Welcome to CMC Forum Virtual Session Latin America 2019

On behalf of the CASSS Board of Directors and the CMC Strategy Forum Global Steering Committee, I would like to extend to you a warm welcome to the 1st Virtual Session of the CMC Forum Virtual Session Latin America 2019 that will be held December 3, 2019. We are very pleased to have the support and participation from ANVISA-National Health Surveillance Agency, as well as participation from Health Canada, FIFARMA-Federacion Latinoamericana de la Industria Farmaceutica and SINDUSFARMA-Syndicate of Pharmaceutical Products in São Paulo.

The Virtual Session “Regulations for Post Approval Changes of Biotherapeutics - Global Developments and Opportunities for the Region” will follow the established model for the technical sessions at the CASSS CMC Forum series including presentations from regulators and industry about issues, solutions and available regulations around post approval changes followed with room for discussion and answering the questions of participants.

We would like to thank the speakers and the panel members who are giving generously of their time and resources and to you for your attendance. The success of the CMC Strategy Forum Latin America will depend on your active participation in discussing and raising issues pertaining to the development of biologics. We encourage you to participate whole-heartedly in the panel discussions that have been designed to stimulate exchange of ideas and information.
08:00 – 08:10  Why We Need Effective LCM Regulatory Systems Now and Even More in the Future – An Introduction  
Thomas Schreitmüller, *F. Hoffmann-La Roche Ltd., Switzerland* (representing *FIFARMA*)

08:10 – 08:25  The WHO Guidelines on Procedures and Data Requirements for Changes to Approved Biotherapeutic Products: Evaluation Principles in the New Guidelines (Main Body)  
Hugo Hamel, *Health Canada, Canada*

08:25 – 08:40  The WHO Guidelines on Procedures and Data Requirements for Changes to Approved Biotherapeutic Products: How to Use WHO Guidelines on Post-approval Changes (Appendices)  
Hugo Hamel, *Health Canada, Canada*

08:40 – 08:55  Reviewing Process of the Stability and Post-approval Change Regulations for Biological Products in Brasil  
Carolina Damas Rocha Zarate Blades, *ANVISA-Brazilian National Health Surveillance Agency, Brasil*

08:55 – 09:10  Case Study: How Can We Use the WHO Guidelines on Procedures and Data Requirements for Changes to Approved Biotherapeutic Products in Real-life Examples?  
Maria Cristina Mota Pina, *AbbVie, Inc., USA*

09:10 – 09:30  Panel Discussion – Questions and Answers  
Carolina Damas Rocha Zarate Blades, *ANVISA-Brazilian National Health Surveillance Agency, Brasil*  
Hugo Hamel, *Health Canada, Canada*  
Maria Cristina Mota Pina, *AbbVie, Inc., USA*  
Thomas Schreitmüller, *F. Hoffmann-La Roche Ltd., Switzerland* (representing *FIFARMA*)
Presenter’s Abstracts

Why We Need Effective LCM Regulatory Systems Now and Even More in the Future – An Introduction

Thomas Schreitmüller

F. Hoffmann-La Roche Ltd., Switzerland (representing FIFARMA)

NOTES:
The WHO Guidelines on Procedures and Data Requirements for Changes to Approved Biotherapeutic Products: Evaluation Principles in the New Guidelines (Main Body)

To be presented by Hugo Hamel, Health Canada, Canada

Biotherapeutic products are an increasingly important component of global health care and several WHO guidelines on the regulatory evaluation of these products are available. During international consultations on the development of these WHO guidelines, and also during their implementation, it became clear that there was also a need to develop WHO guidelines for changes to approved biotherapeutic products in order to help address complexity and other challenges associated with the global life cycle management of such products.

In 2014, the 67th World Health Assembly adopted two relevant resolutions: one on promoting access to biotherapeutic products and ensuring their quality, safety and efficacy and the other on regulatory systems strengthening. In support of these resolutions, WHO was requested to provide guidance on how to deal with increasingly complex biotherapeutic products, including similar biotherapeutic products (SBPs). In addition, the 16th International Conference of Drug Regulatory Authorities (ICDRA) recommended that WHO assist Member States in ensuring regulatory oversight throughout the life-cycle of biotherapeutic products.

Manufacturing processes are often altered after regulatory approval and medicines can undergo changes during their product lifecycle. Changes are essential for the continual improvement of the manufacturing process and for maintaining state-of-the-art controls of biotherapeutic products, and often need to be implemented after the product has been approved. The WHO guidelines on procedures and data requirements for changes to approved biotherapeutic products were developed to provide guidance to national regulatory authorities (NRAs) and manufacturers on regulating changes to already licensed biotherapeutic products, including biosimilars, in order to assure their continued quality, safety and efficacy, as well as continuity in supply and access. The guidelines were the result of three rounds of international consultations and one informal consultation in 2016 – 2017 and adopted by the WHO Expert Committee on Biological Standardization (ECBS) in Oct 2017. The guidelines note that implementation of new regulations should not affect product supply and access to products. Therefore, NRAs are strongly encouraged to establish requirements that are commensurate with their own regulatory capacity, experience and resources and to apply the concepts of reliance or work sharing or to use collaborative approaches when reviewing post-approval changes. NRAs of countries procuring products are encouraged to consider establishing procedures for the expedited approval of changes based on previous expert review and approval of the same changes by the NRAs of the countries where these products are licensed or based on the decision of a recognized regional regulatory authority.

NOTES:
The WHO Guidelines on Procedures and Data Requirements for Changes to Approved Biotherapeutic Products: How to Use WHO Guidelines on Post-approval Changes (Appendices)

Hugo Hamel

Health Canada, Canada

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While the previous talk focuses on the evaluation principles written in the main body of the guidelines, this presentation will provide an overview on how to use the WHO post-approval changes guidelines with specific examples taken from Appendix 2 and Appendix 3.

NOTES:
Reviewing Process of the Stability and Post-approval Change Regulations for Biological Products in Brasil

Carolina Damas Rocha Zarate Blades

ANVISA-Brazilian National Health Surveillance Agency, Brasil

In 2018, the Office of Biological Products started the discussions for the review of the regulatory requirements for stability (Resolution 50/2011) and post-registration of biological products (Resolution 49/2011). One of the objectives of this review process is to seek the harmonization of Anvisa’s legal framework with ICH, WHO and other international guidelines.

Regarding the Resolution on Stability the reference guideline is the Q5C ICH and our main objective is to update the procedures and conditions for conducting stability studies of biological products.

For the Resolution on post-registration, the draft is being prepared using as main references the following documents:

- WHO: Guidelines on procedures and data requirements for changes to approved biotherapeutic products (2017);
- WHO: Guidelines on procedures and data requirements for changes to approved vaccines (2015);

Our goal is moving towards more efficient regulatory systems, promoting access to biological products with quality, safety and efficacy throughout their life cycle, taking into consideration the Brazilian context.

NOTES:
Case Study: How Can We Use the WHO Guidelines on Procedures and Data Requirements for Changes to Approved Biotherapeutic Products in Real-life Examples?

Maria Cristina Mota Pina

*AbbVie, Inc., USA*

This presentation will focus in the applicability of the guideline using a case study for a complex post approval change. Post-approval changes are part of the life cycle of a product. The case study exemplifies a post-approval change and will assess how the WHO guideline can support the industry when assessing changes, using ICH-CTD nomenclature.

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