Attachments

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

Part II

The European Medicines Agency Road Map Implementation Plan

Attachment 1

Area of Scientific Advice

Key Principles

Scientific advice to be provided by the Scientific Committees of the Agency facilitates access of medicinal products to patients and users of medicines in optimising R&D, reducing uncertainties in regulatory outcomes and accelerating time for approval.

The EMEA will establish the best possible environment for the provision of scientific advice on human and veterinary medicinal products by its Scientific Committees, in particular for new therapies. In order to achieve this objective, the EMEA will revise the current procedural framework to strengthen the provision of scientific advice.

The revised procedure should allow for open discussions and proactive identification of difficulties, hence facilitating the availability of proposals to sponsors.

All future users of the centralised procedure will be encouraged to engage, as early as possible, in an ongoing dialogue with the Agency on the development of their product. This will include regulatory advice allowing the EMEA to develop a secure landing zone for all sponsors.

In addition, specific efforts will be made to support SMEs and to develop protocol assistance for orphan medicinal products. Further developments of similar initiatives in the veterinary sector will be pursued, dependent in part on the outcome of the pilot project allowing free advise for medicines intended for minor uses/minor species.

Scientific advice procedures will include possibilities for face-to-face meetings between sponsors and regulators at the different stages of the development of medicinal products, as well as the involvement of specific and complementary expertise on an individual basis, through panels of experts or involvement of other fora (e.g. the Vaccine Experts Working Parrty in order to address specific issues related to vaccines). In addition, consultation of patients representatives will be developed particularly for rare diseases. Opportunities for parallel advice with the FDA will be proposed for breakthrough medicines on a voluntary basis, in particular for “global” development programmes. Guidance to sponsors on how to apply for such parallel scientific advice has been made available jointly by the EMEA and the FDA. The level of involvement of sponsors in the EMEA-FDA discussions has been addressed in such guidance.

The processes for scientific advice will develop towards differential procedures depending on the scope of the requests, the type of products and their stage of development. Early interactions with sponsors and pre-filing advice should complete the possibilities offered to sponsors for advice during development and should provide a necessary continuity from the R&D phase to the licensing phase. The scope of the scientific advice procedure will also be reinforced to better address post-authorisation, pharmacovigilance and risk management/risk minimisation aspects. Involvement of specific pharmacovigilance expertise to adequately handle such requests for scientific advice will be foreseen. These initiatives will be phased in as necessary on the veterinary side.

It should be noted that the provision of scientific advice is not limited to innovative medicines but is also available to address specific issues related to generic medicines and OTC medicines.

Furthermore, the publication of advice provided will be reconsidered. In reviewing the current procedure the Agency will need to find the most adequate point in time for the public release of advice in order not to freeze or hinder the development of medicines.

Although the possibility for the pharmaceutical industry to obtain scientific advice at national level is recognised, there is a need for enhanced transparency as regards the provision of scientific advice at EU and national level. This will be facilitated by appropriate communication between the Agency and NCAs on the scientific advice given and the development of a Best Practice Guide for the pharmaceutical industry on how to obtain scientific advice. Furthermore, in order to ensure that consistency on the scientific advice provided by regulators on various medicines is obtained, the internal database, currently containing previous EMEA advice given, will be extended to incorporate previous national advice given.

Action Plan

In summary, in order to implement the EMEA's vision in the area of scientific advice, the following will be undertaken:

Action	**Timeframe for Completion**
▪ To implement new Community legislation in relation to the further improvement of the scientific advice procedure.	4th Quarter 2005.
▪ To review experience gained with the parallel scientific advice procedure established at EMEA and FDA level for human and veterinary medicines.	3rd Quarter 2005.
▪ To implement any changes to the parallel scientific advice procedure for human and veterinary medicines.	1st Quarter 2006.
▪ To extend the existing internal database on previous EMEA advice given in order to include previous national advice given.	3rd Quarter 2006.

