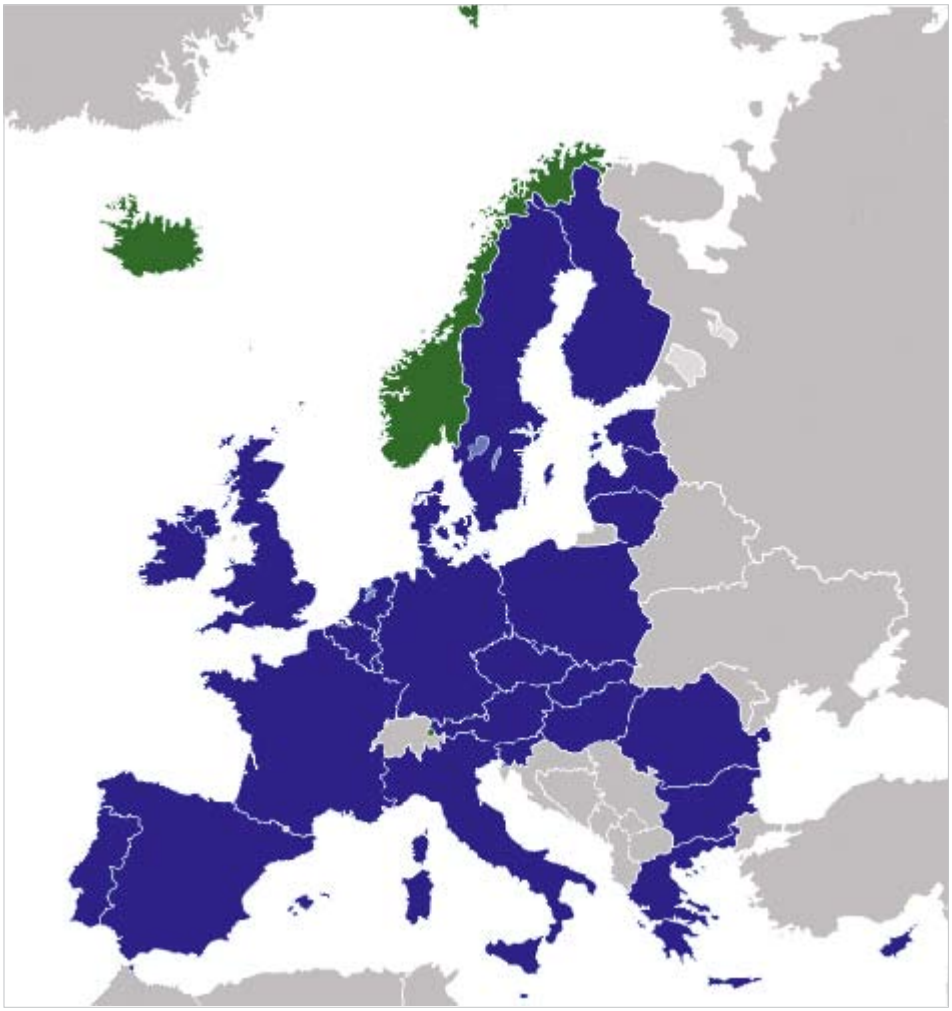
HMA
Heads of Medicines Agencies

2011–2012 Annual Report of the HMA Strategy

HMA

Heads of Medicines Agencies



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Chairman's Introduction

Aginus Kalis
Chair of the HMA Management Group
Executive Director of the Medicines Evaluation Board, Netherlands (CBG-MEB)

It is my pleasure to introduce to you the 2011/12 Annual Report of the HMA Strategy, the first such report in the new five year strategy cycle.

Since work first started on the new Strategy in 2009, the HMA was keen to see that the strategy document would be a blueprint to be acted on and not something to gather dust on the shelves. In this year's Annual Report, we can see that much progress has been made in the first year and also the potential for further achievement in the future.

Since its inception in 1995, the HMA has demonstrated how effective and productive an informal, voluntary network of National Competent Authorities can be. The themes of the 2011-15 Strategy are firmly rooted in the shared interests and values between HMA members that have made this partnership a success. The first theme underlies the primary mission which unites all our agencies, to safeguard public and animal health. The second theme reflects the commitment of the HMA to support innovation within Europe, in a rapidly changing landscape of medicine production and development. The third theme illustrates the role of the HMA in maintaining connections between national agencies to ensure an effective decentralised and mutual recognition route to market authorisation for human and veterinary medicines, running complementary and in cooperation with the centralised system maintained by the EMA.

2011 has been a busy year for the medicines regulatory network. Much work has been undertaken in readiness for the imminent implementation of the new pharmacovigilance and falsified medicines legislation. There has been considerable progress in international collaborations to share experience and reduce unnecessary burdens on industry, such as the cooperation on third country inspections initiated between the US FDA and European inspectorates. Later in the year, I was delighted to see my colleague Guido Rasi, who has served in the HMA Management Group, elected as the new Executive Director of the European Medicines Agency.

The summaries from the work area leads and updates from the individual working groups compiled in this Report reveal how well the HMA has responded to the year's challenges. Within the decentralised procedure, we have moved to a position where there are now sufficient slots available to meet industry's needs. There has also been a significant reduction in referrals for the MRP/DCP as well as an increase in transparency and efficiency of the procedures. In human clinical trials, it is pleasing to see the growing takeup by academia and industry of the Voluntary Harmonisation Procedure. Work is continuing on benchmarking, streamlining and harmonisation within the Network, on both the human and veterinary side. On medical devices, the HMA has formed a stronger relationship with its counterpart in European devices regulation, the CAMD, which will hopefully form a sound basis for formal cooperation in the future.

Making the 2011-15 Strategy a reality has involved much hard work from a number of individuals in the Network. I would like to thank Kent Woods and his team from the Strategy II Task Force for their work in producing the Strategy document and in the implementation work that has followed. Special thanks are also due to the HMA Permanent Secretariat and Management Group, and the Work Area Leads and Chairs of working groups, for coordinating the strategy work going forward. I would also like to particularly note the work of the Hungarian and Polish presidencies during 2011 in making the first year of the Strategy such a success.

2012 will be another important year for medicine regulation. We will see the implementation of the Pharmacovigilance legislation and the Falsified Medicines Directive and continue discussions on revisions of the European legislation on clinical trials, medical devices and veterinary medicine. In endorsing this Report to you, I am confident that the Heads of Medicines Agencies and the wider European Medicines Regulatory Network will meet these challenges and continue to grow from strength to strength.

The European Medicines Regulatory Network

The European Medicines Regulatory Network (EMRN, 'the Network') is composed of the national competent authorities (NCAs) for human and veterinary medicines regulation, the European Medicines Agency (EMA) and the European Commission.

There are 45 national agencies from the 27 European Union (EU) member states and the three countries from the European Economic Area – Iceland, Liechtenstein and Norway.

Of the 45 NCAs, 14 have responsibility only for human medicines; 14 are purely veterinary agencies; 17 are joint veterinary and human 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 have joint responsibility for medicines and medical devices. All are accountable to their national governments.

The EMA is a key part of the Network and all 45 NCAs work closely with it. Yet in addition to their role in supporting centralised EU processes, NCAs also have major responsibilities for the functioning and efficiency of national and decentralised activities.

Established in 1995, the Heads of Medicines Agencies (HMA) 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.

Mission of the Heads of Medicines Agencies

The HMA works to foster an effective and efficient European medicines regulatory system.

Key activities

- To address key strategic issues for the EMRN; to exchange information and to share best practices within the Network;
- To share responsibility for all areas of medicines regulation, especially the Mutual Recognition and Decentralised Procedures (MRP/DCP);
- To focus on the development, co-ordination and consistency of the EMRN;
- To provide support to the Network through provision of high quality professional and scientific resource; and
- To provide a focus for making the most effective use of resources across the Network e.g. through developing and overseeing arrangements for work-sharing.

The initial focus of the HMA was on the smooth functioning of non-Centralised regulatory applications, through regular meetings and working groups, such as the Co-ordination Group for Mutual Recognition and Centralised Procedures for human and veterinary medicines(CMDh and CMDv).

Over the years, HMA has extended its coordination activities to encompass clinical trials authorisation; worksharing of periodic safety update reports (PSURs) and paediatric indications; interpretation of legal provisions; inspection and enforcement operations; and product testing. New European pharmacovigilance law will further endow CMDh with decision-making powers.

Common initiatives to strengthen the system have resulted in Europe-wide projects concerning information technology (IT) infrastructure, communication policy, training programs, audit, benchmarking and more.

70 per cent of the National Competent Authorities for human medicines within the HMA also have authority for human medical device regulation, and the HMA works closely with its counterpart in medical devices, the Competent Authority for Medical Devices and Central Management Committee (CAMD, CMC).

Governance of the HMA

The Heads of Medicines Agencies is supported by working groups covering specific areas of responsibility. Most of these groups are specific to the HMA, others are legally separate but share joint mandates for activity (such as CMDh,and the Pharmacovigilance Working Parties).

The HMA Management Group (HMA MG) has as its main objective the co-ordination and facilitation of the operation of the HMA, and the supervision and management of the HMA Permanent Secretariat (HMA PS). The Permanent Secretariat facilitates and supports the work of HMA, HMA MG and the EU Presidency by ensuring co-ordination, consistency and continuity of their work and activities and providing the collective memory of the HMA.

Cooperation with the EMA

The HMA works in close coordination with the European Medicines Agency and the EMA plays an active role in HMA meetings and in the operation of HMA working groups. The EMA provides support and facilities for a number of working groups, including the Coordination Groups for Mutual Recognition and Decentralised Procedures and the Pharmacovigilance Working Parties, and also for HMA working groups. Other working groups, such as the GMP/GDP Inspectors Working Group, are jointly mandated to the HMA and EMA. The EMA also provides a significant proportion of the IT infrastructure used by the Network. Furthermore, a number of the activities detailed in this report result from joint HMA and EMA initiatives, such as the Office of Training and the joint working group on transparency. The close partnership of the HMA and EMA has become an essential foundation for the smooth operation of the European Medicines Regulatory Network.

Meetings

The HMA usually meets in full session twice during each Presidency of the Council of the EU (i.e. four times per year). After each HMA meeting a stakeholders information document is published on the HMA website. The working groups also meet several times per year, physically and by teleconference.

Photo: Christer Backman

The HMA Strategy 2011–15

In July 2009, the HMA commissioned a new five year Strategy for its activities within the Network, covering the period 2011-15. This is intended to build upon the work of the first Strategy (2006-10) and also complement the European Medicines Agency's Roadmap to 2015.

The aim of the Strategy is *to identify the key challenges which face the Network and how the HMA can best respond to these challenges for the benefit of the European population.*

The new Strategy recognises that there have been significant political, economic, social and legislative developments since the first Strategy was published. These include the global economic downturn, influenza virus pandemics and changes within the pharmaceutical industry with increasing use of third countries for production and innovation.

While the Strategy covers the diverse activities of the HMA's contribution to the EMRN, three key themes also emerged where the HMA believes it can make a real difference in the next five years:

(1) Safeguarding Public and Animal Health

The HMA is dedicated to strengthening surveillance of the benefits and risks of medicines in the European population, including: improving spontaneous reporting systems to enable early detection of risks; strengthening monitoring of the quality of medicines (including risk-based inspections); and targeted action against falsified medicines.

(2) Supporting Innovation

The HMA will continue to support the efficient and proportionate regulation of new medicines, and clinical trials in humans, through initiatives such as the new Voluntary Harmonisation Procedure (VHP) and through the provision of excellent scientific and regulatory advice.

(3) Further Improving the Operational Efficiency of Medicines Authorisation by the Decentralised and Mutual Recognition Procedures (DCP/MRP)

The HMA is dedicated to excellence in the operation of the DCP/MRP. This will be achieved through the promotion of risk-based proportionate regulation; the harmonisation of assessment; work-sharing; the best use of information technology; dialogue with industry on operational matters, such as streamlining validation procedures; the harmonisation of training; and the promotion of good communication channels.

Legislative Changes

The Strategy also identified a number of key changes in European legislation that the HMA will need to respond to during 2011-15. These include the impact on NCAs, healthcare and industry of the Pharmacovigilance and Falsified Medicines Directives; an expected recast of the medical devices legislation; an expected revision the Clinical Trials Directive; and reviews and updates to veterinary legislation. Implementation of European legislation will also have significant resource implications for National Competent Authorities.

