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16.02.2022

Tags: Spain, Generics, AESEG, Association, Coronavirus, Manufacturing, Supply Chain

Ángel Luis Rodríguez de la Cuerda, longtime secretary general of AESEG, the trade association of generic producers in Spain, comments on the key role played by generic medicines during the COVID-19 pandemic and the importance of new investment to increase Spain's generic production capabilities. In addition, he outlines specific policy changes that could expand patient access and create significant savings for the public health system.

Given that generic medicines were a key weapon in the fight against COVID-19, particularly during the first wave of the pandemic, can you share the role that AESEG and its members have played in the past 20 months?

The pandemic has had a devastating effect that no one foresaw. The main objective of AESEG and its members has been to collaborate closely with the government in ensuring the supply of medicines both for COVID-19 patients and for other pathologies and ailments, always guaranteeing the safety of workers.

To this end, different measures were taken in coordination with authorities, including the Ministry of Health (MoH), the Spanish Agency for Medicines and Health Products (AEMPS), the Ministry of Industry, the General Directorate of Customs, and other health institutions.

Since the beginning of the pandemic, generic drug laboratories have been working at full capacity to guarantee the production and supply of drugs to all hospitals and pharmacies in the country, multiplying production by ten for some essential products used in ICUs (cisatracurium besilate, propofol, midazolam, fentanyl, chloroquine, and hydroxychloroquine, among others), and hospitals, where 70 percent of total products declared by AEMPS were generics, demonstrating their commitment and production capacity at a time when shortages were affecting countries worldwide… The first wave of COVID-19 was mainly treated with off-patent drugs.

Moreover, generic drug companies are participating in clinical research around repurposing existing medicines for the treatment of COVID-19s and have contributed through donations to supply healthcare professionals with protective equipment.

To what extent did the pandemic improve the standing of the generics industry in Spain and how can your members capitalise on the opportunity it has presented?

The COVID-19 pandemic revealed that the country in the best position is the one that has the most manufacturing plants and, within Europe, Spain and Italy are the two leading producers of generic medicines. The country has learned that it needs to bet on and promote Spanish production to avoid being dependent on third countries, which will guarantee security of supply for the population while boosting the economy.

Fortunately, after 22 years of investment and industrial focus on the sector, we have a magnificent industrial platform; today, 70 percent of generic drugs consumed in Spain are manufactured in the country. Given that there is a strong commitment from the industry, and large opportunities in the market, it is imperative that significant stimuli and incentives are offered by the public sector.

In that regard, AESEG is advocating for the elimination of “exclusivity” measures such as auctions or other restrictive rules, an increase of the national healthcare budget to meet new health and socioeconomic needs, and the inclusion of minimum profitability thresholds that guarantee that pharmaceutical companies continue to bet on the development and launch of generic drugs.

The pandemic crisis has created an opportunity for our sector, and we must use common sense, building a future together with innovative pharma companies because both industries complement each other in a way that benefits the entire population. Many already believe this to be true, but we must continue working in that direction.

AESEG is advocating for increased investment in the local production of generic medicines, but are you concerned that this might have a negative impact on the price of those products?

To fully appreciate the value of having a strong generics manufacturing base, the country must implement pharmaceutical policies in which price is not the only criteria used when evaluating medicines. Do we want to have a very low price but depend on third countries for supply, or have a reasonable price, the certainty that patients will not experience shortages during emergencies, and a larger industry that will boost economic output and jobs? For us, the answer is clear.

At a European level, there is important work being done in this regard, such as the Strategic Plan for Pharmaceutical Policy led by Dolors Montserrat. The European plan has five pillars: an update of pharmaceutical policies that put patients at the centre, boosting R&D investment for pharma products, new measures to guarantee the sustainability of the health system – which positions generics as a crucial sector –, incentives to increase industrial investment in laboratories with a manufacturing plant in the European Union, and focusing on diseases that do not have alternative treatments.

