



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 November 2015
EMA/719296/2015
Corporate Stakeholders Department – SME Office

European Medicines Agency roundtable with stakeholders on the 10-year anniversary of the SME Office

27 November 2015
European Medicines Agency, London, United Kingdom



Background and objectives

On 15 December 2015 the Commission Regulation (EC) No 2049/2005 (SME Regulation) reaches a 10-year anniversary milestone. To mark the occasion, the European Medicine Agency's SME Office is hosting this roundtable meeting with stakeholders.

The objectives of the meeting will be to provide an update on the 10 years since the implementation of the SME initiative, and to present the results of the most recent EMA SME survey. A tour de table with stakeholders will follow, and all invited speakers and participants will have the opportunity to exchange views on achievements, challenges and opportunities in light of the themes identified in the latest SME Survey.

Programme details

Friday, 27 November 2015

09.30 Registration

09.45 Review of Experience with SME Initiative

Welcome and opening remarks 5'

Noel Wathion, Chief Policy Adviser, Head of Stakeholders and Communication Division (Ad Interim), EMA

Introduction

Melanie Carr (Chairperson), Head of Corporate Stakeholders, EMA

Keynote speech from DG SANTE 15'

Andrzej Jan Rys, DG Health and Food Safety

Keynote speech from DG Research and Innovation 15'

Antoine Mialhe, DG Research and Innovation

Keynote speech from DG GROW 15'

Krista De Spiegeleer, DG Internal Market, Industry, Entrepreneurship and SMEs

10-year milestone of the implementation of the SME regulation (Commission Regulation (EC) No 2049/2005): SME Office 20'

Constantinos Ziogas, Head of SME Office (Ad Interim)

SME Survey: presentation of results 20'

Angela-Christina Schmidt, SME Office

Presentation of experience by SMEs 15'

Ajan Reginald, Cell Therapy Ltd

11:30 Coffee break

11:45 Feedback from stakeholders

Human Medicines

EuropaBio, presentation by Miriam Gargesi

EBE

EUCOPE, presentation by Alexander Natz

Euopharm SMC, presentation by Telma Costa

EFPIA

AESGP

Vaccines Europe, presentation by Chris Bailey

EUCROF, presentation by Stefano Marini

Veterinary Medicines

EGGVP, presentation by Elsa Vecino

IFAH-Europe

National Enterprise and Innovation support structures

Innovation Office & IP Management, Paul-Ehrlich-Institut

Roundtable discussion on the themes identified by the Survey

All

13:30

Closing remarks by Chair

Melanie Carr, Head of Corporate Stakeholders, EMA

List of speakers and participants

Regulatory Network

European Commission

Andrzej	Jan Rys	Directorate-General for Health and Food Safety (DG SANTE)
Antoine	Mialhe	Directorate-General for Research and Innovation (DG RTD)
Krista	Spiegeleer	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)

National Competent Authorities

Bettina	Ziegele	Paul-Ehrlich-Institut
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European Medicines Agency

Noel	Wathion	Chief Policy Adviser Stakeholders and Communication Division
Melanie	Carr	Corporate Stakeholders
Constantinos	Ziogas	Corporate Stakeholders, SME Office
Helene	Casaert	Corporate Stakeholders, SME Office
Nadia	Amaouche	Corporate Stakeholders, SME Office
Corinne	de Vries	Regulatory, Science and Innovation Support
Monica	Ensini	Patients and Healthcare Professionals
Marie-Agnes	Heine	Communication Department
Minna	Leppanen	Veterinary Medicines
Jordi	Llinares Garcia	Product Development Scientific Support
Marisa	Papaluca	Human Medicines Research and Development Support
Marie-Helene	Pinheiro	Corporate Stakeholders
Karen	Quigley	Veterinary Medicines
Angela-Christina	Schmidt	Corporate Stakeholders, SME Office
Enrico	Tognana	Regulatory, Science and Innovation Support
Fia	Westerholm	Veterinary Medicines