Emerging Issues

The Strategy identified a number of key emerging issues for medicines regulation in the next five years. These include changing patterns of disease e.g. emerging antibiotic resistance in both humans and animals and new pathogens and viral strains. In addition, innovation of medicines will lead to more advanced therapies for humans and animals, as well as personalised medicines, medicine/medical device combinations and further development of new technologies such as nanotechnology. Regulatory science will continue to develop, with advances for example in risk-benefit modelling. More Member States are increasing their use of Health Technology Assessment (HTA) to estimate clinical effectiveness and cost-effectiveness of health care interventions. Finally, there is a call for greater transparency in the processes of regulation.

Trade and industry

The European Commission has expressed concerns about the rising cost and apparent declining productivity of pharmaceutical innovation in Europe. In addition, the effects of globalisation have created new needs for quality assurance of medicines and Active Pharmaceutical Ingredients (APIs) sourced from one or more third countries, as well as the need for robust measures against counterfeit medicines.

Furthermore, the Strategy needs to be mindful of the financial constraints, in public organisations and private companies, currently experienced across the member states of the regulatory Network.

Looking forward

The Strategy outlines the direction of travel the HMA wishes to take in the next five years. However, it is not possible to predict with certainty what may happen over 2011-15 and how priorities might change. Through the regular meetings of the HMA and its working groups, and its annual reviews of the progress of the Strategy, the HMA retains the ability to adapt to and meet the challenges of the future.

Strategy Implementation Plan

The HMA formally adopted the HMA Strategy at its October 2010 meeting in Antwerp. A strategy implementation plan was agreed in February 2011 at the following meeting in Budapest. The purpose of the implementation plan is to ensure that the efforts of the HMA remain focused on the key goals of the Strategy throughout its lifetime.

The key elements of the strategy implementation plan are as follows:

(1) *Use of Working Groups*

An analysis of the Strategy document revealed 50 specific objectives for HMA activity during 2011-15 (see pages 10–11). These objectives were assigned to the existing working groups of the HMA, who would carry responsibility for the practical implementation of these objectives.

(2) Creation of Work Area Leads

To help coordinate and support the efforts of the working groups, eight 'work areas' were created, subserving the three main themes of the Strategy. Each work area has been allocated a 'work area lead' drawn from the heads of European NCAs. The work areas leads liaise with the chairs of the respective working groups, as well as the HMA Management Group, to ensure that necessary progress is being made and to provide high-level support when required.

(3) Targets and Deliverables

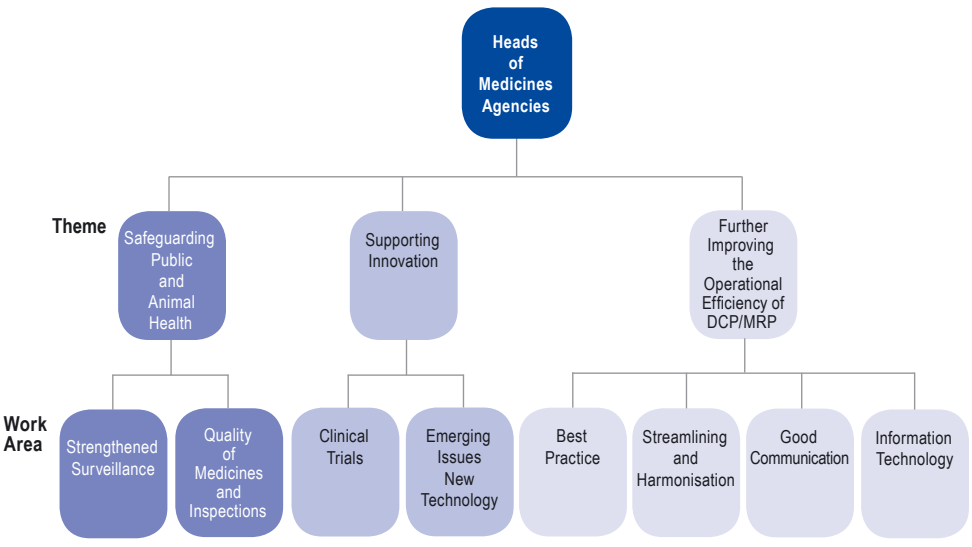
A further role of the work area leads and working groups is to identify key targets and priority areas where success can be measured on an annual basis. Several such targets are identified in this document.

(4) Annual Review

For the Strategy 2011-15, there will be a yearly review process to assess progress. This will take place at the first HMA meeting of each year. This annual report forms a key part of the 2011-12 review process.

(5) Embed Strategy into Joint Sessions of HMA Meetings

The joint (human and veterinary) sessions of HMA meetings are now organised thematically, so that each of the three themes are now considered in turn. It is intended that this way each theme and work area of the Strategy will be given the necessary attention and resource. The July 2011 meeting in Warsaw was the first meeting to adopt this thematic approach.



Specific Objectives of the HMA Strategy

	Specific objective	Principal Working Group (s)	Work Area
1	Improve on variations between Member States in spontaneous reporting of Adverse Drug Reactions (ADRs); through education, motivation, facilitation, promotion and forthcoming pharmacovigilance (PhV) legislation	PhVWP(h/v) ERMS FG	Strengthened surveillance
2	Improve safety profile of vaccines and antivirals and implementation of real-time signal detection	PhVWP (h) ERMS FG	Strengthened surveillance
3	Good pharmacovigilance practice and systems efficiency, data quality (metrics)	PhVWP (h) ERMS FG WGQM	Strengthened surveillance
4	Integration of new methodologies into PhV systems, raise standards of PhV across Network to complement further development of Eudravigilance by EMA	PhVWP (h) ERMSFG	Strengthened surveillance
5	Benefit/risk communication, transparency and patient engagement	PhVWP (h) ERMS FG HMA/EMA WG T WGCP	Strengthened surveillance
6	Influencing development of revised EU legislation on veterinary PhV to ensure that a PhV master file system is introduced	PhVWP(v) ESS WG, TFIVL	Strengthened surveillance
7	Strengthening regulatory sanctions to ensure that veterinary Marketing Authorisation Holders (MAHs) meet vigilance responsibilities for their products, using guidance, regulatory powers and pharmacovigilance inspections	PhVWP (v) ESS WG	Strengthened surveillance
8	Raising ADR reporting levels by veterinarians and farmers	PhVWP (v) ESS WG	Strengthened surveillance
9	Simplifying veterinary reporting process; taking forward development of EudraVigilance (EV) Vet and systems for electronic ADR reporting	PhVWP (v) ESS WG	Strengthened surveillance
10	Releasing resources by increasing the flexibility of Perioidic Safety Update Reports (PSUR) submissions	PhVWP (v) ESS WG, TFIVL	Strengthened surveillance
11	Protect public health through inspections and laboratory control of all stages of pharmaceutical supply chain, human and veterinary	WGPT GMP/GDP IWG	Quality and Inspections
12	Develop co-ordinated response to risk of counterfeit medicines; cooperation within Network, industry and other agencies to share intelligence and inspection data; cooperation between NCAs, authorities, police, customs etc.	WGEO	Quality and Inspections

	Specific objective	Principal Working Group (s)	Work Area
13	Risk-based redeployment of inspections leading to greater focus on third country manufacturers	GMP/GDP IWG	Quality and Inspections
14	Enhanced legal powers against falsified medicines	WGEO GDP/GMP IWG EMACOLEX	Quality and Inspections
15	Use of EudraGMP and EDQM databse for product testing to share intelligence within Network	WGPT GDP/GMP IWG	Quality and Inspections
16	Efficiency of use of Official Medicines Control Laboratories for sample testing	WGPT	Quality and Inspections
17	Emerging areas of regulation – new technology (including medical devices, advanced therapy medicinal products, tissues and cells, novel foods, cosmetics)	ERMS FG TFIVL EMACOLEX	Emerging Issues New Technology
18	Best linkage between regulation and HTA – consultation with stakeholders	Polish presidency (in 2011)	Emerging Issues New Techno-logy
19	Closer engagement of HMA Group in considering medical devices strategy	HMA/CAMD/ CMC Steering Group	Emerging Issues New Technology
20	Availability of medicines issues – human and veterinary – including possible new legislation	AMWG TFIVL (EMACOLEX)	Emerging Issues New Technology
21	Publication of Summary of Product Characteristics (SPCs) for authorised products on national agency websites and/or Eudrapharm	NCAs, EMA TSG	Streamlining and Harmonisation
22	Devising better risk based, proportionate, efficient regulation which maintains public confidence	EMACOLEX TFIVL, EMA/HMA WG T	Emerging Issues / New Technology
23	Developing work-sharing across NCAs in regulation	WGQM TSG, HMP WG	BestPractice / Streamlining & Harmonisation
24	Harmonisation of clinical trials procedures and processes; creating an efficient and unified regulatory environment for clinical trials in Europe that encourages innovation and high quality research	CTFG	Clinical Trials
25	Implementation of revised Clinical Trials Directive	CTFG EMACOLEX	Clinical Trials
26	Work sharing approaches to assessment of clinical trials	CTFG	Clinical Trials

	Specific objective	Principal Working Group (s)	Work Area
27	Cooperation with EMA and Commission on common clinical trials regulatory environment and its promotion/communication	CTFG	Clinical Trials
28	Voluntary Harmonisation Procedure – implementation and streamlining	CTFG	Clinical Trials
29	Regulation of veterinary medicines, including consideration of the extent to which human and veterinary medicines legislation should diverge and active participation of HMA in modification of veterinary legislation (including medicated feeds)	TFIVL CMDv	Streamlining and Harmonisation
30	Strengthen collaboration with international agencies and resources applicable to veterinary medicines; align with European Technology Platform for Animal Health, OIE, Codex Alimentarius	ESS WG	Good Communication
31	To take steps to help reduce the development of antimicrobial resistance and help communicate policies on responsible use to healthcare workers	vAMR TF PhVWP(h/v) TFIVL	Emerging Issues/ New Technology
32	To consider whether a collaborative and proportionate arrangement for control clinical trials in food producing species is necessary.	CMDv TFIVL	Streamlining and Harmonisation
33	To gather information on unregulated areas for products used in animals and borderline areas and explore the need for proportionate regulation and co-operation in the network.	CMDv TFIVL	Streamlining and Harmonisation
34	Influence the development of revised legislation for feedingstuffs to ensure that it is risk based and addresses specific challenges of antimicrobials	TFIVL vAMR TF	Streamlining and Harmonisation
35	Build and strengthen regular communications with HMA stakeholders; ensure efficient interaction with pharmaceutical industry	WGCP	Good Communication
36	Developing the HMA web presence	WGCP	Good Communication
37	Crisis communication links – interactions between regulators	WGCP TSG	Good Communication
38	Optimum utilisation of resources	TF R in DCP WGQM BEMA SG	Best Practice
39	Making decentralised processes work better	CMDh/v WGQM TF R in DCP	Streamlining and Harmonisation
40	Extending new EU variation regulation provisions to national variations	CMDh/v	Streamlining and Harmonisation

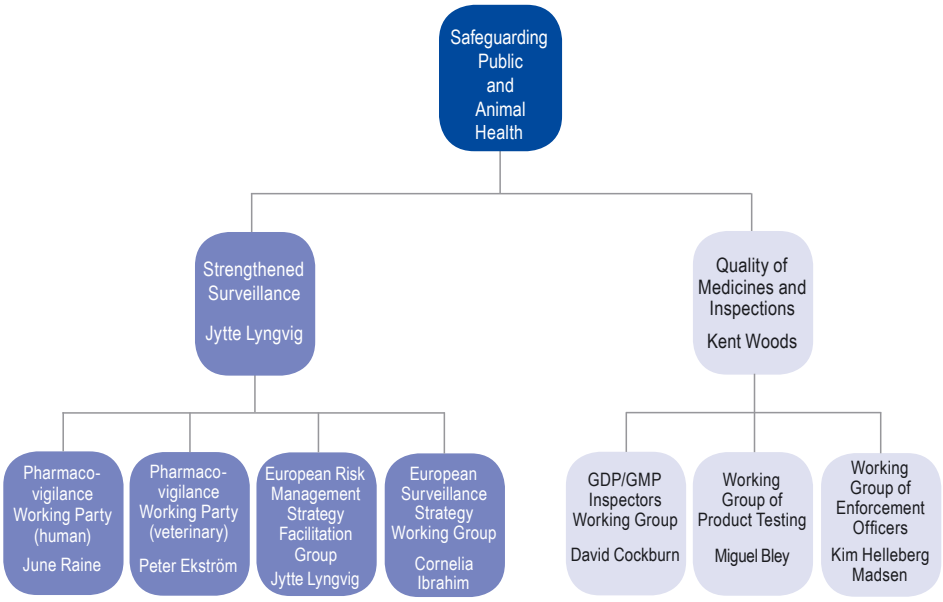
	Specific objective	Principal Working Group (s)	Work Area
41	Supporting new functionality bestowed on CMDh by strengthened pharmacovigilance legislation	CMDh TF R in DCP	Streamlining and Harmonisation
42	Providing more authorised medicines for children and implementation of paediatric regulation provisions	CMDh TF R in DCP	Streamlining and Harmonisation
43	Promoting work sharing and principle of fair distribution of work across the Network	CMDh/v TF R in DCP	Streamlining and Harmonisation
44	HMA Common Portal for MRP/DCP applicants	TSG	Information Technology
45	Promoting inter-operability of NCA systems with best use of telematics	TSG	Information Technology
46	Communications plan to ensure that stakeholders are provided with up-to-date information on telematics	TSG WGCP	Information Technology
47	Support of internal communications platforms for each working group of HMA	TSG WGCP	Information Technology
48	Further development for benchmarking of European medicines agencies (BEMA) programme	BEMA SG WGQM	Best Practice
49	Implementation of harmonised training strategy across network to improve quality and consistency, including harmonised interpretation of guidelines	OTSG	Steamlining and Harmonisation
50	Providing basic and specialised training to all staff members of competent authorities	OTSG	Streamlining and Harmonisation

Safeguarding Public and Animal Health

Theme Overview

This theme encompasses the cooperative efforts of the European Medicines Regulatory Network to maintain and improve European pharmacovigilance for human and veterinary medicines as well as ensuring that the supply chain of medicines remains of the highest quality. There are two work areas within this theme: (1) Strengthened Surveillance and (2) Quality of Medicines and Inspections.

