



A Strategy for the Heads of Medicines Agencies, 2011-15

adopted at the HMA meeting on 25 October 2010

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A Strategy for the Heads of Medicines Agencies, 2011-15

1. Executive Summary

- 1.1 In July 2009, the European Heads of Medicines Agencies (HMA) endorsed a proposal to draft a five-year strategy for the European Medicines Regulatory Network (known as the Network). The Strategy, which will run from 2011-2015, will build upon the work of the first HMA Strategy, which was published in 2007. Details of the first HMA Strategy and its implementation can be found at: www.hma.eu
- 1.2 The aim of the new strategy is to identify key challenges which face the network over the next five years and how the network can best respond to these challenges for the benefit of the European population.
- 1.3 While the strategy covers the diverse activities of the Network, a number of key themes have emerged where the HMA believe they can make a real difference over the next five years. They are:
 - **Safeguarding public and animal health**, particularly through:
 - strengthening surveillance of the *benefits and risks of medicines* in the European population including by improving spontaneous reporting systems to enable early detection of risks.
 - good *communication*, including work on the HMA website
 - strengthened monitoring of the *quality* of medicines including risk-based redeployment of inspections
 - **Supporting innovation**, particularly through:
 - efficient and proportionate regulation of new medicines and clinical trials e.g. by using Voluntary Harmonisation Procedure (VHP); and
 - the provision of excellent scientific and regulatory advice.
 - **Further improving the operational efficiency of medicines authorisation by the Decentralised and Mutual Recognition Procedures (DCP/MRP)**, particularly through:
 - Identifying with stakeholders areas to address and more targeted communication
 - risk-based proportionate regulation
 - harmonisation of assessment
 - work-sharing
 - training – harmonised training that helps achieve high-quality performance
 - best use of IT – ensuring interoperability of national IT systems within the European network, creating a competitive, boundary-free regulatory environment
 - dialogue with industry on operational matters, including through streamlining validation procedures
- 1.4 This work is timely in relation to the European Medicines Agency's (EMA) developing Roadmap to 2015 and the recently published Ernst & Young report, for the European Commission, of the EMA and the system for marketing authorisation of medicines in the EU. The HMA's Strategy is intended to complement and not duplicate that work. The EMA is a key part of the Network and all 44 National Competent Authorities (NCAs) work closely with it. Yet in addition to their role in supporting centralised EU processes, NCAs also have major responsibilities for national and decentralised activities which draw on (and compete for) the same scientific and technical resources. Through their close links with national structures for

human and animal health and with their own populations, NCAs have a special contribution to make to communication with these sectors.

2. The 2011-2015 Strategy in its wider context

A Changing Environment

2.1 Since the first HMA Strategy was published in 2007, there have been significant political, economic, social and legislative developments, such as the global economic downturn and the recent H1N1 pandemic. These together with ongoing rapid technological change, scientific innovation and other factors which impact on human and animal health illustrate the need for an updated HMA Strategy. Indeed, the extent of change over these years has been so large that the HMA began its work with a detailed environmental review. Its key findings are set out in Chapter 3.

The National Competent Authorities

2.2 The HMA group represents a diverse network of 44 National Competent Authorities (NCAs) from the 27 EU Member States and three Member States of the European Economic Area-European Free Trade Association (EEA-EFTA), namely: Iceland, Liechtenstein and Norway. A fuller description of the HMA network is set out at Annex 6.

2.3 Of the 44 NCAs, 13 have responsibility only for human medicines; 13 are purely veterinary agencies; 18 have responsibility for human and veterinary medicines (joint agencies); and some veterinary agencies are integrated with their respective national food safety agencies. Some have responsibility for pricing and reimbursement of human medicines (22 are joint medicines / medical devices agencies), while others are also responsible for anti-counterfeiting work, the regulation of medical devices, blood products, cosmetics, biocides, novel foods, and herbal medicines. All are accountable to their national governments.

2.4 Across Europe, the funding arrangements for NCAs vary. Some are financed mainly through licence fees, some are funded by their national governments; others have mixed funding arrangements. Some NCAs are small in size, employing 50 staff or less, while some are significantly larger with over 1000 staff. In total, they employ over 10,000 staff. These collectively support centralised, multi-national and national responsibilities.

2.5 So, the picture that emerges is one of diversity in the size, historical origins, role, resources and funding regimes of the Network's members. In many ways the HMA group reflects the heterogeneity and complexity of modern Europe.

The complementary roles of EMA and NCAs

2.6 The effective functioning of the Network depends on the co-ordinated activity of EMA and NCAs to implement an EU-wide system of medicines regulation. This in turn rests on mutual trust and a shared commitment to the Network principle. Whilst having its base in EU law, the regulatory framework must meet the needs of national populations which differ in many ways – for example in patterns of health care and animal husbandry; professional organisation and regulation; public expectations and mass communication; and in industry presence and research base.

2.7 Within the legal framework, certain medicines are authorised centrally under the co-ordination of the EMA and drawing on the scientific and technical resources of the NCAs. The centrally co-ordinated tasks include assessment led by rapporteur and co-rapporteur, inspection and pharmacovigilance through the life cycle. Other medicines gain multi-state authorisation by either a decentralised (DCP) or a mutual recognition procedure (MRP). The NCAs have prime responsibility for the efficient operation of MRP and DCP, for national marketing authorisations and also for clinical trial authorisation (CTA) for human medicinal products. Nevertheless the EMA has an important role in supporting non-centralised functions, for example by maintaining the Eudravigilance database, the EudraCT database and supporting a range of scientific committees and the coordination group for MRP and DCP.

2.8 In developing this HMA Strategy, particular attention has been given to:

- ensuring the efficient operation of those tasks for which NCAs (either individually or collectively) have the prime responsibility
- supporting effectively the NCA contribution to centralised processes.

As the Network takes on new tasks, the distribution of responsibilities between EMA and NCAs must be kept under review so that the resources of the whole network are used as efficiently and as effectively as possible. Those resources include not only the specialist skills available, but also capital invested in IT and communications infrastructures.

3. Key challenges facing the Network over the next five years

3.1 The HMA began its work in the autumn of 2009 by drafting an environmental analysis. During that process, the Task Force identified a number of key factors and challenges which the Network will most likely have to face over the next five years. The most challenging tasks which impact on NCAs and industry are listed below.

3.1.1 Legal

- The impact on NCAs and industry of new pharmaceutical legislation on pharmacovigilance, counterfeit ('falsified') medicines and information to patients.
- An assessment expected from the Commission's options for the revision of EU Clinical Trials legislation.
- An expected recast of medical devices legislation.
- Veterinary legislation, currently undergoing consultation, to be reviewed and updated by 2014.

