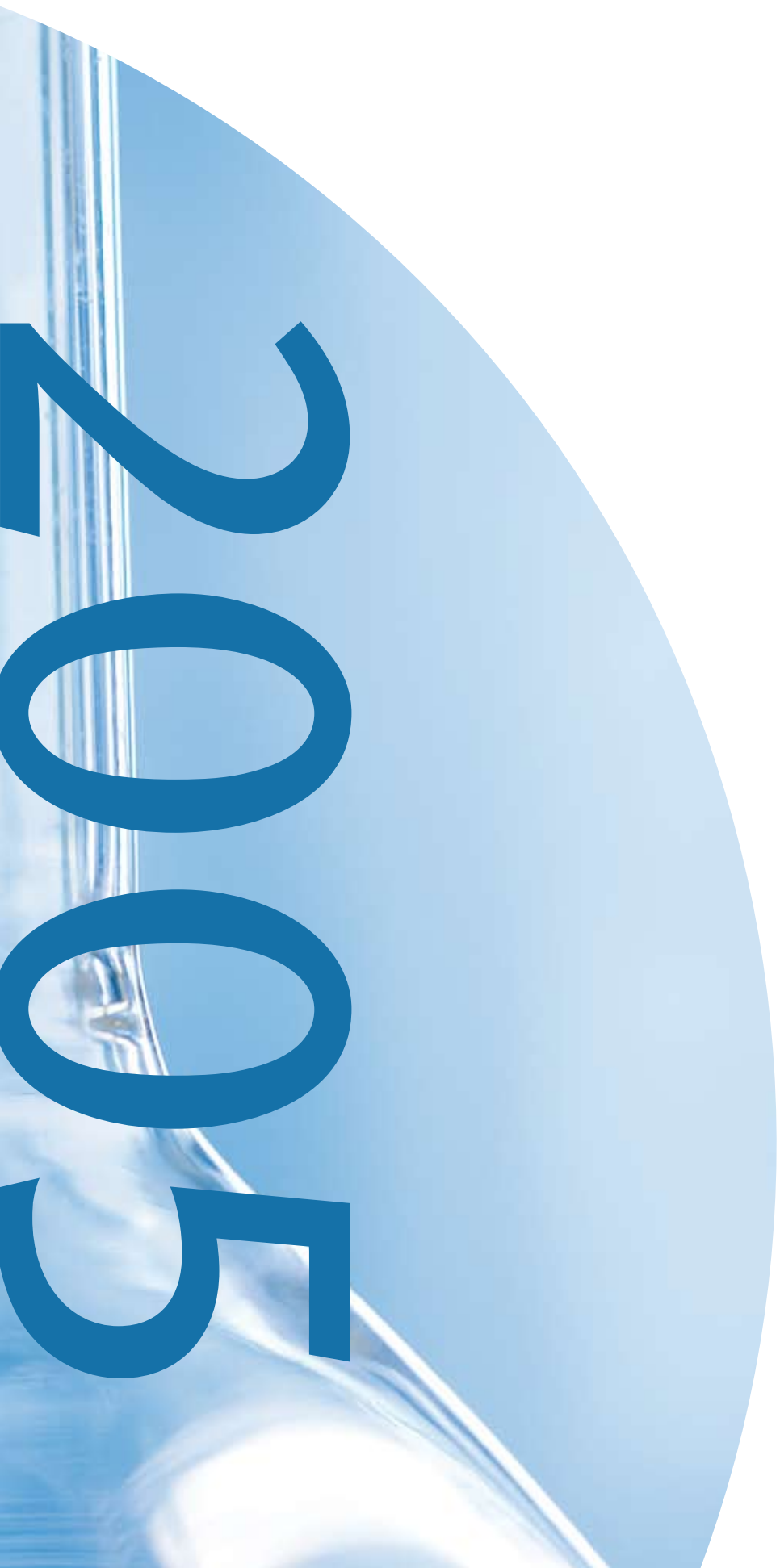
LÆGEMIDDEL STYRELSEN

DANISH MEDICINES AGENCY



2005

REPORT 2005

ENGLISH

Mission

We aim to ensure that effective and safe health care products

– medicinal products, medical devices and new therapies –

are available to all and promote the proper use of such products.

Vision

We want to play a part in the European development of medicinal

products, medical devices and new therapies. We want the health

and welfare of people and animals to be in focus and the associated

socio-economic costs to receive due consideration.

2005

Preface

The effort on ensuring consumer safety became very visible in the spring of 2005 when we decided to set up an individual division under this heading. Initially, we decided that the new division should be responsible for adverse drug reactions, related post-marketing tasks and the interaction database. Later, the responsibilities of the division were expanded to also include the authority activities in the fields of medical devices and clinical trials.

The new Medicines Act entered into force in December. Prior to the effective date, a large number of employees had invested very great efforts in the actual Act as well as in preparing the 39 accompanying executive orders. The new Medicines Act contains many new provisions; for instance tightened rules on medicinal product safety both before and after marketing.

Production and distribution of medicine take place across country borders. Not just in Europe, but all over the world. This places large demands on good collaboration between everyone involved in control tasks and the legal consequences of violating regulatory requirements. This applies internally as well as in our joint work with our European colleagues. Therefore, it represented a clear strengthening of our ability to best perform these tasks when we gathered laboratories, inspection and enforcement tasks in one division in 2005.

