Margarita Alfonsel – General Secretary, Fenin, Spain



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Margarita Alfonsel, general secretary of Fenin, offers her perspective on the state of the MedTech industry in Spain, the changing dynamics between the public and private sector,

and the issues of rolling out value-based healthcare.

What have been the implications of the New Procurement Law of 2016 for medical device manufacturers?

The New Procurement Law has had a significant effect: we have moved to a model with a wider and more complex legislative disposition that doesn't consider special characteristics of the healthcare sector.

We have maintained our institutional relationships with all the political parties involved in the law processing and discussed with them the need for a more concrete development of the current law that considers the healthcare industry. Unfortunately, all those political groups that could have amended the law decided not to do it for political reasons. We hope politicians become more aware of this situation and change this law to include a specification of the healthcare sector.

Medical device manufacturing in Spain is moving towards value-based healthcare – New procurement law is slowing down this implementation, what is your take on that?

The issue is that reality changes before the law does. It is true that in the EU, and in the MedTech sector, there is a growing movement towards value-based healthcare and innovation and although the new law focus on the quality-price relationship and the importance of considering other aspects different from price, the administration and the procurement agents haven’t still moved towards a strategic and value-based procurement.

Following this movement, we are working on a new project in 2019 with the objective to analyse the value and healthcare outcomes obtained after improving a particular healthcare process. Afterwards, we will present these results to the administration to share them with the industry. In addition, we have promoted some projects in collaboration with scientific societies that demonstrate the value of innovation and medical technology.

Which are the communities that are the best performing in terms of success in value-based healthcare?

Rather than the autonomous communities, the ones promoting this initiative are the healthcare professionals and scientific societies along with the industry and different stakeholders in the community. There is not a clear strategy on this area at the regional level and we hope that the healthcare Ministers take the lead and evolve to a strategic plan based on value.

The reason why the industry is boosting the value-based healthcare is to facilitate the access to innovation of patients and healthcare professionals.

Taking all of this into consideration, I would say that the most active autonomous communities in developing a strategy promoting this initiative are Catalonia, Basque Country and Galicia.

What are the opportunities that the growth of the private healthcare sector presents for medical device manufacturers and producers?

From my point of view, the health system should be unique, and the bases should be established for a collaboration model where private and public health can be accommodated in a complementary manner. The synergies and the search for efficiency for the benefit of the patient should be the main objective.

Part of their growth has been driven by their fast incorporation of technical innovation in comparison to public hospitals. This is a big opportunity for our medtech sector.

How do the recent elections and the upcoming community elections affect you?

As a business organization far unrelated from politics, we work in a professional, rigorous and committed way always, regardless of the ideology or the political party in the government. Obviously, political changes can affect the projects initiated with different departments of the Ministries, but we will keep working hard to continue the close relationship that we have with Administration. In this case, the PSOE had been in the government for several months and it will continue there; we still do not know which political alliances they will establish, but their policies will not change in a significant way.

The healthcare competences are transferred to the autonomous communities. This means that the ministries are the ones in charge of the regulation, while the autonomic governments are responsible for all the healthcare-related public procurement processes, purchasing decisions and hospitals and community care management.

Do you feel there is competition to attract investment between the autonomous communities that could be beneficial for the industry or is it really concentrated only in Madrid and Catalonia?

Personally, I believe that, in general, the autonomous communities do not consider the importance of attracting investment or implementing policies that might seem attractive for companies. Only some of them have had initiatives to support them. For example, some technology parks in Valencia, Málaga…offer advantageous conditions to the industry.

We are very much involved in the investment area to support the innovation initiative or our companies.

Moreover, our innovation department created in 2010 a Spanish Platform on Healthcare Technology Innovation supported by the administration to promote innovation in healthcare technologies. We organize forums where we connect investors and ideas, helping good ideas grow and become a reality. We do this in a business environment, with no regard of political affairs.

How fit are the laws around data privacy to adapt to the intrusion of the private sector in the use of digital solutions for the patients?

With the entry into application of the General Data Protection Regulation, in May 2018 there is one set of stronger data protection rules for the companies operating in the EU, that mean more control over the personal data, the processing by individuals, companies or organisations of personal data relating to individuals in the EU.

Fenin is always committed to support the companies and help them adapt to the new regulation, organizing numerous training sessions for our associated companies on data privacy.

The new law is important to guarantee data privacy now that the digitalization is being implemented in all the processes that affect our lives, including healthcare.

In terms of digitalization, the interoperability between the hospitals, public and private and the autonomous communities should be a priority, and probably this will guarantee safer processes. The lack of coordination and interoperability in Spain could facilitate data leakage and security breaches.

Is one of Fenin concerns to foster collaboration for digital solutions?

FENIN is constantly monitoring the development of the Health Service and its modernization from different perspectives.

An example of this can be seen in our active participation in the group of experts convened several years ago by the Spanish Ministry of Health to produce a report on the “e-Health Strategy to transform the National Health System”. In this group, experts representing different stakeholders discussed what was required to bring about such modernization in the National Health System.

The resulting report was approved by the minister’s advisory council, Mrs Ana Mato. Some very interesting conclusions were reached, but sadly they were never taken any further.

