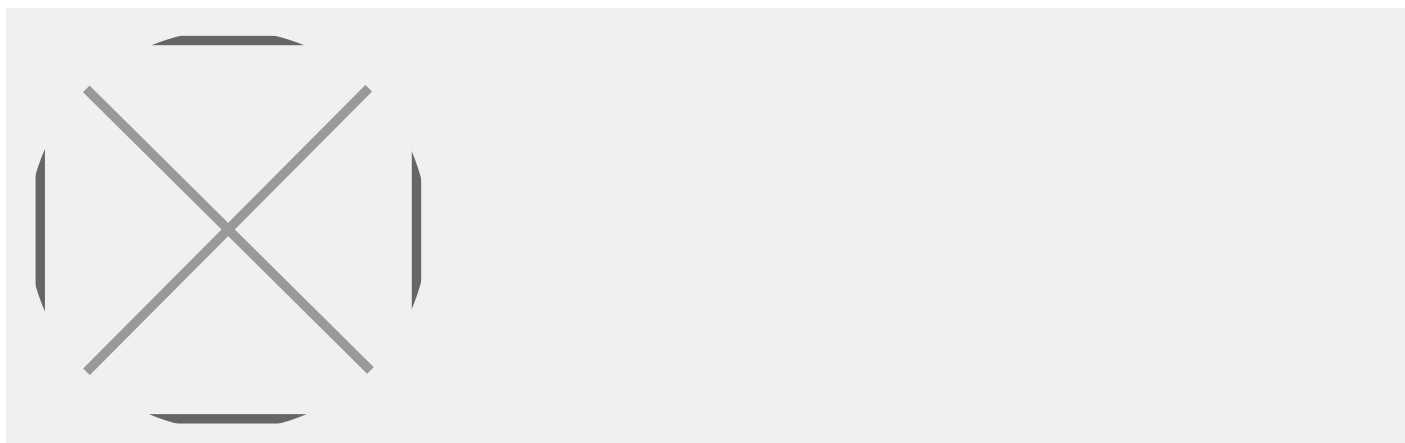


Interview with Alberto Grua, Managing Director, Grunenthal Italy



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Grunenthal-Formenti relies on Formenti's 60 years experience in Italy and is the result of the merger of both the German and Italian entities in 96. How would you describe the process of integrating and combining both cultures to lead an Italo-German company, building on the already existing Italian heritage and integrating Grunenthal's business model?

Despite the fact that the acquisition of Formenti by Grunenthal was completed more than 12 years ago, the previous ownership was still playing a major role until I took the reins as Managing Director in 2005. At this time, the company was still following Formenti's traditional culture, mainly gathering valuable products to be launched on the market, but poorly betting on in-house R&D of new compounds. And on the contrary, Grunenthal had always been built on internal products' development. Therefore, there was a strong need to combine an international portfolio with the local Formenti culture- and in this process, the existing pain products were a bridge between both businesses, allowing the company to get a complete access to Grunenthal's international pain products. As a result, the Italian affiliate is now working on the pre-launch of Tapentadol, a new molecule in the pain area, developed by Grunenthal. In addition, whereas Grunenthal internationally developed a reasonable presence in the contraceptive field, Formenti did not enter this market, even after the merger, considering it was too challenging. In 2005, I took the decision to launch the Group's excellent compounds in this promising area; building a brand new strategy has not been an easy task, but little more than one year after this exciting process started, Grunenthal Italy realized what is now considered as the group's most successful European launch. Such achievements have been concretized thanks to the evolution of the company's mentality and

vision. I personally like to compare Grunenthal Italy as a jewel that used to be covered with dust, and just needed to be “cleaned up” to fully reveal itself.

In the process of finding the right balance between international vision and attention to local values as a key to success, which would you highlight as the main specificities of Italian market and what is Grunenthal's strategy to address them?

