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Market Access Challenges for Innovative Cancer Treatments in the Nordic Region

AT THE *EUROPEAN PHARMACEUTICAL PRICING AND REIMBURSEMENT* CONFERENCE STAGED BY SMI IN LONDON IN OCTOBER 2013, PETER HERTZMAN, DIRECTOR, MARKET ACCESS & EXTERNAL AFFAIRS, BRISTOL-MYERS SQUIBB NORDICS, OFFERED HIS PERSPECTIVE ON THE CHALLENGES FACED BY MANUFACTURERS ATTEMPTING TO ACHIEVE ACCESS TO NEW INNOVATIVE ONCOLOGY PRODUCTS IN THE NORDIC REGION. *FOLLOWING THE MEETING, HE SPOKE TO MICK MARONEY FOR PPR.*

THE NORDIC ECONOMY

Hertzman began by offering a brief overview of the region's economic performance in recent years. "There has been pretty modest economic growth in the Nordic countries over the past decade or so, and it has been more or less flat since 2008. Norway stands out, owing to its oil. They have a GDP [gross domestic product] per capita 50% higher than the other Nordic countries. They have a foundation, a fund that contains NOK5,000 billion (€593 billion; US$814 billion) – that's more than two years' worth of GDP," he noted.

FACTORS INFLUENCING UPTAKE

Against this backdrop of modest growth, Hertzman considered the main factors influencing the uptake of new cancer treatments. "There are three key factors influencing uptake. The first one is the economic/financial element. What resources do you have? What's the cost of treatment? What's the prioritisation that payers are going to use: is it cost-effectiveness, or is it budget impact only? There is also the question of how things are prioritised.

"The second is knowledge about the product, the disease area, the mode of action *etc*. The third, which I find the most difficult, is the structure of the healthcare system," he said.

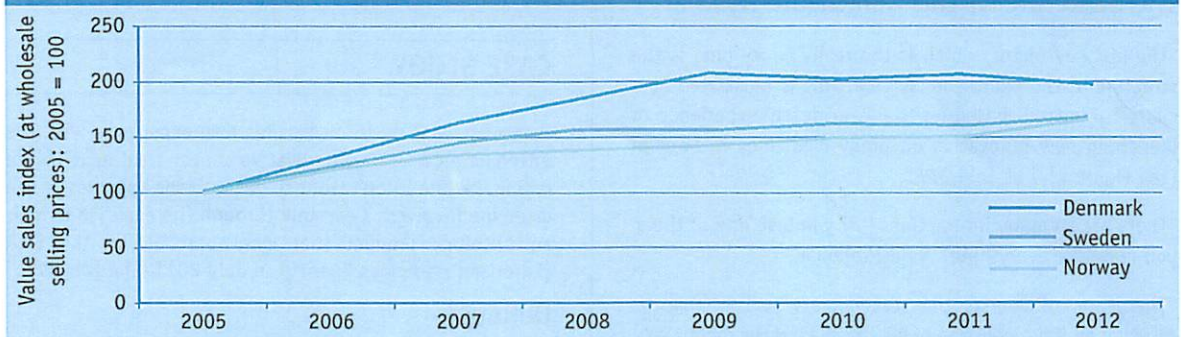
Resources

"In terms of resources, we can see that from 2005 to 2012, spending on oncology medicines in the region has been increasing, although it has been pretty flat since 2008-09 (see Figure 1). Thus, the oncology budget should not be a major issue for payers. We can see that spending in Denmark has been well ahead of that in Norway and Sweden, because there was political prioritisation of oncology products. However, following pretty steep growth, spending has been almost flat over the past few years. The richest country has been spending less than the other two: the Norwegians may be very rich but they don't spend so much on oncology products," observed Hertzman.

Knowledge

"We all know that when launching, if you don't have doctors with hands-on experience of a new medicine, it is very difficult to get uptake. If no-one supports it, you have difficulty," he continued.

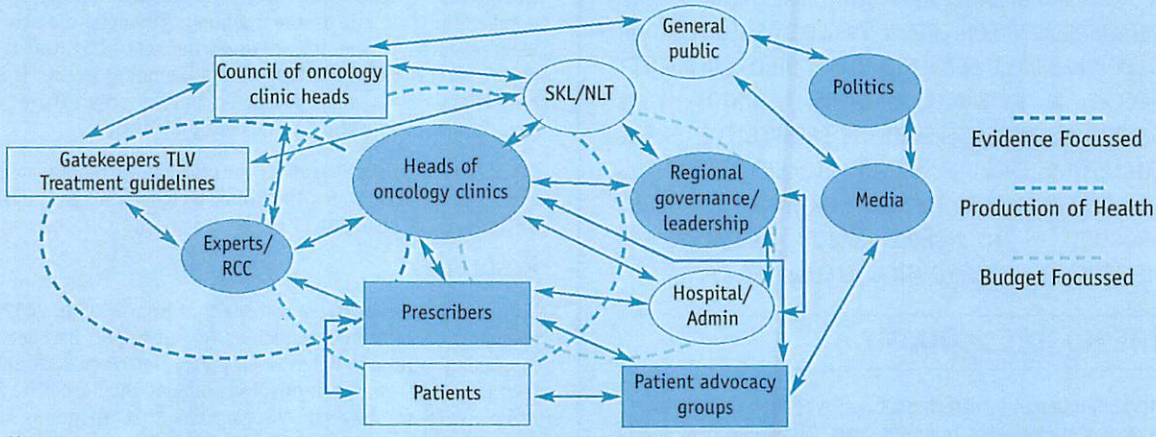
Figure 1: Oncology Sales in Nordic Countries, 2005-12