3.1.2 Scientific: horizon scanning and pipeline work

- More advanced therapies, personalised medicines, medicine/medical device combinations (including medicine/diagnostic combinations), and new technologies e.g. nanotechnology.
- Developments in regulatory science, such as risk-benefit modelling.
- Rapid development in related technologies, such as health informatics, nanotechnology.
- Wider use in many Member States of Health Technology Assessment (HTA) to estimate effectiveness and cost-effectiveness of health care interventions.
- Changing patterns of disease, e.g. emerging antibiotic resistance and new human pathogens.

3.1.3 *Social and political*

- Demographic changes – ageing population, people working longer.
- Environmental changes – effects for human and animal medicines.
- Economic changes as a result of the global recession.
- Major health threats, e.g. pandemics and bioterrorism.
- Political changes in the EU – e.g. Lisbon treaty, changes in DG portfolios.
- Challenges and opportunities at both EU and national level for regulatory simplification and efficiency ('better regulation').
- Increasing patient expectations about healthcare and access to innovative medicines, and increased patient role in treatment decisions and in self-care.
- Increasing animal owners' expectations regarding animal health and welfare – e.g. more and better medicines for pets are awaited.
- Changing patterns of healthcare.
- Changing public expectations of regulators.
- Greater emphasis on the use of preventative medicines, such as vaccines and risk-modifying interventions.
- Increasing demand for food
- New emerging diseases
- Increasing use of the internet by consumers to purchase and obtain information about medicines.

3.1.4 *Trade and industry*

- Globalisation – raising particular concerns over counterfeit ('falsified') medicines; the quality assurance of medicines and Active Pharmaceutical Ingredients (APIs) sourced from one or more third countries; and Good Clinical Practice (GCP) in clinical trials carried out in third countries.
- The impact of any delays facing generic products on the cost of EU healthcare.
- Concerns over the rising cost and apparent declining productivity of pharmaceutical innovation.
- Failure of the market mechanism to support innovation in areas of high public health need, such as antibiotics.
- Continuing industrial consolidation by mergers and acquisitions.
- Different economic settings for the non-prescription and veterinary sectors.
- Impact of the global economy on public finances and on industry.
- Rising demand for food production.

3.1.5 *Financial sustainability*

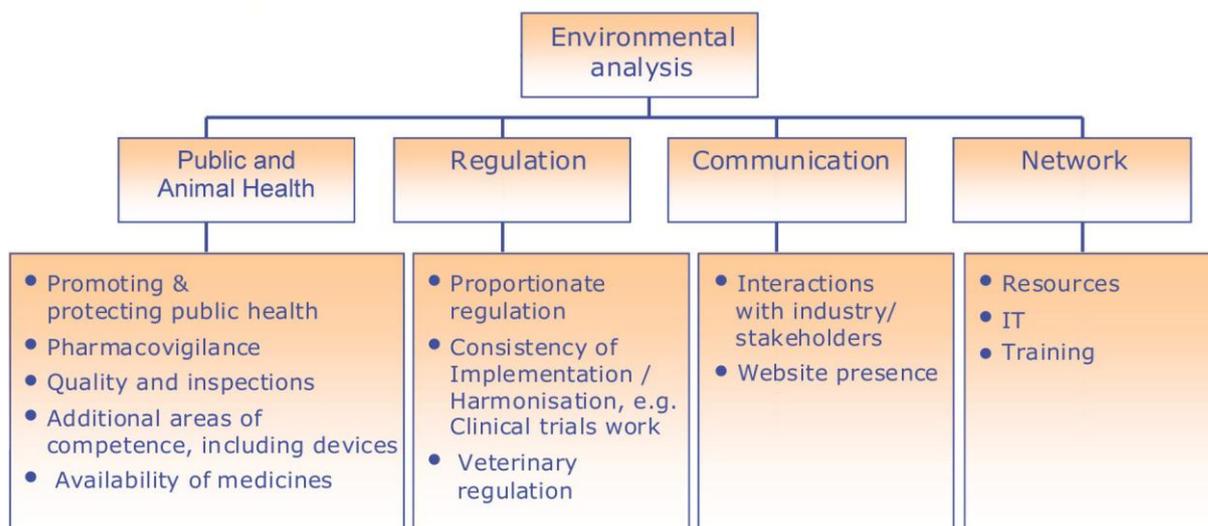
- Financial sustainability of all component parts of the regulatory network at a time of economic constraint in both public and private finances.

3.2 While HMA can contribute to debate and consultations on the future legislative framework, many of these issues and factors stretch well beyond the direct responsibilities of the HMA itself. However, virtually all of them could or should influence the way the Network carries out its work on behalf of the European population. They all deserve consideration in developing a strategy for the next five years.

4 Main themes identified by the Task Force.

4.1 Having reflected on the environmental analysis and consulted the HMA group in a plenary session, the Task Force identified 13 themes for in-depth analysis. These were grouped under four main headings, as shown in Figure 1.

HMA Strategy II



5 How the Network can “make a difference” in the next five years

A. Public and Animal Health

Regulatory contributions to public health and animal health and welfare

5.1 Contributing to public health and to animal health and welfare is seen as the central task of the Network and the primary motivation of NCA staff. For both human and veterinary medicines, regulators must consider the balances of benefits and risks when judging alternative treatment options. For veterinary medicines there is an added level of complexity, in that impacts on human health (via residues in food, or exposure to veterinary medicines during their use) and on the environment are potentially greater and must also be considered, as well as the potentially wider benefits on human health in the case of medicines to control zoonotic diseases.

5.2 Having close links with the end-users of medicines – patients, health care professionals and livestock owners – NCAs are well placed to help identify unmet therapeutic and preventive needs. These unmet needs may have several causes:

- Inadequate innovation, typically seen in areas where the market mechanism fails due to the small size of the target clinical population (orphan drugs; minor use/minor species in the veterinary field), likely small sales volumes even for relatively common conditions (e.g. novel antibiotics) or the lack of wealth to meet the cost of expensive products (many common tropical illnesses) or possibly due to a lack of sufficient data protection in the case of veterinary medicines.
- Failures of supply of medicines due to commercial factors such as parallel trade or small national markets.

- Interruption of medicines supply due to quality failures in manufacture or distribution.
- Inadequate manufacturing capacity in some countries

NCA's see a role to help in resolving some of these issues by advising their national health authorities on alternative sources or substitutions or in the case of veterinary medicines by facilitating the efficient operation of the prescribing cascade. Major commercial or innovation obstacles call for action at an international level. NCA's can support product development by providing scientific and regulatory advice to innovating companies, either at national level or through the EMA. They also wish to see a vigorous pharmaceutical research base in Europe.

