Interview with Leo Neels, General Director, pharma.be

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Mr Neels, can you please begin by introducing our readers to pharma.be and describe its key activities and vision?

pharma.be is the General Association of the Pharmaceutical Industry in Belgium that is currently composed of approximately 140 pharmaceutical companies with operations in Belgium. As a full partner of physicians, pharmacists, hospitals, governments and other stakeholders, our mission is to promote better health through therapeutic innovation in the field of medicinal products for human use. Moreover, the association's top priority is to ensure that patients are granted the opportunity to gain access to innovative medicines arising from research and development, as quickly as possible.

Our top expert team is dedicated to tackling the entire spectrum of issues and developments relevant to the pharmaceuticals industry. This includes everything from packaging standards and the proper management of expired drugs to addressing the particularities and issues related to drug research and development, patent laws and reimbursement issues as well as organizing campaigns advocating the good use of pharmaceuticals. To this end, we have established close relationships with the pertinent authorities and other organizations, intended to foster and develop an environment that is conducive to the evolution of the pharmaceuticals industry.

The last few years have seen a number of major developments in the Belgium pharma industry, which have mostly focused on driving costs down and reducing healthcare expenditure – something the Minister of Health, Mrs. Onkelinx, is aligned with. Can you comment on the major

changes currently happening in the market, and the effect this is having on your members?

In general, Belgium invests significantly in its social security system, which offers everyone in the country easy access to medical facilities. In 2011, for instance, the government had allocated approximately €25 billion for the healthcare budget. Similarly, about €4 billion was expended in 2011 on drug reimbursements. However, as life expectancy and overall wellbeing of its population continues to increase, so does the pressure on its financial resources and healthcare. That is, as people enjoy longer and more active lives, there will be an increase in the drugs consumed in order to help sustain these lifestyles, further exacerbating the budgetary difficulties.

Naturally, these budgetary concerns are having unfavorable repercussions on the pharmaceutical industry's environment and our members' performance. Subsequently, this can lead to a slowdown of investments in new drugs, among others, which could have notable effects on a range of socio-economic subject matters. In the Netherlands, for instance, we have seen the decay of the Utrecht Science Park, which is focused on the life sciences industry, as a result of the continued austerity measures which drove the industry away. Fortunately however, this has not yet transpired in Belgium and I must commend the local industry professionals that have succeeded in maintaining this vital market.

Nonetheless, these austerity trends are by no means sustainable and we must act quickly in order to address the issues that the industry is facing. After all, the pharmaceuticals sector has a long and rich history in Belgium that has helped shape the country's pioneering and innovative nature. In addition to this, knowledge-based industries hold the key to Belgium's future prosperity, as well as for the whole European Union. This is especially demonstrated by the fact that the pharmaceuticals sector is a key driver of the Belgian economy. Hence, pharma.be has partnered up with the respective authorities, insurers and industry to ensure the continued presence and advancement of the pharmaceutical industry that is essential to Belgium's prosperity and health.

During the Belgian Pharmaceutical Conference PwC's Ingrid Maes, together with the FAMHP's Dr. Greet Musch, presented an in-depth analysis of the state of affairs of clinical studies in Belgium, as well as recommendations aimed at safeguarding this research that is essential for Belgian patients and the knowledge-based economy. Can you provide us with an overview of the market situation, how it can be improved and the role pharma.be and its members in this?

Belgium's outstanding expertise in clinical research, both in academic research as well as in industry-sponsored research programs makes it home to some of the world's highest numbers of clinical trials, per capita, in the world. As the industry developed over time, Belgium was imparted

with a high availability of skilled research staff, excellent infrastructure, dense proximity of knowledge centers and suppliers. In fact, among the most attractive features of the Belgian clinical trials market is its comparatively short approval times, by competent authorities, for the commencement of the studies. This has been the case ever since the first EU directive on clinical trials was drafted into Belgian law in May of 2004.

