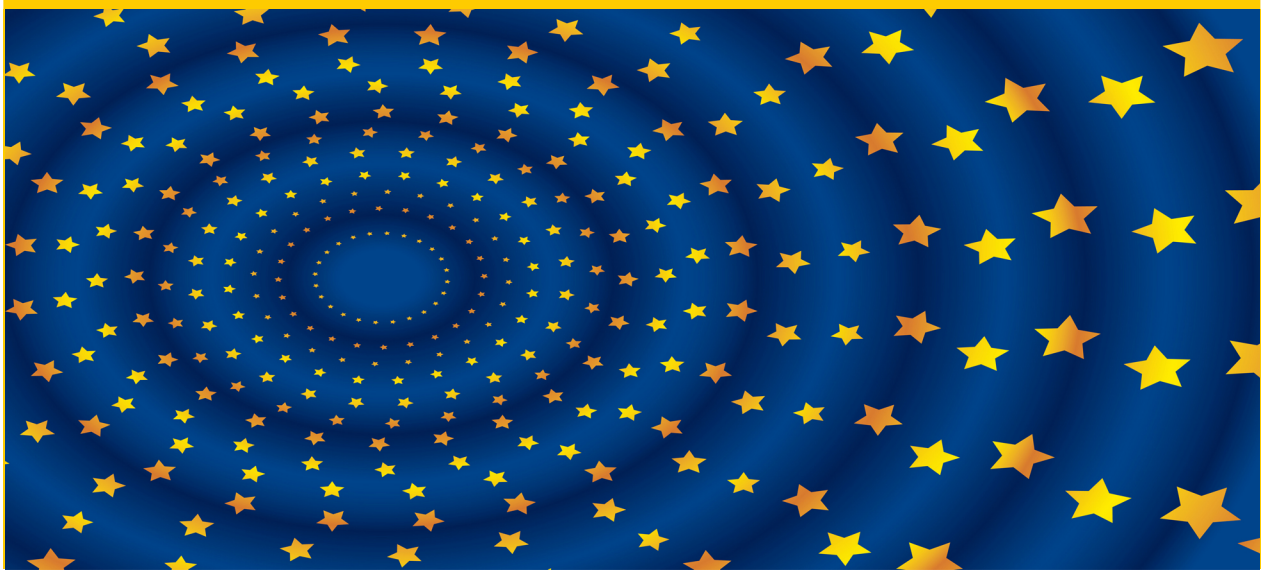
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 October 2010
EMA/499025/2010
Office of the Executive Director

Annual report highlights
2009



7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

Introduction by the Executive Director

Thomas Lönngren

In 2009, the European Medicines Agency delivered very good results across the range of its activities. Core activities relating to medicines for human and veterinary use were conducted to a high level of quality, and regulatory timelines were consistently met. In many areas, the Agency was able to make a significant further contribution to public and animal health in the European Union (EU).

The public-health issue to which the Agency devoted most attention in 2009 was the outbreak and rapid global spread of the H1N1 influenza ('swine flu') virus. The fast-track review of pandemic vaccines – and the close monitoring of these vaccines once they were being used to vaccinate millions of European citizens – demonstrated to Europe and to the world that the European medicines network can deliver high-quality scientific assessments even under enormous pressure.

When the first reported cases of infection emerged from Mexico, in April, the Agency reacted quickly, working closely with its European and international partners to monitor the situation and develop appropriate measures to deal with the emerging crisis, including meeting with vaccine manufacturers and influenza experts from across the EU to prepare for the development and authorisation of vaccines that could be used to protect people and minimise the spread of the virus.

While awaiting the availability of vaccines, the Agency worked to facilitate the use of existing antiviral medicines that had shown effectiveness in treating people infected with the virus. In early May, the Agency's Committee for Medicinal Products for Human Use (CHMP) recommended that the shelf-life of one of these medicines (Tamiflu) be extended, so that stocks of the medicine that would otherwise need to have been disposed of could continue to be used in the event of a pandemic being declared.

Once a pandemic had been officially declared by the World Health Organization and the strain of the virus had been identified, in June, pharmaceutical companies were in a position to begin submitting data on H1N1 vaccines to the Agency. The CHMP took the unprecedented measure of reviewing these data on a rolling-review basis as and when they were received, rather than waiting for exhaustive data to become available. This was done to fast-track the assessment process so that the urgent public-health need for vaccines could be met before the autumn, when an intensification of the spread of the virus was expected in Europe.

Thus, the CHMP was able to give positive recommendations for two pandemic-influenza vaccines (Focetria and Pandemrix) by late September, and for a third one (Celvapan) in early October. On the basis of these scientific recommendations, the European Commission granted EU-wide marketing authorisations for all three vaccines, making them available for use by health authorities in the EU Member States as part of their national vaccination programmes. By the end of the year, 29.4 million people in Europe had been vaccinated with one of these products.

