



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2013
EMA/214813/2013
Human Medicines Development and Evaluation

Pre- and post-authorisation regulatory support for SMEs

Workshop programme

26 April 2013
European Medicines Agency, London, United Kingdom



7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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Background and objectives

Workshops for micro, small and medium-sized enterprises (SMEs) take place at the European Medicines Agency (EMA) annually, and have been organised by the SME Office since 2007.

This year's regulatory workshop aims to provide practical information for SMEs working in the human medicines field. Topics to be covered include orphan designation, scientific advice, the centralised application for marketing authorisation and pharmacovigilance.

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

Programme details

Friday, 26 April 2013

8.30 Registration

9:30 Session 1: Welcome and introduction

Agnes Saint-Raymond (workshop co-chair), Head of Human Medicines Special Areas, EMA

9:40 Session 2: Orphan and paediatric incentives

Key concepts of orphan designation and latest developments

Jordi Llinares Garcia, Head of Orphan Medicines, EMA 25'

Key concepts of the paediatric regulation and latest developments

Paolo Tomasi, Head of Paediatric Medicines, EMA 25'

Additional Panellists

Michael Craig, Innovation Office, MHRA 5'

Bettina Ziegele, Innovation Office, PEI

Questions and discussion moderated by an SME representative

Fred Marin, GMP Orphan SAS 15'

10:50 Coffee break

11:10 Session 3: Early support during development

EMA scientific advice, including qualification of novel methodologies and parallel HTA advice

Jane Moseley, Scientific Administrator, Scientific Advice, EMA 20'

Innovation Task Force

Marisa Papaluca, Head of Scientific Support and Projects, EMA 15'

Questions and discussion moderated by an SME representative

Tilo Netzer, representing Eucope 15'

Additional Panellists

Lars Dagerholt, Innovation Office, MPA 5'

François Cuenot, Innovation Office, ANSM 5'

12:10 **Session 4: Regulatory issues in the run-up to dossier submission (part I)**

MAA pre-submission issues and EMA meeting opportunities

Irene Rager, Regulatory Advisor, Regulatory Affairs, EMA 20'

Data protection, market exclusivity and paediatric rewards

Zaide Frias, Head of Regulatory Affairs, EMA 30'

13:00 **Lunch break**

14:00-16:00 **Afternoon Session**

Tony Humphreys, (workshop co-chair), Head of Regulatory, Procedural and Committee Support, EMA

14:00 **Session 4: Regulatory issues in the run-up to dossier submission (part II)**

An SME perspective on the MAA process (including e-dossier preparation and submission)

Martine Zimmermann, Alexion 20'

Questions and discussion moderated by an SME representative

Andreas Vogel, Laboratoires CTRS 20'

14:40 **Session 5: Pharmacovigilance**

An update on the implementation of the pharmacovigilance legislation

Franck Diafouka, Scientific Administrator,
Pharmacovigilance and Risk Management, EMA 15'

An overview of requirements for the marketing-authorisation holder

Priya Bahri, Scientific Administrator, Coordination and Networking, EMA 25'

Key considerations in risk-management plans

Maarten Lagendijk, Scientific Administrator, Risk Management, EMA 20'

Questions and discussion

Tony Humphreys, Head of Regulatory, Procedural and Committee Support,
EMA 20'

16:00 **Closing remarks by the workshop chair**

List of speakers and moderators

Priya Bahri	Scientific Administrator, Coordination and Networking, EMA
Michael Craig	Innovation Office, MPA
François Cuenot	Innovation Office, ANSM
Lars Dagerholt	Innovation Office, MPA
Franck Diafouka	Scientific Administrator, Pharmacovigilance and Risk Management, EMA
Zaide Frias	Head of Regulatory Affairs, EMA
Jordi Llinares Garcia	Head of Orphan Medicines, EMA
Tony Humphreys (co-chair)	Head of Regulatory, Procedural and Committee Support, EMA
Maarten Legendijk	Scientific Administrator, Risk Management, EMA
Fred Marin	GMP Orphan SAS
Jane Moseley	Scientific Administrator, Scientific Advice, EMA
Tilo Netzer	Representing Eucope
Marisa Papaluca	Head of Scientific Support and Projects, EMA
Irene Rager	Regulatory Advisor, Regulatory Affairs, EMA
Agnes Saint-Raymond (co-chair)	Head of Human Medicines Special Areas, EMA
Paolo Tomasi	Head of Paediatric Medicines, EMA
Andreas Vogel	Laboratoires CTRS
Bettina Ziegele	Innovation Office, PEI
Martine Zimmermann	Alexion

Practical information

Venue

The European Medicines Agency can be reached:

- **By Docklands Light Railway (DLR)**
The Agency is a short walk from either Westferry station or Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.
- **By Underground**
The nearest stop for Westferry Circus is Canary Wharf station on the Jubilee Line.
- **By bus**
Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.
- **By boat**
River services run between Embankment, London Bridge and Canary Wharf throughout the day.
- **From London City Airport**
Take a taxi to Westferry Circus or alternatively catch the Docklands Light Railway, which goes to Westferry station.

Map



Entering the building

The Agency operates a stringent security policy. Upon arrival at ground-floor reception, you will be given a security pass that will allow you to make your way to meeting room 2A on the 2nd floor. Tea and coffee will be available on your arrival in the 2nd-floor foyer.

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 (i.e. 8:30), 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.

Laptop computers

For those of you travelling from the continent and wishing to use your laptop, may we remind you to bring with you an appropriate UK power adapter.

Media disclaimer

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on European Union. The Agency herewith informs attendees that this particular meeting will be recorded and broadcast.

By attending this meeting you consent to any recording or broadcast.

Conference venue and secretariat

European Medicines Agency
7 Westferry Circus, Canary Wharf
London E14 4HB, United Kingdom
Telephone +44 (0)20 7523 6936
Facsimile +44 (0)20 7523 7040
E-mail aliki.synodinou@ema.europa.eu
Website www.ema.europa.eu