Interview: Federico Seghi Recli – Managing Director, Molteni Farmaceutici, Italy

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In 2008 Focus Reports interviewed Mr. Federico Seghi Recli as he prepared to transform Molteni Farmaceutici into an International specialty pharma company. Today we catch up on the progress, investments and strategic decisions which have been made since, and ask how he plans to continue his remarkable growth as well as expand the company's operations in its primary business segments.

Mr. Seghi Recli, to start off, the vast majority of your products are proprietary, how do you seek to differentiate yourself as a company?

The key differentiation lies with the origin of our products, which are mostly opioid derivatives. This makes the positioning of our company very clear: whatever falls inside the area of controlled substances is of interest to us. As a matter of fact, as we have been manufacturing morphine since the early '20s, this unique competence has been historically present within Molteni. We have learned that this market segment still provides some barriers for generics to enter as it involves stricter regulations than standard pharmaceuticals in any single phase of the manufacturing and selling process. Moreover, we believe that, due to the highly sensitive nature of these products, this is still a niche where technology is valued by the payers. If your product is able to limit possible situations of diversion thanks to an abuse deterrent technology or it reduces the quantity of opioids while maintaining the same efficacy through a better delivery system, well all these features are still valued by the different agencies as they provide concrete advantages for the patients.

So in essence the difference between us and other companies lies in our long term competence and absolute focus on opioids.

Is this then where your slogan, ‘a tradition of innovation’ comes from?

Yes, Molteni has been well known throughout its long history for marketing opioids and we are now reinterpreting them, thanks mostly to technological innovation.

As a matter of fact, like most Italian companies, we come from a branded generics background but today a big part of our turnover comes from in-patent products and their share will continue to grow in the future. Note that when talking about patents, I am not referring to new chemical entities, but rather to patents in technology.

Back in 2008, a stated goal for Molteni was establishing an international presence in Europe. How has this progressed?

It has gone quite well. The purpose at that time was to prepare Molteni for a wider presence in Europe. We have been working on several issues regarding this goal, because that critical decision taken back in 2005 indeed changed our company in all its main functions and activities.

First, with regards to manufacturing, after 2005, Molteni has progressively changed the pharmaceutical forms manufactured in its proprietary plant in Florence in order to escape from a relatively diversified approach and refocus its manufacturing volumes on the highly regulated controlled substance segment. To make this possible, in the last few years we have introduced five new manufacturing lines, of which the newest is pectin nasal spray; this patent protected technology, which we licensed from the ProStrakan group, combines the advantage of a very precise and consistent delivery system of *fentanyl* microdoses (a potent opioid for the treatment of breakthrough cancer pain) with unmet abuse deterrent and safety standards. The result of this reorganization is remarkable as today Molteni ranks among the largest manufacturers of opioids pharmaceuticals in Southern Europe and we plan further investments in this direction.

Second, regarding the regulatory challenges surrounding our international expansion, I believe that we have also been very successful as we achieved a truly satisfactory level of competencies and internal skills. We are not perhaps located in the best country to manage the pan-European regulatory environment and so we learned to work with other agencies. This is one reason we are now prioritizing the UK, as we see it as one of the most advanced countries in Europe from a regulatory standpoint with the advantage of a real mutual interaction and clear guidance through the process.

Interestingly, Molteni made the investment in the Fentanyl Nasal Spray at the height of the crisis, investing 5 million euros in a new product line, and creating numerous jobs as a result. Was this only possible because you are a family-owned business?

For this product, we made the largest investment in Molteni’s history, and yes, being a family-owned company was surely an advantage for such a long perspective decision. Considering the big pharma market of today, I guess I would have never gotten it accepted by a top executive sitting in any public company. We liked the prospects of this product since its inception and our first contact with Archimedes (now a subsidiary of the ProStrakan Group) started back in 2008, before the product was even registered. We worked with them on conducting the regulatory trials, and had the product approved by the EMA in 2010. At that time, we decided to make this large investment, and it has proven very successful. We have the exclusive manufacturing rights for Europe, and we are in the final stages of extending this geography to other territories outside Europe

Stepping back a bit, has your focus on highly specialized products acted to insulate you to a certain extent from external shocks and crises?

Yes, as a matter of fact the two therapeutic areas we focus on, drug addiction and pain management, have both experienced a nice growth during these years irrespective of overall market difficulties.

In terms of details, our product portfolio for the treatment of drug addiction proved to be pretty stable and we expect this market to grow further in the coming years mainly due to new kinds of addiction we are already seeing in the US and are very likely to come to Europe in the near future. On the other hand, our narcotic analgesics franchise has grown dramatically during these years, mainly driven by our domestic market. This is because in 2010, the introduction of a new law regarding pain management in Italy really changed the medical practice that until then was highly opioid-phobic; leaving our country with one of the lowest level of per-capita consumption of opioids in the world. There were speculations that this was due to the local influence of the Catholic culture but as soon as the new law removed all the unnecessary and complex restrictions to prescribe such class of products, this market experienced a strong rally in growth, and even today the overall outlook is very positive.

In conclusion, we have benefitted a lot from this legislative change, and our company is still enjoying a period of sustainable strong growth as a result. As usual in Italy this has not been a smooth process, and there have been peaks and valleys, but the direction is certainly the right one, and that is very encouraging to see.

In 2008 your main clients were primarily hospitals, but you saw retail generics becoming a very promising market for Italian companies as well. What does your customer base look like today?

As Molteni, our reference doctors are mainly oncologists, pain specialists, orthopedic, rheumatologists and some selected General Practitioners. However as most of the prescriptions are filled out by the specialists, and most of those are in hospitals, that is where our main customer base continues to be.

Consider also that we have a relatively lean field force, with approximately fifty-five highly trained product specialists in Italy, and fifteen in Poland. This field force is sufficient to cover our core customers, which are definitely out of the main focus of the generics competition.

In Italy Molteni is already an established name, but how have you expanded the company to set yourself up abroad as a reference for specialist pharmaceuticals?

This is a crucial point for us. The situation today is that expanding the geography of Molteni's direct affiliates in Europe has proven to be challenging for us even though it remains out top priority.

Our strategic direction is to accelerate internationalization in the niche market of drug addiction where there is still a clear room and opportunity for a pan-European player, especially now that we are undergoing the launch of *levomethadone*, which represents a novelty in most of Europe. This molecule is as effective as methadone with half the dosage, it shows a significantly better cardiovascular safety profile and I believe it has the potential to completely replace methadone in the future. .

In the pain area, at the moment we do not have the resources and the portfolio to support this same sort of geographic expansion on our own; that is why we entered into a strategic partnership with ProStrakan with whom we expect more projects to come beyond the manufacturing of PecFent and the cross distribution of PecFent and Oramorph in certain European Countries. ProStrakan is a purely commercial organization and we are very happy that they won the auction for PecFent few years ago as we have very little overlapping work activities with them.

What is your vision for the company over the next three to five years?

I hope to resolve the geography challenge; Molteni progressed nicely in the past few years but seventy-five percent of our sales are still coming from Italy, which is more than we had planned for.

I believe there is a lot of potential growth in both the therapeutic areas we are involved active in, especially in Eastern Europe where the treatment of drug addiction as well as the use of narcotic analgesics is still very limited. In Italy, the pain market will continue to grow for the foreseeable future, giving us a solid foundation on which we can continue to build our future portfolio in partnership with ProStrakan.

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