EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Engagement and communication with EMA eligible HCP organisations

Policy Officers' Group (HCP POG) background and progress update from drafting groups

Presented by Ivana Silva on 22 September 2022
Healthcare Professionals and Learned Societies Liaison, European Medicines Agency

Stepping up engagement with 'eligible' organisations

- We currently have 39 eligible healthcare professional organisations (including clinical learned societies)
- The Healthcare Professionals Working Party (HCPWP) is made up of 22 of the eligible organisations
- Scope and objectives for a healthcare professionals policy officer group (HCP POG), following 1-year pilot in 2021:

Further support engagement and communication with EMA eligible HCP organisations

Provide an additional platform for interaction

Provide EMA high-level updates as a complement to HCPWP meetings

Keep a more regular exchange on topics of interest, consultations and meetings

Establish a specific place for organisations to raise points in a coordinated and transparent manner (focusing on remit of EMA activities)

Identify potential (common) needs and requests with a view to handle them in a more efficient way

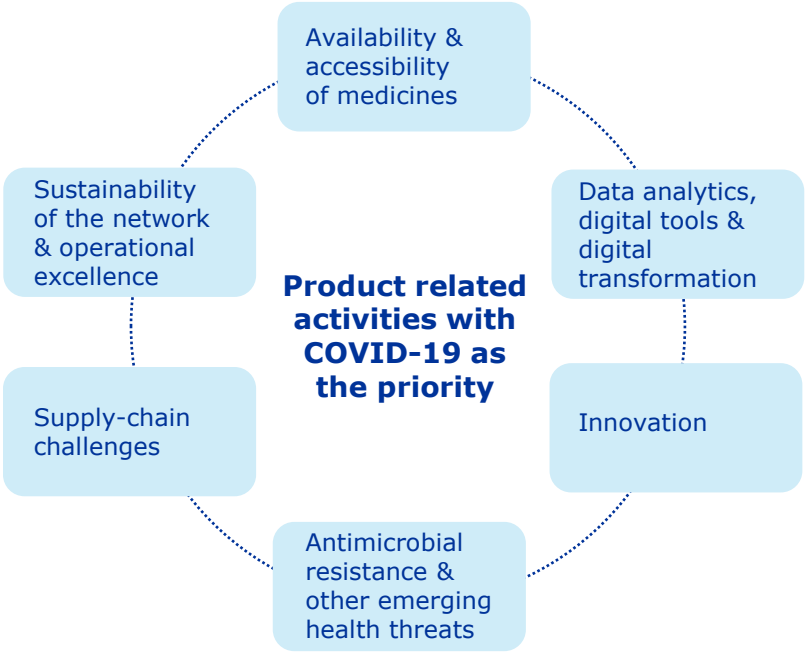
Stepping up engagement with 'eligible' organisations

Map expectations & identify gaps

- Survey to eligible organisations
- Policy officers group (HCP POG)
- HCPWP

Learn & share knowledge

- Bilateral meetings
- Information loop



Increase impact

- Co-developed meetings
- Topic-driven multi-stakeholder platforms
- Training/ Participation in external events

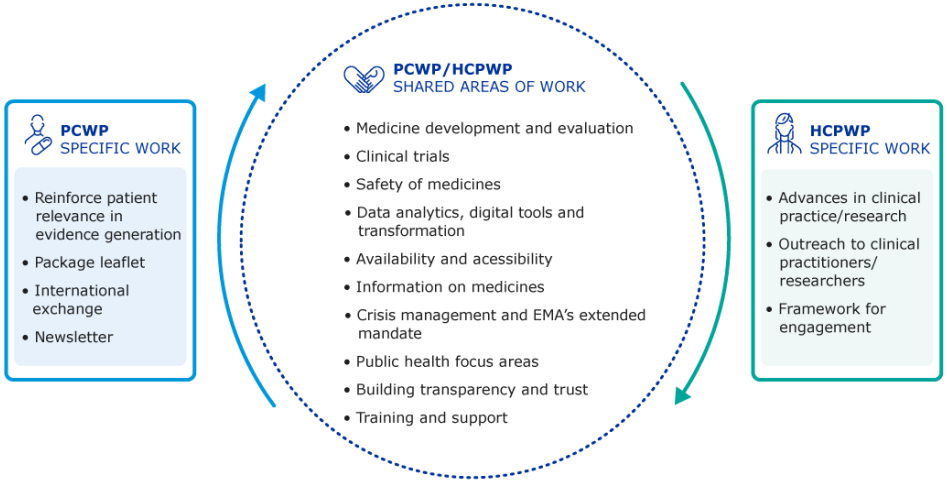
Create awareness

- Publications
- Audiovisual materials
- Annual reports

Stepping up engagement with ‘eligible’ organisations

- Innovation in clinical trials
- RWD/registries
- Special populations
  - Medicines for frail and older people
  - Medicines for people living with a rare disease
  - Medicines use during pregnancy and breastfeeding
  - Medicines for children
- Shortages of medicines
- *Environmental risk-assessment of medicines*

HCPWP
Work plan 2022-2025; structure



HCP POG drafting groups

- Aim to develop position papers with the goal to:
  - Scan new opportunities to learn and share knowledge between healthcare professionals and regulators on matters of concern to the clinical communities
  - Perform a landscaping exercise that could also identify further areas of action/research needed
  - Provide input to specific EMA working areas

  In addition, they could serve to:

  - Promote clarity/awareness about EMA activities amongst clinical communities

Four topics chosen:

