EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 September 2016
Corporate Stakeholders Department - SME Office

SME workshop: Focus on non-clinical aspects

03 October 2016
European Medicines Agency, London, United Kingdom

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Background and objectives

As part of its outreach activities, the SME office hosts educational workshops to increase the regulatory knowledge base of SMEs.

This training workshop will provide an overview of non-clinical data requirements for the authorisation of medicinal products, how to address these during the medicinal product development, and detail the approaches for biological and advanced therapy medicinal products. A regulatory brief on the new PRIME scheme is also included in the programme.

The workshop is open to companies that have been assigned SME status by the EMA and to representatives of stakeholder organisations.

Programme details

Monday, 03 October 2016

08.30 Registration & coffee

09:00 Welcome and introduction

Jan Willem van der Laan, Medicines Evaluation Board (MEB), Chair of SWP ***10'***

09:10 Session 1: Addressing non-clinical requirements during the medicinal product development

Regulatory compliance, how to shape a non-clinical development program and paediatric requirements

Milton Bonelli, Clinical Pharmacology & Non-Clinical Support, EMA ***25'***

Janina Karres, Paediatric Medicines, EMA ***20'***

Key aspects of non-clinical pharmacodynamics and pharmacokinetics in the evaluation of safety

David Jones, Medicines and Healthcare Products Regulatory Agency (MHRA), SWP ***35'***

Questions and discussion

Moderator: **Gabor Veres,** bluebird bio, Inc. ***20'***

Additional panellist: **Markku Pasanen**, University of Eastern Finland, SWP

10:50 Coffee break

11:10 Session 2: Focusing on non-clinical aspects of biological and advanced therapy medicinal products

Considerations for the development of biological medicinal products

Camilla Svensson, Medical Product Agency (MPA) ***40'***

Approaches to the non-clinical development of advanced therapy medicinal products

Fernando Méndez, Spanish Agency of Medicines and Medical Devices (AEMPS) ***40'***

Questions and discussion

Moderator: **Michaela Sharpe,** Cell and Gene Therapy Catapult ***20'***

12:50 Lunch break

14:00 Session 3: Overcoming specific non-clinical challenges of marketing authorisations for new chemical entities

Approaches to genotoxicity and carcinogenicity assessment

Peter Kasper, Federal Institute for Drugs and Medical Devices (BfArM), SWP ***35'***

Perspectives on reproductive performance and developmental toxicity assessment

Günter Waxenecker, Austrian Agency for Health and Food Safety (AGES), SWP ***35'***

Questions and discussion

Moderator: **Gabor Veres,** bluebird bio, Inc. ***20'***

15:30 Session 4: Priority medicines (PRIME) scheme

Regulatory brief on the new PRIME scheme

Zahra Hanaizi, Scientific & Regulatory Management, EMA ***30'***

Questions and discussion ***20'***

16:20 Closing remarks by workshop chair

Jan Willem van der Laan, Medicines Evaluation Board (MEB), Chair of SWP

List of speakers, panellists and moderators

David Jones	Medicines & Healthcare Products Regulatory Agency (MHRA), UK
Peter Kasper	Federal Institute for Drugs and Medical Devices (BfArM), Germany
Fernando Méndez	Spanish Agency of Medicines and Medical Devices (AEMPS), Spain
Markku Pasanen	University of Eastern Finland
Michaela Sharpe	Cell and Gene Therapy Catapult (SME)
Camilla Svensson	Medical Product Agency (MPA), Sweden
Gabor Veres	bluebird bio, Inc. (SME)
Jan Willem van der Laan	Medicines Evaluation Board (MEB), Netherlands
Günter Waxenecker	Austrian Agency for Health and Food Safety (AGES), Austria
Milton Bonelli	Clinical Pharmacology & Non-Clinical Support, EMA
Zahra Hanaizi	Scientific & Regulatory Management, EMA
Janina Karres	Paediatric Medicines, EMA

Practical information

Venue

The European Medicines Agency can be reached:

- **By Underground**
  The nearest stop for Churchill Place is Canary Wharf station on the Jubilee Line. From East exit (NB. This is the closest exit to 30 Churchill Place): exit the station and turn left into Upper Bank Street, turn right at Canada Square and continue straight into Churchill Place.

