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Jørgen Schøler Kristensen explains the role of the Danish Medicines Council, providing guidance about new medicines for use in the Danish hospital sector. Kristensen also tackles the thorny issues of price considerations, assessing the long-term efficacy of innovative new therapies, and working collaboratively with private industry.

Could you introduce yourself and the Danish Medicines Council?

I am a haematologist by profession and have also worked extensively on the digitalisation of the Danish healthcare system as project manager for the electronic health record (EHR) development.

Having become the leader of the Department of Haematology at Aarhus University Hospital in the early 2000s, I noticed that we were running out of money every year due to medicine expenses. To remedy this, we created a horizon scanning initiative within the department – in effect a small-scale health technology assessment (HTA) – to predict spending on each item needed the coming year. We then sent this to the politicians to bluntly explain, in an itemised manner, the investment needed to provide treatment to patients. Broadly, this initiative was a success and led to the Department having enough capital with which to operate.

Following this experience, I helped create a similar small-scale horizon scanning HTA in haematology between the Danish regions before, in 2009, forming RADS. RADS was a national council estimating the value of new medicines and providing treatment guidelines for different diseases. The organisation did not have a mandate to make recommendations regarding the pricing of new medicines, only their value for patients. RADS was active until 2016 before being replaced by the Medicines Council in 2017.

The concept of a Medicines Council had been discussed during the Danish election process back in 2015. Following the election, the Danish government laid out seven principles for the Medicines Council's work across the five regions to assess value for patients and costs for society, before making recommendations. We are not a formal decision-making council, rather we make recommendations to the regions which run the hospitals and the primary sector based on those original seven principles.

The regions were happy that the Medicines Council was initiated because they have a fixed budget set by the state every year, within which sits all medicine spending. If expenses go up, this created problems and the regions, therefore, wanted to see prioritisation inside the system.

How similar is the Danish Medicines Council to HTA bodies in other countries such as NICE in the UK? To what extent is it a very particular Danish model?

In many ways, it is quite similar to NICE, utilising very systematic HTA-like grade systems in its assessments. We take pride in having the medical profession heavily involved in the decision-making process; a group of experts from all over Denmark, including patient representatives, is involved in every recommendation we make. We also have industry involvement in the Council and good collaboration with other Danish authorities like the Medicines Agency.

Our principles include getting more value for patients for the same spending, allowing treatment for patients even when it is not recommended as a general treatment, ensuring equal treatment across the country, making evidence-based decisions and rapid access to new well-documented treatments – when a company apply for an assessment by the Medicines Council, we only have 12-16 weeks to finish our assessment. In many instances we are one of the first institutes in the world to deal with these new medicines.

Given the Medicines Council's consultative model, how challenging is ensuring that new medicines are assessed at speed?

The fact that the Medicines Council is well-structured and well-organized helps. We have a very experienced director from the central administration, Torben Klein, who is a biologist by profession but has worked in various ministries and is politically very experienced. Torben has implemented schemes for the entire process – what should happen on each day – which helps with the organisation. There are a lot of moving parts and we need to read and sign many documents every day so the fact that the Council has the electronic layout for a meeting seven days in advance, for example, is a big help.

Does the Medicines Council only assess drugs that are to be used in the hospital setting? How wide is its remit?

The Danish Medicines Council has two jobs: We assess new drugs as possible standard treatment at hospitals, and we prepare guides for the best medical treatment within various therapeutical areas.

Although we mainly assess hospital medicine, our remit also covers some medicine prescribed by specialist physicians.

The company with the authorization to market a new medicine can apply for a new drug to be recommended as standard treatment by the Council. When the Medicines Council makes its broader treatment guidelines it can be on the initiative of, for instance, the regions, professional bodies, patient associations, the pharmaceutical industry, or even citizens.

Although the Medicines Council does not have a pricing mandate, as we move towards the era of high-priced cell and gene therapies, to what extent does pricing play into your discussions and assessments?

The Medicines Council decides whether a new drug is recommended as standard treatment based on the negotiated price and the medical assessment of effect and side effects of the treatment. The price negotiations are handled by Amgros and the company.

Therefore, pricing does play a major role in our discussions. If a drug costs more than the existing standard treatment the value for the patients needs to be greater. Otherwise, we waste resources

that could benefit patients in other parts of our shared healthcare system.

