The European Medicines Agency

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The European Medicines Agency Road Map to 2010: Preparing the Ground for the Future

Executive Summary

As part of its proactive approach to the continuing evolution of the pharmaceutical arena within the European Union (EU), the European Medicines Agency (EMEA) has developed a strategy that will contribute to better protection and promotion of public and animal health, improve the regulatory environment for medicinal products, and help to stimulate innovation, research and development in the EU.

Involving its partners and stakeholders in the consultation process on its strategy allowed the EMEA to achieve a broad consensus on the best way forward for the Agency in view of the significant changes to its operating environment.

The resulting Road Map is one that takes a realistic view of the challenges facing the Agency and the EU regulatory system as a whole, while offering viable proposals as to how those challenges can be met.

The ultimate objective of the Road Map exercise is to ensure that, building on the achievements of its first 10 years, the EMEA adequately prepares the ground for further success in the future.

A challenging regulatory environment

Recent political, institutional, legislative and scientific developments in the EU will have a significant impact on the regulatory environment over the coming years.

The enlargement of the EU on 1 May 2004 and the entry into force of new Community pharmaceutical legislation by November 2005 both present considerable challenges for the EMEA and its partners and stakeholders in the EU regulatory system.

The integration of 10 new Member States (MSs) and their National Competent Authorities (NCAs), and the likely accession of a further two states in 2007, increases the complexity of operating an efficient regulatory system, while new legislation extending the scope of the Agency's activities increases pressure on its resources and on its ability to meet the expectations of its stakeholders.

Political orientations such as the Lisbon strategy for economic, social and environmental renewal are important factors to increase the competitiveness of EU based pharmaceutical industry.

Meanwhile, the scientific environment is likely to change dramatically with the introduction of new technologies and emerging therapies, such as gene therapy, pharmacogenomics,

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 20
E-mail: mail@emea.eu.int http://www.emea.eu.int

proteomics and xenotransplants. These developments will need to be addressed in the context of continuing globalisation.

Faced with these challenges, the EMEA will have to demonstrate that the networking model on which it is based, involving institutional partners, 42 or more NCAs and over 3,500 scientific experts, is still able to deliver high quality in the areas it is responsible for.

Consequences for the EMEA

These developments are to be seen as opportunities as well as challenges. The EMEA will acquire new responsibilities with a greater focus on public and animal health; the scientific components of the Agency's activity will become more important; its visibility and influence in both the EU and the international regulatory environment will grow at a faster rate.

Ultimately, the consequence of the changing environment, and the Agency's strategy for adapting to it, will be that the EU regulatory system is in a more secure position to become one of the foremost in the world, with the greatest benefit for the citizens of Europe.

New action plan

The political, institutional, legislative and scientific developments within the EU prompted the EMEA to launch an exercise at the beginning of 2004 to determine a plan of action for the future. In April, the Agency produced a discussion paper, "The European Medicines Agency Road Map to 2010: Preparing the Ground for the Future", which was released for public consultation.

During the three-month consultation period, some 65 contributors — EU institutions, national health authorities, patient groups, professional healthcare organisations, pharmaceutical companies, trade associations, academics and other interested parties — submitted comments, which were taken into account.

The Road Map sets out a vision for the Agency, its objectives, and the specific actions it will implement to achieve those objectives.

Vision of the EMEA

The key aspects of the Agency's vision for the coming years are to allow rapid access to safe and effective medicines, provide for adequately informed patients and users of medicines, encourage and facilitate innovation and research in the EU, tackle emerging public health challenges, prepare for developments in the pharmaceutical field, and reinforce the partnership between the EMEA and the NCAs to establish a network of excellence at EU level.

The Agency will work to maintain and further strengthen its position as a regulatory authority that is public-health oriented, science-driven, transparent in the way it operates, and committed to applying good administrative practices.

Prerequisites for successful development

A further strengthening of the Agency's networking model, building on the firm partnership which already exists between the EU Regulatory Authorities, will lead to the establishment of a network of excellence at EU level, and will be vital to the future success of the EU Regulatory System.

NCAs will need to consider how they can best contribute to the overall regulatory system. Emphasis is placed on the need for them to continue and, where possible, augment their provision of high-quality scientific resources to the EMEA. The availability of highly specialised experts is of critical importance.

The Agency will have to put a robust quality assurance system in place to guarantee the overall quality and efficiency of its operations. This should result in a governance system at

EU level which assures quality and regulatory and scientific consistency of the evaluation processes.

Together with MSs, the EMEA will need to further develop and implement the EU-wide telematics strategy in order to provide a high-quality IT infrastructure across the EU that facilitates collaboration between the NCAs and the EMEA.

In view of its new and extended tasks, the EMEA Secretariat will need to review its processes and organisational structure in order to maximise efficiency. In particular, given the enhanced scientific role of the Secretariat, it will be critical to raise the scientific profile of its staff members and identify those areas where resources need to be strengthened.