- 5.3 NCA's are significant contributors to devising and implementing public health plans and programmes. Again, this is most likely to occur at national level through their links into national public health initiatives such as smoking cessation (e.g. supporting the non-prescription availability of Nicotine Replacement Products) or control of antibiotic resistance (e.g. through policies for the proper use of antibiotics in both human and veterinary practice). In the recent influenza pandemic, NCA's had a large role to play both at the European level in supporting rapid central authorisation of vaccines and nationally in the areas of medicines distribution and pharmacovigilance under conditions of exceptional stress and urgency.
- 5.4 The International "One World One Health" concept deals with a world strategy for managing health and food risks at the animal-human interface. It recognises that the health of animals and humans are integrally linked. Veterinary medicines have an important role in ensuring the security of food supply and preventing the spread of diseases from animals to humans.
- 5.5 The HMA believes that the increasing engagement of NCA's in public health programmes should be acknowledged, contributing their specialist expertise to national healthcare systems and using their established networks to support multinational and Europe-wide efforts as the circumstances demand.

Pharmacovigilance - human

- 5.6 Pharmacovigilance is a primary front-line function for the European regulatory network, protecting and safeguarding the health of EU citizens. The overarching goal is to optimise the benefit/risk of medicines in use. Key to the effectiveness of European pharmacovigilance is the role of national Agencies, and their ability to develop and maintain an effective two-way interface with health professionals, industry, patients and the public.
- 5.7 The European population base of 500 million people offers a unique opportunity for rapid detection of signals of new and changing risk in relation to medicines throughout the life-cycle of the product on the market.
- 5.8 Previous work showed wide variations between Member States in spontaneous reporting rates for suspected Adverse Drug Reactions (ADRs). Levers to improve such rates include:
- *education* – of healthcare professionals, patients and the public.
 - *motivation* – using incentives for reporting, such as prompt feedback.
 - *facilitation* – maximising the use of Information Technology.
 - *promotion* – general awareness raising on the importance of pharmacovigilance for public health protection.
- 5.9 HMA will seek to promote consistently high standards of spontaneous reporting throughout the Network, using the forthcoming pharmacovigilance legislation and the opportunities for

spreading best practice through the existing scientific contacts among the NCAs and at the EMA. This will be complemented by robust signal evaluation conducted in NCAs, supported by “Best Practice” guidance.

- 5.10 Communication of benefit/risk is an integral part of effective pharmacovigilance, enabling health professionals and patients to gain from prompt access to the comprehensive information which supports appropriate therapeutic action. The publication from September 2009 of a regular monthly bulletin from the Pharmacovigilance Working Party has been an important step forward in supporting consistent messages about risk for use at the level of national Agencies.
- 5.11 In the last year, the pandemic H1N1 influenza and the mass immunization of around 50 million EU citizens have focussed attention on the efficiency of determining the safety profile of vaccines and antiviral medicines in wide clinical use. The resulting progress in implementing real-time signal detection represents an important step forward and now needs to be integrated by member states into their pharmacovigilance practices.
- 5.12 Wider uptake of patient reporting of suspected ADRs, intensive monitoring of new medicinal products and the gathering of data on both risks and benefits of medicines from clinical data systems all offer scope to raise the standard of pharmacovigilance across the Network. Such initiatives will complement the necessary further development of Eudravigilance at the EMA to create an outstanding public health resource for understanding benefit-risk of medicines across the EU.
- 5.13 Taking into account the new challenges, the HMA Strategy to 2015 in the area of human pharmacovigilance will focus on three main themes:
 - Good pharmacovigilance practice and systems efficiency;
 - Integration of new methodologies into pharmacovigilance systems;
 - Benefit/risk communication, transparency and enhancing patient engagement.

Pharmacovigilance – veterinary

- 5.14 The current situation for veterinary pharmacovigilance is substantially different in some areas from that for human medicines. The Eudravigilance veterinary tool is less well developed than the corresponding human database and hence there is currently inadequate pooling of veterinary pharmacovigilance. Some parallels can be drawn between human and veterinary pharmacovigilance, although the veterinary system is arguably less mature. In particular there are wide variations between Member States in spontaneous reporting rates for suspected ADRs and the levers to improve such rates are the same. There are wide variations in the level of reporting of adverse reactions between the different livestock sectors.
- 5.15 It is necessary to strengthen the responsibility of the Marketing Authorisation Holder (MAH) for pharmacovigilance of their products. This can be encouraged by providing guidance and where this fails using risk based regulatory powers and by increasing pharmacovigilance inspections where appropriate.
- 5.16 In order to free resource within NCAs for veterinary pharmacovigilance, consideration should be given to the true value of Periodic Safety Update Reports for veterinary medicines. There may be a case for redeploying the effort currently expended on these to more effective pharmacovigilance activities.

- 5.17 Reporting by veterinarians and farmers/owners could be improved by simplifying the reporting process – ideally through electronic means– whilst maintaining the quality of the information reported. This would need to be aided by providing a programme of education on the value of reporting.
- 5.18 Work is under way to design the third version of the veterinary Eudravigilance system, EV Vet. Ultimately this should achieve a functional level which will allow direct reporting into it rather than into national databases. However, considerable further development will be required in order to reach that point.
- 5.19 The main areas for Network activity in veterinary pharmacovigilance over the next five years were therefore defined by the HMA as:
- Influencing the development of revised EU legislation on veterinary pharmacovigilance to ensure that a pharmacovigilance master file system is introduced; that risk-based, proportionate approaches are used; that responsibilities are clear; and that resources in industry and NCAs can be used effectively.
 - Influencing and encouraging the strengthening of the regulatory sanctions to ensure that MAHs meet their vigilance responsibilities for their products.
 - Raising ADR reporting levels by veterinarians and farmers/owners and ensuring the quality of these reports.
 - Taking forward the further development of EV Vet and systems for electronic ADR reporting.
 - Releasing resources by increasing the flexibility for PSUR submissions

Inspections and quality issues

- 5.20 The ultimate aim of inspections and control is to protect public and animal health, by contributing to the availability of medicines that meet appropriate quality, safety and efficacy standards. To this end, pharmaceutical inspectorates exert due assessment, supervision and control over agents involved in the pharmaceutical supply chain, such as the manufacturing/importing authorisation holders, but also active substance manufacturers and wholesalers, to assure that the legal requirements governing medicinal products are complied with.
- 5.21 Competent authorities seek assurance, by means of inspections and laboratory control, that medicinal products are manufactured or imported into the EEA in compliance with Good Manufacturing Practices and with their marketing authorisations. Products are sampled for control in Official Medicines Control Laboratories and manufacturers are inspected periodically by competent authorities. Inspections can also be performed unannounced or together with laboratory control be triggered by other findings (e.g. complaints or detection of quality defects) or suspicions of non-compliance.
- 5.22 It is also necessary to exercise supervision and control over the chain of distribution of medicinal products, from their manufacturing to the persons entitled to supply medicines to the public. This is to ensure that products are adequately stored, transported and handled, that traceability systems are in place and that counterfeit ('falsified') medicines are prevented from entering the legal supply chain. Good Distribution Practices are currently under review by experts from EEA countries under EMA coordination.
- 5.23 As far as the veterinary sector is concerned particular attention is paid to the medicinal products used in food producing animals in order to ensure that the European regulation related to maximum residue limits is respected.

