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Margarita Alfonsel, general secretary of Fenin, the Spanish Federation of Healthcare Technology Companies, reflects on the COVID-19 pandemic, the changing dynamics of the medical technology industry in Spain, and comments on key policy changes that Fenin's members are advocating for.

The COVID-19 pandemic has put the health technology industry in the spotlight as it raced to produce personal protective equipment and diagnosis tests. How has the pandemic affected the Spanish industry and what role did Fenin play?

I believe that the most important thing is to reflect on how we lived during the pandemic to understand how we are getting out of it. Right from the start, we formed a new crisis committee to put in place a well-defined strategic plan and opened the organization to the national and regional health authorities and other key stakeholders as well.

During this unprecedented situation, thanks to our knowledge of the market and our organizational expertise, we worked closely together with all stakeholders and our own members, collaborating side-by-side at a moment when all manufacturers increased production to support the population; at the same time, some manufacturers were able to transform their regular processes to generate other types of products. All was done with the approval of the health authorities.

On the other hand, distributors had to adapt as well in order to navigate country lockdowns, ensuring that all products arrived. Importers were fundamental since the global supply chains had to pass by far away countries like China. Fenin, along with Iberia and Oesía group, created a “sanitary air corridor” to establish efficient routes between Shanghai and Madrid. Thanks this altruist initiative, and through 32 flights along two months, we managed to bring 700 tons of cargo successfully.

Furthermore, the pandemic has put our sector in the spotlight, and we have shown that we are an innovative and committed industry. The association increased awareness in the general public about the most recent science-based information regarding protective equipment, monitoring and diagnosis equipment and tests. We cannot forget that the health-tech industry provides solutions for prevention, diagnosis and treatment considered essential to fight against COVID-19. From a financial point of view, in general terms, the market grew 11 percent, which is quite positive, however, this was not a homogeneous trend. Actually in 2020 our associates have experienced different results as the cessation of the no-COVID hospital activity had significant and negative impact in the companies of sectors such as Implants and Surgical Devices.

Can you comment on the regulatory situation in the country and the key policy changes that Fenin is advocating for?

Even before the pandemic, the regulatory environment in Spain and Europe was undergoing deep structural changes, but they had to be put on standby since the crisis took all of our attention. In part, the process had to slow down because many notified bodies [organizations designated by EU Member States to assess the conformity of the products before being placed on the market] haven´t yet been designated for the new regulation. Another big topic is the new regulation regarding in-vitro diagnostics medical devices because it will be challenging to apply it unless more time is given to companies and governments.

In this sense, we are advocating to speed up the designation of the AEMPS as a Spanish notified body for the new regulations as this is a priority matter for the Spanish manufacturers or international manufacturers with production facilities in our country and other companies from Latin America.

Despite the setbacks, our sector has a very close relationship with AEMPS and regional bodies and we have worked together to provide the products that were more necessary during the pandemic. They appreciate the industry’s effort to adapt production lines in order to supply skyrocketing

demand.

Additionally, it is important to highlight that the companies that were very active in imports were forced to overcome complicated logistical, economic and political barriers. The Administration made an effort to be flexible so as to guarantee that critical products were allowed in a timely manner, of course, making sure that products were safe, efficient and of high quality.

In a country that lags behind other European countries in healthcare spending as percentage of GDP, how can the health-tech industry help increase investment?

That is an interesting question because one of our requests to the healthcare authorities is the increase in the health budget because the level of spending on health is insufficient to cover the population's demands. On that point, the new funds coming from the European Union could provide much-needed help; In this context, Fenin has promoted a project in which we identify all health-tech areas that require substantial investment to modernize and transform the system, improving patient outcomes. Current investment is not enough to face challenges such as the increment of chronic diseases and population ageing and Spain lags behind other European countries. It is important to maximize the investment in Healthcare of the EU funds to introduce structural changes to the healthcare system to improve it is quality and efficiency; we could make a big leap forward.

For instance, we need to invest more to digitalize the system, which is one key area being addressed by the Administration, and to reindustrialize the health-tech sector as well, because it is now clear that we rely too much on foreign countries, in this sense, Spain must guarantee security of supply.

The sector is also focusing on a plan to renovate outdated hospital equipment called "Plan de Inversión de Equipos de Alta Tecnología" (INVEAT) and another one to increase the level of R&D investment. And linked to this, our industry is looking for support to internationalize while providing more growth opportunities for startups.

Looking towards the future, how do you envision the future of the association?

The question is particularly relevant today because the organization recently went through some changes, including a change of president. The team has been focusing on defining the most

important challenges faced by our associates, which in summary are: more investment in healthcare, a need to closely examine opportunities provided by EU funds, successfully implement specific projects such as the medical equipment renovation or reindustrialization of this Sector and boost the Value-based healthcare and Value-based procurement.

Moreover, we are analyzing the value-added tax (VAT) for health products since Spain has three types of VAT, a very reduced one (4 percent) for specific products designed for people with disabilities; a slightly reduced VAT (10 percent) which covers important products such as implants, and, finally, a regular VAT (21 percent) for the vast majority of products. Our goal, now that EU regulations are providing more decision-making capacity to member states, is to secure a permanent reduced VAT for the entire sector, since it has been categorized as an “essential sector”. As in Spain Medicines have a 4 percent VAT, we firmly believe that health technology should also receive a similar type of incentive.

On the other hand, since 2007 Fenin runs a foundation focused on demonstrating how technology adds value to the diagnosis and prevention of diseases. Linked to this foundation we are working to develop a multi-university academic course to strengthen the industry’s relationship with academia, thereby helping young students be part of the health technology revolution.

Finally, looking towards the future**,** Fenin will keep being a solid and rigorous organization, one that represents the true interests of the sector through a growing influence capacity. Having mutually beneficial relationships with the Government is key for our industry, to work together to introduce innovative therapies and technologies in the Healthcare system to improve the clinical results and the quality of life of the patients.

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