The Strengthened Surveillance work area is led by Jytte Lyngvig of the DKMA (DK). The work is supported by the **Pharmacovigilance Working Party, human** (PhVWPh) which provides advice on the safety of human medicinal products and investigates adverse drug reactions to enable identification, assessment and management of risk. In 2012, a new organisation, the Pharmacovigilance Risk Assessment Committee (PRAC) will be mandated to cover all aspects of the risk management of the use of medicinal products in humans, including the detection, assessment, minimisation and communication of adverse reactions. **The Pharmacovigilance Working Party, veterinary** (PhVWPv) provides advice to the CVMP on the supervision and coordination of pharmacovigilance of centrally authorised veterinary medicinal products, as well as to the Member States for nationally authorised products or products authorised through the MRP or DCP. The **European Risk Management Strategy Facilitation Group** (ERMS FG) aims to develop a European Strategy for risk management, built on the NCA's resources and expertise, and incorporating the EMA's role in the coordination and the supervision of products authorised through the Community. The **European Surveillance Strategy Working Group** (ESS WG) is the initiative for a closer cooperation of EU member states and EMA in a pro-active approach to veterinary pharmacovigilance. This includes setting up strategies for continuous monitoring of products, further development of harmonised risk management strategies, risk communication, work sharing and resource optimisation.



The Quality of Medicines and Inspections work area is led by Kent Woods of the MHRA (UK). The work area includes the work of the **Working Group of Enforcement Officers** (WGEO), which ensures adherence to the regulation of the manufacturing and distribution chains of medicinal products, the disruption of illegal activities and the sharing of information relevant to enforcement operations. The **Working Group of Product Testing** (WGPT) is mandated by the HMA for quality and control product testing of MRP and DCP products. Major elements of its endeavours are the rational use of resources and a risk based approach to defining which medicinal products should be tested for the benefit of patients. The **Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group** (GMP/GDP IWG) provides input and recommendations on all matters relating directly or indirectly to GMP or GDP, irrespective of the marketing authorisation procedure, through different reporting lines to the European Commission, the EMA and the HMA. For the HMA, the GMP/GDP IWG takes responsibility for overseeing the Joint Audit Programme (JAP) as well as liaison and cooperation with the WGEO.

Photo: Bruno Ehrs

Strengthened Surveillance
Work Area Lead Update

Jytte Lyngvig
Work area lead for Strengthened Surveillance
Chief Executive of Danish Medicines Agency (DKMA)

The work area of Strengthened Surveillance covers pharmacovigilance activities for both medicinal products for human use and veterinary medicinal products.

Medicinal Products for Human Use

In this area the core priority of the work and also the designated priority area for 2011-12 is the implementation of the new pharmacovigilance legislation.
Members of the PhVWP , the ERMS FG and the WGCP have all contributed to the on-going implementation of the new pharmacovigilance legislation, through a dedicated governance structure relying on a Project Coordination Group and six project teams involving representatives from EMA, the Committee for Medicinal Products for Human Use (CHMP), CMDh and Member States.

Much still remains to be fully implemented but progress has been good throughout 2011 (e.g. technical contributions to draft EC Implementing Measures were prepared; transitional arrangements were proposed in relation to adverse drug reactions (ADR) reporting; the move from the Detailed Description of Pharmacovigilance (PhV) Systems to the PhV Master File and the preparation of several key reflection papers, including a reflection paper on the revised ADR definition).

Veterinary Medicinal Products

In the area of veterinary medicinal products, the main body of work in 2011 has been the incident management plan. Even though the incident management plan is not part of the specific objectives of the strategy implementation plan, the finalisation of the incident management plan covering all veterinary medicinal products irrespective of authorisation procedure strengthens surveillance of veterinary medicinal products and thereby will contribute to the realisation of HMA's vision.

The specific Strategy objectives on respectively a PhV master file and flexibility of PSURs submissions were fulfilled for the time being by their inclusion in an updated reflection paper on the improvement of veterinary pharmaceutical legislation that was sent to the European Commission.

The specific Strategy objective on raising ADR reporting levels by veterinarians and farmers was designated a priority area of Strengthened Surveillance in regard to veterinary medicinal products. Actions to implement the objective were discussed in detail and a number of actions are included in the European Surveillance Strategy Action Plan. Further discussion on the implementation of this priority action will take place at the ESS WG meeting in January 2012 and throughout 2012. Member States' input will at some point be requested to collect experience on what works or doesn't work to raise reporting levels.

Quality of Medicines and Inspections
Work Area Lead Update

Sir Kent Woods
Work area lead for Quality and Inspections
Chief Executive of MHRA , UK
Chairman of the EMA Management Group

The Quality of Medicines and Inspections work area covers a range of regulatory activity from the risk based deployment of inspections, the efficiency of product testing, to the detection of counterfeit medicines.

Enforcement

2011 has been a successful year in the campaign to combat counterfeit medicines. The international week of action against counterfeit medications, Operation PANGEA IV, was the largest yet and involved 27 WGEO member countries. The operation led to the seizure of 8000 packages and 5m Euros worth of counterfeit goods, as well as the taking down of 13,500 websites selling counterfeit medicines.

This year has also seen the adoption by WGEO of a five year strategy to complement the overall HMA Strategy. The WGEO strategy will include sharing experience and best practices for the European Union's Falsified Medicines Directive and Council of Europe (CoE) Medicrime Convention.

The Falsified Medicines Directive is aimed at tightening the EU/EEA medicine supply chain to prevent the penetration of falsified medicines. The CoE Medicrime Convention is the first international criminal law instrument against falsified medicines, criminalising the counterfeiting and unauthorised manufacture/supply of medicines and similar crimes.

Product Testing

2011 also saw the roll-out of a pilot project on the risk based selection of medicinal products for testing by the WGPT. This will enable the production of new guidance on risk based product testing in 2012.

Inspections

The necessity to conduct more inspections in third countries and the impact of new European legislation will place more pressure on resources. To help agencies coordinate their inspection efforts to third countries, and to reduce the burden on industry of duplicate inspections, we will introduce as a target for 2012 the adoption of a third countries planning module for EudraGMP, as proposed by the GMP/GDP IWG. A further step in this direction has been the publication of the IWG document on "Enhancing GMP Inspection Cooperation with the FDA" to reduce the number of duplicative US/EU inspections.

Closer to home, a central element in assuring the quality of HMA member's inspections programmes is the Joint Audit Programme (JAP). The effectiveness of this programme depends on all Member States making a contribution and it is essential that the resourcing of this programme is increased so that the JAP is conducting a minimum of five to six audits in Europe per year. During 2012, we will be considering closely the resourcing and performance of the JAP.

Priorities for 2012

As we look to 2012, we can expect another busy year for the Quality of Medicines and Inspections work area. As well as the establishment of a third countries planning module for EudraGMP, we will expect to see another round of the PANGEA work against counterfeit medicines and the roll-out of new product testing guidance. A key topic in the year to come will be the availability of resources, including for the Joint Audit Programme and for the implementation of the Falsified Medicines Directive.

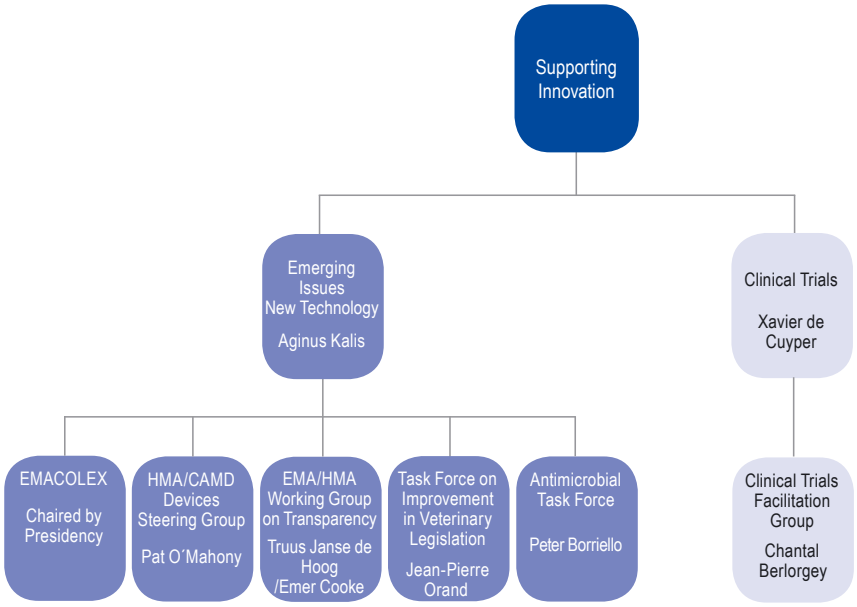
Supporting Innovation

Theme Overview

The Supporting Innovation theme considers the work of the HMA to ensure that Europe provides the best regulatory environment for the development of new treatments for humans and animals. The theme consists of two work areas: (1) Emerging Issues, New Technology and (2) Clinical Trials.

The Emerging Issues, New Technology work area is led by Aginus Kalis, Executive Director of CBG-MEB (NL). The **European Medicines Agencies Cooperation on Legal and Legislative Issues** (EMACOLEX) enhances knowledge, trust and confidence between legal staff and others involved in legal matters to ensure the best legal assistance to the EMRN and the individual national competent authorities. The **Task Force for Improvement in Veterinary Legislation** (TFIVL) works on all the HMA Strategy objectives relevant for a modification of the EU legislation regarding pharmacovigilance, availability, emerging issues, antimicrobial resistance, marketing authorisation and consideration of legislation in the human side. The main purpose of the TFIVL is: to identify by way of consensus the possible improvements of the veterinary legislation and regulation in a short, medium and long term; to propose changes in more detail for the revision of the veterinary legislation and regulation; and to flag other areas where a revision may be needed in the near future. The **HMA veterinary Antimicrobial Resistance Task Force** (vAMR TF) has been established to develop and then progress an action plan designed to deliver the HMA's veterinary strategy on antimicrobial issues. The **HMA/EMA Working Group on Transparency** works to achieve greater harmonisation, consistency and efficiency of National Competent Authorities on issues related to transparency. **The HMA/CAMD/CMC Steering Group,** formed in 2011, seeks to improve the cooperation between HMA and the European devices regulatory network.

The Clinical Trials work area is led by Xavier de Cuyper, Chief Executive of FAMHP (BE). The **Clinical Trials Facilitation Group** (CTFG) aims to foster a common approach to the regulation of clinical trials conducted in the EU. To this end, the CTFG establishes and improves communication channels within the EMRN and develops and promotes common processes and procedures relating to clinical trials within the scope and duties of the National Competent Authorities.



