Junio 15 de 2015

Dr. Ruben Dario Espinoza

Director – DIGEMID

Dear Dr. Espinoza,

I am writing on behalf of the Latin American Federation of Pharmaceutical Industry (FIFARMA), a regional organization which was created on August 4th,1962, and represents 10 Research and Development Pharmaceutical Companies and 7 local Trade Associations across the Latin American region. FIFARMA members are involved in the research and development of innovative healthcare products, and provide state of the art healthcare solutions through a variety of products and services aimed to improve and save patients' lives across the globe, placing patient safety as one of our main objectives. In this effort to improve global health, FIFARMA works closely with intergovernmental bodies, nongovernmental organizations, Latin American health authorities and civil society organizations among others.

FIFARMA would like to acknowledge DIGEMID and the Peruvian Ministry of Health for the preparation of the biologics and biosimilars regulation. The Ministerial Resolution Nro. 180 & 181-2015/MINSA is setting clear standards and requirements for registration of these products according to current scientific advances. Both regulations are well elaborated, comply with regional as well as international standards, and promote access to products that are affordable, safe, efficacious and of quality. We welcome the public consultation process for the draft guidelines that the Peruvian Ministry of Health has initiated.

In that context FIFARMA would like to offer some important considerations regarding patient's safety. The Peruvian draft regulation is largely aligned with the current World Health Organization Guidance on Scientific Principles for Regulatory Assessment of Biotherapeutic Products draft (WHO/RRA BT_DRAFT/10 December 2014). With respect to the risk assessment proposed for products already approved under Decreto Supremo 010-97-SA, FIFARMA wants to highlight the important work of the Peruvian the authorities in considering the potential risk presented by those products which may not have performed biosimilarity studies according to the proposed guidance.

Concerning products pending approval we would like to suggest the addition of a process under the paragraph "ADDITIONAL TRANSITIONAL PROVISIONS" that will address those biologic products currently submitted to Digemid, and/or under Digemid's evaluation. By this process the sponsor of the submission should be required to submit all necessary quality-, pre-clinical- and clinical biosimilarity data in accordance with the requirements set out in the WHO Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs) published already in 2009, well known to all manufacturers of biologics and globally accepted. Without compliance to the data requirements outlined in the WHO document approval should not be granted.

Along the same lines, we also would like to suggest the development of specific technical guidance covering the immunogenicity assessment of biologics including biosimilars. Issuance of such guidance by

Digemid could be an implementation activity separate from the approval of the resolutions. Immunogenicity is one of the key safety concerns specific for biotherapeutics and can only be addressed by clinical assessments. While the current draft Ministerial Resolution Nro. 180 & 181-2015/MINSA is certainly mentioning the need of immunogenicity data for the approval of biologics and biosimilars, referencing guidelines internationally available, it is lacking the details. Having a separate guidance document in place on that specific topic would further strengthen the resolutions and may be also important to guide manufacturers through both the approval of new products as well as the risk assessment to be performed for product already approved. FIFARMA believes that properly performed immunogenicity testing is necessary to avoid putting patients at risk of adverse effects from immunogenic reactions, and to ensure that the risks for developing immunogenicity are within the expected rate in any given patient regardless of the chosen therapeutic alternative.

Additionally, FIFARMA would like Digemid to take into account the thorough evaluation and assessment of the list of reference NRAs in order to ensure only high vigilance Health Authorities are considered. Ideally the list should be made publicly available.

FIFARMA encourages Digemid to take the necessary steps towards the prompt completion and publication of this Ministerial Resolution. Herewith we also would like to offer our expertise and experience in resolving some of the issues identified, in the future development of additional guidance documents and during the implementation process. Should you require any additional information please do not hesitate to contact us.

Respectfully submitted,

Luis Villalba

FIFARMA Executive Director