Stakeholders

Thomas	Allvin	EFPIA
Chris	Bailey	Vaccines Europe
Aysha	Blagolash	AESGP
William	Brooks	Chardon Consulting
Rick	Clayton	IFAH-Europe
Telma	Costa	Europharm SMC
Jiri	Deml	EATRIS European Infrastructure for Translational Medicines
Barbara	Freischem	EBE
Miriam	Gargesi	EuropaBio
Marc	de Garidel	EFPIA
Roberto	Gradnik	EBE
Margherita	Marini	Enterprise Europe Network
Stefano	Marini	EUCROF
Alexander	Natz	EUCOPE
Ajan	Reginald	Cell Therapy Ltd
Elsa	Vecino	EGGVP
Sander	van Deventer	Forbion

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)**

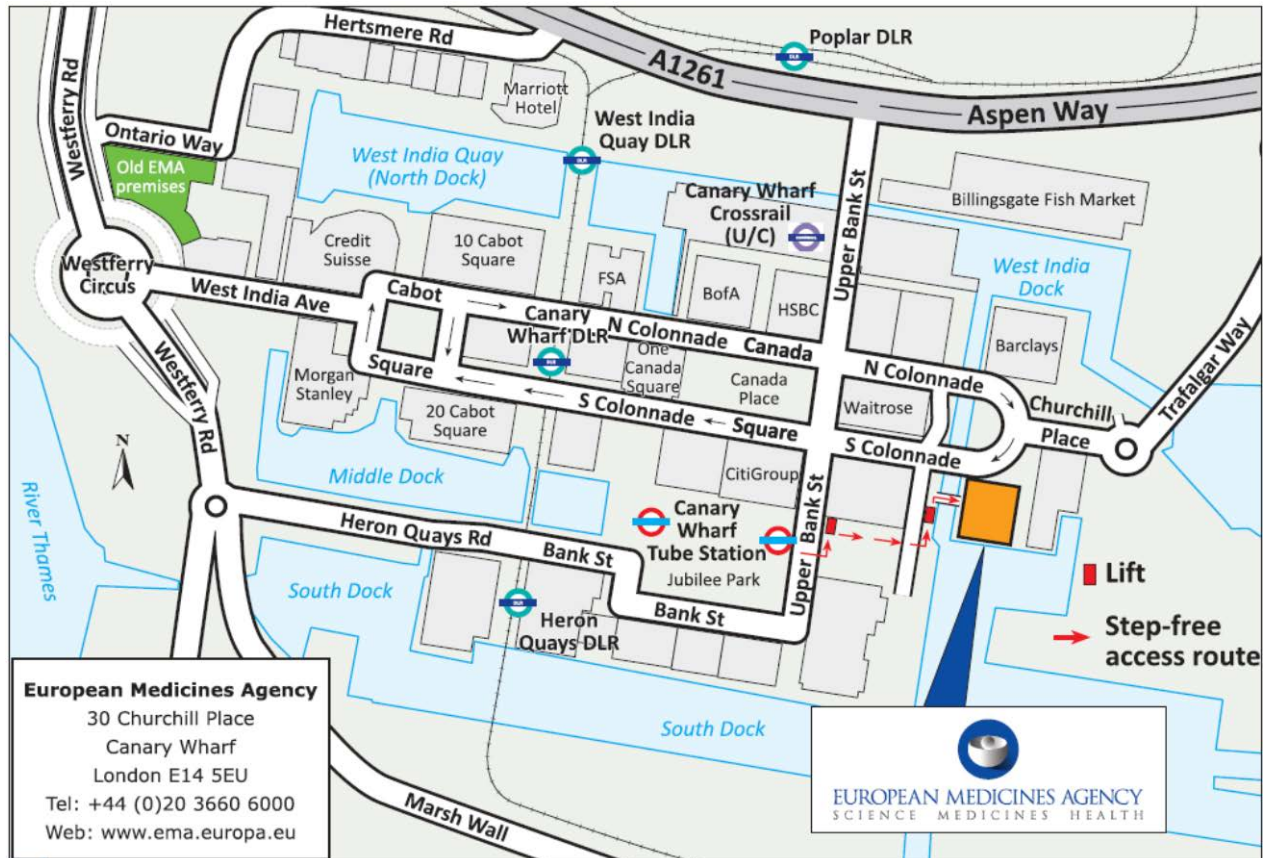
The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

- **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 meeting, to allow you time for registration and settling down.

Presentations

Printouts of speakers' presentations will not be distributed. Presentations will be circulated by email, after the event.

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.

Conference venue and secretariat

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