- 5.24 The HMA noted the large impact of globalised trade on the supply of pharmaceuticals over the past 20 years. The great majority of Active Pharmaceutical Ingredients (APIs) are sourced from outside Europe or North America. Finished products, especially generics, are also very likely to come into the EEA from countries with rapidly expanding pharmaceutical manufacture, such as India.
- 5.25 The growth of international trade through more complex supply routes has created opportunities for organised crime to move into counterfeit ('falsified') medicines, where potential profits are large and criminal penalties generally low. This has been further stimulated by the growth of illicit manufacturing capacity capable of producing convincing products and packaging.
- 5.26 The WHO has estimated that, worldwide, some 10% of prescription medicines are counterfeit ('falsified'). In some regions, such as West Africa and parts of South America, the figure is much higher and the adverse public health effect is large. Europe has so far been affected to a much lesser extent but instances of counterfeits (either in the legitimate supply chain or illegally sold over the internet) have increased in the last ten years. This is a problem which regulatory authorities around the world share; there is much to be gained by international co-operation. It is necessary to develop a co-ordinated response to the risk of counterfeit medicines penetrating the legal supply chain.
- 5.27 Other major public health incidents due to failures of quality of imported pharmaceuticals have also resulted from criminal activity. A notable recent example was the supply of contaminated heparins to both EU and US markets, following deliberate adulteration of API with Over Sulphated Chondroitin Sulphate (OSCS). This incident caused around 100 deaths in the US. It was fortunate that the impact in Europe was minor, with no confirmed deaths.
- 5.28 The potential threat posed by substandard manufacturing of products used in advanced therapies is particularly concerning because of the scarce and highly specialised skills needed for inspection. Effective enforcement of medicines legislation cannot be achieved without close co-operation and co-ordination between the regulator and law enforcement as well as international organisations and agencies like Europol, Interpol, the WHO and the World Customs Organisation (WCO).
- 5.29 The HMA identified the following priorities for the next five years:
- Risk-based redeployment of inspections leading to a greater focus on third country manufacturers.
 - Enhanced legal powers against counterfeit ('falsified') medicines, through for example (i) the legislative package for human medicines now passing through the EU institutions; (ii) adoption of the Council of Europe's MEDICRIME Convention; (iii) use of national powers to strengthen deterrence, such as Proceeds of Crime legislation.
 - Co-operation within the Network, with industry and between the EU and non-EU regulators, to share intelligence and inspection data under formal agreements and to pool their expertise in the most specialised areas.
 - Co-operation between NCAs and other authorities, notably the police and customs, both nationally and internationally, in order to prevent and combat effectively counterfeit medicines and similar crimes. The work of WGEO has been active in this area.
 - Use of the EudraGMP and EDQM database for product testing to share intelligence within the Network

- Efficient use of OMCL (Official Medicines Control Laboratories) capacity for sample testing in ways which will deliver the greatest public health gain for the resources used.

Additional areas of competence, including devices for human therapy

- 5.30 HMA member agencies will increasingly encompass, either directly or indirectly, a range of additional areas of competence over the next five years including medical devices, advanced therapy medicinal products, tissues and cells and perhaps novel foods, cosmetics and Health Technology Assessment (HTA).
- 5.31 The HMA noted that the EU regulatory system for advanced therapy medicinal products (gene therapy, stem cell therapy and tissue-engineered products) is actively being developed in the EMA with NCA support and did not consider it further.
- 5.32 Preliminary consideration was given to Health Technology Assessment. There is a wider discussion required to define the best linkage between regulation and HTA. There could be scope to simplify product development by ensuring that the data needed for subsequent regulatory assessment and for HTA are collected in an efficient way. However, the criteria for market authorisation (safety, quality and efficacy) are distinct from the criteria used when HTA is used to inform decisions on reimbursement or health care planning (effectiveness and cost-effectiveness). There is a risk if decisions on market authorisation were to be suspected of being influenced by issues of priority or affordability. It would be preferable for HMA to have plenary discussions and confer with stakeholders on this complex area before reaching strategic decisions.
- 5.33 The HMA considered at some length whether there was a place for medical devices regulation in this five-year strategy. As has been noted, most Member States have placed the Competent Authority function for medical devices in the national medicines agency. This has advantages when considering the increasing number of new therapies which are based on a medicine/device combination (e.g. drug-eluting stents) or drug/diagnostic combination (e.g. Herceptin and Her-2 test in breast cancer).
- 5.34 However, the legal basis for medical device regulation (currently the three device Directives) is fundamentally different from medicines regulation. The manufacturer applies a CE mark having met the essential requirements either by self-certification or by confirmation from a Notified Body, depending on the class of device. The role of the NCA is to designate and audit Notified Bodies; to register manufacturers; to approve clinical investigations and to carry out market surveillance and vigilance activities.
- 5.35 The HMA noted that the Commission and others have expressed concern over the need to improve harmonisation which is provided for in the three Directives. In 2008 the EU Commission undertook a public consultation on possible amendments to the regulatory regime for medical devices and more recently has consulted again over a possible 'recast' of the Devices Directives. It is currently unclear what line the Commission will follow.
- 5.36 As things stand, however, the HMA was of the view that there should be closer engagement of the HMA group in considering medical devices strategy. This is currently under discussion.

Availability of medicines

- 5.37 In 2007 and 2008 the HMA reviewed the current situation concerning the lack of availability of human and veterinary medicinal products in some Member States. It was found that the lack of availability predominantly reflected the problem of economically unattractive markets and that the existing legal framework was insufficient to solve the problem of unavailability of medicines even if all given possibilities were optimally used, including a very broad interpretation of some provisions. This is why the HMA has considered how to implement in a more rational way the current legislation, as well as which changes could be made to future legislation. The new legislation should be proportionate and must not hinder the availability of medicinal products in the EU.
- 5.38 A helpful distinction has been made between action that might be possible under current legislation (e.g. providing information about what is available on the market and the scale of issues relating to availability) as opposed to action that would require new legal powers
- 5.39 Regarding the veterinary sector, the situation is different: there is a need to consider what could be done under a new legislative framework as the question is currently posed by the Commission in a consultation.
- 5.40 In the meantime, to help with the effective operation of the prescribing cascade the HMA will work towards all agencies publishing SPCs for authorised products on their website and/or Eudrapharm.

