European Medicines Agency

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Highlights 2008

Summary of the European Medicines Agency's annual report for 2008

Contents

A full annual report of activities in 2008 is available on the Agency's website at:
http://www.emea.europa.eu/htms/general/direct/ar.htm

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The year in brief

The year 2008 was one of consolidation and steady progress for the European Medicines Agency (EMEA), rather than one of major leaps and bounds.

However, set against a background of continuing globalisation of the pharmaceutical sector, further rapid advances in medical science and the unrelenting pace of regulatory activity in the medicines network of the European Union (EU), it was by no means a 'dull' year for the Agency.

As pharmaceutical development and clinical trials of medicines move increasingly beyond the traditional spheres of Europe and North America, regulators are becoming more keenly aware of the need for international cooperation on ensuring that safe and ethical practices are being used for the development and testing of medicinal products in all parts of the world. In 2008, the Agency intensified its cooperation with international partners to ensure its contribution to global efforts for safer and better medicines around the world.

Closer to home, the Agency continued to work with its EU institutional partners and the national regulatory authorities of the Member States to stimulate innovation in the pharmaceutical sector, strengthen the safety-monitoring of medicines, exchange expertise on a wide range of issues, and forge close relations to build the best possible regulatory system for Europe.

In terms of the core assessment work of the Agency, 2008 was a highly productive year. The number of positive opinions adopted on marketing-authorisation applications for medicines for human use was higher than in any year to date. As a result, 66 new medicines — including ones for the prevention or treatment of serious and debilitating conditions such as bone cancer in children, immune-system diseases, HIV and rheumatoid arthritis — will become available to European citizens.

Assessment work in relation to paediatric medicines, rare-disease medicines, herbal medicines and veterinary medicines was intensive in 2008 too, while the volume of work in relation to the provision of scientific advice, the drafting of guidelines, the processing of variation applications and the conduct of pharmacovigilance activities was reasonably high overall.

The Agency devoted much effort during the year to preparing for the entry into force of the EU's new Advanced Therapies Regulation — a piece of legislation that will greatly strengthen regulatory procedures relating to medicines at the cutting edge of medical science.

The next few pages provide brief highlights of the Agency's activities in each of its priority areas for the year, together with key figures to demonstrate the volume and evolution of its core scientific and regulatory procedures.

Key activities in 2008

This section provides an overview of the main activities of the European Medicines Agency in 2008, listed according to priority areas the Agency set itself in its work programme for the year.

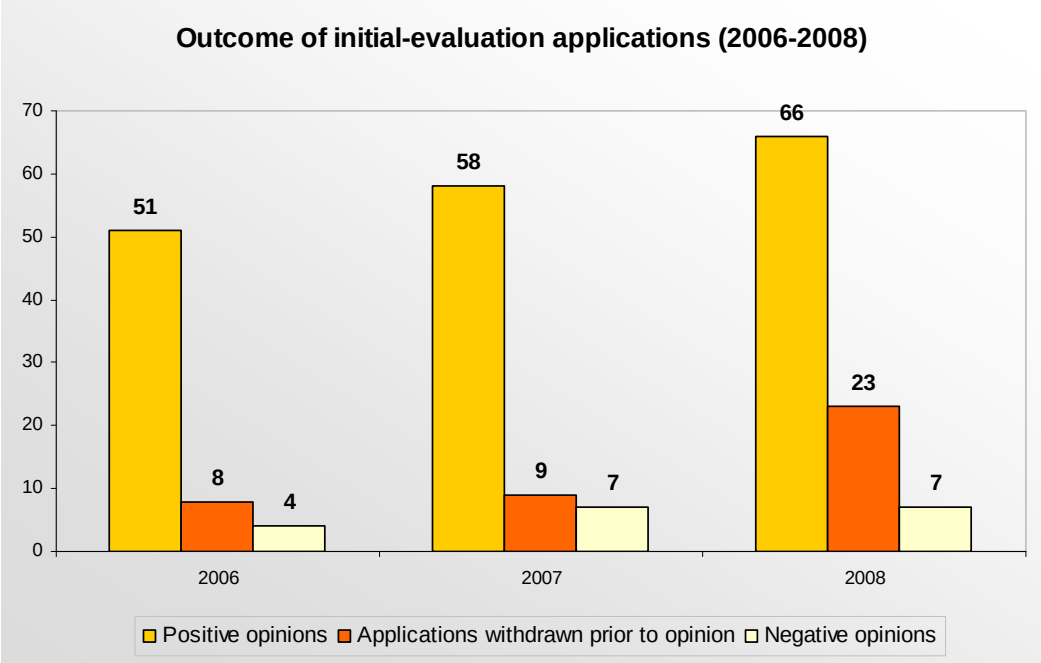
Evaluating medicines for human use

Record number of positive opinions adopted for new human medicines

In 2008, the Agency's Committee for Medicinal Products for Human Use (CHMP) adopted 66 positive opinions[1] — the highest number ever adopted in a single year — following its completion of initial-evaluation procedures[2] for new medicines for human use.

The majority of positive CHMP opinions adopted in 2008 related to cancer medicines, followed by anti-infectives and medicines for the treatment of neurological and central-nervous-system conditions.

One further positive opinion was adopted in favour of granting a conditional marketing authorisation (a one-year authorisation, renewable annually, on condition that certain specific obligations are met), while negative opinions were adopted for 7 applications. Twenty-three applications were withdrawn by applicants before completion of the evaluation procedure.



[1] The CHMP adopts opinions after a rigorous evaluation of the scientific data submitted by pharmaceutical companies in support of their applications for approval of their medicinal products. It assesses the quality, safety and efficacy of the medicine concerned, and adopts a positive opinion if it is satisfied that the data submitted demonstrate that the medicine's benefits outweigh any risks associated with its use.
A CHMP opinion is a recommendation to the European Commission on whether or not it should grant a Community marketing authorisation (or licence) that allows the medicine concerned to be placed on the market in all 30 European Economic Area countries (the 27 European Union Member States, plus Iceland, Liechtenstein and Norway).