During the year, the Agency continuously monitored the safety data for influenza vaccines and antivirals, to establish and revise, where necessary, their benefit-risk profile. Updated product information in all EU languages, weekly pharmacovigilance reports and much other scientific and regulatory information was published in a dedicated section of the Agency's website.

That the EU medicines system was able to deliver an appropriate response to this public-health crisis was further evidence of its robustness and good functioning. The results achieved under intense pressure were due to the sustained commitment and cooperation of the national authorities of the Member States, the European Commission, the European Directorate for the Quality of Medicines and

HealthCare, the European Centre for Disease Prevention and Control, the European Food Safety Agency and the European Medicines Agency, as well, of course, of the pharmaceutical industry.

The influenza pandemic was by definition a global challenge, so much credit for the achievements in Europe is also owed to the international partners with which the EU enjoys a mutually beneficial working relationship, notably the World Health Organization and the medicines authorities of the United States, Japan, Canada and Australia, among others.

Although the Agency devoted significant time and resources in 2009 to its involvement in managing the unanticipated influenza pandemic, it was still able to achieve very good results in delivering on its ambitious work programme for the year.

For their outstanding dedication and hard work throughout what was one of the most active and challenging years in the history of the Agency, I am very grateful to all members of the Agency's scientific committees, working parties, staff and Management Board, whose efforts contributed greatly once again not only to the success of our organisation, but to the protection of public and animal health in Europe.

Highlights from the Agency's annual report 2009

The outbreak of the 2009 H1N1 influenza pandemic put significant pressure on the European Medicines Agency and the European medicines network. However, due to the strength of the network, the Agency was not only able to contribute to the EU-wide response to the pandemic by providing its scientific opinion on H1N1 vaccines and antiviral medicines, it was also able to deliver good results across the range of its activities. In many areas, the Agency was able to make a significant further contribution to public and animal health in the European Union (EU).

Improving the effectiveness and efficiency of the Agency's core activities

Core activities relating to medicines for human and veterinary use were conducted to a high level of quality, and regulatory timelines were consistently met. Substantial increases were seen across many of the core areas relating to human medicines, including scientific advice, orphan designations, variations and safety-related activities. While the rate of submission of applications for veterinary medicines was reasonably steady, there was a considerable increase in the number of requests relating to veterinary scientific advice and pharmacovigilance activities.

Consolidating the Agency's international strategy in the light of global challenges

The development of the Agency's international strategy started with the appointment of an International Liaison Officer in the beginning of 2009. By the end of the year, the international strategy was included as an important part of the Agency's 'Road map to 2015', adopted by the Agency's Management Board for public consultation.

In August 2009, the Agency signed its latest confidentiality arrangement with the Australian Therapeutic Goods Administration (TGA), bringing the number of confidentiality arrangements in place to four.

Bilateral relations with the US Food and Drug Administration (FDA) and the Japanese authorities were greatly enhanced when the notion of liaison placements was agreed. In June 2009, an FDA official took up a posting at the Agency, followed by an official from the Japanese authorities in November 2009. The European Medicines Agency appointed a staff member as a liaison officer to the FDA in July 2009.

The H1N1 influenza pandemic resulted in an unprecedented level of international cooperation activity at bilateral and multilateral level. The Agency had regular exchanges with regulators from Australia, Canada, Japan, the United States and experts from the World Health Organization (WHO).

A number of pilot projects fostering international collaboration in the area of inspections were also launched during the year.

Strengthening the European medicines network

The network demonstrated its strength during the 2009 H1N1 influenza pandemic. The Agency was immediately engaged in monitoring the situation following the initial outbreak, in April, and subsequently stepped up its activities as the WHO raised the pandemic level. The mobilisation of scientific experts from all over the EU made it possible to fast-track the scientific review of vaccines, so that by October 2009 three centrally authorised pandemic H1N1 vaccines were available for use by public-health authorities in the EU Member States.

While many resources were devoted to dealing with the influenza pandemic, the European medicines network also made progress on a number of other initiatives during the year: work on the European Risk Management Strategy (ERMS) continued in accordance with the rolling two-year work programme; the Agency worked jointly with the Heads of Medicines Agencies (HMA) on developing a training strategy for the regulatory network; further progress was made on simplifying the contractual arrangements with the Member States for services provided to the Agency through the development of a Cooperation Agreement.

Improving the safety-monitoring of medicines

Pharmacovigilance of antivirals and vaccines used during the influenza pandemic was a major activity in 2009. The Agency developed a European strategy for benefit/risk monitoring of A/H1N1 influenza vaccines, in close collaboration with the European Centre for Disease Prevention and Control (ECDC) and the HMA.

A pilot phase of the EU regulatory system incident-management plan for medicines for human use was launched on 1 June 2009. This plan is designed to improve the handling and coordination of any potential crisis involving a medicine in the European medicines system.

The Agency-led PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium) project was accepted for funding by the Innovative Medicines Initiative Joint Undertaking (IMI JU). PROTECT is a collaborative European project bringing together 29 public and private partners, which aims to develop innovative methods in pharmacoepidemiology and pharmacovigilance.

