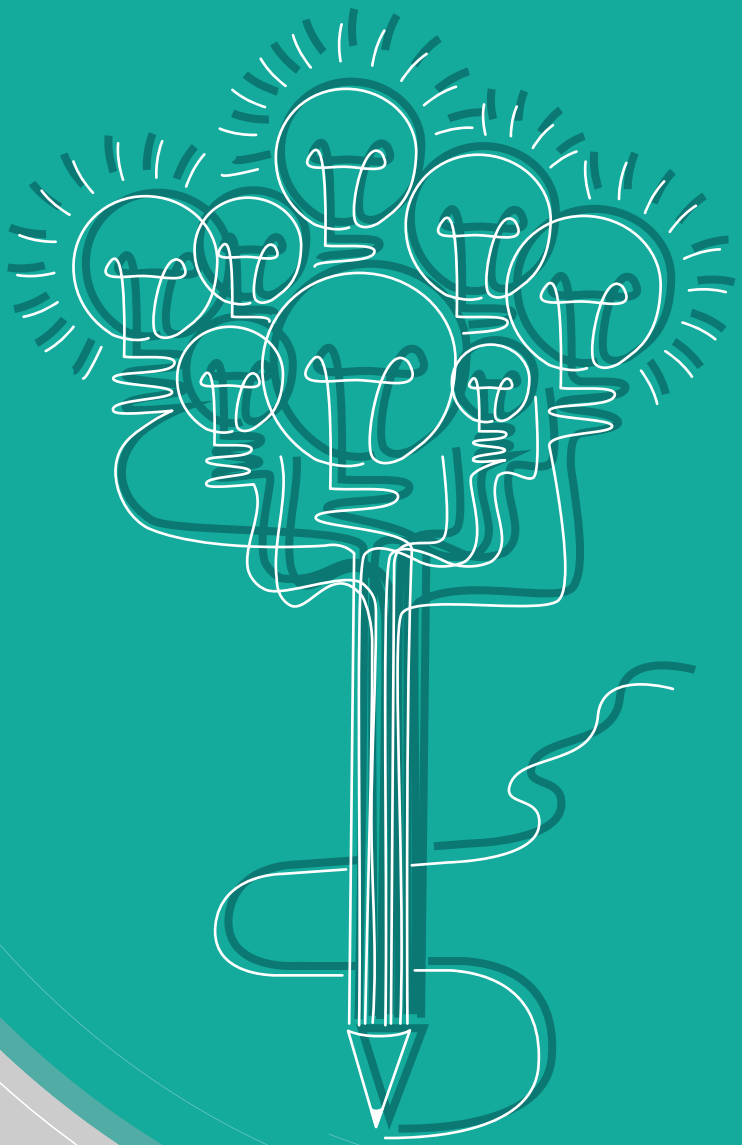


EMA - Regulatory Science to 2025

Launch of Veterinary Stakeholder Consultation

Thursday 6 December 2018

European Medicines Agency

London, United Kingdom

EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Background and objectives

The European Medicines Agency (EMA) is holding a multi-stakeholder workshop (invitation only) on 6 December 2018 aiming to gather initial thoughts on the key areas to be covered in the current reflection on EMA's Regulatory Science to 2025. On this occasion, we will share the proposals for veterinary medicines. This should facilitate:

- A shared reflection on the key regulatory science faced by the various scientific committees and working parties of the Agency and opportunities to address these;
- An understanding of the process by which the proposed strategic goals and core recommendations were elaborated to date;
- Highlighting areas that are of particular relevance to various stakeholder groups to focus on during the public consultation.

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. This pass will allow you to enter 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 there.

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.

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.

Venue

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

Telephone +44 (0)20 3660 6000
E-mail: RegulatoryScience2025@ema.europa.eu
Website: www.ema.europa.eu

Thursday 6 December 2018, 14:00 - 19:00 - meeting room 3E

Welcome and introductions ..... / *14:00*

- *Guido Rasi, Executive Director, EMA / 10'*

Session 1: Regulation of veterinary medicinal products in the 21st century – Addressing challenges and opportunities across the European Regulatory Framework ..... / *14:10*

- EMA's Regulatory Science Response */ 15'*
  Ivo Claassen, EMA
- Integration of Agency committees and Network into delivery of the strategy / *10'*
  David Murphy, Chair of CVMP
- View from the European Commission / *10'*
  Christian Siebert, DG-SANTE
- View from the European Medicines Regulatory Network (EMRN) / *10'*
  Jean-Pierre Orand, HMA Management Group
- View from the veterinarians / *10'*
  Nancy de Briyne, Federation of Veterinarians of Europe
- View from the animal medicines industry / *10'*
  Alexander Böttner, AnimalhealthEurope

