

THE MALTA BUSINESS WEEKLY

THE MALTA
INDEPENDENT
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The Malta
BUSINESS WEEKLY

THE MALTA
INDEPENDENT
ON SUNDAY

Thursday, May 18, 2006

<http://www.maltabusinessweek.com>

Niche market with a huge potential

by David Kelleher

The generic pharmaceutical sector in Malta continues to expand at a very healthy rate. There are currently 15 companies producing generics and between them they directly and indirectly provide employment for over 700 people. In this three-part series, David Kelleher analyses this fast-growing industry and how, with careful planning, it could become a centre of excellence in the Mediterranean.

It is estimated that by next year, exports of pharmaceutical products will exceed Euro200m and the sector will generate more than 800 jobs in Malta.

At a time when the manufacturing industry is being buffeted by globalisation pressures and increased competition from low-cost countries like China, targeting niche markets that offer high value added products is the only viable option for countries like Malta.

Since 2003, government has acknowledged this reality and for the past few years it has been actively targeting niche areas such as information and communication technology (ICT), the services industry and the health sector, to "replace" traditional textile factories which either succumbed to competition pressures or have moved to a cheaper location.

The need to attract companies operating in the niche markets mentioned above was recently emphasised by the Minister for Investment, Industry and IT Dr Austin Gatt.

"When we find niche industries, we need to do all we can to exploit them. We cannot remain tied to the past," he said.

This strategy appears to have been very successful especially in the pharmaceutical and IT sectors. In the health sector, especially, the growth registered has been extremely positive and recent announcements by a number of generic pharmaceutical companies that they are going to expand their operations in Malta is a clear sign of the potential for growth that the industry has here.

At present there are 15 pharmaceutical companies producing generic medicines in Malta and they directly employ over 500 people. However, the economic chain is much wider and a number of cluster companies have joined the bandwagon. Today they provide essential services, such as product packaging and labelling, to these companies and as the major players continue to grow, these cluster companies have also benefited and they, in turn, are now generating employment.

The local industry's potential should not be underestimated. In an interview with The Financial Times some time ago, Robert Wessman, CEO of Icelandic company Actavis, which operates the largest generic company in Malta, was quoted as saying: "Malta will be the powerhouse for western Europe for our production and increasingly for the development of new products."

Coupled with a highly favourable clause in the legislation, a highly skilled workforce, and a package of incentives aimed at encouraging these companies to set up shop here, Malta is in the

right position, at the right time, to exploit these opportunities.

The production of generics is only the first of a three-phased strategy in this highly-competitive sector.

Mario Galea, chief officer – business development at Malta Enterprise, explained the rationale behind ME's efforts in this sector.

"A number of sectors were identified as being of crucial importance to the economy, health care being one of them," Mr Galea said.

Malta Enterprise identified three sub-sectors that are, in their own right, mini industries: generic pharmaceuticals, health/hospital products and health services.

"From the outset we realised that through generics we can build the necessary infrastructure to attract branded medicine companies. We saw a niche market in generics that could, over a period of time, lead to the creation of a Mediterranean healthcare centre of excellence," Mr Galea explained. The timeframe for the development of the health care sector is between 10 and 12 years.

The first phase has been completed and now Malta Enterprise is actively looking at the second phase, that of offering pre-clinical and clinical trials in Malta.

That, however, does not mean that ME is not trying to attract more top quality generic manufacturers to Malta.

"Negotiations are at an advanced stage with a number of generic pharmaceutical companies from the UK, Switzerland, Italy and India. There is a growing interest from non-European companies producing top quality generics to set up base in Malta, and to benefit from Malta's position as an EU member," Mr Galea said. At the same time, Malta Enterprise is also having discussions with various entities to encourage them to start pre-clinical trials in Malta.

Generic pharmaceutical companies believe that they will have a distinct competitive advantage within the next few years. In such a competitive industry, timing holds the key to success and Malta offers the key blend.

There are two overriding reasons for the recent boom in this sector in Malta: 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 Bolar provision governs intellectual property rights for research and patents in the highly pharmaceutical industry, was first introduced by the United States and later by the European Union.

Malta's interpretation of the provision allows companies developing low-priced, generic versions of patented pharmaceuticals to begin developing copycat products six years after a pharmaceutical company first applies for authorisation to market a new drug, even while the drug is still under patent protection.

While no pharmaceutical based on the same chemical composition can be launched until the first patent expires, the extra three to four years lead time for research and development provides a key advantage in the low-margin, highly competitive generic sector of the industry.

Thanks to a derogation obtained during Malta's EU accession talks, Malta has a market opening of some 15 years, during which time companies would be allowed to develop and register products in Malta and begin selling them at midnight of the expiry date of the previous patents.

EU membership has also served to consolidate Malta's position further by enabling generics manufacturers operating in the island to easily promote their medicines in North African markets, where there are established trading routes for onward delivery to the sub-Saharan region.

The growth of the industry in Malta would not have been possible if the Maltese government had not taken the initiative to ensure that the supporting infrastructure developed in tandem.

More importantly, from a human resources aspect, the education system is slowly adapting to the needs of this growing industry and providing highly skilled employees. This fact is not lost on the major players.

As Actavis' CEO Robert Wessman told me in an interview last November, "we came to Malta because government offered an excellent environment in which to do business and invest. You also have a highly-skilled workforce and the majority of people speak English. We have looked at other locations but Malta is very competitive compared to other places".

The economic impact of the presence of these generic pharmaceutical companies goes beyond the investment and jobs that they generate in Malta. The availability of top quality generics on the local market that are produced in Malta is expected to positively affect the government's health bill. In fact, according to Malta Enterprise, the government stands to save between Lm3-4m a year on its health bill.

The key to success in this industry will depend to a great extent on the coordinated efforts of government, Malta Enterprise

and the stakeholders in the sector. Meeting human resource needs, improving the

infrastructure and catering for the

expected growth are also important considerations.

Next week: Meeting the needs of the stakeholders

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