Dino Mangion â?? Head of Operations, Medichem-Combino Pharm Malta

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Dino Mangion, head of Malta Operations at Medichem-Combino Pharm, has been leading the company through the harmonization of operations between Medichem and Combino Pharm and explains his strategy to increase the synergies between the two sites as well as the key advantages of Malta for manufacturers.

As Head of Malta Operations for Medichem-Combino Pharm, can you begin by explaining how the company has evolved and what some of the major milestones have been?

The company is a family-owned business which has been operating in the pharmaceutical sector for 46 years. Its headquarters are in Barcelona, Spain. It started off as an active pharmaceutical ingredients (API) manufacturer, under the name of Medichem. In the 90s it branched into the pharmaceutical products business under the name of Combino Pharm. For some time, these two wings operated side-by-side, having the same shareholding, but existing somewhat independently from each other. In the last few years, the strategy has been to bring the two parts of the enterprise closer together.

The two companies have merged in Spain and as a result, Combino Pharm S.L. and Medichem S.A. are now one company, called Medichem. Therefore, today, Medichem is a company that develops and manufactures both active ingredients and finished dosage forms (FDFs). Bringing the two companies closer together has created synergies which were not exploited before.

The main driver for bringing the two companies closer was a reorientation of strategy for the entire group, with a primary focus on more complex and value-adding drug substances and drug products and a bigger emphasis on the US market.

With this reorientation strategy, synergies have become possible and important. We now have a common portfolio of products. More often than not, we are working on projects in a more vertically integrated manner in which both API and the finished dosage form are being developed and manufactured within our group.

What has been the impact of the integration of activities so far?

Although in Malta Combino Pharm and Medichem still exist as two separate legal entities, we are today working much more closely together.

The merger of the Spanish entities has led to changes in the organizational structure of the Maltese operations. We now have a common management system as well as a common management team, where I am responsible for both API and FDF operations at the local sites. My team of managers has

dual responsibilities on the API side and on the FDF side.

We are also harmonizing operations within the various departments, and different departments are at different stages of harmonization, depending on the specific exigencies of the particular department. There are departments such as that of human resources and administration that are fully integrated into one unit that manages the needs of our combined operations. On the other end of the spectrum, our R&D departments are still largely separate because of the distinct nature of their activities. Irrespective of the degree of integration, there are a wide variety of synergies that can be benefitted from, not just as a consequence of optimizing oneâ??s human resources, but also by optimizing oneâ??s knowledge and information flows.

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And why was the US chosen as a target market?

The US is still the major pharmaceutical market in the world, accounting for about 45 percent of the global pharmaceutical market. On the API side we have a longstanding presence in the US market. Over the years we have developed a very strong and healthy client base, a great track record with the US FDA, and a good understanding of how the US market functions and what the US regulator requires and expects. Therefore, it is logical to direct our FDF business in that direction as well.

As a group, our API operations have been US FDA-inspected since 1984 while our API operations in Malta have been US FDA-inspected since 2007, which is only two years after the start of activity in Malta. A huge portion of our business â?? globally it is over 50 percent, but here in Malta it can go up to 80 percent and higher â?? ends up on the US market.

On the FDF side, we have started working on some products which are destined for the US market. We have three products that have reached the regulatory submission stage. In two of these we act as Contract Manufacturer for third parties, while in the third we are developer and manufacturer. These regulatory submissions triggered the first US FDA inspection of our finished dosage forms facility here in Malta, which happened in February 2017 and was very successful.

Therefore, today, both our API and FDF operations here in Malta are US FDA inspected and have a green light to act as manufacturing sites for products that will end up on the US market. Increasingly, we are working on products for which we develop both the API and the FDF.

What can be seen today as the main reason for positioning Malta as a manufacturing hub and what are some of the main advantages for companies looking to come to the island?

One of the main attractive features of Malta at the moment is its patent and intellectual property landscape. There are a significant number of patents that, for various historical reasons, have not been filed in Malta. This allows an operator on the island to manufacture a product that is patented elsewhere and export the product to other countries in which a particular patent is either absent, revoked or just expired. The attractiveness of this situation has to be considered on a product-by-product basis but in the right cases it can provide an incredible advantage. When you couple this with the fact that we are an EU member state and operate within an EU framework of regulations (including EU GMP), you get a very attractive combination of factors that can open up unique or semi-unique opportunities that bigger nations might not be able to benefit from.

Of course, different companies have different reasons for being in Malta. For example, for companies that have a strong presence outside of the EU but limited presence within the EU, Malta can act as an EU gateway.

There are other significant advantages as well. An English-speaking workforce makes communication easier and a good educational level facilitates the availability of technically skilled people.

The political stability of the nation and the pro-business attitude of the government and its agencies, including Malta Enterprise and the Malta Medicines Authority, are also important factors for the enterprises operating on the island or for those who are considering setting up operations here. Our small size has its benefits in this regard. The government and its agencies are accessible and able to react rapidly to the needs of the industry.