Attachment 2

Area of Scientific Assessment

Key Principles

The European Medicines Agency has, in accordance with Community legislation, to provide science-based opinions. Scientific opinions have to be based on sound and robust scientific assessment. This should ensure that the Public and Animal Health objectives of the scientific assessment performed by the Scientific Committees are met, in particular in case of centrally processed applications and referral /arbitration procedures, or other scientific aspects for which the Committees have responsibilities.

The assessment process for human and veterinary medicines is characterised by three pillars: a scientific, a regulatory and a procedural pillar. The EMEA Secretariat will, in accordance with new Community legislation, develop a complementary function by providing scientific support to the Scientific Committees, while having full direct responsibilities for the two other pillars. Such scientific support, as already described in detail in Part II, Chapter 2.2 "The European Medicines Agency Secretariat", will mainly relate to ensuring the regulatory and scientific quality and consistency, hence contributing to an increased quality output of the EMEA Scientific Committees. Process developments will ensure that the assessment is thorough, consistent, operated in the framework of an Integrated Quality Management System, performed by required competences and expertise, whilst compliance with Good Practices (e.g. GMP, GLP[7], GCP) is ensured.

The EU system should be based on a high quality initial assessment supported by an adequate system of peer review, and in all situations high-level expertise should be involved. Members of the EMEA Scientific Committees should be encouraged to participate as much as possible in such peer review process in the different stages of the scientific review procedure. In addition, the principle of lifecycle management of medicines should be supported. For the initial assessment, sufficient time to perform the tasks adequately is necessary in order to provide the Scientific Committees with Assessment Reports of the highest quality, prepared in compliance with established guidance. The largest possible use of additional expertise should be provided all along the process. The Scientific Committees will explore if the scientific evaluation process should include, where appropriate, a more systematic scientific contribution, complementary to the Scientific Advisory Groups, from its other Working Parties. Building on the experience already obtained (e.g. the Biotechnology Working Party and the Vaccine Experts Working Party) the Committees will take as much as possible advantage of the best expertise available at EU level. Where necessary, additional specific expertise should be provided at the level of the Committees and the Scientific Advisory Groups (e.g. in the field of pharmacovigilance and risk management/risk minimisation) in charge of human medicines.

The peer review concept should ensure a quality control on the initial assessment, without duplication of the assessment already conducted. It should both relate to the content and the format, and should provide additional and complementary critical expertise to the initial assessment.

The peer review process should be carried out in a completely transparent manner. This could be best ensured by a systematic and sufficient involvement of a peer review team from the Committees, and the additional assurance that all Committee Members have expressed their views in a timely manner. Furthermore, all aspects concerning scientific consistency and compliance with guidance and regulatory aspects should be checked by the Secretariat of the Agency. This framework will offer optimisation of timelines and opportunities for scientific discussions between the assessors and the Secretariat, and will lead to a cost

[7] GLP: Good Laboratory Practices.

efficient system. The involvement of the pharmaceutical industry in such quality assurance/peer review activities will be limited to the provision of feedback in case existing rules and/or guidance has not been adhered to, hence endangering the scientific and regulatory consistency of the outcome at the level of the EMEA Scientific committees.

Finally, as has already been indicated before, a culture of continual process improvement should be developed. The Agency will contribute to this objective by continuously monitoring the scientific evaluation process and looking at further efficiency of operation.

Action Plan

In summary, in order to implement the EMEA's vision in the area of scientific assessment, the following will be undertaken:

Action	**Timeframe for Completion**
▪ To initiate a revision of the scientific assessment procedure, with particular emphasis on the initial assessment and the peer review system, alongside the implementation of new Community legislation (such revision should take due account of the follow-up to the audits of the EMEA Scientific Committees).	3rd Quarter 2006.
▪ To review the revised scientific assessment procedure and to introduce further improvements, where relevant.	1st Quarter 2008.

