Interview with Cornelia Yzer , CEO, VFA

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2007 was a turning point for the German Pharmaceutical Industry as the Healthcare Reform from 2007 took place and the Special SHI enhancement Act entered into force. Two years down the line, how have these two events affected the industry, especially the members of the VFA, the German Association of Research-based Pharmaceutical Companies?

With the Health Care Reform Act that went into force on the 1st of April of 2007 the German Ministry of Heath intended to provide a new base for the general financing of the health care sector, as well as modifying part of the legal framework for the pharmaceutical industry.

It established a cost-benefit assessment performed by the IQWIG (NE: Institute for Quality and Economy in Health Care), an agency implemented by the government, whose main objective is to give recommendations to the G-BA – the body that unites health insurers, physicians associations and hospitals deciding on the cost effectiveness of therapies.

The establishment of the IQWIG meant that Germany would have to follow international standards on cost-benefit assessment. Even with the cost-benefit assessment the manufacturer has immediate market access after the launch of a product, reimbursement after launch and market pricing – so the market pricing is still set by the companies.

Therefore, the Health Care Reform – as far as cost-benefit assessment is concerned – has had no major impact on our industry up to now. This may change in the future depending on the outcome of the upcoming elections in September 27th. As the partners of the Grand Coalition in power have

different approaches towards the future health care system, we cannot predict the role that cost-benefit assessment will have in the future. Certainly it will not disappear – the question is how much impact it will have on the future of our industry.

Other market-driven instruments were implemented during the Health Care Reform of 2007. For instance, a new system of contracting between single healthcare insurers and the pharmaceutical industry was established. These instruments were directed especially towards the generics segment of the market. It had a serious impact on this market, as prices dropped dramatically and important savings were made in the healthcare system. With the price drop, the volume of sales of prescribed generics increased significantly.

Theoretically, contracts between the pharmaceutical industry and healthcare insures on the innovative sector are also possible. However, due to excessive regulation of the market – with reference pricing, central cost-benefit assessment, central reimbursement procedures and so on – they still work as pilot projects and are doomed to stay as such if further reforms in the right direction don’t happen.

Companies in general are in favour of new contracting models. However, simple rebate contracts will not work in the innovative sector. Innovative products have a long history where contracting models are of no use: 12 years of research in general and an average of US$ 800 million invested in R&D.

The advantage of widening the scope in which companies can establish contracts would naturally allow the actors involved to build a common understanding of the goals and objectives behind new investments in innovation. It’s a win-win situation where patients enjoy a continuous improvement of the treatment of their diseases, and companies have a mechanism that guarantees a fair price that takes into account all the elements previously involved on the investments in R&D.

Countries are naturally applying cost-containment policies that have their advantages and drawbacks. Looking into the German market, do you think the high level of regulation currently in place is putting at risk R&D and, therefore, the future of the German pharmaceutical industry?

The German government imposes a high level of regulation. However, our politicians have to be aware that whenever they come up with further restrictive rules against the innovative sector, this will have a negative effect on R&D in Germany. At the moment, politicians are aware of this fact. The Federal Government has done a lot in the last two years to promote R&D in the pharmaceutical industry. For instance, there is a new program that will strengthen the public R&D institutions in Germany and encourage them to closely cooperate with the pharmaceutical industry. The

government has understood that the only way to make these projects work and to promote long-term R&D in Germany is to cooperate closely with the industry.

German politicians are aware that the investments in the pharmaceutical industry have a very positive effect and high importance for the German economy. The pharmaceutical industry is a strong R&D basis but also a strong production platform and therefore an asset to German economy. To illustrate in numbers, the expenses in R&D in 2008 increased by 7 per cent and reached €5 billion, counting only our member companies – this represents nearly €13 million per day.

How do you asses the commitment of the Federal Government regarding prompt access to innovative products in Germany?

The big advantage that Germany has compared to other countries is that it enjoys immediate market access and reimbursement after launch. That’s a big asset compared to other European countries and it’s essential for the German industry that the government sticks to it in the future. The current system helps to explain the overall image of Germany as a R&D friendly country; this obviously benefits considerably German’s patients, who have access to the best treatment available in the world without unnecessary delays, which might cost many lives.

Compared with other countries and faced with growing competition from large emerging markets such as India and China, what are the main strengths of the German pharmaceutical industry?

First, there is a strong link between R&D and production. Companies have the tendency to do the scale up in the country in which they invested in R&D. Therefore, as long as Germany has strong R&D it will be a good basis for future production and investment. Other important advantages are Germany’s unique infrastructure and its technical and engineering experience, which is very important for the production sides of high technical quality such as biotech – where Germany is number two worldwide.

Germany offers a unique mix of highly specialised academics and brilliantly trained workers, a combination that unites deep knowledge and refined technique, and explains the leadership of the country on the most advanced industries. Germany is one of the biggest pharmaceutical markets worldwide, the largest in Europe. It has not only good R&D and production base but it is also a very generic friendly country, where innovative and generics play an important role in the industry. What do other countries in Europe and around the world have to learn from the German model about the compatibility between Generics and Innovators?

There is a natural need for more competition on the generic market and for more incentives to premium innovation, and both the industry and the government understand this issue.

The innovative industry has always followed the idea of creating headroom for innovation to make sure that every patient has access to innovative products, especially in the case of serious life-threatening or chronic diseases. In the past, generic prices were considerably high in Germany and more competition imposed by contracting has brought its prices down. As soon as the patents expire generics come rapidly into the market and the prices drop dramatically. This dynamic is regarded as necessary and the industry is very much aware that the resources in all health care systems around the world are limited, being also the case in Germany.

As an example of how this can positively affect the viability of healthcare systems, the expiring of patents in 2010 will represent savings of one billion euro per year to German insurers. The pipelines for innovative companies may not be as filled as they were in the past, but there is still a big amount of products that will enter the market and will improve the lives of patients. In 2008 alone our members brought 31 new products into the market in Germany, and we expect a similar amount for the coming years. This is especially true in the fields where innovations are most necessary, for instance in oncology.

Thanks to those scientific advances, the industry expects to transform death-threatening diseases such as cancer into chronic diseases. In some fields like breast cancer it’s already working. A woman diagnosed in an early stage with new innovative medicine stands a good chance that the cancer will not come back after the treatment. We recently released the vaccine for cervical cancer – the first of its kind. These have been major advances. Therefore, what governments must make sure is that those new treatments are available to our patients immediately.

Those are some examples of why the system has to support and encourage the premium for innovation – even at a cost of losing profits on the generic market. The increasing competition and price policies also affect our member companies whose original products lose sometimes 90% of the market share and the prices decrease substantially.

In short, what is your assessment of the state of the German pharmaceutical sector?

Germany is the leading market in Europe and one of the leading markets worldwide, the global healthcare market is a growing industry and Germany has the potential to maintain its leadership in global markets in the future. Let’s hope that the legal frame that we have in place will continue to foster innovation – not to block it.

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