On 1 April, a new reimbursement system was introduced. A change of this nature will always give rise to a series of technical modifications of the existing system. In addition, an entirely new task was assigned to us because the Danish Parliament has decided that the reimbursement status of medicines must be regularly reviewed. This is a demanding task, so our first endeavour was to create the right framework.

Openness is one of our core values. A concrete manifestation is that we published the case handling times for authorisation of medicines at the national level on the Internet, and that we did so in a way which allows the individual companies to keep track of their own cases. It is worth noticing that this is also the one case area which, over the years, has given us most difficulties in terms of coping with excessively long case handling times. This problem was efficiently addressed with new successful work processes. Another example of openness is that we put a calendar at our website to enable anyone interested to stay abreast of all the meetings and events that we participate in and host.

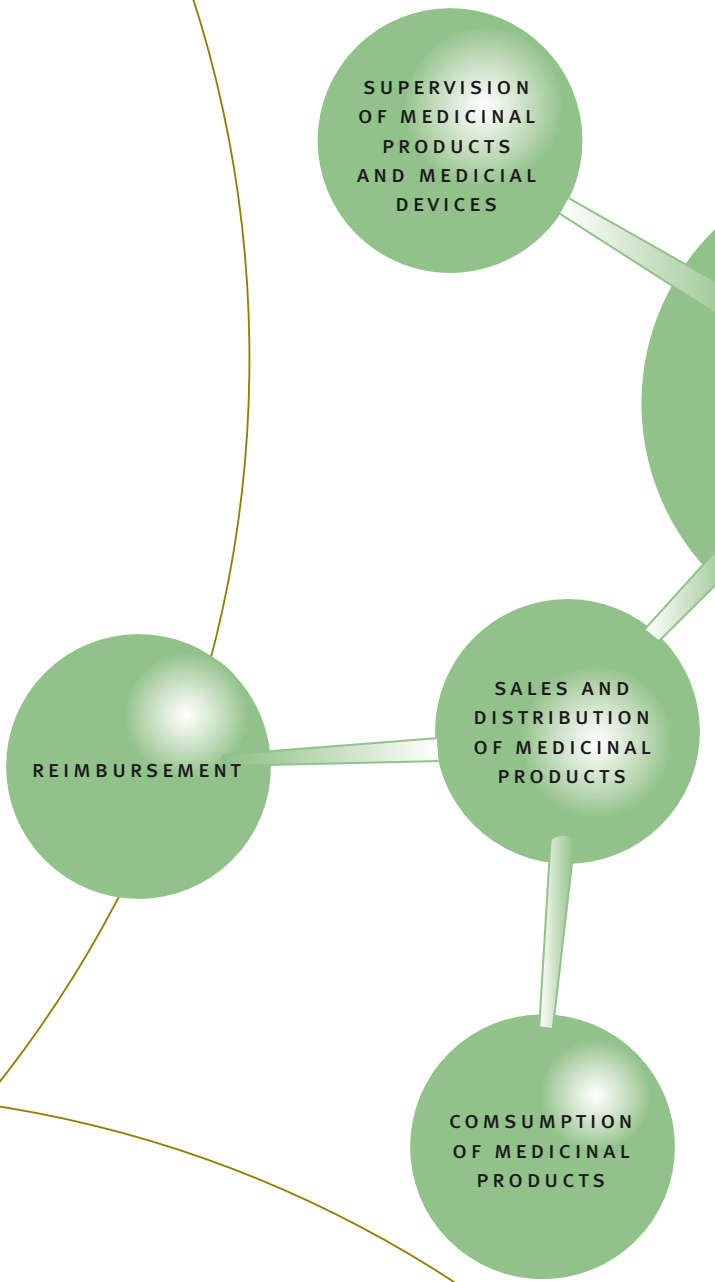
The employees of the Danish Medicines Agency are very knowledgeable but also require new knowledge in order for their work to meet the level of quality requested by us. Continued competence development therefore requires close contact with R&D environments. We have been given the chance to maintain this contact in practice through our participation in a large EU project on biosimulation and by being a partner in DRA, the Drug Research Academy under the Danish University of Pharmaceutical Sciences. Under the auspices of DRA, we participate actively in three PhD projects with employees from the Danish Medicines Agency as project supervisors.

In 2005, we also enlisted as a pilot company in the process that will make all organisations under the Danish state prepare budgets and accounts in accordance with the expense-based principle, which is new for the Danish state. This requires an opening balance to be defined, adjustment of the accounts, budgeting of depreciation and amortisation and much more. The advantage of this effort is that the management will be better supported by budgets and accounts focussing on activities and covering several years.

2005 was a year full of challenges which we did our best to meet in a responsive and active manner.

Jytte Lyngvig
Chief Executive Officer

Content




AUTHORISATION OF COMPANIES
AUTHORISATION OF MEDICINAL PRODUCTS
INSPECTION OF MEDICINAL PRODUCTS
DANISH MEDICINES AGENCY
CLINICAL TRIALS

Safety of medicines for animals

When speaking of consumer safety in connection with medicines, focus is often on treatment of humans. Increasing efficiency improvements and production optimisation in agriculture makes it necessary also to pay attention to medicines for prevention and controlling diseases in animal production, not least because it gives rise to questions of animal welfare, resistance and medicine residues in food. There is also increasing focus on safe and efficient medicines for treatment of sick pet animals such as dogs, cats and horses.

