

## Interview: Attila Santa - General Manager, Sanosan - Romania

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*The owner of an indigenous producer and contract manufacturer explains the plethora of new opportunities unfolding for customized industrial batch manufacturing and the impact that EU accession had on the local pharma manufacturing industry.*

### **How has domestic pharmaceutical production evolved in Romania?**

One of the landmark moments for Romanian pharmaceutical production was when the national legislation was harmonized with Europe-wide manufacturing standards in the months prior to EU accession. In 2005, we were obliged by the NAMMD to swiftly implement GMP standards and subjected to a very challenging timetable to achieve that transition. This inevitably produced a certain shakeout across the industry with a number of the smaller and less secure players disappearing entirely from the scene. Those that managed to adapt to the new rules of the game, however, were soon rewarded for their perseverance and rigor with a whole new host of foreign partnership and market opportunities unfolding. Ever since, the trajectory has been a very positive one with manufacturing standards improving year on year across the board and local producers leveraging newfound exposure to Western Europe markets as an opportunity to upgrade their facilities and remain at the cutting edge of the technology curve.

At Sanosan, we relocated to a state-of-the-art production facility in our local neighborhood of Brasov that had been designed according to the latest EU CGMP regulations. Our research and

development team has the goal of delivering several new products every year. Expert professionals dedicate their attention on generic drug formulation, analytical development, pilot scale production and stability trials ensuring industrial application.

**How important is it to complement production with an in-house distribution arm?**

There have also been transformative changes on the distribution side of the business. Local manufacturers have to be attentive to the market accessibility of their products because of the specific nature of the Romanian supply chain where the market tends to be dominated by a handful of large wholesalers and pharmacy chains that can be fairly selective about who they do business with. For that reason, there is a case for engaging in some sort of vertical integration and for adopting a more holistic approach where manufacturing is considered not in isolation, but in tandem with supply and distribution.

At Sanosan, we decided to opt out of this game and supply independent pharmacies through our own distribution mechanism. The advantage of this is it mitigates a situation where we could potentially find ourselves held hostage by powerful wholesalers and having to abide by strict minimum production requirements or locked into unfavorable terms and conditions. Instead we can be much more flexible and versatile in our development strategies and it is in fact this in-built capacity for adaptability which we consider to be one of our core strengths. Having that extra dimension delivers up different options which can be strategically useful when running a business of this nature.

**Another step you have employed with a view to shoring up our cash flow has been to conduct more work with external foreign partners. Tell us about this.**

Having a secure distribution arm to complement your manufacturing business is not enough in itself to protect yourself on the local market despite it being an important component of operations. This is primarily due to the long payment terms and underlying unpredictability that you are faced with as a local producer. Basically there is little security that payments from the pharmacies will be made on time even when it's a question of state reimbursements and this is liable to wreak havoc with your cash flow and destabilize your long term investment plans.

Currently we have invoices that should have been paid within 60 days which we are still waiting on a full 6 months later and the excuse from the CNAS is that state budgets have not yet received congressional approval. Even worse than the long delays is the unpredictability of the length of those delays. If I can rely upon being paid within 90 days instead of the original 60-day limit then at least I can make contingency plans and determine my growth strategies on that basis, but the

reality is I have little idea from one month to the next when those revenue flows will materialise. As you can imagine, navigating this sort of chaos in the payment chain was taking up a great deal of my day-to-day energies that really should have been focused elsewhere.

The solution has been to increasingly orientate towards foreign partners than can be relied upon to abide by the stipulated payment timeframes. EU partners generally respect the payment terms because they can be sanctioned if they fail to do so. This shields us from disruption in planning and enables our cash flow to become progressively healthier. Right now a full 50 percent of our workload is directly with foreign partners and by the end of the year this could well increase to a level of 65-70 percent. This is an emerging trend you can expect to see more of in the years to come until there is more reliability in the national market.