The Italian market is extremely peculiar, in both its positive and negative aspects. On one hand, the country offers a relatively reasonable access to new treatments, with many drugs being reimbursed- which is a very favourable trend for both the industry and the community. But on the other hand, the easy market access is balanced by a very low price level. Pharmaceutical expenditure is wrongfully managed as a variable budget that can be cut whenever needed, therefore reducing the industry's potential margins, which is extremely discouraging for companies willing to exploit their products' value in the country. Indeed, Grunenthal recently launched Kolibri, an extremely successful combination of paracetamol and tramadol, but had to renounce to get the product reimbursed as it is in most countries, since the price offered was 40% lower than the lowest of the European prices. A similar paradox can be found in the field of clinical studies. Italy can rely on the most qualified professors, and top-level research centres, many of them being broadly recognized at the European level; but when running phase I or II clinical studies in the country, the necessary time frame is dramatically longer than in other markets. Processes are slower and to some extent more expensive, which really penalized Italy's competitiveness and attractiveness as a regional platform for clinical research. Surely this is also why companies like Grunenthal are extremely pro-active in adapting their model to ever-changing trends.

Looking back at this adaptation process, which would you highlight as the main milestones and achievements of the company since 2005?

In terms of products, a first success has been the full re-launch of the pain product portfolio, in which sales have increased by 50%. It has been followed by the crucial decision to enter the gynaecology area. And the third achievement relied on the renewal of a strong partnership with the Danish company Leo pharma, which enabled Grunenthal to reach a leading position in the psoriasis field, and opened the way for new products launch in the future. Organization-wise, the company has been deeply re-shuffled- most of the current employees are relatively new and can bring constructive experiences from other companies. We have heavily invested on people management through top quality development programs. People represent our main resource so we dedicate a huge effort in helping people to improve their management skills. Last but not least, a key success factor has been the increasing importance of Grunenthal's plant in Origgio, which is now one of the group's Centres of Excellence. Indeed, back in 2005, the opportunity was offered to a few affiliates to become in charge of Tapentadol's production. Winning this internal competition allowed the Italian site to attract additional investments- as more than Euros 20 million has been

invested in Origgio since then. As a result, not only has the capacity doubled in terms of production and volumes, but a very strict cost-control policy also enabled to significantly reduce the cost per unit produced. The Italian manufacture is therefore the most competitive among Grunenthal Group itself, but also to the eyes of the industry, with some players now willing to outsource part of their production to Origgio. Surely such a path puts Italy as an example for other affiliates.

Could you describe the subsidiary's relative importance in terms of revenues and growth from a global perspective- and to which extent is Italy a priority for Grunenthal?

Four years ago, Italy was the group's fourth affiliate, following Germany, Spain and France. At present, it overcame France to reach the third rank. But it is worth highlighting that for the third consecutive year, Grunenthal Italy has kept growing faster than the market in 2008. Its 2005 market share of 0,6 % has now reached 0,76%, reflecting a steady growth in terms of sales and production. Indeed, starting from less than a billion yearly production in 2005, 2 billion units have been produced in 2008 and we expect to further increase in 2009.

What was the rationale behind choosing the Italian production site as a GMP Centre of Excellence for oral solid formulations, therefore making Italy a hub to supply other European affiliates?

As Formenti's historical plant, Origgio was originally aimed at local production. Then, it has been assigned Tramadol's production, which accounts for more than half a million units a year. At this stage, various sites were eligible as Centres of Excellence for tablets' production –but the Chinese one was not offering a favourable environment, and the Spanish one was at the time mostly dedicated to third part production. Therefore, Origgio was lucky enough to be the only plant combining the requested criteria. Heavy investments have been conducted since then in order to further improve the site's efficiency- which enabled a 40% reduction of the cost per unit produced. As a result of this successful policy, combined with the increasing demand from the market, the plant is now producing 2 billion units per year, to be exported in more than 60 countries.

As we see more and more companies of all sizes developing contract manufacturing in Italy to keep the production facilities profitable and sustain investments; what will make Origgio a key partner for customers in need to outsource their production, compared to other companies that are also GMP compliant and able to realize the full production cycle?