[2] Initial-evaluation procedures relate to applications for new medicines that have not previously been authorised in the European Union.

Public-health benefits of medicines recommended for authorisation in 2008

Of the 66 medicines to receive a positive opinion from the CHMP in 2008, those that are of particular note include:

- the first medicine for use as maintenance treatment in adults with acute myeloid leukaemia (a type of cancer affecting the white blood cells), in combination with interleukin-2 (an anticancer medicine). It can be used during a patient's first remission (a period without symptoms of the disease after the first course of treatment).
- a medicine to treat high-grade, non-metastatic osteosarcoma (a rare bone cancer) in children, adolescents and young adults. It can be used with other anticancer medicines after the cancer has been removed by surgery.
- a medicine for use in adults with long-term immune thrombocytopenic purpura, a rare disease in which the patient's immune system destroys the blood platelets that help blood to clot whenever the person bleeds.
- a medicine for the treatment of adults who cannot have a bone-marrow transplant and suffer from myelodysplastic syndromes (conditions where the bone marrow produces too few blood cells).
- a medicine to treat hyperphenylalaninaemia (high levels of phenylalanine in the blood) in patients with the genetic disorders phenylketonuria or tetrahydrobiopterin deficiency.
- a new compound in an existing class of antiretroviral medicines that can be used to treat adults infected with HIV-1 (the virus that causes AIDS) in whom treatment with other medicines in the same class has been unsuccessful.
- an anti-rheumatic biological agent (interleukin-6 receptor antagonist) that can be used in combination with methotrexate to treat adults with moderate to severe active rheumatoid arthritis (an immune disease causing inflammation of the joints). It is intended for use in patients who do not respond well to, or cannot tolerate, conventional arthritis treatments.
- the first vaccine for adults against Japanese encephalitis, a disease transmitted by mosquitoes that causes inflammation of the brain and which can lead to long-term disability or death.
- two new mock-up vaccines that can be adapted for use in an influenza pandemic. These mock-ups are not themselves intended for production, but can be used to greatly speed up the authorisation procedure for 'real' vaccines once the strain of the virus causing the pandemic has been identified.
- the first pre-pandemic vaccine for use in adults against the H5N1 subtype of the influenza-A virus, which may cause avian influenza in humans.
- two medicines used to prevent the formation of venous thromboembolism (blood clots in the veins), which can be administered orally and therefore provide an alternative to conventional therapy by injection.

Number of initial-evaluation applications for human medicines up by 14%

Initial-evaluation applications relate to new medicines that have not previously been authorised in any form in the European Union.

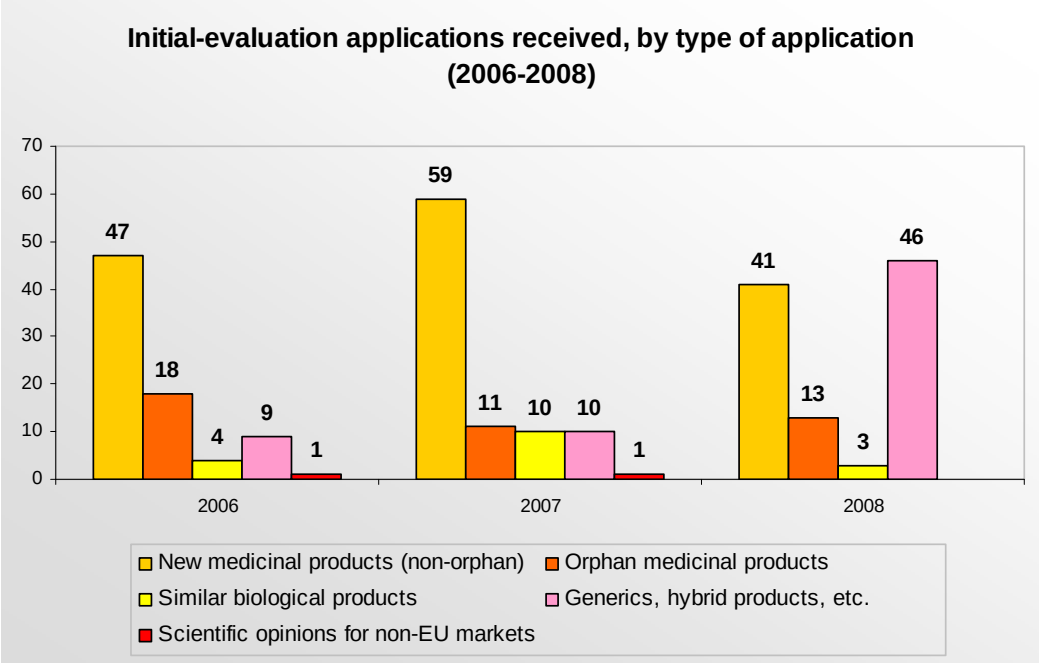
The number of initial-evaluation applications submitted to the Agency in 2008 for evaluation of new medicines for use in humans was 103 — a 14% increase on the number received in 2007.

The CHMP will process these applications within 210 days, as stipulated in EU legislation, and adopt opinions in each case as to whether or not it recommends that a marketing authorisation should be granted.

Of the 103 applications received in 2008:

- 73 related to medicines with a new active substance, i.e. a chemical or biological compound that has not previously been used in an authorised medicine;
- 13 related to 'orphan' medicines, i.e. ones intended for use in the diagnosis, prevention or treatment of rare and seriously debilitating diseases or conditions;
- 46 were for generic or hybrid medicines, i.e. medicines whose active substance is essentially the same as that of a previously authorised medicine;
- 3 were for 'similar biological medicines', i.e. medicines whose active substance is made by, or derived from, a living organism, and is similar to that of a previously authorised medicine.