A more recent example last year was as a business initiative spearheaded by Fenin and developed by the Spanish Employers’ Confederation, which produced a document setting out an experimental project to transform the National Health System.

This project was presented to members of the Spanish Parliament during the term of the previous Government. We look forward to taking it up again for development with the current Administration.

And as a final example, I would mention the project that we are currently developing with COTEC Foundation for Innovation to ascertain the degree of digital transformation in Spain's different Autonomous Communities. To this end, we have produced a questionnaire and are visiting managers in different Autonomous Community institutions to draw up a map of the overall situation in our country.

What is Fenin's role in the internationalization process of the Spanish medtech companies?

FENIN has been working in this area since 1996. We have a department for the strategic management of our business sector abroad, responsible for leading and coordinating the attendance of Spanish manufacturers at trade fairs and missions.

I myself attended the most recent edition of the Medical Trade Fair held in Dusseldorf in 2018.

We also attended the Arab Health Trade Fair and Conference in Dubai with some 60 Spanish companies. It was a very interesting experience and we are seeing an upswing in our export figures. Our trade balance is still negative, but we have identified this as a challenge that we are addressing through the "Sector Exports Plan" drawn up jointly with ICEX (Spain Export and Investment) and based on priorities expressed by our member companies.

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Which are your main priorities for the coming years?

First and foremost, our aim is to continue providing support to our member companies and draw up the road map for guiding our activities.

At the annual meetings of our governing bodies, we discuss overall strategy and work priorities, with the focus on:

1. Training and updating our members as regard the new legislation applicable to the sector due to come into force in 2020 and 2022,and working actively with the Government to familiarize ourselves with legislative texts during the linguistic and technical review stages to ensure their correct interpretation.

In addition, at the present time, deadlines make re-designation of the Spanish Notified Body for product certification based on new regulations a matter of urgency. For our national or multinational companies with manufacturing plants, this would offer added value for certifying their products via the Spanish National Organization. If the political decisions for re-designating this Body are not taken, these companies will be forced to use Notified Bodies in other Member States.

2. The Public Sector Contracts Law (public procurement) has been one of the most widely debated legislative texts prior to its publication.

All contracts with Public Administrations are based on this legislation, which is not specific to the healthcare sector but does present some opportunities for changing the models used in Autonomous Communities which make procurement decisions based on price, and not on the value of the technologies themselves.

However, we believe that there needs to be a cultural change in this respect, prioritizing procurement based on the value of health technology given the benefits for patients and professionals alike. Obtaining results is crucial for effective, efficient management of resources.

3. Another area of concern is technological obsolescence. We are in possession of a highly interesting report which focuses on 11 technologies (high-tech) and provides conclusive information on the obsolescence of technological equipment installed in our hospitals. It is an extremely useful document, in that it uses the so-called European “golden rules” to establish the degree of obsolescence of equipment installed in hospitals in different Autonomous Communities and serves as a starting point for quantifying how this technological inventory needs to be upgraded. This study is currently being updated and once it is complete, it will be published so that Autonomous Communities can adhere to it and decisions taken to ensure safety for professionals and users, and also to ensure that correct diagnoses are made.
4. The Debt Observatory continues to be an essential tool for monitoring Autonomous Community payments, both as regards the volume of debt pending payment and the average timescale for debt collection.

This matter reached a critical point in 2000 and 2012, with the government introducing a scheme for significantly alleviating accumulated Autonomous Community debt. At that moment it took the form of an injection of over 5000 M€ for our companies. The law is not currently being fully complied with by all of the Autonomous Communities, but the situation is not as critical as it was in the past.

We continue to work with this Observatory to continuously monitor payments to suppliers, since this is an area that we must not overlook.

5. The overseas expansion of our companies is a challenge that we are successfully addressing, as we have already commented on.
6. Innovation is our sector driver. We have a platform for innovation in health technology which is pioneering in Europe and co-financed by the Government. It has allowed us to set up a knowledge and contact network for all stakeholders, the aim of which is to identify ideas and come up with formulas for financing through investment.

We are working on a large number of initiatives relating to this platform, amongst which are investment forums for promoting researchers to investment companies who are seeking opportunities.

The platform works in coordination with numerous research bodies, setting work priorities and seeking funding for high-value projects.

7. Lastly, I would like to mention our ethical code of self-regulation which governs the relationships between professionals and industry.

This code was developed by MedTech Europe and organizations in all countries, including Spain, have adopted it for regulating their activities.

We launched an intensive scheme for training and informing our member companies which is continuing in 2019. A particular characteristic is “indirect sponsorship” which creates formulas for changing the relationship between professionals and companies, with a great many nuances which have required a great deal of work.

We have a unit for controlling and monitoring this code of ethics in FENIN, and this unit is furthermore responsible for oversight of compliance with the code.

FENIN works with a consultancy firm, and our in-house team manages an event validation platform.

Do you have any final message for our international audience?

I am very grateful for this opportunity to talk about Fenin. We have been working diligently and with a lot of excitement for the last 40 years, and I believe that our sector will be the future of healthcare. The technical developments that we are looking at now will change the way healthcare is perceived.

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