Interview: Ã•ngel Luis RodrÃguez de la Cuerda â?? Secretary General, AESEG, Spain

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Ã•ngel Luis RodrÃguez de la Cuerda, secretary general of AESEG, the trade association of generic producers in Spain, discusses the initiatives that the organization is undertaking to develop a true generic culture in the country and a new proposal changing the requirement for

originator drugs to remain at the same price as generics when the patent expires.

Could you please share with our international audience the full picture of the Spanish generic sector?

The penetration of generic drugs in Spain is still far away from the European average, which is around 65 percent in terms of volume. Generic drugs contribute to considerable savings and effectively reduce the cost of medicines by between 40 to 70 percent. In terms of numbers, in Spain, the generic medicines market represented 20 percent of the total pharmaceutical market in value and 40 percent in volume over the past year. Overall, compared to other EU countries that have a less conservative approach to generic drugs, the segment grew much slower in the last 20 years. This is primarily due to the facts that Spain was one of the last countries to introduce generics as well as legislation which requires originator drugs to remain at the same price as generics when the patent expires.

Right after the financial crisis, the 17 autonomous regions of Spain started to consider generic drugs as a precious tool to save money and were, as a result, very generic-receptive. However, in 2014, 2015 and 2016 the penetration of generics stabilized at 40 percent of the total market in units.

The importance of generics is two-fold. Firstly, they help create a sustainable healthcare system by alleviating costs to the state to the tune of around EUR one billion per year in Spain. Secondly, from a value point of view, greater generic drug penetration drastically increases patientsâ?? access to medicines. For instance, the cost of treating one patient with the simvastatine brand â?? which was launched 15 years ago â?? 23 additional patients could be treated in Spain with the generic equivalent. This clearly shows the fundamental importance of generics within the industry. At the moment, eight out of ten patients in Spain consider generics a valuable alternative to branded products.

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How receptive are the authorities to generics and what initiatives are you currently engaged in to promote generic drugs?

In our opinion, the reason why the generic segment stabilized over the last few years is because the current health administration is giving special focus on ways to finance innovative drugs, control hospital expenses, and introduce biosimilars and orphan drugs, rather than prioritizing generics.

AESEG has developed proposals with a dual objective: first, to make the Pharmaceutical Generic Equivalent (EFG) constitute a useful mechanism to control pharmaceutical expenses at a structural level and, at the same time, to develop a true generic medicine culture in our country. Furthermore, we organized an advisory board last year with the help of scientific physicians pharmaceutical and patientsâ?? councils and societies, industry officials, and members of the Congress and Senate in order to obtain a consensus to discuss the importance of generics in building a sustainable healthcare system. The proposal included, among other things, price differentiation between the originator and the generic drug as a way to maintain fair competitiveness as, at the moment, given the new bill on price equality approved in 2016, it is not yet the case. In fact, as soon as the patent of a branded product expires, it is mandatory by law to equalize the price to its generic version. Right now, the international non-proprietary name (INN) prescription is recommended by law and very well accepted by patients. To increase INN prescriptions is a useful tool to increase generics dispensation in pharmacies.

To this purpose, together with Medicines for Europe, AESEG would like to propose a â??National Plan for Generic Medicinesâ??. Could you please expand on this plan?

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We pulled together various suggestions, but it is true that we are giving special emphasis on this price differentiation bill because we are the only pharmaceutical market in Europe where the generic and the originator are required to be at the same price. We consider this to be a great disadvantage for our industry as well as an imperfection of the system. For this reason, we think that the best way to go about it is to have a price difference again. We understand that even originator brands could be interested because not all are happy to have to lower the price from the first day of the patent expiration and go to the private market with a low price.

Increasing INN prescriptions in tandem with greater generics dispensation and more alignment among Spainâ??s 17 regions would also be useful for the development of generics. In Andalusia for example, pharmaceutical companies joining the tender system often have less than two percent of the market share, which leads to uncertainty of supply and eventually a serious risk of medicine shortages.

Many governments around the world are ruling to differentiate generics and biosimilars as they prepare for the new wave of biologics in healthcare. What advancement has Spain made

in this regard?

About three years ago BioSim, the Spanish Association of Biosimilars, was founded, which welcomes and represents all the pharmaceutical companies established in Spain that research, develop, manufacture and commercialize biosimilar medicines. BioSim opens its doors to laboratories that are already operating in the biosimilar market and to original product companies that have set up, or are going to launch, a biosimilar division; be it for development, production or commercialization. Biosimilars introduction and development is being followed with great interest by Spainâ??s health administration, stakeholders, and patients.

As the head of the association what are your strategic priorities in the next four to five years?

We are currently in negotiations with the Ministry of Health and Ministry of Economy to obtain a special agreement to reinforce and boost the generic industry in Spain. On this line, the Spanish administration recently announced that the Ministry of Health, in coordination with other departments, is preparing a national strategy which will be able to reinforce the penetration of these essential drugs in Spain for the sake of the sustainability of the National Health System (SNS). If such law is put in place, we are willing to reward those autonomous regions who are more proactive in promoting the greater uptake of generics. It is a win-win situation.

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