GaBI Educational Workshops

20 January 2015, Sheraton Mexico City, Mexico

# First Latin American Educational Workshop on Similar Biotherapeutic Products – **regulatory approval, pharmacovigilance, and risk management**

## Welcoming remarks by Mikel Arriola Peñalosa, JP, MPP
## Federal Commissioner, COFEPRIS, Department of Health, Mexico

Good morning, ladies and gentlemen,

I want to first thank all of you for inviting me. Good morning. It is a great pleasure to greet Professor Philip D Wilson, Editor-in-chief of Generics and Biosimilars Initiative Journal, Dr Robin Thorp, Deputy Editor-in-chief of this journal, as well as all our dear friends that I see today, that are experts on the topics that we are going to be talking about today. But I would also like to say that for me it's a great joy that the first Latin American Educational Workshop on Similar Biotherapeutic products is being held in Mexico. I am going to use these five minutes to give you some very clear numbers regarding the efforts Mexico has made in these two areas.

As you know the pharmaceutical policies of the Mexican Federal Government follow a main premise. The premise is that our legal framework must be focused on our consumers, and this means that the users must have access to a wide variety of innovative products including generic drug products and biosimilars and of course this access must include the best prices and the best quality. Our pharmaceutical policies are based on four fundamental premises.

Firstly, we need to have certainty in the quality and efficiency of the supplies, that is our main mandate, and this mandate is what motivates us to go forward on a daily basis. Secondly, to be efficient in our mission of medicines registrations we know that safety, quality and efficacy are not isolated from efficiency. The consumer, the Mexican consumer, needs to have a transparent agency that can translate this into economic benefits. We know that our public and private healthcare expenses still have very large margins, and these can be reduced; and we are working on that. Thirdly, we must align our regulations with the best international practices. And fourth, we must eliminate the many barriers to entrance of pharmaceutical products. We have been eliminating these many barriers gradually.

One of the most successful policies in pharmaceuticals in our country is called the "Policy of generics" that was designed so that Mexican families can save money. The policy of generics in our country began in a very important way with the new legal framework and the reform that our Congress created in 2005 when they stated that there could only be two types of drugs in our market: innovative ones and generics. But the generics would test bioequivalence. This gave Mexico a stamp of distinction compared to the great majority of the countries in Latin America. Mexico only defines two types of drugs. In 2011, taking advantage of the renovation of all the medicines in Mexico we followed this strategy to focus generics on the 75 or 80 per cent of the causes for mortality in our country, meaning chronic degenerative diseases. I'm covering about this very quickly, but we are talking about what has happened in three and a half years.

In October 2011, Mexico became the country with the largest number of generics in a given amount of time. We have 240 registrations of different generic medicines. We have treated millions of cases, and the prices in Mexico have gone down 60 per cent. The per capita savings is of 1,000 pesos. We are talking about 32 active substances that were monopolized in 2011 that have now become 340 health registries. That means that Mexico is the leading country with respect to this policy of penetration. So, in terms of units, we went from 51 per cent to 85 per cent and in invoicing we have gone from 30 per cent to 54 per cent. This means that today Mexico is the leading country in terms of market penetration of generics. This is evidence that our generic strategies work well to reduce prices to treat the effects of the three main diseases that affect Mexicans and other people in the developed world. The greatest savings have been in the treatment of cardio-vascular diseases, cancer and diabetes, where in Mexico prices have been reduced by 90 per cent.

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The second topic is biosimilars. Mexico reformed its law in 2009 to incorporate biotechnological medicine into our legal framework. As most of you know we generated relevant reforms to be able to bring biologicals into the Mexican market. One specific element created registries for biosimilars that were awarded marketing approval before the reform and these products were given more relaxed requirements compared to the products considered after the reform. On 11 December 2014, Mexico issued Standard 257 to resolve the problems of biosimilars and innovator products. So, what did Mexico do? Mexico proposed a transitional framework so that biosimilars that were already in the market could present clinical studies within a certain limited period, but that after that period, by next year (2016), in Mexico we will no longer have approved biosimilars without clinical studies. We now have the reference medicines as an example of the clinical studies that must take place. But we are not asking that the biosimilars have the same efforts in terms of research as do the original products. In summary, Mexico has added a request for new molecules. COFEPRIS received 35 per cent of biosimilar molecules or biotechnological ones based on this reform and after this reform we have already been able to approve 26 innovative drugs or biosimilars and the executive policy is to increase the value of the portfolio of the drugs that is available for Mexicans: with the generic medicines, with biocomparable medicines or with innovative ones but at better prices. We have increased the supply of new molecules in Mexico from 2011 up to now, by 4,500 per cent. We went from three to 133 new molecules, and this will be up to 150 this year. So, I want to emphasize that the policies in Mexico have been successful. We have been able to increase the quality of the portfolio but to reduce the prices like no other country in the world. We have been able to offer the consumers and patients the attention required by the main purpose of all our legal framework. So, I leave these reflections on the table so that you can criticise and debate them, but today Mexico knows where it's going in terms of pharmaceutical policies and that it has changed the availability profile for the consumers in the last three or four years. Thank you very much and have a wonderful day.

to the physicians to make sure they will be convinced enough in moving towards using Biosimilar products.

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