A large proportion of the medicinal products for animals and humans that are available on the Danish market is authorised within the EU and therefore subject to pan-European rules. In order to influence European developments and ensure that the quality of the medicinal products is up to the high standard in the area, in 2005 the Danish Medicines Agency again devoted a fair amount of resources to participating in various working groups under the European Medicines Agency, EMEA.

Evaluation of veterinary medicines in the EU

CVMP is EMEA's committee for veterinary medicines. EU member states each have one seat on the committee, and an extra five seats are reserved for experts with special qualifications.

CVMP deals with authorisation of medicines for all animal species and with defining Maximum Residue Level (MRL) values. MRL is an expression of the amount of residual substances allowed to be present in animals before slaughter in order for consumers to avoid harmful residues of medicine in food. MRL values are defined centrally at EU level following comprehensive investigations of the effects and excretion of the substances.

In addition, CVMP is responsible for organising the input from the 8 underlying working groups and generally decide on new pan-European guidelines.

The Danish Medicines Agency and CVMP

Veterinarian Anja Holm of the Danish Medicines Agency currently represents Denmark as member of CVMP. Veterinarian Lotte Winther is her alternate. Professor Christian Friis of the Royal Veterinary and Agricultural University is a co-opted member in his capacity as a specially qualified expert.

As a CVMP member, Anja Holm participates in three-day meetings in London once a month together with Christian Friis. Between the meetings, she collects and coordinates comments from colleagues in the Danish Medicines Agency and other agencies. Including preparation, the work in CVMP takes up approximately half her work time.

EMEA

The European Agency for the Evaluation of Medicinal Products – EMEA – was established by a Regulation of 22 July 1993. EMEA is structured around a Management Board of 34 members with representatives of each of the member states, members of the European Parliament, the European Commission and individual interest groups. The Agency is responsible for coordinating the member states' resources for evaluating and monitoring the use of medicinal products in humans and animals. EMEA is located in London.

Jytte Lyngvig, Chief Executive Officer of the Danish Medicines Agency, is currently Vice Chairman of the EMEA Management Board.

Diversity and professional breadth

”The CVMP members have very different backgrounds and competences. Some come from medicines agencies and others from university environments with a strong scientific background. CVMP is thus a group with a broad professional scope, which makes our joint work exciting”, says Anja Holm. She believes that the large diversity of the members caters for a wide span of opinions while at the same time forcing members to reconsider their beliefs in order to understand their European colleagues.

Generally, the most experienced members from North and Central Europe speak with the strongest voices. Also, it is clear that members with good English skills find it easier to argue and gain acceptance of their own views and thus take a dominant position.

National versus EU interests

”Members must be able to safeguard the national interests that they have been mandated with promoting while at the same time accepting that decisions may be made though the members not always agree. When attempting to reach pan-European compromises, you should be able to both maintain and relax your demands in the discussions”, says Anja Holm.

To her, participating in the meetings is always an experience, even though it is most interesting when Denmark is on the agenda. There is an extra excitement involved when trying to reach compromises that also take account of the views of the other members.

CVMP

CVMP (the Committee for Medicinal Products for Veterinary Use) has 30 members appointed by the member states. The members are on the Committee for periods of three years.

Every time the Committee reviews an application for marketing authorisation, a rapporteur and a co-rapporteur are appointed from among the members to assess the application.

Milestones in 2005

In 2005, CVMP processed more than 50 medicines cases, i.e. authorisations, variations, renewals etc. In addition, work within adverse effect monitoring, global collaboration and the approval of European guidelines developed positively in 2005. In particular, more focus was given to assessing potential risks to the environment, e.g. when medicine residues are released in liquid manure. Furthermore, ”user safety” received more attention, i.e. the safety of the individual who administrates the medicine or is in contact with the animal treated.

”CVMP is the most central committee in the EU in the field of medicines for animals, and it will continue to be the venue for making the most important scientific decisions and settling disputes between member states. Therefore, it is important to invest resources in maintaining Denmark’s strong position in this field”, declares Anja Holm and continues; “The future will also present major challenges, e.g. in connection with the avian flu in Europe and, in the longer term, the enhanced availability of medicines for “minor” animal species, such as honeybees, dairy goats, rabbits etc.”.

The new Medicines Act

The new Medicines Act – as adopted by a very large majority in the Danish Parliament – entered into force on 17 December 2005. The Act was the climax of four years' work on revising the regulatory framework for medicinal products in Europe and the end product of a major challenge for the Danish Medicines Agency and the other European medicines agencies.

Birgitte Drewes, Head of Administrative Support, was one of the key figures behind the work of the Danish Medicines Agency on the new Medicines Act. She explains the following on the importance of the Act: "It will have a significant influence in respect of enhancing the safety of medicines and thus also the safety of medicine users. The Act ensures this by providing the authorities with better insight into the companies' reporting of adverse reactions, greater powers to examine the products, better tools for tracking the medicine and ensuing better chances of becoming aware of adverse effects".

The European process

Although the Danish Medicines Agency worked on the Act for four years, the initiative is considerably older. The harmonisation of medicines legislation in the EU began already in 1965 and was followed by regulation of still larger parts of the area. And as more and more directives were introduced in the field, it became increasingly difficult to maintain an overview.

Birgitte Drewes explains: "As a result, and in order to make the rules more clear, in 2001, the European Commission tabled a proposal for new directives for both humans and animals, and a new Regulation. The proposals were followed by intense discussions at European level until the spring of 2004 when they were adopted by the European Parliament. The deadline for implementing the new directives and the Regulation in the different EU countries was 30 October 2005, and even though the Act was not finally passed in Denmark until 6 December, we were among the first to get this far".