Attachment 3

Area of Monitoring of Medicinal Products

Key Principles

Post-authorisation activities cover a wide range of areas, aiming at ensuring a continuous monitoring of the human and veterinary medicinal products available on the market. Such activities include variations to marketing authorisations and pharmacovigilance related activities (please also refer to Part II, Attachment 6 for further post-authorisation activities). The area of pharmacovigilance, which is a very important aspect of post-authorisation activities, is one of the cornerstones of the EU networking model. New Community legislation will further reinforce the EMEA coordinating role in this networking model. In order to create a network of excellence at EU level, the Agency, in close collaboration with NCAs, will therefore explore how to further strengthen such concept of partnership. In addition, building on the initiatives already taken at EU Heads of Medicines Agencies level, efforts need to continue to further increase the quality of the output of the Regulatory System in the field of pharmacovigilance by further improving the national pharmacovigilance systems (this could include a review of the current adverse drug reaction reporting practices at national level). Clear roles and responsibilities for all parties involved in the EU pharmacovigilance network will be further defined. Such definition of roles and responsibilities needs to take into account recent developments, i.e. the electronic reporting of adverse drug reactions through the EudraVigilance system.

The EMEA vision on post-authorisation activities will be driven by a proactive conduct of pharmacovigilance, throughout the lifecycle of a medicinal product in order to further strengthen public and animal health protection in an enlarged EU. It should lead to the best knowledge of the safety profile of a medicinal product at the moment of the granting of the marketing authorisation, with the scientifically most robust programme of post-authorisation studies to be performed, where appropriate, and a continuous and adequate monitoring of the safety of medicinal products, once put on the EU market.

In order to reach such an objective, the Agency will use the new legal tools provided by Community legislation, such as

(1) the introduction of risk management/risk minimisation plans, whereby the main challenge for centrally processed medicines will be the implementation of such plans in all MSs, and

(2) the monitoring by the Agency of the implementation by Marketing Authorisation Holders of their pharmacovigilance obligations and the subsequent action in case of non-compliance.

In addition to the area of pharmacovigilance, the EMEA will carefully review, in close cooperation with its partners and stakeholders, whether other process improvements, complementary to the legislative changes, can be introduced, for instance in the field of variations to marketing authorisations. It has to be recognised that the post-authorisation phase is a very work intensive and resource-demanding period in the lifecycle of a medicinal product. Hence the continuous need for efficiency of operation, avoidance of unnecessary duplication of work and best use of limited resources (both at the level of Regulatory Authorities and the pharmaceutical industry), without compromising the safety of patients and users of medicines.

The EMEA Risk Management Strategy, which underpins the Agency's proactive conduct of pharmacovigilance on the human side, will be further developed. A variety of activities will be undertaken, ranging from an extension of the scope of the scientific advice procedure to include post-authorisation, pharmacovigilance and risk management/risk minimisation aspects, to more adequate post-authorisation safety studies. Furthermore, particular

emphasis will be put on ensuring that the EudraVigilance system, which is one of the key pillars of such Risk Management Strategy, is fully operational with appropriate methodologies for the effective early detection of safety signals in order to allow successful contribution to the best evidence approach.

In relation to the most adequate conduct of post-authorisation safety studies, the possibility of performing independent studies should be facilitated in the EU. Of particular importance in this respect is the funding of such studies which is increasingly becoming an issue and consequently requires careful consideration. Although the most ideal situation would be the establishment of a network of academic centres of excellence capable of conducting independent studies targeted on safety, one needs to consider the financial limitations of putting in place such a system. In order to achieve the objective of avoiding direct links between a pharmaceutical company and the study to be performed, other ways of funding of post-authorisation safety studies, simulating a general funding, should be considered. A debate with all concerned stakeholders needs to be started in order to discuss this funding problem, as well as other issues such as when to perform independent studies, what should be the aim of the studies, what should be the involvement of the pharmaceutical industry, etc.

In addition, one needs to consider the particularities of certain classes of medicines, such as vaccines (e.g. because of the need for large studies to evaluate the safety and efficacy of vaccines; the existence of different surveillance systems, policies and recommendations for vaccines at national level). This will require close collaboration between the EMEA and the ECDC to develop methods and processes appropriate for the conduct of high-quality post-authorisation studies.