Session 2: Catalysing the integration of science & technology in drug development ... / *15:15*

- Catalysing the integration of science & technology in drug development / *10'*
  Rory Breathnach, Chair of SAWPv
- Questions and panel discussion / *30'*
  Panellist:
  Carmen Jungbäck, International Alliance for Biological Standardization
  Lindsay Marshall, Humane Society International
  Wilhelm Schlumbohm, CVMP
  Klaus Hellmann, Association of Veterinary Consultants
  Jackie Atkinson, AnimalhealthEurope

Coffee break ..... / *16:05*

Session 3: Driving collaborative evidence generation and improving the scientific quality of evaluations ..... / *16:20*

- Driving collaborative evidence generation and improving the scientific quality of evaluations / *20'*
  Nicholas Jarrett, EMA
- Questions and panel discussion / *40'*
  Panellists:
  Jason Weeks, CVMP
  James Wood, University of Cambridge
  Jacques Lechenet, AnimalhealthEurope
  Elsa Vecino, European Group for Generic Veterinary Products

Session 4: Addressing emerging health threats and availability/therapeutic challenges ..... / *17:20*

- Addressing emerging health threats and availability/therapeutic challenges / *20'*
  Helen Jukes, CVMP
- Questions and panel discussion / *40'*
  Panellists:
  Rens van Dobbenburgh, Federation of Veterinarians of Europe
  Jordi Torren Edo, EMA
  Carmen Jungbäck, International Alliance for Biological Standardization
  Georg von Samson-Himmelstjerna, Freie Universität Berlin
  Alexander Böttner, AnimalhealthEurope

Session 5: Enabling and leveraging research and innovation in regulatory science ..... / *18:20*

- Enabling and leveraging research and innovation in regulatory science / *15'*
  Tony Humphreys, EMA
- Questions and panel discussion / *20'*
  Panellists:
  Jean-Charles Cavitte, EC DG AGRI
  James Wood, University of Cambridge
  Valentin Nicorescu, EMA

Closing remarks ..... / *18:55*

- *Ivo Claassen, Head of Division, Veterinary Medicines, EMA / 5'*

Networking event ..... / *19:00*

List of sessions & proposed core recommendations

Session 1 **Regulation of veterinary medicinal products in the 21st century – Addressing challenges and opportunities across the European Regulatory Framework**

Session 2 **Catalysing the integration of science & technology in drug development**

- *Transform the regulatory framework for innovative veterinary medicines*
- *Reinforce and further embed application of the 3Rs*
- *Facilitate implementation of novel manufacturing models*

Session 3 **Driving collaborative evidence generation and improving the scientific quality of evaluations**

- *Update Environmental Risk Assessments (ERAs) in line with the latest scientific knowledge*
- *Apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines*
- *Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance*
- *Develop new and improved communication and engagement channels and methods to reach out to stakeholders*
- *Develop new approaches to improve the benefit/risk assessment of veterinary medicinal products*

Session 4 **Addressing emerging health threats and availability/therapeutic challenges**

- *Continue to promote the responsible use of antimicrobials and their alternatives*
- *Coordinate Network activities to improve data collection on antimicrobial use in animals*
- *Engage with stakeholders to minimise the risks of antiparasitic resistance*
- *Promote and support development of veterinary vaccines*

Session 5 **Enabling and leveraging research and innovation in regulatory science**

- *Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science*
- *Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions*
- *Identify and enable access to the best expertise across Europe and internationally*
- *Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders*

Organising Committee

Scientific Coordination Board (SciCoBo):

David Murphy	CVMP Chair, *The Health Products Regulatory Authority (HPRA), Ireland*
Rory Breathnach	SAWPv Chair, *The Health Products Regulatory Authority (HPRA), Ireland*

European Medicines Agency (EMA):

Ivo Claassen	*Veterinary Medicines Division*
Melanie Carr	*Stakeholders & Communication Division*
Anthony Humphreys	*Scientific Committees Regulatory Science Strategy Division*
Marie-Helene Pinheiro	*Industry Stakeholders' Liaison - Corporate Stakeholders*

Practical information

Registration

We advise you to arrive at least half an hour before the start of the workshop (i.e. at 13:30) to allow sufficient time for registration and settling down. Registration will take place in the foyer on the 3rd floor.

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.

WiFi access

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

Meeting room

There is no seating plan in the room except for a number of reserved seats for the speakers, panellists and chairs of the workshop.

Presentations

We will not circulate printouts of speakers' presentations beforehand. However, you will be able to download the presentations from the workshop website approximately one week after the event.

