

EMA's framework of engagement with healthcare professionals and their organisations

Reflection on the need to review – points to consider

Healthcare Professionals' Working Party (HCPWP) 10th anniversary

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Points to consider

- Current framework was last revised in 2016
- Integration of experience and learnings
- Impact of recent and foreseen developments in EMA's engagement with HCPs
- Alignment with other frameworks for engagement
- How to adjust to increased interest from European health sciences students' associations as the future generations of professionals
- Inclusion of veterinarians as per request of EMA's Management Board at the time of last revision





10 years of implementation of framework

- Diversity and number of organisations with eligibility status –
 healthcare professional organisations and clinical learned societies
 - Mission: Health care/public health focussed; Clinical and research driven
 - Types: alliances; specialised fields; disease/condition specific; professional groups
 - From first 20 organisations in 2012 to a total of 38 organisations in 2023
- Type and maturity of interaction
 - · from individualised to targeted to specific professional groups (e.g. GPs) and multidisciplinary
 - · from introductory to highly technical
 - from policy and advocacy to specialised expertise
- Impact of engagement relevance and challenges of monitoring and reporting (qualitative and quantitative)





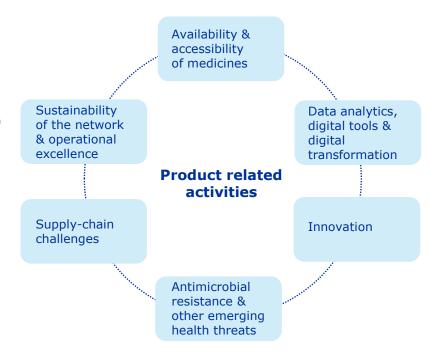
Stepping up engagement with 'eligible' HCP organisations/ Learned societies

Map expectations & identify gaps

- HCPWP (4th mandate)
- Survey to eligible organisations (2021 & 2023)
- HCP policy officers group (2021 pilot; 2023 reassessment)

Learn & share knowledge

- Bilateral meetings
- Information loop



Increase impact

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

Create awareness

- Publications
- Audiovisual materials
- Annual reports





Strategic position of the HCPWP in relation to EMA structures

- From a working group (HCPWG) operating since November 2006 to a Working Party in 2013; progressed to EMA's working party due to cross-committee nature
- Interactions with the Patients and Consumers Working Party (PCWP) operating since 2005
 - Meetings predominantly run jointly; first three-year joint workplan (2019-2022) adopted in June 2019
 - Joint work (e.g. topic group on social media in 2015-2017; drafting group on ICH E6(R3) GCP in 2022-2023)
- Scientific Committees' consultations and close monitoring of engagement methodologies
 - Pilot working group on enhancing PRAC's engagement with patients and healthcare professionals (PRISMA) (2022)
 - CHMP early contact to healthcare professional organisations (2023)
- Interaction with recently reorganised EMA's working parties to be further explored



- HCPWP topic groups (2015-2017) on:
 - Academia, learned societies and healthcare professionals' organisations
 - EMA/CHMP/PRAC projects on information on medicines
 - Risk minimisation measures and assessment of their effectiveness
 - Consolidated report
- Creation of the healthcare professional policy officers' group (HCP POG) in 2021 to complement HCPWP
 - One-year pilot review
 - Drafting groups on medicines for frail and older people, surrogate endpoints, medication errors and shortages
 - Re-assessment and lessons learnt to be developed end of 2023



Other areas of learning

- Post-COVID learnings for engagement in times of public health crises
 - Pooling efforts for coordinated communication and addressing misinformation
 - Adapting to disruption in normal activities; re-prioritising workstreams
- Establishing pools of experts and registration of individual HCPs
 - Access the best possible independent expertise to incorporate real-world experience and scientific progress into drug development, benefit/risk evaluation and monitoring



POINTS TO CONSIDER

Impact of recent and foreseen developments in EMA's engagement with HCPs

- · EMA's regulatory science research agenda
- European Medicines Agencies Network strategy to 2025
- EMA's extended mandate
- EMA's strategic plan for multistakeholder engagement to 2025
- Digital tools, data analytics and digital transformation
- New EU pharmaceutical legislation
- EMA's working parties domains covering quality, non-clinical, methodology, clinical and veterinary





POINTS TO CONSIDER

Alignment with other frameworks for engagement

- The framework for EMA's engagement with patients, consumers and their organisations was updated in 2021 and published early 2022
- There are ongoing discussions to review EMA's framework for collaboration with academia (adopted in 2017)
- EMA's framework for interaction with industry stakeholders was adopted in 2015



Next steps











Jun 2023 Points to consider circulated in advance of HCPWP meeting Jun/Jul 2023
Discussion at HCPWP
Written consultation
on points to consider

Early consultation

phase

Analysis & drafting

Jul/Sep 2023
Analysis of comments
Drafting of revised
text, as needed

Consultation on revised text

Sep/Oct 2023 Written consultation on revised text

Nov 2023 Final version ready for endorsement

Endorsement

Dec 2023 HCPWP

Mar 2024 Management Board

Publication

Mar/Apr 2024 Publication on EMA's website



Any questions?

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