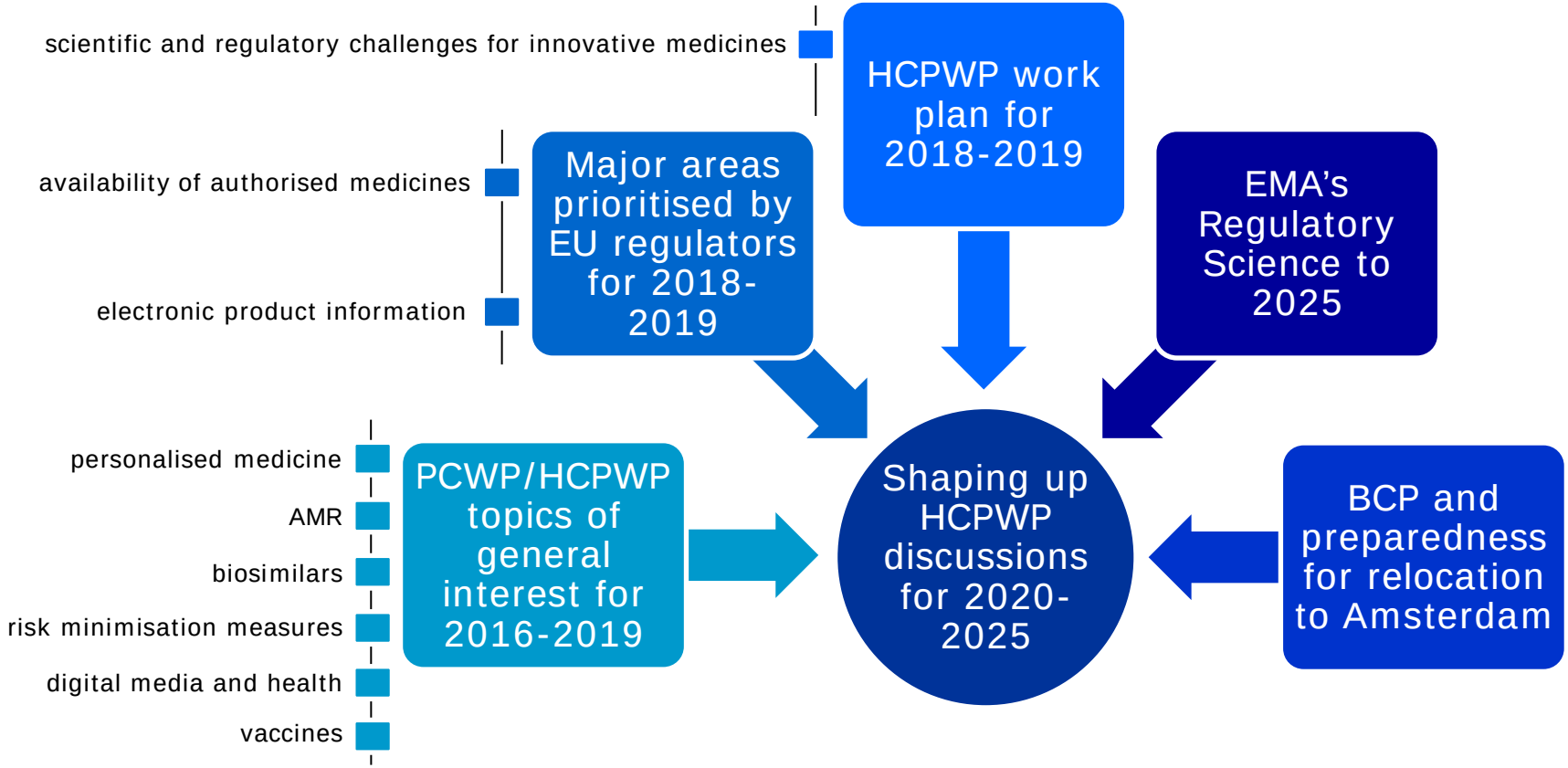
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Survey on HCPWP role to address upcoming scientific /regulatory challenges impacting clinical practice

Identifying priorities for 2020-2025

Presented by Ivana Silva
HCPWP meeting, 26 September 2018

Why are we having this discussion?



