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

Part I

The European Medicines Agency Strategy

Chapter 1
Introduction

The key aspect of the European Medicines Agency (EMEA) vision for the coming years is to further strengthen the protection and promotion of public and animal health in the European Union (EU), whilst encouraging and facilitating innovation and research in an enlarged EU. In order to provide for an adequate implementation it will be paramount to further strengthen the current Agency networking model and to reinforce the firm partnership between all EU Regulatory Authorities, resulting in the establishment of a network of excellence at EU level.

Part I of the EMEA Road Map will address

(1) the positioning of the EMEA over the coming years in a changing environment,

(2) the consequent development of the EMEA in such an environment, including the objectives to be achieved, and

(3) the prerequisites that need to be fulfilled in order to allow the Agency to successfully achieve the objectives.

Chapter 2
A Changing Environment

2.1 The Current Environment

The EMEA was established in 1995.

Its current Mission Statement is “to contribute to the protection and promotion of public and animal health by

(1) mobilising scientific resources from throughout the EU to provide high quality evaluation of medicinal products, to advise on research and development programmes and to provide useful and clear information to users and health care professionals,

(2) developing efficient and transparent procedures to allow timely access by users to innovative medicines through a single European marketing authorisation, and

(3) controlling the safety of medicines for humans and animals, in particular through a pharmacovigilance network and the establishment of safe limits for residues in food producing animals.”

The EMEA works as a network, bringing together the scientific resources of the Member States (MSs) to ensure the highest level of evaluation and supervision of medicines in the EU. The Agency cooperates closely with international partners, reinforcing the EU contribution to global harmonisation.

The current EU Regulatory System is unique in the international regulatory environment in so far that Community legislation has provided for a network between all national regulatory bodies, coordinated by the EMEA.

The benefits of such networking model are numerous. It has allowed for the best scientific expertise available in the National Competent Authorities (NCAs) to be brought together at the level of the EMEA in order to assess innovative medicines using common standards and to subsequently provide for rapid access to such medicines for EU patients/users of medicines. It has also contributed to the harmonisation process between all MSs by further standardising the requirements for the evaluation and supervision of medicines irrespective of the licensing route and, as a result, has led to coordinated approaches in several fields.

However, it needs to be recognised that there exist areas where the overall successful networking model could still benefit from further strengthening, particularly in the light of the challenges the EU Regulatory System is facing in the coming years. Best use of the available limited resources, hence avoiding duplication of work, and increasing the efficiency of operation of the system is to be encouraged, together with the need for further coordination to ensure a harmonised approach in fields such as scientific advice, transparency, communication and monitoring of the impact of the regulatory action taken. All such initiatives should be undertaken in concert with the application of good regulatory practice. Furthermore, an adequate IT infrastructure at EU level, compatible with the national IT systems, is paramount to underpin the regulatory activities.

2.2 The New Environment

The EU Regulatory System is being confronted with significant changes of a legislative (impact of new Community legislation) and institutional (impact of the 2004 enlargement of the EU) nature.

In addition to these significant challenges having an immediate impact on the overall system, other developing factors which are nonetheless important will have to be taken

into account. Amongst them are political factors such as the continuation of the EU enlargement after 2004 with Bulgaria and Romania joining in 2007 and other countries such as Turkey also seeking membership.

In addition, one also needs to take into account important political orientations such as the Lisbon strategy for economic, social and environmental renewal set out in March 2000. Pharmaceuticals and healthcare biotechnology are leading pillars of the EU's knowledge economy. Pharmaceutical and healthcare industries remain cornerstones of the EU's industrial competitiveness. Therefore, they take a prominent place in the EU's pursuit of the goals set at the Lisbon European Council for the EU's economic competitiveness.

One of the key issues for Regulatory Authorities over the next years will be their ability to adequately monitor the medicinal products on the market, especially from a safety perspective. Recent worldwide withdrawals of high-profile medicines have indicated the need for a proactive approach to pharmacovigilance, to be translated in adequate systems, methodologies and processes, hence providing the best protection for public and animal health.

Another issue to be addressed by the international regulatory environment will be its ability to tackle the fall in innovative productivity, despite a sharp increase in global Research & Development (R&D) expenditure over the past years. Another factor to be considered is the international regulatory environment's ability to prepare adequately for the introduction of new technologies, from a scientific, legal and regulatory perspective. Appropriate measures will have to be taken in order to ensure that the pharmaceutical industry can take advantage of new pharmaceutical technologies in the manufacturing and analytical areas, and anticipate the implications of emerging therapies.