From a regulatory standpoint, institutions across all member countries must collaborate, sharing data and best practices.

AESEG and its members are in a great position to help Spain become a leader in at least two of the five European priorities, guaranteeing the sustainability of the system and increasing industrial investment.

What is the message you try to communicate to the Spanish authorities about the value of generic medicines for the healthcare system?

Generic medicines play a fundamental role for the healthcare system because they introduce competition to the market, resulting in lower prices and helping to regulate prices. The decrease in pharmaceutical prices translates into savings for taxpayers, which are projected to be around EUR 1 billion per year. The money saved through generics can make space for innovative products and better health infrastructure.

From the patient’s point of view, generic medicines increase access to treatment simply because they cost less. The average price of generics in Spain is EUR 1.60. To illustrate the value of generic medicines for Spanish patients, let’s use the case of omeprazole, which had a price of EUR 36 per

box twenty years ago, and today costs EUR 2. Fortunately, the population is very welcoming of generics, understanding their value and safety after years of educational campaigns; eight out of ten Spanish patients trust generics.

In terms of pricing policies, are there any accomplishments by AESEG that you would like to highlight?

Prices of prescription drugs are fixed by the Spanish Ministry of Health, which decides the price and whether it is reimbursed by the public system; according to the country's current regulations, generic medicines must be launched with at least a 40 percent discount from the originator drug.

Any company looking gain reimbursement for a pharma product must present a dossier to the Interministerial Commission on Drug Prices (CIMP) – which includes members from different ministries and autonomous communities – which evaluates and decides whether a product will be reimbursed by the National Health System (SNS) and sets its price.

However, years ago, we put forward the idea that it was unnecessary for generic medicines to go through that procedure if they complied with the mandatory 40 percent discount.

The CIMP agreed and waived generic medicines from that process as long as the price was 40 percent lower that the originator. It was an important win for the industry and patients.

However, a challenge remains since, after a price has been set by the CIMP, medicines must go through a reference price system that gradually results in price erosion. Reference prices are revised each year, but the MoH often asks for price cuts to newcomers which, if accepted, result in a decrease of price for everyone. AESEG is asking the MoH to maintain the price for at least one year for companies to have a predictable business and legal security.

Looking at recent data, the penetration of generic drugs in terms of units has remained at 40 percent for the last the last five years. How do you explain the situation and which measures is the association advocating for to increase the uptake of generics?

Generics penetration has stagnated for the last five years due to an outdated reference price system, an increase in production costs, and a lack of specific regulations that differentiate generics from originator medicines. Generics account for 40 percent of the total prescription drugs market in terms of units, not even half of the potential market and far from the 65 percent average

in the European Union.

Reflecting on the last two decades, it is true that the penetration rate of generics has improved greatly, and has almost tripled in the last 13 years, but, taking a closer look, we observe that the success of generics coincided with the 2007-2008 financial crisis, a time when the government was very interested in lowering prices. Many new regulations were introduced, including one that required pharmacists to dispense generic drugs when the price was identical to the originators. Additionally, doctors received incentives for prescribing generics and pharmacists obtained better margins on these products, higher than the usual 27 percent. Finally, generics enjoyed months of price advantage because the reference price basket was not formed until the generic molecule had been available in the market for one year. This last rule was later eliminated, forcing originator products to match the price of generics from the start. Originator companies did not necessarily benefit from this measure since lowering their price for the public system had repercussions in the private system.

AESEG is advocating for better regulations that differentiate between patent and off-patent medicines because the industries behind them are in different positions and add value in different manners. If we compare Spain to neighbouring countries such as Portugal, France, Greece or Italy, we observe that all of them have begun to establish policies that incentivise the use of generic drugs, both through “traditional” measures – prescription by active principle, incentive programs for prescribers, allowing drug substitution or educational campaigns – as well as more innovative measures such as partial reimbursement of non-generic drugs or other economic incentives.

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