Applications relating to medicines for use against cancers, infectious diseases, metabolic diseases or alimentary-tract diseases were proportionally higher than ones relating to medicines for any other therapeutic use.



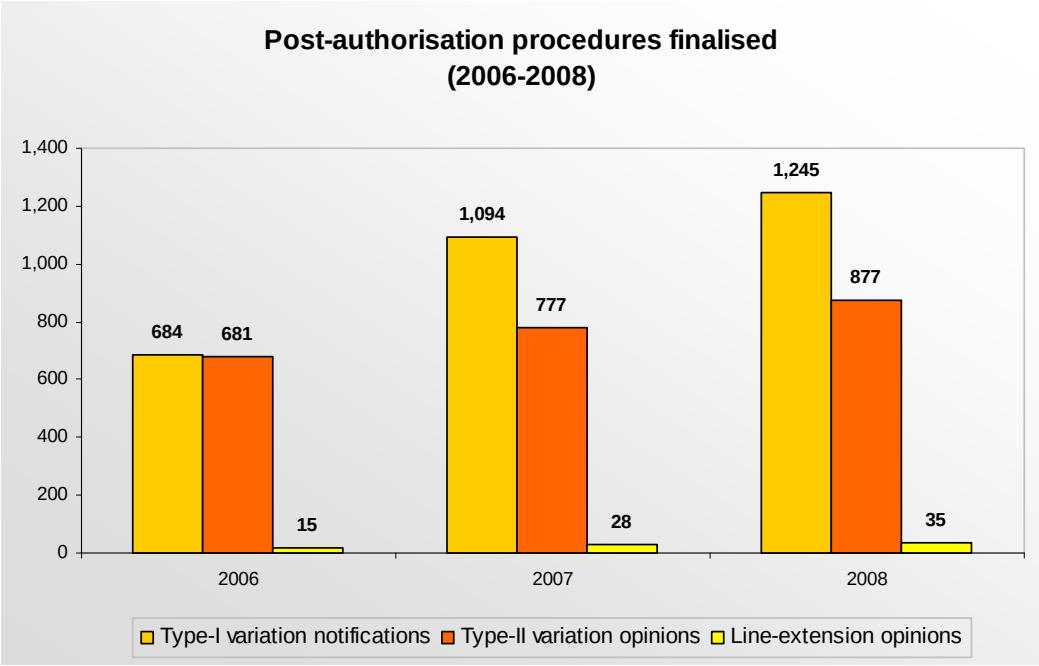
Volume of post-authorisation procedures finalised for human medicines increased by 13%

'Post-authorisation procedures' relate to the processing of applications received from marketing-authorisation holders (licensees) who wish to make changes to their authorised medicines, or who are obliged to do so (for example, to include new safety warnings in the prescribing information).

Minor changes require only that a notification be sent to the Agency for validation. For major changes, the marketing-authorisation holder is usually obliged to submit new data for evaluation by the CHMP and adoption of an opinion on the acceptability of the proposed change.

In 2008, the total number of post-authorisation procedures finalised was 2,157, or some 13% higher than in the previous year. Of these:

- 31 were type-II variation procedures that resulted in positive opinions from the CHMP on the extension of indication of authorised medicines. This will allow doctors a wider scope when prescribing these medicines to patients, which benefits patients by extending the treatment options available to them;
- over 100 were type-II variation procedures that resulted in new information, including safety warnings or precautions, being added to the prescribing information for authorised medicines, thereby helping to reduce the risk of misuse or unwanted side-effects associated with the use of these medicines;
- 1 procedure resulted in the first-ever positive opinion from the CHMP on changing the classification of an authorised medicine from 'prescription only' to 'non-prescription'. The medicine concerned was an anti-obesity medicine.



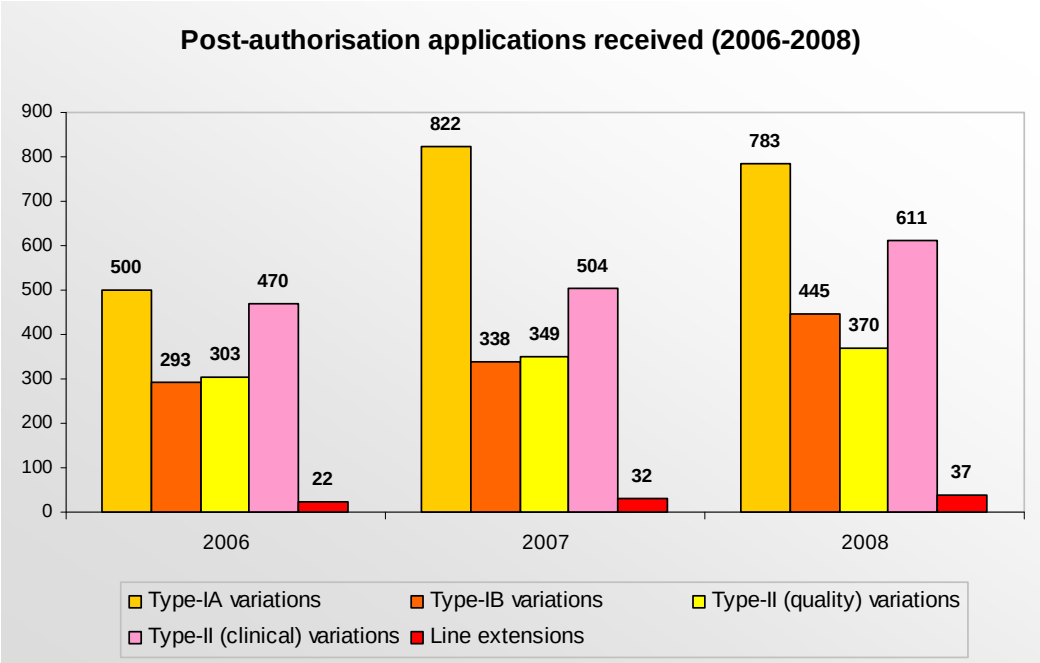
Explanation of post-authorisation categories:

- Type-I variations relate to minor changes to the marketing authorisation for a medicine, such as a change in the name of the medicine, change of the marketing-authorisation holder's or manufacturer's name or address, minor changes to the components of the medicine or their manufacturing processes, or minor changes to the packaging materials.
- Type-II variations relate to major changes to the marketing authorisation for a medicine, such as a change in the medicine's indication (the type of disease or condition it can be used to treat), or a substantial change to the packaging or to the information that accompanies the medicine.

