Interview: João Goncalves – Secretary General, APORMED, Portugal



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Secretary General João Goncalves

of the Portuguese Trade Association for Medical Devices Companies (APORMED) – Portugal's medtech association – welcomes readers to explore relevant trades in the medical devices segment. Although initially an association dominated by domestic players and now by the multinationals, under Goncalves's vision, the group intends to include start-ups, heavy equipment, and health IT services, while providing a voice for companies tackling challenges such as the implementation of the new code of ethics, late payments and procurement.

What was the rationale behind establishing APORMED?

APORMED is the Portuguese Trade Association for medical devices companies founded in 1990. At the outset, the major companies associated with APORMED were Portuguese; however, we have seen a sea change in the average company profile. The majority of our associated companies are now international and the biggest players operating in Portugal. APORMED includes companies such as Medtronic, B Braun, J&J, Alcon, Baxter, etc. We also have Portuguese companies, manufacturers and multi-branded distributors, such as Medicinalia Cormedica, Pulmocor, Normax, Bastos Viegas, Fapomed, among others representing all stakeholders across the value chain. 63 companies are members, which represents around 50 percent of the total market which is rated in 1.2 billion euros. The reason why we do not represent a higher percentage of the market is because IVD (in vitro diagnostics) products fall within APIFARMA's scope of operations—not

APORMED—although technically speaking IVD are medical devices.

Another reason is because we do not yet host any companies that represent heavy equipment, such as Phillips, GE, Toshiba or Siemens; this is our main focus in terms of recruitment of new companies. Typically, our members are the larger hospital providers. The most significant medical devices manufacturers companies in Portugal are Bastos Viegas, Codan and Fapomed; indeed, these companies export further afield than the PALOPs countries, and access worldwide markets.

In an encouraging economic climate whereby economic growth is consistently above two percent, what are your priorities?

Despite that our economy is growing there are historical problems that despite our efforts remain unsolved. I refer specifically to public debt issues and the late payments that are overdue to public hospitals in Portugal. On average, public hospitals in Portugal face one-year payment delays and of course, this impacts the financial performance of our companies. Regardless of our companies' status as a multinational or a local, they are affected. The situation in Portugal has persisted for two decades and is a chronic underfunding problem within healthcare. When compared with Southern European countries, Portugal's debt issues are normal; nevertheless, our neighbors in Spain have managed to resolve debt issues, and in Italy, the situation is also better.

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As the head of the association, and the spokesperson for medical device companies, how do you remedy the situation?

We have a team of debt-focused personnel within APORMED working hard to attempt to find solutions—which focuses heavily on convincing our entities to pay on time. We meet regularly with the ACSS, the public stakeholder that receives government funds for diffusion to public hospitals; and at times we approach the Portuguese government individually, during meetings part of the Healthcare Commission of the Portuguese Parliament. We highlight the gravity of the situation at these meetings and promote change. In 2017, we were successful in establishing an agreement with a financial company that intends to resolve delayed payment issues across "factoring" contracts. To sum up, meeting with key stakeholders, improving communication between government and industry, and engaging with government officials combine to create a strong case for reversing the currently serious debt situation are our priorities. However, this challenge is long-standing and needs dire improvement.

What other challenges do medical devices companies face?

The public procurement environment is challenging for many companies in Portugal. In general, companies depend on as much as 70 percent on public hospitals, and the primary means of selling a product through a public hospital is through a public tender. Unfortunately, the only reward criteria in recent years has been the lowest price. A system based on the lowest price does not focus on outcomes-based methods nor does it incorporate a long-term view, because the lowest priced product is not necessarily the most efficient or lasting. Consequently, for companies that offer innovative and differentiated products and services, are negatively impacted. One of our most notable challenges is convincing the authorities that high-quality, innovative products are more cost-effective in the medium to long-term because they improve efficiency and often these products are longer-lasting. We must work together in a collaborative spirit to shift the paradigm away from targeting purely low prices and instead, enhance the sustainability of the healthcare system.

How have recent reforms to the HTA impacted the system?

When the government released the new SiNATS legislation in June 2015, which forms part of Portugal's HTA, there were three main changes. First and foremost, medical devices would be included within the HTA infrastructure from 2015 onwards. Secondly, SiNATS' refers to the creation of two evaluation or testing periods; the first of which is upon the launch of a new product. Following a period of time there will be a second evaluation "ex post". The reevaluation serves to make clear—using real-world evidence—the added value of the treatment. The third reform is related to risk-sharing, so that when a company launches a new product, and the product is proved to be inefficient following a year on the market, the public entity pays less to the company.

In the medical devices segment, few devices are included within the HTA; therefore, the SiNATS reforms were less critical for APORMED, and changes to the HTA have, so far, minimal impact. The cycle of medical devices is roughly 18 to 24 months. That means that a new product or a significant upgrade launches every two years. In the pharma sector, a new product or molecule is brought in every 10 to 12 years. Moreover, in Portugal, we have over 600,000 active medical devices products.

How does market access for medical devices compare with market access in the pharmaceutical sector?

In general, market access for medical devices in Portugal is easier because the criteria are less stringent than pharma. Provided that the medical device has a CE mark provided by a Notified Body should be sold in a EU country. However, in Portugal, every medical device must have a CDM,

a medical devices code. Public hospitals cannot buy a product without this code. The codification process it represents a considerable workload for the companies and adds to the delays in terms of time to market in Portugal. For instance, sometimes companies have to wait for several weeks before they receive the number which they can present in a proposal for a public tender. Naturally, this is a context cost for companies as they are obliged to employee more administrative staff working in regulatory affairs, or they are forced to contract external companies to take on the extra workload.

2012 marked the beginning of this process, and the whole range of medical devices products are included within the scope of activities. The codification process was a direct impact of Troika and a way of controlling the expenditure of every medical device sold in the healthcare system.

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What other changes have you observed in the medical devices sector?

In 2017, a new reform founded on the transparency and publicity of medical devices addressed issues within the sector. Every educational grant that a company gives to a hospital or other entity for a health care professional training must be registered on an INFARMED platform to show a grant received and published. Also, the entity must perform the same process. Furthermore, if a public hospital wants to host an event related to a new product launch must request permission from the Secretary of INFARMED. Pragmatically speaking, this legislation initially causes some disruption, but overall, it increases trust within the system.

What are Portugal's strengths?

Above all, I observe that the quality of education and qualifications of the talent pool in Portugal is excellent. Furthermore, Portuguese people are very comfortable with change and are happy to adapt, particularly when we compare to other European states.

What does the future of APORMED hold?

In the short-term, we have started to collaborate with start-ups, and as such we have reduced our membership fees to a symbolic amount for start-up companies. We soon hope to sign up new companies to APORMED and to be more engaged in the start-up world because there are lots of fresh, up-and-coming start-ups in the exciting medical devices space in Portugal.

Long term, we hope to increase the number of members, and based on the past three years' growth, during which we have signed up 25 new companies, we are confident in becoming an even

stronger association, which is even more representative of the market, offering a package of added value to our members, in order to serve the collective and legitimate interest of our companies. Finally, I would like to see heavy equipment companies join APORMED, along with companies that work in healthcare information technology.

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