

Interview: Radu Cazacincu - Management Board Member, Magistra C&C - Romania



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One of the directors of Romania's number one producer of suppositories and the only in-country manufacturer of contraceptive ovules speaks out about how the country is fast becoming a regional manufacturing hub and preferred destination for final batch customisation. He also talks extensively about the state of GMP in the country.

Magistra C&C stands today as one of the most important local producers of generics in Romania. Maybe you can start by introducing how the firm was set up and its evolution over time?

Magistra C&C was established in 1993 with an orientation towards manufacturing solid forms: essentially tablets and semi-solids. The company was originally created when my parents, both of whom had pharmacy backgrounds, built a pharmaceutical factory in our city, Constanta. Over time, the management of the firm has been kept within the family.

In the early years we concentrated on responding to the demands of the national market, but in line with momentous events unfolding around us, soon embarked upon more expansive activities. Both the liberalization of Former Soviet Union (FSU) countries and Romania's accession to the EU can be considered critical junctures heralding unique opportunities.

In our case, Magistra C&C established distribution contracts with partners interested to market our products in the former CIS. From 1999, we started conducting business with FSU countries: namely

Russia, Belarus and Ukraine. Then, from 2008, we started entering into deals for contract manufacturing and were granted significant contracts from Western European companies. The fact that these kinds of companies were willing to place trust in our manufacturing practices is indicative of the sheer progress we have made in terms of the quality of the medicines that we are bringing to market.

Today we are proud to have become the largest producer of suppositories and lone in-country manufacturer of contraceptive ovules. For tablets, we have an even spread of around 40 molecules in our portfolio and we are the market leader for both suppositories and contraceptive ovules. This dominance has been established by virtue of a strong sales force covering the entire country and through attentiveness to the latest technology. Our suppositories, for example, are packaged in a user-friendly manner so that they are easy to open by hand anytime, anyplace. Our closest competitors still don't use this kind of packaging. It's a minor detail, but makes huge a difference when consumers are expressing their preferences.

EU accession required step-change in manufacturing practices for the pharmaceutical production sector. How difficult was it to align with the new standards and what benefits have these adjustments brought?

In the early 2000s, it was very difficult to enact the changeover, because the authorities handed us strict deadlines to bring ourselves entirely in line with European Union norms for pharmaceutical manufacturing. You can describe it as a short, sharp shock. When other Central and East European countries were readying themselves for joining the EU a certain number of allowances were made. In other European countries, a lot of GMP rules and norms could be delayed, so that the companies could adjust and conform in time. For Romanian firms there was no such leeway. We felt as though we were being told to make the changes almost overnight.

Once we found ourselves aligned with international norms, however, the business opportunities were phenomenal. Having GMP certification opened the door to a whole world of new possibilities hitherto unknown. Conscious that GMP is an ongoing process of optimization, we set about building an entire new production facility, because our former factory offered limited space and we always kept in mind that evolution and expansion is our future. Our new factory, by contrast, was constructed with an eye to extensions and upgrades. When we received the first visits from West European companies seeking to establish contract-manufacturing alliances with Eastern European local entities, they were visibly impressed and a steady flow of contracts soon ensued.

To what extent is Romania becoming a hub for contract manufacturing?

We can see a niche emerging for small and medium size Romanian local producers such as Magistra C&C engaging in contract manufacturing. Our size and geographical proximity means that we are flexible enough to respond to the evolving demands of our clients at pretty short notice. If, for example, a Western European client operational across 20 odd countries in the region wants to suddenly respond to sales fluctuations by redistributing batches from one EU market to another, then we have the capabilities to facilitate this without delay.

Romania can blossom as a manufacturing hub because we offer competitive and more affordable prices compared to the rest of the EU and yet our quality standards are equivalent and, in some cases, even superior due to the modernity of our factories. The GMP inspections bear this out. Global trends are also on our side with clients increasingly demonstrating a willingness to withdraw their contract manufacturing networks from Asia and re-situate them within Europe. This is because EU regulations are increasingly strict and there have been some high profile cases where western firms have been forced to retreat their products as a result of failed bioequivalence studies on products they had manufactured in India and China.

One of the most important points for Romania in this segment of contract manufacturing is that virtually any town in Europe is reachable in a couple of hours. Our clients may have to pay slightly more to have their products fabricated here, but in the long run that extra expense is worth it because they are nearby. They can send over inspections at short notice if they want to ensure the quality of the production process. They can change the nature of their orders at the last minute and not suffer long delays. Also, should there be any issue they need to resolve, then they can be over here with us within the same day.

For our part, we can ensure our competitive advantage over Chinese or Indian-based competitors by using European sourced manufacturing equipment that is of the latest generation and highest specification. Our clients can place trust in us to manufacture their products to the highest quality because we are using German and Italian top of the range machines and adhering strictly to EU best practice. It's exactly the equivalent of them performing the operations in Western Europe, but at a cheaper price because of the lower labor, property and production costs. Unlike Asia, we offer peace of mind, reduced risk, but still affordable prices.