- Line-extension applications relate to changes to the active substance(s), strength, pharmaceutical form (e.g. powder, ointment or tablet) or route of administration (e.g. oral, intravenous or subcutaneous) of an authorised medicine.

Volume of post-authorisation procedures initiated for human medicines increased by 10%

A total of 2,246 applications relating to post-authorisation activities concerning medicines for human use were received in 2008 — a 10% increase on the number received in the previous year. As in previous years, the majority (55%) relate to marketing-authorisation holders notifying the Agency about minor changes to their authorised medicines.



Supervising the development of medicines for children

Companies intending to submit a marketing-authorisation application for a medicine they are developing for use in children or adolescents must first submit a paediatric investigation plan (PIP), setting out the studies they will conduct to demonstrate the quality, safety and efficacy of their medicine when used in these populations. Alternatively, if their medicine is not intended for paediatric use, they must apply for a waiver from the obligation to submit a PIP.

Holders of marketing authorisations for medicines that are already approved for use in adults can apply for a paediatric-use marketing authorisation (PUMA) if they wish their medicine to be approved for use in children or adolescents.

Applications for approval of PIPs, waivers and PUMAs are assessed by the Agency's Paediatric Committee, which also conducts compliance-checks to verify that companies applying for a marketing authorisation have developed their medicine in accordance with their approved PIP.

In 2008, the Paediatric Committee:

- received 271 applications for PIPs;
- adopted 129 positive and 4 negative opinions on PIP applications, and 8 positive opinions on modification of agreed PIPs;
- adopted 48 opinions on applications for product-specific waivers;

- adopted 35 decisions on class waivers[3];
- conducted 5 compliance-checks as part of the validation process for marketing-authorisation applications;
- made 1 positive recommendation on extending the use of a medicine authorised for use in adults to use in children, based on clinical-trial data generated in accordance with an agreed PIP.

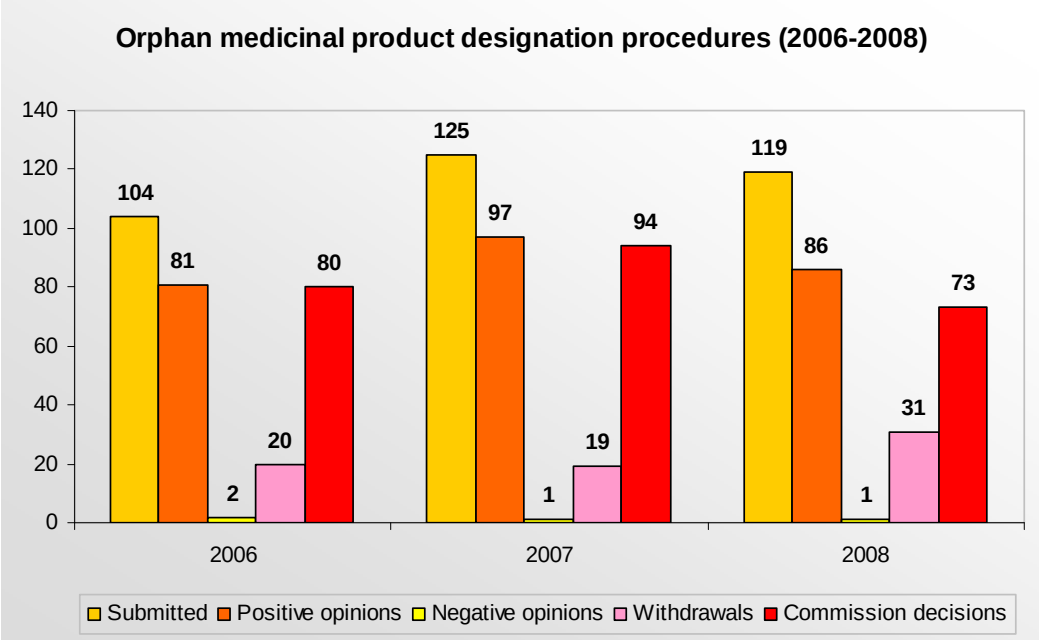
Assessing applications for orphan designation

'Orphan' medicines are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions that affect not more than five in 10,000 persons in the European Union. The EU offers pharmaceutical companies incentives to develop such medicines, so that patients suffering from rare diseases may benefit from a similar quality of medical treatment as other patients.

To be eligible for these incentives, the company must first submit an application to the Agency, which, through its Committee for Orphan Medicinal Products (COMP), assesses whether or not the medicine should be designated as an orphan medicine. The COMP's opinion is forwarded to the European Commission, which takes the final decision on orphan designation.

In 2008:

- 119 orphan-designation applications were submitted to the Agency;
- the COMP adopted 86 positive opinions and 1 negative opinion;
- more positive opinions on orphan designation were given in respect of cancer medicines than any other type of medicines;
- almost two thirds of orphan designations were for medicines to treat conditions affecting children.



[3] The Paediatric Committee adopts decisions on certain classes of medicines for which no PIP needs to be established, such as medicines intended to treat conditions that do not affect children or adolescents (e.g. Parkinson's disease). Applicants are exempt from the obligation to submit a product-specific waiver application if the medicine for which they are seeking a marketing authorisation belongs to one of these classes.

Establishing scientific opinions on herbal medicines

The authorisation of herbal medicines (i.e. medicinal plants or parts thereof, or medicinal preparations containing these) in the European Union usually takes place in accordance with the national procedures of individual countries.