Emerging Issues, New Technology

Work Area Lead Update

Aginus Kalis
Work area lead for Emerging Issues, New Technology
Chair of the HMA Management Group
Executive Director of the Medicines Evaluation Board, Netherlands (CBG-MEB)

The Emerging Issues, New Technology work area covers a wide variety of topics regarding both human and veterinary medicinal products. The overall objective is to achieve more harmonisation and consistency among the Network in new areas of regulation and to use the resources and staff of the National Competent Authorities more efficiently.

Progress in 2011

A key emerging issue for 2011 has been the regulation of medical devices and the creation of a Steering Group on Devices involving the HMA and the Competent Authority for Medical Devices(CAMD) and devices Central Management Committee (CMC) networks, with two meetings in 2011 and four agreed workstreams. This cooperation will be further developed in 2012.

The role of Health Technology Assessment (HTA) in medicines regulation was made a key theme of the Polish presidency of the HMA in the latter half of 2011. Although there are significant differences in national approach to HTA between the HMA member states, many potential areas for interaction between regulatory assessment and HTA were identified.

The Task Force for Improvement in Veterinary Legislation has also been active in 2011, organising a focus group with stakeholders aiming to provide a shared vision for proposals for improvement in the future of the veterinary legal framework, and preparing the Reflection position paper of the HMAv, which was adopted by the HMAv during its July meeting and sent to the European Commission.

EMACOLEX has been progressing on legal issues during 2011 and has also made an overview of the possibilities for a legal basis for the HMA. Sessions have been held on transparency, advertising issues and transposition issues around the pharmacovigilance and falsified medicinal products directives.

The HMA/EMA Working Group on transparency worked extensively on achieving consistency of approaches to release of information, publishing a draft guidance for consultation in June.

Priorities in 2012

Transparency remains a vital issue in regulation and in 2012 the HMA/EMA Working Group on Transparency will finalise guidance on the identification of commercial confidential information and personal data in marketing authorisation applications, allowing HMA member states to move forward with making regulatory processes as transparent to public scrutiny as possible.

The work of the HMA on the issue of European devices regulation will progress, with HMA providing input to the European Commission's work on the recast of the medical devices legislation in 2012. Consideration will also be given to more formal cooperation with the HMA network and the CAMD/CMC.

On the side of the veterinary legislation, the Task Force for Improvement in Veterinary Legislation will provide input on the revised veterinary and feedingstuff legislation, which is due to be published by the Commission at the end of 2012.

Clinical Trials

Work Area Lead Update

Xavier de Cuyper
Chief Executive of FAHMP, Belgium
Work area lead for Clinical Trials

Core priorities of work in 2011 – Priorities of the Work Plan

The core priorities of the Clinical Trials Work Plan in 2011 were to promote active participation of Member States in the Voluntary Harmonisation Procedure (VHP) and also the implementation of worksharing of clinical trials safety information. Other priority items were the use of risk based approaches to simplifying the processes and assessment of clinical trials; improved transparency and communication to stakeholders; improvement of information systems to facilitate worksharing and simplify processes; and the effective allocation of resources by the use of Vitero to improve networking and enhance expert's participation.

Progress and development – Achievements in 2011

In 2011 we have seen increased acceptance and efficiency of the VHP, with a total of 97 applications (2009–2011) of which more than 50 were in the first six months of 2011. There were an average of six participating member states (P-NCA) per VHP with an average 50.4 days for CTFG assessment of CT applications, and the introduction of reference NCA and possible co-reference states.

Other achievements included: the introduction of clinical trials safety common assessment; a pilot phase of Annual Safety Reports Voluntary assessment allowing sharing of experience and best practice; publication of Questions and Answers on frequently asked questions; and establishment and publication of a draft concept paper on a risk based quality management system, together with the Good Clinical Practice Inspectors Working Group (GCP IWG).

Added value and impact of the HMA network

The Clinical Trials Facilitation Group is progressively achieving regulatory consistency in the European Union by developing a harmonised view on the interpretation of the legislation and a harmonised project for the future legislation on Clinical Trials in the EU. In addition, scientific consistency in the EU is being achieved through the development and enhancement of VHP and development of safety data worksharing.

Targets and priorities for 2012

There will be four priorities in 2012 : (1) active participation and preparation for the revision of the clinical trials directive; (2) to continue to promote and improve the VHP and develop Standard Operating Procedures; (3) to increase Development Safety Update Report (DSUR) work sharing; (4) to develop and use appropriate IT tools to efficiently share information.

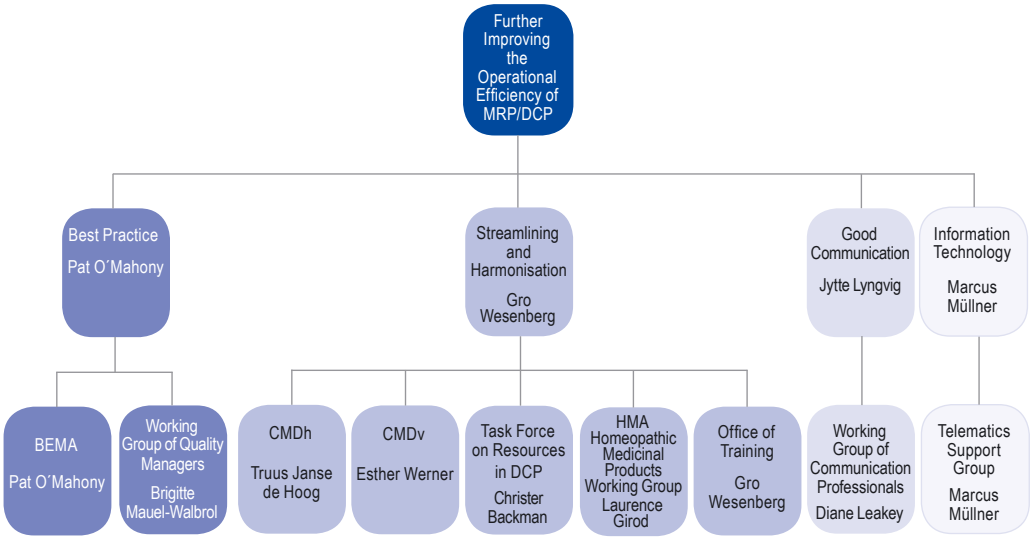
Further Improving the Operational Efficiency of MRP/DCP

Theme Overview

This theme is dedicated to ensuring the smooth functioning and commitment to best practice of the decentralised and mutual recognition procedures. The theme has four work areas: (1) Best Practice, (2) Streamlining and Harmonisation, (3) Good Communication and (4) Information Technology.

The Best Practice work area is led by Pat O'Mahony, Chief Executive of IMB (IE). The **Benchmarking of European Medicines Agencies Steering Group** (BEMA SG) works to develop and agree on a number of high level indicators, supported by specific performance indicators, to achieve the best practice standards; to define procedures and methodology for self assessment and assessment; to coordinate information gathering activity; to validate outcomes through peer review; and to make recommendations to HMA for an approach to continuous quality improvement, and EU wide implementation in the future. The **HMA Working Group of Quality Managers** (WGQM) provides guidance related to quality management and best practice benchmarking, and operates to improve the exchange of quality management expertise.

The Streamlining and Harmonisation work area is led by Gro Wesenberg, Chief Executive of Statens legemiddelverk (NO). The **Coordination Group for Mutual Recognition and Decentralised Procedures (human and veterinary)** (CMDh, CMDv) considers points of disagreement raised by Member States during Mutual Recognition and Decentralised procedures, in relation to the assessment report, Summary of Product Characteristics (SPC), labelling and package leaflet of a medicinal product (human or veterinary), as related to new applications, variations and renewals.



The **Task Force on Resources in DCP** was established with the aim of analysing the availability of resources in National Competent Authorities for acting as Reference Member State (RMS) in MRP and DCP procedures. This initiative was due to the difficulties for NCAs in providing industry with slot times, mainly in the DCP, a fact which had been heavily criticised by pharmaceutical companies and trade associations. The Task Force was to identify the problem areas and prepare recommendations. The **Joint HMA/EMA Office of Training Steering Group** (OTSG) is a group of experienced assessors and regulatory experts from HMA and EMA, mandated to provide harmonised, high quality training and to manage the creation of the EU Office of Training, as well as providing strategic guidance to its subsequent operation. The **HMA Homeopathic Medicinal Products Working Group** (HMP WG) is a forum for the exchange of regulatory and scientific expertise regarding the assessment of the quality and safety of homeopathic medicinal products in the Member States.

The Good Communication work area is led by Jytte Lyngvig, Chief Executive of DKMA (DK). The HMA **Working Group of Communication Professionals** (WGCP) is set up to promote best practice and to improve communications across the Network and its stakeholders (e.g. patients, doctors, veterinarians, the pharmaceutical industry) and the general public (including the media).

The Information Technology work area is led by Marcus Müllner, Chief Executive of AGES PharmMed (AT). The **HMA Telematics Support Group** (TSG) facilitates communication between European and national IT systems and gives advice on other IT activities undertaken by the EMRN.

Photo: Christer Backman

Best Practice

Work Area Lead Update

Pat O'Mahony
Work area lead for Best Practice
Chief Executive of Irish Medicines Board

Established core priorities

BEMA III, the third benchmarking cycle, is being developed to improve the process of sharing best practices among medicines agencies and provide assurance that they are developing in line with the HMA Strategy, and making a contribution relative to their size and stage of development. Other improvements include the work of the Working Group of Quality Managers (WGQM) on sharing experience and best practices for quality management systems and devising a new five year WGQM workplan.

Progress and development to date

A substantial review of the benchmarking programme was undertaken in 2011, taking into account the HMA Strategy, experience from earlier cycles and feedback from agencies and BEMA assessors. Some of the points from the HMA Strategy have been added to the new questionnaire, which also streamlines previous indicators, removes redundant ones, and clarifies requirements. The new BEMA III questionnaire covers management systems, interfaces, scientific decision-making, impact of scientific work, pharmacovigilance audits, and inspections. The rating system has been changed to provide a better guide to the standard required for each rating level and to focus more on the effectiveness of the systems and processes in place. A new database is being developed to allow tracking, uploading of reports and searches.

A summary of the findings of the first half of the BEMA II visits was issued in July. During the year, agencies agreed to reduce national requirements for marketing authorisation applications in the mutual recognition and decentralised procedures and to harmonise and simplify validation requirements.

In July, a paper was prepared for the European Commission proposing changes to the veterinary legislation. Specific measures included simplifying the authorisation process and reducing the administrative burden for animal health companies, while still maintaining proportionate safeguards for public and animal health.

Developments adding value and impact to the network

The interim report from the second BEMA cycle indicates the status of the network in relation to the key performance indicators. This report also provides a valuable resource on best practices that individual agencies can use for future reference.

The indicators and rating maturity statements for the third cycle should help provide agencies with new standards for appropriate levels of management and scientific work.

Improvements and standardisation in the mutual recognition and decentralised procedures will also help make these applications easier to submit and more efficient to process.

Targets and priority areas for 2012

The priorities for 2012 are to finalise the questionnaire for the third BEMA cycle by February, agree the implementation of the outcomes, complete the training of new assessors and start visits by October. The quality managers will help ensure that agencies have the knowledge and skills to manage their self-assessment and benchmarking visit. There is also a target to issue the final report of the second BEMA cycle by September.

Within the mutual recognition and decentralised procedures implementation of the simplifications agreed during 2011 will be monitored and more areas for work-sharing will be examined.

Streamlining and Harmonisation

Work Area Lead Update

Gro Wesenberg
Work area lead for Streamlining and Harmonisation
Chief Executive of Statens legemiddelverk, Norway

The Streamlining and Harmonisation work area focuses on improving the ability of the Network to operate the decentralised and mutual recognition procedures, through optimisation of processes, consistency of approach, best use of resources and the provision of excellent training.

Resources in DCP/MRP

The work of the Task Force on Resources in DCP/MRP this year has highlighted the need to improve transparency on the availability of slots for DCP applications and there has been a reduction in the number of complaints from industry about a lack of slots in DCP. Furthermore, the number of national requirements for marketing authorisation applications has been reduced. Dialogue will continue with industry, through the Task Force, to further improve the DCP procedure. In February 2011, for example, the CMDh established a new task force to make MRP/DCP more attractive to the self-medication sector.

Future of CMDh

The new Pharmacovigilance Directive will give CMDh extra responsibilities and to prepare for this CMDh has established a working group on the future of CMDh. The implementation plan of this group was agreed in June 2011.