Other factors to be considered include the impact of an ageing population, increased demands for medicines in areas of unmet medical need, the possible unavailability of medicines both in the human and veterinary field, the ever increasing concerns about the development of antimicrobial resistance, the adequate management of bioterrorism and chemical terrorism agents and other major public health issues (such as an influenza pandemic, another SARS outbreak, etc.).

In the veterinary sector the safety of medicines in food producing animals will be underpinned by the Agency's continued role in the establishment of Maximum Residue Limits (MRLs) for substances used in food producing animal species for the purpose of setting adequate withdrawal periods and for the control of residues in foodstuffs of animal origin.

It should also be emphasised that all the above developments should be increasingly handled in a context of continuing globalisation.

These changes are not to be regarded as pure challenges, but rather as new opportunities, which, through adequate proactive initiatives should lead to an enhanced protection and promotion of public and animal health in an enlarged EU.

Chapter 3
The European Medicines Agency in the Changing Environment

3.1 Impact Analysis

The impact of the changing environment on the EMEA will be considerable. The Agency with its network of 42 NCAs in the European Economic Area (EEA), through which scientific resources are made available to the Agency, will become one of the world's foremost Regulatory Authorities for medicinal products. The EMEA will have to demonstrate that, after enlargement, the networking Agency model is still able to perform competently in the different fields of medicines regulation, with no negative consequences for the quality of the work which is undertaken, in close collaboration with 42 and possibly more NCAs. One of the major tasks of the Agency will continue to be the coordination of the scientific resources provided by the MSs and such task will be further extended, e.g. in the field of Good Manufacturing Practices (GMP), where inspections of the manufacturers of active ingredients will soon need to commence, and in pharmacovigilance.

Collaboration with Health Organisations will not remain limited to the Agency's interaction with NCAs. Cooperation with other EU Institutions in the field of public health needs to be established, such as the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC).

The impact of the EMEA's scientific opinions will become increasingly important, both from a public/animal health perspective and an economic viewpoint. Moreover, the influence of the Agency in both the EU and the international regulatory environment will continue to increase due to a further strengthening of its role and responsibilities, hence leading to a higher visibility towards the outside world. In addition, its role and responsibilities will also change, and the scientific component of the EMEA's activities will become more important.

Another example of increased responsibilities for the Agency is the implementation of Community legislation on herbal medicines and the establishment of a new Scientific Committee, the Committee on Herbal Medicinal Products (HMPC).

The European paediatric initiative will also have important consequences for the EMEA. New Community legislation would aim to increase the development of medicines for children (both new and existing medicines) and improve the availability of information on the use of medicines in children. A new Scientific Committee, the Paediatric Board, will be established at the Agency and the EMEA will be requested to coordinate an European paediatric network for performing paediatric studies.

The EMEA's international role will also be further developed. Building on existing initiatives, such as interaction with non-EU Regulatory Authorities, the important contribution to the global harmonisation process of (V)-ICH and the collaboration with the World Health Organisation (WHO), the latter currently mainly in the field of pharmacovigilance, the Agency will provide increased support to non-EU countries, in close cooperation with WHO.

3.2 Challenges Ahead

The main challenge for the EMEA over the next few years will be its ability to meet the increasing expectations of its stakeholders. The Agency will particularly focus on the needs and expectations of patients and users of medicines. The EMEA will have to find the right balance in terms of expectations such as applying high scientific knowledge for the timely delivery of science based opinions, increased involvement in the protection and promotion of public and animal health, regulatory and scientific

consistency, predictability, greater transparency, better information and enhanced communication.

In addition, the EMEA will have to address issues stemming from the Lisbon strategy for economic, social and environmental renewal, since the Agency's role in enabling the pharmaceutical industry to achieve the objective of industrial competitiveness is crucial. The EMEA has an essential role in bringing safe and effective innovative medicines as quickly as possible to patients and users of medicines. Apart from economic competitiveness, the EMEA also contributes to the EU citizens' quality of life.

In responding to the above challenges the Agency will have to adequately address:

(1) additional tasks allocated to the EMEA in accordance with new Community legislation,

(2) new developments such as the perception of the safety of medicines and the environmental impact of the use of medicines,

(3) the assessment of new types of products (such as gene therapy, pharmacogenomics, proteomics, xenotransplants), and

(4) bi/multilateral scientific cooperations.

