Philippe Truelle â?? President, CDM Lavoisier, France

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Philippe Truelle, President of CDM Lavoisier, highlights the financial impact of the EUâ??s Falsified Medicines Directive (FMD) on SMEs across Europe and explains how France is becoming increasingly attractive to foreign investors under the Macron Presidency. He also speaks out about CDM Lavoisierâ??s longstanding legacy in France and outlines the companyâ??s ambitious expansion plans.

What have been the most significant changes since we last spoke with you three years ago?

While we still maintain our highly successful partnership with Coloplast, which is due to be renewed this year, we also signed a landmark cooperation agreement with Sanofi Pasteur one year ago. The goal of this collaboration is to supply sodium chloride for specific vaccines they are producing. As we

have never collaborated with each other before, modifications to our operations were required so as to better align with their business model and be able to deliver bespoke solutions tailor-made to the clientâ??s specific needs. The partnership has been overwhelmingly positive so far and we will actually be deepening the nature of our cooperation with Sanofi Pasteur, as there are fresh projects already lined up.

You celebrated 130 years of existence last month; what is the legacy and overall perception of the CDM Lavoisier brand in France?

This company started off as a family run and owned boutique pharmacy with fewer than ten employees and competencies in manufacturing drugs mostly based on animal extract. Since then, CDM Lavoisier has evolved significantly and developed into a modern pharma company specializing in injectable drugs. We also can lay claim to a long-lasting tradition of sterilizing products, which also dates back to our founding year, 1888. When looking back at the initial priorities of my mother and grandfather in managing and maturing CDM Lavoisier, it becomes clear that there have been deep-seated changes to the surrounding operating environment. Previously, the focus was pretty much solely on business development, while, during the course of the past decade, the regulation of drugs both in France and internationally has become so complex and stringent that it is nowadays my primary concern and takes up a substantial part of my time and energy. It is absolutely no exaggeration to say that every month we are encountering new regulations that we have to implement and norms to align with.

What have been your experiences in implementing the FMD?

The Falsified Medicines Directive (FMD), introduced by the EU, has had a considerable impact on our financial operations, as the burdens placed on SMEs through this decree, have not been underestimated or ignored. Currently, we have to pay for additional machine and IT systems so as to conform to its guidelines. Altogether this comes in at a cost of EUR 300.000 (USD341.000) for us, which is nearly half of our annual envelope of investment. While this is an upfront payment, we are also finding ourselves burdened by yearly costs of EUR 50,000 (USD 56,000) for the IT system and also EUR 20,000 (USD 23,000) as a contribution to maintaining the National MVO and European MVO. For SMEs like us, the negative impact with regard to increased overheads is clearly very serious for the financial health and viability of the business.

Are you against the FMD in general or is it more to do with the way it has been implemented without properly taking into consideration the daily needs of small and medium sized businesses and the parameters under which they have to operate. ?

Precisely. The FMD is a great initiative, as falsified medicines have been a big problem in some markets and modern healthcare systems cannot accept this threat. Nevertheless, the study conducted on falsified medicine has not been very precise and I would have preferred to see a step-by-step implementation of the directive. CDM Lavoisierâ??s products are inexpensive, have very small margins and are not easy to falsify, so we simply are not an attractive target for this type of criminal endeavour.

Through a more gradualist, step-wise approach, the authorities would have discovered that it makes more sense to first include in the directive only those products that carry a high price tag and

generate high margins. The bureaucrats in Brussels are clearly detached from the realities on the ground. We are in a very fortunate position that in France, at the behest of the LEEM, it has been agreed that industry will share the burden via a more proportional contribution system, which lowers our contribution to the European hub to EUR 4.000 (USD4.550) per year. This has been a big relief for SMEs, as the model that the EU was advocating mandated that companies like us would have to pay exactly the same amount as big multinationals such as Sanofi. Clearly, this would have been unfair.

Though industry might have managed to strike an acceptable deal in France, this is certainly not the case in many other European member states, so we have been alerting the EU to this issue and the fact that the FMD in its current guise can constitute an existential threat to certain smaller companies. This is because there are no subsidies towards implementing the changes that would offset the cost. In my capacity as president of the association for small and mid-size pharma manufacturers, I have been speaking to SMEs in markets like Spain and Italy that have literally had to stop the distribution of certain products because the fees have been eating up the margins of these products to the extent that it makes no economic sense to continue trading. I have absolutely no doubt that many companies will disappear as a direct result of the implementation of the FMD and the associated costs incurred.

Can you give us an overview of your plans to upgrade and extend your manufacturing capabilities?

The current factory, built in 1992, has reached its production and storage limit to the point that we have to store 300 pallets of finished products and raw material outside the factory, which is a huge cost factor. Another issue has been a lack of office space and, as we are hiring new employees constantly, we are now struggling to accommodate them in adequate surroundings. These limitations on our production capacity and the additional activities that we have committed to as part of our ongoing partnerships encouraged us to enlarge our facility. This will include a fourth production line as well as more office and storage space.

Which segments and products within them, are generating the most revenues and driving growth right now?