- Shortages
- Frailty and older people considerations in medicine development and evaluation
- Surrogate endpoints and new ways of conducting clinical trials
- Pharmacovigilance, with a focus on medication errors

Drafting groups – process and timelines

1. Discussion on scope and objectives – 24 May
2. Feedback from EMA topic leads – 31 May
3. 1st Draft by drafting group – 5 July
4. Written comments by HCP POG and EMA – July/August
5. 2nd Draft by drafting group – early September
6. Presentation to HCPWP on 22 September
7. Written comments by HCPWP – mid-October
8. Review by drafting group – Oct/November
9. Presentation to HCP POG on 7 December
10. Publication – Q1 2023
11. Follow up with EMA

Drafting group on frailty and older people considerations in medicine development and evaluation -1

Topic lead(s): Michael Denkinger (EuGMS)

Volunteer contributors: Anita Simonds (European Respiratory Society, ESR), Antonio Cherubini (EuGMS), Christos Lionis (European Forum for Primary Care, EFPC/ WONCA Europe), Denis Lacombe (European Organisation for research and Treatment of Cancer, EORTC), Elena Petelos (European Forum for Primary Care, EFPC)/ European Public Health Association, EUPHA), Mary McCarthy (European Union of General Practitioners, UEMO), Patrick Ouvrard (European Union of General Practitioners, UEMO), Philip Van Kerrebroeck (European Association of Urology, EAU), Wilma Knol (EuGMS)

Scope: Provide a narrative overview on current challenges in medicine development and evaluation and propose/recommend useful approaches to overcome or improve the situation

Drafting group on frailty and older people considerations in medicine development and evaluation -2

Provisional title: Frailty and older People Considerations in Medicine Development and Evaluation – Recommendations from an ad hoc Working Party of the Healthcare Professional Organisation Policy Officers Group of European Medicine Agency (HCP POG)

Key message: While participation of older people in trials has improved, inclusion of frail older adults has not, and relevant outcomes are rarely reported. Involvement in all phases of drug development must be clearly improved. To summarize options eight important measures are suggested.

Audience: EMA/CHMP/ICH officials in charge of trial legislation, politics, stakeholders and pharmaceutical companies + all interested healthcare professionals

Drafting group on shortages

Topic lead(s): Elena Petelos (EFPC/EUPHA) and Stephanie Kohl (EAHP)

Volunteer contributors: Adamos Hadjipanayis (EAP), Amélie de Martini (EANM), Dimitra Lingri (EFPC), Jean-Pierre Jacquet (UEMO), Jorge Batista (PGEU), Marcin Rodzinka-Verhelle (CPME), Mark Turner (EAP), Mary McCarthy (UEMO), Michael Denkinger (EuGMS),Robin Doeswijk (EHA), Sonja Niederkofler (EANM),

Scope: Existing shortage mechanisms, therapeutic areas & HCPs affected, link to extended EMA mandate, mitigation measures

Key message: Identifying risks & mechanisms of mitigating them

A – Key aspects of extended mandate (to raise awareness among HCPs)

B – Preventive and reactive shortage mitigation measures

C - Case studies and links to other initiatives (e.g. Joint Action on Shortages)

Audience: HCPs, industry, patients, payers, policy makers

Drafting group on surrogate endpoints and new ways of conducting clinical trials - 1

Topic lead(s): Piotr Szymańsk (ESC) and Ioanna Psalti (EU EYE)

Volunteer contributors: Denis Lacombe (EORTC); Elena Petelos (EFPC, and EUPHA); Gualberto Gussoni (EFIM); Ioana Agache (EAACI); Maria Luisa Ronconi (ESC); Michael Denkinger (EuGMS); Monika Brüggemann (EHA); Robin Doeswijk (EHA); Stephane Auvin (ILAE); Yoanna Nedelcheva (EASL); Jörn Schattenberg (EASL); Loreta Kondili (European Association for the Study of the Liver, EASL); Rob van Marum (EuGMS); Sara Román Galdrán (EHA)

Scope: Informing on clinical perspectives on the use and analysis of surrogate endpoints in clinical trials, link to innovation & CT market, link to patient information and health literacy practices

Drafting group on surrogate endpoints and new ways of conducting clinical trials - 2

Provisional title: 1. Rethinking the surrogate endpoints in approval and post-market phases - a clinical view (report for EMA including a work plan, actions & available resources)

2. Social and ethical dimensions in the sustainability of clinical trials: the case of surrogate endpoints (editorial)

Key message: Identifying definition, classification and other methodological needs in using surrogate endpoints to support innovation in clinical trial design while maintaining well-being of patients

Audience: EMA, policy makers, HCPs, researchers & CT networks, industry, patients, payers

Drafting group on pharmacovigilance, with a focus on medication errors

Topic Lead: Paolo Martelletti (EHF)

Volunteer contributors: Enrica Alteri (EHF), Michael Delkinger (EuGMS), Stephanie Kohl (EAHP), Christian Lampl (EHF), Antoinette Maassen van den Brink (EHF), Elena Petelos (EFPC/EUPHA), Piotr Szymanski (ESC), Ber Oomen (ESNO), Ioanna Psalti (EU EYE), Jorge Batista (PGEU).

Scope: Define the points of contact between the legislative and clinical practice definitions of medication errors.

Provisional title: Position paper on medication errors: from legislative to clinical definition

Key message: Medication errors as harmful delivery or failure in treatment process

Audience: Healthcare professionals

Any questions?

Further information

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