Veterinary issues

Progress has been made on borderline products issues, with the CMDv establishing a dedicated working group on borderlines, which has identified a European Borderline Assessment Network(EUBAN) and created a list of contact points in each Member State. CMDv has also commenced a project to achieve the harmonisation of SPCs with a pilot procedure commenced in 2011. An additional area identified for harmonisation is product packaging. A harmonised packaging system would improve multilingual label conditions, decrease manufacturing cost and increase the availability of veterinary medicinal products in smaller markets. Progress on this, including recommendations for a revision of veterinary legislation, is expected in 2012.

Training

2011 has been the first year of operation of the Office of Training Steering Group (OTSG) and already a great deal has been achieved. As a first step towards harmonisation for training, an inventory of all training available from the National Competent Authorities and the EMA has been assembled and distributed. The web page has also been revised. 2011 has also seen a particular focus on the training needs of Quality Assessors, with a pilot project in this area completed and endorsed by the HMA.

Priorities in 2012

The Task Force on Resources in DCP will continue to encourage a reduction in national requirements through HMA and CMDh. On the veterinary side, 2012 will see a review and discussion of the European Commission report on better regulation of veterinary medicines and CMDv will play an active role in advising on any proposed changes to the Veterinary Directive. Within training, the work of the OTSG will be further expanded in 2012 with the compilation and prioritisation of new requests for competence requirements; cooperation with the EMA on new training methods such as webinars; and exploration of joint work with the Innovative Medicines Initiative (IMI).

Good Communication

Work Area Lead Update

Jytte Lyngvig
Work area lead for Good Communication
Chief Executive of Danish Medicines Agency (DKMA)

In order for the HMA to deliver its strategy it must communicate effectively both with its internal and external stakeholders. Communication is by its very nature a two-way process and when delivered effectively it helps ensure that the HMA's Strategy evolves and continually improves following feedback from its stakeholders, and that stakeholders understand the HMA's objectives and are in a position to help deliver these.

Progress in 2011

With the HMA being primarily a virtual organisation, good communication is the 'glue' that helps bind it together. Bearing these aims in mind the key priorities for developing good communication over the past year were therefore to refocus the current HMA's website, improve the HMA's interactions with its stakeholders, develop internal communication channels and produce procedures and protocols for handling communications in a crisis. Help was also asked during the year in delivering the commitments to the forthcoming pharmacovigilance legislation.

Communication has helped the HMA focus on its primary stakeholders i.e. industry and other National Competent Authorities. A brochure was produced for the Drug Information Association (DIA) conference in Chicago helping explain the role of the HMA. A plan was also drawn up to refocus the web site in two stages. The first stage is to update and edit the current content with a second phase to make the site more user friendly and accessible.

An internal website has been produced for collaboration and communication within the group but usage is still low. However the sharing and discussions over this platform for the development of procedures in media relations and crisis management did work.

Priorities for 2012

By far and away the most value good communications brings is the sharing of best practice. An example is the rapid development of digital media and the potential it offers. Shared experience across the communications network by those who have already started to use this medium has helped others to learn and try it out for themselves. This is an example where good communication across the network has both strengthened it and helped with co-ordination.

Priorities for the coming year are ensuring commitments to the forthcoming pharmacovigilance legislation are delivered across the network and work continues on delivering a refocused website for the HMA.

Information Technology

Work Area Lead Update

Marcus Müllner
Work area lead for Information Technology
Chief Executive of AGES PharmMed (Austria)

The two major components of the HMA's IT work in 2011 has been on the IT communications plan and the work on the Common EU Submission Platform (CESP).

IT Communications Plan

This plan is a joint project with the Working Group of Communications Professionals (WGCP). The IT Communication Plan will be a periodic means to update the HMA about the benefits of EU IT projects, the impact of these on individual National Competent Authority's IT development, the current state of play and the future outlook. In 2011 the first draft of the plan was circulated to the Telematics Support Group and received input from the WGCP.

CESP project

For 2011 the core priorities for the Common EU Submissions Platform project has been to proof the technical feasibility and set the requirements for a first production version of the CESP system.

Initiated by the TSG in March 2011, two face to face meetings were organised, one strategic and one technical. Both meetings involved representatives from the NCAs, the EMA and the pharmaceutical industry. A proposal was agreed to ask the HMA for endorsement to start a Proof of Concept (POC) for CESP. This was endorsed by the HMA in April 2011 and the POC system was created by the Irish Medicines Board (IMB) over the summer period. In September and October, 22 pharmaceutical companies and 14 NCAs have been testing the POC system. The results and conclusion were discussed in a face to face meeting in October and proposed next steps were presented to, and endorsed by, the HMA meeting in November 2011 in Poland.

The result of the POC were very encouraging. Both Industry and NCAs are satisfied with the results and want to continue the CESP initiative with moving the POC to a next level where it can be used as a real production system. Presentations and demonstrations were shown at the CMD(h), the Telematics Implementation Group for electronic submission (TIGes) and Eudrapharm Telematics Implementation Group meetings. All groups confirmed that CESP will be a major and important improvement to our current environment and specifically will strengthen the position of the MRP/DCP procedures within the regulatory network.

Targets and priority areas for 2012

For the IT communications plan, the main target in 2012 is for the TSG and HMA to agree on and ratify a finalised plan. Following this, an information toolkit will be compiled and maintained, with access via the HMA website.

The main target for 2012 for CESP is to move towards a full production solution. For that two major subtasks have been identified : (1) building the technical solution including gathering all the technical and functional requirements with a focus to keep it simple and (2) to come up with a model for the governance and financing of the solution. HMA will be updated through the Telematics Support Group reports on progress and developments around CESP.

Progress Reports on Specific Objectives of Strategy

Strategy Objective	Achievements 2011	Priorities 2012
(1) Improve on variation between Member States in spontaneous reporting of adverse drug reactions (ADRs); through education, motivation, facilitation, promotion and forthcoming pharmacovigilance legislation.	European Risk Management Strategy Facilitation Group (ERMS FG) has proposed and endorsed transitional arrangements in relation to ADR reporting and the move from a Detailed Description of Pharmacovigilance Systems (DDPS) to the Pharmacovigilance Master File and is developing a Reflection Paper on revised definition of an ADR. The PhVWP(h) informal meeting in October included a workshop on patient reporting and the annual two-day training for assessors in November addressed signal detection in Member States.	ERMS FG will provide clarification for Member States on the revised definition of an ADR. Under the programme of work for the new pharmacovigilance legislation, information on web based ADR reporting forms will be shared; and a suite of documents is proposed by PhVWP(h) to explain the new pharmacovigilance provisions to healthcare professionals and the public.
(2) Improve safety profile of vaccines and antivirals and implementation of real-time signal detection.	PhVWP(h) contributed to the influenza pandemic “lessons learned” exercise, including the importance of exposure data in Member States and background event data, and participated in updating the core Risk Management Plans.	On the basis of the lessons learned during the H1N1 influenza pandemic, the PhVWP(h) will contribute to enhanced plans for pharmacovigilance of vaccines via the EMA Pandemic Task Force.
(3) Good pharmacovigilance practice and systems efficiency, data quality (metrics).	The PhVWP(h) has contributed to all the Good Vigilance Practice modules drafted under the new pharmacovigilance legislation and has convened ad hoc drafting groups to address key issues. Working Group of Quality Managers (WGQM) has been sharing experience and best practice for Quality Management Systems and the new pharmacovigilance legislation.	The main priority for PhVWP(h) in 2012 is to complete the second wave of Good Vigilance Practice modules, to consider the responses to consultation and to sign off the guidance in time for introduction of the new legislation in July 2012. WGQM will review pharmacovigilance system requirements for the implementation of the new legislation and the integration in the existing quality management systems.

Strategy Objective	Achievements 2011	Priorities 2012
(4) Integration of new methodologies into pharmacovigilance systems; raise standards of pharmacovigilance across Network to complement further development of Eudravigilance by EMA.	PhVWP(h) has completed a successful pilot of signal detection with Member State participation. Bilateral meetings have been held with CMDh to consider key aspects of the new pharmacovigilance legislation for nationally authorised products. The main work of the ERMS FG relates to the implementation of the PhV legislation and its role as the Project Oversight Committee for implementation of new pharmacovigilance legislation. ERMS FG received progress updates from the Project Co-ordination Group and has overseen tracking of major items. Draft technical contributions to Implementing Measures and Reflection Papers were agreed and there was proactive planning to ensure HMA kept up to date on progress.	In 2012, PhVWP(h) will roll out the signal detection procedures for all Member States, with the inclusion of key performance indicators. The ERMS FG will continue to oversee implementation of the legislation taking into account the budgetary constraints; and to consider and agree transitional arrangements for other areas of the legislation.
(5) Benefit/risk communication, transparency and patient engagement.	The PhVWP(h) has published regular monthly reports of its safety reviews of nationally authorised products. A dedicated drafting group has received all Direct Healthcare Professional Communications, and communication plans have been prepared for key items in accordance with a specific template to ensure consistency. Patient observers are present at all meetings, and the PhVWP(h) has consulted the Patient and Consumer Working Party on particular communications for patients. The WGCP entered a dialogue with the EMA on the implementation of the forthcoming pharmacovigilance legislation with respect to transparency; setting up a new initiative on public hearings; co-ordination of safety messages; and an audit on what information should be on national competent authority's websites.	The PhVWP(h) will continue to work on patient and public engagement, and co-ordination of safety messages in the context of preparing Good Vigilance Practice guidelines. WGCP will assist member states in implementing the requirements for the new pharmacovigilance legislation, particularly those in relation to communication. HMA/EMA working group on transparency will provide input to the transparency discussions in context of new Pharmacovigilance legislation.
(6) Influencing development of revised EU legislation on veterinary pharmacovigilance to ensure that a pharmaco-vigilance master file system is introduced.	The Task Force for Improvement in Veterinary Legislation (TFIVL) linked with the European Surveillance Strategy Working Group (ESS WG) for a review of veterinary legislation, in particular which elements from new human pharmacovigilance legislation would suit veterinary legislation.	TFIVL will produce a position paper on the draft regulation provided by the Commission (Draft announced for Q4 2012 or Q1 2013).

Strategy Objective	Achievements 2011	Priorities 2012
(7) Strengthening regulatory sanctions to ensure that veterinary Marketing Authorisation Holders (MAHs) meet vigilance responsibilities for their products, using guidance, regulatory powers and pharmacovigilance inspections.	At HMA Warsaw in July 2011 the HMA concluded a discussion on a common document, elaborating on various aspects to be considered by the European Commission in the forthcoming process of revision of the EU veterinary legislation. The paper is now published on the HMA website. HMA also adopted a Veterinary Incident Management Plan (IMP) for Veterinary Medicines to be applied in a two year pilot phase.	Pilot phase for veterinary IMP to continue. TFIVL will produce a position paper on the draft proposal of the Commission.
(8) Raising adverse drug reaction (ADR) reporting levels by veterinarians and farmers.	The veterinary Pharmacovigilance Working Party (PhVWP(v)) initiated the development of a reflection paper on risk/pharmacovigilance communication.	Raising ADR reporting levels by veterinarians and farmers has been designated a priority area of Strengthened Surveillance in regard to veterinary medicinal products. Actions to implement the objective were discussed in detail and a number of actions are included in the European Surveillance Strategy Working Group Action Plan. Further discussion on the implementation of this priority action will take place at the ESS WG meetings throughout 2012. Member States' input will at some point be requested to collect experience on what works or doesn't work to raise reporting levels. PhVWP(v) will continue the development of the reflection paper on pharmacovigilance communication.

