EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency (EMA)/ European Generic medicines Association (EGA)

Joint workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms

Programme

30 April 2015
European Medicines Agency, London, United Kingdom

Room 3A

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Objective of the workshop

EMA/EGA workshop is planned for 30 April 2015 to discuss impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms. It aims at fostering a common understanding and interpretation of regulatory expectations before 1 June 2015, when the guideline will come into effect.

Please register using the registration form provided.

The primary purpose of the EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms is to define the studies necessary to investigate the efficacy, safety, biopharmaceutic and pharmacokinetic properties of modified release formulations following oral, intramuscular and subcutaneous administration and transdermal dosage forms in man and to set out general principles for designing, conducting and evaluating such studies. It is important that the rationale behind regulatory requirements and that the regulatory expectations are clarified upfront for both regulators and applicants in order to foster a common interpretation by the date of entry into force of the guideline i.e., 1 June 2015.

Discuss practical implementation of the approaches to establish bioequivalence of modified release dosage forms.

Attendant profile: Clinical development, Regulatory, Biopharmaceutics, Formulation Development, Biostatistics, CRO.

Programme overview

Sessions

Session 1 Orally administered modified release products

Session 2 Injectable modified release products

Session 3 Transdermal products (PK + adhesion + irritation / sensitization)

Session 4 Line extension of immediate release products

Session 5 Questions & Answers

Organising Committee

List of speakers:

Jan Welink
Kevan Cassidy
Henrike Potthast
Yu Chung Tsang
Sotiris Michaleas
Gerald Beuerle
Jan Neuhauser
Bjoern Schurad
Alfredo García Arieta
Susana Almeida
Andrzej Dzierbicki
Beata Stepniewska
Enrica Alteri

EGA:

Koen Nauwelaerts
Julie Maréchal

EMA:

Falk Ehmann
Monica Simeoni

Programme details

08:30-09:00 **Registration**

Registration and badge collection at the reception on the ground floor. The workshop room is room 3A on the third floor

09:00-09:10 **Welcome and opening**

EMA: **Enrica Alteri**, Head of Medicines Evaluation Division, EMA

EGA: **Beata Stepniewska**, Deputy Director General and Head of Regulatory Affairs, EGA

Day Chairs

Jan Welink, Senior Clinical Assessor, Dutch Medicines Evaluation Board (MEB) and Chair Pharmacokinetic Working Party, European Medicines Agency (EMA)

Kevan Cassidy, Director and Owner Biokinetix Limited, Co-Chair EGA Bioequivalence working Group

09:10-11:00 **Session 1: Orally administered modified release products**

EMA: **Henrike Potthast**, Biopharmaceutic Expert/Scientist, Federal Institute for Drugs and Medical Devices (Germany)

EGA: **Gerald Beuerle**, Head of Clinical Development / Biopharmaceutics, ratiopharm

11:00-11:30 **Coffee break**

11:30-12:15 **Session 2: Injectable modified release products**

EMA: **Sotiris Michaleas**, Assistant Professor, European University (Cyprus)

EGA: **Yu Chung Tsang**, Chief Scientific Office, Biopharmaceutics & Biostatistics, Apotex Inc.

12:15-13:15 **Lunch**

13:15-14:45 **Session 3: Transdermal products (PK + adhesion + irritation / sensitization)**

EMA: **Jan Neuhauser**, Deputy Head of Department Clinical Assessment of Safety & Efficacymedical Assessor, AGES (Austria)

EGA: **Bjoern Schurad**, Head of Transdermal Development, Acino

14:45-15:00 **Coffee break**

15:00-16:00 Session 4: Line extension of immediate release products

Alfredo García Arieta, Head of Service on Pharmacokinetics and Generics of the Division of Pharmacology and Clinical Evaluation in the Spanish Agency for Medicines and Health Care Products

Andrzej Dzierbicki, Biopharmaceutics and Clinical Director, Polpharma

16:00-16:45 Session 5: Questions & answers

EMA: **Drafting Group**

EGA: **Susana Almeida**, Leader of Clinical/Non-clinical Projects Area, Tecnimede

16:45-17:00 Closing remarks