The role of the Agency is to prepare, through its Committee on Herbal Medicinal Products (HMPC), scientific opinions on the quality, safety and efficacy of such medicines, so that regulatory information relating to them can be harmonised across the EU.

In 2008, the HMPC:

- finalised 17 Community herbal monographs[4] for traditional and well-established herbal medicines;
- released for public consultation 14 draft Community herbal monographs for traditional and well-established herbal medicines;
- adopted 5 entries to the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'[5]. One draft entry was released for public consultation.

Evaluating medicines for veterinary use

Thirteen positive opinions adopted for new veterinary medicines

The number of initial-evaluation procedures finalised by the Agency in relation to veterinary medicines in 2008 was 13.

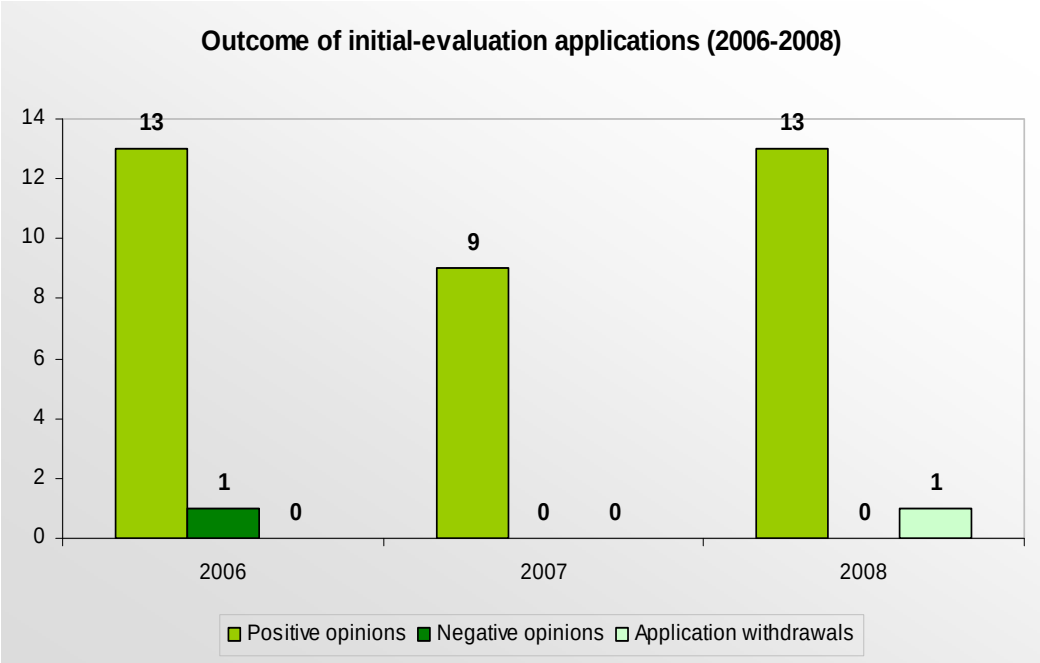
All 13 procedures resulted in a positive opinion being adopted by the Agency's Committee for Medicinal Products for Veterinary Use (CVMP). Of these:

- 7 related to medicines for the treatment of a variety of conditions in dogs, including pain, tumours and musculo-skeletal disorders;
- 1 related to a painkiller for use in dogs and cats;
- 1 related to a painkiller/anti-inflammatory for use in horses;
- 1 related to a medicine for the treatment of respiratory disease in cattle;
- 1 related to a vaccine for the prevention of West Nile Virus in horses and ponies;
- 1 related to a medicine to combat porcine circovirus in pigs;
- 1 related to a medicine for the treatment of bovine mastitis in bovines.

One further application was withdrawn by the applicant before completion of the evaluation procedure.

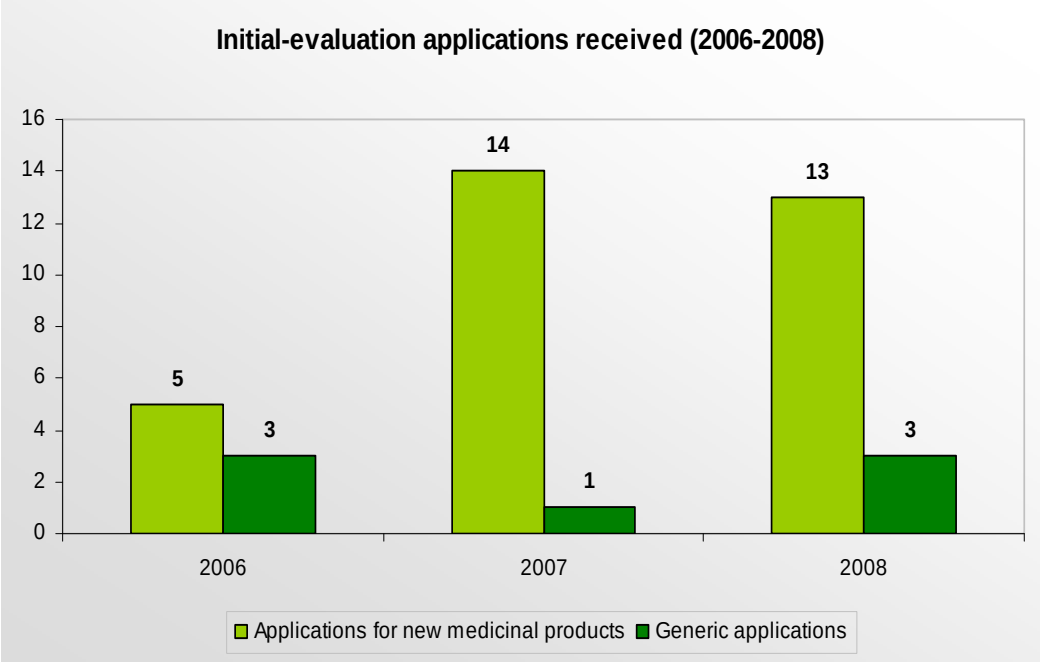
[4] A herbal monograph is a collection of all relevant information concerning a herbal medicine, including its composition, use, safety precautions, etc.

