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European Medicines Agency

# EMA/eligible healthcare professional organisations policy officers' group (HCP POG) pilot: one-year review

January 2021 – January 2022

## 1. Background

EMA's Framework for interaction with healthcare professionals and their organisations lays out the principles and processes guiding EMA's efforts for engaging with this stakeholder group in its activities to increase impact of regulatory outputs. It also foresees the continuous scanning of new opportunities to learn and share knowledge with healthcare professionals.

By January 2021, a total of 33 healthcare professional organisations (including clinical learned societies) had been granted eligibility status to become involved in EMA activities. These represent different fields of clinical expertise and practitioners in Europe active in clinical research and health care. Due to the diverse nature and broad spectrum of organisations, it is important to continuously map expectations and identify potential communication and knowledge gaps as well as areas of common interest. However, it is also essential to create an environment where organisations' representatives can shape their motivations for engagement. This is the essence of the Healthcare Professionals Working Party (HCPWP), established in 2013. Nevertheless, the frequency of HCPWP meetings as well as the increasing number of eligible organisations that outgrew the working party's membership limit made it clear that additional routes for a more regular exchange with all organisations would need to be considered. It also took into account the fact that most of the HCPWP meetings occur now jointly held with patients and consumers organisations

The idea of creating a policy officers' group (HCP POG) emerged from interactions with eligible organisations during the past years. This included the fact that organisations were stepping up their interaction with EMA through newly appointed policy officers, some organisations maintained regular contacts with EMA and active contributions via policy officers, and requests for experts and consultations were handled via policy officers.

The S-PH department agreed to run a pilot in 2021 to explore whether such a group could be a valuable, efficient and sustainable solution.

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# 2. HCP POG pilot

For many eligible organisations, policy officers act as the single point of contact for EMA activities. They are generally a staff member of the organisation, can be either a healthcare professional or an individual with another background, and they follow EMA activities and liaise within their organisations' network to gather input and identify experts. Some policy officers are also HCPWP members. However, some organisations have identified a different profile for their single point of contact with EMA, which in this case is the clinician/practitioner representing the organisation in the HCPWP.

## *2.1. Goal, objectives and methods*

The **pilot goal** was to organise 6 conference calls of 1.5-hours in months where no HCPWP meeting would take place, throughout 2021, and review the experience upon completion of the last call, through an online survey to participants.

The first two conference calls, organised in February and April, were used to establish a group dynamic, provide general information and agree on objectives and how the group wanted to work, including topic prioritisation.

Participants agreed the group's **objectives** were to:

- Further support engagement and communication with EMA eligible healthcare professional organisations;
- Establish a common place for organisations to raise points with EMA in a coordinated and transparent manner – focusing on the remit of EMA activities;
- Provide complementary EMA updates to HCPWP meetings.

**Topic prioritisation**, building on the results from a survey to all eligible HCP organisations carried out in Jan/February 2021, guided the 4 remaining calls, which were dedicated to:

- Innovation in clinical trials (May)
- RWD and registries (July)
- Special populations: geriatrics, rare diseases, pregnancy and lactation (October)
- Shortages (December)

A briefing note for each of the four topics was prepared in advance of the respective meeting. Input from organisations was also collected in advance of the meetings, annexed to each briefing note and shared with EMA colleagues working in the relevant areas.

A rolling agenda and action points document was continuously updated.

Documents prepared as part of the pilot were shared with all eligible organisations, regardless of their active participation in the conference calls.

## *2.2. Participants*

All eligible organisations were invited to nominate a participant for the kick-off call in February. Organisations were asked to identify a policy officer and/or a different participant profile, at their own discretion, considering the pilot goal and the proposed agenda. Upon request from organisations, up to two participants could join each conference call.

