

Massimo Scaccabarozzi - President, Farmindustria



Italy has a key role to play in the EU objective of guaranteeing continuity of supply during emergencies.

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Massimo Scaccabarozzi, President of Farmindustria, discusses Italy's response to the pandemic and the association's key priorities, which include maintaining Italy's position as a European leader in terms of production.

Italy became the first epicenter of the pandemic outside of China. What conclusions have you made on the experience of the country and the pharmaceutical association?

I think that Italy has achieved extraordinary results with the COVID vaccination campaign. More than 136 million doses have been administered which has resulted in 91 percent of the population over 12 years of age having at least one dose, and almost 90 percent fully vaccinated. The results are extraordinary considering that, in just two years, we have gone from having no knowledge about a novel virus to discovering, testing and producing several vaccines and treatments. The industry suffered attacks at the beginning because we were not able to produce fast enough, but we can now look back and be proud of what has been collectively achieved.

The success is due to the industry's R&D, manufacturing capabilities as well as the activities carried out by the Special Commissioner for Covid-19, General Francesco Paolo Figliuolo, who did an outstanding job in partnering with the industry.

What we are taking home as a lesson from this pandemic, apart from what I just mentioned, is the need to sharpen the strategic role of health moving forward and the need to reorganize the

national healthcare system.

While Italy already has an extraordinary universal healthcare system, different stakeholders have realized that we must invest more, looking at it not as cost but rather as an investment.

Additionally, I think that we have improved our reputation among the population because they appreciate the R&D effort that was made, especially looking at the more than 300 vaccine projects started across the world of which only five have succeeded in getting European approval. This shows that R&D is not as simple.

Can you walk our audience through the decision-making process, how the industry came together to help Italy manage the crisis?

Because we are one of the top producers in Europe, Italy had a big responsibility not only to help develop and produce vaccines, but also to continue to produce drugs for other people. Right at the beginning of the pandemic we decided to create several task forces knowing that the responsibility behind continuity of supply would fall on us, impacting not only Italy but the rest of the world since 85 percent of our production is exported.

The first task force was in charge of creating safe conditions for our workers because they are ultimately the ones making production possible. Another area of focus was R&D since Italy is one of the top countries by number of clinical trials globally and they had to continue receiving treatment; it was a life-or-death situation for many of them.

As you can imagine, it was important to develop new procedures, changing the general approach to clinical trials so that digital tools could fill some of the gaps. We discovered a new way of collaboration with health authorities to decentralize some activities and supply medicines directly to patients instead of them travelling to health centers that were saturated.

The industry also accelerated the expansion of telemedicine and introduced that digital approach to production operations. Our reaction was very fast and appreciated by health authorities, patient organizations and the community at large. As a result, we recently signed an agreement with the *Istituto Superiore di Sanità* continue using the decentralized procedure in clinical trials after the pandemic which will increase the number of trials and patients enrolled.

The hope is that the extraordinary things we did during the COVID pandemic can become the ordinary moving forward. If we look at the European Medicines Agency, for instance, we can see

that they also took the chance to improve their approval process with mechanisms like rolling review that allowed the exchange of preliminary data.

As the pandemic starts to slow down, what are the association's priorities moving forward? What discussions are you looking to have with the government?

The first priority for our industry is to remain the European leader in terms of production, something that was achieved in the last few years thanks to the dedication and quality of our people. As I explained, more than 85 percent of our production is exported around the world. The production value of our industry stands at EUR 34 billion, a number that jumps to EUR 65 billion if we add the production of the companies that work with us; even the CDMOs are European leaders. Italy has a key role to play in the EU objective of guaranteeing continuity of supply during emergencies.

Last but not least, it is important to facilitate R&D activity in the country. Our members already invest EUR 700 million every year in clinical trials; Italy accounts for 20-23 percent of all clinical trials conducted in Europe. However, we need to facilitate the process, reduce bureaucracy, with the understanding that clinical trials are essential to patients, who receive innovative treatments, as well as physicians, who get the chance to learn. With the help of an Italian school of economics, we have been able to demonstrate that every euro invested in clinical trials returns 2.8 euros to the national healthcare system; in some areas like oncology the return is more than three euros.

Italy needs a different governance model because the current one, put in place in 2007, is penalizing, through clawbacks, companies that invest. We must get away from that model and rather invest more money to make the healthcare system more efficient. A highly regulated industry like ours must be considered a partner and I am happy to see that the government is working to change its approach.

What is your view on the competition for clinical trials with countries like Spain?

If Italy wants to increase its involvement in clinical trials, it must be able to reduce the bureaucracy at a national level, increase the speed at which centers enroll patients and apply the new European model. We mustn't forget that R&D is an expensive, time consuming, process that requires people involved to work at high speed; being fast means expanding the number of centers across the country. I believe that the industry will always choose places where R&D activities are supported

by the government. Fortunately, we have a strong academic ecosystem that consistently ranks in the top three by number of publications in the most important journals.

However, looking to healthcare's next frontier with CAR-T and other advanced therapies, we believe that we need to invest in infrastructure. Italy's Resiliency and Recovery plan will be a unique opportunity to do that. Our country has the perfect mix: more than 200 pharmaceutical companies, of which 43 percent are Italian-owned. An important characteristic of Italian companies is their high level of internationalization as 70 percent of their business comes from abroad. On the other hand, international companies have invested in R&D and manufacturing, not only commercial activities. The institutions and the government should capitalize on this in order to continue to attract investment.

To what extent is the industry's effort to bring more clinical trials thwarted by challenges around market access for innovative products and pricing?

We are not there yet due to the clawback system. The price is negotiated with the government but depends on prices in other countries, plus the purchasing power and the political and economic situation of Italy. And then, at the end of the year we have to pay significant clawbacks...This is why we should move to a more modern governance model that can help the National Healthcare System be sustainable.

That being said, I believe that we are moving in the right direction. The government has announced an increase of funding of EUR two billion for the National Healthcare System over the next three years, including EUR 100 million per year for innovative products.

On a personal note, you have been very involved with charity efforts, playing in a rock band and writing a book called *Captain, my Captain. When work becomes passion: travel and life notes*. What can you tell us about that part of your professional experience?

In the last five to six years, I have been asked to visit many schools, from primary schools to universities, to share my leadership style to young people because I strongly believe in the younger generations. We continue to say that the future is for them, but no one is asking them what kind of future they want.

Our role as leaders with experience is to involve them in shaping the future; from my point of view, leadership is about teamwork. Leadership is about being yourself, being credible, trustable, ethical and committed to the task at hand.

My leadership style is based on people.

During those discussions with students, I also showed them what we did with a rock band that played for charities, raising funds, all over the world in more than 140 concerts. During the pandemic, we were asked by associations to perform remotely so that money could be raised for personal protective equipment. As the band's front man, I was given the nickname of "Captain" and an editor suggested that I should write a book about my experience. I decided to donate the revenue from the book to a charity working with cancer patients. I hope that the book can inspire the young generation.

The message I pass it to the young generation is to always believe in themselves. Although there is always a confrontation between older and younger generations, I constantly see young people with incredible talent, willing to achieve success and open new dialogues.

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