[5] The 'Community list…' is an official list, established by the HMPC and approved by the European Commission, of herbal substances and preparations that have been in medicinal use for a sufficiently long time, and which are therefore considered not to be harmful under normal conditions of use.



Number of initial-evaluation applications received for veterinary medicines remains stable

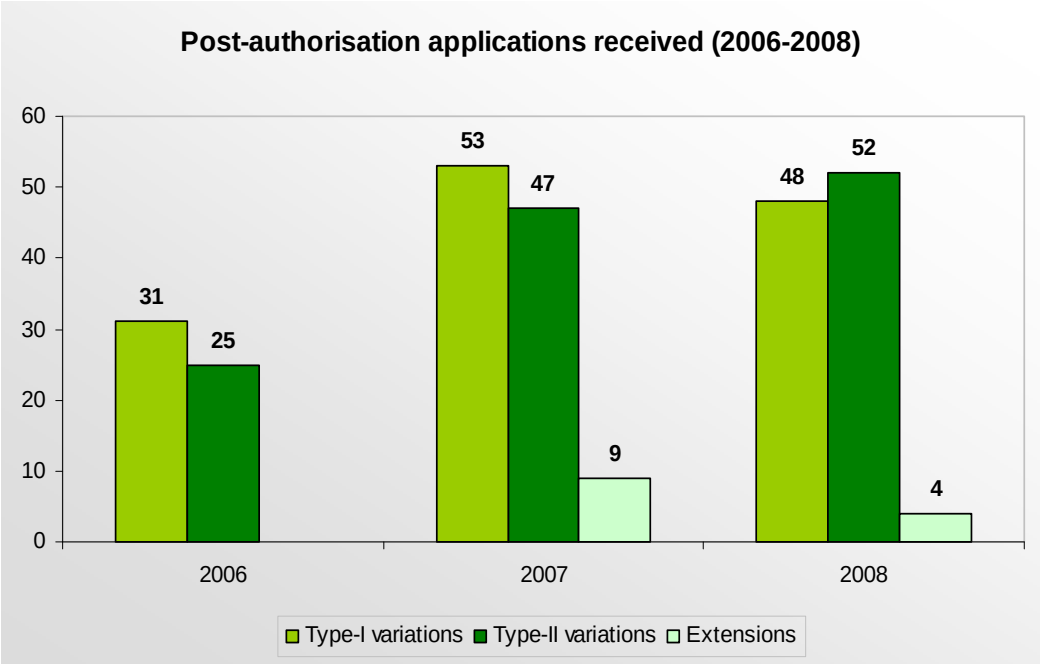
The volume of applications received by the Agency in 2008 for initial evaluation of new veterinary medicines was, at 16 applications, similar to the volume seen in 2007. Three of these applications concerned generic versions of previously authorised medicines.



Volume of post-authorisation procedures initiated for veterinary medicines remains stable

A total of 104 applications for post-authorisation evaluation of veterinary medicines were received in 2008 — just slightly fewer than the 109 received in 2007.

Roughly half of these applications related to type-I variations (minor changes) and half to type-II variations (major changes). Four were line-extension applications.



Monitoring the safety of medicines

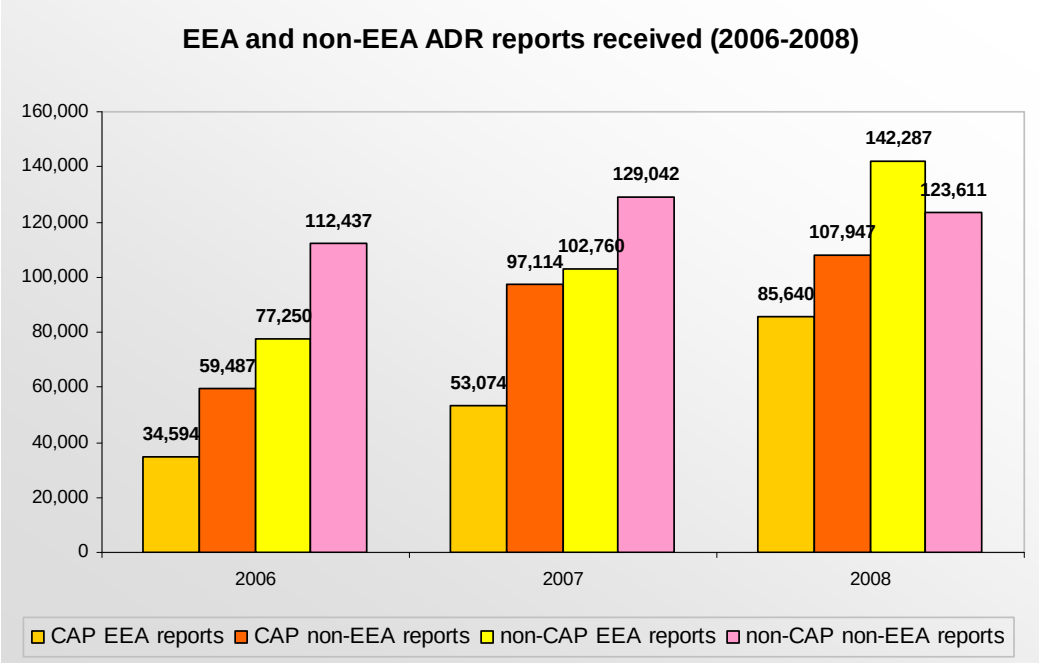
Reporting in EudraVigilance

In 2008, a total of 459,485 reports of adverse drug reactions (ADRs) associated with the use of medicines in humans were entered into EudraVigilance. These reports cover all adverse reactions (unwanted side-effects) that have been observed, whether within the European Economic Area (EEA)[6] or elsewhere in the world, and concern both centrally authorised[7] and non-centrally authorised medicines (shown as 'CAP' and 'non-CAP', respectively, in the chart below).