Until today, third part manufacturing has not been a priority, and Grunenthal Italy was mainly focused on attracting investment from the headquarters, improving the organization's efficiency, and renewing its offices and infrastructures. Indeed, investing in machinery and human capital were pre-requisites to start external growth and attract third parties at a later stage, relying on a credible and qualitative image. Now that the first steps of development have been successfully achieved, the company is progressively entering this phase of external development. When the

modernization of infrastructures will be fully achieved by mid-2009, Grunenthal shall start responding to the solicitations already received from players considering Origgio as a potential back-up plant. I am personally confident in our competitiveness in this regard. Origgio is extremely cost-effective, the machine's depreciations will soon start, and external production will surely become a main asset. In little more than 18 months, the Italian subsidiary should become a centre of profits rather than a centre of costs. The other most important feature of the Italian branch is the hard work it puts into innovation, with 25 researchers collaborating with 100 centres.

To which extent are the Italian R&D activities going to play a strategic role in the future?

Grunenthal Italy's R&D activities are only production-orientated. No clinical trials are conducted at the moment, and the affiliate's 25 researchers are fully dedicated to research and development, working on stability, bioequivalence and trial batches for production. Having had the opportunity to start R&D processes from the beginning of the development cycle creates considerable opportunities to future production. In the same way that high volumes of Tapentadol are produced here to be launched by mid-2010 in two major European countries, the Origgio plant will remain extremely important to fuel Grunenthal's pipeline. Looking at the future pipeline, Grunenthal group is mainly focused on pain management, but as diversification seems to be the current trend, also increasingly working in dermatology and expanding to gynaecology.

Which therapeutic sectors do you think have the most potential to contribute to the company's future sustainable growth and offset the end of important patents?

In-house R&D is still heavily focused in pain, with a couple of promising molecules in phase I and II. In the dermatologic area, the fruitful collaboration with Leo Pharma will keep providing both companies with a dynamic product portfolio, and new launches balancing patents expirations. Regarding gynaecology, three new projects are currently under registration; a new compound should be launched in the coming years, and be complemented by a potential acquisition at the local or international level. At the local level, growing together with Italy for Grunenthal goes beyond productivity and research, as the company works in educating both patients and physicians through a number of CSR initiatives.

What do projects such as P.A.I.N initiatives say about Grunenthal's commitment to the future of the country and the health of its community on the long term?

Grunenthal Italy has always been a leader in pain management- and such a leadership position does not only imply a deep knowledge of the market, but also an extensive understanding of the patients' expectations. For this reason, an educational strategy has been put in place and addressed to different targets- GPs, pain therapists, oncologists, and more recently pharmacists, who have an increasing influence on final purchasing and can play an important role in putting an end to the patients' traditional confusion between anti-inflammatory and anti-pain products. This offer has been

developed in partnership with the Italian Association of Pain Therapists, and the best experts have been invited on board. Such activities also play an important role in building the company's image.

Where do you see further room for improvement in Italy in terms of brand recognition?

Grunenthal was almost unknown in Italy until four years ago because the company was only communicating under the Formenti name. This is why in the dermatologic field, products are still marketed as Grunenthal-Formenti. The first compound launched under the new brand has been Belara, our contraceptive pill, in 2006. As a result, Grunenthal is the second most appreciated company in the gynaecological field, in terms of support, quality and professionalism. In the pain area, all products are now Grunenthal- branded, but some of them are still recognized as part of the Formenti portfolio, so we have to work in avoiding potential confusions for prescribers and patients. In this regard, the launch of Tapentadol will surely ensure Grunenthal a stronger recognition, as it will be the first compound fully resulting from the group in-house R&D.

Where do you want to take the company in the next three to five years?

Personally, my main priority is to provide Grunenthal with a stronger pain franchise, which will rely on both Tapentadol's launch and further portfolio expansion through products' acquisitions. The company will also position itself as the leader for psoriasis treatments, and surely enhance the quality and quantity of efforts orientated towards the dermatological market. A third pillar will be gynaecology, an area which will probably expand through acquisitions- as it cannot rely on the same level of products and resources internally provided by Grunenthal group as the two other pillars.

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