Participation was high, with all calls gathering at least half of all eligible organisations:

- 26 out of 33 eligible organisations participated in one of the pilot calls;
- 18 out of 33 eligible organisations participated in 4 or more pilot calls;
- 6 out of 33 eligible organisations participated in all pilot calls.


| Organisation | Field of expertise/ practice | Profile of participants | Calls attended |
|---|---|---|---|
| BioMed Alliance | Multi-disciplinary/ clinical research | Policy officer | 5 (Shortages; RWD/Registries; Innovation/Clinical Trials; April; February) |
| CPME | Doctors in general | HCPWP member<br>Policy officer | All |
| EAACI | Allergology and clinical immunology | HCPWP member | 4 (Shortages; Innovation/Clinical Trials; April; February) |
| EACPT | Clinical pharmacology | HCPWP member | 2 (Shortages; Special Populations) |
| EAHP | Hospital pharmacy | Policy officer | All) |
| EAN | Neurology | HCPWP member<br>Policy officer | 2 (Shortages; Special Populations) |
| EASD | Diabetology | HCPWP member | 3 (Innovation/Clinical Trials; April; February) |
| EASL | Hepatology | Policy officer | 5 (Shortages; Special Populations; RWD/Registries; Innovation/Clinical Trials; February) |
| EAU | Urology | Policy officer | 5 (Shortages; Special Populations; RWD/Registries; Innovation/Clinical Trials; February) |
| EFIM | Internal medicine | HCPWP member | 1 (April) |
| EFPC | Primary care | Expert | 5 (Shortages; Special Populations; RWD/Registries; Innovation/Clinical Trials; April) |

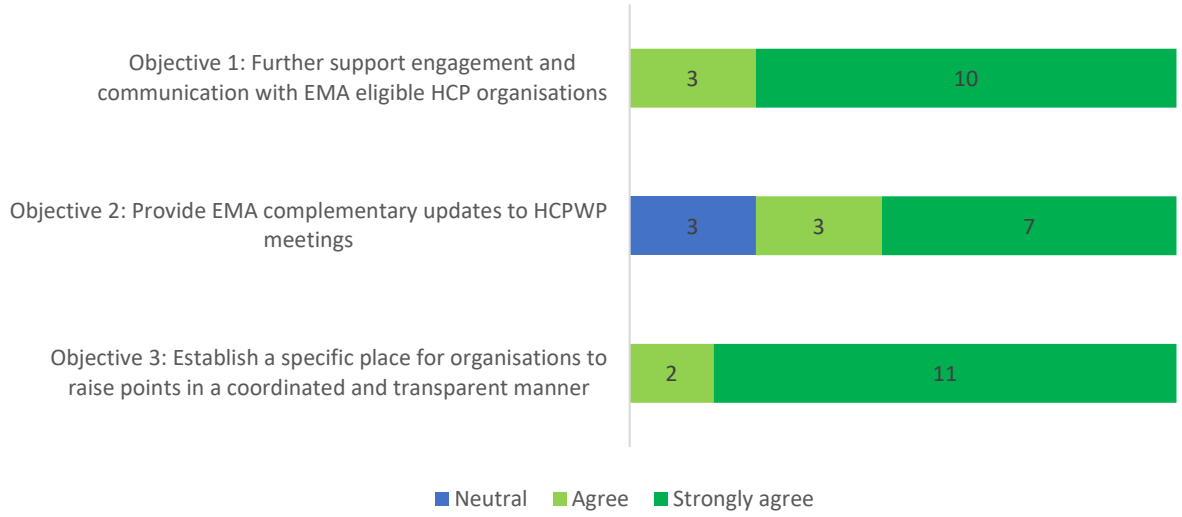
| Organisation | Field of expertise/ practice | Profile of participants | Calls attended |
|---|---|---|---|
| EHA | Haematology | Policy officer | 3 (Innovation/Clinical Trials; April; February) |
| EHF | Headache | Expert | 1 (RWD/Registries) |
| EORTC | Oncology | Expert | 4 (RWD/Registries; Innovation/Clinical Trials; April; February) |
| EPA | Psychiatry | Policy officer | 4 (Shortages; RWD/Registries; Innovation/Clinical Trials; February) |
| ERS | Respiratory | HCPWP member | All |
| ESC | Cardiology | HCPWP member<br>Expert | 5 (shortages; special populations; Innovation/Clinical Trials; April; February) |
| ESE | Endocrinology | Policy officer | 2 (shortages; RWD/registries) |
| ESMO | Oncology | HCPWP member<br>Policy officer | All |
| ESR | Radiology | Policy officer | 4 (shortages; special populations; April; February) |
| EU-EYE | Ophthalmology | Policy officer | 5 (special populations; RWD/Registries; Innovation/Clinical Trials; April; February) |
| EuGMS | Geriatric medicine | HCPWP member | 2 (special populations; Innovation/Clinical Trials) |
| EULAR | Rheumatology | HCPWP member<br>Policy officer | All |
| PGEU | Community pharmacy | HCPWP member | 5 (shortages; special populations; RWD/Registries; Innovation/Clinical Trials; February) |
| UEG | Gastroenterology | Policy officer | 4 (RWD/Registries; Innovation/Clinical Trials; April; February) |
| UEMO | General practice | HCPWP member<br>Policy officer | All |