The process in Denmark

The Danish Medicines Act dates from 1975 and has been amended 21 times up till 2005. Therefore, the Danish Medicines Agency decided that the EU harmonisation presented an obvious opportunity to clean up and thoroughly revise the Danish Act. In February 2004, the Danish Medicines Agency set up a working group commissioned to draft a bill, and in September 2004 the first draft was submitted for consultation. The intention was to subsequently present the bill in the Danish Parliament as quickly as possible.

However, parliamentary elections got in the way in January 2005, and therefore the bill was not read in Parliament as planned. The Danish Medicines Agency consequently continued the work on the bill which was submitted for consultation again in March 2005 and presented in May 2005. But due to the summer recess of the Parliament, the bill lapsed the following month.

In July 2005, the Danish Medicines Agency submitted a consolidated package of executive orders relating to the Act for consultation. Seeing that the implementation deadline was 30 October 2005, it would be difficult to meet the deadline because the bill was to be reintroduced in October. Therefore, the Danish Medicines Agency drew up a great number of transitional executive orders introducing those directives that could be implemented under the previous Act.

On 6 December 2005, the Act was finally passed by the Danish Parliament, and it entered into force on 17 December 2005. The fact that there is now e.g. 110 sections instead of the previous 52, and 38 new executive orders, gives an idea of the scope of the work invested in the final result.

Information about the new Medicines Act

The Danish Medicines Agency informed about the new Medicines Act at its annual meeting in November and held a follow-up meeting to inform the pharmaceutical industry in January 2006.

In this connection, we published a list of answers to a large number of questions to the Act at www.dkma.dk.

We also published Danish and English versions of the Medicines Act with explanatory notes, an index to the sections which shows the relation between old and new provisions, and a comprehensive subject index.

About the process in the internal working group at the Danish Medicines Agency

Birgitte Drewes explains: ”Our working group consisted of four legal professionals who worked with the law texts through 12 months. The level of ambition within and outside the Danish Medicines Agency was high, as we strived towards creating an entirely new Medicines Act with a more logical structure and greater consistency. An Act which was overall easier to read. The work was hard, fun and rewarding, and the entire process was very intense. And even though the working group considered during the process if it would not have been easier to just amend the old Medicines Act, we are very pleased with the result today”.

”This is because the outcome of the process is a far more clear and easily accessible Act compared to its predecessor – even though it has grown considerably longer. At the same time, we have attempted to create greater consistency between the Act and the executive orders as well as internally between the executive orders by standardising the language. Finally, Denmark was one of the first countries to implement the new Medicines Directives”, Birgitte Drewes says, not without a touch of pride.

Main features of the changes to the Medicines Act

- One single objects clause
- A new authorisation procedure (decentralised)
- Longer data protection period for new medicinal products
- Requirement of compliance with good manufacturing practice for certain ingredients
- Increased monitoring and control
- Greater openness and more information about medicine
- Enhanced supply obligation
- Clarification of the independence of the Danish Medicines Agency from the pharmaceutical industry.

The Danish Medicines Agency participates in research

Research and development projects are not core tasks of an agency whose primary function is to manage legislation. Yet, being a consumer of research-based knowledge, the Danish Medicines Agency has a natural and necessary interest in following and taking active part in medicinal research.

External supervisor of three PhD projects

In 2005, three employees at the Danish Medicines Agency became external supervisors of three PhD projects under the Drug Research Academy (DRA) - a research school under the auspices of the Danish University of Pharmaceutical Sciences (DUPS). In this connection, the Danish Medicines Agency and DRA made an agreement on joint funding of the three projects, which deal with subjects as diverse as:

- Comparison of protein structures by means of physical-chemical methods
- Environmental risk assessment of anticoccidial feed additives in the poultry industry
- Comparative investigations of medicine use in the primary and secondary healthcare sectors.

Our involvement is based on a requirement that the projects generate new knowledge of importance to our field of work. And in addition to strengthening the research effort in the three chosen fields, the projects also contribute to enhancing our collaboration with selected research institutions. We expect to see the first results by the end of 2006.

Rector of DUPS, professor Sven Frøkjær, says: "At DUPS, we are really pleased that we participate, through DRA, in facilitating the direct contact between the academic world, the pharmaceutical industry and the Danish Medicines Agency. A joint activity within research contributes to creating a mutual understanding of the overall goals set by each of us for our work, and to developing new and safer medicines."

Better medicines through computer modelling

In 2005, the Danish Medicines Agency was also involved in a project on biological simulation. This is a process whereby computer models are made of the human organism, thus making it possible to retrieve far more, and more reliable information from trials with medicines. The goal is to be able to stop development projects at a far earlier stage than would otherwise be possible. Furthermore, researchers will be better at predicting or explaining adverse effects and generally develop better, safer and cheaper medicines.

A five-year EU research programme

Our involvement is part of a five-year EU research programme: ”BioSim, Biosimulation – a new tool in drug development”. The objective of the programme is to establish a network between the multiple European research groups in the area – exactly with a view to ensuring better, safer and cheaper medicines.

