, e.g. in the field of biomarkers.
- Discussions with the Agency's partners and stakeholders on the most adequate balance between the increasing demands of patients/users of medicines and healthcare professionals on earlier information and the need to respect commercial confidentiality of proprietary information, could not be undertaken in 2005, as initially planned. Such discussions will take place in 2006.

Area of provision of information on human medicines to patients

- As already stated in Section II, "Interaction with the Agency's Stakeholders, Interaction with patients", the recommendations from the EMEA/CHMP Working Group with Patients and Consumers Organisations were finalised and published in 2005. Several of these recommendations impacting only on the EMEA were already implemented in 2005.

Area of GXP

- The implementation of new Community legislation, e.g. in the GMP coordination of finished products and active substances was achieved as planned. All documents required were prepared and subsequently published.
- Input has also been provided by the EMEA to the European Commission's responsible services in relation to Community legislation on certain excipients, with some further work to be undertaken in 2006.
- A policy and procedure was developed in relation to the coordination of inspections in the context of the PMF and VAMF certification schemes. Monitoring of these deliverables will take place during 2006.