In addition, specific segments of the pharmaceutical market deserve special attention, such as Small and Medium-sized Enterprises (SMEs).

The EU Regulatory System concept requires the EMEA to find adequate answers to the above challenges in close cooperation with its Member State partners. Therefore, the continuation and adaptation of the Agency's networking model will also require that MSs are able to adequately respond to the changing environment, which will result from the political, institutional, legislative and scientific developments. In order for the EU Regulatory System to position itself successfully in the international environment as one of the world's foremost regulatory systems, NCAs should carefully examine how they can best contribute to the future system since this will be key for the overall success. It should be emphasised that the network between the EMEA and NCAs can only be optimised if there is a stronger cohesion between all parties concerned, looking at complementing the achievements already obtained by introducing further actions aiming at reinforcing the networking model. In order to achieve such aims a common understanding on the architecture of the future EU Regulatory System is paramount. Once such common understanding has been obtained, in a next step important issues such as roles and responsibilities (in different fields such as regulatory, scientific, organisational and technical) of all involved parties need to be addressed in order to reach complete transparency on the accountability for the different activities to be undertaken in the context of the EU Regulatory System.

Chapter 4
The Future Development of the European Medicines Agency

4.1 The European Medicines Agency Vision

The EMEA will strive to maintain and further develop its position as one of the leading regulatory authorities, which is science-driven, and transparent in the way it operates, whilst applying good administrative practices.

Its aim, within the context of a continuing globalisation, is to

(1) allow rapid access to safe and effective human and veterinary medicines[1, 2], whilst providing for adequately informed patients and users of medicines,

(2) encourage and facilitate innovation and research in an enlarged EU, and

(3) adequately tackle emerging public health challenges and prepare for developments in the pharmaceutical field.

The Agency should be supported by high quality scientific resources made available by the NCAs and a high standard IT infrastructure which provides an adequate and secure network in order to meet such a target.

A further strengthening of the current networking model and a reinforcement of the firm partnership which has already been established between all EU Regulatory Authorities, hence leading to a network of excellence at EU level, will be vital in order to implement this vision.

In summary, the EMEA will strengthen its base over the next few years, by better integrating the 25 MSs within the networking model, by modernising its functioning and by reducing administrative impediments. This will be accompanied by reliable budgetary and activities planning. Maximising the overall quality and efficiency of operation will be a key objective for the Agency, since this will be a prerequisite for the establishment of a regulatory public body which provides for a modern, high standard civil service.

Consequently, taking into account the EMEA's extended scope of activities as per new Community legislation, the Agency's initial Mission Statement is revised as follows:

"The EMEA's Mission Statement is, in the context of a continuing globalisation, to protect and promote public and animal health by

(1) developing efficient and transparent procedures to allow rapid access by users to safe and effective innovative medicines and to generic and non-prescription medicines through a single European marketing authorisation,

(2) controlling the safety of medicines for humans and animals, in particular through a pharmacovigilance network and the establishment of safe limits for residues in food producing animals,

(3) facilitating innovation and stimulating research, hence contributing to the competitiveness of EU based pharmaceutical industry, and

(4) mobilising and coordinating scientific resources from throughout the EU to provide high quality evaluation of medicinal products, to advise on research and development programmes, to perform inspections for ensuring fundamental

[1] This applies to both innovative medicines and generic and non-prescription medicines.

[2] This also relates to the provision of scientific opinions on medicinal products for non-EU countries in the framework of the EMEA/WHO cooperation.

GXP[3] provisions are consistently achieved, and to provide useful and clear information to users and health care professionals."

4.2 Objectives to be Achieved

In order to enable the EMEA, as a networking Agency model, to reach such aspirations before the end of the decade, a number of objectives should be achieved:

Top Quality Scientific Assessment

With more complex global development programmes and increasing R&D costs for a new active substance, predictability of outcome is becoming key in development programmes. New Community legislation, especially a reinforced scientific advice process as well as the introduction of Scientific Advisory Groups will contribute to the resolution of the pharmaceutical industry's concerns in this field, but should be complemented by other initiatives which do not warrant legislative changes, and underpinned by a robust Quality Assurance System, managed by the EMEA. A strengthening of the peer review system to which the Agency should actively contribute in terms of regulatory and scientific memory, hence reinforcing the consistency of the outcome of the scientific assessment, should be key in such a Quality Assurance System.