The Danish Medicines Agency participates together with the medicines authorities of Spain, the Netherlands and Sweden and is responsible for coordinating the work of the authorities. Professor Erik Mosekilde of the Technical University of Denmark (DTU) is leading the project. The other participants are research groups from 26 universities in the EU, 9 small and medium-sized pharmaceuticals and Novo Nordisk.

As part of the project, we organised an international symposium in September 2005 entitled ”Predictability of Quality, Safety and Efficacy of New Medicines. A Biosimulation Approach”. The purpose was to exchange ideas and review the status quo.

Professor Erik Mosekilde of DTU says: ”With its broad pharmacological experience and its many contacts, the Danish Medicines Agency can make an important contribution to the success of BioSim. The symposium held in the autumn of 2005 thus brought together a great number of representatives from the industry and from the regulatory authorities in other countries. BioSim can provide the Danish Medicines Agency with an opportunity to assume more research-oriented tasks in collaboration with the partners of the network”.

Research in an international context

As a consequence of the EU and the increasing globalisation, knowledge and knowledge sharing travel across country borders. And since this is a factor which highly influences our work, it is quite natural that the future projects in which we will participate may be national as well as international.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Licensing on right track

Making up for delays in case handling times can be difficult once they have taken hold and resulted in an ever increasing number of case files. By early 2005, the Danish Medicines Agency was, however, well in the process of eliminating a bottleneck for case handling times for medicinal product licensing applications, and during the spring things started looking up in several areas.

Methods of reducing case handling times

So what was it that put case handling times back on the right track? Per Helboe, Senior Director of Division, says: "On a general level, we changed the routines in the licensing area to enable us to continuously adapt our resources to the future tasks we will be solving. We did this by introducing a "workflow concept", which gives us a good overview of the cases and thus facilitates planning. We also managed to organise our staff in a more expedient way, plus we devoted more resources to the area, for instance by hiring a workflow manager and introducing a new IT system".

The greatest challenge during the process was to match supply and demand. The problem is that we can never predict the number of applications we receive, and this makes work planning somewhat difficult. However, many other companies and institutions work under the same conditions, which now also govern the work of the Danish Medicines Agency.

National variation applications

Applications for amending authorisations already granted.

The national procedure

Through the national procedure, a medicinal product is authorised in one EU/EEA member state only. At a later point, this authorisation may constitute the basis for an application via the mutual recognition procedure by which the product will be authorised in another or several other EU/EEA member states.

Performance in 2005

During the first half of 2005, we managed to bring down case handling times significantly for new national applications and parallel import applications. In addition, we reduced the lead time from a company submitting a case until we started processing it.

On 1 September, we published a list (order book) at www.dkma.dk of national medicinal product licensing applications currently awaiting processing. Following this, companies could go to the Internet and get an impression of when to expect us to start processing a given application. Now, they could also be certain that we did not begin work on an application before we had sufficient capacity to complete all phases as one continuous process within the set time-limits.

At the end of the year, we had obtained a significant reduction of the content in the order book and in the delay in starting phase one of the case handling.

Future perspectives of licensing

In 2006, we have placed focus on reducing case handling times for certain types of national variation applications and creating more openness in the process. Therefore, we are working on launching a new order book for variations on the Internet and a plan of how to reduce case handling times.

As an additional challenge, we have got an extra application procedure – for decentralised applications. Under this procedure, case handling must be initiated immediately, subject to a time frame set by the EU, which means that these cases, by definition, will jump the queue. We are thus faced with handling the new type of cases while at the same time working off the last remaining delays for national applications and reducing the case handling times for variation applications. "We don't seem to be running short of challenges in 2006 either", Per Helboe concludes.

Globalisation and consumer safety

Focus on effective and safe healthcare products – medicinal products, medical devices and new therapies – and focus on their correct use. This is the mission of the Danish Medicines Agency, which means that we give top priority to consumer safety. Ensuring consumer safety is a current mantra and a very important task to bear in mind, not least because the pharmaceutical sector, and consequently the safety of Danish consumers, is not only affected by factors within the borders of Denmark, but also ever more by events in and outside of the EU.

In consequence, in 2005 the Danish Medicines Agency set up a dedicated Consumer Safety Division focussing on the expectations and requirements set by consumers and the rest of society and aiming at enhancing the cohesion, and thus also the quality, in this field. The increased attention on consumer safety was, however, in part a reaction to a period with several serious adverse drug reaction cases - e.g. the anti-obesity drug Letigen and analgesics of the COX-2 inhibitor type.

Among the duties assigned to the new division was responsibility for adverse drug reaction reporting from doctors and patients as well as exchange of knowledge about adverse drug reactions in the EU.

Female doctor at the helm of consumer safety

On 1 May 2005, Elin Andersen was employed as Director of the Consumer Safety Division. In addition to her background as a doctor, Elin Andersen had previously worked as a Drug Safety Consultant in her own company besides working for a number of years at two major Danish pharmaceutical companies and at a medical equipment manufacturer.

Following a few years as a hospital physician, she has been working with clinical studies, medicinal product safety and safety monitoring of medical devices since 1993. These are all areas which have undergone very significant developments in precisely that period of time. Furthermore, particularly the safety area has received increasing attention in recent years.

”Working with all elements of the safety aspect has been challenging, and my new tasks in the Danish Medicines Agency now give me the chance to see it from the point of view of the authorities”, says Elin Andersen.

