

# Taking a global view

*With Sweden taking on the EU presidency this month, Vera Franzén and Margareth Jorvid talked to Dr Christina Åkerman, Director General of the Swedish Medical Products Agency, about the MPA's regulatory aims and achievements. In an interview conducted in April, Dr Åkerman addressed a wide range of topics including European cooperation, the acceptance of electronic submissions as originals, abandonment of the Swedish pharmacy monopoly, and how the agency is seeking to tackle counterfeit medicines.*



**Q** You are a physician and have specialised in clinical pharmacology, but you also have experience in the pharmaceutical industry. What made you apply for the position as DG of the MPA?

**A** Actually, I did not apply but was contacted by the recruitment agent. My first reaction was 'absolutely not', but on second thoughts I realised it was an exciting position with a broad field of responsibility. The MPA is in charge of veterinary medicinal products and medical devices in addition to human medicinal products, and it also has a sectoral responsibility for environmental issues related to medicinal products. The possibility of taking an active part in the development of these areas was very attractive to me, and then it all happened very quickly.

**Q** I assume you have been very busy from the start, your name has appeared in connection with many conferences and debates. Do you have a favourite topic?

**A** I think it is important to put the MPA on the map; in Sweden and internationally. It is important to know what is expected of

us. Kjell Strandberg, DG at the time Sweden became a member of the EU, stated that Sweden would become one of the top agencies and that was a very important standpoint. If we are active, we can have an influence and promote or counteract developments we see coming.

One topic that I am very interested in is to avoid duplicate work. Before a new product reaches the patient, it has a long way to go. First it needs to be approved but then there are a number of steps. In Sweden, the Dental and Pharmaceutical Benefits Agency (TLV) decides whether a prescription-only pharmaceutical product or medical device shall be subsidised after assessing documentation supporting clinical benefit and cost effectiveness. Then there is the Swedish Association of Local Authorities and Regions, ie, the payers, who want to make their own assessment, and in addition there are regional and national groups issuing recommendations.

The MPA will start a pilot project where companies can get joint scientific advice from the MPA and the TLV so that they will be aware of the expectations not only of the MPA but also of the TLV.

**Q** It will be a busy year for the MPA when Sweden takes over the EU presidency. How has the MPA prepared for this period?

**A** Preparations started two years ago. Meetings have been planned and an international conference organisation has been contracted. Approximately 100 of the 550 MPA employees are actively involved in preparing some 20 informal meetings with 1,250 participants. The MPA will also support the Ministry of Health and Social Affairs in about ten Council meetings to be held in Brussels.

**Q** Is there any issue that you are hoping to resolve during the presidency, or any new aspect you would like to introduce?

**A** The Ministry of Health and Social Affairs will arrange a meeting on 29th July together with the MPA and the TLV on assessing drug effectiveness – common opportunities and challenges for Europe. It is not until a product has been on the market for some time that it is possible to assess its true value. Even though there are preset frames for the evaluation of safety and efficacy in the approval phase, it is not until the product

## 'Access to a European network is essential for promoting human and animal health in the individual member states'

is used on a larger scale that sufficient information can be gained, and evaluation on a European level is an attractive model. This is especially true of orphan drugs.

In Sweden, the ARTIS project for evaluation of medicinal products used in rheumatology is an example of a project evaluating products on the market, and the idea is to start European pilot projects to evaluate the value of products on the market. Representatives of the Commission and the EMEA will be present, and invitations are sent out to all member states.

Additionally, the MPA will arrange a conference together with the Ministry of the Environment on environmental issues. There will also be a conference on antibiotics with the focus on how to make companies develop new products that we are hoping there will not be a need for – rather than on microbial resistance, which has been on the agenda for a long time.

We will also try to find common ways to clear up the choked situation with the mutual recognition and decentralised procedures with respect to allocation of assessment times. Preferably, applications should be made via a common procedure to facilitate estimation of what applications are to be expected when.

In the area of medical technology, we are working on the Code of Statutes related to the new Directive approved in March (2007/47/EC) changing previous Directives.

The MPA has initiated a project together with the National Board of Health and Welfare, the Swedish Association of Local Authorities and Regions, caregivers and trade associations with the aim of providing assistance to companies with respect to classification. The Commission has shown an interest in this project and the document is now undergoing translation into English.

**Q** What is the greatest advantage with European cooperation?

**A** Access to a European network is essential for promoting human and animal health in the individual member states. It is important that work-sharing can be continued and

increased, and the EMEA is a natural coordinator for this.

Also, the financial situation needs to be scrutinised. The question is, what is most important and what is less important? National agencies should be compensated for work carried out which is deemed important. Otherwise, there is a risk that priorities are chosen on the wrong basis.

However, travelling should be reduced and many meetings, say a third of them, can probably take place as virtual meetings, although there will also be a need for face-to-face meetings in the future.

**Q** From 1 April, the MPA has accepted electronic applications as originals, irrespective of the type of procedure. In what ways has this changed work processes at the MPA?

