

The future lies in research and development

by David Kelleher

The government's strategy to develop a pharmaceutical industry in Malta has been relatively successful with 15 companies setting up shop here. Together they employ over 700 people. In the last article of a series on the pharmaceutical industry in Malta, David Kelleher explores the potential that exists in other sectors, in particular R&D, clinical trials and hub services.

There is no doubt that the generic pharmaceutical industry has developed at a healthy pace, bringing into Malta much needed foreign direct investment, generating employment in a highly skilled sector, and spawning a number of cluster companies that provide ancillary services to the generics manufacturers.

Government's and Malta Enterprise's target to establish the generics sector within three to four years has been met, the companies in Malta appear to be more than happy with what they have here and the majority have long-term plans for the sector. Practically, the major operations in Malta are all having discussions with ME regarding substantial expansion projects.

But is this enough? Is the sector just a temporary opportunity for Malta to maximise its investment for a fixed number of years or is it part of a long-term strategy that encompasses not only generic manufacturers but the Big Ten pharmaceutical companies as well? Are we solely focused on manufacturing or have we tried to look beyond the horizon and target a different market?

The generic pharmaceutical companies come to Malta for two main reasons: the inclusion of the Bolar exemption into the country's patent legislation, and the very limited number of patents that have been registered in Malta to date.

The question that arises, however, is: "What is going to happen in 15 years' time when the Bolar exemption no longer applies?" Although 15 years seems to be quite far off, that does not mean that government or Malta Enterprise can sit back and take a wait-and-see attitude. The solution, which Malta Enterprise is actively working on, is to tap new markets. Two of these are clinical trials and research and development (R&D).

I spoke to Ivan Micallef, CPO head with Novartis Pharma Services, one of the top pharmaceutical companies in the world, to get an idea of what he believes lies beyond the manufacture of medicines, especially generics, and how Malta can benefit if it plays its cards right.

"I am very happy that Malta has decided to focus on this industry. I believe that there is ample scope to further develop the sector especially when it comes to research and development and clinical trials. These are the two areas that Malta has to target in the coming years," Mr Micallef said.

He said it was important that Malta had a long term vision for the sector because the benefits companies enjoyed today would not last forever. "The Bolar exception is a major reason why generic companies come to Malta. Within the next 15 years, however, the benefits will be lost. What will happen then? What are their plans, or rather, what are Malta's plans when this happens?" Mr Micallef asked.

He said that Malta had to be in a position to compete, especially when other countries like Poland, one of the new member States, and Ireland, a long-term member, were taking full advantage of the sector. Rather than focusing on manufacturing, which is the least one that attract foreign direct investment, they had targeted the big multinationals, multi-billion

dollar R&D accounts.

"Let me give you an example. Novartis, the company I work for last year spent \$4.8bn on research and development. Now, you can imagine the amount of money that the whole industry pumps into R&D on a yearly basis. This is where the big money is and if Malta manages the get a chunk of that investment we will do very well," Mr Micallef said.

He does, however, have a word of warning. "We must be careful that we do not try to achieve what is beyond our ability. We have to build on our strengths and develop the sector within the constraints that a small island imposes on us.

"We cannot expect to have massive R&D facilities like they have in Ireland where one single biotech plant can cost up to \$2bn dollars." We have to be realistic. However, there is nothing stopping us from encouraging the big pharmaceutical companies from carrying out clinical trials of their products here in Malta," he added.

Although there is room for small scale ab initio research if the required laboratory facilities are in place, clinical trials appear to be the better option. First, they are not taxing on the infrastructure. Second, they leave much more money behind. Third, there is no need for a huge capital investment, and fourth, the spin-offs are much higher, with society in general gaining quite a lot over the long term.

When a hospital is involved in a clinical trial, the infrastructure has to be upgraded to meet the strict protocols and standards required. However, this should not be seen as expenditure but rather an investment that will have long-term benefits on society.

"Clinical trials call for a certain level of investment in the hospital; however they leave so much money behind that these companies end up partly funding the hospital itself. Society also benefits because the improved services and the quality of equipment required for these trials can be used after the clinical trials has been concluded. It can be a win-win situation," Mr Micallef explained.

