Interview: Nicholas Falzon – President & Margot Pisani – Secretary General, Pharmaceutical Research-based Industry Malta Association (PRIMA)

> “Market access is an issue in most European countries but in Malta it is even more visible due to a lack of medicine reimbursement that is present in the country”

22.05.2018

Tags:

Malta, PRIMA, Association, Market Access

Nicholas Falzon and Margot Pisani, respectively president and secretary general at the Pharmaceutical Research-based Industry Malta Association (PRIMA), discuss the business environment for originators in the island as well as the efforts of the government to provide more innovative solutions to Maltese patients.

Can you please introduce yourself to our international audience as well as the main activities and priorities of the association in Malta?

Margot Pisani (MP): I have been involved with PRIMA since its inception in 2005 and I held various positions before becoming the secretary general. We are the voice of global research-based companies in Malta. Therefore, our main activities consist of discussing current laws being drafted, working on transparency reports and implementing locally, where possible, EFPIA’s initiatives.

Nicholas Falzon (NF): Currently, we count eight members who are mainly commercializing finished innovative products in the market, however, we are looking to welcome more members to the association. By attracting other companies, we are ensuring that they have a voice when decisions are taken by the government and that potential new regulations will not impact them negatively. At times we face legal difficulties when a company wants to join our association while being present in Malta only through a distributor, but we hope to welcome one or two more members in the

upcoming years.

As a pharmacist by education, I started my career in the industry after my graduation in 2001 and I have been involved in the distribution segment ever since. With almost 17 years of experience, I was elected president of PRIMA last year. My mandate will last two years and during this time, one of our major priorities is the implementation of the Falsified Medicines Directive (FMD) in Malta as it will have important repercussions on the Maltese healthcare system. Therefore, PRIMA has taken the lead in this initiative and in partnership with local stakeholders, we are currently establishing the Maltese Medicines Verification Organization (MaMVO) in order to implement the FMD by February 2019.

How cooperative are Maltese healthcare players regarding this FMD implementation?

NF: As we are advancing with the implementation of the system, we have been in touch with all stakeholders in Malta who gave us rather positive feedback. One of the most decisive steps is the contact we initiated with a software provider who will be in charge of coordinating all pharmaceutical outlets to ultimately ensure Maltese citizens that the medication given to them is not falsified. In this regard, we have written a letter of intent with one of the providers and the final contract should be signed soon.

This implementation will require some changes within the point of sales to be compatible with the system, but so far, the local players have been cooperative. We have also collected a good number of funds for the project. The next step will be to resolve the few legal issues arising and advance towards the first system testing which should happen between late September – early October and last for the following four months. As of now, we are confident that we can achieve our targets.

What are the main challenges that originators are facing in the country?

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NF: Market access is an issue in most European countries but in Malta it is even more visible due to lack of medicine reimbursement that is present in the country. Indeed, the Maltese healthcare system is ranked as the fifth best system worldwide partly due to its universal healthcare system and the government invests around eight percent of Malta’s GDP on healthcare which allows a rather good service. Considering we are a small island with a population of just over 400,000 people and since we do not have price registration in the private market, most drugs are accessible on the private market fairly quickly. When looking at the big picture, it is an important achievement for our citizens. However, it raises price challenges for companies, especially in regard to most innovative solutions as these important medicines are not on the government registry yet, which leads to consequent out-of-pocket expense for patients.

MP: As originators, we are proud to be present in Malta but indeed, the reimbursement issue goes even further as important delays are present in the process. On a positive side, patients can count on charities to deliver the newest treatments, especially in oncology and the government plans to purchase these drugs for patients in the upcoming years. In the meantime, there is a new board that allows healthcare professionals to issue special requests. Another step in the right direction has been the openness of institutions. In the past couple of years, the purchasing department at the Ministry of Health has been more open. We also have a very efficient Malta Medicines Authority who is ready to discuss with the industry. Our size can actually be an advantage as it is easier for us to collaborate with different stakeholders.

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Considering the close relations between Malta and the United Kingdom, how will Brexit impact the industry?

NF: We will be one of the European countries that will be the most affected by Brexit as 60 percent of our imports come from the UK due to fact that we share the same language, consequently avoiding repackaging the products.

MP: Following Brexit, some products will not be available from the UK anymore leading us to source from other countries. A lot of administrative paperwork will also be added to our tasks. However, as we are sharing the same burden as our Irish counterparts, so I am sure that solutions will be found. We remain positive for the future and we have already established a few options in case a hard or soft Brexit.

Maltese legislation is rather favourable to the healthcare industry. How do you see the healthcare environment evolving in the next few years, especially for innovative companies?

NF: Malta has implemented the Roche-Bolar provision which attracted many generics players. On the contrary, I do not see any specific incentives to attract more innovative companies in Malta. To attract more innovation, I would encourage the government to participate in some of the EU programs for research. We also believe that a better collaboration with universities on European levels could help as well.

MP: The Valletta declaration has been signed in order to negotiate with the pharmaceutical industry on drug pricing for medicines and increase access to drugs for patients in the countries' that are participating in this collaboration. As PRIMA we endorse the EFPIA general principles and access policy positioning (differential Pricing).

Where do you see opportunities in Malta?

MP: As IQVIA is not present in Malta and no other entity is gathering and providing data in Healthcare, we are roughly counting on a total market of EUR 100 million with the public market higher in volume and the private market higher in value. However, as data collection is moving from clinical trials to more real-life data, Malta could be part of studies that collect real life data for specific disease areas.

NF: There are good opportunities here. Malta is actually a very competitive market, so newcomers will have to evaluate their main segment. Patients give value to the healthcare system, so they request the best medication available. Overall, in regard to the small number of patients, the Maltese market is actually rather large compared to the small number of residents.

We also have 13 manufacturing sites in Malta, that consists of mainly generics and while the positioning of the island is very good, the logistics to distribute innovative products can be more complicated. For this reason, I don't see much innovation manufacturing happening any time soon. However, we are very motivated in PRIMA to provide the best solutions to Maltese patients. We have the Maltese healthcare at heart and with the FMD project, we have the ambition to ensure that no other falsified solution will go into a patient's hands.

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