LÆGEMIDDEL STYRELSEN

DANISH MEDICINES AGENCY

REPORT 2006

Mission

We aim to ensure the availability of effective and safe healthcare products – medicinal products, medical devices and new therapies – and we promote the proper use of such products.

Vision

We will influence the international development of medicinal products and other healthcare products. We will focus on the health and welfare of both people and animals with due consideration to affordable and economic treatments.

Foreword

In the report for 2006, we have chosen to bring you samples of how we put our values into practice in our daily activities.

We make many decisions during the course of a year. Some decisions are major, some small, but regardless of size, they all have in common that they impact other people. It is our responsibility to make decisions according to the framework laid down by the Danish Parliament and to carry out our activities impartially on an informed basis.

Everyday, we communicate with companies and citizens, not only from Denmark, but also from other countries inside and outside Europe. Our job is relevant and interesting because we must show empathy and mutual respect.

Communication is increasingly expanding in modern society, so we constantly develop and professionalise the way we communicate. We consider form and content carefully, and our choice of communication channels is made consciously. This is crucial, not least because our capacity as a Danish international government agency requires of us to communicate in both Danish and English.

The employees *make up* the Danish Medicines Agency. It is the people that make the big, positive difference when we communicate with the outside world, generate results and associate with our fellow colleagues every day.

Have a taste of some of our activities in 2006 on the next pages. The recipe is competent and committed employees added the right amount of our common values:

We are *competent*
trustworthy
attentive
receptive
European

I hope you will enjoy the report.

Jytte Lyngvig
Chief Executive Officer

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2006

Consumption of medicinal products

Reimbursement

Sale and distribution of medicinal products

Supervision of medicinal products and medical devices

Danish Medicines Agency

Authorisation of companies

Clinical trials

Authorisation of medicinal products

Control of medicinal products

We are competent

We implement our decisions into definite, timely and effective action. We place emphasis on allowing the authorisation of innovative healthcare products, for the benefit of people and animals, without unnecessary delay.

The Danish Medicines Agency strives not only to respond, but also to take a proactive approach.

Increased cooperation and campaign against counterfeit medicinal products

Today, the risk of coming across counterfeit medicine is real as a result of a globalised production and distribution. We need to be particularly alert at the Danish Medicines Agency, so that consumers who receive a prescription from their doctor and buy the medicine either at a pharmacy or legally via the internet can rest assured that it is okay. We cannot do this on our own, and we therefore coordinate a new Danish network launched to intensify efforts against and information about counterfeit medicine. All stakeholders join in: the Danish Tax Authorities, the Danish Police, the Danish Medicine Wholesalers Association, the Danish Patent and Trademark Office, the Danish Veterinary and Food Administration, the Danish Association of the Pharmaceutical Industry, the Danish Pharmaceutical Association, the Danish Industrial Association of Veterinary Medicine, the

Danish Industry Association for Generic Medicines, the Danish Association of Parallel Importers, the Association of Danish Pharmacists and the Danish Medical Association.

We have also launched a nationwide information campaign under the slogan "Take care of yourself – also when you take medicine". We advise consumers to think twice if they contemplate skipping their GP visit and buying prescription-only medicine cheaply on the internet or if they feel tempted to buy a seemingly harmless health product at the fitness centre with promises of slimmer thighs or bigger biceps. The aim of the campaign is to sharpen the consumers critical sense both towards the use of medicine and the distribution channels. The campaign was kicked off with advertisements and information on the internet and continues in 2007 with user surveys and information targeted at the most obvious segments.

Increased focus on the tissue area
In April 2006, new European legislation became effective. It lays down standards of quality and safety for the donation, procurement and preparation of human tissues and cells. The new legislation also requires that fertility clinics, sperm banks and other establishments handling human tissues and cells must now be authorised by the Danish Medicines Agency.

These legislative requirements have been implemented by a number of executive orders, and all tissue establishments seeking to be licensed must therefore be inspected and approved by officers from the Danish Medicines Agency before 7 April 2007. Thus, we are one of the first medicines agencies within the EU to implement the European tissues directives and enhance the safety in this area.

Doctors' affiliation to the pharmaceutical industry
In 2006, we decided together with the Danish Medical Association, among others, to take measures to make doctors seek approval if they cooperate with the pharmaceutical industry. The Danish Parliament has adopted that doctors must do so. This is described in section 3(2) of the Danish Pharmacy Act. The knowledge of this requirement has not been sufficient enough among doctors, and we have therefore found it necessary to initiate special information activities. In this connection, we have developed a digital solution that enables the individual doctor to report his or her interests via the website of the Danish Medicines Agency.