Strategy Objective	Achievements 2011	Priorities 2012
(9) Simplifying veterinary reporting process; taking forward development of EudraVigilance (EV) Vet and systems for electronic ADR reporting.	The Committee for Medicinal Products for Veterinary use (CVMP) recommendation for the basic surveillance of EudraVigilance Veterinary (EVVet) data (EMA/385081/2010) was adopted in February 2011 and implemented in August 2011. PhVWP(v) provided advice to the Joint Implementation Group (JIG) for the continued development of EVVet 3 via the EVVet Vet JIG technical advisory group. The annual review of the second revision of the Combined VeDDRA List of Clinical Terms for Reporting Suspected Adverse Reactions in Animals and Humans to Veterinary Medicinal Products (EMEA/CVMP/10418/2009), and also the List of Species and Breeds (EMEA/CVMP/553/03), was undertaken. Good progress was made to develop the concepts for a risk or pharmacovigilance based approach and signal detection methods for surveillance of veterinary medicinal products.	PhVWP(v) will promote and develop the use of EudraVigilance Veterinary (EVVet) and the EVVet DataWarehouse in case of non-urgent safety reports and rapid alerts and for the systematic monitoring of adverse events in particular for the surveillance of Non-Centrally Authorised Procedures. PhVWP(v) will continue to elaborate on principles for a risk/pharmacovigilance based approach to, and signal detection for, surveillance of veterinary medicinal products, for the update of the CVMP recommendation for the basic surveillance of EV Vet data. PhVWP(v) will continue supporting EMA in the development of EV VET3 together with the EVVet Joint Implementation Group.
(10) Releasing resources by increasing the flexibility of periodic safety update reports (PSUR) submissions.	HMA agreed, at its Budapest February 2011 meeting, on the measures for further improvement on the PSUR worksharing in the framework of European Surveillance Strategy. There was an agreement that all Member States should act at least once a year as Member State in charge of making the PSUR assessment report (P-RMS). HMA was asked to promote the existence of the work sharing system to Marketing Authorisation holders nationally.	
(11) Protect public health through inspections and laboratory control of all stages of the pharmaceutical supply chain, human and veterinary.	Proposals have been drawn up to share inspection planning information via EudraGMP in order to make best use of resources in National Competent Authorities and industry.	The GMP/GDP Inspectors Working Group (IWG) has requested from HMA resources to develop the IWG programme. Priorities will include developing the planning facility within EudraGMP, including a third countries planning module; and developing a risk assessment template for wholesalers and brokers.

Strategy Objective	Achievements 2011	Priorities 2012
(12) Develop a coordinated response to the risk of counterfeit medicines; cooperation within Network, industry and other agencies to share intelligence and inspection data; cooperation between National Competent Authorities, other authorities, police, customs etc.	Operation PANGEA IV, a week of action against internet sale of counterfeit and illegal medicines, supported by the Working Group of Enforcement Officers (WGEO), is now in its fourth year and coordinated by INTERPOL. 81 countries (including 27 WGEO member countries) and 165 agencies participated; over 45,000 packages were inspected and 8 000 packages seized containing 2.5 m doses of counterfeit medication(approx value 5 m Euros); in addition 13,500 websites were taken down WGEO also prepared a 5 year Strategy, discussed in Warsaw, October 2011, and with a final paper to be tabled in Jan 2012. This includes sharing experience and best practices for Falsified Medicine Directive and Council of Europe Medicrime Convention (opened for signature October 2011). A specific training internet seminar and written guidance for conducting basic internet investigations was presented. The WGEO Rapid Alert System to alert members of threat products discovered in the illicit supply chain in the EU/EEA was used 40 times in 2011. A survey of incidents of counterfeit medicines discovered in the legitimate EU/EEA supply chain 2005-2010 was completed. This will be followed by a communication strategy for handling survey data dissemination, being developed with HMA WGCP.	Specific aims of the WGEO 5 year strategy include: coordinating a common understanding of definition of Falsified Medicines in Europe; developing a Communication Strategy with HMA WGCP on dissemination of counterfeit medicines data from the EU/ EEA legitimate supply chain 2005-10; developing a risk assessment template for wholesalers and brokers; developing best practices on controlling imports for exports; continuing to coordinate action against on-line sale of medicinal products (PANGEA); developing guidance on web-site take-down; developing a range of measures that target falsified medicines in Europe; promoting information sharing, within Europe and internationally; promoting and organising training, including an enforcement field manual; developing expertise in enforcement issues related to cells, tissues and advanced therapies.
(13) Risk-based redeployment of inspections leading to greater focus on third country manufacturers.	Activities started on enhanced co-operation between GMP/GDP Inspectors Working Group (IWG) and the US Food and Drug Administration (FDA) as a reciprocal arrangement. This is focused on Centrally Authorised Products (CAPs) with the intention, starting in 2012, of reducing the number of inspections of CAPs by EU NCAs in the USA. GMP/GDP IWG has also been working on: enhancing active pharmaceutical ingredient (API) inspection planning and co-operation between EU Member States, FDA and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme (PIC/S); proposals discussed on using GMP inspection information generated by international partners of the EU; and further co-operation between IWG and PIC/S.	Within the Quality and Inspections work area, a target for 2012 is the funding and rollout of the EudraGMP planning module. This will allow NCAs to log future in-spections of third country sites, and view those of other NCAs, enhancing coordination/ col-laboration. Regarding reciprocal inspections arrangements, consideration will be given to extending the cooperation between EU and FDA beyond centrally authorised products, to other routes (national, MRP and DCP).

Strategy Objective	Achievements 2011	Priorities 2012
(14) Enhanced legal powers against falsified medicines.	Since the Falsified Medicines Directive was published, 33 individual areas of activity have been identified by the GMP/GDP IWG. Most relate to GMP and GDP areas and have been added to IWG's work plan. Activities have been set out in three levels of priority in agreement with DG Sanco/European Commission.	GMP/GDP and WGEO will aim to coordinate a common understanding of the definition of Falsified Medicines in Europe and focus on activities required to be in place by the first legislative milestone (2nd January 2013). Activities requiring subsequent legislation (e.g. safety features) will be added to the GMP/GDP IWG work plan.
(15) Use of EudraGMP and European Directorate for the Quality of Medicines & Healthcare (EDQM) database for product testing to share intelligence within Network.	The HMA in its November 2011 meeting at Sopot agreed to the continuation of the Memorandum of Understanding for EDQM access to data from the Communication and Tracking System (CTS) for the EDQM's MRP/DCP Product Market Surveillance Programme database and in the framework of the EDQM's certification of suitability to the monographs of the European Pharmacopoeia activities.	Working Group of Product Testing (WGPT) will set up the EU Product Testing Interface project (along with HMA Telematics Support Group).
(16) Efficiency of use of Official Medicines Control Laboratories (OMCLs).	WGPT has launched a pilot project on risk-based selection of MRP/DCP medicinal products for testing. Phase I of the pilot, on quality assessor's risk factor identification, has started. The requirements for Phase II, inspector's and OMCLs risk-based assessment of outstanding risk-factors for the selection of MRP/DCP authorised products for testing, have been completed.	WGPT will complete pilot results analysis and present to HMA. This will lead to drafting of new guidance on risk based selection of MRP/DCP medicinal products for testing by the relevant regulatory Working Groups, following on from pilot project outcome.
(17) Emerging areas of regulation – new technology (including medical devices, advanced therapy medicinal products, tissues and cells, novel foods, cosmetics).	**Devices:** see objective **(19)** **Advanced Therapy Medicinal Products:** New guidance for advanced therapy medicinal products was drawn up by the GMP/GDP Inspectors Working Group (IWG) in accordance with Article 5 of the ATMP Regulation. The entire text of EU GMP Annex 2 was revised and new and updated guidance on the full range of biological medicinal products was provided.This text is now with the Commission for final review and will be published in Eudralex Volume IV in 2012.	**Veterinary (TFIVL):** TFIVL will produce a position paper for the Commission, reflecting on which new technology should be regulated and how it should be regulated(Q1-2).

Strategy Objective	Achievements 2011	Priorities 2012
(18) Best linkage between regulation and HTA, including consultation with stakeholders.	The Polish presidency held a session on "Defining the linkage between Regulatory Assessment(RA) and Health Technology Assessment(HTA)" at the HMA meeting in Warsaw in July 2011. This identified areas where improvement is needed and recognised national differences requiring some further reflections. Also discussed were interactions between RA and HTA and scope for joint work such as EPARs, PARs;scientific advice; clinical guidelines; SmPCs and PILs; and pharmacovigilance.	A follow up agenda item has been arranged for the February HMA meeting to continue work on this issue.
(19) Closer engagement of HMA Group in considering medical devices strategy.	During 2011 much progress was made in further developing co-operation between the HMA and the existing medical device networks i.e. Competent Authority for Medical Device (CAMD) and the Central Management Committee (CMC) for medical devices. A steering group on developing this cooperation with representatives of HMA, CAMD and CMC was established in 2011, chaired by Pat O'Mahony (HMA). Two workshops were held between HMA and medical device authorities (CAMD and CMC) hosted by the Hungarian presidency (April 2011) and Austrian AGES Pharmed (September 2011). Agreed workstreams: (1) Cooperation between the HMA and CAMD/CMC networks – areas for cooperation, benefit & challenges, support structures, role in regulatory framework for devices. (2) Funding and resourcing of the medical devices regulatory network – optimising resource, funding key activities, alternative fee structures. (3) Drug-device combination and borderline products – decision making, qualification, classification, effective regulatory assessments. (4) Clinical research of healthcare products – exchange of experience and best practices, effective assessment of combination products	Following on from progress updates to the HMA and CAMD meetings and feedback and advice from the members and the steering group, priorities for 2012 will include: (1) to further develop this cooperation. Key detailed aspects of the cooperation, structural development and support are all for further discussion and agreement. (2) to further develop discussions and proposals of optimising funding and resourcing of the medical devices regulatory network. (3) to explore the possible role of any formal cooperative structure established in the current and future regulatory frameworks for healthcare products. (4) to develop work started in workshop subgroups on drug-device combinations and on clinical research. Subgroups will continue to explore topics of mutual interest. (5) the Polish Presidency has kindly agreed to host up to two HMA-CAMD/CMC workshops during 2012 if required. (6) It was proposed at the workshop in Vienna to hold a joint session of the HMA and CAMD in Dublin in January 2013 and that this may be the target date for initiating a formal cooperation between the two networks.

Strategy Objective	Achievements 2011	Priorities 2012
(20) Availability of medicines issues – human and veterinary – including possible new legislation	The HMA established a task force to research the availability of medicines on the human side in February 2007. The follow-up to the action plan and the updated report and proposals were presented at HMA Budapest in February 2011. The HMA noted the summary of the work and agreed on the recommendations and closing down the Task Force. The Task Force for Improvement in Veterinary Legislation adopted the *Reflection Position Paper of the HMAv* and sent it to the European Commission.	The Task Force for Improvement in Veterinary Legislation will consider the Commission's impact assessment. The HMA will also make more specific proposals concerning the revision of the legislation. TFIVL will produce a position paper on the draft regulation provided by the Commission (Draft announced for Q4 2012 or Q1 2013).
(21) Publication of SPCs for authorised products on national agency websites and/or Eudrapharm	At HMA Budapest February 2011 the HMA supported the CMDv Annual Work programme and the SPC harmonisation project, which included a pilot procedure for harmonisation of SPCs.	A task-force of HMA and EMA members will provide a businessplan with several options to HMA. Once HMA has reached a conclusion on the most appropriate way forward, a project to plan the next steps (including finance and governance) will be started.
(22) Devising better risk based, proportionate, efficient regulation which maintains public confidence.	HMA/EMA WG on Transparency has met three times in 2011. In addition, they organised in March a meeting where representatives from all Member States were invited to discuss the Guidance paper on identification of Commercial Confidential Information (CCI) and Protection of Personal Data (PPD) in Marketing Authorisation applications. A consultation procedure document for EU NCAs to follow when third parties request access to assessment reports that have been written in the context of an European procedure involving more than one Member State, was agreed and sent to HMA for endorsement. A Guidance document *"HMA/EMA Guidance on the identification of commercially confidential information and protection of personal data in the Marketing Authorisation Application (MAA)"* has been drafted and presented to HMA. A public consultation started afterwards and comments from 24 organisations were received. The comments have been discussed in two meetings. They have been supportive and relevant.	HMA/EMA WG on Transparency: Planned Actions in 2012 (1) Finalisation of Guidance Document on the identification of CCI and PPD in MA application. (2) Meeting with Interested parties to explain the Guidance document. (3) Discussion in ICH/other global regulatory authorities on possibilities to create a format of the dossier without confidential data. (4) Organisation of workshop to present case studies on the handling of requests from the Cochrane Institute. (5) Input to transparency discussions in context of new Pharmacovigilance legislation. In 2012 consideration will be given to developing, with EMA, general guidance on which sections of a veterinary dossier may be releasable.