The EudraVigilance reporting system, which is managed by the European Medicines Agency, allows the safety of authorised medicines to be monitored continuously, so that appropriate regulatory action, such as the suspension of a marketing authorisation, can be taken rapidly whenever there is a risk to public health.

[6] The European Economic Area includes the 27 Member States of the European Union, plus Iceland, Liechtenstein and Norway.

[7] Centrally authorised medicines are ones that have been simultaneously approved in all EEA countries, through procedures operated by the European Medicines Agency, whereas non-centrally authorised medicines have been approved separately by one or more EEA countries.



Reporting in EudraVigilance Veterinary

An equivalent system, called EudraVigilance Veterinary, exists to receive reports of adverse reactions occurring through the use of authorised veterinary medicines.

A total of 1,943 reports of adverse reactions in animals were recorded in EudraVigilance Veterinary in 2008, of which 1,712 related to reactions in companion animals (971 in dogs and 704 in cats) and 231 in food-producing animals (cows, pigs, etc.). A further 308 reports related to adverse reactions occurring in humans following exposure to veterinary medicines.

Reviewing periodic safety update reports for human and veterinary medicines

Besides monitoring adverse-reaction reports, the Agency also reviews periodic safety update reports that marketing-authorisations holders are obliged to submit in respect of their centrally authorised medicines. These reports compile all known safety data relating to the use of the medicine concerned, including information that becomes available through additional trials conducted after the medicine has been authorised.

In 2008, the Agency reviewed 391 such reports relating to medicines for human use and 91 relating to veterinary medicines.

Implementing the European Risk Management Strategy

The European Risk Management Strategy is a strategy developed by the Agency and its partners in the European regulatory network for medicines. Its aim is to put in place measures that allow the early detection, assessment, minimisation and communication of risks associated with medicines throughout their lifecycle.

The main initiative undertaken in 2008 within the framework of this strategy was the introduction of an early notification system for improved communication between European regulatory authorities, as well as with the US Food and Drug Administration, on envisaged regulatory action to be taken in response to (emerging) safety issues. This system allows the Agency and its partners to take a more proactive and coherent approach to communicating on safety concerns within the network.

Supporting innovation and the availability of medicines

Supporting SMEs

Small and medium-sized enterprises (SMEs) operating in the human and veterinary pharmaceutical sectors are often innovators of new technologies and emerging therapies. In recognition of this, special provisions have been made in EU legislation to offer financial incentives for such companies, including the reduction or deferment of fees payable to the Agency for regulatory procedures such as marketing-authorisation applications or, for veterinary medicines, the establishment of maximum residue limits[8].

A dedicated SME Office within the Agency provides support to SMEs on these and related issues, to help them maximise the benefits available to them, and thus contributes towards stimulating innovation of new medicines and improving their availability to patients.

In 2008, the SME Office:

- published a revised and updated version of its SME User Guide on the Agency's website;
- continued its work on identifying specific guidance needs relating to advanced therapies;
- reviewed and approved 84 applications from SMEs for the reduction or deferment of fees;
- processed 337 applications for qualification or renewal of SME status;
- received 85 requests for administrative assistance.

Providing scientific advice to support the development of medicines

The Agency contributes towards accelerating the availability of medicines through its provision of scientific advice to companies.

At any stage in their development of a medicine, a company can request scientific advice on how best to conduct the various trials and studies that are necessary to demonstrate the quality, safety and efficacy of their product, and thus improve their chances of obtaining a marketing authorisation for it.

A special form of scientific advice, called protocol assistance, can be provided to help developers of orphan-designated medicines demonstrate that their medicine offers a significant benefit over other available treatments, which is a necessary condition for receiving a marketing authorisation for an orphan medicine.

In 2008, the Agency, through its relevant scientific committees and working parties:

- finalised a record number of 328 scientific-advice and protocol-assistance requests relating to medicines for human use (up 14% on the number of requests finalised in 2007);
- received 320 new or follow-up requests for scientific advice or protocol assistance relating to medicines for human use;
- received 5 requests for scientific advice relating to veterinary medicines.

Preparing for the establishment of the Committee on Advanced Therapies

The Agency devoted considerable effort in 2008 to setting up its sixth scientific committee — the Committee for Advanced Therapies (CAT) — and putting in place all relevant procedures and personnel ahead of the Committee's inaugural meeting in January 2009.

The establishment of the CAT was stipulated in the EU's Advanced Therapies Regulation[9] — a new and important piece of legislation that introduces special procedures for the evaluation and authorisation of 'advanced therapy medicinal products' — medicines derived from gene therapy, somatic cell therapy or tissue engineering — which offer groundbreaking treatment options for patients.

[8] Maximum residue limit: the maximum acceptable concentration of the residue of a medicine in a food product obtained from a treated animal.

[9] Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

Strengthening cooperation with European and international partners

Strengthening the European medicines network

The European medicines network is a partnership of more than 40 national regulatory authorities across the European Economic Area. Collectively, these partner organisations provide the best-available scientific expertise to ensure a sound regulatory system for medicines in Europe. It is from within this network that the Agency sources most of the experts that serve as members of its scientific committees, working parties and related groups.

As part of its ongoing efforts to strengthen the efficiency of the network, the Agency focused in 2008 on:

- improving resource-planning, notably by providing regular estimates of resources required for forthcoming applications for regulatory procedures;
- improving the organisation of meetings at the Agency, notably by improving the availability of video- and teleconferencing facilities, thus reducing the need for experts to travel to the Agency's premises;
- improving competence-development, notably by providing a series of training sessions for experts and assessors on a range of specialised topics.

