Interview: Eric le Roy â?? CEO, SNITEM, France

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Eric Le Roy, CEO of the SNITEM

(Syndicat National de lâ??Industrie des Technologies MÃ©dicales, The National Association of Medical Technologies Industry), reveals how the French medical devices market is valued at around 20 billion euros (USD 21.92 billion), and employs 65,000 people. He goes on to discuss how the SNITEM represents over 375 companies and why medical devices represent an opportunity for greater patient autonomy.

What is the importance of the medical devices industry to the French healthcare ecosystem and what role does the SNITEM play within it?

The medical device sector is a manufacturing industry. It is a global market worth around 20 billion Euros (USD 21.92 billion), employing 65,000 people in France. The SNITEM is the leading professional organization and represents the greater part of the medical device and the Healthcare Information and Communication Technology (Healthcare ICT) industries. The scope of activity of SNITEM is estimated to be 12 billion euros (USD 13.15 billion), drawing together over 375 companies, many of which are SMEs. Out of a total industrial fabric of over 1,000 companies, 94 percent are SMEs, including 45 percent of Very Small Enterprises (fewer than 20 employees) and 2 percent mid-caps. SNITEM is no exception to the rule and to date 89 percent of our members are SMEs with less than 250 employees.

Several reports published in recent years (such as the Gallois report on French competitiveness published in November 2012 and the Lauvergeon report entitled Innovation Commission 2030, published in October 2013) highlight that health is a promising technological sector in France, opening up avenues for increased research, innovation and growth. The medical device sector, which encompasses a large range of technologies and whose contributions are manifold, is strategic in this respect. Innovations in our sector contribute to an increase in out-patient care and therefore a

potential decrease in costs for our health system. These innovations can also be a contributing factor to a decrease in the length of hospital stays and greater efficiency of care, and in this way to a faster return to work. This represents an opportunity for greater patient autonomy and the development of home-based care, providing both personal and economic advantages. One of our roles at the SNITEM is to highlight the role that a booming medical devices industry can play in reducing overall healthcare expenses.

You have been the Chief Executive Officer of the SNITEM since 2011. What have been the main trends and dynamics in the French medical devices market since you began your term?

There have been a number of notable events during my mandate, both in France, and within a European context. When I became general manager of the SNITEM, the debate around the Bertrand Law was closed, soon after the Mediator scandal. In December 2011, the French Parliament passed a statute widely referred to as the Bertrand Law, inspired by the US Sunshine Act of 2010. The Bertrand Law aimed to restore the confidence of patients in their healthcare system by ensuring transparent, professional, and impartial relationships among healthcare providers and pharmaceutical and medical device companies. Furthermore, at the EU level the medical device directive has been comprehensively updated. Our sector is experiencing an unprecedented uptrend in regulatory requirements, coupled with strong economic regulation that is posing a challenge to our industry. This is due in part to the measures within the Bertrand Act and the regulation on medical devices from the European Commission, but can also be seen in the many provisions on standards and experimentation being put together that range from environmental schemes to telemedicine/e-health. The increasing complexity of the regulatory framework in which businesses have to operate and develop means that the SNITEM is attracting an ever greater number of members.

Do the authorities recognize the value of medical devices in the French economy?

Specialists of the medical device world are well acquainted with its diversity and drive. However, there is still a general lack of awareness surrounding the contributions provided by the innovations which we provide. Such innovations allow for appropriate solutions to the very diverse needs of patients regarding prevention, diagnosis and treatment. Many of these innovations, whether incremental or disruptive, play a positive part in the organization of medical care and indeed in the organization of the health system.

To contribute to improving awareness surround our sector, the SNITEM has created a Media Prize for Medical Devices (MPMD). This prize rewards print/web articles, radio, TV reports or articles submitted by students of schools of journalism regarding innovations in the medical device sector. The eight-member independent jury chaired by Professor Jacques Marescaux, a French doctor of international renown, received nearly 50 submissions for the first event in 2013. At the last edition, in December 2015, we had an increase of 35% submissions

How has the visibility of medical devices evolved in France?

For many years the medical devices sector was lacking visibility in France. This was not merely due to the fact that the market was smaller than it is today, but that the status of medical devices is relatively recent, coming into force in 1998. Indeed, when you look at SNITEMâ??s name, there is no mention of medical devices but rather medical technologies. The SNITEM was set up in 1987, before the concept of a medical device even existed. While the pharmaceutical world is clearly delineated, people often have difficulty in identifying what falls into the medical device sector. With the regulatory status created in 1998, it became obvious that there were in fact clearly identifiable medical device products. The pharmaceutical and medical device business models are different.

The level of investment, the return on investment, market size, the cost of market access in the pharmaceutical industry are not comparable with the medical device industry. The scale is considerably smaller in medical devices. Furthermore, there can be no placebo effect when it comes to medical devices. A drug either works or it does not. In most instances, medical devices do not work alone. For the patient, differentiating between the work of the doctor and the work of the medical device can be extremely challenging. The results of a pharmaceutical product are clear to see, but this is not the case in our sector, where the clinical outcome is a result of a close combination from the product and the practitioner.

How does the French medical devices environment compare to that of other European markets? What are the particularities of the French medical devices industry?

The French healthcare market is more heavily regulated than any other in Europe. If a manufacturer wishes to market a new medical device in France that is covered by an existing GHS (Groupes Homogenes de Sejours) procedure code, then CE marking may be and most often the only prerequisite. However, if the new medical device is not covered by an existing GHS procedure code or needs to be added to the LPPR (Liste des Produits et Prestations Remboursables), the access to the market is very limited. This market access process can take three to four years although it must be mentioned that there are exceptional procedures for some innovative products. Time to market is a real issue today.

The SNITEM acts as a bridge between the industry and the authorities, ensuring that the French medical devices industry speaks as one voice. What are the responsibilities that come with this position?

The SNITEM maintains constant exchanges with all the stakeholders in the medical devices environment on a regular basis, involving its members as much as possible. Set up by The SNITEM in 2008, the Look at Healthcare Club (RSS Club) is a club for informal discussion and debate between SNITEMâ??s members companies and key figures from the world of healthcare, political and administrative decision-makers, and healthcare professionals.

Our association also makes an important contribution to the training of people, in particular, regarding the economic knowledge of medical devices. To guarantee a better fit between company needs and student skills, the SNITEM has worked with several partners to set up initial and ongoing training programs adapted to the sector and which enable students to acquire the skills required by companies.

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