Note: Based on sales of antineoplastic agents and endocrine therapies (ATC groups L01 and L02)

Source: Peter Hertzman, based on IMS Health data

Figure 2: Stakeholder Interactions/Processes for a Hospital-only Product in Sweden



Notes:
SKL = *Sveriges Kommuner och Landsting* (Association of Local Authorities and Regions)
NLT = *Nya läkemedelsterapier* (New Drug Therapies Group)
TLV = *Tandvårds- och läkemedelsförmånsverket* (Dental and Pharmaceutical Benefits Agency)
RCC = Regional Cancer Committees

Source: Peter Hertzman

"The clinical trial is of course a key element of knowledge building. In Sweden, the number of new clinical trials fell by 50% between 2004 and 2012, partly because major parts of the Swedish pharma industry moved away from the country. The reduction in trials causes problems: knowledge of new medicines is falling," said Hertzman.

The Structure of the Healthcare System

"The last key factor, which is the really tricky one, is the structure of the healthcare system. This is illustrated by a chart I prepared, based on the 'near-death' experience of launching new innovative oncology medicines in Sweden (see Figure 2)," he told *PPR*.

"There are so many interactions – if you lose one of them, you may lose everything," said Hertzman.

"There are, of course, the stakeholders/decision makers focusing on the production of health: the treating physicians, nurses and of course patients. There are others whose role is to make recommendations based on scientific evidence, *eg* the TLV in Sweden. Finally there are those stakeholders whose primary role is to ensure that healthcare is delivered within given budget and resource constraints.

"If you don't manage all this from an access perspective, you may have problems. This is like a living organism, and all the parts are interdependent. It's a construct of politics, economics and science," he noted.

CASE STUDY

Hertzman went on to discuss his own experience with the introduction of a new innovative cancer treatment in the region. "While I don't want to get into the specifics of the medicine involved, I can talk through the experience with an oncology product that was approved by the EMA (European Medicines Agency) in July 2011," he told *PPR*.

Denmark

"In Denmark, there was full access for the product within three months. At that time, there was a fairly simple HTA

(health technology assessment) process that was driven primarily by scientific evidence – the treating doctors and KOLs [key opinion leaders] were in the driving seat. Those people close to the science, as well as the patients, were taking the lead," observed Hertzman.

"However, now things have changed. A new central organisation was established in 2012 – KRIS (*Koordineringsrådet for Ibrugtagning af Sygehusmedicin*, the Co-ordination Council for the Use of Hospital Medicines – see *PPR* August 2013 p244; April 2013, p116 *et al*). So now there is a new process, with regional ownership of the evaluation of hospital medicines – *ie* closer to the budget. Of the 16 products KRIS has been asked to look at, it has rejected five. So things are getting tougher in Denmark as well."

Norway

As discussed by Hertzman, as Norway is not part of the European Union, a separate marketing authorisation process applies. "The product was approved via this process a little later than through the EMA, in October 2011," he advised. "The Norwegian experience was extraordinary. It was a very central and politically-driven process, driven by the Ministry of Health (MoH), the Directorate of Health and NoMA (the Norwegian Medicines Agency), as well as the regions reporting directly to the MoH.

"There was an HTA element and they said that the clinical data was not complete or convincing, despite the fact that the product had been approved by the EMA," he continued. "They said 'that's not good for Norwegians – we have to do our own studies in Norway'.

"Following an HTA and a negotiation process, the Health Directorate said they were not going to approve funding for the product – despite huge media interest in the topic. The negative decision was made on a Friday. On the following Monday, after massive media coverage and social media interactions over the weekend, the decision was changed. The Minister of Health said 'we're going to do an all-Norwegian study and pay for all the patients'. On the basis of this, he approved the drug. That was an excellent decision for patients and their families. However, it took 18 months to come to this conclusion and many patients who were in desperate need of treatment never received this new life-saving drug.

