



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

02 October 2013
EMA/339258/2013
Veterinary Medicines Division

Veterinary regulatory support for SMEs

Workshop programme

7 November 2013
European Medicines Agency, London, United Kingdom



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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. The workshops had joint human-veterinary topics until 2012.

This year we have initiated a veterinary specific workshop which aims to provide practical information for SMEs working in the veterinary medicines field. Topics to be covered include MUMS designation, scientific advice, the centralised application for marketing authorisation and inspections.

The workshop is open to companies that have been assigned SME status by the EMA and to representatives of stakeholder organisations. Other participants will be welcome space permitting.

Programme details

Thursday, 7 November 2013

13.30 Registration

Upon arrival at the European Medicines Agency you will be issued with a visitor's pass at the ground floor reception. This pass will give you access to the conference room 4A. Please note that there is a possibility of queues developing at the security gates, so we would recommend that you arrive at least 30 minutes in advance.

14:00 Session 1: Welcome and introduction - Workshop Co-Chairs: David Mackay, Karen Quigley

Introduction from EMA Veterinary Medicines Division 10'
David Mackay, EMA

Update from SME office 20'
Constantinos Ziogas, EMA

Discussion 10'

14:40 Session 2: Early support during development

MUMS designation and latest developments 15'
Karen Quigley, EMA

EMA Scientific advice 25'
Rory Breathnach, Chair SAWP-V, IMB, Ireland

Discussion 15'

15:35 Coffee break

15:50 Session 3: Regulatory issues in the run-up to dossier submission

Regulatory issues in the run-up to dossier submission: Inspections 10'
Claudio Facchini, EMA

MRLs for active substances and excipients 10'
Isaura Duarte, EMA

Marketing Authorisation Issues for SMEs 15'
Anna-Maria Brady, VMD, United Kingdom

Issues for Immunologicals for SME applicants 15'
Jean-Claude Rouby, Chair of IWP, ANSES, France

Eligibility issues and meeting opportunities 15'
Fia Westerholm, EMA

Discussion 15'

17:10

Session 4

Key elements of the review of veterinary legislation

20'

David Mackay, EMA

17:30

Closing remarks

Opportunity to meet EMA staff to discuss specific questions

List of speakers and moderators

Anna-Maria Brady	Senior Assessor in immunological assessment team, Veterinary Medicines Directorate, United Kingdom
Rory Breathnach	Chair SAWP-V, Irish Medicines Board, Ireland
Isaura Duarte	Veterinary Medicines Division, EMA
Claudio Facchini	Inspections & Human Medicines Pharmacovigilance Division, EMA
David Mackay	Veterinary Medicines Division Head, EMA
Karen Quigley	Veterinary Medicines Division, EMA
Jean-Claude Rouby	Chair of IWP, Head of Unit, Immunological Assessments, ANSES, France
Fia Westerholm	Veterinary Medicines Division, EMA
Constantinos Ziogas	SME Office, EMA

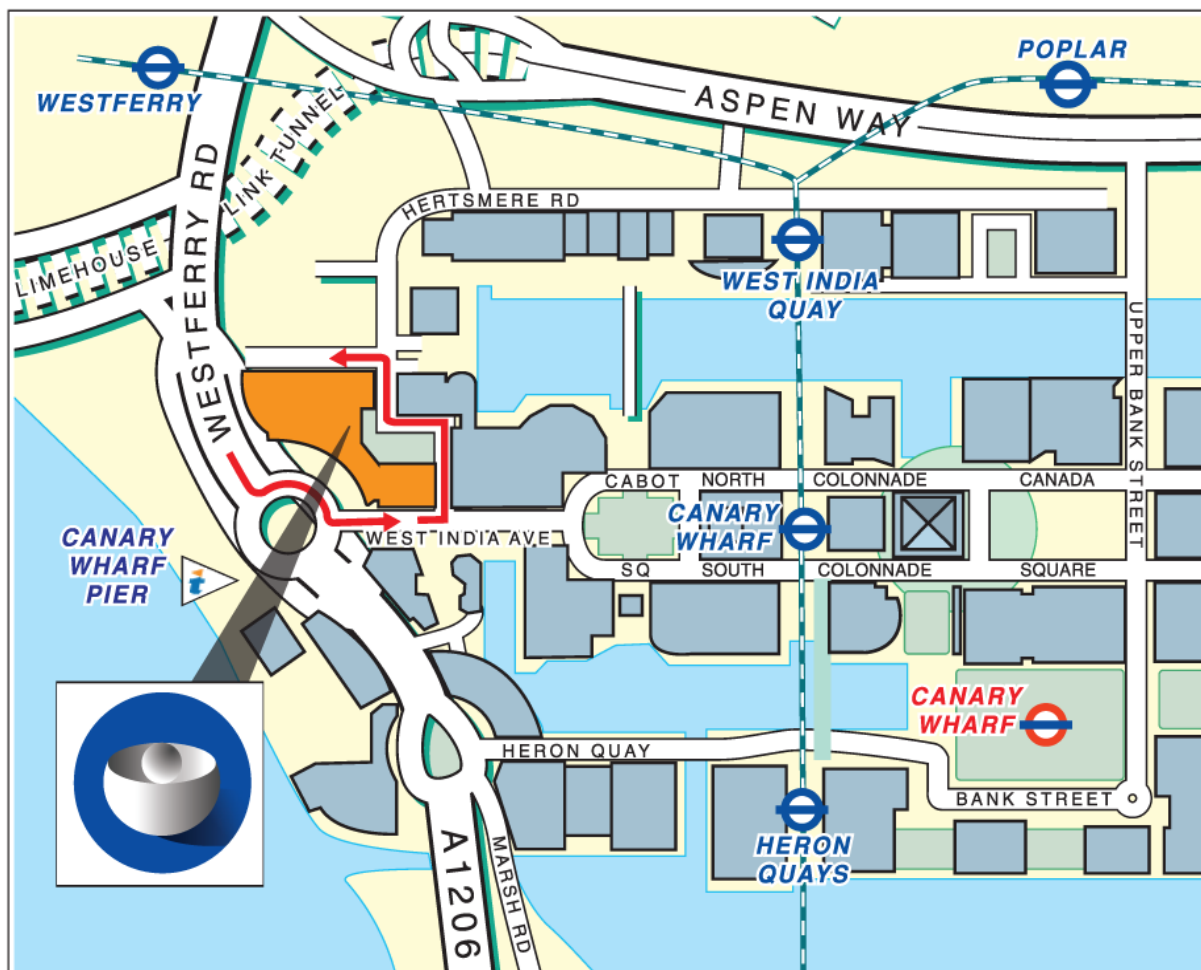
Practical information

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 4A on the 4th floor. Tea and coffee will be available on your arrival in the 4th 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, 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

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