More recently however, the EU has released a new proposal for the regulation of clinical trials in the union as a result of the high costs and lack of harmonisation of the applicable rules necessary for multinational clinical trials in the region. Ultimately, the new proposal aims to overcome these impediments which have contributed to a significant decline in the number of clinical trials conducted in the EU by 25% between 2007 and 2011. Although we welcome this initiative, Belgium is at risk of being stripped of its competitive advantage associated with its rapid approval timeframe, as a result of regulatory harmonization.

Therefore, pharma.be is actively engaging in discussions with governmental bodies and organizational associations to ensure the necessary steps are taken to maintain its positioning in clinical trials. In any case, Belgium should avoid being complacent given its current strength in the sector and strive to remain ahead of the pack. In doing so, we are advocating that these new regulations are implemented as quickly as possible while leveraging the industry’s experience with rapid timelines and existing infrastructure.

Pharma companies in Belgium have voiced their concern with regards to the reference pricing system that they insist leads to a continuous downward spiral as a result of reference countries also adopting these systems. What is your view on the pricing system in Belgium and what would be some of pharma.be’s propositions?

Unfortunately, the reference pricing system was only very recently introduced by the state without the consultation or consideration of industry members. I believe that this is a collateral accident, especially for a country with such a strong presence of the pharmaceutical industry. It is the most unintelligent, unproductive and short sighted measure that Belgium can adopt. Effectively, this pricing system serves to drive the prices of drugs to lower levels, limiting the resources available for further investments in growth, R&D and in new innovative products.

The Belgian pharmaceutical sector has a leading role in the achievement of R&D investment targets which the EU member states set themselves as part of the Lisbon Strategy. In fact, the pharmaceuticals industry worldwide is the largest contributor to overall R&D, investing about 17-18% of their turnover into research activities. In Belgium, this figure is more than double the

world’s average with companies reinvesting up to 52% of their turnover back into R&D. As a result, it comes as no surprise that Belgium is ranked among the top countries in terms of the number of medicines under development per capita.

Therefore, this system of reference pricing can ultimately have a highly detrimental effect on the local industry as a whole by redirecting investments to more cost-effective locales, limiting the number of new drug introductions, diluting the industry’s strength while increasing foreign imports into the country.

Naturally, as the association of pharmaceutical companies, we have brought together industry members to voice our concerns over the negative long-term effects of this system. pharma.be is therefore in discussions with the federal agency for medicines and health products (FAMHP), the Ministry of Health as well as INAMI – the National Institute for Sickness and Invalidity Insurance among others, to strike a balance between the governments mandate to reduce expenses and the industry’s sustainability. Our objective is to highlight the inevitable detrimental impact of the system on the industry and a whole range of other socio-economic factors, especially in the case of a country such as Belgium that is host to a so far formidable pharmaceuticals industry. Given the importance of the subject matter and the common interests of both parties, I am optimistic that we will be able to come to a constructive solution on the subject matter.

What is on the agenda of the pharma.be for the coming 1-2 years? What challenges to you wish to overcome for your members, and what reforms would you like to precipitate in the market?

It is imperative for Belgium and its government to realize the importance of the pharmaceuticals industry for the wellbeing of the healthcare system and its people as well as its economic success. After all, the industry is a significant contributor to the country’s GDP and employs in excess of 30,000 people. Therefore, we aim to join efforts and intelligently overcome the challenges resulting from these austerity measures. Furthermore, if you consider the 52% reinvestment rate of pharmaceutical companies in Belgium, this effectively means that for every euro reimbursed by the government, more than half of it would be reinvested into R&D activities. Naturally, this reinvestment fuels the development of innovative products, stimulates growth and invigorates our knowledge-based economy. That is an important message for us since many in politics tend to focus only on the cost factor of healthcare. But innovation and investment in our system creates many benefits to our overall economy and generates added value to society as a whole.

Moreover, we intend to eliminate the elements that hinder and disable pharmaceutical professionals from defending and promoting their industry on an international level. In addition to this, we are determined to transpose the EU’s new proposal for clinical trials regulation to at least

maintain the industry and sustain Belgium’s leadership position within it. Certainly, we cannot achieve these goals on our own and neither can any other individual authoritative or commercial entity. We must come together and aggregate our efforts to safeguard Belgium’s leadership position in the international pharmaceuticals arena.

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