EudraVigilance, the EU database and data-processing network for adverse drug reactions, was further developed in line with the project plan agreed by the EudraVigilance Steering Committee.

The EudraVigilance Support Programme was initiated at the end of January 2009 to assist Member States with their signal-detection and evaluation activities. The European Pharmacovigilance Issues Tracking Tool (EPITT) is now routinely used to support the signal-management process.

Involvement in the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) continued in 2009, with efforts focusing on establishing the database of ENCePP research centres (made publicly available in December 2009, to be populated in 2010), establishing the ENCePP Steering Group, and drafting an ENCePP code of conduct and a checklist of methodological research standards (both of which were released for public consultation in November 2009).

Initiatives were taken to facilitate the monitoring of adverse drug reactions in children using centrally authorised medicines. An action plan on paediatric pharmacovigilance, based on EudraVigilance data, was adopted in May 2009 to further strengthen the intensive monitoring of paediatric use of medicines.

A reflection paper on the concept of risk-management plans for veterinary medicines was published for consultation.

The implementation and development of EudraVigilance Veterinary (EVVet) continued in 2009. Thirty-two competent authorities are now registered, with a total of 150 different users. There are also 111 organisations registered (marketing-authorisation holders and third parties), with a total of 176 different users. All major companies are now registered and operating electronic reporting via EVVet.

Implementing and operating the Advanced Therapies Regulation and other new legislation

The Agency's sixth scientific committee, the Committee for Advanced Therapies (CAT), was inaugurated in January 2009, in accordance with provisions contained in the new legislation on advanced therapy medicinal products (ATMPs). The Committee deals with ATMPs for human use that are based on gene therapy, somatic cell therapy or tissue engineering. These innovative medicines offer groundbreaking new treatment opportunities for diseases and injuries of the human body.

The CAT is a multidisciplinary committee made up of some of the best experts in the field. A large part of their work in 2009 was dedicated to implementing and further developing the regulatory framework for ATMPs by drafting procedural and scientific guidelines for public consultation, and to helping applicants prepare their applications for procedures introduced by the new legislation.

By the end of 2009, the Agency had received marketing-authorisation applications for three ATMPs. For one of these medicines, a tissue-engineered product containing chondrocytes, the CAT proposed a positive opinion to the Agency's Committee for Medicinal Products for Human Use (CHMP). For a gene-therapy product, the CAT adopted a draft negative opinion. The third medicine, another gene-therapy product, was withdrawn by the applicant prior to the adoption of a final opinion by the CHMP.

Preparing for the implementation of the Variations Regulation, the Agency provided to the European Commission, at the end of February 2009, draft guidelines on the detailed classification of variations and on the procedure for handling of variations in accordance with the new legislation. Existing regulatory guidance documents were also updated, to take account of the new rules.

Fostering transparency, communication and the provision of information

Responding to increasing stakeholder expectations, the Agency launched a public-consultation process on a new transparency policy, bringing together in one comprehensive document the Agency's vision on its level of openness towards its stakeholders.

The need for continuous reflection on the Agency's activities in the area of transparency was underlined by the continuing increase in the number of requests received for access to documents and information.

Public consultation on draft EudraVigilance access policies in relation to human and veterinary medicines was completed in the spring of 2009, and work on revising the draft policies began.

In cooperation with King's College London, the Agency initiated a study on its benefit-risk communication activities, aimed at describing the Agency's approach to benefit-risk communication and identifying proposals for future implementation. In addition, the Agency published, in June 2009, a report on patients', consumers' and healthcare professionals' expectations with regard to information on the benefit-risk evaluation of medicines.

The Agency unveiled its new visual identity on 8 December 2009. The new identity was developed primarily to ensure that the communications materials of the Agency are created with a consistent look and feel, and to communicate to the public a clearer message about its role and activities.

Development of a new public website for the Agency – designed with the needs of the public in mind, offering improved navigation and search functionality, and better access to information on public-health issues – was also a significant undertaking during the course of 2009.

Contributing to improved availability of medicines

The Agency delivered good results on a number of processes and procedures that contribute to the innovation and availability of medicines for human and animal use. Scientific-advice activities for human and veterinary medicines were significantly up, as were activities relating to the provision of support to small and medium-sized enterprises.

Looking to the future of medicines development, the Agency invites discussion on innovative therapeutic approaches and new development methods for human medicines. Topics covered in 2009 included biomarkers and other novel development methods, nanotechnologies in life sciences and reinforced coordination between pharmaceuticals and devices authorities for the evaluation of targeted and combined medicinal products.

Promoting the availability of veterinary medicines, the Agency continued its contribution to the implementation of the action plan arising from the HMA Taskforce on Availability. A particular highlight was the introduction, in September 2009, of a range of measures to promote the authorisation of products for minor uses, minor species and limited markets.

The Agency also cooperated closely with the European Commission on fostering innovation in the context of the Innovative Medicines Initiative (IMI), the 7th Framework Programme and the European Technology Platform for Global Animal Health.