In addition, globalisation of development programmes will drive the need for an enhanced collaboration with other non-EU Regulatory Authorities, in particular the FDA/USDA, ideally leading to parallel reviews in the key areas of the scientific assessment process, resulting in global development programmes, especially for new important medicines and new technologies. As the impact of the EMEA review will become more influential due to the consequences of enlargement and legislative changes, the public scrutiny of the review process is expected to increase. Benchmarking with other non-EU Regulatory Authorities, whilst acknowledging the different regulatory environments such authorities are operating in, will become more critical as to differential outcomes, hence leading to the need for a robust EU assessment standard.

One of the strengths of the EU system is the ability to source expertise from whatever location in the EU. One needs, however, to emphasise that the system will be confronted with particular challenges, such as in the field of new therapies, due to the scarcity of experts in these areas and their possible involvement in the pharmaceutical industry. Transparent and robust conflict of interest mechanisms, to be operated in a smooth and practical way, will need to be available to reassure the public. Whereas in some fields one might face a scarcity of scientific expertise, in other areas one might be confronted with an overcapacity of such expertise, due to a shift in workload. The introduction of the new Regulatory Authorities as a result of the recent EU enlargement could have a further impact on this situation. In order not to endanger the quality of the EU system, adequate measures need to be taken to ensure that the existing pool of scientific experts is maintained at the highest level of expertise.

Timely Access to Safe and Effective Innovative Medicines

The current centralised procedure has shown to be very stable with respect to timing and has demonstrated to be capable of delivering fast reviews. New Community legislation will, despite the absence of a real rolling review concept, provide several new legislative tools, which will allow a more rapid access to safe and effective innovative medicines. In addition, the Agency, building on its culture of continuous improvement of its processes, will strive for a further gain in efficiency of the operation

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

of the centralised procedure without compromising the quality of the assessment process, hence complementing the legislative initiatives.

The need for rapid access for patients and users of medicines to innovative medicines also requires to explore which factors are responsible for the worldwide decrease in innovative productivity despite higher investments made. Particular attention will be put on identifying the bottlenecks in the drug development process and what remedial actions can be undertaken. Such a global problem will require a coordinated approach amongst all concerned parties.

Timely access to innovative medicines is also a key target for the provision of scientific opinions on medicinal products for non-EU countries in the context of the EMEA's collaboration with WHO, hence enabling the development of a rapid and global standard of assessment for these countries.

Continuous Monitoring of Medicinal Products

This is probably the most challenging area with the greatest potential of vulnerability for the Agency. A proactive approach to pharmacovigilance and the further development of risk management strategies will enhance the continuous monitoring of medicinal products on the EU market. In order to achieve this, a further reinforcement of the close collaboration with MSs is of paramount importance. These issues will be addressed in the context of the ongoing discussions on the European Risk Management Strategy (for human medicines) and the European Surveillance Strategy (for veterinary medicines). Such discussions will allow for interaction with Interested Parties.

Although new legislative tools will be made available in order to strengthen the conduct of pharmacovigilance, regulators will have to make sure that the overall system is equipped to deal in an efficient and timely way with crisis situations in terms of robust scientific assessment, sound regulatory action, adequate transparency, appropriate communication and monitoring of the impact of the regulatory action taken. In this respect, it needs to be recognised that the area of monitoring of the impact of regulatory action taken by Regulatory Authorities, especially the effects on public health, is currently a rather untouched field. Furthermore, links with other relevant institutions/organisations such as the ECDC will be established.

New therapies will constitute once again a particular challenge with respect to the adequacy of the legal tools, since their exposure within a population of ~ 456 million remains an unknown factor. A strengthening of the collaboration with other non-EU Regulatory Authorities will be particularly important in this innovative field.

Another important aspect of the monitoring of human and veterinary medicines relates to the activities undertaken by the national Official Medicines Control Laboratories (OMCLs). The continuous monitoring provided by the contribution of the OMCLs in post-authorisation testing should be strengthened through the reinforcement of the collaboration with the OMCL network under the aegis of the European Directorate for the Quality of Medicines (EDQM) / Council of Europe.

Access to Information

Several initiatives, either through legislative changes or as a follow-up to the G10 Recommendations[4] and the Resolution of the Council of Health Ministers[5] will be taken to improve access to information. The EMEA, within the framework of its mandate, will work closely together with the European Commission's responsible services and provide the necessary support to the European Commission to adequately follow-up on the agreed initiatives aiming at enhancing access to information.