B. Regulation

Risk-based management of resources, reducing administrative burden and improving regulatory efficiency

- 5.41 Proportionate regulation is about getting the level of regulation aligned with the risks involved. Regulation can be disproportionate in more than one way:
- It could be too lax: and reduce patients' or animal owners' confidence in healthcare systems and the medicines they use and in the companies that provide them. In the case of veterinary medicines it could also reduce consumer confidence in food safety and lead to environmental problems.
 - It could be too risk-averse: increasing costs of developing pharmaceuticals and bringing them to the market, and reducing availability of innovative products.
- 5.42 Risk is not a stable concept, especially in healthcare:
- Tolerance for risk varies between individual patients; there are complex trade-offs between long-term and short-term effects;
 - Acceptable risk is critically dependent on benefits (the lower the benefit of a given therapy, the less the acceptable risk).
 - The risk environment for veterinary medicines is different. Risks are multi-dimensional in the case of veterinary medicines.
- 5.43 Proportionate regulation needs high levels of understanding about risk on the part of the public, or at least high levels of confidence in the system that oversees medicines. Is there a faster and more efficient system for medicines regulation that can both get useful pharmaceuticals to patients quicker and maintain confidence in the products? This is a complex area where there are very strong public health and economic reasons to ensure that regulation is proportionate, but there are real challenges in getting the balance right.
- 5.44 Practical challenges are seen at all points of the drug life-cycle:

- New drug development technologies; e.g. to what extent are toxicology strategies developed for small molecule drugs relevant to biological molecules of high target specificity?
- Pressure to get new medicines to patients as quickly as possible – especially ‘breakthrough’ products in areas of unmet clinical need. At what point in the conventional clinical trials programme do we know enough to approve market authorisation? How much reliance should be placed on surrogate markers of efficacy and safety?
- Personalised medicine: to what extent is the next generation of products to be more tailored to the individual patient, and how should this modify the development programme required by regulators? How are ‘companion diagnostics’ best developed and regulated?
- Risk-based regulatory processes e.g. in inspection and assessment; how can limited resources and scarce skills be accurately targeted where they will deliver the greatest public health gain?

5.45 The HMA believes that all regulatory requirements and processes must show proportionality – a challenge both for legislators and regulatory agencies in the coming years. There are links between proportionate regulation and the public communication of benefit-risk information. At the societal level, informed public debate helps regulators to maintain public confidence in what they do and why; it also enables them to act as proxy for the public in decision-making. At the individual level, good communication empowers patients and animal owners to make their own decisions on matters of benefit and risk. Regulation must also be efficient, through for example work-sharing across NCAs where possible.

Human Clinical Trials – consistency of implementation / harmonisation

5.46 HMA envision the creation of an efficient and unified regulatory environment for clinical trials in Europe that encourages innovation and high quality clinical research, by improving efficiency and reducing duplication, focussing assessment and inspections for clinical trials on a risk-based approach and promoting harmonised interpretation and implementation of guidelines and legislation related to clinical trials.

5.47 When published in 2001, the CTD aimed to harmonise the many existing, different regulatory requirements for the commencement and conduct of a clinical trial in the Member State (MS) of the European Economic Area (EEA). It required MS to incorporate the CTD’s provisions into their national legislation in order to provide a common and consistent regulatory framework for clinical trials across the EU. It also required the Commission, in consultation with the MS, to prepare detailed guidance to clarify the provisions of the CTD and also for the European Medicines Agency (EMA) to establish databases to facilitate the exchange of information.

5.48 The Clinical Trials Facilitation Group (CTFG) was established in 2004 by the HMA, shortly after the implementation of the Clinical Trials Directive (CTD). Its role is to assist in the operation and harmonisation of the implementation of the CTD in the MS.

5.49 It should be noted that most clinical trials are carried out on a national (and not multi-national) basis, although it tends to be the bigger trials with more people enrolled that are multi-national. Moreover, the approval of clinical trials operates within a two-pillar system, with national ethical committees.

- 5.50 Over the next five years the HMA will ensure MS co-operate to further harmonise both our processes and procedures related to clinical trial authorisation and also scientific review, to provide a consistent approach to decision making by all MS. It will also develop and implement work-sharing approaches to the assessment of CTA applications and safety information so that the protection of public health is achieved with the most efficient use of resources.
- 5.51 The HMA will ensure that MS continue to work with the EMA and the Commission to facilitate a common regulatory environment within the EU. It will also ensure that effective channels of communication are available and used, to share and discuss the details of its work with interested parties.
- 5.52 The Voluntary Harmonisation Procedure (VHP) has been an important initiative of Clinical Trials Facilitation Group (CTFG) to facilitate multinational trials. Assessors in NCAs work together to reach a shared position on a single CTA application within a defined timescale. Refining a decentralised procedure of this type in the coming years has clear advantages over the setting up of a centralised procedure for the 25% of all trials which are multinational. It enables good links to be maintained at the national level between NCAs and Ethics Committees. We do not envisage any possibility of an EU-wide structure for ethical review.
- 5.53 HMA will give high priority to the further development and streamlining of the VHP, working with the research community, EMA and the Commission. The identification and resolution of national differences in requirements will also continue, building on the successes already achieved through CTFG and the Commission's ad hoc group.

Regulation of Veterinary Medicines

- 5.54 HMA has identified five key drivers that need to be kept in mind when addressing its responsibilities in the field of veterinary medicines:
- The need to provide adequate protection for animal health and public health and the environment in Europe.
 - The Single European Act as well as the Lisbon Agenda, and the European sustainable strategy.
 - The 'Better Regulation' principles, considering the simplification of authorisation requirements to reduce the administrative burden on companies, veterinarians, farmers and authorities.
 - The principles laid down in Council Directive 86/609/EC regarding the protection of animals used for experimental and other scientific purposes (including in the development of human as well as veterinary medicines) in order to minimise the number of animals used for testing in the field of veterinary medicines.
 - The improvement of availability of veterinary medicines in order to ensure adequate prevention and treatment of diseases in animals, both now and in the future.
- 5.55 The HMA Strategy 2011-2015 is aimed at contributing to a global vision for veterinary medicine legislation based on the five key drivers mentioned above, and how its implementation should be managed for the benefit of public health and animal health at large.