Adequate workload and resource planning, including financial considerations, must be a priority if the EMEA is to focus on making safe and effective medicinal products available to patients and users of medicines in the shortest possible timeframe.

Objectives set out in the Road Map

The Road Map identifies the following as priority objectives that need to be achieved before the end of this decade.

Top-quality scientific assessment

The increasing complexity and cost of developing new active ingredients in today's globalised pharmaceutical industry demands a reinforced scientific advice process underpinned by a robust quality assurance system, including a strengthened peer review system that can improve the consistency of scientific assessments. In addition, there is a need for greater collaboration with – and for benchmarking against – non-EU regulatory authorities. Scarcity of scientific expertise in particular areas and overcapacity in others are issues that need to be addressed satisfactorily. Adequate measures need to be taken to ensure the highest level of expertise among the existing pool of experts. Elements of the new Community legislation will contribute to improving all these issues.

Timely access to safe and effective innovative medicines

The EMEA must strive for further gains in the operating efficiency of the centralised procedure, without compromising the quality of the assessment process that assures the safety of medicines reaching the market. Patients suffering from severe or life-threatening conditions in particular will benefit from timely access to innovative medicinal products. The Agency will continue to assist international efforts to develop a global standard for the assessment of such products. Revised Community legislation also provides for several new tools here.

Continuous monitoring of medicinal products

A proactive approach to pharmacovigilance and the introduction of risk management plans will enhance the continuous monitoring of products on the EU market. Further, closer collaboration with the MSs is of paramount importance here, and collaboration with non-EU Regulatory Authorities will be particularly important in the innovative field of new therapies. Regulators need to make sure the overall pharmacovigilance system is equipped to deal with safety concerns in an efficient and timely manner. New legislative tools will be made available to help.

Access to Information

The EMEA will follow up on initiatives agreed with the European Commission to improve access to information and enhance the Agency's profile in the outside world as an approachable, informative and transparent organisation. Systematic feedback will be obtained from health care professionals, patients, users of medicines, academia and learned societies in order to continuously improve the adequacy and targeting of information released by the EMEA for its stakeholders and the general public. EuroPharm and EudraVigilance will be key channels for providing high-quality information about medicinal products. Implementation of transparency policy measures and other transparency tools stemming

from the new legal provisions will result in the development of an EU Transparency and Communication strategy, to be undertaken in cooperation with NCAs.

Specific needs for veterinary medicines

A number of important veterinary issues demand specific attention, including the lack of availability of medicinal products for minor uses and minor species (MUMS), the potential development of antimicrobial resistance in man and animals, the environmental safety of some classes of medicinal products, and the effective application of good pharmacovigilance practice throughout the EU.

Specific actions

In order to meet the key objectives it has set itself, the EMEA has drafted an implementation plan that covers the following specific actions:

- Reinforce the partnership between all EU Regulatory Authorities in the different fields of medicines regulation, leading to the establishment of a network of excellence at EU level; renew efforts to acquire the best available personnel for the scientific activities of the Agency and the NCAs, taking pains to reinforce the network in areas where expertise is insufficient;
- Revise the current procedural framework to establish the best possible environment for the provision of scientific advice; increase the level of scientific support provided by the EMEA Secretariat to the Scientific Committees to improve the quality and regulatory and scientific consistency of their scientific assessment work;
- Implement procedures foreseen by the new legislation which allow for more rapid access to medicines without compromising the safety of patients; implement special measures for innovative medicines, technologies and therapies, veterinary medicines, generic/non-prescription medicines and herbal medicines;
- Explore options to enhance the continuous monitoring of medicinal products on the EU market, especially by applying a more proactive approach to pharmacovigilance;
- Stimulate research and innovation in the EU's pharmaceutical, biotechnology and healthcare industries, leading to the development of an adequate product development toolkit, able to address the bottlenecks during the development of innovative medicines;
- Provide incentives for Small and Medium-sized Enterprises;
- Strengthen the coordination of good manufacturing and clinical practices across the EU;
- Follow-up on initiatives to improve the Agency's transparency and communication, with special emphasis on the provision of useful, clear and comprehensive information to patients/users of medicines, and health care professionals;
- Engage more fully in dialogue with health organisations, academia, learned societies and other stakeholders;
- Continue the roll-out and development of EU-wide telematics systems;
- Strengthen the EMEA's international collaboration with non-EU Regulatory Authorities.

A considerable number of the actions set out in the Road Map implementation plan are already incorporated in the Agency's planning process for 2005. Fine-tuning those initiatives will continue throughout 2005, in close collaboration with the Agency's partners and stakeholders. The remaining actions are to be included in future work programmes, with the aim of full implementation by 2010.

Regular reviews will be done to investigate the need for additional initiatives to be undertaken. Feedback on progress made will be provided to the EMEA Management Board and the European Commission at regular intervals.