GaBI Educational Workshops

1 September 2015, Dubai, United Arab Emirates

First MENA Educational Workshop on **Similar Biotherapeutic Products/Biosimilars**

Welcoming remarks by H E Dr Amin Hussein Al Amiri, Assistant Undersecretary of Public Health Policy and Licensing, MOH, UAE

Good morning, Ladies and Gentlemen,

Good morning, Ladies and Gentlemen, it is our pleasure to be here with you, joining the workshop, discussing the biosimilar usage. I think it is an emerging product, which will be in the market swing, strongly more than what is there for the time being. We at the United Arab Emirates (UAE) always so keen in supporting such workshops, scientific events, and we at the MoH (Ministry of Health) are so delighted that this workshop is being organised in the UAE, specifically Dubai. As you know, biosimilar is the product which is similar to the existing biopharmaceutical products, either it is not completely identical, or is very similar to what is available, and there are many guidelines which have been adopted either by the European Medicines Agency (EMA) , US Food and Drug Administration (FDA) or health organizations by different places. Despite the GCC (Gulf Cooperation Council) guidelines there is the registration and acceptance of the biosimilar products in our countries. Although there is a sort of reluctance or hesitation from physicians to use biosimilar products, and we cannot blame them because for the time being physicians are not entitled to understand the similarity between the biosimilar products and the existing biopharmaceutical products, and therefore I think it is your role as regulatory managers, and the Ministry of Health of the regions to make sure that the proper information and the guidelines will be forwarded to the physicians to make sure they will be convinced enough in moving towards using Biosimilar products.

We as a Ministry of Health have close to 8,000 products registered with different types of classifications, conventional, herbal, biosimilar and biologicals. Despite that we have close to 452 biosimilar products now registered in the UAE, for more than five years we have been so keen to introduce such products here at the UAE depending on the guidelines adopted or released by the EMA and the FDA. We are always so keen to manage the execution office of the GCC for the Gulf Corporation Countries, and also benefiting from the guidelines which have been released by them, but we are always so impulsive, keen and supporting the International pharmaceutical companies, which thanks to the them we have above 95% of the regional offices based here in the UAE. To support the fast track registration products whether it is biopharmaceutical products or biosimilars and therefore Emirates, speaking on behalf of the best media for the international and regional pharmaceutical companies in registering their products with us. For us as the Ministry of Health and for UAE it is very important to host and organize such workshops here at the Emirates in having participants from different countries, and as you from the organizing committee, that we have members from Gulf state countries, from some of the Arab countries, and we have speakers from the US and some other countries in which they will be able to enforce and enhance the scientific programme of this workshop, but my request from you as a participant and also as the speakers to have a strong interaction and to benefit from your experiences, and the experience from the countries in which they have a vast experience in dealing with the biosimilar products and to make sure that our region not only the Gulf state countries, but also the Middle East and North Africa region (MENA) region to be host for having or registering biosimilar products in our countries and to make sure that our needy patients are helped. It is our responsibility to help and support them, and that we will be able to provide them with the best product specially taking into consideration that many biopharmaceutical products are expired or nearly to be expired, and the biosimilar is a time or emerging to come into the market although it will be more equal. It is our responsibility as the government that the product to be provided to the patients, and at acceptable prices to the different level of people living in our countries, and to have access to such products without any sort of problems. Taking into consideration the countries that are going behind medical tourism, their responsibility is to reduce the cost and to increase the access to the Health Care Services, including the pharmaceutical products.

Ladies and gentlemen, I do not want to take much from your time and I will close here and wish you all the best not only benefiting from this workshop, and to benefit from the experiences, which will be given to you or already given to you yesterday from eminent guest speakers, which have been invited for this workshop. So I wish you all the best and your stay in this beautiful city, Dubai, and our beautiful country United Arab Emirates, which is a country of inspiration and innovation, and a country of science and knowledge and therefore we welcome you all here. We wish you all the best and a fruitful stay in Dubai, and make sure that you will be able to visit some places in Dubai and UAE, and I'm sure you will enjoy it.

Thank you very much and I wish you all the best