



Challenges in Evaluating Similar Biotherapeutic Products

Saturday 27th November, 2010 – Suntec City, Singapore

(version Sept. 24, 2010)

Invitation to IABS, IFPMA and EGA* Workshop on Biologicals: Challenges in Evaluating Similar Biotherapeutic Products Saturday 27th November, 2010 – Suntec City, Singapore

Please register at: www.ifpma.org/IABS-2010-Singapore

Workshop Vision:

- To provide a forum where regulators, industries and other experts from around the world discuss and learn complexities in developing, evaluating and using biosimilars.

Workshop Objectives:

- To provide an overview of regulatory models for evaluating similar biotherapeutic products that are currently in place, or under development: perspectives of regulatory authorities, industry and academic clinicians
- To discuss the quality, safety and efficacy factors that need to be considered to ensure patient safety when registering similar biotherapeutic products
- To discuss complexities in evaluating quality, safety and efficacy of biologicals in general to ensure patient safety

Workshop Venue:

Suntec Singapore
International Convention & Exhibition Centre
1 Raffles Boulevard Suntec City, Singapore 039593

Co-Chairs:

Dr Martina Weise : Head, Unit on Endocrinology/Diabetes, BfArM, Germany
Dr Sannie Chong SF: Acting Director, Health Science Authority, Singapore

Participants:

Maximum of 160 delegates, including WHO, regulators, academic clinicians, industry experts from IFPMA, EGA and local producers.

Registration fees:

Regulators – CHF 40
Academic clinicians – CHF 40
Industries - CHF 300

For more information, please contact:

IABS
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IFPMA
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EGA
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* EGA is the European Generic medicines Association which is the official representative body of the European generic and biosimilar pharmaceutical industry.



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Workshop Draft Program Saturday, November 27, 2010, Suntec City, Singapore		
Co-Chairs: Dr Martina Weise (BfArM, Germany) and Dr Sannie Chong (HSA, Singapore)		
Registration		07:30 – 08:30
Opening session:		08:30 – 09:15
Opening remarks by IABS (10 mins)	Elwyn Griffiths IABS & Health Canada, Canada	
Opening keynote lecture: Global regulatory landscape in evaluating biologicals, including biosimilars (35 mins)	Chris Holloway ERA Consulting, Germany	
Scientific principles used in regulatory approaches:		09:15 – 10:10
WHO Guidelines for evaluation of similar biotherapeutic products (25 mins)	Ivana Knezevick World Health Organization	
Quality attributes: how similar is similar enough? Challenges and lessons learned in the EU (25 mins)	Michael Pfeleiderer Paul-Ehrlich Institute, Germany	
Networking Refreshment Break 10:10 – 10:30		
Efficacy and safety assessment of biosimilars	Martina Weise BfArM, Germany	10:30 – 12:30
Challenges in implementing WHO guidelines for evaluation of similar biotherapeutic products – Singapore's perspective (25 mins)	Tam Kai Tong Health Science Authority, Singapore	
Discussions, questions and answers (65 mins)		
Lunch Break 12:30 – 13:45		
Perspective from industry in developing biologicals, including biosimilars:		13:45 – 15:30
Views on implementation of the WHO Guidelines for evaluation of similar biotherapeutic products (25 mins)	Martin Schiestl Sandoz, on behalf of EGA	
Challenges in developing biologicals (25 mins)	Anton Haselbeck Roche, on behalf of IFPMA	
Emerging country producer (25 mins)	TBD	
Discussions, questions and answers (30 mins)		
Refreshment Break 15:30 – 16:00		
Post authorization and future developments:		16:00 – 18:00
Importance of stringent regulations: Case studies from Thailand: (25 mins)	Kriang Tungsanga Chulalongkorn University, Thailand	
Pharmacovigilance, identification/traceability and risk management (25 mins)	TBD	
Current status of EU draft guideline on similar biological medicinal products containing monoclonal antibodies (25 mins)	Michael Pfeleiderer and Martina Weise	
Discussions (45 mins)		
Summary, next steps and closing remarks by co-chairs (15 min)		
Workshop reception (Suntec City) 19:00 – 23:00		