Interview with Elisabeth Prchla, Managing Director, Merck Austria

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elisabeth-prchla-managing-director.jpg

Prchla, you have been leading Merck's Austrian subsidiary over the past eighteen months. What do you see as the key strengths of your company today?

Mirroring the company's structure, the Austrian affiliate gathers several divisions under one roof. Merck Serono is the largest division of Merck Austria: it markets innovative prescription drugs of chemical and biotechnological origin. Merck Serono focuses on highly specialized therapeutic areas such as Neurodegenerative Diseases, Oncology, Fertility, Endocrinology and Rheumatology. In Austria it includes also a broad product portfolio in the area of Cardiovascular diseases and Diabetes including several local products. Our Consumer Health division offers high-quality over-the-counter products to enhance the quality of life for consumers. In addition we have a small local chemical business in the area of bio-monitoring.

Our strengths are definitely our people: we have an excellent working climate with a culture that fosters cooperation and creativity. Customers can feel this! On top of selling medication we offer a wide range of innovative services to Health Care Providers, for example in the areas of continuous medical education and patient support, in order to improve the patients' quality of life. I still see room for improvement in the area of Market Access and Governmental Affairs, which have been neglected in the past, but it is increasingly important to tackle the current and upcoming challenges in the Austrian (and European) Health Care environment. We have built up a Market Access department throughout 2012 and are on the right track to become a relevant partner, not only for Healthcare Practitioners (HCPs), but also for payers and healthcare decision makers. Here, we

cooperate firmly with the Industry Associations in order to make sure that Austrian patients have access to innovative medical treatments, now and in the future.

How does the company position itself in the market?

Due to its strong product portfolio, Merck Serono Austria is No. 13 in the Austrian pharmaceutical market, well ahead of the worldwide rank of Merck Serono. Our growth engine is our strategic biotechnology portfolio, especially Oncology, where we offer personalized treatment options for colorectal and head & neck cancer as well as Neurology with our product to treat Multiple sclerosis. In addition, we still have excellent growth with some of our established products in cardiovascular diseases and Endocrinology. On the other hand, governmental cost containment measures have had an impact on our performance in the primary care business, which led to the downsizing of our primary care sales force in the beginning of 2012.

Like every other country in the European Union (EU), Austria suffers from a lack of financial resources in the health care system, aggravated by the financial crisis and the ageing population. The pharmaceutical industry has been the prime target for cost containment measures which has meant that patient access to innovative medicines is difficult. Our objective at Merck Serono, together with the Austrian industry associations, is to cooperate with politicians and payers in order to develop conditions that allow easier patient access to innovative medicines.

Another topic that needs to be addressed is the lack of efficiency in the Austrian healthcare system: Austria ranks among the top 5 in the EU in terms of healthcare spending in relation to GDP. On the other hand a recent research on health outcomes has shown that it only achieves a mid-level result concerning outcome oriented performance. The Austrian Ministry of Health has started to address this gap with the formulation of 10 healthcare goals together with 30 major political and healthcare institutions. These 10 goals should set the frame for Health policy over the next 20 years with the objective to increase the number of healthy life years for Austrian citizens. The Austrian pharmaceutical industry is striving to support the implementation of the relevant measures to reach these goals. An example for this cooperation is the “Pharma-rahmenvertrag”, where the pharmaceutical Industry committed to pay from 2011 to 2015 a solidarity contribution of 82M€ in order to support projects in the frame of these healthcare goals, with a focus on health and disease prevention in children.

How active has Merck been in partnering with the industry recently?

Currently most of the bigger pharmaceutical companies have a rather dry pipeline, leaving the competition for interesting molecules and small biotechnology companies very high. Merck Serono is currently involved in a deep restructuring program that will prepare the ground for high profitable growth with innovative biotechnology medicines. In this context, several agreements have been closed in 2012.

Merck Serono has expanded its EGFR-targeted portfolio by acquiring exclusive worldwide license of phase II Oncology drug candidate Sym004 from Symphogen, a novel investigational antibody mixture targeting the epidermal growth factor receptor (EGFR). The current clinical program in advanced metastatic colorectal cancer and in squamous cell carcinoma of the head and neck builds upon the long history of scientific and clinical success with Erbitux® (Cetuximab) and complements Merck's existing EGFR franchise.

Merck Serono and Threshold announced a global agreement to co-develop and commercialize phase III Hypoxia-targeted drug TH-302. TH-302 is currently being investigated in a global Phase III clinical trial in patients with soft tissue sarcoma, a randomized Phase II trial in patients with advanced pancreatic cancer, as well as additional clinical studies in other solid tumors and hematological malignancies.