[4] G10 Recommendations of the High Level Group on Innovation and the Provision of Medicines.
[5] Resolution of the Council of Health Ministers of 1 and 2 December 2003.

The EMEA will take advantage of this situation by increasing its profile with the outside world as an "approachable" informative and transparent organisation, hence making the general public better aware of the Agency's added value towards public and animal health. Information needs to be presented in a more accessible way, i.e. disease category driven, in order to provide the public with comprehensive information on products available in a given area. Systematic feedback from health care professionals, patients and users of medicines, academia and learned societies will be obtained in order to continuously improve the information released by the EMEA and to provide adequate and targeted information to the Agency's stakeholders. This will include the concept of user testing in order to allow for information that is easy to read and be understood by patients and users of medicines. Adequate electronic systems will have to be available in order to allow the EMEA to build up a unique resource of data regarding pharmaceuticals. EuroPharm and EudraVigilance will be key channels in order to provide the general public with high-quality information on medicines.

These initiatives, alongside with the implementation of the new EMEA transparency policy measures[6] and other transparency tools stemming from the new legal provisions, will result in the development of an EMEA Transparency and Communication Strategy. The EMEA Transparency and Communication Strategy will be a major component of an EU wide Transparency and Communication Strategy, to be developed in cooperation with the NCAs.

Such Transparency and Communication Strategy will clearly define the roles and responsibilities of all concerned parties, not only at the level of the Regulatory Authorities, but also at the level of the Agency's stakeholders.

There is also a need in this respect to address the role of the pharmaceutical industry in the provision of information. Consequently, Interested Parties will be consulted on the elaboration of both Transparency and Communication Strategies.

Specific Needs for Veterinary Medicines

The EMEA is jointly responsible for human and veterinary medicines, and many of the challenges facing the Agency in the EU Regulatory System in the next few years are common to both sectors and are, therefore, addressed in the body of this document. However, there are specific issues which relate to veterinary medicines and need adequate consideration. One needs to bear in mind that veterinary medicines are not only essential for protecting animal health and welfare, but where food derived from animals is an essential part of the human diet there may also be a significant impact on public health that needs to be considered, particularly through the establishment of MRLs.

There are then a number of important issues which will need specific consideration in the veterinary sector by the EMEA which include concerns about the lack of availability of veterinary medicines, especially for minor species and minor indications, unease in relation to 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.

4.3 Prerequisites to be Fulfilled

In order to allow the EMEA to successfully achieve the above objectives, the following prerequisites should be fulfilled:

[6] New EMEA Transparency Policy Measures (EMEA/MB/52/03/Adopted) – 2 October 2003.

Provision of High-quality Scientific Resources by the National Competent Authorities

The continuation and even strengthening of the provision of high-quality scientific resources by NCAs to the EMEA activities is key for the success of the EU Regulatory System. The pitfalls in relation to this prerequisite, e.g. in terms of availability of a critical mass of highly specialised experts, have already been addressed above. Important choices will have to be made also at national level on how to best contribute to the overall regulatory system.

In order to develop a network of excellence at EU level, the EMEA, in close collaboration with NCAs, will initiate actions to reach such a target. Taking into account the architecture of the EU Regulatory System, consisting of an EU and a national component, any initiatives to be taken to reinforce the network will need to address both components. The ultimate objective should be to further strengthen the overall quality of the system and, therefore, initiatives should first target quality improvements. This will be of benefit to all EU Regulatory Authorities. Gradually, over the next years, the system could then further develop in a network of centres of assessment/specialised centres in order to better address all challenges the EU Regulatory System will have to face.

Availability of an Adequate Quality Assurance System

The overall quality and efficiency of operation will be key for the Agency to position itself successfully in the regulatory environment and to meet its stakeholders' expectations. This necessitates an even stronger Integrated Quality Management System at the EMEA (e.g. strengthening of the audit system, introduction of more sophisticated performance indicators, further implementation of the risk management concept) in order to achieve an adequate level of quality and scientific and regulatory consistency in the outcome of the scientific evaluation processes.

The requirements for good governance, good regulatory practices and integrated quality management will extend from the EMEA Secretariat towards its Scientific Committees, their Working Parties, and also to the NCAs who act in the network as scientific resource providers. The previous benchmarking with Accession Countries will be extended to all MSs, hence leading to the creation of an EU Benchmarking System. This EU Benchmarking System should lead to a regular cycle of benchmarking in order to achieve a strengthening of the Quality Assurance Systems in place at the level of all EU Regulatory Authorities, hence developing a coordinated approach to continuous quality improvement.

