Eric Le Roy â?? Director General, SNITEM, France

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(*Syndicat National de lâ??Industrie des Technologies MÃ©dicales, The French National Association of the Medical Technologies Industry) discusses the profile of French medtech today, the key trends and challenges its stakeholders are facing, and the top priorities for change he and his members expect to see from health administrators.*

What is the profile of SNITEM and the French medical technology sector today?

Today, SNITEM represents over 420 member companies in France representing approximately 90 percent of the turnover of this market (excluding optic & IVD) which collectively have a turnover of EUR 28 billion â??of which EUR eight billion are from exports. There are 85,000 employees in France working in the sector. SNITEMâ??s own growth has been in line with this trend and we are faced with the same challenge of the MedTech environment becoming increasingly complex. The economic and regulatory pressure being faced by the sector has never been so high and our main priority is to continue representing and supporting our members.

Over 92 percent of the French medical technology sector is made up of SMEs and the new regulatory changes which will go into effect in May 2020 will be an enormous hurdle to face. In fact, we have already seen companies which are unable to adapt and continue their business. There are many niche markets in medical devices concerned by the impact of the cuts of the last Social Security Bill (LFSS for 2019). It is highly important to bear in mind that when a company is about to suffer from a significant budget cut (non-reimbursed) of maybe 50 percent like we observe in many of the niches and sectors we coverâ?¦. We have highly-concerning issues to face. The authorities are not conscious enough that the pressures that are thinning out small players are consequently reducing the overall product offering within the sector which ultimately affects patients.

How do you assess France as an innovative market for medical devices?

France is ranked fourth in the world and second in Europe for medical devices and technologies. The French system today is well positioned to breed many startup companies and can offer plenty of economic help. However, once these products obtain their CE mark and are manufactured in France, the current environment makes introducing the device in the country nearly impossible for a

small innovation-driven company. Unfortunately, we are starting to see that some companies are choosing to not introduce their new technologies in France. Moreover, this creates further hurdles as companies expand internationally and lose credulity due to a lack of presence in their own domestic market.

It is important to note that we are in a sector that has huge potential and access to opportunities. In France, there are excellent clinical researchers and many innovative start-up companies in the market. Therefore, it is imperative that we support this environment to ensure that the newest technology and best quality is delivered to patients. To achieve this ambition, we need to see a regulatory and administrative framework that reflects this value and encourages companies within the MedTech sector.

What are the challenges being faced by SNITEM and its member companies?

One of the biggest issues in France is that while the administrators are very well informed about the pharmaceutical industry, they lack knowledge when it comes to medical devices. This is logical since the pharma industry has been regulated for decades whereas medical devices have only been regulated to the extent it is today within the past 20 years. Unlike pharmaceuticals which have a directly traceable effect on a patient, the performance medical devices can be influenced by a variety of external factors.

Secondly, we are in a sector that is very diverse and complex. Technology and innovation are everywhere. Medical devices range from cardiology technology to bandages and medical textiles. There are huge differences between profit margins and business models within the sector, but the regulations do not match this unique need.

There need to be changes made to not only secure the safety of products but also match the evaluation measures to the market. It is unfeasible to ask for a EUR 20 million study for a niche market that is valued at less than EUR 10 million.

What implications has the 8th meeting of the Strategic Council of Health Industries (CSIS) held in July 2018, had on the MedTech sector?

Historically, the CSIS was a pharmaceutical industry initiative, so medical devices were not a central topic of discussion. Nevertheless, we had joined the council since the last three or four gatherings and during the 8th meeting, we focused on issues of market access and the valuation of innovation.

One of the positive evolutions of this CSIS is the creation of a follow-up committee to help the effective implementation of the decisions. It allows a better continue dialogue with the authorities between two CSIS.

There are two types of innovation; breaking and incremental. Most medical devices are innovated incrementally but looking at the implants that were available 20 years ago compared to those which exist today, it is clear how important this type of innovation is. Therefore, incentives must be given to incremental innovation and it must be properly valued in order to continue the critical development of medical devices.

How do you view the Macron administrationâ??s positioning towards these issues?

We see a willingness by the Macron government and his team to better address the MedTech industry, but this is not reflected through the entire administration. Social security has made irresponsible decisions which not only impacted the industry put patients as well, for example, cutting the prices of breast pumps by 30 percent. The French market for this device was at EUR 60 million but has been reduced to EUR 40 million. In an effort to cut EUR 200 million of budget, a niche which accounts for less than one percent of expenditure is now contributing to ten percent of economic cuts.

How is SNITEM working to raise awareness and build a strong network within the medical device space?

This May, SNITEM will organize a startup day which will bring together more than 1,000 stakeholders from the medical device sector. MedTech Europe, the European Federation of the sector, has decided to no longer only organize their conference in Brussels, but all across Europe starting this year in Paris. Together, we are creating a three-day medical device sector event, starting with SNITEMâ??s start-up day followed by the two-day forum. This is the most important event of the year for MedTech and in fact, the forum was attended by AgnÃ¨s Buzyn last years and Emmanuel Macron (through video) two years ago.

How is digitalization playing a role in shaping the future of medical devices in France?

Looking globally, one of the world leaders in health data structure is without a doubt France. Thanks to our singular administrative database, there is a unique opportunity to be on the vanguard of eHealth and digitalization. At this moment, we must seize the chance to apply these capabilities into the MedTech sector and produce conclusions that are more robust than any clinical studies. All SNITEMâ??s members will leverage digital technologies to create more efficient, precise, and integrated devices that can revolutionize the way we deal with healthcare and the patient journey.

What are your strategic priorities as Director General of SNITEM moving forward?

The medical device space is very diversified and complex, so it can be difficult for the public to measure the impacts of these trends. Therefore, the sector is often caricatured by misleading and inaccurate news. There are many aspects that can impact the performance of a medical device which may be intangible and a challenge to measure. For example, if a hip replacement is bothering a patient, perhaps the competence of the surgeon was poor, the hospital did not allow a patient to stay long enough to heal properly, or the patient themselves did not care for themselves properly after the procedure.

SNITEM wants to raise the awareness of the MedTech sector to the administrators to ensure that sustainable decisions are made in regard to health budgets and regulations. We are working to spread this knowledge to create a better understanding of how legislation impacts the sector and what the special needs are by creating dialogues, creating information content, and increasing our communication efforts.

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