"The fact is that there is a need for a new approach for new innovative hospital medicines in Norway – a more transparent approach. The MoH is initiating a new process for these products, involving HTA as well as horizon scanning," he observed (see *PPR* August 2013, p246 et al).

Sweden

Hertzman offered a little more detail on the experience with the new product in Sweden. "Between a year and 18 months after approval, there was access in the 21 county councils. There was very limited treatment before that, although some county councils recommended its use several months before the others. So we lost between a year and a year and a half of patient access, from the EMA approval. This has gone – we cannot recoup it.

"The whole process was very upsetting for all those affected – including patients, their families and doctors. It was also very difficult for us in the company. You have a product that can help people survive and you don't get it through. Of course because the drug is perceived to be expensive, this raises questions about the price. I can't get into that. But I can say that it is crucial how you communicate price and value to the payers and budget holders early on," he advised.

Complex Process

"What I can say is that there is a ponderous and complex process in Sweden, which the TLV is beginning to use for all new oncology hospital products (although it is still a pilot project [see p23]). At the outset, the department heads across the country, except in the south, said they were not going to prescribe the medicine, until it had been through the central TLV process.

"Three months after marketing authorisation, the TLV asked us to provide it with data, which we delivered on time. So it was five months from EMA approval until TLV began its analysis. This was followed by a NICE [National Institute for Health and Care Excellence]-type HTA assessment, over which the TLV took as long as stipulated – six months.

"Following this, we entered a negotiation with the SKL's New Drug Therapies Group (NLT), based on the TLV's analysis. Once the negotiation with the SKL/NLT was concluded, the NLT sent out a recommendation to the county councils, telling them that a deal had been struck. However, as this was just a recommendation, it took between a further month and six months to reach agreement and sign contracts

with the individual county councils. The whole process was enormous," he told *PPR*.

Local Decisions

As discussed by Hertzman, local decision makers play a crucial role in Sweden. "There is a tension between the county councils – who are primarily interested only in what affects their own geographies – and the central organisations, such as the SKL. Some of the large county councils are less interested in national solutions. At the end of the day it's the county councils that decide how to use the money – you need to follow that money.

"You have to be there, at the local level, to discuss and educate and to support the introduction of your medicine. The big county councils influence the others, and are very much in the driving seat in this respect. And if a drug is approved in one county council, patients become aware that they can get treatment there, so there's pressure on the other county councils to do something.

"But it's not good enough to sit in Stockholm and say that you are in contact with the county councils. You need to have some sort of network out there," he commented.

CONCLUSIONS

"There is a lot of work involved in launching a new product, including from an access perspective," noted Hertzman. "The whole access network demands a lot of interactions with an increasing number of stakeholders. In the case of the product discussed, we had to increase our activities and our investment in market access, to get it through to patients. Clearly, if we could just gain 12 or even six months through earlier and stronger access activities – and I believe we could – patients would get access a lot sooner. But you have to start early: you have to move the access investment much earlier, before launch – including at the local country level," he said.

"You need to be clear on the strengths and weaknesses of your clinical data. If not, you have problems once you get into a negotiation. You also need to ensure that you have local clinical experience, including the option of early access programmes. You must also have external advocates that believe in your product," he continued.

"To gain access you need to work through a complex network, rather than a linear process. It's like a living organism that you have to manage. Local, regional and central networks need to be integrated. This requires strong dialogue and communication. You also have to have your HTA file in good order for submission and manage HTA processes effectively.

"Hospital clinics have to prioritise. Should they invest in breast cancer or prostate cancer, and how do they deal with this? You need to find ways to work with them, for budget optimisation in relation to outcomes," said Hertzman.

Alternative Pricing Models

"Finally, payers are looking for alternatives to the current pricing model where we sell pills and vials," he noted.

In Hertzman's view, payers are looking at a range of alternative approaches in this respect, including:

- Rebates/discounts
- Performance-based risk sharing
- Financial risk sharing
- Novel pricing.

"It looks like in future more flexibility will be required in terms of contracts and pricing. The industry will have to play a proactive role," he told *PPR*.

"At the end of the day, we in the industry are also focusing on the fact that patients need to have access to new and improved medicines as soon as possible. However, we need to consider how to deal with the issue of high up-front fixed cost (related to investment in the expensive and risky drug development process) when we have fairly small patient populations.

"With regards to pricing, I think we need to look at other industries as well. In the IT industry, for example, they manage high fixed costs and low marginal costs in a different way. Often it is possible to pay an up-front subscription, after which there is a pretty low operating cost. Or we could look at contracting mechanisms, in order to reach agreements on pricing.

"All parties have to work for solutions, to find the right mechanisms, in order that we all feel like we gain on this. Ultimately, that will also impact on how we do business in this industry," he concluded PPR

Peter Hertzman would like to stress that the views expressed in this article are his own and not those of Bristol-Myers Squibb.