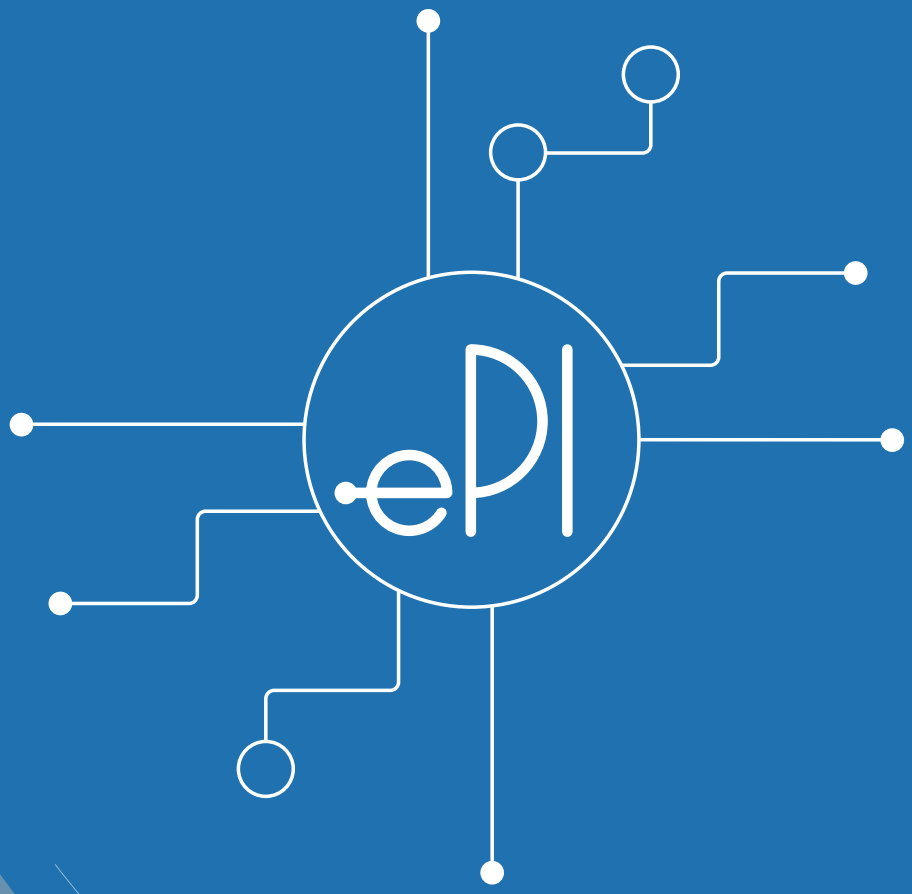

EMA/HMA/EC workshop on electronic Product Information (ePI)

Improving access to the EU medicines' product information

Wednesday, 28 November 2018

European Medicines Agency
London, United Kingdom

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

European Commission

Background and objectives

The European Medicines Agency (EMA), Heads of Medicines Agencies (HMA) and European Commission (EC) are working together to facilitate the development of electronic product information (ePI) for medicines, including the Summary of Product Characteristics (SmPC) and Package Leaflet (PL), to improve access by patients and healthcare professionals.

In this workshop, we aim to agree with all stakeholders on draft EU key principles for the use of ePI in the EU prior to a public consultation. This will involve consideration of:

- opportunities, needs and concerns identified by different stakeholder groups
- ongoing initiatives in the EU
- how ePI fits into other EU and global initiatives

Arrival at the Agency and registration

On arriving for your meeting at 30 Churchill Place, please report to reception where you will be issued with an access pass. Registrations will take place from 08.30 to 09.00 on the 2nd floor (in front of meeting room 2A).

We strongly advise you to arrive up to 30 minutes before the start of the workshop, to allow you time for registration. Please note that the Agency requires all visitors to provide a valid photo ID on arrival, such as passport, identity card or driving licence.

Participants without a valid photo ID may be turned away.

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.

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. For more information about processing of personal data by EMA, please visit the EMA website or contact: dataprotection@ema.europa.eu

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

Live broadcast and social media

The workshop will be live streamed. Please follow the link on the event page. No registration or password is required.

Participants interested in tweeting on this event are invited to use the hastag **#ePI4Medicines**.