**A** Administratively, work has changed substantially. Many practical aspects have had to be resolved, eg, the question of accessibility.

Then there is the workflow within the MPA, which has been a major project for us since 2004. It will not be finished by 2010 as originally planned, but it will be possible to handle the most important procedures electronically.

Today, we have a documentation handling system, and we will now be concentrating on the evaluation procedures.

**Q** Is there any advice you would like to give to those member states which have not got as far?

**A** It is easy to get carried away by electronic visions but it is essential to first understand the processes; what exactly is the flow of papers? The IT tools should support the processes. Also you need good negotiating skills; do not let the IT function take the upper hand, and set a realistic time schedule. In summary: write a project description, make an investment plan and follow up!

**Q** From 30 December 2008, a new Regulation applies for advanced therapy medicinal products. The implementation of this legislation is one of the EMEA's focus issues in 2009. How has the MPA prepared for this new legislation?

**A** Advanced therapy is partly a new area. The MPA has taken an active part on the Committee for Advanced Therapy (CAT). Moreover, a multidisciplinary group has been created at the MPA with representatives from all units that are in contact with this category of products; the MPA CAT member represents medicinal products and the alternate member belongs to the Medical Device unit.

**Q** An important change in Sweden is the effect of the decision to abandon the Swedish pharmacy monopoly, which will create much work at the MPA. What is the most important role of the MPA?

**A** When the legal proposal is ready, the MPA will finalise provisions. We are working on what requirements will have to be met by those in charge of a pharmacy and on the procedure for application. The MPA will have an increased responsibility for independent product information, which is in the public interest. As there is already a well-developed organisation for advice to the public by health professionals, this structure will also be used for information about medicinal products, and pharmacists will be employed to carry out this service. Pharmacists at the MPA will serve as back-up. Pharmacies will be responsible for supplying independent product information and this aspect will be monitored by the MPA.

**Q** In the Pharma Package published in December last year, counterfeit medicines is one important aspect. In Sweden, the MPA has tackled this problem in a somewhat unconventional way. Can you tell us a little about the campaign?

**A** Last autumn, the MPA launched a nationwide campaign to inform the public of the risks of buying medicines on the internet. It has been shown that more than 60% of prescription drugs sold on the internet are either dangerous or ineffective. The strategy the MPA chose was unconventional – television and newspapers showed advertisements for a company called Crime Medicine. An enchanting female physician gave startling information and referred to a website for Crime Medicine. The website first looks like a website for a normal online pharmacy but after a little while, the facade falls apart and instead, authentic police pictures of filthy basements where manufacture takes place are shown and patients who have suffered from counterfeit medicines are

described. The idea is to reach those who are potential customers of fake medicines.

Most of the feedback has been positive and it is believed that the campaign has been very effective. While the interest for shopping on the internet has generally increased, the interest in buying medications on the internet has decreased dramatically.

**Q** There is a wish for greater harmonisation of Nordic labelling between competent authorities, as some countries have very low sales and it is costly to develop separate artwork when countries cannot agree on a common label. Are there any plans to facilitate harmonised approval?

**A** Often, companies want more languages on the label and the legislation is clear as to what information is required as a minimum. The best recommendation is to be very careful in the application and check what the proposed wording would look like on the actual label.

This issue has been much discussed and meetings are held between the Nordic agencies and also with trade associations to identify and try to resolve problems.

**Q** The MPA is known to place great importance on environmental issues. How are environmental issues taken into consideration when new products are approved?

**A** Since 2007, the MPA has had a sectoral responsibility for environmental issues, and since September 2008 the MPA has had a new responsibility area – Environment – under Scientific Quality Management. Applicants should identify possible risks related to their products and if risks to the environment are identified, there should be strategies for minimising these risks. One way of doing this is to control the disposal and, for human medicinal products, identified risks to the environment do not prevent authorisation. For veterinary medicinal products, environmental risk is part of the risk–benefit evaluation.

In Sweden, the MPA works together with other organisations such as the Swedish Chemicals Agency and the Swedish Environmental Protection Agency to find ways of reducing the risks related to the manufacture of active pharmaceutical ingredients. A proactive approach is essential.

**Q** What do you think is your most important asset as head of the MPA?

**A** The combination of experience from clinical research and leading positions in the pharmaceutical industry on a national and international basis is a good platform.

I am a good listener and try to understand. I have a talent for seeing structures and building and developing good teams. I am not an oracle and prefer clear mandates and realistic timeframes.

**Q** If you could have one wish fulfilled, what would you choose?

**A** Professionally, I would like people to think of the MPA under my leadership as an agency which has contributed strongly to create the red thread nationally and internationally. I would like the MPA to be a leading agency not only in Sweden and Europe but also on a global scale. We have a great competence and I want us to make maximum use of it.

On a more private note, I want my daughters to be able to live in a socio-economically-environmentally sustainable world.

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