SURVEY

- Aim: proposing priorities/directions for HCPWP discussions for 2020-2025
- Prepared with contributions from co-chairs, 2 HCPWP members, EMA secretariat
- Sent to all members and alternates
- Open from 13 to 20 September 2018

15 responses covering 12 out of 20 organisations

UEG; ESR; EULAR; EHA; ESC; ESNO; EUGMS; EFIM; EAU; PGEU; CPME; EAHP

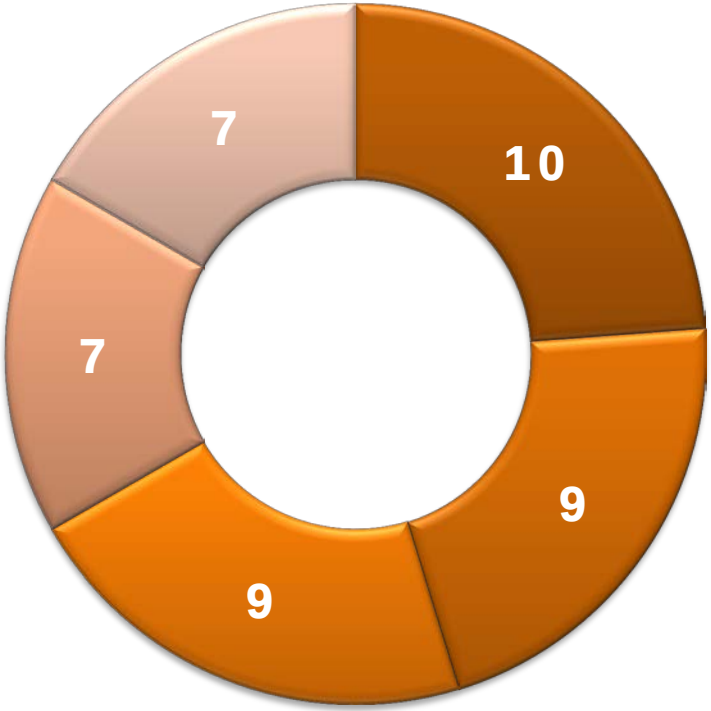
and 1 out of 6 Scientific Committees

COMP

What do you want to see discussed at future meetings?

EUROPEAN MEDICINES AGENCY

Answers



- Cluster 1: Integration of science & technology in drug development
- Cluster 2: Evidence generation and communication
- Cluster 3: Access to medicines
- Cluster 4: Emerging health threats and availabliity/ therapeutic challenges
- Cluster 5: Research and innovation in regulatory science

What do you want to see discussed at future meetings?

EUROPEAN MEDICINES AGENCY

- Cluster 1: Integration of science & technology in drug development

How to promote early dialogue (patients, clinicians, regulators, industry, payers, HTA…)
Developments in personalised medicine, biomarkers and 'omics'
Reflection on new diagnostic methods and how their clinical validation (or lack of it) impacts on use of medicines
Other
No Answer

- 1 organisation *(ESC)*
- **8 organisations + COMP** *(UEG; ESR; EULAR; EHA; ESNO; EFIM; EAU; EAHP)*

For discussion: How would members like to further address the topic of **personalised medicine**?

- 3 organisations **did not select** cluster 1 *(EUGMS, CPME, PGEU)*

What do you want to see discussed at future meetings?

EUROPEAN MEDICINES AGENCY

- Cluster 2: Evidence generation and communication

Benefit-risk assessment and communication
Registries, status and results; identifying where are the bottlenecks
Data collection, what is being done (including big data projects), problems and opportunities
Digital health and digital literacy
Other
No Answer

- 4 organisations *(EFIM; PGEU; CPME; EAHP)*
- 2 organisations *(EULAR; ESC)*
- 2 organisations *(EAU; CPME)* + COMP
- 1 organisation *(UEG)*
- 4 organisations **did not select** cluster 2 *(ESR; EHA; ESNO; EUGMS)*

For discussion: Where should the focus be?