# 3. Survey results

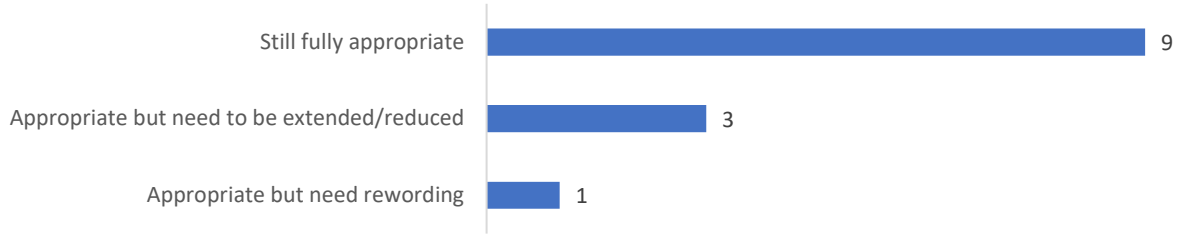
## *3.1. Feedback from participants representing their organisations*

Half of the organisations participating in one or more calls of the pilot responded to the evaluation survey (n=13).

**Do you feel the HCP POG pilot achieved the three pre-agreed objectives?**




If the HCP POG were to continue, do you feel the above objectives are:



