María Ángeles Figuerola, Director, SEVeM, Spain

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María Ángeles Figuerola, director of SEVeM - the Spanish Medicines Verification System – introduces the mission and mandate of the institute, major challenges, and SEVeM's role within Spain's healthcare ecosystem.

Please start by introducing the mission and the mandate of the institute.

In accordance with the EU Delegated Regulation 2016/161, SEVeM is one of the legal entities tasked with managing a national repository, in this instance, the national repository for Spain. In addition, we have a second purpose concerning the information in our repository. The idea is to harness that data in order to calculate the reimbursement due by the pharmacy offices to the pharmaceutical companies and distribution entities for those products that are dispensed outside the national health system.

Given that so much of what SEVeM does revolves around information collection and transmission between different stakeholders, is it helpful that you, yourself, have a varied background transcending both private enterprise and state administration?

Yes. For several years I worked in private companies as a quality manager and as a consultant. I think this has given me a background related to managing complex projects, helping people achieve objectives, and being very much aware of the financial bottom line. Then in the Spanish administration and as a public servant, I worked in different Ministries for many years. I was first in Science and Technology and then in Industry and Commerce. In a way, our client was the

pharmaceutical industry. In addition, we collaborate with the Ministry of Health as member of the Commission for Prices and Reimbursement. I am therefore well equipped to understand a situation from the perspective of different stakeholders: private or public. I also spent four years at the pharmaceutical legislation unit of the European Commission so I now have a good awareness of the Europe-wide dimension.

Do you understand how the Brussels system works and the ins and outs of policymaking at the supranational level?

That was one part of it. Also, it was really the unit that was preparing all the proposals related to pharmaceutical legislation. As a result, I was very much involved, for example, in this directive related to counterfeit and falsified medicine. I was also taking care of the dossier relating to China, India, and Russia and I therefore had to travel to China to talk about this directive. We should not forget that, even though I am in charge of the Spanish repository, this is actually a European project with global implications.

You were appointed two years ago. What have been your major challenges?

The main challenge is really to set up the system and get it up and running on time. That means everything has to be operational before the February 2019 deadline that all member states have to adhere to. We are working on that but we have not achieved it yet. From the beginning, the first challenge was to start a company because SEVeM did not exist and had to be established from scratch. It was first set up on 21st July 2016. When I came here, we were lucky that we had the office, and we had to organise everything else from choosing furniture and equipment to requesting a VAT number anything that was related to setting up a company. I then had to recruit a team, which I am now very happy with.

We have four people. Aside from the general manager, we have a project leader, quality assurance, and then a technical and an administrative supervisor. For the Spanish project, our project leader is someone with a lot of experience and a background in implementing software projects. A lot of the weight of the project falls on him. The quality assurance person has a relevance in Spain which is probably higher than in other countries.

Why is that?

Because our project is a little bit different. We have specific requirements. For example, the national authorities have requested that the hosting of the Spanish data lies with a local host in Spain. This moves us away from the main European infrastructure, where most other countries use

the same infrastructure from the IT provider. That means we cannot use all the results from their quality assurance and testing and we will have to do our own. The reason is that the agency, in accordance with regulation, is the one in charge of surveying the system, so to carry out that role they wanted the data to be here.

What was really good for us is that we have been working with Oesia a technical consultancy firm that has an agreement with us for this project, and they have provided the technical people for the project. It is a Spanish firm that came here at the beginning of the tender when we were looking for the IT provider. The advantage for us was that they had not only provided people with the adequate technical background that we required but also had the flexibility to provide support at the moment we needed it. The team was not that big in the beginning and we have grown quite slowly, but during these two years, they have joined the team right at the moment when we most needed to grow.

How did you go about recruitment and human capital sourcing?

It was easy because we had this flexibility. At any moment, if they did not have the right profile, we could change. They have the “SEVeM spirit” and were motivated in terms of the project and the technical skills, which is what we were really looking for. For the time being, we don’t expect to grow anymore. We may need some help at the end of this year because if all end-users decide to connect to the system at the last minute, then we will have an increase that will require backup support to manage smoothly.

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What about in terms of the resources that you have available? How is Spain’s current austerity impacting you?

This is an area that was easier for Spain than for other countries. It was because we were able to negotiate a loan with a bank which we shall begin to reimburse in the middle of next year, as part of a five years plan. This means that, when we started, we had no shortage of money. We had enough money at SEVeM to hire resources, rent the offices, and we could concentrate on the project. We don’t need to worry about money because we have a good cash-flow and we shall start charging fees to the pharmaceutical companies at the beginning of next year. In other countries, they need those fees in advance, so they have to set up some system of reduction, but that was not our case and that made things considerably easier for us.

How confident are you that everything will go to plan and you will meet the February 2019 deadline?

Now I am quite confident, however it was not so clear at the beginning of the project. As I said, our project had some peculiarities, some things were quite different, like the local hosting which meant in principle longer delivery times. In our planning, we knew we would fall behind the other countries but we have managed to get the local hosting up and running and we are aligned with other countries on the project timelines. This week we are doing the assessment 2 with EMVO and, assuming we pass, we will be awarded our credentials later in the month.

What are the next steps?

So the next step, once we get our credentials is that, during the rest of the summer, we are going to conduct some performance testing.

Does that mean the rollout of pilot programs?