And finally, on a somewhat â??softerâ?? note, the cosmopolitan nature of the island and its great weather are also factors to take into account, especially if an enterprise is considering the relocation of people from other countries.

How significant is the Maltese affiliate today within the group?

The companyâ??s assets in Malta represent an important contribution to the group. We have close to 100 employees working in Malta, out of a total workforce of about 450 worldwide, and two modern manufacturing facilities. Over 50 percent of the workforce at our Malta sites has a University-level education, which is illustrative of the high-level work done here.

When considering our portfolio of products, particularly those that have recently entered the pipeline, you will find that the local operations make an important contribution to the R&D activity of the group. Overall, the group boasts of attractive product portfolios in both its API and FDF operations with over 60 APIs and 30 finished forms in various lifecycle stages, from early development to fully commercial, large-scale manufacture.

Furthermore, our Maltese API manufacturing site has the capability to develop and manufacture highly potent APIs which require special containment equipment due to their potent therapeutic effects. This can be done thanks to a high potency API suite which was custom-designed for our needs and installed on site a few years ago. This facility is based on the latest technology in the sector that includes total containment systems that allow personnel to work within the unit without being encumbered by special protective gear. It contains within it, facilities for both R&D process design, as well as manufacture under GMP.

Concerning Malta, Medichem is also one of the largest manufacturers on the island. How has the company been evolving and growing?

Both Medichem and Combino Pharm started activity in Malta in 2005 and we are therefore in our 13 th year of operation. I think that we have come a long way since those early foundation years! Today we have two well-established sites which boast of EU GMP and US FDA certifications with very attractive track-records. We have been, and continue to be, instrumental in the development and industrialization of a large number of products, both API and FDF, which make up the groupâ??s product portfolio.

What would you highlight as the main competitive advantages of Medichem?

The patent advantage places Malta in a very attractive situation because in most western countries patent legislation is well established. Here in Malta you can benefit from the opportunities arising from the nationâ??s advantageous intellectual property situation while still enjoying the peace of mind of having a European manufacturing site that operates within an EU framework. However, recent moves at EU level on intellectual property legislation that are directed towards waiving the SPC (supplementary patent certificate) extension for EU manufacturers in order to allow them to

export to non-SPC countries could eventually curtail this advantage. Nonetheless, while this advantage still exists, Medichem provides a ready opportunity to manufacture for launch on day 1 after patent expiry in Europe or for export outside the European Union ahead of patent expiry, from a high-tech, European site that enjoys EU GMP and US FDA certification. Companies that have encountered special opportunities that may require an early launch site but do not have such an asset within their portfolio might wish to team up with us in order to harness such opportunities.

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How can you remain competitive once the playing field becomes level and Malta loses its legislative advantage?

The advantageous patent situation we benefit from today in Malta will not last forever. However, our portfolio of products is attractive not only because of the intellectual property opportunities some of our products offer, but also because the products that make it into our portfolio have been carefully selected to cater for a variety of industry needs.

We have been operating in the sector for a long time and over the years we have developed a strong know-how on how to design and develop robust, industrially-viable and economically-feasible manufacturing processes for both our APIs and finished dosage forms. Furthermore, we have many years of experience in successful regulatory filings for both APIs and FDFs in a variety of geographical regions including the EU, USA, and Asia.

We are now venturing into more complex molecules and formulations that require specialized know-how and advanced technologies. This also opens up opportunities that are not accessible through more traditional technologies and approaches.

Our strategy is to distinguish ourselves as a reliable and knowledgeable partner that not only provides quality products at competitive prices, but also adds value through knowledge, collaboration and expertise, factors that are particularly important when dealing with more complex products.

What do you want our readers to think of Medichem and what do you see as the companyâ??s main contribution to the development of the Maltese manufacturing industry?

We are a strong company, with decades of honed expertise in APIs and finished dosage forms, and with a track record to prove it. Our regulatory certifications are exemplary and our portfolio of products is vibrant, diverse and attractive. We invest heavily in our product pipeline, our workforce and in new technologies. Our aim is to cultivate a motivated and knowledgeable workforce, who in turn design and produce intelligently and with purpose. I tend to think of us as a â??boutiqueâ?? enterprise, rather than a â??supermarketâ??, that provides special products and customized approaches to customersâ?? needs, rather than a one-size-fits-all.

You were head of Medichem before the harmonization of operations and you are now looking for more synergy between the two companies. What has been your proudest achievement?

The first steps towards harmonizing the two sites, which had evolved independently over a span of about 12 years, were tough. Realigning systems, ways of working and people culture was a big challenge. Shortly after the decision to harmonize the two sites was taken, we were also notified of our first US FDA inspection at Combino Pharm. The inspection was a great success and today we are one team that manages an operation that develops and manufactures both APIs and drug products. Achieving these momentous milestones in such a short period of time has definitely been a big challenge and finally a great achievement. It has only been possible thanks to the combined effort and strong determination of a large team of people, both locally as well as from other sites within the group.

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