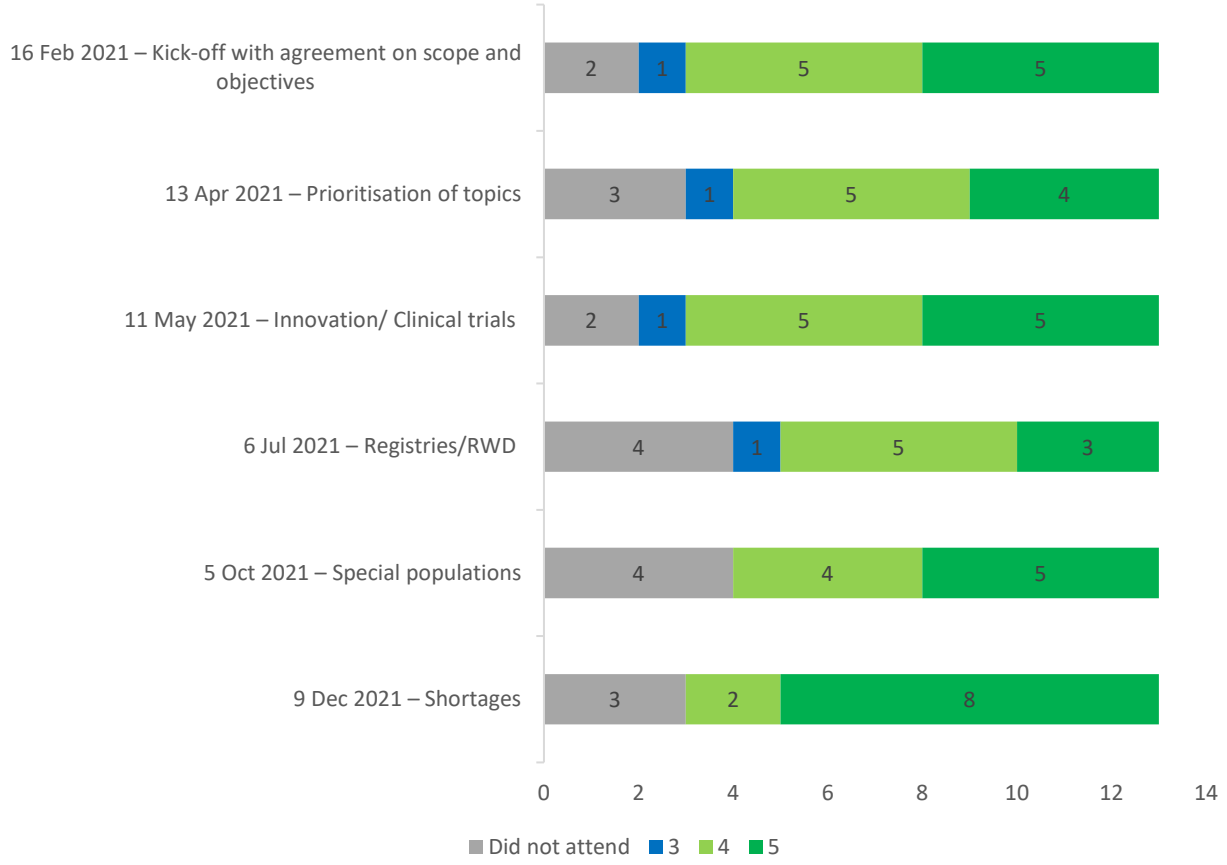

Suggestions:

- To supplement Objective 3: in addition to establishing a specific place to raise points, to also establish a specific framework with a set of tools and processes to show how the points raised are incorporated into drug development and regulatory decision-making in short- and long-term.
- Given the extended scope of the EMA into high risk medical devices, etc an additional objective would be to explicitly refer to Increase understanding of the EMA's extended scope (as this will lead to additional training sessions).
- For objective 3 I would make more active rather than passive. i.e. something like 'Establish a specific place for organisations to raise points, engage and participate in a coordinated and transparent manner'. It also means we should probably define some clear deliverables e.g. publications, communication aids, webinars etc.
- The step further would be to better define the deliverables so that the community can follow up on the outcomes this initiative delivers. When possible, ensure that concrete activities do

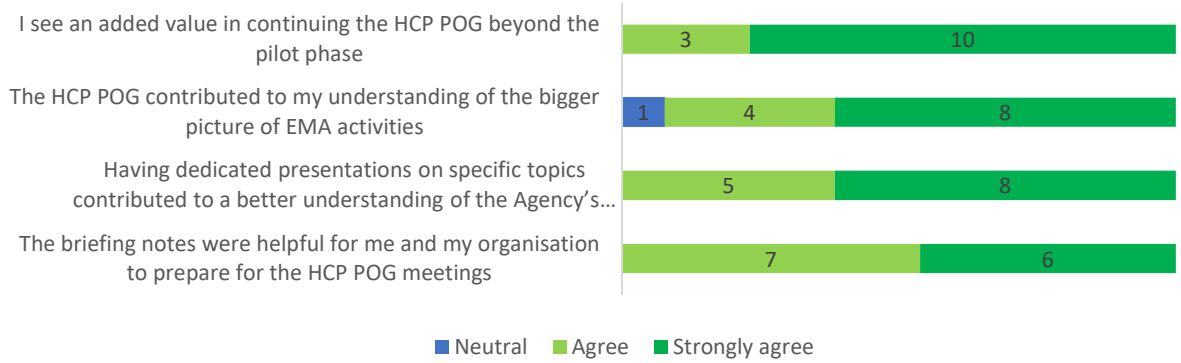
emerge to address the points of the academic community. Some examples already exist in that respect so to be more structural to the initiative.

- For topics already covered, suggest moving beyond the general exchange of information and views to more actionable outcomes of the meeting.

**How would you rate the content (and discussion) of the 6 calls organised during the pilot phase (1 very poor; 5 very good)?**