The further development of the EMEA Risk Management Strategy will be an important contribution to the ongoing elaboration of the EU Risk Management Strategy, being undertaken at the level of the EU Heads of Medicines Agencies with responsibility for human medicines. Such EU Risk Management Strategy should preferably tackle additional issues such as the development of a common language of risk and the harmonisation of risk assessment methodologies. Taking into account the consequences of both the EMEA and the EU Risk Management Strategies on the pharmaceutical sector, appropriate consultation with all stakeholders of the EU Regulatory System will be indispensable.

Chapter 3.3, “Specific Needs for Veterinary Medicines” of Part II, already highlighted the need for further discussions on a more adequate organisation of the EU veterinary pharmacovigilance system. These discussions will be undertaken, particularly with the Heads of Medicines Agencies with responsibility for veterinary medicines, in the context of the European Surveillance Strategy and will focus on Good Pharmacovigilance Practice for veterinary medicines.

Finally, the EMEA Secretariat will further develop (please also refer to Part II, Chapter 2.2 “The European Medicines Agency Secretariat”) in order to complement its regulatory and procedural competences by scientific competences, mainly through the development of a pharmacovigilance function, in order to provide adequate support to the Rapporteurs, the EMEA Scientific Committees and the high-level specialised expertise providing the necessary assistance. Such increased competences of the EMEA Secretariat will be developed in an enhanced Integrated Quality Management System in order to achieve, through the support provided by the Secretariat, an adequate level of quality and scientific and regulatory consistency in the outcome of the scientific evaluation processes.

Action Plan

In summary, in order to implement the EMEA's vision in the area of monitoring of medicinal products, the following will be undertaken:

Action	Timeframe for Completion
▪ To implement the new legislative tools in the post-authorisation phase (such as the introduction of risk management/risk minimisation plans) provided by revised Community legislation.	4th Quarter 2005.
▪ To review, in close collaboration with the Agency's partners and stakeholders, whether complementary process improvements can be introduced in areas such as variations to marketing authorisations.	4th Quarter 2006.
▪ To further develop the EMEA Risk Management Strategy in the field of human medicines by taking a number of initiatives, such as[8]:	
- Introducing additional functionalities in the EudraVigilance database in order to allow for effective early detection of safety signals.	4th Quarter 2005.
- Strengthening active surveillance methods to improve pharmacovigilance data collection through	
i) an identification of academic centres to be involved in intensive monitoring of targeted medicines.	3rd Quarter 2005.
ii) the development of a network of such academic centres in order to allow subsequent practical implementation.	3rd Quarter 2006.
- Reinforcing the scientific advice procedure to better address post-authorisation aspects.	3rd Quarter 2005.
- Exploring with all concerned stakeholders the most adequate conduct of post-authorisation safety studies.	2nd Quarter 2006.
- Initiating discussions with the ECDC on the development of methods and processes appropriate for the conduct of high-quality post-authorisation studies for vaccines.	1st Quarter 2006.
▪ To identify additional issues to be addressed in the context of the EU Risk Management Strategy for human medicines (e.g. a reinforcement of the involvement of regional centres).	2nd Quarter 2005.
▪ To ensure timely implementation of initiatives agreed by the CVMP to reinforce optimal adverse event reporting for centrally authorised products and for nationally authorised products throughout the EU in collaboration with NCAs and in accordance with the European Surveillance Strategy.	3rd Quarter 2005.

[8] A detailed action plan on the various initiatives to be undertaken in the context of the EMEA Risk Management Strategy will be published during the 2nd Quarter 2005.

Attachment 4

Area of Transparency and Communication

Key Principles

The EMEA began in 1995 with a small number of legal obligations to publish information about its activities, in particular the publication of European Public Assessment Reports (EPARs). This initiative was significant in the context of the otherwise largely secretive pharmaceutical industry, particularly in Europe.

Since 1995 the Agency has continuously reviewed its Transparency Policy, leading to an increased openness, whilst having to respect some legal restraints. This resulted in the most recent measures, adopted by the EMEA's Management Board in October 2003.

The outcome of the EU Review 2001 of pharmaceutical legislation provides for even more transparency and, in addition, strengthens the Agency's role in the provision of information.

