

Interview with Juliet Seifert , Executive Director, Australian Self Medication Industry(ASMI)



21.02.2012

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Molteni was created in 1892 and progressively developed a strong manufacturing base, a very active R&D department and a growing international presence. Could you introduce the story behind such achievements?

The company was founded over a century ago by Leone Molteni in the backyard of Farmacia Molteni located in the wonderful Piazza della Signoria in the historic centre of Florence. Then the business was run for several decades by the Alitti family, before my father Giovanni took over the company in the late 1970's. Throughout all these years, Molteni developed a strong experience and know-how in the field of opioids, from the manufacturing to the marketing of innovative pharmaceutical products and more traditional compounds. This is a truly complex field with a lot of different Country specific regulations and our long term experience provides us with a unique competence in this market segment. Relying on this special knowledge, at the beginning of 2000, Molteni decided to further strengthen its focus on the opioids core business. Molteni invested in its comprehensive portfolio of narcotic pharmaceuticals for the treatment of pain management and drug addiction and, at the same time, up scaled its activities at an international level with the aim of becoming a pan-European leader in this market. As a result, all the acquisitions and licensing agreements concluded in the past years, as well as most of the R&D expenses, have been targeting the narcotic analgesics and addiction areas.

How do you assess Molteni's performance in 2008?

The main two challenges of 2008 were to establish our core brand products (such as Oramorph, morphine sulfate IR, Depalgos, oxycodone/paracetamol fixed dose combination and Eptadone, methadone hydrochloride) in the selected key European markets and to strengthen our pipeline of in-patent products in the mid to long term. In this respect, we are relatively satisfied of our 2008 performance: the European sales of the currently available products recorded a significant growth and, at the same time, we were able to progress with the regulatory approvals of new products / territories in line with our plans. Regarding our future pipeline, during 2008 we acquired the marketing rights of an innovative patented product for the treatment of breakthrough cancer pain for few selected EU territories where we expect to launch by mid 2010. Being a family owned company is a crucial advantage to reach such ambitious targets, as it allows the organization to follow mid to long term plans instead of being constantly restricted to short-term objectives.

How active is Molteni in co-operating with multinationals and what makes it the partner of choice for long-term distribution and manufacturing agreements?

Beside our long term presence in some territories such as Italy and Poland (Molteni Polska Sp.zo.o. is operating in Poland with head-office in Cracow since 1994), the appeal of Molteni as a European partner lies on our unique competence in dealing with complex therapeutical areas such as narcotic analgesics and drug addiction. Where directly present, Molteni has a proven expertise in dealing with practically every single hospital (from big structures to small clinics) and our specialty field force together with our network of key accounts are targeting all relevant stakeholders such as oncologists, anaesthesiologists, psychiatrists, geriatricians, rheumatologists and other policy makers. From the manufacturing standpoint, our focus on opioids is adequately reflected in the production characteristics of our main site located in the suburbs of Florence which is mostly dedicated to the manufacturing of narcotics in oral solutions and injectables.

In a country that strongly relies on its tradition of excellence to face increasing competition from emerging markets at all levels, what is Molteni's strategy to meet its customer's requirements in terms of quality?

In our very special field, the strategy is very straight; as Molteni, we rely on in-house manufacturing with full control of the production & logistic process, profiting on our specific competences, wide experience and highly qualified personnel.

In this context, to which extent does Molteni bet on toll manufacturing as a strategic asset to ensure its plant's profitability?

Third parties manufacturing was never the core business of Molteni even though we have a track record of successful cooperation with several multinational on specific products. Molteni is currently increasing the production capacity of its narcotic products franchise in order to adequately support the growing International sales.

Molteni is surely a well-established local success story. Looking at its ambitions on an international footprint, where are its products present today and which countries are you looking at for the future?

Our future growth depends very much from our capability of developing a pan European presence of our products franchise, both in the narcotic analgesic and drug addiction areas. To achieve this target, partnering with local specialty pharmaceutical companies, in Countries where we do not have direct operations in place, represents a key success factor for our international strategy and we are really satisfied about the quality of partnership that we have experienced so far in most of Europe. Coming to our core brands, as of today, the most advanced product in this process of internationalisation is definitely Oramorph, (morphine sulfate IR) which is marketed in all the biggest European territories and Eptadone (methadone hydrochloride) which was recently launched in Germany beside other Territories where is already available.

Which opportunities do you see for Molteni's generics in the Italian market, and how do you assess the remaining growth potential for generic companies in the country?

As a matter of clarity, I think it is appropriate to discriminate between the retail generics (Gx) and the hospital generics (Hx) markets as our competitive situation in these two segments is very different. In fact, considering that the Italian retail generic market is mostly driven by aggressive commercial policies at pharmacy level where Molteni has a limited experience, our approach to this market could be defined rather opportunistic. More in details, Molteni was among the first players to enter this market with the successful launch of few molecules (such as Gliclazide and Allopurinolo) as soon as the first legislation regarding generics was introduced in Italy and, despite the limited number of molecules in portfolio, the company quickly gained a leading position in this new market. Later on, the aggressive marketing policy of most of the multinational generic players and the strategic decision of focusing on our opioids core business discouraged Molteni to make additional investments other than maintaining the leading position gained on some molecules by its early entries. Coming to hospital generics (Hx), the situation is substantially different: our long term experience with hospital supplies, together with our scientific relation with most of the specialty physicians working in the hospitals, makes Molteni a very competitive player in this field. The recent agreement reached with Actavis Hx Division for the exclusive distribution in Italy of their hospital portfolio (mostly oncology products manufactured at the famous former Farmitalia's site of Nerviano) confirms the value of Molteni in this area. Regarding the future of generics in Italy, despite most of the Italian players have always neglected this segment, I feel there is still a lot of potential to be exploited even though regulatory changes and the implementation of a clear legal framework is needed to offer to generic players a concrete room for improvement. Another challenge for the development of this segment is represented by the growing role in Gx substitution of both physicians and patients, two target groups that have traditionally been out of the market

dynamic until now. Some Italian companies could still step in the generic field, as brand recognition is becoming a key success factor and for newcomers Gx companies, the last chance to enter the Italian market is to liaise somehow to a well established local player.

In terms of image and brand recognition, what does Molteni stands for today in Italy and worldwide, and where is there further room for improvement?

In Italy, where our Company is present for more than a century, Molteni is a familiar brand name which stands for a reliable local pharmaceutical company with a prestigious history and a promising future. Outside Italy, our aim is to establish Molteni as the specialty pharmaceutical reference company in the field of drug addiction and narcotic analgesics.

Coming back to your family business after a long working experience in a multinational, which would you identify as the main challenges and opportunities provided by familial structures?

In my case, I did not experience major differences in terms of working environment, as the multinational which I used to work for was promoting the entrepreneurial spirit of its managers. I consider my experience outside Molteni as a crucial career step, which taught me how to base decisions on analysis more than feelings, how to privilege team work and shared strategies against individual intuitions; a culture of management which is not yet a standard practise in traditional Italian family industries.

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