5.56 A pivotal part of the Strategy in the area of veterinary medicines is to establish in principle the extent to which requirements for veterinary medicines should deviate from those of human medicines and to continue to actively participate in the current reflection on the modification of the veterinary legislation, in particular on the authorization process and in the area of data protection.

5.57 Other important areas of strategy for veterinary medicines are:

- To align work with the European Technology Platform for Animal Health so contributing to the development of medicines to tackle emerging diseases.
- To consider whether a collaborative and proportionate arrangement for control clinical trials in food producing species is necessary.
- To strengthen links with OIE (World Organisation for Animal Health).
- To contribute effectively to the work of Codex Alimentarius.
- To work in collaboration with those bodies running residue surveillance programmes.
- To influence the development of revised legislation for feedingstuffs to ensure that it is risk-based and addresses the specific challenges of antimicrobials delivered via drinking water or feed.
- To gather information on unregulated areas (medical devices, diagnostics, including radiological contrast media, new technologies) and borderline areas (divide between unauthorized products and veterinary medicines, divide between biocides and veterinary medicines) and explore the need for proportionate regulation and co-operation in the network.

C. Communications

Interactions with industry /stakeholders, and website presence

5.58 For its wider strategy to be deliverable, the HMA must communicate effectively with its internal and external stakeholders. Communication is, by definition, a two-way process. Delivered effectively, it will ensure that:

- the HMA's strategy evolves and is refined in the light of ongoing stakeholder feedback; and
- stakeholders understand the HMA's objectives, and are able and willing to play their part in delivering those.

5.59 In communicating, the HMA's overarching aim is to safeguard human and animal health in Europe. Although the relationships between regulators and health professionals and patients' associations are extremely important, they are best handled by each agency at national level. In addition, the EMA undertakes its own targeted work with patients and consumer organisations. However, the specific focus of HMA's activity is with industry and other regulators. Its key objectives are:

- to ensure that the *pharmaceutical industry* can have efficient, effective and appropriate interactions with a regulatory system which safeguards consumer and animal health, and that the industry has confidence that concerns it raises will be dealt with expeditiously
- to ensure that other *regulators* recognise the European regulatory system as a key player on the international stage, and exchange information with that system.

5.60 At this stage there are two areas which need to be developed over the lifetime of this strategy. They are:

Developing opportunities for dialogue with stakeholders

- 5.61 The HMA has a number of stakeholders – that is people or organisations who stand to be affected by its actions. These include the general public; patients (i.e. those amongst the public who consider themselves to be patients); healthcare professionals, both human and veterinary; Governments/governmental bodies, both national and Europe-wide; academics and researchers; news media – both general and specialist; the staff of the various national competent authorities (NCAs) within Europe; the human and veterinary pharmaceutical industry; and other medicines regulators outside Europe. All of these are likely to have a stake in the HMA's actions, even if they are not personally aware of the HMA's existence or have any day-to-day interaction with it.
- 5.62 In order to have effective relationships with industry and other regulators, the HMA needs to build regular two-way communication with them. Although this has been done on a periodic basis in the past, it has tended to be somewhat ad-hoc. Moving forward, this needs to be done on a sustained and sustainable basis to build trust, genuine dialogue, and a shared commitment to working together on protecting and promoting public and animal health in Europe.

Developing the HMA web presence

5.63 The HMA has hosted its own website for many years. As the HMA covers such a large geographic area, and as its primary audiences are highly dispersed, the website is a vital communication tool. However, its utility can be enhanced by:

- more targeted communication, aimed specifically at the HMA's primary audiences.
- more effective communication – for example, by enhancing the navigability and searchability of web content.
- more timely communication, ensuring that content is updated regularly, and in a short time-frame after key changes in policy or direction; and ensuring that product information is accurate.
- more proactive communication – identifying likely areas of interest amongst priority audiences, and developing web content to meet those specific needs.

D. Strengthening the Network

Resources

- 5.64 Resources of the Network are an overarching issue that cover the human and financial resources as well as the expertise available in the human resources. Many resources are required to cover the wide range of responsibilities that the agencies of the Network have from medicines evaluation and licensing – being the common denominator for the agencies – over pharmacovigilance and inspections to reimbursement and medical devices or cosmetics. Each area of responsibility has a need for resources.
- 5.65 When discussing resources it is important to bear in mind that the Network operates on three levels that all require resources and that all three levels are equally important:
- Centralised procedure and other resource-requiring tasks for the centralised European medicines system.
 - The common EU procedures, i.e. MRP, DCP, and VHP for human clinical trials.
 - National procedures and tasks.

Making decentralised processes work better

- 5.66 One important practical role for HMA group (and NCAs) is to ensure the smooth running of the mutual recognition and decentralised procedures. An important way for this to happen is through the work of the Coordination Groups for the Mutual Recognition and Decentralised Procedures (CMD) as they take forward work to ensure appropriately harmonised implementation across the network. This work will include extending new EU variation regulation provisions to national variations; supporting important new functionality bestowed on the CMD-h by the strengthened PhV legislation; and providing more authorised medicines for children in the community as CMDh implements the paediatric regulation provisions.
- 5.67 In striving for improved MR and DC procedures, it is important to deliver a streamlined system which complements the Centralised Procedure. It should be attractive to all sectors of the pharmaceutical industry, and offer choice of RMS and MS involved, different product names across markets, prescription status to match national health provisions. Improved procedures should ensure predictability of timelines and introduce real opportunities for early closure.
- 5.68 HMA will manage the national competent authority resource available for the efficient running of MRP/DCP by encouraging policies of better regulation and mutual trust between MS in order that work undertaken is proportionate, targeted and adds value, and avoids duplication of effort. Tools such as work sharing will be used to best effect with all Heads committed to the principle of a fair distribution of work across the network. CMD members will have a strong mandate for decision making to achieve a common harmonised view and ensure implementation of agreements in each NCA.

Information Technology

- 5.69 HMA endorses the strategic goal for a one entry submission point for MR/DC applicants alongside the interoperability of NCA systems. Developments in IT will allow the creation of a competitive, boundary-free regulatory environment in the EEA that takes advantage of the strengths of each NCA through global telematic interoperability in a secure, reliable and timely manner.
- 5.70 The HMA understands the benefits of EU IT projects and the impact on NCA individual IT development. HMA aims to achieve interoperability of systems and efficiency of resources across the network, enabling National Competent Authorities to make the best strategic telematics decisions to support their business needs and those of the European Medicines Regulatory Network. When considering telematics HMA keeps in mind that telematics is a tool to support business and could offer resource savings. To achieve this, the HMA will want to contribute to pan-European projects, which will need to be prioritised. Where the need for new telematic systems is identified, the HMA will work together where appropriate to use resources across the network to best effect.
- 5.71 HMA will develop a communications plan to ensure that stakeholders are provided with up-to-date information on telematics activities in the EMRN.
- 5.72 HMA will support internal communication platforms for each working group of HMA

Benchmarking

- 5.73 A programme for benchmarking European medicines agencies (BEMA) is currently in its second cycle. It provides a mechanism for agencies to assess their performance against a

common set of best practice standards and to benefit from a peer-review. HMA is committed to further developing this programme to ensure continuous improvement among the network agencies.

