



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction and points for information

Update since April 2018

Presented by Juan Garcia Burgos, 25 September 2018
PCWP/HCPWP joint meeting

An agency of the European Union



What has happened since April 2018

- EMA **regulatory science strategy** – introductory webinar on 17 May; progress to be presented today
- Written consultation on proposal for **PCWP and HCPWP meetings for 2018 and 2019** – 22 May; positive feedback received; although dates need to be revisited (BCP-phase 3)
- **Public hearing** on quinolones and fluoroquinolones – 13 June
- **Stakeholders Engagement report 2017** published – 28 June
- **ePI** – meeting in Madrid attended by PCWP and HCPWP co-chairs, BEUC, EAHP and PGEU – 3 July; progress to be presented today
- **Streamlined process for eligibility** status of organisations – launched 3 July after an info webinar on 20 June; work in progress

What has happened since April 2018

- **Meeting with civil society representatives of EMA committees** – 16 July and revision of Roles of patients and healthcare professionals on committees document
- EMA/HMA collaboration on **shortages and availability of medicines** – progress to be presented today
- Revision of **PCWP/HCPWP mandates and rules of procedure** – internal review concluded; documents will be circulated for PCWP/HCPWP written consultation as follow up action of today's meeting
- **Digital media and health topic group** had TCs in May, June and September – progress report to be presented today
- **12th Pharmacovigilance stakeholder forum** – 24 September – feedback to be presented today

EMA preparedness on Brexit and relocation

- Brexit business continuity plan (BCP) will **enter its third phase** on **1 October**
 - address physical move to Amsterdam and cope with significant staff loss
 - safeguard core activities related to the evaluation, maintenance and supervision of medicines
- Activities to be **scaled back or suspended** in the third phase include:
 - collaboration at international level
 - development and revision of guidelines
 - holding of non-product related working parties
 - programmes and projects
 - organisation and attendance at stakeholder meetings (limited to Brexit-related interactions)
 - clinical data publication

EMA preparedness on Brexit and relocation

- Impact in PCWP/HCPWP activities in **2018**

- PCWP and HCPWP June meetings cancelled
- Meeting with all eligible organisations and training day in November cancelled
- Reducing topic group activity as from October
- No annual report

- Multi-stakeholder workshops on availability of medicines and electronic product information
- Virtual meeting in December (update on Brexit-related activities)
- Conclusion of eligibility re-evaluation 2018
- Conclusion of mandates' revision

Doodle pool for virtual meeting in December – please respond by tomorrow

<https://doodle.com/poll/9s2zncvru77d2rat>

EMA preparedness on Brexit and relocation

- Impact in PCWP/HCPWP activities in **2019**

➤ No meetings until June-October 2019, depending on capacity to resume these activities (may be revised)

Our channels of communication with the working parties remain open via PCWPsecretariat@ema.europa.eu and HCPsecretariat@ema.europa.eu

- Focus on patient and HCP involvement in product-related activities (SA, SAGs, written consultations, review of documents - safety communications, DHPCs, medicines overview, PLs)
- Extraordinary virtual meeting in early 2019 for update on Brexit-related activities
- Timelines for PCWP and HCPWP mandates 2019-2021 unchanged
- Election of new co-chairs as soon as physical meetings can be resumed