We are European

We participate actively in the European arena – in individual cases, in formulating general requirements and in setting a common course for the better regulation of healthcare products.

The Danish Medicines Agency is European in almost every aspect. We work with and for Europe and the European consumers and companies when we attend to the variety of our tasks.

Denmark – the preferred authorisation country
The pharmaceutical and the medical devices industries and their markets are international. This is also reflected in the applicable law.

Medicinal products must be approved before they reach the hands of consumers, just as medicinal products and medical devices must be monitored throughout Europe. This is because goods and people move freely across European borders.

When it comes to the approval of medicinal products, companies increasingly select the Danish Medicines Agency when they apply for approval under the mutual recognition procedure (MRP) and the decentralised procedure (DCP). In fact, our popularity in these areas also means that we

agency to maintain focus on continued development of quality and efficacy. The evaluation, which was based on an analysis of questionnaires etc., provides an overall picture of the agencies' way of organising their work whether it is activities before and after the approval of a medicinal product, pharmacovigilance, risk assessments, risk management or inspection and market surveillance. The evaluation of the Danish Medicines Agency in March 2006 was an educational and comprehensive process, which fortunately showed an outstanding result. On a scale from one to five, one being the lowest score and five the highest, we achieved an average of 4.2. BEMA will be repeated in 2008-2009.

have difficulties in keeping pace with the excessive demand at present. Historically, Denmark is also among the most active countries in terms of applications under the centralised procedure and scientific advice.

Rewarding international cooperation
We put many working hours into international tasks and cooperation because we want to influence development in the technical areas that we work with. We are represented in more than 130 international contexts. European cooperation takes place in both technical and scientific working groups and committees as well as in forums where the employees contribute with negotiating and preparing proposals for EU legislation and guidelines. The cooperation is rewarding from both a professional and collegial perspective. We derive great benefit and inspiration from it to solve our own national challenges, just as we hopefully inspire our fellow colleagues in other countries.

In 2006, the Danish representative in CVMP, EMEA's scientific advisory committee for medicinal products for veterinary use, was elected deputy chairman of the committee.

The Danish Medicines Agency participates in European benchmark project
A European benchmark analysis of the European medicines agencies gave Denmark a high score in 2006.

The BEMA project – an acronym for Benchmarking of European Medicines Agencies – is a tool used by all human and veterinary medicinal agencies within EU (more than 40) that helps the individual

We are attentive

We are continuously in touch with our partners and other associates. We see criticism as an invitation to dialogue to improve our performance.

We the Danish Medicines Agency are here to serve society. With this statement comes an obligation to continuously stay in tune with the outside world's requirements and expectations to us. We do this in many different ways e.g. through conferences, networks, user surveys and in particular when we are in direct contact with many people, among them reporters, as part of our daily activities.

User satisfaction survey
In May 2006, the research firm Epinion studied the pharmaceutical companies' view on the work of the Danish Medicines Agency.

Generally, there was widespread satisfaction with our performance. As many as 63 percent of the companies were satisfied with the Danish Medicines Agency all in all, and our employees received many positive comments along the way. The survey also gave us criticism and revealed areas with room for improvement. We have listened and will do our best to work even harder.

Media and consumers
Not a day goes by that we are not contacted by the media – newspapers, radio and TV stations. Stories about medicine and healthcare products is 'hot stuff' with a wide audience. Medicine consumption is interesting to many, and we therefore get a lot

of questions in this area. To meet this demand for information, we have posted consumption statistics on our website in both Danish and English, allowing anyone with access to the internet to search for information directly.

Another area that receives a lot of attention is side effects from taking medicine and adverse incidents related to medical devices. We make all possible information available to the public, which primarily equals European Data. This is a complex area in several respects, in part because it requires high technical expertise to assess data and in part because there must always be an appropriate balance between the requirement for openness on one side and the requirement for confidentiality on the other. For this reason, we sometimes see that the people who have requested access to data do not always find the answers to be adequate. Our vision is that the data that we are allowed to publish will be available digitally within a few years.

The annual meeting of the pharmaceutical industry
On 1 November 2006, the Danish Medicines Agency hosted the annual meeting of the pharmaceutical industry and other interested partners and associates at the Royal Library in Copenhagen. The purpose of this annually recurring conference is to promote dialogue by putting focus on relevant and current topics. The agenda is prepared and composed based on proposals from the participants. 2006 focused on the new rules for reimbursement of medicine, the launch of electronic reporting via DKMAnet – Prices & Packages, changes in Pharmacovigilance inspections, and increased requirements to the reporting of adverse reactions and naturally also case-handling times.