The new legal obligations should also be seen in the context of the new rules introduced in October 2003 on access to documents held by the EMEA and the implementing rules which came in force in April 2004.

All this will have at least two long-term policy consequences. Firstly, the Agency's scope and margin for self-determined manoeuvre may now be more limited. Secondly, the Agency's obligations are enforceable by citizens/companies and decisions not to release information can be more easily challenged, not just as bad administrative practice in complaints to the Ombudsman, but now also before the Courts.

In order to address the above challenges, the EMEA will actively but carefully embrace its new communication mandate, to take due account of the resource consequences stemming from such proactive approach, not just in the visible areas of communication (press office, website, etc) but also in the preparation of documents intended for distribution to the public.

This will result in a gradual and stepwise increase in the Agency's level of transparency, which will in a first phase primarily focus on an improved transparency in the field of non-product related issues, with particular emphasis on the availability of agendas and meeting summaries and the organisation of regular infodays with Interested Parties. Any such infodays will in addition be broadcasted on the Internet in order to allow for the widest possible audience. Increased transparency on non-product related issues will also mean more involvement of Interested Parties on discussions of general interest, such as endpoints in clinical trials, through the organisation of specific workshops.

In a second phase the Agency will explore how to complement, in addition to the new legal provisions, the release of information on product related issues, such as details on ongoing applications for marketing authorisation or changes to marketing authorisations. When searching for the most adequate balance between the increasing demands of patients/users of medicines and health care professionals on earlier information on possible treatments and the need to respect commercial confidentiality of proprietary information, the Agency will take due account of the approaches taken in other regions. This is of particular importance in order not to disadvantage neither the general public nor the pharmaceutical industry. All key principles and resulting initiatives will be brought together in an EMEA Transparency and Communication Strategy which will be further discussed with the Agency's partners and stakeholders before finalisation. Particular attention will be given to the development of effective communication tools for patients and health care professionals, especially in relation to new Community legislation concepts such as conditional approvals, and in case of important quality/safety/efficacy concerns affecting a medicine which require urgent dissemination. The Agency will also further widen its circle of communication partners by systematically providing relevant information to academia and learned societies.

Since it will be crucial for the whole EU Regulatory System to have a similar approach towards transparency and communication, discussions will be initiated at EU level with all Regulatory Authorities. This should result in the development of an EU Transparency and Communication Strategy. The availability of such EU wide strategy will be of particular importance in the field of communication on post-authorisation safety data which warrants a common approach at the level of all EU Regulatory Authorities.

Action Plan

In summary, in order to implement the EMEA's vision in the area of transparency and communication, the following will be undertaken:

Action	**Timeframe for Completion**
▪ To implement all EMEA Transparency Policy Measures adopted by the EMEA Management Board in October 2003.	4th Quarter 2005.
▪ To improve the EMEA transparency in the field of non-product related issues by:	
- At Management Board level, publishing agendas and minutes of Board meetings and making available relevant supporting documentation.	1st Quarter 2006.
- At the level of the Scientific Committees, organising regular infodays with Interested Parties, broadcasting such infodays on the Internet and following-up on the infodays by publishing meeting summaries.[9]	3rd Quarter 2006.
- At the level of the Scientific Committees, publishing meeting summaries on non-product related issues.	1st Quarter 2007.
- At the level of the Scientific Committees' Working Parties, organising open workshops (with involvement of academia and learned societies, as well as representatives from the pharmaceutical industry) to discuss general scientific issues (such as endpoints in clinical trials).	1st Quarter 2006.
- At the level of the Scientific Committees' Working Parties, publishing meeting summaries on non-product related issues.	3rd Quarter 2007.
▪ To improve the EMEA transparency in the field of product related issues by:	
- Exploring, through a debate with the Agency's partners and stakeholders, the most adequate balance between the increasing demands of patient/users of medicines and health care professionals on earlier information and the need to respect commercial confidentiality of proprietary information (taking due account of the situation in other regions).	3rd Quarter 2005.

[9] It should be noted that at the level of the CVMP and the COMP such infodays are already being organised.