**To what extent do you agree or disagree with the following statements?**



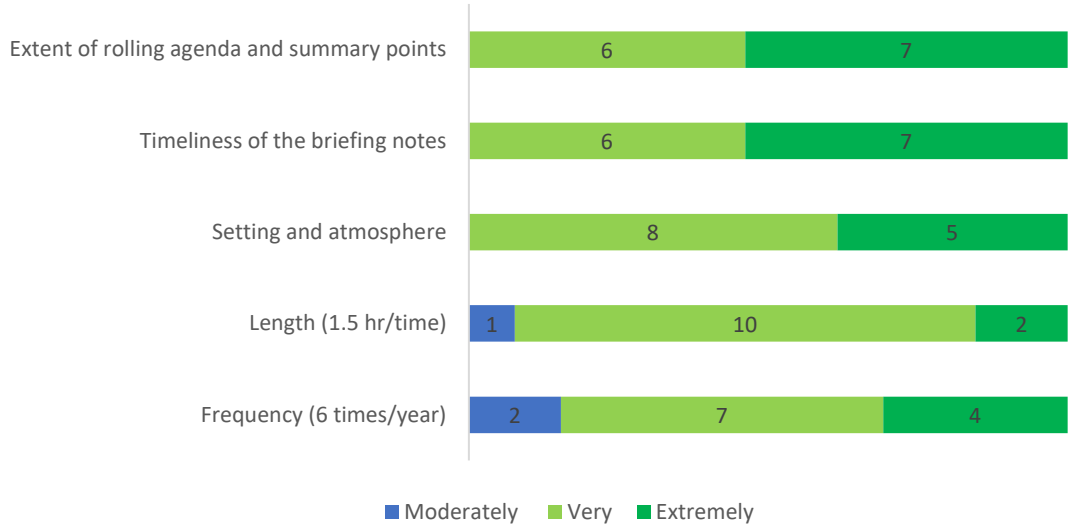

Further comments:

- I really feel the extended time we had with HCP POG enabled me and my organisation to better understand the complexity of EMA work, its interconnectedness and how we can support and

communicate EMA's role better. I was also much more able to understand perspectives of other groups especially GPs and Pharmacists.

- The main value for me is the extended opportunity to discuss and learn about a specific topic more in detail with other HCPWP organisations and doing so in an informal manner which helps to stimulate a productive discussion.

**From an operational perspective, how appropriate did you find the following aspects of the HCP POG meetings?**




If the HCP POG were to continue, what would be your preferred frequency and length of meetings?

- Either slightly longer sessions or additional sessions for topics that demand more time than others. For example, the discussions on registry-based studies and big data could benefit from additional time as there are many subtopics within the two themes. Also, the themes are interlinked so another idea would be to have a session for topics that are interlinked e.g. big data and registry-based studies, etc.
- Same frequency and length, or either prolonged with an extra 30 minutes.
- I fully support the proposed frequency of 6 times/year. 1.5h duration of the meetings is reasonable and probably the most appropriate, although there are times when we need to cut a discussion short due to time constraints. I believe that this could be addressed with lighter agenda while keeping the current time frame.
- The meeting frequency used for the pilot (6 meetings per year) was very good. I would recommend keeping this frequency. The meeting length could be extended to 2 hours in order to allow more time for discussion.
- 4 times per year /(1.5 hr/time)
- For us the larger meetings with the HCPWP are sometimes too long to fit in a normal working day. Prefer the short and more precise discussions @HCP although we were not always able to attend.