Venue

European Medicines Agency
30 Churchill Place, Canary Wharf
London E14 5EU,
United Kingdom

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E-mail:pcwpsecretariat@ema.europa.eu
Website: www.ema.europa.eu

EMA/HMA/EC workshop on electronic Product Information (ePI)

Wednesday, 28 November 2018, 09:00 - 18:00 - meeting room 2A

Registration and reimbursement arrangements ..... / 08:30

Welcome, health and safety information and workshop objectives ..... / 09:00

Melanie Carr (EMA)

Video message from Vytenis Andriukaitis, European Commissioner for Health and Food Safety ..... / 09:10

Session 1: Setting the scene - Why ePI?

Chaired by Olga Solomon (EC) and Alexios Skarlatos (EMA)

- Towards digital transformation of health and care ..... / 09:20
  Kristina Kurgonaitė (EC) and Patrizia Tosetti (EC)
- Opportunities for expanding access to product information for medicines: stakeholders' needs and challenges ..... / 09:30
  Fakhredin Sayed Tabatabaei (MEB)
  Kaisa Immonen (EPF)
  Sine Jensen (BEUC)
  Darragh O'Loughlin (PGEU)
  Gesine Bejeuhr (IATF)
- Questions and answers ..... / 10:30

Coffee ..... / 10:40

Session 2: Current landscape - How does ePI fit in with other initiatives?

Chaired by Maria Jesús Lamas Diaz (HMA/AEMPS) and Juan García Burgos (EMA)

- Overview of initiatives from the EMA-HMA mapping ..... / 11:00
  Rosa González-Quevedo (EMA)
- Initiatives from national competent authorities ..... / 11:15
  César Hernández (AEMPS)
  Vibeke Åbyholm (NOMA)
  Kim Sherwood (MPA)
- Questions and answers ..... / 12:00

Lunch ..... / 12:15

- Initiatives from stakeholders ..... / 13:15
  Gunilla Englund (Fass - Digital product information, Sweden)
  John Moreland (electronic Medicines Compendium [eMC], United Kingdom)
  Nathalie Lambot (ePIL Pilot Project, Belgium and Luxembourg)
  Georg Lang (Gebrauchsinformation 4.0 consortium, Germany)
  Giovanna Ferrari (proposed public-private partnership for research initiative)
- Questions and answers ..... / 14:20

Coffee ..... / 14:30

Session 3: Towards an EU ePI

Chaired by Zaide Frias (EMA) and Melanie Carr (EMA)

- Common electronic standard: potential features and use cases ..... / *14:50*
  Elizabeth Scanlan (EMA)
- Analysis and discussion on proposed key principles for ePI: ..... / *15:15*
  - Definition of ePI
  - Common EU electronic standard
  - Expanding access to medicines information
  - Acessibility
  - Complementing paper package leaflet
  - Regulatory-approved information only
  - EU multilingual context
  - Interdependency with EU and global initiatives
  - Implementation
  - Process governance

  Facilitated discussion with participants aimed at consensus building (EMA/HMA/EC)

Concluding remarks and next steps ..... / *17:30*

Melanie Carr (EMA)