Action	Timeframe for Completion
- Providing recommendations to the EMEA Management Board on how to complement, in addition to the new legal provisions, the release of information on product related issues.	3rd Quarter 2006.
▪ To initiate discussions with the EMEA's partners and stakeholders on the issues of transparency, communication and provision of information in order to arrive at a common approach at EU level.	4th Quarter 2005.
▪ To subsequently develop an EU Transparency and Communication Strategy.	3rd Quarter 2006.

Attachment 5

Area of Provision of Information on Human Medicines to Patients

Key Principles

It needs to be emphasised that patients' approach towards the provision of information has changed significantly over the past years. The patient, having been a passive recipient of healthcare and advice, has turned into a more empowered and proactive consumer of health care. Patients are now actively looking for information on diseases and medicines since they want to be more involved in their own health care decisions. Providers of information should take due account of this trend.

An important challenge will be to provide adequate (targeted to patients), correct (preferably validated), properly balanced (benefits vis-à-vis the risks associated with the use of a medicine), timely and easily accessible information on medicines to patients. The EMEA vision on the provision of such information should be driven by taking the appropriate measures, resulting in more adequate and accessible information to patients, in order to promote a better use of medicines. This will require a more appropriate involvement of patients and/or patients groups in the regulatory framework of medicines licensing to optimise the way information is given to patients. In addition, a close interaction with MSs in order to arrive at a common approach at EU level is paramount. However, optimisation and further strengthening of the current networking model will be necessary, especially as regards the development of an EU Transparency and Communication Strategy, as outlined in Attachment 4.

In order to reach the above objective, the Agency will launch several initiatives in order to address

(1) the outcome of the EU Review 2001 of pharmaceutical legislation,

(2) the G10 Recommendations stemming from the High Level Group on Innovation and the Provision of Medicines, and

(3) the Resolution of the Council of Health Ministers of 1 and 2 December 2003.

The Agency has already started to prepare for the implementation of these initiatives. It has created an EMEA/CHMP Working Group with Patients Organisations. Such Working Group has extensively debated further improvements to be achieved in the areas of transparency, dissemination of information, product information and pharmacovigilance, in order to

(1) provide information adapted to patients' needs,

(2) develop appropriate communication tools, and

(3) increase the awareness of the public in relation to the use of medicines.

Such debate resulted in the development of specific recommendations, which have been subject to a consultation exercise with the Agency's partners and stakeholders.

The recommendations from the Working Group will be the first element of the Agency's reply to the G10 Recommendations and the Resolution of the Council of Health Ministers, and will be an important contribution to the initiatives undertaken by the European Commission on enhanced information, especially since several of these recommendations require a harmonised approach at EU level.

In addition, the EMEA will support other elements of the European Commission's action plan on enhanced information, in particular the establishment of a public-private partnership in order to address the quality of existing information to patients and the accessibility of high quality information through the Internet.

Action Plan

In summary, in order to implement the EMEA's vision in the area of provision of information on human medicines to patients, the following will be undertaken:

Action	Timeframe for Completion
▪ To finalise the recommendations stemming from the EMEA/CHMP Working Group with Patients Organisations.	1st Quarter 2005.
▪ To implement the recommendations only affecting the EMEA, including the new legal provisions originating from revised Community legislation.	2nd Quarter 2006.
▪ To initiate discussions with the European Commission and NCAs on the other recommendations requiring an EU-wide approach, in order to provide the necessary support to the public-private partnership project under the auspices of the European Commission.	To Be Determined.

Attachment 6

Area of GXP

Key Principles

An adequate quality system for ensuring fundamental GXP provisions are consistently achieved is a cornerstone of any robust regulatory system. In the current changing environment which combines enlargement of the EU, the implementation of the EU Directive on clinical trials, the introduction of new technologies and new approaches to the use of technology in the manufacturing and control areas, the EU Regulatory System faces particular challenges in the years ahead.