**Now that your cash flow is more stable, where lies your present focus?**

It liberates us to concentrate more on the meat of our business which is ramping up the production side. Over the past couple of years much of our attention was on staying afloat from one month to the next and firefighting. Now we have the space and time to get to the heart of the business and render ourselves a producer of the very highest caliber. This is emblematic, I think, of the direction in which the remaining local manufacturers are heading.

It's only relatively recently that local producers started securing contracts with 'big pharma' multinationals and that is testament to the fact that many of us have now reached a level where we can easily pass audits to the highest of international standards. I am confident to say that Western EU countries are increasingly satisfied with the quality of the "made in Romania" brand. No doubt this has been abetted by acquisitions where household international names such as Pfizer, GSK and Sun Pharma have been buying up local manufacturing entities.

Nevertheless, it's a quite leap to be able to manufacture products that are eligible to be submitted in any of the EU countries. That requires adhering to well-defined processes, maintaining the relevant documentation and passing rigorous validation mechanisms. We mustn't underestimate the tangible progress made. Let's be clear that there are no short cuts, loopholes or alternatives. As an industry we can be proud of the distance we have travelled and I am personally especially proud that Sanosan is one of those leading the pack in this respect. We have embraced the opportunities that EU accession presented to the maximum.

**To what extent then does Romania hold a competitive advantage in contract manufacturing?**

This is a real growth area for Romania. For a multinational to engage you for contract manufacturing they have to have a high degree of trust in you, because in many respect this is equivalent to handing over to another entity the responsibility for the quality of your product. Not surprisingly firms don't undertake such a decision lightly. The fact that Romania is now becoming a destination for such an activity demonstrates how our attentiveness to quality has improved in leaps and bounds.

Ten years ago those contract manufacturing agreements were going to India and China but now, as EU regulations become evermore strict and more audits have to be performed, the logistical limitations of these arrangements becomes increasingly apparent and the entire business model requires a rethink. Relocating your production lines outside of the EU is no longer considered best practice and tends to be avoided. Countries like Romania are primary beneficiaries.

Suddenly it makes much more sense to shift the epicenter of contract manufacturing to those countries with lower production costs that are nevertheless still members of the EU and thus where quality can be more tightly assured. This is where countries like Romania and Bulgaria.

University cities such as Cluj, Iasi and Brasov are establishing solid track records in manufacturing because of the availability of skilled labor. For example, in Brasov, there are three well-established and decently sized pharmaceutical facilities: owned by us, Europharma and Farmacom respectively.

From an economic perspective there is also a strong case for leveraging countries located on the fringes of the EU like Romania for product conditioning, packaging and customization because of the attractive cost differentials. The EU comprises 27 states of very different sizes each with their own market specificities and these needs require segmenting. Romania in many respects offers a platform for last-minute customization of the batches. The smaller the batches being prepared, the more the overheads become pronounced and its in instances like this when the cheaper, more flexible, but highly skilled Romanian labor pool and cheaper logistics owing to geographic proximity really come to the fore. As a nation, we recognize these unique selling points and are increasingly starting to make the most of them.

### **How healthy do you consider the Romanian generics market?**

To be fair, the generics market struggles at times. There have been a lot of teething problems that have held back the advancement of that market segment. The biggest barrier is most definitely the claw-back mechanism. The way in which generic producers are subjected to the same level of claw-back contributions as an innovator is mind-boggling. This simply cannot be considered fair. What's

more it produces irregular features in the generics landscape. Products with very fine margins cannot cope with what is tantamount to 25 percent on the spot sales tax so strategic decisions are taken to discontinue them and the get taken of the market. What remains highly invested in are the branded generics that occupy a comfortable space with no equivalent competitor products to the extent that slapping a high price tag on them will not really risk a collapse in sales. This is how we end up with a curious scenario where certain generics are more expensive in Romania than in the UK when individual purchasing power is one of the lowest in the EU.