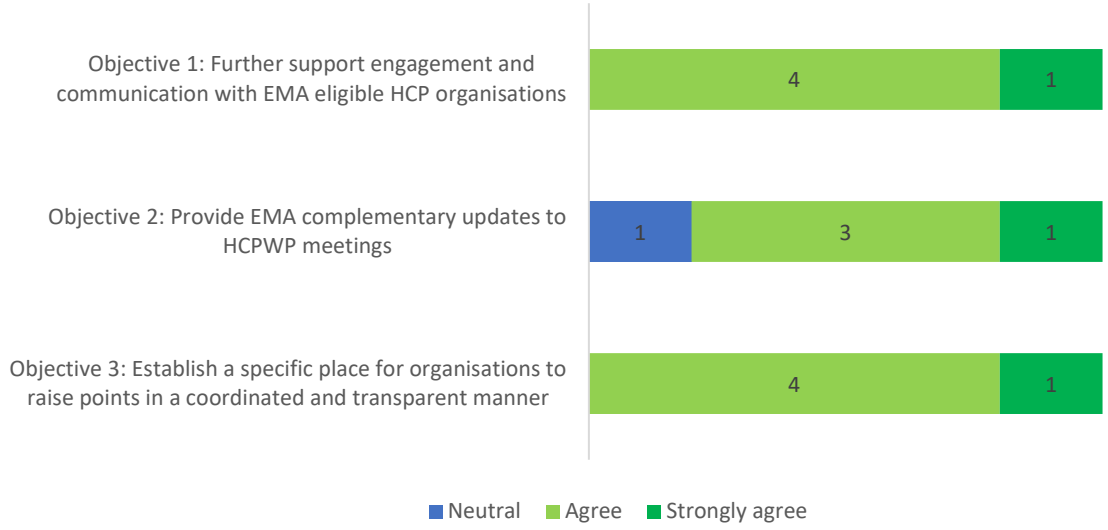
**Qualitative feedback:**

- Occasionally the tasks were not clear. Additional briefing material could help or a session of Q&A to supplement sessions on topics that are more complex than others.
- It may be of benefit if the HCP POG were given (or better if they select themselves) a clear task to complete for the year that would benefit the EMA and at the same time increase collaboration among the officers of the organisations (this can be supervised by the EMA or just supported) e.g. creation of a paper with collective views on a specific topic of interest e.g. unmet needs, perspectives on benefit-risk assessments. Letting the organisations work this together will be valuable for when the time comes to support new work with the EMA. It will be beneficial to identify overlap and work as a team-building exercise for the organisations involved.
- It is not clear what the EMA does with the feedback given by the different organisations before a session starts or afterwards or in the long-term. It would be good to report on this whenever these views are used in any of the EMA work, not in great detail but with some reference and acknowledgement for the organisations involved. Such transparency will raise enthusiasm and instil sustainability in engagement.
- I really hope this initiative continues, as I think we achieve more in depth than is possible at HCPWP/PCWP meetings. I especially enjoyed learning about Darwin and all the Big Data projects. Thanks too to whole team for making the HCP POG process instructive, accessible, and enjoyable.
- The challenge is the variability of the participants who represent different types of organisations and objectives. So the challenge is to keep all motivated. EMA is demonstrating a real and appreciated opening towards the academic community. Thank you
- A session on lessons learned from implementation of Guidelines to MS in terms of capacity strengthening and bringing raw materials and manufacturing capacity back to Europe would be interesting.
- The establishment of the POG's meetings allowed for greater involvement of our organisations in the EMA's work. For us, it results in gaining greater insight into the Agency's activities which we can share with our members. It also gives us the opportunity to further communicate our views or ask questions on the discussed topics. All in all, I believe the pilot was successful and the meetings should be continued.
- More feedback from participating HCPs driving the meetings agenda and the POG priorities.
- The HCP POG pilot provides important opportunities for being involved in the initiatives of the EMA and conveying news on oncology-related studies and developments that may be important for the work of the EMA. The HCP POG pilot has also been instrumental for supporting the work that is being done in the HCPWP. Lastly, being a part of the HCP POG is also of great support for the initiatives that are being undertaken by the eligible HCP organisations in relation to the topics that were discussed at the HCP POG meetings. It would therefore definitely be valuable to continue the HCP POG beyond the pilot phase.
- Thank you very much for this great initiative and for the excellent preparation, organisation and follow-up of these meetings. It is highly appreciated.
- The HCP PGO pilot is a great initiative that will hopefully be continued in 2022. Thank you to all EMA staff involved in its organisation.