In late 2005, after Elin Andersen’s first six months in the executive chair, the Consumer Safety Division assumed responsibility for medicinal product safety in clinical trials and monitoring of medical device safety, of post-marketing medicinal product safety and of advertisements for medicinal products, respectively. The redistribution of responsibilities was one of several initiatives aimed at providing better safety for consumers and making the Danish Medicines Agency better equipped to respond to the many challenges of globalisation.

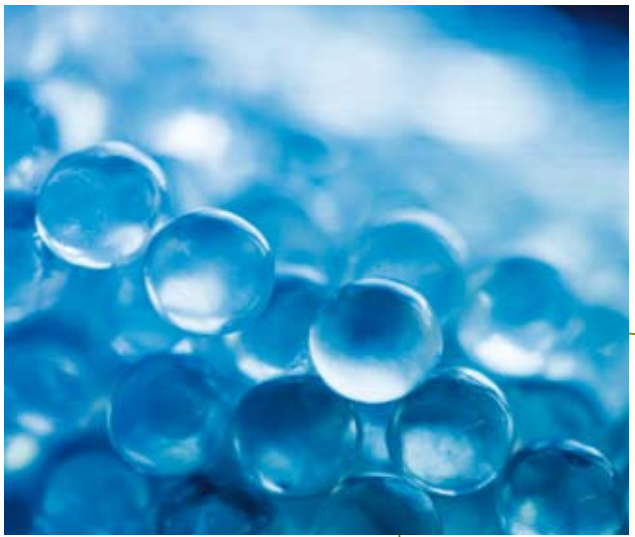
Future perspectives of consumer safety

”All things considered, this will enable us to see the work in the Consumer Safety Division in a much larger perspective which may provide a basis of efficient decision-making and efforts concerning consumer safety”, states Elin Andersen, who continues: ”The future will present a whole series of new challenges within medicine and medical devices. It is no longer just the traditional new chemical substances and medical devices that will be studied in clinical trials and later marketed. There will be a broad range of new, advanced therapies, highly potent biological medicinal products and implantable medical devices combined with active medicinal products”.

“These developments will place large demands on the ability of an authority such as the Danish Medicines Agency to continuously assess whether the balance between benefits and risks remains acceptable in respect of clinical trials and the routine safety monitoring of the many complex therapies that are marketed. It also places significant demands on the European authorities in terms of their ability to collaborate and quickly exchange information, but also in a larger perspective. Most therapies are namely used globally and therefore it is not sufficient to merely consider the safety information that is available on a national level”.

Elin Andersen thinks that it will prove an equally great challenge to manage, coordinate and use the enormous information flows that are part and parcel of the global community. Every day, new safety data are published on websites of authorities all over the world and in the literature as well as discussed in national media etc. And more often than not, these data do not convey the same message. This means that the consumers are confronted with an unsorted pile of information to which they cannot easily relate. Because what are the implications for me in my situation?

”Many people are afraid of the adverse effects that they read about, because it is rarely explained how frequent they are – e.g. if there have been two adverse reactions when 10 million people have received the therapy. And since all medicines have adverse effects, the balance between benefits and risks is really important. Therefore, one of our major tasks will be to disseminate important new knowledge about safety in a way that the consumers can relate to. It is particularly important that we reach the doctors prescribing the products, but also the consumers.In other words, it should always be clearly stated how much the new knowledge about safety affects the overall balance between the risks and benefits of a given therapy”, assesses Elin Andersen.



The single reimbursement system in practice

Everyone living in Denmark is entitled to services from the National Health Service, for instance in the form of free medical care and reimbursement for medicinal products. The National Health Service thus pays a considerable share of the expenses for medicines eligible for reimbursement – more specifically two-thirds. The vast majority of medicines prescribed by doctors is subject to general (automatic) reimbursement. The doctor may apply to the Danish Medicines Agency for reimbursement for the remaining share of the treatment expenses for the individual patient (single reimbursement).

Single reimbursement applications doubled from 1999 to 2005

The number of applications for single reimbursement has increased over the years and saw a doubling in the period from 1999 – 2005. In 2005, the Danish Medicines Agency received approximately 110,000 applications for single reimbursement. This equals some 600 applications each day.

The past and present of the single reimbursement system

Karen Kolenda, Head of Department, has been working with medicinal product reimbursement in the Danish Medicines Agency for the last 20 years. When she was first employed, only three employees handled reimbursement issues. Today, the section has 19 employees, of which 9 are pharmacists, 8 are clerks and two are medical doctors working part-time. Karen Kolenda explains:

"Developments in the single reimbursement area have followed the digitalisation. In the beginning, the Danish Medicines Agency used old-fashioned index cards, but then the computers took over, and we started using software for scanning in the applications and creating grants and rejection letters electronically. Today, we store the information in electronic form only".

The daily routines of the Reimbursement Section

The majority of the applications arrive by mail. Therefore, the day starts with sorting the many applications into different main groups – e.g. osteoporosis drugs, cholesterol reducing agents, dementia medication and blood thinners.

Subsequently, the applications are distributed to the administrative officers, each of whom is responsible for specific groups of medicinal products. For instance, one handles applications for osteoporosis and dementia medication, while another handles applications for blood thinners. The daily volume of applications received is usually distributed among at least 20 different groups of medicine, and each administrative officer receives an average of 50 to 100 applications per day.

None of the administrative officers works full time on application handling, because some 120 phone calls about reimbursement need to be answered every day, too. Approx. 1/3 is from consumers, 1/3 from doctors/healthcare professionals, a little less than 1/3 from pharmacies and a few from pharmaceutical companies. The employees help each other answer the many calls.

