

Interview: Else Smith, Director General, CEO, The Danish Health and Medicines Authority



16.07.2013

Tags: [regulator](#), [regulation](#)

After the big milestone last year— the Danish Medicines Agency merging with the Danish National Board of Health— can you please comment on why this decision was taken and what synergies have since emerged?

Part of this decision was due to economic reasons; we reviewed the institutions that we have under the Ministry of Health and since there were several, it was decided that fusing them could be more cost efficient.

However, this was not purely economical. Merging the Agency and the National Board made a lot of sense since there are many synergies in the discussions and challenges for driving health, as well as safety in regard to patients, pharmaceuticals and medical devices. These types of linked discussions between health and medicine have turned out to be very fruitful when unified, because we are bringing all that knowledge together; the guidance you can give to the minister, the medical doctors, and the whole population has resulted in a greater value.

On the other hand, it has become clear that we need to have a focus on quality, how we measure it, and how we can make sure that the patients receive the safest medicines. Being one entity enables us to better control these factors, as well as to ensure that the authorized health staff is operating in a proper and safe way. There was a lot of similarities and parallel work of both organizations on the issue of involvement in patients' safety and efficiency in general, therefore

the merge has been very productive.

As the Danish Health and Medicines Authority is also responsible for reimbursement, can you briefly explain to our readers what are the criteria that you use in order to ensure that patients have equal access to optimal medical treatment?

By law, our institution can decide that some medicines will have some compensation and others will not. Also by political decision this institution will make what we call “national clinical guidelines” on good treatment and on good examination of patients, which also may involve treatment of medicine.

In regard to prescriptions, it is the medical doctor who decides what treatment the patient will take. However, when the patient goes to the pharmacy, (despite what was prescribed) the pharmacist can suggest a similar product that is cheaper. Then it is the patient’s choice. Many people decide that they want the cheaper medication because it’s chemically the same as that prescribed by the doctor.

The interesting aspect here is that all these similar drugs have to update their prices every two weeks, which certainly generates a lot in competition in the market. Evidently, not all drugs have a substitution, so we have a whole council that helps us to decide on which drugs we can support and in which way, i.e., partial reimbursement.

As the CEO of this new institution, what is on the agenda for the next two years and which are the main challenges you foresee?

Some of the challenges are definitely linked to the economy, with the fusion we had a reduction in staff of more than 100 jobs, and to get rid of so many people was really tough. Furthermore, we had to reorganize and physically move in order to mix the former institutions.

The expectations of this new organization are very high, we’re the most quoted government institution, since we deal with issues that are very interesting for the population and the press, and therefore we should be able to give good answers on every single subject.

Since the budget and the staff have been cut, how will you guarantee that the population will have the same quality and efficiencies of the service that they used to have with separate institutions?

How we organize the work is a challenge, and we’re right in the middle of that ongoing discussion. Since the resources are limited, it is up to me and the rest of the leaders to review how we can

better organize the work load, as well as how we can improve by using IT more efficiently.

In other subjects, you participate actively in the European arena. How would you grade the integration of the various agencies across Europe and do you think there is still room for improvement?

We are definitely concerned about the international collaborations, especially in the medicines area; we try to be active in the EU, at Council and Commission level, and in the EMA-related activities.

We have seen improvements, but what I would say needs to be more prioritized is the integration of medical devices. There are many health institutions and medicine authorities in Europe, but in some countries medical devices are not included and have separate institutions. Therefore, the heads of medicines agencies should attempt to integrate this important area. Whether it is fusing with your institutions or you are having them function separately, it is very important that we see medical devices under the same cohesive health care umbrella.

Medical devices are very important, for instance, people in my age and those who are older will most likely die having at least one device in them— e.g. a new hip, a knee, or a pacemaker. Also, more of the daily medication will require a device pairing, versus just taking a pill. We as patients are becoming much more in charge, therefore medical device will have to have a better structure and play a more important role in health care systems.

Since we are discussing major changes in the health care systems, in your view, is there a solution where the industry and the health care sector can co-operate better?

We do need more and better collaboration. As we cannot afford everything for everyone, we'll have to find ways out, and I think the industry can help us in that. If we get the collaboration better then we may move forward more focused and faster.

At least in a country like Denmark, where a lot of things are publicly paid (included in the taxes we pay) there must be a dialogue with the industry. We have an interest, the industry has an interest and the patients have an interest, so if we collaborate we can certainly collectively find better ways, especially since we have a government that strongly believes in a public health sector.

Denmark has one of the most efficient health care systems, what do you think the world can learn about the Danish way?

The perception is that we all have equal rights and access to health, because it is paid by our tax, hence health is not a matter of what one can pay. This has been the foundation of our structure, which is how we, as Danish citizens, simply expect it to be. And our GPs are the gatekeepers to nearly all specialized treatment and examinations.

Another highlight of the Danish way is that we have a good tradition for documentation; we have data that proves what works and what doesn't, we monitor what we do and see the direct outcome, which allow us to constantly adapt and improve.

Lastly, I believe we have made a big change in our hospital structure with fewer hospitals and few places offering highly specialized treatments. Also, we are now trying to focus on the involvement of patients.

Do you think this will be possible to replicate on a bigger scale, say with countries with 100 million people?

I think it is possible, but in that case maybe splitting into smaller units will be the key, otherwise there could be countless delays, e.g. making it more difficult to have access to day-to-day data.

What would you like to be your final message for our readers?

Health is definitely a very relevant issue for all of us. It's important that we recognize that health is something that we all have a responsibility for, so we should create societies that have the quality and capacity to help us in health-related issues. Therefore, we should enhance collaboration between different sectors in order to build up a stronger health care system, including prevention.

On a more personal note, I understand you have been working in the public sector for a long time, so what is the most rewarding part of being a public servant?

The distance between what you know, what you say and write, and what actually happens is short. Realizing that what you proposed ended up being the right solution to benefit the whole country is an incredible reward.

[See more interviews](#)