For some of these new therapies coming into the market, the pricing is one consideration but assessing the long-term efficacy and safety is a challenge as the data perhaps does not exist. How do you navigate that conundrum?

This is something that we are discussing intensely. The Medicines Council holds a meeting every month on this issue which sometimes goes on for over eight hours!

Our decisions are often challenged – and our discussions prolonged – by the lack of long-term data on both effect and possible side effects. And in the mix, we see very high prices that will weigh heavily into the hospital budgets.

In collaboration with Amgros, we are beginning to strike new, innovative agreements with the industry and are exploring the possibilities of creating different models. While we have certainly not reached our destination, we are trying to find solutions to challenging questions. For example, how do we evaluate new drugs which are given once but which are potentially effective for life? Which stakeholder carries the risk of a drug not working five years into the future? Could we make a payment model so that the risk is shared? Also, given the nature of some of the new drugs coming to market, if a company wants to make a deal for a large group of patients in different areas, could we make a bigger basket of agreements?

I would like to mention that Denmark has the best collection of healthcare data in the world. The Danish Regions have built a health data authority to which we deliver a lot of data from the hospitals as well as some from GPs. Currently, we and the health data authority are co-chairing a National Hospital Medicine Registry which receives data from the hospitals on the use of expensive drugs. We are currently only using part of this data, but it is a highly promising project, and we hope to see the results of it in one or two years.

In terms of the industry, I would love to discuss the possibility of making agreements based on post-treatment data and real-world evidence with industry associations like Lif and EFPIA. Perhaps we can find ways to collect data in new collaborative ways that will enable us to evaluate treatments and make innovative agreements.

Given the close and collaborative relationship between public sector stakeholders and private industry in Denmark, how do you ensure that – in the eyes of the Danish public – organisations like the Medicines Council are not seen as overly influenced by profit-driven companies?

In Denmark, the general population have confidence in the public sector. People believe – and have reason to believe – that authorities are not corrupt; they do what they say they will and can be relied upon.

In addition to that, we have a clear code of conduct regarding non-involvement with the pharmaceutical industry. That means that while for instance, a doctor is assessing a new drug for the Medicines Council, she or he cannot simultaneously collaborate with a company that is developing drugs within the same field.

That being said, there is a necessity for collaboration between the healthcare sector and the industry. Without this collaboration, innovation will not occur, and new drugs will not make it to market, which will have a detrimental effect on patient outcomes.

What does Danish society want in terms of the medicines that are coming to market? Are they accepting of drugs that may have a huge price tag, but which potentially only offer a minor improvement to patients?

With the experience of the last four years behind us, we sometimes recommend drugs that represent only a small improvement compared to the existing treatment, but for which we can count the evidence. The Medicines Council is positive towards new drugs, even those with a very high price tag, if they represent a real improvement. This has been the experience with Luxturna, Zolgensma, and Spinraza, even though we were heavily criticised in some quarters for not going as far as other countries with Spinraza, only suggesting its use for younger patients.

How would you assess the performance of the Medicines Council since its inception and what are your aspirations for the future?

The Danish Medicines Council has been quite successful to date, with acceptance from doctors and implementation based on our recommendations. The regions are satisfied with the work we do, as are most politicians, who recognise our work and efforts to ensure the most and best healthcare for

all patients.

But I am convinced that we can do even better. We have recently moved to using quality adjusted life years (QALY), which we hope will be helpful, especially in terms of comparing ourselves to other countries using the same methods and comparing benefits and prices of new drugs across different patient groups and diseases.

Do you have a final message for our international audience on Denmark and the Danish Medicines Council?

The industry is doing an excellent job in developing new medicine, sometimes even to patients without prior medical treatment and Denmark is a frontrunner in using new drugs and implementing them broadly.

However, we need to ensure the best possible healthcare for all patients, also those who are not candidates for new innovative and expensive medical treatment. Therefore, the effect of the new drugs brought to market needs to be better documented and the price fair. We see drugs that have been tested on less than 50 patients, with no control groups, followed for short periods even though the drug allegedly lasts for life.

So, my message is this: Let’s continue the progress in bringing new medicines to people in difficult situations. But we need to have better documentation for the effect and side effects of new drugs. And we need fair and transparent pricing so that the more invisible groups – those for instance in need of care and warm hands – are not left behind.

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