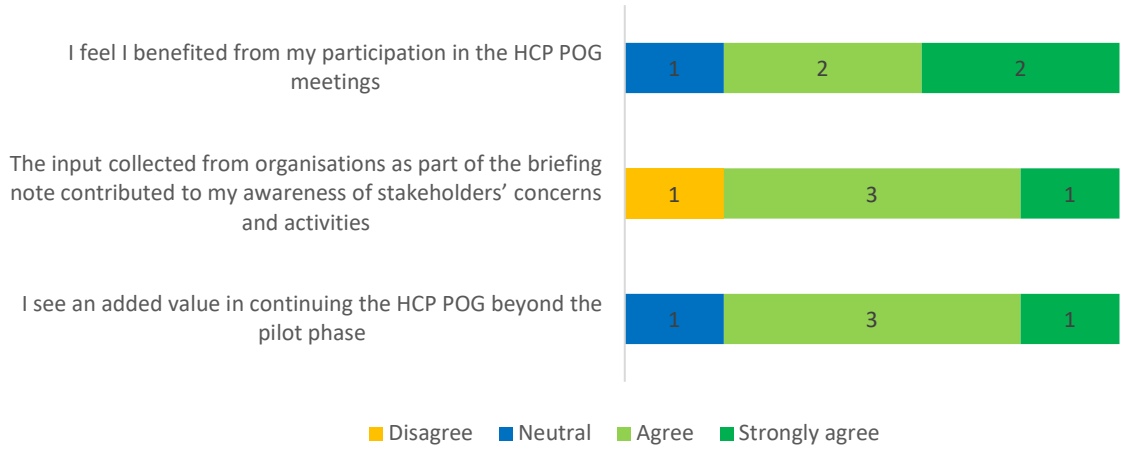
## *3.2. Feedback from EMA staff*

A survey was sent to all EMA speakers and colleagues who supported the preparatory work for the calls. Feedback was received from 5 out of 11 participants.

**For the HCP POG sessions you attended, did you feel the following objectives were achieved?**




**To what extent do you agree or disagree with the following statements?**




**What could be improved?**

- Personally (I was there for the pregnancy topic) I'd like to see more connection with some of the other topics (registries, clinical trials) also at these meetings. This, both for purposes of achieving more synergy between EMA actions & initiatives and because in my view it strengthens our messages to the stakeholders.
- It would be beneficial to have presentations from HCP on their activities as well.

**Is there anything else you would like to share with us on the HCP POG pilot?**

- I only ever participated in one meeting on the special populations, and for my particular topic there was not much input but having said that I still think it was worth raising the awareness at the meeting.

- It seems a very useful thing to do - it seems we get more, and valuable, input from HCPs in this way.
- Very positive interaction and of particular importance for medicine shortages.

## *3.3. Observations and lessons learnt*

**What we observed**

- Most people attending did not have the **overall picture of what EMA does or plans to do** in each of the chosen areas; the intention was to:
  - allow organisations to gain a better understanding of the topic from an EMA perspective to support and guide their interaction with EMA and
  - identify areas their organisations might be working on that can have synergies with EMA activities.
- Relevance of **complementing the high-level presentation provided in PCWP/HCPWP** meetings for organisations to better understand where EMA work fits within the wider context of EU policy and clinical research in their fields of expertise.
- Some participants had very **specific questions** due to their areas of interest and would appreciate to gain a better understanding of what EMA can and cannot do within its remit and be guided to more specific pathways to the information they might be looking for.
- The paediatric population was not part of the call addressing special populations due to time limitations. In addition, one participant raised the topic of environmental risk-assessment of medicines as one that could be addressed in a future HCP POG meeting.

**What worked well**

- The meetings provided EMA with **insights** on what the organisations' concerns are, their expectations and areas of work that provide indicators to EMA of additional topics for which we may need to develop more targeted communication/training.
- Concrete **areas for exploration were identified** and specific input was collected. This is compiled in annex 1 and full details can be found in each of the briefing notes.
- As shown by the survey results, the overall **content and organisational aspects** around the calls were well received by participants.
- There is a preference to maintain the meetings 6 times/year with a 1.5-hour duration, although an additional 30min could be considered depending on the topic.

**What could be improved**

- **Focus on a specific topic** and keep a low number of presentations – the special populations call had too many topics which would merit more time for presentation and discussion; the shortages call was a good example of how a single topic allowed for more discussion and clarification questions.
- Shape agendas together with the organistions to encourage **more presentations from organisations** – upon EMA request, only one organisation expressed interest to present during the pilot.
- Provide **more detailed feedback** on how EMA will use input collected from organisations.

# 4. Conclusion

The overall feedback received from both organisations and EMA participants involved during the pilot is very positive and reflects the usefulness and benefit of such a group, as a complement to the HCPWP.

There is strong support to continue the HCP POG beyond this pilot, incorporating the learnings and experience gained.

**Way forward**

- Maintain the HCP POG during 2022 and re-assess its continued usefulness and sustainability as well as impact on eligible organisations' satisfaction levels in Q1 2023.
- Use the input collected as part of the review/updating of EMA's Framework of interaction with Healthcare professionals to take place between 2022-2025.