Catering

A light dinner will be provided immediately after the workshop for delegates. It will be free of charge to allow opportunities for discussion and networking.

Live broadcast

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

Twitter

Participants interested in tweeting on this event are invited to use the hashtag #RegScience2025.

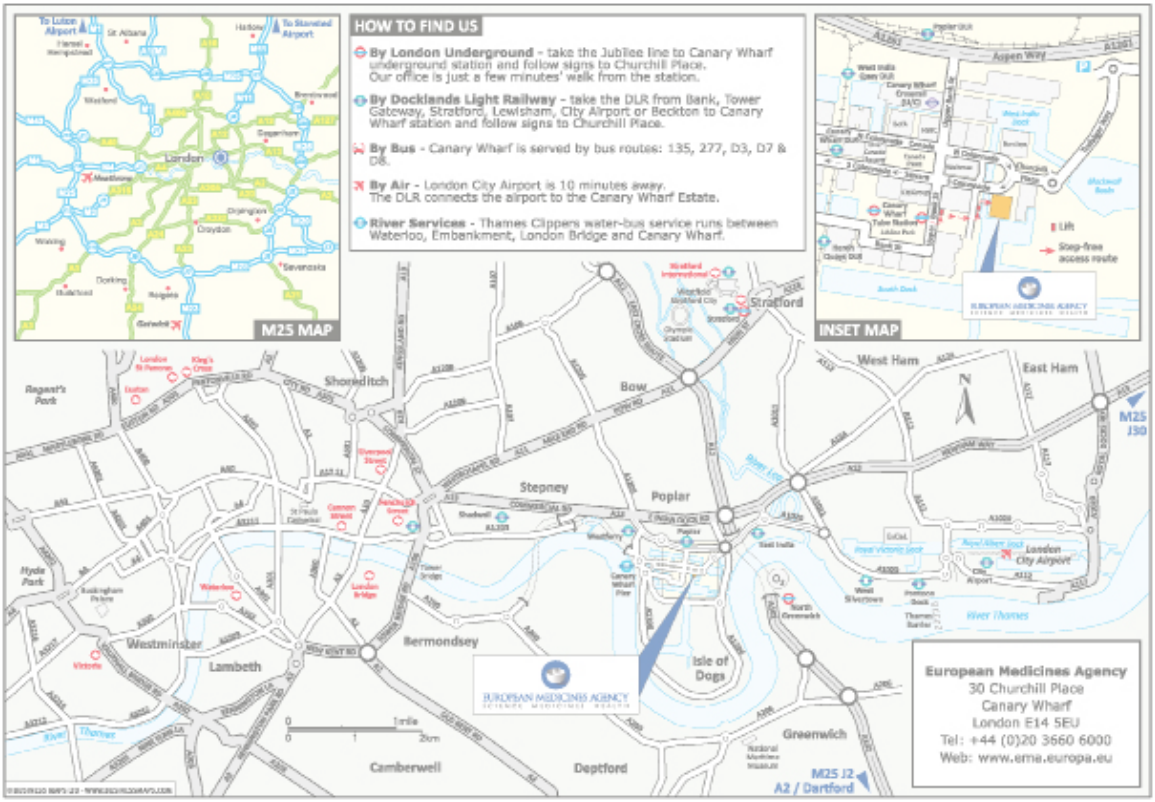
Contact

Should you have any questions, please contact Laetitia Kpenou or Aline Caromelle via RegulatoryScience2025@ema.europa.eu.

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.

River services

River services run between Embankment, London Bridge and Canary Wharf throughout the day. Canary Wharf pier is roughly a 15-minute walk from the European Medicines Agency.

From London City Airport

Take DLR City Airport to Canary Wharf (journey time is around 20 minutes).

From Heathrow Airport

Take the London underground Piccadilly Line to Green Park, change to the Jubilee Line to Canary Wharf (journey time around 1hr 20 minutes).
Alternatively, take the Heathrow Express train to Paddington, then the Circle or Bakerloo line to Baker Street, then the Jubilee Line to Canary Wharf (journey time around 1hr 20 minutes).
Alternatively, you can take the Heathrow Express train to Paddington, then the District or Circle Line to Tower Hill then the Docklands Light Railway (DLR) to Canary Wharf (journey time around 1hr 30 minutes).

From Stansted Airport

Take the Stansted Express to London Liverpool Street then the Circle Line to Tower Hill and change onto the DLR to Canary Wharf (journey time around 70 minutes).

From Luton Airport

Take a First Capital Connect train to London Bridge then the Jubilee Line to Canary Wharf (journey time around 60 minutes).

From St Pancras International train station

Take the Northern Line to London Bridge then the Jubilee Line to Canary Wharf (journey time around 45 minutes).