Our medtech section is growing steadily and currently makes up 15-16 percent or our revenues, which is quite respectable considering we have only started manufacturing such products in 2007. The CMO share is around 10 percent and registers the biggest growth potential, as we see a very high demand for manufacturing medium-sized batches, and a broadening out of the client base. For example, for the fabrication plastic ampules, both big MNCs and SMEs of French and international origin have come calling. This is a unique opportunity for CDM Lavoisier, as it gives us the chance to work with companies we would never meet usually and also learn from the know-how of other companies. Every request is assessed thoroughly to see if we have the necessary capacity and what modifications to production are needed. At this point, we cannot accept all requests, as we simply do not possess enough capacity. Moreover, we currently find ourselves being approached by many US companies, and while it is a future goal, we are not yet FDA approved, meaning that we are unable to cater to these requests either. Our ongoing collaborations are with Coloplast, Groupe LFB and Sanofi Pasteur.

That said, it is not our intention that CMO activity should constitute our main activity in the future as the bulk of our capacity is ring-fenced for the fabrication of our own drugs and products. Sodium

Chloride, which we propose in different packaging options and sizes, such as glass and plastic ampules, glass and plastic bottles and vats, remains our star product. Our customers very much value this diversity, as it makes us a one-stop-shop for this product.

Where is your main competition coming from?

At the moment we are facing strong competition from other European companies such as B. Braun and Fresenius. These are obviously huge companies; however, their core business is not the business CDM Lavoisier is in. Surprisingly, these companies do face the same struggles in production capacity just like us, despite the considerable difference in size. On two occasions, we have been approached by a group of university hospitals in France, which were facing an out-of-stock situation. As their normal supplier could not meet demand, despite its massive production capacity, CDM Lavoisier was able to jump in to supply the product. So, there are obviously still gaps in the market, as the demand for products in our market is increasing.

In terms of international expansion, which specific markets will you be targeting next?

In our business, the main difficulty is managing production costs, as these are considerably higher in Europe than in China or India. This has been challenging in the North African markets, as they tend to go for the cheaper products and hence approach Indian and Chinese firms. We find it hard to overcome this barrier, as HR costs in France are higher than in other European countries like Italy or Spain, and there is no comparison to Asian countries. Hence, we have only increased our exports by 1-2 percent since 2015, mainly to Europe as some competitors have disappeared in this region.

Nevertheless, we are currently planning to approach new markets in Africa and South America, by collaborating with local manufacturing partners. At the moment, products like Sodium Chloride are imported from Asia to these regions; however, these are products that are needed immediately, so we are looking to fill this gap by producing nearer to these countries. This year, we have started assessing the option of transferring know-how to a newly established company in Central Africa to out-license our products.

Looking at the operating environment in France, what has been, if any, the tangible impact of the pro-business Macron government policies along with the Strategic Council of the Healthcare Industry (CSIS) and the action plan for growth and business transformation (Loi PACTE)?

One of the significant measures of the Loi PACTE was the dividing up of tenders for products between more manufacturers, which made sense, as we were facing tender growth rates, which we could not respond to, without neglecting some or all of our other customers. This will also help to avoid out-of-stock situations in our hospitals. Another positive impact of the Macron government is the new, fresh image France now possesses on the global stage.

Macron has brought in a young spirit and the mere fact that he speaks English very well, is also an advantage when negotiating with international investors and stakeholders. This has resulted in an increase in foreign investment in France (EUR 6 billion in 2017), which is significant difference compared to what previous governments have achieved. It will certainly help France domestically and internationally, as it brings positive impacts on the whole supply chain.

However French people do not possess much patience and therefore it will be important for the new administration to properly manage expectations. The pharmaceutical industry is a very regulated area, which makes it hard see immediate impacts. The current regulation, along with the new FMD, makes it very difficult for SMEs to profitable and the reduction of the social security deficit will not allow any price increases to compensate. Hence, some SMEs are considering externalizing the commercialization of their product to bigger companies, to balance the costs. Nevertheless, there is hope, as there is the political will to change the regulatory processes and also the French pensions scheme. This will be a necessary reform and patience is needed, as the results will probably only manifest themselves in three to five years time.

Any concluding words?

One can say France is back, however, there is still a lot of work to do, as we have been losing expertise and manufacturing capacities to other countries during the past 15 years. Things are changing but the situation remains still very fragile. While the CSIS was very promising, today we do not see any changes in the Social Security Financing Bill (PLFFS). There is still the need to convince the government and the public, that the pharma industry is a reliable partner. The policymaking mindset of the past 15 years, seeing only the price of medicine to the exclusion of all other factors, has clearly been a mistake and, though we are now seeing a much more enlightened approach from the top-down, it will take time to overturn ingrained behaviours at the level of the administration. We do need to succeed in developing our local capacities to be able to export more and have more innovative and complex products produced in France. Most importantly, France needs to be able to meet the demand of its own market, as we cannot be too dependent on the imports of pharmaceutical products, given global political winds and rise of protectionist and nationalist tendencies.

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