# Annex 1: Concrete areas for exploration identified and input collected

## *Innovation / Clinical trials (CTs), 11 May 2021*

- Specific input collected from 14 organisations; areas of greatest interest: new CT methodology (including explicit reference to Adaptive trial); clinically meaningful or patient relevant outcomes; representation of 'neglected' populations (child/rare diseases/ pregnant women/elder); academic or non-commercial research
- Opportunities for engaging with healthcare professionals - involvement of experts in early dialogues to discuss appropriate trial designs, and clinical data management
- Review of which fields innovation takes place in and in which it does not, evaluation of in how far this matches medical needs, and identification of potential obstacles for innovation on the regulatory side
- Further development of (multi) staged more flexible market access, based on multistage - adaptive trial design model
- Research on processes in clinical trials for evidence-based trial regulations
- Innovation-oriented review of current EMA clinical trial guidelines

## *Registries/RWD, 6 July 2021*

- Specific input collected from 16 organisations
- Importance of data standardisation and satisfaction to see ethical aspects being considered as part of the Big Data Work Plan
- In relation to DARWIN EU, there is interest to further understand how it links to the Joint Action Towards the European Health Data Space (TEHDAS)
- Ensuring delivery of concrete results that take into account what is happening in the clinical research and clinical practice fields
- suggested to further liaise with the HCP representatives in the Big Data Steering Group (Ioana Agache, EAACI) and the DARWIN EU Advisory Board (Aldo Maggioni, ESC) to ensure input from different organisations and clinical realities are collected and inform use cases
- In relation to EMA's guideline on registry-based studies, questions requiring additional clarification could be collected to inform a Q&A document

## *Special populations, 5 October 2021*

- Specific input collected from 4 organisations
- There is an expectation that new platform trials will provide a chance to address appropriate inclusion of elderly, pregnant women, etc, and that combining RCTs and RWD is needed
- Medicines for frail and older people - EMA will raise with CHMP and the Scientific Advice Working Party (SAWP) the messages provided by EuGMS and participants to enforce guidance to developers to include physical frailty/ function parameters in clinical trials with older adults and the importance of learning from patients in identifying design features that meet the needs, capabilities and limitations of older patients as part of the development process

- Medicines for people living with a rare disease - continue to update on upcoming opportunities for contributing to topic-related consultations as well as on EMA's areas of interaction with the European Reference Networks (ERNs)
- Medicines use during pregnancy and breastfeeding - share with EMA any ongoing (or planned) activities towards addressing representation of pregnant and breastfeeding women in medicines research and development

## *EMA shortages-related activities, 9 December 2021*

- Specific input collected from 2 organisations
- Following the set-up of EMA common principles for member states to collect demand data, in the context of the COVID19 pandemic, a list of critical medicines will be agreed. EMA will reach out to HCP organisations and learned societies to bring their input into the list, which is intended to go beyond medicines used in ICU patients
- Contribute to continuous monitoring of shortages by e.g., surveys – discuss need to include specific questions in order to provide more transversal elements across different medical fields that can inform EMA discussions
- Promote early signal detection of shortages in clinical practice through discussing what could be early signals for which HCP organisations and learned societies could contribute to in order to shift from mitigation to prevention of shortages (including in the area of clarifying practices in the face of off-label and repurposing of medicines such as the one seen with dexamethasone during the COVID19 pandemic)
- Discuss how HCPs can support prevention of stockpiling (including consumer/patient-driven stockpiling)
- In addition to what is already happening with industry associations, maintain direct interactions with HCP organisations and learned societies to gain a better understanding of what is happening in the healthcare frontline
- Encourage organisations to write editorials (and/or special issues on shortages) to raise awareness about EMA activities, including visibility of the SPOC network, compile some success stories around how many shortages have been prevented, and showcase what has been done and what is the pipeline - liaise with EMA's scientific publication strategy lead
- Work further with academia to study for example ways for matching supply and demand data and how fluxes of use of medicines affect shortages (e.g. off-label use and repurposing of medicines used for RMD during the pandemic impacted non-COVID patients)
- Discuss the findings of the EC's final report on Future-proofing pharmaceutical legislation – study on medicine shortages, including commercial reasons leading to shortages
- Provide more space for discussing also shortages of companion diagnostics and in vitro medical diagnostics medical devices in the context of EMA's extended mandate
- Explain what is EMA's role in discussions at global level
- Encourage harmonised communications and early signalling of shortages to both patient and healthcare professional organisations