All applications are scanned into a computer system. This applies to those applications that will be sent back to doctors with requests for more information as well as those that have been returned with additional information.

Reimbursement or rejection

The case handling time for single reimbursement is around 14 days, and more than 90 % of the medicine users are granted reimbursement. Applications not clearly satisfying the reimbursement criteria are assessed by a doctor. In a few cases, the applications are also reviewed by the Reimbursement Committee, which is our medical scientific advisor concerning National Health Service reimbursement for medication.

In situations where the patient cannot get a reimbursement, the doctor will receive a rejection with an explanation. Most often, the reason is that the guiding criteria have not been complied with. The criteria are also sent to the doctor in order for him or her to see the requirements for granting the medicine user a single reimbursement.

Pharmacist Safiye Er says: ”The interesting part of this job is the professional challenge. In general, we have a positive rapport with the doctors because we can give them the information they need. We experience that the doctors are satisfied when, for instance, given a reason for the criteria for single reimbursement for a given medicinal product. It is also satisfactory to know that the system exists to the benefit of the medicine users, because not many countries allow for reimbursement in special cases”.

Electronic applications reduce case handling times

During the autumn of 2006, the Danish Medicines Agency will have a new electronic system ready (e-medisys) which will enable doctors to submit single reimbursement applications to us electronically via the Personal Electronic Medicine Profile. Doctors, patients and the Agency will benefit because the system will ease the application process and may reduce case handling times.

Case handling times

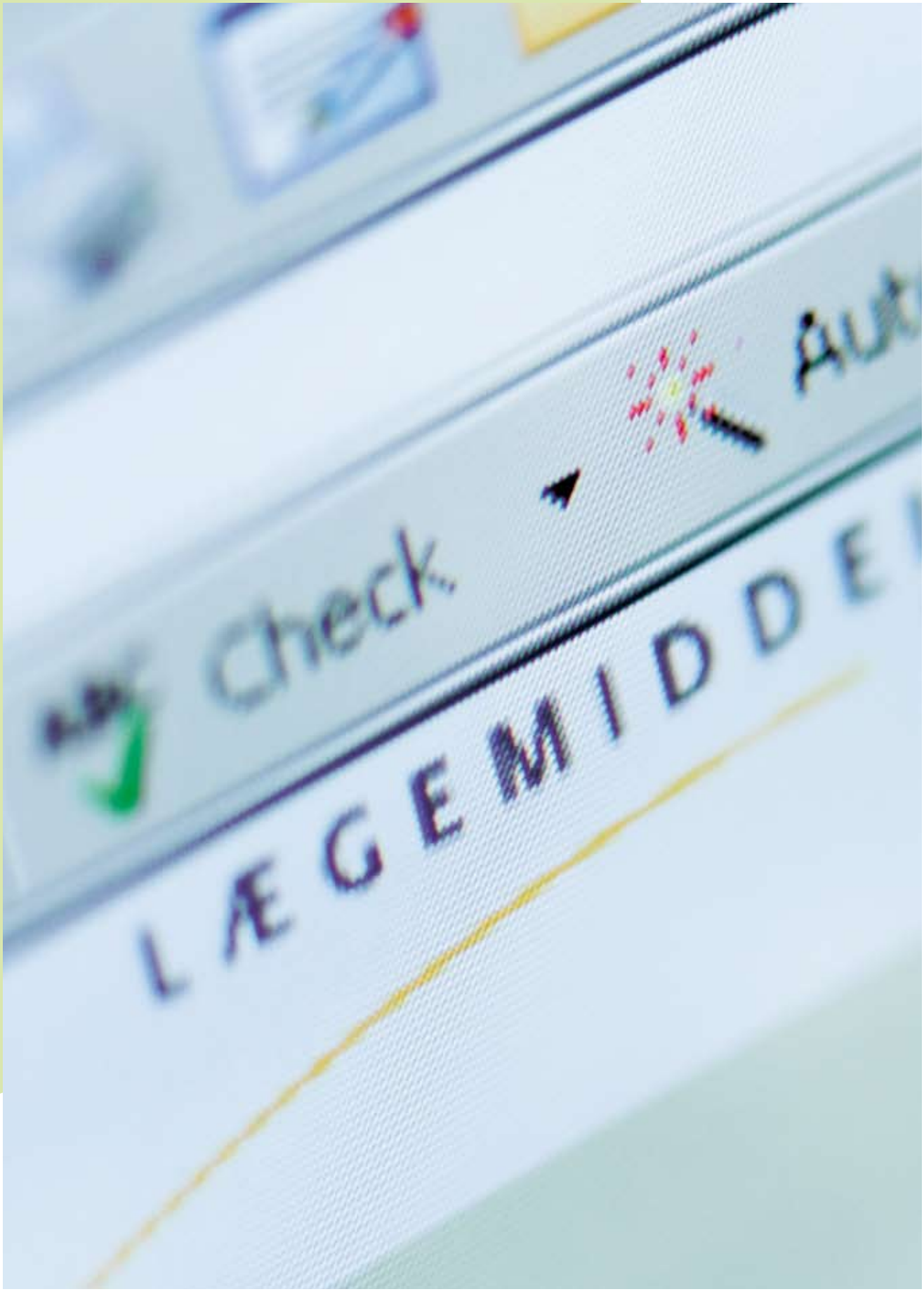
The case handling time for single reimbursement, reimbursement for the chronically ill and increased reimbursement is some 14 days. In special cases where the Reimbursement Committee reviews the application, the case handling time may be 1 – 2 months for single reimbursement and reimbursement for the chronically ill. The case handling time for reimbursement for the terminally ill is 1 – 2 days.

