Michele Uda – Director General, Egualia, Italy

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Formerly known as Assogenerici, Egualia is an Italian industry association representing generics and biosimilar companies. Michele Uda, its director-general, speaks about the industry's impressive response to the COVID-19 pandemic and analyses the potential impact of recent changes to Italy's pricing and reimbursement system.

The generics industry was put under the spotlight during the COVID-19 pandemic, particularly in Italy as the first European epicentre. Having seen it firsthand, can you outline the industry's reaction and what you learned from this period?

Our industry was a positive story during the horrific situation brought on by the COVID-19 pandemic. 70 percent of medicines dispensed at ICUs in the northern part of Italy, and the rest of the country, were off-patent generic medicines, basic and essential medicines that helped many people in ICU. Since the pharmaceuticals available to physicians and clinicians inside hospitals were medicines that have existed for many years, our members played a key role, particularly at the start when vaccines and new treatments were not available.

Our association, formerly called Assogenerici, rebranded to Egualia in 2020 and was part of a joint task force along with the Italian Medicines Agency (AIFA). The task force worked around the clock to provide any medicine needed by regional authorities, which was not easy since few Italian companies were able to manufacture them. Fortunately, multinational companies managed to

activate their global networks at a time when borders closed.

The success part of the story is related to the elimination of shortages in a brief period; also, the collaboration with AIFA was key, especially because they had to work from home and managed to digitalise the process in a couple of days. It was an opportunity for the agency to reshape and digitalise its administrative operations. The public and private sectors joined forces to overcome the main challenges of the pandemic; we were not the only solution but an important part of it.

At the same time, some of the challenges were the result of 20 years of an incomplete industrial policy for the pharma industry. Generic and biosimilar medicines play an important role in European healthcare ecosystems, as evidenced by the more than 500 manufacturing sites and around 26 R&D sites across the continent. Italy alone has 40 manufacturing sites that employ directly over 10,000 people. However, without a comprehensive industrial policy for over a decade, we were relying too much on India and China for active pharmaceutical ingredients (APIs), especially intermediate ingredients.

We were able to activate the international network during the pandemic to supply patients with medicines without interruption but realised that the entire pharma value chain for Europe and the US was compromised.

A few questions have been raised. Does Europe want to invest in manufacturing or not? If the answer is yes, will we be able to restructure our procurement process and our pricing and reimbursement system for the off-patent industry? We will not be able to sustain public and private manufacturing investment with the current system; we have reached an unsustainable point. If a generic medicine industry body is saying this, we are really at the bottom.

In Italy, the pricing and reimbursement scheme was changed recently after the publication of a decree-law which introduced many new elements to negotiations for both innovative and generic medicines. We want to simplify most of the authorisation processes, helping companies go faster.

Can you expand on the challenge facing Europe and the role that Italy can play as one of the largest pharma producers on the continent?

There is a piece of European legislation that is blocking pharma manufacturing investment from public authorities. Each member state can decide what to do but there is a limit. The industry across the continent wants to be able to respond more efficiently in future pandemics. However, being competitive at a global level will require public-private partnerships, just as companies and

governments have done for vaccine manufacturing scale-up.

Italy is already first in Europe regarding manufacturing capabilities and volume for pharmaceuticals. The Italian manufacturing network is based on small and medium-sized enterprises, which require help to scale up their capacity.

There are seven main manufacturing countries in Europe: Italy, Germany, Spain, France, Greece, Poland and Hungary. If those countries fail to scale-up production, we will keep relying on external forces.

You mentioned the obstacles faced by pharmaceutical companies looking for public funding. Have they looked at private investors as an alternative?

The generics and biosimilar industries have always been attractive to investors and many of our companies are already involved with financial institutions. The Italian generics market is concentrated at the top with big multinationals such as Viatris, Sandoz, Teva and the STADA Group, plus an Italian-born company, DOC Generici, but there are also plenty of small and medium-sized companies that add value and could go to the next level if provided with the opportunity.

What was the reasoning behind the rebranding of the association, changing its name from Assogenerici to Egualia?

The main reason is that the previous name, Assogenerici, encompassed the backbone of the generics industry, but, after 25 years, our membership has become heterogeneous, and we now represent traditional generics companies and biosimilar companies as well as those working in value-added medicines, APIs and medical devices. Egualia recalls the Italian word meaning equality, which encapsulates our ambition of making medicine accessible to everyone.

What are the current dynamics shaping the generics and biosimilars market in Italy, a country that has a particular history regarding patent protection for medicines?

According to the latest reporting, our members account for 22.5 percent of the entire market. Our industry is quite different from that in other European countries because, when the generics industry started in Italy in 2001, we faced not only originator medicines but also multinational

companies that had co-marketing agreements with Italian organisations and copy products; medicines introduced to the market before the introduction of patent protection in 1978.

Italy has an off-patent market where most of the medicines in the retail and hospital segments do not have patent protection. The main difference between both segments is that 60 percent of the volume in the hospital setting is made up of off patent medicine but they account for only eight percent of their expenditure. The small percentage of innovative in-patent medicines account for 92 percent of hospital expenditure.

You mentioned that Italy's pricing and reimbursement scheme was changed recently. What is Egualia's position on the developments and what should our readers know about them?

The government launched a new pricing and reimbursement scheme for medicines which has been challenged by both Farmindustria and Egualia. On one hand, there is a balance in the market because the medicines agency simplified many administrative processes. However, resources available for pharmaceutical expenditure are not enough; Italy is spending 19 percent less than other European countries.

In addition, we have a payback system that forces companies to give money back if the ceiling of the public budget is crossed. The two elements I just outlined are putting the long-term sustainability of the system in question.

If we take off-patent medicines sold through tenders as an example, companies offer products at the lowest price possible while navigating a challenging process and can be asked to pay back at the end of the year. Because of that, many companies are avoiding many tender opportunities. Egualia is advocating for more resources to be allocated for pharmaceutical expenditure and for paybacks are avoided whenever possible.

How can data extracted from electronic clinical records help address the challenges you just outlined?

Italy has one of the largest eldercare databases in the world. With a vast amount of data, the Italian government can analyse and make better decisions, but they must invest more regardless. There are misconceptions about the industry's role, our members are only meeting the demand

coming from the healthcare system and patients.

That being said, we have made progress with the new government. As partners, we should reconsider the budget ceiling for the hospital and retail segments in order to better respond to patient needs, taking advantage of big data. The procurement system should consider awarding tenders to more than one company, and not focus on just the lowest price which creates a race to the bottom and results in shortages.

Are biosimilars facing a similar situation?

For biosimilars, we have regulation in place that is imposing multi-winner tenders when there are more than three competitors. In terms of penetration, we are the first country in Europe and a success story. With high competition on price, no shortages and good penetration, the system is working. The question of sustainability is also present for biosimilars but, at least for the moment, the system is working.

Is there a final message you would like to send on behalf of Egualia and its members to our international audience?

The fundamental goal of Egualia is to federate the entire off patent industry in the country. The pandemic showed us the importance of putting patients at the centre, but we must ensure that they continue having access to medicines. If we all aim in that direction, the public-private partnerships created during the pandemic will endure, benefiting patients. The value chain is fragile and not easy to manage, but we are strong enough.

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