The final result should be a governance system at EU level that ensures that all aspects in relation to the scientific evaluation process (both from a procedure and contents perspective) are correctly applied.

Availability of an Adequate Product Development Toolkit

Independent research has revealed that one of the contributing factors to the fall in innovative productivity lies in bottlenecks during the development of innovative medicines. Therefore, initiatives should focus on addressing the encountered difficulties in the development stage by exploring innovative approaches in drug development. This should facilitate the process between basic research and the development of a commercial product. In identifying solutions to the critical questions raised, the best expertise available at EU level will be brought together to establish an adequate product development toolkit, especially in the field of emerging therapies, without compromising the safety and efficacy norms of medicinal products.

Availability of a High-quality IT Infrastructure

Taking into account the Agency's new role as the coordinator and hub in the harmonised collection, validation, evaluation and dissemination of authorative information on medicinal products, the EMEA will host, operate and support a family of European information systems to make regulatory procedures more efficient and more transparent. In order to achieve such objective the Agency should gradually replace the fragmented administrative and operational information systems by an integrated form of information repositories and electronic workflow tools. This should enable the introduction of near-real time electronic business reporting.

Since the quality of the overall IT infrastructure, underpinning the EU Regulatory System, will be vital for the success of such system, there is a need in further developing the EU wide IT strategy, in close collaboration with the MSs. The initiatives undertaken in July 2003 by the European Commission, NCAs and the EMEA, leading to the creation of the document "Telematics in the Pharmaceutical Sector-Strategy Paper", consist of measures in order to arrive at a high-quality IT infrastructure at EU level. Such measures will include adequate descriptions of any new databases, appropriate involvement of all relevant stakeholders in the design of the system and inclusion of a benefit/cost evaluation for each design.

Taking into account the aspect of globalisation, there is also a need to align IT architectural and procedural concepts with those of other regions, where practical and possible, taking into account regional specificities.

Availability of a High-quality European Medicines Agency Professional Workforce

The changing role of the Agency necessitating an increased scientific input has already been addressed above. Such a changing role should be underpinned by a higher scientific profile of its Staff Members. It will be critical to identify the areas of scientific competence where the EMEA needs to strengthen its resources. Subsequently, a full training and competence development programme will be put together and implemented.

In view of its new and extended tasks, the organisational structure of the EMEA will also be looked at and changes introduced, where relevant. Taking into account the Agency's increasing competence which go far beyond its role in the primary evaluation, a reappraisal of the establishment plan is necessary in order to allow the EMEA to meet its stakeholders' expectations.

Finally, the Agency's changing role will also have important consequences in terms of logistical and administrative support. The EMEA will critically examine and, where appropriate, re-engineer existing business processes to maximise efficiency and suitability for the new environment.

Adequate Workload and Resource Planning

It needs to be emphasised that the Agency's increasing role in the regulation of human and veterinary medicines will necessitate adequate multi-annual project planning with careful workload, resource and financial consideration. This will require project prioritisation whereby the main focus will be the need for the EMEA to make safe and effective medicines available in the shortest possible timeframe to patients and users of medicines.

However, such adequate planning process should not be restricted to the EMEA. Taking into account the Agency's networking model, characterised by the NCAs acting as scientific resources providers, a coordinated planning of resources at EU level will be paramount.

In relation to the financing of the Agency, particular emphasis will be put on the funding of collateral activities in the areas of orphan drugs (and similarly in the veterinary sector), consumer information, safety monitoring, etc.

Chapter 5
Conclusion

Part I, “The European Medicines Agency Strategy”, elaborates on the EMEA’s viewpoint on planning up to 2010. It also provides high-level information on how this should be achieved. Initiatives to be undertaken consist of the implementation of new legal provisions, to be complemented by other activities that do not require legislative amendments. A joint partnership with NCAs and an adequate interaction with all relevant Interested Parties is paramount to meet this challenge. It would seem appropriate for other parties to complement the EMEA’s contribution to the future EU Regulatory System by elaborating on own initiatives that will be undertaken in order to reinforce the global networking model.

Part II, “The European Medicines Agency Road Map Implementation Plan”, will provide information on how the Agency’s vision will be implemented, including detailed actions and estimated timeframes for completion of these actions.