

Interview: Antonio Sommei – Plant Director, Amino Chemicals, Malta



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Antonio Sommei, plant director of Amino Chemicals, the leading API manufacturer on the island of Malta, documents the impact of the recent merger with ABA Chemical Corporation on local operations, the increased capacities the company will have, and their focus on expansion to new markets globally with the intention of finding a partner for co-development of final dosage forms to position themselves as an integral solution provider.

Can you introduce yourself to our international audience as well as the key milestones of the company in the recent years?

I am a plant director and the CEO of the company and I started working for Amino Chemicals 25 years ago. Currently, the company is experiencing a change of the ownership with last year’s acquisition by ABA Chemical Corporation. In terms of production, we are changing our strategy while continuing the activities of manufacturing and development of APIs.

Our new strategy focuses on expansion and entrance to the regulated markets of South America and Asia such as China, Korea, Japan, Brazil, Argentina and Chile. Amino Chemicals already received accreditation from PMDA, FDA, EDQM which speaks clearly of the level of quality standards we follow. Nevertheless, the strategy of expansion will allow us to increase our turnover overseas. In addition, we are focusing on the manufacturing of complex molecules in small quantities in order to reduce the difficulties in terms of waste management.

Malta is not the right place for manufacturing in bulk, as the cost of energy, waste disposal and transports are rather high and the margins on products are rather low. Therefore, we prefer to focus

our strategy on production of specialized and niche products while investing in new equipment as we are currently not able to produce certain types of products- such as anti-cancer or high potency products. At the moment, we are producing generic compounds and one controlled substance, while in the future, we see our production focused on anti-cancer, orphan drugs and specific substances.

You mentioned last year's merger with ABA Chemical Corporation. What was the impact of the merger on the local operations?

We have experienced a positive change. The merger resulted in keeping the same operative staff that will help in maintaining the local production and activities. Nevertheless, we are implementing a different approach as we want to integrate the group into a homogenous organisation. This means that we can manufacture intermediates in China and follow the path of Amino Chemicals to reach the next manufacturing step. We already have the approval from local health authorities which will make the process easier for us as it is indeed convenient to manufacture intermediates at the mother company and continue with the API production in our site with submission of common technical documents to authorities in the name of Amino Chemicals.

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How have you seen the needs of your clients evolve during the years?

As we are focusing on new processes, there are interesting new substances. Now we would also like to consolidate the actual product portfolio. This means that we can increase the quantities of products considering the good relationship with our customers and we can be competitive in the market. Currently, we have 34 registrations and we are looking to register more. In some cases, it is also possible to reduce the prices. Given the increased production quantities, the turnover would increase regardless of lower price. At the moment, our clients are mainly from Europe and we have experienced a reduction in the US market. Nevertheless, due to our expansion strategy, we are looking to also increase the number of clients in different countries globally.

API industry globally is very competitive. What are the main trends you identify in the industry?

I believe that recent trends in the API industry are marked by increased demand of companies looking to purchase APIs from European API manufacturers. Even though China and India have developed in the API industry, companies are shifting to the European APIs due to the quality standards they provide and delivery on time with full documentation guarantee. Many API producers in China and India have been closed by the government due to environmental issues and the inability to guarantee the continuity of API supplies, therefore the shift hasn't been surprising. Even though prices might be higher, companies prefer to invest more money to ensure the best quality standards along with the continuity of the supply. I would like to highlight the importance of Malta's membership in the EU and benefits of the Roche Bolar provision that is still in place, that is certainly beneficial for the supply of our customers before the patent expiry. I believe this is the biggest advantage of Malta that makes it competitive with many other countries. For every new process, there are many patents recorded in different countries. In this case, it's difficult to cut the road of competitors, therefore, the legislation of Malta indeed makes the difference. We can continue using this advantage in the next years and this will certainly be an opportunity for Malta to continue growing and increase its importance in this aspect. We are not the only company using the benefits of this process; I recall that in the past we were blocked to proceed with our route of synthesis as another company on the other side of the world registered the product just several hours before. Therefore, I believe this is not a strategy, but rather a way to arrive in time. Until the common patent is not introduced, this is an excellent opportunity for the local companies as after registration,

anyway we should maintain some privileges in the old registered processes; the supply of the products cannot be stopped for few years after the registration.

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What are some of the future investments planned for the upcoming years?

Current production capacity is not fully exploited which means we have the flexibility regarding the batch size- we can produce capacities ranging from few hundred grams in the laboratory GMP production equipment up to hundreds kgs in the main production plant. Our chemical plant consists of 18 reactors featuring different construction material and different volumes. We can manage our production starting from small batch size and if necessary, we have capabilities to deliver bigger quantities. Nevertheless, if we need to manufacture specific substance, we will need to add the production line. The intention is to expand and change the layout using another facility and relocate some areas to improve the GMP standard and to create more space for the development of the new plant. We already started with some projects- like the refurbishment of the quality control area and R&D area. The application to the authorities was submitted and some projects to change the layout of the site are already ongoing. The plant will be operational next year which will not only significantly increase our capabilities, but also bring more flexibility in terms of production to be able to organize better our production plan.

How do you ensure to remain competitive?

We are the biggest API producer in Malta, however, I believe we need to continue with the registration of new processes. In order to be able to avoid the local competition, we need to put our efforts in choosing the right family of compounds to produce. Our competitors produce anticoagulants, steroids etc. Therefore, different class of compounds can avoid the overlap of the patent and constraints. We are looking to be unique in the production of certain compounds. Nevertheless, as our approach is always focused on maintenance of leadership in the sector, we would like to find a partner for cooperation and co-development of products and final dosage form. We will then be able to offer the integral solutions: intermediates, APIs and final dosage forms.

What are your objectives for the next three years?

Given the recent new structure of the company and having a mother company in China, we want to use their support and leverage these increased capabilities to expand into new markets and offer an ever-evolving service to our clients. We have never been present in the Chinese market, but now many companies are looking into this market and there is big consumption and opportunities. Using experience of a mother company, we can leverage this and increase our opportunities there.

The report will be read by over 50,000 readers globally. What would you like them to think when they hear about Amino Chemicals?

I hope they consider Amino Chemicals as potential supplier and partner of choice for the future. We indeed have built a great reputation in the market which is the result of expertise we have developed over the years. As we are fostering a collaborative approach to be able to support our clients with their requests, we are looking forward to extending partnerships and relationships with all stakeholders in different parts of the world.

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