Merck Serono and Dr. Reddy's Laboratories Ltd., Hyderabad, India, announced a partnership to co-develop a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies. The partnership covers co-development, manufacturing and commercialization of the compounds around the globe, with some specific country exceptions.

How do you evaluate the role of the industry as the engine of economic recovery and development for Austria?

Pharma business is usually described as crisis-proof, however, as mentioned before, major challenges lie ahead. Nevertheless, in Europe, pharmaceutical companies spend more on Research and Development (R&D) than any other branch, the R&D/sales ratio amounts to 15.9%. In addition, 49 new biological/chemical substances were created between 2006 and 2010.

About 640,000 people are working directly for R&D of pharmaceutical companies in Europe, and 3 to 4 times more indirectly. The trade balance of the EU´s R&D Pharma is 47b Euros, the best trade balance of all branches.

In Austria, there are more than 220 pharmaceutical companies, with around 11,000 employees. Pharmaceutical production generates a value of 2.45b Euros. Exports are exceeding imports by 13.3 % (6.21 vs. 5.48b Euros).

Merck conducts its R&D activities mainly in the headquarters, however, we run a production site in Carinthia, Spittal, employing around 280 people. Due to increased production, nearly 4m Euros are currently invested into a new analytical laboratory, thus, Merck is creating new jobs there.

How would you define Merck's commitment to the local population?

Merck has three global lighthouse projects: Merck Praziquantel Donation Program, a joint effort with World Health Organization (WHO) to eliminate the tropical worm disease schistosomiasis in

Africa; the GPHF-Minilab Donation Program to identify Counterfeit medicines and Deutsche Philharmonie Merck.

Since 2005 Merck is a Member of the United Nations Global Compact (UNGC) and reports according to the Global Reporting Initiative Standards. Merck steers its Corporate Responsibility (CR) policy strategically and according to external principles, so aims are set and the impact can be measured. Furthermore, Merck evaluates its legal entity CR engagement every year. In order to obtain a comprehensive overview of the numerous activities, the legal entities are asked to complete a survey on activities that demonstrate their commitment to society. With the survey, we orient ourselves toward recognized models for recording and evaluating social commitment, for example the guidelines of the Bertelsmann Foundation for the social engagement of companies and the model developed by the London Benchmarking Group.

Out of a total number of 167 legal entities, 95 completed the survey. 53 legal entities – or 32% – reported a total of 125 engagement projects (excluding Lighthouse projects).

Merck Austria is a partner in the local UNGC network, participating in working groups to share experiences and best practices. We foster programs for children with chronic diseases and support the oncology run. We provide a program called “Fit @ Merck” for our employees and offer fitness training, fresh fruit and vegetables twice a week and we plan to do more. I am leading the working group “Responsibility” within the FOPI – Association of Research and Development Based Pharmaceutical Industry in Austria (25 companies), where we want to join forces and strengthen our Workplace Health Promotion Management guided by external benchmarks.

Furthermore, we would like to initiate a Stakeholder dialogue, to better understand their needs and demands. This is an effort to meet criticism and gain back trust. Within some stakeholder groups Pharma still does not have a positive image.

What is your vision for the future of the Austrian pharmaceutical industry and the specific role Merck will play within it?

The industry is already undergoing dramatic changes and will do so even more. There is some inertia in the industry as we tend to stick to the traditional business model and we have to be careful not to miss the boat. The pharmaceutical industry is a partner in the health care system and will offer integral solutions increasingly more often, rather than just medicines. This diversification will be reflected more in the different partnerships and cooperations, rather than the established licensing deals.

With its broad portfolio and the 2 pillars of the Pharma and the chemical business, Merck has a great chance to be at the forefront of this transformation. Already, we are investing in devices such as Rebismart™, an electronic auto-injector for patients with MS which really makes a difference not

only in easing the pain and discomfort of the injections, but also providing means to track the adherence of the patients to the treatment. This allows more effective treatment and paves the way for alternative cost effective reimbursement systems where Health insurances pay only for drugs that are taken.

Another trend that is currently heavily discussed is personalized medicine.

This is about tailoring the medication to the characteristics of a patient or patient group, for example, genetic tumor characteristics, but also age and performance status amongst other variables, with the aim of avoiding treating non-responders, and eventually increasing treatment effectiveness and improving health outcomes. Merck Serono offers a monoclonal antibody for the treatment of metastatic colorectal cancer where a patient group of responders can be clearly identified by a biomarker test. Currently Merck Serono includes testing for biomarkers and specific gene characteristics in 80% of its pipeline.

The future of personalized medicine will depend on the flexibility of stakeholders in the HC system including regulatory authorities and payers.

Timely personalized treatment with innovative compounds can minimize the long term effects of diseases and thus help reduce high costs in the healthcare system in the long run – so long-term thinking is required.

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