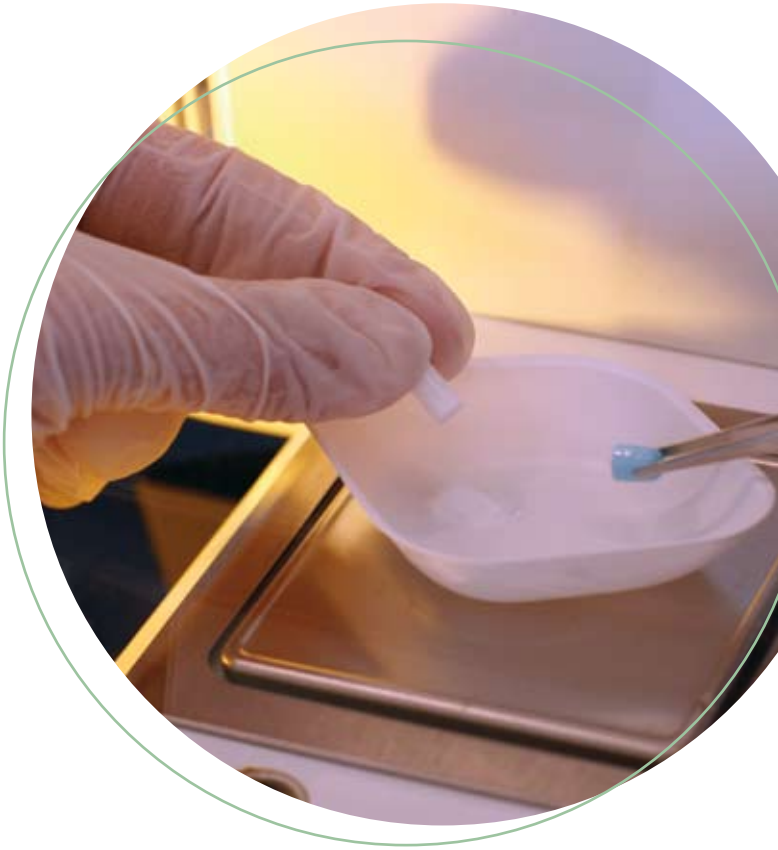
We are trustworthy

We are receptive to new knowledge and sound argument, but resist pressure from special interest groups.

There must never be reason to question our trustworthiness, neither professionally nor personally. We must continuously focus on professional knowledge and quality.

We are impartial – also when the legal system has spoken

The decisions by the Danish Medicines Agency rest on an objective and informed basis. Naturally, it sometimes occurs that someone challenges our assessments and brings a decision before the court. When it happens it is satisfying when a decision is confirmed, telling us that we are on the right track. This was the case in December 2006 when the Eastern High Court ruled in favour of the Danish Medicines Agency and the Ministry for the Interior and Health in a case on general reimbursement. The case had been raised by a pharmaceutical company that wished to test a rejection by the Danish Medicines Agency in a case on general reimbursement.



Research in focus
The Danish Medicines Agency has teamed up with the Drug Research Academy under the Faculty of Pharmaceutical Sciences at the University of Copenhagen, cooperating on three PhD projects. In 2006, we co-financed three projects, and the employees from the Danish Medicines Agency are moreover affiliated as external supervisors. The projects cover subjects as diverse as:

- Comparison of protein structures by means of physico-chemical methods
- Environmental risk of anticoccidial feed additives in the poultry industry
- Comparative investigations of medicine use in the primary and secondary health sector

Our participation implies that we make our knowledge and experience available to research, which in turn keeps us abreast of the latest developments. It gives a good overview and implies that our work and decisions are founded on a credible basis.

We are receptive

We base our work on our expert knowledge and scientific data. We attach great importance to openness and honesty and in sharing knowledge and data with others.

Our house is packed with knowledge and data. It comes natural to us in capacity as government agency to be open about what we do and to communicate this externally.

Increased interest in our knowledge and data
The Danish Medicines Agency harbours a wealth of knowledge e.g. in the form of statistics on medicine consumption. In recent years, we have seen a steady increase in requirements to disclose this knowledge also from other authorities, nationally and internationally. We often see scientists requesting information from us to study connections between diseases and medicine consumption. The demand for data places heavy demands on how we communicate our – often quite technical – knowledge in an easy-to-understand and accessible manner – both orally and written as well as on the internet.

Internet self-service
It is important to integrate the digital media to make everyday activities smoother and increase accessibility for healthcare professionals and consumers alike. In 2006, we realised a number of new digital features.