The sluggishness of registration can also be considered a significant barrier that very much shapes the way local producers like Sanosan organize their activities. Launching a new product can be very time consuming. It can literally take several years from the point you initiate the development of a new product to actually securing the relevant authorizations to place it on the market. By that time the market conditions could be entirely different and your proposed product may no longer viable. This is therefore a risky business. This naturally diminishes our keenness for developing our own brands. Instead a more conservative and assured strategy is to perform contract manufacturing. It's here that I believe Sanosan and Romania in general can offer a real competitive advantage. That said, the day the NAMMD enhances its capabilities and product authorization speeds up we will be ready to grasp whatever new possibilities present themselves.

**We have been hearing that Romanians are very brand conscious and that this has hindered the penetration of generics. Do you agree with this hypothesis?**

I agree that Romanians do express a preference for brands, but I see this phenomenon as symptomatic of the market make-up rather than a driver in itself. Customers tend to be brand conscious because they've never been familiarized with having a real choice of generics on the market. These behaviors and consumer preferences are very much the result of daily habits. If you are used to buying a product where you recognize the name, you may not even try to look for cheaper alternatives. Meanwhile the big pharmacy chains are very rationally and logically promoting those medicines where they will accrue the biggest profit margins which are those products with a high price tag. Meanwhile many of the branded generics don't face real competition so are highly priced and there is little pressure from the government to either lower those prices or explain them. Once the consumer has proper choice at his or her disposal and fully understands that generics offer exactly the same therapeutic benefits as the originators or branded-versions, then I am confident they will adapt their behaviors accordingly as everywhere else in the world.

## **How stiff is the competition for local manufacturers when faced with the might of companies such as Sandoz and Zentiva?**

We've certainly seen a tendency in the past for multinational generics companies to buy up local manufacturers which is a trend also witnessed across the CEE. That was a time when there were easy pickings, when there were weaker local players present on the market. Nowadays most of the indigenous entities that remain can more than hold their own. Either they have managed to occupy a niche of their own or to work in tandem with big pharma or both. Collaborating with multinational pharma actually presents a pretty decent solution because with a decent international partner you can establish a steady business that helps you grow to a level that you can branch out on your own developing your very own generic portfolios. At that point the competition could become more intense, but for the reasons that I have already described, we are still a good few years away from that point. That's when we could maybe encounter a whole new round of mergers and acquisitions.

## **To what extent is parallel trade here to stay?**

Parallel trade has become a big business. It is based on the principles of free movement of goods within the EES and enhances competition in products that would otherwise be in a monopoly-like position, obstructing competitive trade practices and pricing. When it first arrived on the scene in the 1970s everyone thought it was a flash-in-the-pan sort of phenomenon, but it has proved to be much more enduring as direct effect of the distorting conditions of the local legal and regulatory frameworks. To my mind it has reached a degree that is too intensive with a wide range of products manufactured within Romania that are difficult to acquire on the local market. In this respect, I think the ministry is totally within its rights to produce a list of APIs and molecules that are prohibited from being sold outside of the country. That is the only way to curb this practice to the sense that the right health outcomes are maintained within the country. Many of the big importers happen to also be the big exporters and to my mind there are moral and ethical restraints that should be adhered to with regard to ensuring what is in the best interest of the Romanian patient.

## **What is Sanosan's outlook for the coming 4 to 5 years?**

I see the future as very bright. We are planning numerous new contract manufacturing and development products and are increasingly engaging in arrangements where we repackage or conduct last minute customization of products for distribution on nearby European markets. We are now very well positioned to fulfill outsourcing needs for compressed tablets for pilot batch production, re-control and release of commercial batches and contract manufacturing of industrial

batches. Moreover we have products pending authorization in more than 12 countries across Western European countries like Germany and the UK, Scandinavia and CEE states such as Poland. There is growing potential to tap into regional supply networked and we are grasping this with both hands. There is no doubt these are exciting times.

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