An efficient operation of the EMEA networking model within the context of an adequate Quality Assurance System will be required in order to successfully tackle these challenges. In particular, an effective coordination by the EMEA of GXP inspections performed by the NCAs is of utmost importance, especially as regards inspections carried-out in non-EU countries. Coordination should cover inspections in the framework of centralised licensed medicines with a strong link to decentralised licensed medicines in order to avoid duplication of work. This role of the EMEA can only be effective when resources for inspections at the level of the MSs are sufficiently available. A strong scientific input into coordination will improve quality, as well as efficiency and effectiveness from inspections, specifically by improving cooperation between scientific assessors and inspectors. This will be further supported through training activities, e.g. professional seminars.

The Agency will also be proactive in ensuring that industry can take advantage of new pharmaceutical technologies and approaches in the manufacturing and analytical areas, as well as anticipating the implications of emerging therapies, such as gene and cell therapy. Part of this work will build on existing activities organised by the EMEA to facilitate knowledge and understanding between assessors and GXP inspectors, with a view towards avoiding duplication of effort and promoting a synergistic approach that makes the best use of both Community and international resources.

On the GMP side the work of the Joint Audit Programme for EU GMP inspectorates assures an appropriate Quality Assurance System. This should be supported by appropriate training. It will ensure that excellence can be guaranteed across an enlarged EU. Furthermore, the new roles and responsibilities for the Agency in the GMP coordination of finished products, active substances and certain excipients will have a significant impact on the overall transparency of the EU as regards manufacturing information. The introduction of an EU wide database on manufacturing authorisations, inspection information and GMP certificates creates an opportunity to provide better information to regulators, while promoting the best use of Community resources and avoiding duplication. Any new GMP requirements for excipients will be carefully considered with all stakeholders.

Coordination of efforts and resources will be the cornerstone of an optimally functioning EU system for supervision of manufacturers. This is of particular importance in the case of the Plasma Master File (PMF) and Vaccine Antigen Master File (VAMF) certification schemes. The EMEA will further support the above initiatives through contributions to international discussions on risk management from a quality perspective and through its cooperation with WHO in relation to regulatory information provided to non-EU countries.

The entry into force of the EU Directive on clinical trials at the same time as the enlargement created both challenges and opportunities. The Agency will help to meet the challenge of implementation through the work of the GCP inspection services group on the harmonisation of practices, procedures, development of common approaches and joint training initiatives. The Agency's support to the clinical trial related databases will contribute to increased communication and availability of information for regulators and appropriate access to information for patients, e.g. in the field of adverse event reporting in the context of clinical trials. As in the GMP and quality assessment area, efforts to create better understanding

between clinical assessors and GCP inspectors will promote synergies and robustness in the assessment and monitoring areas. Furthermore, special attention will be paid to the inspection of clinical trials in new fields and to bioavailability studies, in particular the Clinical Research Organisations which conduct Phase I studies.

In the post-authorisation area, enhancing the supervision of the quality and safety of medicinal products on the EU market will be achieved by strengthening the monitoring of product quality and safety through post-authorisation testing performed by OMCLs under the aegis of the EDQM, monitoring of product defects and pharmacovigilance inspections.

In relation to the important issue of counterfeits, the contribution of OMCLs in identifying counterfeits should be developed.

Action Plan

In summary, in order to implement the EMEA's vision in the area of GXP, the following will be undertaken:

Action	**Timeframe for Completion**
▪ To implement new Community legislation, e.g. in the GMP coordination of finished products, active substances and certain excipients.	4th Quarter 2005.
▪ To establish an EU wide database on manufacturing authorisations, inspection information and GMP certificates by developing a first production version.	4th Quarter 2006.
▪ To facilitate the implementation of clinical trials legislation by providing support to NCAs, e.g. in the fields of harmonisation of procedures and practices, and competence development.	4th Quarter 2007.
▪ To strengthen the coordination of inspections in the context of the PMF and VAMF certification schemes.	4th Quarter 2006.
▪ To optimise the European Joint Audit Programme.	1st Quarter 2006.
▪ To facilitate the introduction of new manufacturing and control approaches through the EMEA PAT team and cooperation at ICH level.	4th Quarter 2007.