Training

5.74 The HMA recognized early on the need for harmonised training to help ensure that the European Medicines Regulatory Network (EMRN) achieves on an ongoing basis harmonized high-quality performance standards in assessment, inspection and control.

5.75 The overall objectives of the HMA's training strategy are:

- To improve the quality and consistency of the work of the European Regulatory Network;
- To foster science-based, pragmatic and consistent assessment, inspection and laboratory control practices and decision making;
- To promote harmonised interpretation of guidelines and operation of the regulatory framework throughout the European Regulatory Network;
- To provide continuous professional development for staff of regulatory agencies and, possibly, others involved in regulation of medicines.

5.76 The main principle underlying this strategy is that basic training should be provided to all staff members of a competent authority and that additional specialized training should also be provided to those that need it. The HMA has recently set up a virtual central EU office of training. This work should help do the following:

- harmonise decisions in the network;
- continuously improve the standard of the network;
- support work sharing and mutual trust; and
- ensure the prudent use of resources.

6. Conclusion

6.1 The HMA Strategy, which complements other similar work (notably the Roadmap produced by the EMA), sets out a challenging and ambitious agenda for the work of the HMA over the next 5 years. With their responsibilities for contributing to work at all the parts of the EU medicines licensing network (centralised, decentralised, mutual recognition and national), the Heads of Medicines Agencies have a pivotal role in making the European medicines regulation network operate effectively. Implementation of the Strategy will be taken forward by structured follow up in the HMA meetings themselves and through close working between the HMA and its working groups.

APPENDICES

ANNEX 1: Bibliography

EMA Roadmap to 2015

EU Commission's report on the Pharmaceutical Sector Inquiry (November 2008)

EU Commission White Paper: Together for Health: A Strategic Approach for the EU 2008-2013 (October 2007)

Communication from the Commission: Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector (December 2008)

EC Assessment of the Functioning of the "Clinical Trials Directive" 2001/20/EC

ANNEX 2: Glossary of terms

This glossary is intended to provide a short description of the technical terms, organisations, committees and networks referred to in this document.

Adverse Drug Reaction (ADR): A reaction which is harmful and unintended and which occurs at a dose normally used for prophylaxis, diagnosis or treatment.

The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organisation (FAO) and World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

Eudravigilance: Eudravigilance is the European database for the exchange, processing and evaluation of Individual Case Safety Reports (ICSRs) on medicinal products authorised in the European Economic Area.

International Conference on Harmonisation (ICH) The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) brings together the regulatory authorities to achieve greater harmonisation for product registration and to reduce the need for duplicate testing during the development of new medicines.

Marketing Authorisation (MA): In European law medicines which meet appropriate standards of safety, quality and efficacy, are granted a Marketing Authorisation (MA) which is normally necessary before they can be sold or advertised.

Pharmacovigilance: Pharmacovigilance is the process of (a) monitoring medicines to identify previously unrecognised, or changes in the patterns of, adverse effects; (b) assessing the risks and benefits of medicines to determine what action is necessary to improve their safe use; (c) providing information to users to optimise the safe and effective use of medicines; (d) monitoring the impact of any action taken.

ANNEX 3: List of abbreviations

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
CA	Competent Authority
CMD	Coordination Group for the Mutual Recognition and Decentralised Procedures
CTA	Clinical Trials Authorisation
CTD	Clinical Trials Directive
CTFG	Clinical Trials Facilitation Group

DCP	Decentralised Procedure
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EMA	European Medicines Agency (formerly, EMEA)
ERMS	European Risk Management Strategy
EMRN	European Medicines Regulatory Network
ESS	European Surveillance Strategy
EU	European Union
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
ICH	International Conference on Harmonisation
IT	Information Technology
MA	Marketing Authorisation
MAH	Marketing Authorisation Holders
MRP	Mutual Recognition Procedure
MS	Member State
NCA	National Competent Authority
OMCL	Official Medicines Control Laboratories
OIE	World Organisation for Animal Health
PhVWP	Pharmacovigilance Working Party
PSURs	Periodic Safety Update Reports
QP	Qualified Person
TSC /TSG	Telematics Steering Committee / Group
VHP	Voluntary Harmonisation Procedure
VICH	Veterinary International Conference on Harmonisation
WHO	World Health Organization

ANNEX 4: *The Task Force's methodology*

At its meeting in Stockholm in July 2009, the HMA endorsed the formation of a task force to lead this work. The task force, which numbered approximately 25 officials, was mainly comprised of heads of national agencies (see Annex 5). In order to make best use of resources the Task Force met rarely on a face to face basis, as all discussion papers were circulated electronically and commented on by email, and subsequently at the regular pan-European telephone conferences. This approach saved time and resources, and illustrates how technology can be a great enabler.

The Task Force's approach was to review what had been achieved since the first Strategy was published in 2007. As part of this stock take, the Task Force drafted an environmental analysis, which involved horizon scanning. From this, the Task Force identified areas of work, such as new areas of competence, which would form part of the second document. In total, thirteen such areas were identified; the subsequent topic papers helped inform the Task Force's emerging strategy.

For each of the thirteen themes, a short topic review was drafted by one or two members of the Task Force. This was circulated for comment and discussed at one or more teleconferences of the whole Task Force. The objective was to ensure that all the essential issues had been identified and debated and a consensus reached on its place in the Strategy. This strategy document draws together the conclusions reached

Throughout this process the wider HMA was kept informed. Moreover, to further help develop the Strategy II document, the Task Force consulted a range of stakeholders across Europe in July 2010. In drafting the second Strategy, the Task Force reflected on the earlier (first) Strategy document, the EMA Roadmap 2015, as well as other relevant publications.