New rules as at 1 April 2005

The rules on reimbursement for medicines were last changed on 1 April 2005. The new rules mean that the amount of the reimbursement will be calculated on the basis of the price of the cheapest medicinal product among the different products with the same effect and the same active ingredients.

Easy access to reimbursement

In order to facilitate the procedure for the doctors, the Danish Medicines Agency has developed special check-off forms for the medicines for which doctors most frequently apply for reimbursement to patients. Only doctors may apply for individual reimbursement. The application forms are available at the website of the Danish Medical Association; www.laeger.dk.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Openness and communication

Openness as well as focused and plain communication have long been an integral part of the planning processes at the Danish Medicines Agency. For instance, we regularly reconsider whether we are informing about the tasks and results that are of interest to our users, whether we do so in the right way and through the right channels.

The Internet is dominating our contact with healthcare professionals

Even though our contacts with the world around us are mediated through a wide range of different channels, the Internet dominates our communications and the performance of our tasks as an authority. And as more and more companies, consumers, doctors, pharmacies etc. are turning to the Internet as an information and contact channel, we must, in our capacity as an authority, ensure that our systems can keep up and meet the users' demands and requests. Therefore, we focus increasingly on developing and improving our information and services on the web, taking into account the very diverse audiences we are addressing.

Insight into the users' interests and needs

In order to identify the type of users visiting our websites and what they are interested in, we set up a new statistics module in 2005. Communications employee Maria Høy explains: "The system quickly proved an efficient tool to guide the weighting of the websites content. We could see that the majority of visitors are professionals from the healthcare sector and the pharmaceutical industry who are primarily interested in news and explanations of legislative issues. That the majority of our visitors are professionals does not mean, however, that we give lower priority to the rest of our users, but that we try to pay even more attention to facilitating and enhancing our services for professional users".

Among the initiatives in this connection was the publication in 2005 of a so-called order book at www.dkma.dk of national applications for marketing authorisation. The order book gives companies access to information on when they can expect us to begin processing their cases. In addition, we also publish statistics of case handling times for the specific application procedures on a regular basis.

Easier reporting to the Danish Medicines Agency

The Danish Medicines Agency also began work on developing an extranet in 2005. The extranet has long been on the drawing board and its first function will be to give companies access to electronically report prices and changes to their product ranges. In addition to easier and more secure reporting, the extranet provides the individual companies with an overview of their product range. We expect to launch the electronic reporting component by the end of 2006.

Continued focus on dialogue and targeted information

Medicines legislation is complex, and this is, in and of itself, a good reason for paying extra attention to communications. And since we know that many users take a particular interest in legislation, we placed great emphasis on communicating, for instance, the new Medicines Act which entered into force in December 2005. In the beginning of 2006, we also enhanced the accessibility of relevant legislation at our website.

However, targeted communication is not just a question of reaching a specific target group with clear and explicit information. It is also about making it easy and simple for companies, doctors, pharmacies, consumers etc. to get in touch with the right employee at the Danish Medicines Agency. Therefore, throughout 2005 we worked on creating a new directory at www.dkma.dk which allows users to search for staff by initials, first name, last name and division. The directory was launched in the spring of 2006.

Key Financial Figures

In 2005, the Danish Medicines Agency generated operating income of DKK 208.2 million from sales, fees and annual charges. Operating costs were DKK 257.1 million, which included staff costs of DKK 140.5 million. The net income amounted to DKK –48.9 million before our state grant funding and consumption of funding reserves of DKK 63.1 million. The net result is better than anticipated at the start of the year, which is primarily due to a larger fee income than budgeted. The Danish Medicines Agency considers the overall accounts for 2005 to be satisfactory.

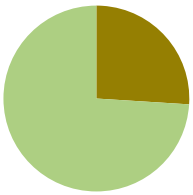
Million DKK

Key Financial Figures	
Operating income	208.2
Operating costs	257.1
Of which staff costs	140.5
Result for the year (before net funding)	–48.9
Net funding, including supplementary funding, cost-based	63.1

Distribution between professional groups

Doctors	12%
Pharmacists	31%
Other academics	22%
Clerical workers	24%
Others (e.g. lab technicians and pharmaconomists)	11%

Gender distribution



Men	26%
Women	74%

Average age

Average age	40 years

New and resigned employees

New employees	60
Resigned employees	32

Number of adverse reactions reported

By patients	160
By doctors	2,191

Controls and authorisations of clinical trials

Controls of trials	19
Authorisations for clinical trials	287

Authorisations

Of companies	approx. 300
Of healthcare products	approx. 300

Controls of companies

Medicinal product distributors	47
Sales outlets (other than pharmacies and pharmacy outlets)	509

Medical device controls

Medical devices	99

Reimbursements granted

General reimbursement	49
Single reimbursement	100,967

Contact with users on the Internet

	DK www.laegemiddelstyrelsen.dk	UK www.dkma.dk
Unique visitors	195,427	67,304
Subscriptions to NetNyt news	892	142
Calendar displays	26,494	
Adverse reaction notices (page displays)	65,819	25,457
Contact page	87,867	6,491

Further information...

www.dkma.dk

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