Previously, the pharmaceutical companies reported changes in medicine prices and product range by fax to the Danish Medicines Agency. In 2006, we launched our internet-based self-service extranet DKMAnet – Prices & Packages. Here the companies can transfer or enter changes to prices or product range directly, just as they can adjust or add own data easily. The new solution offers far better data security and reduces the companies' workload. It also gives greater flexibility and a better overview of prices and products.

We also introduced digital application forms for single reimbursement and a digital form for reporting adverse reactions. In other words, we have seriously kicked off the coming years' expansion of digital solutions on our website www.dkma.dk.

What does the law say?
Acts, executive orders and guidelines are now available in Danish in a user friendly and clear format on our website. The most important texts are even available in English. Thus, anyone interested has direct access to relevant legal texts within the areas of our responsibility.

Knowledge is also available to consumers
In July 2006, we opened a new and improved version of the service www.medicinpriser.dk. Here the consumers can calculate medical expenses, find prices on all medicinal products, track the product price development and see the amount of reimbursement to which they are entitled. Medicinpriser.dk was developed to give consumers a clearer picture of the development in medicine prices and to give everyone the possibility to calculate the cost borne by the patient and the rate of reimbursement. In 2006, the Register of Medicinal Product Statistics at the Danish Medicines Agency came in an English version at www.dkma.dk.

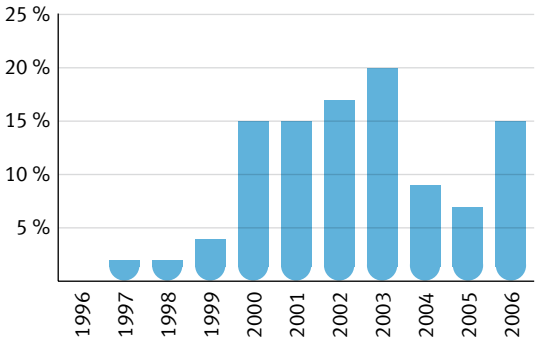
Open doors at the Danish Medicines Agency
The word openness should also be taken literally. In 2006, we opened the doors to the public for the fourth consecutive year at the Night of Culture in Copenhagen. This year's theme was "Children and Medicine" – and one of the attractions was a teddy bear casualty ward where children could have their sick or injured teddy bears diagnosed and treated. Yet, the theme did have a more serious background, viz. an array of new EU rules stipulating that medicine intended for children should also be tested on children in future. Two of our employees therefore gave a presentation to the adult audience about what the new rules actually mean for children and the pharmaceutical companies .

Financial highlights

The Danish Medicines Agency expresses satisfaction with the financial statements for 2006. In particular, the year saw increased income from the decentralised recognition procedure, under which companies apply for authorisation in several EU (EEC) countries at the same time, and income from tasks performed on behalf of the European Medicines Agency, EMEA. Total income from fees and annual charges, etc. accounted for DKK 211.5 million in 2006 up from DKK 183.4 million in 2005, corresponding to an increase of DKK 28.1 million or 15 percent.

Financial highlights	DKKm
Operating income	241.6
Operating costs	292.1
Of which staff costs	163.3
Result for the year (before net funding)	- 50.5
Net funding, including supplementary funding, cost-based	73.2

The Danish Medicines Agency has seen an increase in activities for several years and with it a strong increase in income. The diagram below illustrates the development in activities year-by-year, reflecting the percentage increase in fees on the year before.



CEO Jytte Lyngvig comments. "Our fees are related to our activities. In principle, when the activity level increases, our fees and expenditure go up, and when the number of cases drop, our fees and expenditure decrease accordingly. The increase in fee-generated income therefore reflects increased activities. Among other things, we have spent the extra income to engage more employees so as to strengthen our case-handling capacity."

Average age of employees

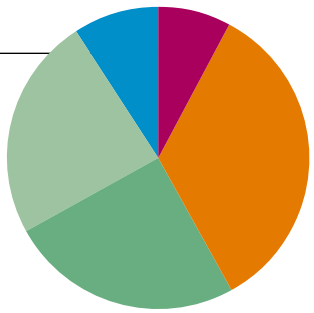
Average age of employees	41 years

Staff turnover

New employees	100
Resigned employees	80

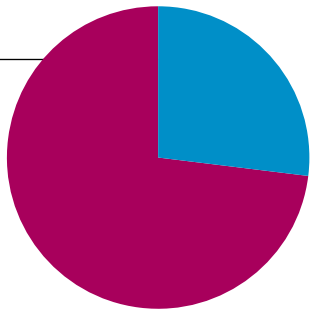
Employees broken down by professional groups

Doctors	8%
Pharmacists	34%
Other academics	25%
Clerical workers	24%
Others	9%



Gender distribution

Men	27%
Women	73%



Want to know more ...

www.dkma.dk

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