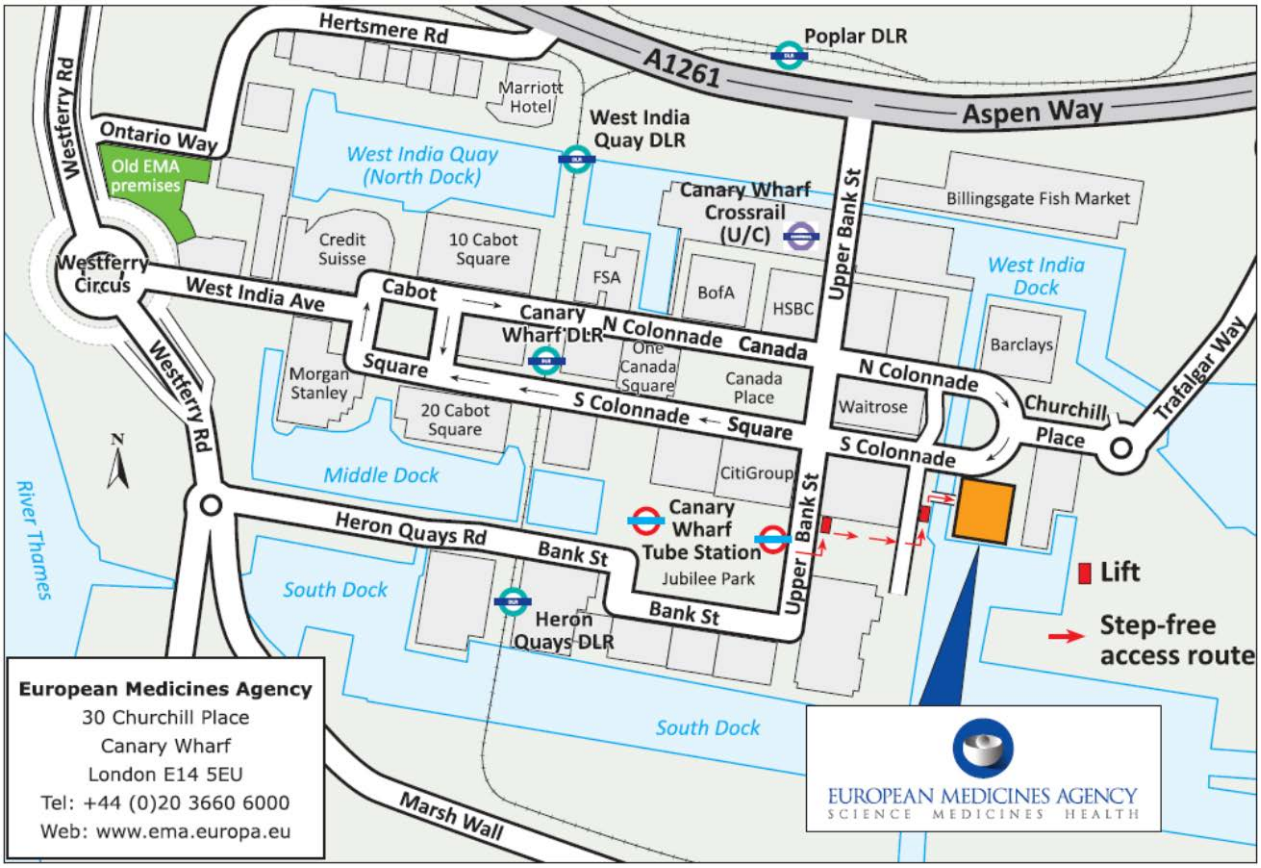
- **By Docklands Light Railway (DLR)**
  The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

- **By car**

  There are no parking facilities at 30 Churchill Place and it is recommended that you take public transport. However, four nearby public car parks are operated by Canary Wharf. Rates and further information can be found on the Canary Wharf website:

  http://www.canarywharf.com/aboutus/The-Estate/Travel-/Roads--Parking/

Map



Arrival at the Agency

On arriving for your meeting at 30 Churchill Place, please report to reception where you will be issued with an access pass. This pass will allow you to access our industry lounge, which you are welcome to utilise during your visit. The industry lounge is located through the sliding doors to the right of the reception desk past the security turnstiles. Your EMA contact point will meet you here.

Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We strongly advise you to arrive up to 30 minutes before the start of the workshop, to allow you time for registration and settling down.

Meeting room

You will be able to sit wherever you wish; note that the only reserved seats are for the speakers, panellists and organisers of the workshop.

Presentations

We will not circulate printouts of speakers' presentations. However, you will be able to download them from the Agency's website approximately two weeks after the end of the workshop.

Wi-Fi access & Laptop computers

Wi-Fi is available throughout the EMA. Login details can be found on the back of your EMA access pass.

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Conference venue and secretariat

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