Interview with Hilary Paul Agius, President, PRIMA

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Can you give our readers an overview of the main characteristics of the Maltese Pharmaceutical market for innovators?

Hilary Agius: In a nutshell, in Malta there are two distinct markets; the first is the private market, which is when a patient gets medication or a prescription from the doctor and pays for it in full, it includes many POMs, but only in the case of over-the-counter drugs. A large majority of our POMs are paid for by the patient, even the innovative drugs. The second is a different kind of market, where the government buys medicines for certain categories of people suffering from a variety of conditions. In this case the government decides what drugs or molecules to buy and decides from where to buy them. This is where Malta differs from many other European countries where a government would decide on the molecule, but the pharmacy can choose where to buy it from, as long as it is the same molecule. In Malta however, there is government intervention in the choice of supplier, a decision it will take of course bearing in mind quality and price but the point is it takes the decision.

Do you think there will be changes in this government intervention in the coming years?

HA: We certainly hope that there will be changes in this regard, because we are talking about the lifeblood of R&D companies, competing for the latest technological advances and so on. There have been a few changes recently in governmental involvement towards healthcare and a few new molecules have been introduced, which is a step in the right direction, albeit a small step and there is still a long way to go.

Of course we hope that one day Malta will be able to catch up with our European counterparts, in Italy, Germany, France etc. But as it stands today, in these countries, as soon as a new molecule is launched by an R&D company, the governments release an agreement together with a governmental reimbursement for a certain number of patients from particular categories at the end of each year. This is not the case today in Malta, but this is the direction we are heading in and PRIMA is lobbying for this kind of system to be implemented.

Worldwide there is a strong trend towards personalized and integrated treatments that integrate both the drugs (often biotech products) and technological platforms, creating a new “medical chain” based on innovation and technologies, for example in areas such as oncology. How can Malta guarantee that it will offer such an “innovation chain” to its patients, despite the small population and the hefty investments that this represents?

HA: There are products available and good technologies available, but this sort of higher level “integrated treatments” are harder to attain in Malta!

Margot Pisani (Hon Secretary of PRIMA): Malta is slowly addressing the deficit in Oncology both with the introduction of oncology medicine’s and technologies. So we are certainly now catching up on that deficit. There has also been a push for training, so that we can get the best out of this new technology.

The government has highlighted the three areas for concentrated development since they are the areas that we are most lagging behind in: oncology, followed by diabetes and CNS diseases. But again, this will take time, because in the large majority of cases the responsibility and cost falls upon of the government, since the patient often isn’t paying for it directly. It goes without saying that as with most other European countries, we are also dealing with financial restraints. So Malta is moving forward but there are still many challenges ahead.

What efforts are the PRIMA members making in order to guarantee access to modern treatments for patients in Malta?

MP: We are suggesting some sort of reimbursement system, where the newer drugs can therefore be introduced at a quicker pace. Our role is to lobby for our member companies; now obviously the more the government buys a drug, the quicker access to the drug increases and the better for the patients. So an oncology product, which costs thousands of Euro to purchase will be available to the patients on the national health system. If only available on the private market and the patients can’t afford it, then essentially it is redundant. So just like any other country until the drug is reimbursed uptake is very small.

A number of R&D based companies are conducting clinical trials on the island. What's the rationale behind choosing Malta as a clinical trial hub in the Mediterranean region?

HA: As far as my parent company is concerned, Malta is not a clinical trial hub as such, but it is participating as part of a wider European network. My local entity was involved in a pan-European clinical trial, in which Malta played a role; in this instance therefore Malta isn't necessarily a hub but part of this larger entity. However, on one hand it would make sense to have Malta as a hub because epidemiologically, the island has a captive population, in that there is not much movement, which is exactly what an epidemiologist is looking for. On the other hand, if you are carrying out clinical trials on some rare disease, in a population like Malta's you will find few variations, so this can also be a limitation.

The Maltese government is trying to attract innovation and technology; indeed, Malta Enterprise is investing in a new science park, do you think Malta as a role to play in innovation?

HA: Generally, the number of research sites are is being reduced and we are going towards a more centralized system. The main driver it to maximise efficiency and financial returns as R&D is a very expensive activity.

MP: I think it is important to remember that Malta does not have a tradition of pharmaceutical innovation like some other countries do. For instance, we don't house the bench where Louis Pasteur used to work! And this is a very complex industry, so you also can't just wake up one day and decide that you are going to play an important role, it takes years and years.

Sometimes it is better when a country really plays to its strengths. As an example, Malta has a long tradition of textile industry. Although today we would be competing with countries that can afford to be much cheaper, such as Asia, but at least Malta would be basing the innovation and technology in manufacturing on 50 years of tradition in an industry!

The pharmaceutical industry has been targeted as a sector for development in Malta, but given the patent legislation incentives that encourage FDI in the generics industry, we are not seeing the same kind of incentives for R&D based pharmaceutical companies.

HA: Indirectly in competition, it is very difficult to marry the two aspects of the pharma industry together in a small country. You either make it favourable for one type of industry or you make it favourable for the other; you cannot do both. So if Malta has at the moment chosen to promote the generics industry through the "Bolar exemption", it is hard to promote innovative pharmaceutical companies at the same time.

MP: In the case of a country as small as Malta is, I believe you should chose one type of industry and specialise in that.

Given that Malta has been extremely successful in attracting API and generic manufacturers, do you think there is an opportunity in the future for Malta to attract investment from R&D based Labs in manufacturing?

MP: Unfortunately, the attraction of these companies depends greatly on the “Bolar exemption”. There are fiscal incentives, such as tax credits, but these are I guess comparative with other European countries.(better check this tax information with more competent people such as people at Malta Enterprise) I think it’s good that the government has been successful in attracting such business; ultimately I’m all for anything that is good for Malta.

HA: R&D has a unique nature. We are talking about building something from nothing, screening thousands of molecules, creating molecules from scratch based on the receptors in the target organ that need to be hit! This requires very specialised scientists, and we don’t have these sorts of specialists on the island. We do have very good quality workforce, qualified, English speaking – which is of course particularly important in this industry. We cannot afford to specialise in everything eg high level molecular biology on an island so small, and therefore Malta ends up having to generalise. In addition, realistically these kinds of specialists need to have PhDs and post-docs and the university of Malta just cannot support that level across the board.

That said, this has got nothing to do with the Maltese lacking any kind of intellect or potential in the subject, since many Maltese people who travel abroad for their training are also very successful, not to mention there are lots of successful Maltese working in high positions in the industry around the world!

What is your final message to the readers of Pharmaceutical Executive who are looking at entering the market?

PRIMA’s aim is to lobby for changes in the reimbursement system. We welcome the fact that the generics companies are also present here and that they receive support from the government, they also obviously play a vital role in this industry because they liberate money to spend on innovative medicines. Therefore we should have a symbiotic relationship. PRIMA is supporting the innovative R&D based companies in order to ensure that we keep the R&D industry at the forefront.

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