There are four types of clinical trials. Phase I and Phase I involve the testing of the product in laboratories at various levels. The focus here is mainly on safety. Phase III and Phase IV trials involve cohorts of patients who accept to try the new medicine in a very strictly controlled environment where very rigorous protocols and procedures are followed.

Phase III and Phase IV testing is first carried out in healthy individuals and then in patients suffering from that condition for which the drug has been developed, for instance, hypertension (high blood pressure). After that, the drug is given to patients with concomitant conditions, such as those suffering from hypertension and diabetes or high cholesterol levels.

"Malta has a number of advantages. First of all, we have some of the best doctors around. Heads of department in Malta are not only respected locally but also among their peers abroad. They have an excellent reputation. These factors all work in favour of the hospital when it is trying to encourage pharma companies to carry out their clinical trials here. What needs to be done, though, is empower local doctors, the specialists who know exactly what is going on in their field, to take the initiative, with the authorities' backing, to go after these trials.

Malta's unique advantage in respect of clinical trials is that the island itself creates a controlled environment. A successful trial depends a lot on the number of people taking part remaining relatively constant throughout. In large cities, there is always the risk that people will move from one place to another, however, in Malta this risk is greatly reduced.

According to the a recent Eurobarometer survey, Malta placed among the top three countries with regard to the prevalence of certain diseases such as hypertension, diabetes, asthma and breast cancer. While this is of concern to the health authorities, it does provide the perfect set up and environment for pharmaceutical companies to carry out clinical trials of medicines developed for these conditions.

There are other benefits apart from financial considerations. Having clinical trial would mean that Maltese patients would have the opportunity to try out cutting-edge medicines well in advance of their market release. Earlier treatment could possibly mean faster

recovery rates and help to reduce the high prevalence of certain medical conditions.

"The most difficult challenge is to bring the first few trials to Malta. If they are done successfully and Malta gains a reputation of excellence and credibility, then the business will start coming in," Mr Micallef explained.

He also strongly believes in Malta's potential as a regional hub for pharmaceutical services. With markets opening up at a fast rate, Malta has a number of advantages that could convince the big pharma companies to set up a regional hub in Malta from where they can do business with countries like Morocco, Tunisia or Algiers, for instance.

"These regional hubs generate trade within the local economy as well. They are renting or purchasing premises, hiring staff, creating ancillary services. Even if they employ expatriates, these individuals are contributing to the Maltese economy as well," Mr Micallef said.

The advantages of setting up here, he added, were numerous.

"Malta is a member of the European Union, we have a highly skilled workforce, we speak English, our legislation is good, and we are a safe country. We have two loaded guns compared to our competitors."

Government and Malta Enterprise are aware of the huge opportunities that exist in this sector. Government has made it clear that R&D, in all sectors of the economy, has to become a leading driver and this is also reflected in the strategic policy it has for the pharma industry.

Mario Galea, chief officer, business development at Malta Enterprise told The Malta Business Weekly that government's strategy for the pharmaceutical sector extends well beyond just manufacturing of generics.

"We have a three-phase plan for this sector that will take between 10 to 12 years to be fully developed. We started off with the generics sector and now that it has been established and continues to expand, we can start looking at other areas which can be of benefit to Malta," Mr Galea explained.

He said that ME believes that more research and development work will take place in Malta, and the infrastructural requirements of the industry must become available in parallel.

ME strongly believes that the time is right to attract R&D in Malta. R&D work will attract more high calibre people to the industry.

"We can develop niches within R&D where Malta can be most competitive. We are studying the feedback that we got from our first approaches."

The healthcare sector is gradually becoming a sustainable pillar of the Maltese economy placing Malta, slowly but surely, as a centre of quality in healthcare operations, be they industrial or service oriented, Mr Galea said.

With billions of dollars invested in research and development every year, Malta has an excellent opportunity, given the right conditions and a clear and defined product, to attract the big guns in the pharmaceutical industry. Finding the right momentum and bringing in the right companies will be a challenge in the years to come. However, few will doubt the potential that exists to make Malta a healthcare centre of excellence in the Mediterranean. That was, and remains, Malta Enterprise's dream.