ANNEX 5: Membership of the Task Force

Austria

Marcus Muellner, Head of Agency, Austrian Agency for Health and Food Safety

Belgium

Xavier De Cuyper, General Administrator, Federal Agency for Medicines and Health Products

Denmark

Jytte Lyngvig, Chief Executive, Danish Medicines Agency (DKMA)

Tina Soon Engraff, Legal Adviser, DKMA

France

Jean Marimbert, Director General, AFSSAPS (human medicines)

Patrick Dehaumont (until 30 June 2010), AFSSA (veterinary medicines)

Catherine Lambert, Deputy Head of International Affairs, AFSSA

Miquel Bley, Head of European Affairs, AFSSAPS

Germany

Ansgar Schulte, Executive Assistant to the President of the Federal Institute for Drugs and Medical Devices

Cornelia Ibrahim, Deputy Head of Department (Veterinary Drugs) - Federal Office of Consumer Protection and Food Safety

Ireland

Pat O'Mahony, Chief Executive, Irish Medicines Board (IMB)

Ann O'Connor, Director of Human Products Authorisation and Registration, IMB

Italy

Silvia Fabiani, Head of International Relations, Italian Medicines Agency

Latvia

Inguna Adovica, Director, Latvian Medicines Agency

Norway

Gro Wesenberg, Director General, Norwegian Medicines Agency

Spain

Cristina Avendano Sola, Director, Spanish Medicines Agency

Sweden

Christina Åkerman, Director General, Swedish Medicines Agency

Christer Backman, EU Coordinator and Policy Advisor, Swedish Medicines Agency

United Kingdom

Professor Kent Woods, Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA) and Chair of the Task Force

Steve Dean, Chief Executive, Veterinary Medicines Directorate (VMD)

Jackie Atkinson, Director of Authorisations, VMD

Simon Gregor, Director of Communications, MHRA

Jonathan Mogford, Director of Policy, MHRA

Jonathan Hafferty, Clinical Advisor to the Chief Executive, MHRA

Louise Loughlin & Aidan Mclvor, Office of the Chief Executive, MHRA

The Netherlands and HMA Management Group

Aginus Kalis, Executive Director of Medicines Evaluation Board in the Netherlands, and Chair of the HMA Management Group

HMA Permanent Secretariat

Nuno Simões (Portugal), Birte Van Elk (Netherlands), Åsa Kumlin Howell (Sweden), Nuala Harman (Ireland)

Additional participants:

Estonia: Kristin Raudsepp, Director General, Estonian Medicines Agency

Slovenia: Martina Cvelbar, Head of Agency, Agency for Medicinal Products and Medical Devices

ANNEX 6: Background information on HMA network

The Heads of Medicines Agencies is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area. The Heads of Medicines Agencies is supported by working groups covering specific areas of responsibility and by the Heads of Medicines Agencies Management Group and Permanent Secretariat.

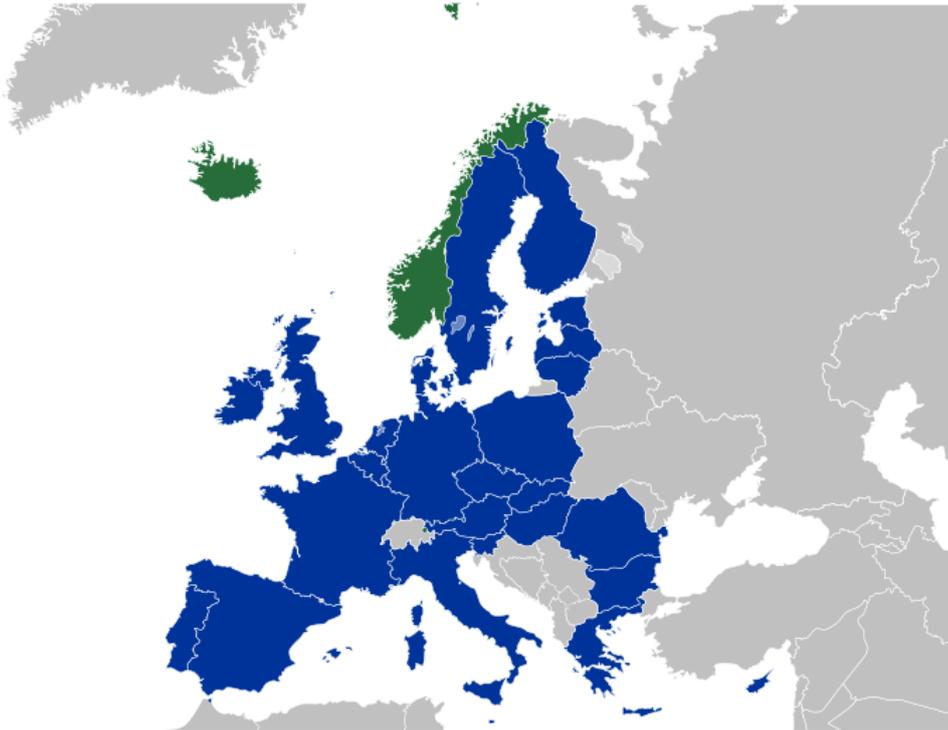
The European Medicines Regulatory System is composed of 44 national competent authorities, the European Medicines Agency (EMA) and the European Commission. These are 44 national agencies from the 27 EU member states and the 3 countries from the European Economic Area: Iceland, Liechtenstein and Norway.

The fundamental role of this system is distinguished by an active contribution to the promotion of public health and by an individual and collective contribution for a high-level European network of expertise, which operate EU authorisation procedures.

The HMA's vision is to protect and promote public and animal health in Europe; its mission is to foster an effective and efficient European medicines regulatory system. The main mission of national agencies aims at the promotion of public health using all resources available in pre or post authorisation phases. The authorisation and assessment processes are present in benefit-risk analysis, under which benefits of medicines must outweigh risks.

European Economic Area (EEA)

The European Economic Area was created in 1994. The EEA combines the countries of the European Union and member countries of EFTA (European Trade Association). Countries that belong to the EEA are: Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.



European Economic Area (EEA)

■ European Union

■ Iceland, Liechtenstein and Norway

The main areas of competence of EU national competent authorities are:

- Medicines of human use
- Medicines of veterinary use
- Medical Devices
- Cosmetics
- Novel foods

The main areas of responsibility of EU national competent authorities are:

- Authorisation of medicines / registration of devices
- Clinical Trials
- Pharmacovigilance / Vigilance / Surveillance
- Inspection / compliance
- Quality control
- Batch release
- Pricing
- Reimbursement / Health Technology Assessment
- Regulatory and scientific advice
- Information to patients
- Information to healthcare professionals
- Medicines advertising control
- Residues monitoring
- Designation and supervision of notified bodies

Areas of competence (number of agencies) – Information from April 2008

Human Medicinal Products	Veterinary Medicinal Products	Medical Devices	Cosmetics
29	25	21	8

Variation of Human Resources (number of agencies)

0 – 49	50 - 149	150 - 400	> 400
6	9	13	8

Funding (number of agencies)

State Budget (only)	Fees (only)	State Budget + Fees
7	5	24