You seem to place a lot of emphasis on possessing expensive, latest generation machinery. Can you elaborate further on how this investment pays off?

Firstly it increases the confidence that our West European clients can have in us. When they do visit our factory for the first time or see our presentation, they promptly acknowledge that our

manufacturing facility is on par, or even better than it is usually seen in contract manufacturing sites all across Europe. Remember that we are also doing a thriving business in analytics and stability studies where customers, often from outside the EU, send their products to our facilities to be analyzed so that they can obtain the relevant certifications. This again bolsters our reputation for quality.

Secondly, possessing British, German or Italian made equipment means the production equipment are easy to maintain. Their reliability is second to none and, if on the off chance there is a malfunction of any kind, then we are close enough to the parent markets so that they can be speedily serviced.

Thirdly, these top-of-the-range machines offer an in-built versatility that allows us to be hyper flexible and adaptable which, as I have explained, is one of the key selling points of Romania as a contract-manufacturing hub. We have a tablet machine that makes up to 4000 tablets per minute so we can easily ramp up our production to meet whatever fluctuations in demand come our way. Our factory reflect this same degree of versatility in their overall design: for each manufacturing space, we placed – already from the design stage – another area, identical in space, which can be modeled in future as additional production space, thus adapting and scaling up for larger production volumes.

How do you evaluate the competition in the local generics market?

We find pharmacies are happy to acquire and further sell to patients our medicines, because the brand Magistra C&C is well known and respected, having been present on the market for over 20 years. Equally, we have had a strong sales force established out in the field for over a decade. We've managed to carve out our own niches and are dominant enough to stave off any competition.

Back in 2008, we faced a huge challenge when physicians were suddenly permitted to write the brand name of originators on prescriptions instead of the molecules and that particular year we were afflicted by a sudden sales drop of about 25 percent. These sorts of issues, however, are long in the past and that particular law was reversed. Nowadays we can outcompete any rivals for suppositories and ovules.

The main challenge today relates to the regulatory climate and in particular the claw-back mechanism that harms local producers much more than foreign multinationals. We increased our sales by 3 percent last year, but the claw-back contribution rose from 10 to 26 percent over the same timeframe, thus decreasing drastically our profit margins. Local producers bear the brunt of

this because the bulk of their sales take place within national territory so the claw-back is applicable. Though the absolute amounts might be greater, in proportional terms, the effect of the claw-back on the worldwide portfolios of the multinationals is minimal.

Local generic companies find it more and more difficult to find financial resources for medical promotion, although 90% of the market still do it.

Doesn't the OTC market offer a potential way out of this conundrum?

It certainly does, but even transitioning to OTC is easier said than done. Nevertheless the 8 OTC products we had on the market the year the government introduced the claw-back for the first time went a long way towards stabilizing our cash-flow. The additional 3 or 4 gels and creams we have recently introduced in the OTC segment are again helping to smooth our budgets at a time when the government is raising the level of the claw-back contribution. At the same time, we are complementing our OTC business that makes up 25 percent of our overall portfolio, with other creative revenue generating initiatives.

Tell us about those other creative strategies...

Our newest product comes through another European company, through the authorization method of "Mutual Recognition" – used a lot between European Member states. It allows us to transfer a product in our name, using a reverse contract-manufacturing contract. In this case, our main target is to sell the product, which is still manufactured by our partner. Usually it's the opposite process whereby we manufacture products for an external client, but in this particular instance it makes sense because it will increase our portfolio easily because the "Mutual Recognition" procedure takes far less time than in our national jurisdiction.

We are simultaneously trying to orientate as much as possible towards the export side. In this moment we are manufacturing products and sell them in various countries, from Africa to Asia: Ghana, Ethiopia, Russia, Kazakhstan, Azerbaijan, Georgia, Ukraine, Iraq, etc. What's more, once you have a product placed on 10 markets, its not just reducing your dependency on the national market, but it also setting the conditions for you to scale up further. Being based out of Constanta is beneficial in this respect because this is Romania's primary port city so logistically convenient for shipping products to Africa and the Caucasus.

What are the other pros and cons of being based out of Constanta?

Well it works both ways. Being the only pharmaceuticals producer in this city, we can achieve a high level of brand recognition locally and having easy access to the port brings logistical bonuses.

Finding skilled personnel for specific jobs is difficult, as in any technical and scientific field. Recruitment is much easier in the capital or the well-known student hubs of Cluj, Brasov and Iasi where many local producers tend to congregate. This necessitates us to invest more on in-house training.

Where will we find Magistra C&C in 5 years time?

A stronger company, a better partner for our clients, with stronger professional network, anchored in the European pharmaceutical industry.

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