Strengthening cooperation with international partners

Medicines regulators around the world share the same objective of establishing adequate procedures for the development, testing, authorisation and monitoring of medicines, in the interest of protecting the populations they represent. In doing so, they also face very similar challenges, and by pooling their experiences, sharing information, exchanging expertise and harmonising their regulatory practices, they stand a better chance of overcoming those challenges.

The Agency engages in an intensive annual programme of activities with its regulatory and scientific partners across Europe, and with their counterparts on other continents, to contribute towards these global efforts for better and safer medicines.

In 2008, key cooperation activities with international partners included:

- participation in a series of projects being run by the World Health Organization, notably the 'Make medicines child size' programme aimed at addressing the need for improved availability of safe medicines for children;
- an ongoing programme of activities designed to help the regulatory authorities of Croatia, Turkey and the former Yugoslav Republic of Macedonia prepare for integration into the European medicines network upon the eventual accession of these countries to the EU;
- further contributions to a series of activities with partners of the tri-partite (EU-USA-Japan) International Conference on Harmonisation (ICH) and its veterinary equivalent (VICH);
- a series of exchanges of information with the medicines authorities of the USA, Canada and Japan, within the framework of confidentiality arrangements signed between the EU and these countries;
- appointment of an International Liaison Officer to oversee the further development of the Agency's activities with its international partners.

Interacting with patients, consumers and healthcare professionals

Healthcare professionals, patients and other consumers of medicines are key stakeholders in the work of the Agency because, besides being the primary end-users of the medicines and information about medicines for which the Agency is responsible, they have specific knowledge and expertise to offer the Agency in return.

The Agency is committed to maintaining a strong working relationship with these important stakeholders, and has created a number of mechanisms for their involvement in a range of its activities, including:

- participating in meetings of the Patients' and Consumers' Working Party or of the Healthcare Professionals' Working Group;
- checking the quality of information about authorised medicines;
- assisting in the preparation of regulatory and procedural guidance documents;
- providing recommendations to the Agency and its scientific committees on all matters of direct or indirect interest to them.

Improving the opportunities for interaction

Efforts made in 2008 to further enhance the involvement of healthcare professionals, patients and consumers in the Agency's activities included:

- extending the scope of patients' and consumers' involvement in reviewing the quality of package leaflets (the information contained in the package of a medicine);
- working with patients and consumers to establish, by means of a survey, their level of satisfaction with their current involvement in the activities of the Agency;
- integrating input received from healthcare professionals, patients and consumers in the development of the Agency's communications strategy.

Fostering transparency, communication and provision of information

Providing greater access to the Agency's information

Activities carried out in 2008 to provide greater transparency of documents and data controlled by the Agency included:

- discussion within the Agency's Management Board about publication of its documents. It was agreed that, from March 2009 onwards, non-confidential Board documents, including agendas and minutes, would be published on the Agency's website[10] following each Board meeting;
- preparing and releasing for consultation a policy on access to documents, which foresees the ability for the public to request access to any document produced or received and held by the Agency;
- preparing and releasing for consultation a policy on appropriate levels of access by regulatory authorities, healthcare professionals, patients, pharmaceutical industry and the general public to information contained in EudraVigilance — the EU's database of adverse reactions to medicines;
- preparing for the future provision of access to certain data contained in EudraCT — the EU's database of clinical-trial information — and preparing an implementation plan for adapting information-technology systems to allow for such access.

[10] Management Board documents: http://www.emea.europa.eu/htms/general/manage/MB/MB_documents.html

Improving the Agency's web communications

A 'public-facing online information project' was launched in 2008 to begin a comprehensive overhaul of the Agency's public website. This process is intended to greatly improve the presentation and functionality of the website, as well as improve the quality of the content accessible through the site.

This project will include consultation with the Agency's primary audiences, including patients, healthcare professionals, regulatory authorities and pharmaceutical companies, and is scheduled to deliver a new website by the end of 2009.

In the meantime, continuous improvements to the Agency's communications via internet were made throughout the year, including:

- launch of the ENCePP website[11], devoted to the activities of the newly created European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), which is coordinated by the Agency;
- creation of a new 'Regulatory and procedural guidelines' section[12] of the Agency's public website, designed to provide convenient access to the main regulatory and procedural guidance documents relevant to the operation of the centralised authorisation procedure;
- creation of a 'Medicines for the elderly' section of the Agency's public website [13], dedicated to providing information on the work the Agency is conducting with its partners to develop harmonised standards for the development, testing, approval and use of medicines for the elderly.

[11] ENCePP website: http://www.encepp.eu
[12] 'Regulatory and procedural guidance': http://www.emea.europa.eu/htms/human/raguidelines/intro.htm
[13] 'Medicines for the elderly': http://www.emea.europa.eu/htms/human/elderly/introduction.htm

Revenue and staffing figures

Revenue increased by 10.7%

The Agency's total revenue in 2008 was 182,895,000 euro — slightly over 10% higher than in 2007.

The table below shows a breakdown of the Agency's revenue for 2007 and 2008, together with the forecast figures for 2009.

	2007		**2008**		**2009** (forecast)	
	€ '000	%	€ '000	%	€ '000	%
Revenue						
Fees	111,753	*67.61*	126,318	*69.07*	138,966	*73.65*
General EU contribution	39,750	*24.05*	39,997	*21.87*	36,390	*19.29*
Special EU contribution for orphan medicines	4,892	*2.96*	6,000	*3.28*	5,500	*2.91*
Contribution from EEA	789	*0.48*	956	*0.52*	888	*0.47*
Community programmes	583	*0.35*	600	*0.33*	300	*0.16*
Other	7,522	*4.55*	9,024	*4.93*	6,645	*3.52*
TOTAL REVENUE	165,289	*100.00*	182,895	*100.00*	188,689	*100.00*

Staffing increased by 14%

The total number of people employed by the Agency at the end of 2008, including regular staff plus contract agents, visiting experts, interims and trainees, was 624, or some 14% more than the 547 employed in 2007.