Strategy Objective	Achievements 2011	Priorities 2012
(23) Developing work-sharing across NCAs in regulation.	In November 2011 the Homeopathic Medicinal Products Working Group (HMP WG) provided a Renewal Application Form. The WG has also been developing worksharing on homeopathic use and safety and is working on a list of 100 stocks with justified homeopathic use.	WGQM will evaluate methods for Risk Management. The HMP WG will continue to work on the list of 100 stocks with justified homeopathic use; promote information sharing in Europe; develop guidance on assessment of homepathic use; and coordinate a common understanding of homeopathy.
(24) Harmonisation of clinical trials procedures and processes; creating an efficient and unified regulatory environment for clinical trials in Europe that encourages innovation and high quality research	CTFG have introduced a Clinical Trials safety common assessment, with three internal pilots of Annual Safety Report Voluntary assessment by some Member States, allowing sharing experience and best practice (common AR template). In addition, CTFG have published a 'Frequently Asked Questions' guide to Clinical Trials safety assessment.	CTFG will promote and organise training on the more frequent issues and continue to promote best practice and harmonisation on regulatory and scientific issues.
(25) Implementation of revised Clinical Trials Directive.		CTFG will participate and prepare actively the revision of the Clinical Trials directive.
(26) Work sharing approaches to assessment of clinical trials	CTFG have established and published a draft concept paper on a risk based quality management system, together with the Good Clinical Practice Inspectors Working Group. Procedures of interactions with CHMP and the Innovation Task Force (ITF) also agreed.	In 2012, CTFG will be aiming to enlarge Development Safety Update Report (DSUR) work sharing and develop and use appropriate IT tools to share efficiently information.
(27) Cooperation with EMA and Commission on common clinical trials regulatory environment and its promotion/communication.	CTFG have actively participated in the establishment of the EU Commission's guidances and held training on a common interpretation of these guidances.	Work with Commission towards a revised Clinical Trials Directive will continue.
(28) Voluntary Harmonization Procedure – implementation and streamlining	Increase acceptance of VHP in 2011: A total of 97 applications (2009–2011) with > 50 in the first six months of 2011. 54 different sponsors coming from US and EU 6 Member States concerned per VHP. 50.4 days average time for CTFG assessment of CT applications. 35 substantial amendments assessed in 20.5 days. Introduction of reference NCA and co-ref and of common assessment report.	CTFG will continue to promote and improve the VHP and develop Standard Operating Procedures (SOPs)

Strategy Objective	Achievements 2011	Priorities 2012
(29) Regulation of veterinary medicines, including consideration of the extent to which human and veterinary medicines legislation should diverge and active participation of HMA in modification of veterinary legislation (including medicated feeds).	HMA submitted to the Commission in July 2011 their proposals for revision of the legislation for veterinary medicines. The TFIVL organised a focus group with stakeholders to provide a shared vision to identify and where possible to agree on concrete proposals for improvement that might be reflected in the future legal framework. The TFIVL prepared the Reflection position paper of the HMAv which was adopted by the HMAv during its July meeting and was sent to the European Commission.	The TFIVL will produce a position paper on the draft regulation provided by the Commission will be drafted by the TFIVL, and a position paper on the draft of medicated feed regulation (Draft announced for Q4 2012 or Q1 2013).
(30) Strengthen collaboration with international agencies and resources applicable to veterinary medicines; align with European Technology Platform for Animal Health, OIE, Codex Alimentarius.		TFIVL will produce a position paper on the draft proposal of the Commission.
(31) To take steps to help reduce the development of antimicrobial resistance and help communicate policies on responsible use to healthcare workers.	The HMA veterinary Antimicrobial Resistance taskforce was formed and held its first teleconference in December 2010. Key activities have included: finalisation and publication of the action plan to deliver the strategy; providing specific proposals in the context of revision of the veterinary medicines legislation; conference held jointly with EMA and report published considering progress in the area of antimicrobial resistance; publication of an overview of NCA activities in the area of antimicrobial resistance; and a summary of surveillance activities.	In 2012 the HMA veterinary Antimicrobial Resistance taskforce aims to conduct a survey of vets, with help from Federation of Veterinarians of Europe (FVE), to establish the factors that influence the prescribing of antimicrobials for animals. In addition key activities will be in the area of co-ordinated communications and working towards developing a more co-ordinated and meaningful approach to surveillance, in particular of target animal pathogens. The taskforce will continue to work closely with EMA, who are represented on the group. TFIVL and AMR WG will also consider and comment on proposals from the Commission relating to antimicrobial resistance.

Strategy Objective	Achievements 2011	Priorities 2012
(32) To consider whether a collaborative and proportionate arrangement for control clinical trials in food producing species is necessary.		TFIVL will produce a position paper on the draft proposal of the Commission.
(33) To gather information on unregulated areas for products used in animals and borderline areas and explore the need for proportionate regulation and cooperation in the Network.	The TFIVL and CMDv has made progress on the following areas: (1) Establishment of a new working group on borderline products to gather information on unregulated and borderlines areas for products used in animals and to consider specific cases of borderline products. (2) Identification of a European Borderline Assessment Network (EUBAN) and creation of a list of contact points in each Member State. (3) Compilation of a full overview of the regulatory framework for veterinary medicinal products, feed (additives) and biocides as well as guidance on borderline products. (4) Preparation of a template and procedure for discussions to classify a candidate product as (non) veterinary medicinal product. (5) Cooperation with the new CVMP ad hoc working group on biologicals and the 'human' Innovation Task Force.	The TFIVL will consider the Commission's impact assessment for the revision of the veterinary medicines legislation and in particular will consider any proposals in the area of control of new technologies. A position paper will be produced. (Draft announced for Q4 2012 or Q1 2013).
(34) Influence the development of revised legislation for feedingstuffs to ensure that it is risk based and addresses the specific challenges of antimicrobials.	Focus group organised by TFIVL (see objective (29)).	The Commission's proposals for revised legislation for medicated feed is expected in 2012. The TFIVL and AMR TF will consider the proposals and a position paper on the draft of medicated feed regulation will be produced. (Draft announced for Q4 2012 or Q1 2013)
(35) Build and strengthen regular communications with HMA stakeholders; ensure efficient interaction with pharmaceutical industry.	WGCP has supported the Network in consolidating the visibility of the HMA through the production and delivery of a dedicated brochure on the occasion of the conference and the exhibit at the 47th Annual Meeting of the Drug Information Association held in Chicago, June 2011.	WGCP will produce a questionnaire or survey asking for stakeholder feedback about the new refocused website.

Strategy Objective	Achievements 2011	Priorities 2012
(36) Developing the HMA web presence	A proposal has been developed by WGCP to refocus the HMA's website in two stages. The first to update and edit the current content, fill in any missing text, remove broken links and remove outdated or redundant information. The second phase will help make the site more user-friendly and accessible.	WGCP will work to deliver an up to date, refocused and accessible web site for the HMA.
(37) Crisis communication links – interactions between regulators.	WGCP has undertaken research and benchmarking on existing protocols and procedures on media relations and crisis management in the Network.	WGCP will develop protocols and procedures on coordination of media relations/crisis management between regulators. WGCP will develop a crisis checklist and methodology for lessons learned following a crisis situation. 2012 will see implementation of proposal.
(38) Optimum utilisation of resources.	5 year WGQM Strategy agreed in Bonn, December 2011, to complement the HMA Strategy. The WGQM strategy promotes sharing experience and best practices for Quality Management Systems and new Pharmacovigilance legislation.	WGQM will review pharmacovigilance system requirements for the implementation of the new legislation and the integration in the existing QMS, and will develop a list of QM-tools, internal Audits, Certification and IT-tools, to get information about the agencies standards and an overview of the different standards with the possibility to create a common QMS-standard.

Strategy Objective	Achievements 2011	Priorities 2012
(39) Making decentralised processes work better.	The Task Force on Resources in DCP report that the number of national requirements for marketing authorisation applications has been reduced, although industry indicate that new national requirements exists that have not showed on the list. A small interaction group with representatives from industry associations has been established to follow up improvement of the DCP. There has also been a reduction of complaints of lack of slots in DCP In addition, a common template for validation criteria and e-submission requirements has been published; there has been agreement in HMA that the Reference Member State (RMS) will make the technical validation on behalf of all Concerned Member States (CMSs); and there has been finalisation and evaluation of a pilot on the assessment feed back form. CMDh established the Task Force on Self-Medication Project in February 2011 to discuss with representatives from the self-medication industry how to facilitiate the access of this sector to MRP/DCP. A Best Practice Guide has been developed taking into account comments from industry and legal interpretations given by the European Commission. The implementation plan for the optimisation of the Referral procedure and for better use of CMDh as a platform for scientic discussions was adopted by CMDh in September 2011, as well as revised versions of the SOP on referral to CMDh and SOP on DCP reflecting the agreed implementation plan.The CMDh has set up a new working group to give input to the discussions on the future of CMDh and the new tasks proposed in the new legislative proposals on pharmacovigilance. CMDv have developed a mechanism to achieve harmonisation of SPCs and to maintain this harmonisation. A pilot procedure with three products was started. There has also been preparation of a strategy for implementation of SPC and standardised Part II of the dossier and preparation of a strategy for transfer to MRP. A Best Practice guide has been developed for harmonisation of veterinary medicinal products after referral according to Article 34. The CMDv packaging working group has re-established work to consider those current packaging requirements which present barriers and which should be simplified. Discussions are proposed to be continued in 2012 to put the issue forward with the aim to finalise this item within the revision of the veterinary legislation.	TF on resources in DCP priorities 2012: (1) Encourage a continued reduction of national requirements through HMA and CMDh. (2) Discuss validation problems in order to find a harmonised approach and, in cooperation with the European Commission, a common legal interpretation. (3) Implementation of the agreement that the RMS will make the technical validation on behalf of all CMSs. (4) Monitor the duration of clock-stops based on statistics from CTS. (5) Continue discussion improvement of national closing phase and exchange national experiences. (6) Examine more areas for work sharing. CMDv priorities 2012: (1) Review of the veterinary legislation - review and discussion of the European Commission report on better regulation of veterinary medicines and resulting impact assessment in preparation for any proposed changes to the Veterinary Directive. (2) Harmonisation of national implementation of commission decisions following article 34 referrals and transfer to MRP of purely national marketing authorisations (MAs) to maintain harmonisation following a referral. (3) Completion of pilot procedure for harmonisation of summary of product characteristics (SPC) and review of lessons learned. (4) Transparency initiatives, particularly in the area of access to document requests concerning the dossiers supporting marketing authorisations. (5) Issues with borderline products. (6) Continue work of packaging working group.

Strategy Objective	Achievements 2011	Priorities 2012
(40) Extending new EU variation regulation provisions to national variations.	The CMDh Workplan for 2011 challenged the CMDh to discuss questions on implementation and request for clarification at the joint CMD/EMA subgroup on variation regulation. Where Member States have different interpretations on the legislation, the CMDh was to seek advice from the European Commission in order to implement the new procedures in a harmonised way. Queries from Industry or Member States were discussed in the joint CMD/EMA subgroup on variations. More Q&A and examples for acceptable/non-acceptable groupings were published and the Best Practice Guide was updated. CMDh representatives attended the EU variation Task Force meetings in June and July 2011 with the European Commission on the revision of the variation legislation to cover medicinal products authorised via national procedures and to make necessary improvements to the current legislation. The CMDh sent comments to the European Commission on the Commission's proposals for implementation of the variation legislation for nationally authorised products.	CMDv will continue work on the implementation of the variations Regulation (1234/2008), particularly with regard to grouping and worksharing, and any possible extension of this Regulation to nationally authorised products.
(41) Supporting new functionality bestowed on CMDh by strengthened pharmacovigilance legislation.	Preparing for the new tasks of CMDh proposed in the new legislative proposals on Pharmacovigilance, the CMDh has set up a new Working Group to give input to the discussions in the Work Plan on the future of CMDh. The CMDh has contributed to the discussions in the different European Working Groups and ERMS FG. The CMDh Working Group on Pharmacovigilance has prepared a checklist of documents that needs to be drafted for the implementation. The WG meets every month and the representatives in the different working groups present an update report and prepare documents for discussion in the CMDh.	Pharmacovigilance legislation will be implemented in 2012, CMDh working groups will continue to provide support.
(42) Providing more authorised medicines for children and implementation of paediatric regulation provisions.	A joint CMDh/EMA Paediatric subgroup has met on a regular basis to discuss questions in relation with the Worksharing and to appoint rapporteurs. Four new waves have started for the assessment of Paediatric data cf Art 45 and the number of Public assessments has increased (in total 69).	

