Interview with Peter Schmidt, President, ProGenerika

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The German Pharmaceutical Industry is not only known for its cutting-edge R&D and production base but also for having a high penetration of generics. In your opinion, what role do generics play in the German pharmaceutical market and how have they managed to achieve such a wide penetration?

Generics play a central role on the German pharmaceutical market. They are responsible for more then 63 percent of the market from the statutory health insurance (SHI) – which covers a vast majority of the population. Besides, in the off-patent market, generics hold more then 79 percent of the market share.The importance of generics lies not only in their market share, but also in the sustainability brought to the national health care system, making social security more affordable and universal coverage an achievable reality. The high penetration of generics in the German pharmaceutical market has only been possible due to public understanding that our industry's support enables the nation to afford its generous health care system.As a result, policies such as the compulsory substitution of original drugs for generics by pharmacies and a strong awareness campaign were implemented in order to boost the consumption and acceptance of generics in Germany.The strong competition on the generic pharmaceutical market also explains why the industry reached such high penetration. Thanks to fierce competition, manufacturers work hard to deliver products with a high quality at reasonable prices, increasing the affordability and competitiveness of generic medicines.

What were the main challenges in achieving such a high penetration?

The main obstacle was the overall resistance to generics. Not more then ten years ago, most physicians and patients saw generics as second class products with lower safety and quality. Consumers and doctors were familiarized with the original brands and showed a strong resistance to shift to new generic brands.However, thanks to a strong awareness campaign people finally understood that generics offered the same quality and safety as originals. This was only possible because Germans trust their laws and institutions. Therefore, once they realised that generics went through the same quality standards and requirements that originals did, they felt free to take advantage of the more competitive prices generics offered.Once a drug goes off-patent, generics producers take up to eight weeks to enter the market and drop average prices by more then 75 percent. This was the final incentive physicians and patients needed to switch from expensive original drugs to cheap high quality generics. This explains the success of generics in the past 10 years in Germany, reaching one of the highest penetrations worldwide. However, high as it may be, there is further room for penetration. Originals generally hold around 20 per cent of the market share of off-patent drugs, something that can be easily overcome. Furthermore, the number of drugs to go off-patent will increase considerably in the coming years, opening promising new markets to generics producers.

How has 2007’s health care reform affected the generic pharmaceutical sector in Germany?

Even though the reform affected the German pharmaceutical industry as a whole, its effects were mostly felt by small and middle size companies, especially those from the generic sector. To better understand the impacts of the health care reform from 2007 on the German pharmaceutical industry it’s necessary to know how the industry is presently structured.The pharmaceutical sector in Germany currently comprised of more then 950 companies. The market is dominated by 40 big players, leaving a small part of the cake to the other 900 companies. Of those, 460 are generic providers. Since there is not much differentiation on the generic pharmaceutical field, the competition on this sector is fiercer then anywhere else.The main change brought by the health care reform from 2007 was the directive that allowed health care insurance companies to rebate directly with pharmaceutical companies. Before, price competition between generic companies was fierce; nowadays, with the additional power given to health care insurers – that can concentrate up to 40 percent of the market in the case of AOK – the competition equilibrium is broken and prices have gone bellow production costs.What is even worse in the new system is that contracts arranged between the pharmaceutical company and the health care insurer last for two years. This leaves competitors out of the market for a long period, forcing many to close their doors. The results are clear, rebate after rebate, the number of players will be fewer and the ones that survive will concentrate more market share. In a very near future healthy competition may disappear.Last

week, at the meeting of the European Generic Medicines Association in Barcelona- Spain, many participants raised the fear that new investments on the generic pharmaceutical industry will migrate from low profitable European countries to growing emerging markets.

How do you assess this new trend?

The fears from European generic manufacturers are justified by the facts. More and more the production of generics and API are switching to developing countries such as India, Bangladesh and China.Until very recently, these countries were responsible only for the first steps of the pharmaceutical value chain due to their lack of appropriate quality and safety procedures. However, western companies that outsource their production in developing nations are already capable of guaranteeing GMP acceptable by the most rigid authorization agencies, such as the FDA and BfArM. This has allowed multinational companies to take advantage of the cost-competitiveness of emerging markets and climb up on the value chain of production. If the German government continues to push for artificial competition to its current unsustainable level the local industry will loose its capacity to invest in higher quality and innovation. In this case, Germany may loose its biggest asset when competing with emerging markets – its superior quality.

How do you think the German Generic Pharmaceutical Industry can remain attractive?

It seems clear that this sector is experiencing a process of consolidation where smaller companies are being overtaken by bigger ones and also substituted by imports. However, Germany will continue to offer great advantages for companies that decide to invest on our generic pharmaceutical industry.Germany has a strong pharmaceutical base that gains from scale and unique know-how; we have one of the most skilled and trained workforce worldwide; the country offers the best infrastructure on the continent and a central localization. Besides, this is the biggest pharmaceutical market in Europe and will remain as such. For the generic pharmaceutical survivors, here is the good news: if you survive in Germany, you can survive anywhere.

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