Absolutely. We need to have given the new system some test runs before it properly streams next year. The pilots start in September. The initial performance testing is related to security and stressing the system to know everything is fine. We can then go into production with the credentials and start the pilot in September. In the pilot, we shall follow up real data coming down into the system from the EU hub.

What, if anything, will be the impact of devolved powers and the administrative fragmentation that is experienced in Spain different regions and multiple layers of bureaucracy?

Spain certainly has its own complexities and that is something we must navigate. Much attention is being given to getting the pharmacies on board because there are about 22,000 spread out across the country. The Delegated Regulation that we have to implement is EU- wide legislation that applies directly and that helps to cut through any bureaucratic resistance compared to changes coming from devolved powers.

That surely cuts out that element of bargaining…

Not completely, but a little. The system must be in place everywhere in the Spanish territory. Having said that, there are many aspects that affect subjects under the competence of the region. For example, the public hospitals are under the remit of the regional administration. As a result, we need to coordinate with these authorities in order to assure that the hospitals are ready. What has

helped us a lot is that we have an Operational Commissions, which is effectively a delegated structure from the management board of SEVeM. Some representatives from the regional administration are participating in this Commission.

How is the falsified directive enforced?

The delegated regulation applies directly Some of the articles though leave aspects to be defined by the authorities of the member states and so to fill those gaps, a national legislation is needed. In Spain, the national legislation is not yet in place. However, the industry is not waiting for the mechanism. The Spanish Agency has been very proactive defining some requirements needed in advance and the industry is doing its homework. The business associations have played a relevant role in transmitting to the authorities the needs of the different stakeholders.

From your perspective what has been the mood of the industry to these changes?

My personal opinion is that, from the very beginning, they have really tried to understand what was coming and what the impact was for them. However, the perspective to approach the project has been different, big companies have managed the project in-house adapting the production lines. But small companies, for example, were looking for different alternatives to serialize their products. Because they couldn’t do everything in-house, equipment was not available, or it could be very expensive. So, there was some need for flexibility. This was one of the points where the agency has helped a lot, contacting the European Commission to give a flexible interpretation of the regulation.

What mechanisms have been in place to help the industry?

I don’t believe there was any specific aids for this project from the administration. However, there are many programs within the ministries, including those related to the digital agenda that were available for the pharmaceutical companies. A session was organised by the business association with the participation of the ministries to explain those programs and measures.

What impacts and benefits do you think this all brings? And what is your response to those that claim Spain didn’t have such a counterfeit drug problem, to begin with so this is all about trying to fix an issue that didn’t exist in the first place?

I have heard this line of argument many times and I usually go to forums and talk about that. Putting aside that any expense that benefits patients, at the end of the day, has a benefit for the whole of society, it is true that Spain is working well against counterfeit medicines, it is not a local problem. Nevertheless, as good community members, we still have to play our part in improving an EU-wide system that, in some places, has indeed been afflicted by this phenomenon.

Any preventative action that can be taken, the sooner the better. While we may not yet be feeling the effects of falsified medicines right now in Spain, I think that, if mitigating steps are not taken, then this could indeed degenerate into a serious problem later on. While these first steps are related to the legal pharmacy chains, from my point of view in the future they can also be used against medicines that are sold on illegal websites.

Looking at it from a different perspective, education for citizens is important. Public knowledge knowing that the system is in place, that there is something that makes these medicines different from the falsified medicines, may help in the future. The people that now go to the illegal online chains repeatedly thinking that they are just buying the same medicines, will now start to think again. This will begin to permeate the public psyche and that's how one ultimately manages to change behaviors.

To what extent is this a system where you can have others piggyback on the infrastructure?

This is the first step. Having each pack identified will open the door to many, many future initiatives. Not only related to improvement in the supply chain, but I think it will also be linked to patients and in following up with their treatments. It's not in the system now, but I think this is the first step we shall have to take. This sort of infrastructure, if properly implemented, can help facilitate the new world of medicine

In terms of how you are contributing to reimbursements, you are helping by the information you are collecting…so can you tell us a little about that?

This task is enshrined within national legislation. In the current legislation, it is stated that the price of the financed medicine has to be less or equal to the sale price for those medicines that are dispensed outside the system. It is foreseen in that legislation that the system to comply with the directive 2001/83 is used to gather this information. That is our second purpose and it will be the second part of the project.

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What kind of capabilities are you going to need to do that?

Not something very different from what we have now. The main information will be in the system, but we will need some additional information gathered from the pharmacies to know the number of packs dispensed outside the national system and to which pharmaceutical companies and distribution entities the refund is due.

However, for the system to work properly you have to take into account that after February 9th, 2019, we will have co-existence in the market concerning that same product serialised and non-serialised packages. The reason is that those packages placed in the market before September 9th do not need to be serialised and they will be in the market for some years without being serialized until they are dispensed or expire.

So how do you cope with that?

We are working with the Spanish Agency on this. A lot of pharmacist training to the will be needed so they are aware that they may find the same product – one serialized and the other not serialized, both of which are correct – at least until the expiration date.

So a lot of investment needs to go into training and awareness?

I think quite a lot if you include the training they need to use the new system. Remember, the system will only work effectively if its users are operating it in the correct manner. Therefore a lot of emphasis has to be placed on raising awareness. The demand for information comes from the colleges because each one will organise the training for the different pharmacists. A clear position from the agency is needed to be transmitted to the pharmacist and other stakeholders so that they know how to deal with the different situations that will come across in the future. It won't be until after February 9th, but we need to plan for it now.

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