Strategy Objective	Achievements 2011	Priorities 2012
(43) Promoting work sharing and principle of fair distribution of work across the Network.	A new joined subgroup including the Quality Working Party (QWP), EMA, CMDv and EDQM has started to discuss the organisation of worksharing for assessment of the Active Substance Master File (ASMF). A procedure was drafted and a new template for the assessment report has been agreed. Further discussions are needed, but Member States have agreed to exchange the assessment reports on a voluntary basis.	Task Force on resources in DCP will be examining more areas for work sharing in 2012. WGQM will be evaluating training plans and modules for Quality Management Systems and Pharmacovigilance.
(44) HMA Common Portal for MRP/DCP applicants.	For 2011 the core priorities for the Telematics Support Group (TSG) Common EU Submissions Portal (CESP) project has been to proof the technical feasibility and set the requirements for a first production version of the CESP system. HMA endorsed the Proof of Concept (POC) for CESP in April 2011 and the POC system was created by the Irish Medicines Board in summer 2011. The results of the POC were very encouraging. Both Industry and NCA's are satisfied with the results and want to continue the CESP initiative.	The main target for 2012 for CESP is to move towards a full production solution. Two major subtasks have been identified: (1) building the technical solution. (2) establishing a model for the governance and financing of CESP.
(45) Promoting inter-operability of NCA systems with best use of telematics.		Telematics Support Group has created a workstream to further develop this area in 2012.
(46) Communications plan to ensure that stakeholders are provided with up-to-date information on telematics.	In 2011 the TSG established an IT Communications Plan to inform the HMA about the benefits of EU IT projects, the impact on individual NCA IT development, the current state of play and future outlook. Input from WGCP has been sought.	Agreement and communication of IT Communications Plan. Update and use HMA website as a repository for the information toolkit and communication channel.
(47) Support of internal communications platforms for each working group of HMA.	An IT platform has been set up by WGCP to help collaboration and communication within the group but usage is low.	WGCP will work with TSG to investigate more useful internal communication platform for use within the wider HMA group.

Strategy Objective	Achievements 2011	Priorities 2012
(48) Further development for Benchmarking of European Medicines Agencies (BEMA) programme.	BEMA SG has completed the interim report on the BEMA II visits, with distribution of the report and the database to all agencies for information and guidance on good practices. There has been a major revision of the questionnaire used in the benchmarking programme in order to introduce a logical sequence, cover both management systems and the core scientific work of medicines agencies and reduce the overall number of indicators. The methodology has also been revised to improve the self-assessment reporting and the reports from the benchmarking visits, as well as to provide a more accessible repository of information in the database for the use of benefit of all agencies. Training of new assessors for the BEMA III programme was also initiated.	BEMA SG priorities: (1) Drafting of the final report on the BEMA II programme, with HMA approval by September 2012. (2) Define the methodology for ensuring implementation of the benchmarking outcomes between agency visits. (3) Finalise the questionnaire and methodology, with HMA approval by February 2012. (4) Complete training of new assessors for the BEMA III programme. (5) Begin self-assessments by agencies against the new questionnaire by April 2012. (6) Commence benchmarking visits to agencies by October 2012. WGQM will review the practical steps to prepare for the BEMA self-assessment and the BEMA visit
(49) Implementation of harmonised training strategy across Network to improve quality and consistency, including harmonised interpretation of guidelines.	At HMA Budapest in February 2011, the HMA endorsed the report of the first year of operation of the Office of Training Steering Group (OTSG) and took note of a list of available scientific and regulatory training events for use by the EMRN during 2011.	In 2012 OTSG will create an understanding of the role of the OTSG in new training initiatives within the network.
(50) Providing basic and specialised training to all staff members of competent authorities	Priorities of the OTSG work plan in 2011: (1) Set up and complete a pilot in the area of quality of medicines. The framework on competence requirements and training need for Quality Assessors was not an obligatory document for the NCAs, but serves as a living document and will provide a model for other areas. (2) A first database/inventory of training available from the NCA and EMA was prepared. (3) Revision of OTSG web page.	OTSG Priorities for 2012: (1) Criteria for OTSG to assist with a request for training. (2) Compile and prioritise new requests for competence requirements and training need in new areas. (3) Prioritise and support two new initiatives. (4) Compile a new list of training opportunities within the network (NCAs and EMA). (5) Look at alternative training methods (webinars etc) in cooperation with the EMA. (6) Look at possible opportunities in the IMI-initiative.

Further Information

HMA website: http://www.hma.eu/

Useful Documents

EMA Roadmap to 2015 http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/01/WC500101373.pdf

HMA Strategy 2011-15 and HMA Strategy 2006-10 http://www.hma.eu/74.html

Useful Websites

Council of Europe Medicrime Convention http://www.coe.int/t/DGHL/StandardSetting/MediCrime/Default_en.asp

EMA website www.ema.europa.eu

Falsified Medicines Legislation http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm

Pharmacovigilance Legislation http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm

Pharmacovigilance Risk Assessment Committee http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2011/06/WC500108031.pdf

Important Dates for 2012

	JANUARY		JULY
		17	Meeting of Central Management Committee on Medical Devices
		18–19	Meeting of Competent Authorities on Medical Devices(CAMD)
	FEBRUARY		**AUGUST**
23–24	HMA Meeting Copenhagen		
	MARCH		**SEPTEMBER**
14	Meeting of Central Management Committee on Medical Devices	3–4	Informal Committee for Medicinal Products for Human Use
15–16	Meeting of Competent Authorities on Medical Devices (CAMD)	20–21	HMA Meeting Limassol Cyprus
22–23	EMACOLEX		
	APRIL		**OCTOBER**
11–13	Pharmacovigilance Inspectors Training Course	1–2	Informal Pharmacovigilace Risk Assessment Committee (PRAC), Paphos Informal Committee for Medicinal Products for Human Use, Paphos
26–27	Committee for Medicinal Products for Human Use	2	Committee on Herbal Medicinal Products, hosted by Poland
26–27	Pharmacovigilance Working Party (human)	11 22 25–26	HMA/CAMD Workshop, hosted by Poland Homeopathic Medicinal Products Working Group, hosted by Poland EMACOLEX
	MAY		**NOVEMBER**
10–11	Coordination Group for Mutual Recognition and Decentralised Procedures – human	5–6	Informal Clinical Trials Facilitation Group meeting, hosted by Belgium
14–16	Working Group of Enforcement Officers	5–7	Working Group of Enforcement Officers, Paphos
23-24	Committee for Orphan Medicinal Products	7–8	HMA Strategy Meeting, Oslo, Norway
24	PDCO – Paediatric Committee		
24–25	Committee for Advanced Therapies		
29	HMA/CAMD Workshop, hosted by Poland		
31–1	Committee for Medicinal Products for Veterinary Use		
	JUNE		**DECEMBER**
4–5	Committee on Herbal Medicinal Products	10	Working Group of Communications Professionals meeting, Copenhagen, Denmark
5–6	Homeopathic Medicinal Products Working Group		
11–15	Annual Meeting of the European Network of Official Medicines Control Laboratories		
14–15	Working Group of Quality Managers		
19–20	HMA Meeting Copenhagen 2		
21	Working Group of Communication Professionals		

Glossary

ADR	Adverse Drug Reaction
AMR TF	Antimicrobial Resistance Task Force (veterinary)
AMWG	Availability of Medicines Working Group (2008-2011)
BEMA	Benchmarking of European Medicines Agencies
BEMA SG	Benchmarking of European Medicines Agencies Steering Group
CAMD	Competent Authority for Medical Devices
CHMP	Committee for Medicinal Products in Human use
CMC	Central Management Committee for medical devices
CMDh/v	Coordination Group for Mutual Recognition and Decentralised Procedures – human and veterinary
CVMP	Committee for Medicinal Products for Veterinary Use
CTFG	Clinical Trials Facilitation Group
DCP	Decentralised Procedure
DKMA	Danish Medicines Agency
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EudraGMP	Community database on manufacturing and import authorisations and Good Manufacturing Practice
EMA	European Medicines Agency
HMA/EMA WGT	HMA/EMA Working Group on Transparency
EMACOLEX	European Medicines Agencies Cooperation on Legal and Legislative Issues
EMRN	European Medicines Regulatory Network
ERMS FG	European Risk Management Strategy Facilitation Group

ESS WG	European Surveillance Strategy Working Group
GMP/GDP IWG	GMP/GDP Inspectors Working Group
HMA	Heads of Medicines Agencies
HMA MG	HMA Management Group
HMA PS	HMA Permanent Secretariat
HMP WG	Homeopathic Medicinal Products Working Group
HTA	Health Technology Assessment
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
OTSG	Office of Training Steering Group
PhV	Pharmacovigilance
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PRAC	Pharmacovigilance risk assessment committee
PSUR	Periodic Safety Update Report
PhVWP	Pharmacovigilance Working Party – human and veterinary
SPC	Summary of Product Characteristics
TFIVL	Task Force for Improvement in Veterinary Legislation
TFR DCP	Task Force on Resources in MRP/DCP
TSG	Telematics Support Group
VHP	Voluntary Harmonisation Procedure for clinical trials
WGCP	Working Group of Communications Professionals
WGEO	Working Group of Enforcement Officers
WGPT	Working Group on Product Testing

HMA
Heads of Medicines Agencies

Austria	**AGES-PharmMed LCM** www.ages.at
Belgium	**Federal Agency for Medicines and Health Products** www.fagg-afmps.be
Bulgaria	**Bulgarian Drug Agency** www.bda.bg
	National Veterinary Service www.nvms.government.bg
Cyprus	**Ministry of Health – Pharmaceutical Services** www.moh.gov.cy
	Veterinary Services-Ministry of Agriculture, Natural Resources and Environment www.moa.gov.cy/moa/vs/vs.nsf
Czech Republic	**State Institute for Drug Control** www.sukl.cz
	Institute for State Control of Veterinary Biologicals and Medicaments www.uskvbl.cz
Denmark	**Danish Medicines Agency** www.dkma.dk
Estonia	**State Agency of Medicines** www.ravimiamet.ee
Finland	**Finnish Medicines Agency** www.fimea.fi
France	**Agence française de sécurité sanitaire des produits de santé** www.afssaps.sante.fr
	ANMV – Agence nationale du Médicament Vétérinaire www.anmv.anses.fr
Germany	**BfArM** www.bfarm.de
	Paul-Ehrlich Institut www.pei.de
	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit www.bvl.bund.de
Greece	**National Organization for Medicines** www.eof.gr

Hungary	**National Institute of Pharmacy** www.ogyi.hu
	Institute for Veterinary Medicinal Products www.ivmp.gov.hu
Iceland	**Icelandic Medicines Control Agency** www.imca.is
Ireland	**Irish Medicines Board** www.imb.ie
Italy	**Agenzia Italiana del Farmaco** www.agenziafarmaco.it
	Ministero della Salute, Direzione Generale della Sanità Pubblica Veterinaria, la nutrizione e la Sicurezza degli alimenti, Direzione Generale della Sanità Animale e del Farmaco Veterinario www.salute.gov.it
Latvia	**State Agency of medicines** www.zva.gov.lv
	Food and Veterinary Service www.pvd.gov.lv
Liechtenstein	**Office of Health/Dpt. of Pharmaceuticals** www.llv.li
Lithuania	**State Medicines Control Agency** www.vvkt.lt
	State Food and Veterinary Service www.vet.lt
	Lithuanian State Inspection on Veterinary Preparations
Luxembourg	**Direction de la Santé Villa Louvigny Division de la Pharmacie et des Medicaments** www.ms.etat.lu
Malta	**Medicines Authority** www.medicinesauthority.gov.mt
	Veterinary Medicines Unit, **Food & Veternary Regulatory Division** http://vafd.gov.mt/home
Netherlands	**College ter Beoordeling van Geneesmiddelen** **Medicines Evaluation Board** www.cbg-meb.nl
Norway	**The Norwegian Medicines Agency** www.legemiddelverket.no
Poland	**Office for Registration of Medicinal Products, Medical Devices and Biocidal Products** www.urpl.gov.pl

Portugal	**INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.** www.infarmed.pt
	DGV – Direcção Geral de Veterinária, Divisão de Meios de Defesa da Saúde Animal
	Direcção Geral de Veterinária
Romania	**National Medicines Agency** www.anm.ro
	Institutul pentru Controlul Prodeselor Biologice si Medicamentelor de Uz Veterinar www.icbmv.ro
Slovakia	**State Institute for Drug Control** www.sukl.sk
	Institute for State Control of Veterinary Biologicals and Medicaments www.uskvbl.sk
Slovenia	**Agencija za zdravila in medicinske pripomocke** www.jazmp.si
Spain	**Agencia Española de Medicamentos y Productos Sanitarios** www.aemps.gob.es
Sweden	**Medical Products Agency** www.lakemedelsverket.se
United Kingdom	**Medicines and Healthcare products Regulatory Agency** www.mhra.gov.uk
	VMD – Veterinary Medicines Directorate www.vmd.gov.uk

HMA

Heads of Medicines Agencies

http://www.hma.eu/
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Permanent Secretariat,
c/o Irish Medicines Board,
Earlsfort Centre, Earlsfort Terrace,
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