End of meeting ..... / *18:00*

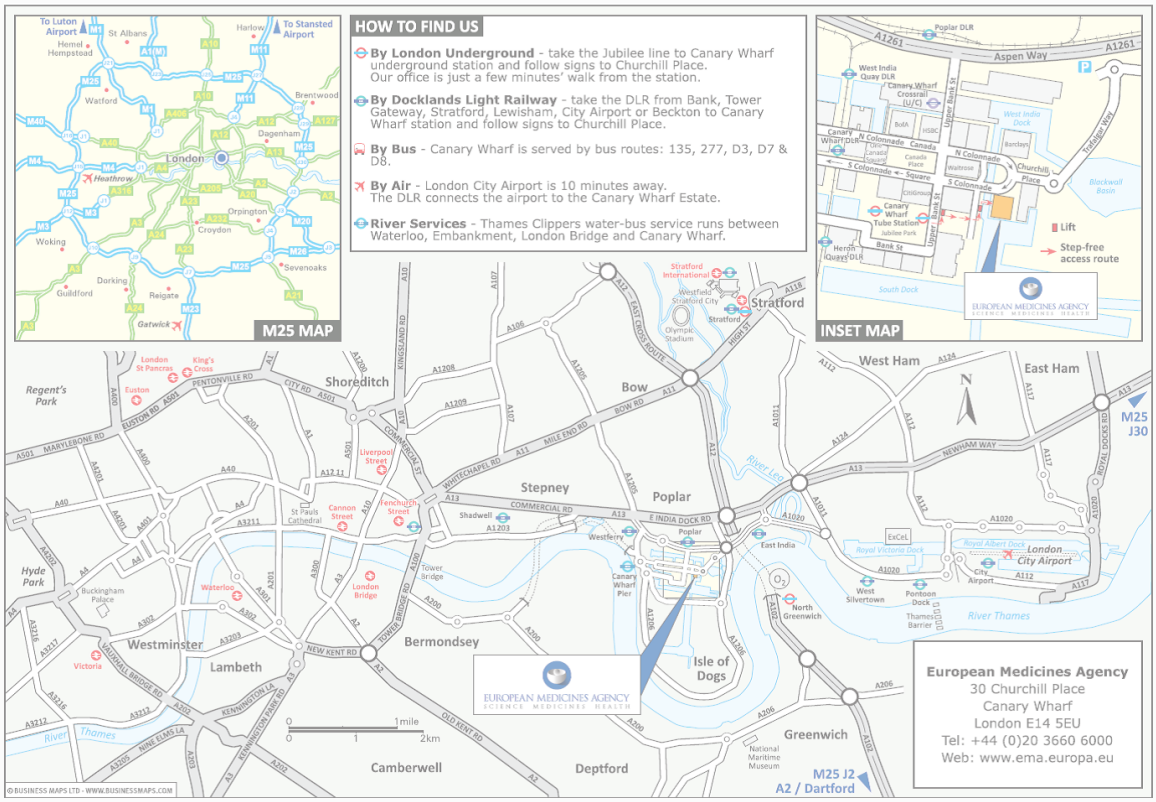
Chairs and speakers

Melanie Carr	Head of Stakeholders and Communication (EMA)
Vytenis Andriukaitis	European Commissioner for Health and Food Safety (EC)
Olga Solomon	Head of Unit for Medicines: Policy, Authorisation and Monitoring – DG Santé (EC)
Alexios Skarlatos	Head of Labeling Review and Standards (EMA)
Kristina Kurgonaitė	Medicines: Policy, Authorisation and Monitoring – DG Santé (EC)
Patrizia Tosetti	European Reference Networks and Digital Health - DG Santé (EC)
Fakhredin Sayed Tabatabaei	Medicines Evaluation Board (MEB)
Kaisa Immonen	European Patient's Forum (EPF)
Sine Jensen	European Consumers' Organisation (BEUC)
Darragh O'Loughlin	Pharmaceutical Group of the European Union (PGEU)
Gesine Bejeuhr	Industry's Inter-Association Task Force (IATF)
Maria Jesús Lamas Diaz	Director of Spanish Agency of Medicines and Medical Devices (HMA/AEMPS)
Juan García Burgos	Head of Public Engagement (EMA)
Rosa González-Quevedo	Medical and Health Information (EMA)
César Hernández	Head of Department of Medicines for Human Use (AEMPS)
Vibeke Åbyholm	Norwegian Medicines Agency (NOMA)
Kim Sherwood	Swedish Medical Products Agency (MPA)
Gunilla Englund	Swedish Pharmaceutical Industry Association (LIF)
John Moreland	Datapharm
Nathalie Lambot	General Association of the Pharmaceutical Industry in Belgium (Pharma.be)
Georg Lang	Gebrauchsinformation 4.0 consortium, Germany
Giovanna Ferrari	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Zaide Frias	Head of Human Medicines Evaluation (EMA)
Elizabeth Scanlan	Medical and Health Information (EMA)

Getting to Canary Wharf

The EMA is located in Canary Wharf, a business district in the east of London.
Please find below the public transport options for travelling to Canary Wharf together with the approximate journey times and the map of the area.

Directions to European Medicines Agency and map of the area



By Docklands Light Railway (DLR)

Both venues are a short walk from Canary Wharf or Heron Quays station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.

By Underground

The nearest stop for both venues 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 Bus

Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.