What do you want to see discussed at future meetings?

EUROPEAN MEDICINES AGENCY

- Cluster 3: Access to medicines

How to avoid disconnection between regulatory approval and reimbursement schemes
How regulations and requirements for new therapies (e.g. biologics, gene therapies) may affect distribution/access to these medicines
Shortages of inexpensive medicines
Other
No Answer

- 4 organisations *(EULAR; ESNO; CPME; EAHP)* + COMP

For discussion: Would this topic interest more organisations?

- 2 organisations *(EFIM; PGEU)*
- 1 organisation *(ESC)* *early access programmes through HCPs*
- 4 organisations **did not select** cluster 3 *(UEG; ESR; EUGMS; EAU)*

For discussion: Where should the focus be?

What do you want to see discussed at future meetings?

EUROPEAN MEDICINES AGENCY

- Cluster 4: Emerging health needs and availability/therapeutic challenges

Antimicrobial resistance: What is capacity building and training in the context of considerable increase in immunosuppressed patients due to use of monoclonal antibodies in oncology, haematology, rheumatology, dermatology, gastroenterology
Antimicrobial resistance: Contribution to wider EU debate on AMR (e.g. diagnostic tests for use in community care settings; European awareness campaigns)
Vaccination: Vaccine issues under EMA remit (development, scientific support to study design, communication and safety monitoring, shortages)
Vaccination: Contribution to wider EU debate on vaccination (e.g. immunization strategies and issues around vaccination policy)
Other
No Answer

- 1 organisation *(EULAR)*
- 5 organisations *(ESC; EFIM; PGEU; CPME; EAHP)*
- COMP

For discussion: How would interested members like to address this topic further?

- 6 organisations **did not select** cluster 4 *(UEG; ESR; EHA; ESNO; EAU; EUGMS)*

What do you want to see discussed at future meetings?

EUROPEAN MEDICINES AGENCY

- Cluster 5: Research and innovation in regulatory science

How to set up research taking in patient outcome measures for new medicines (and devices)
How to capture the effectiveness of innovative drugs (RWE)
How to collect real clinical needs (development driven by gaps in patient care)
Supporting academic research/initiatives
Other
No Answer

- 1 organisations *(UEG)*
- 3 organisations *(ESC; CPME; EAHP)*
- COMP

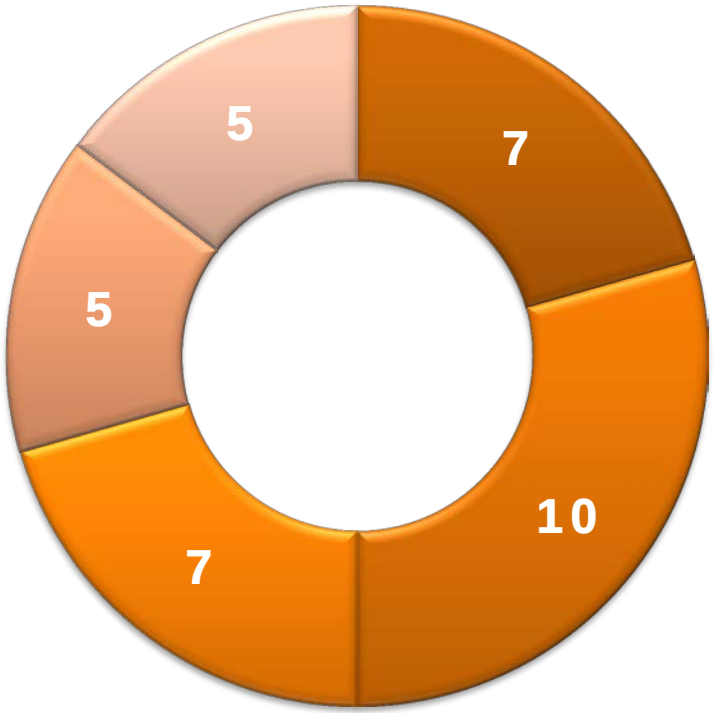
For discussion: Where should the focus be?

- 1 organisation *(EHA)*
- 1 organisation *(EUGMS)* *geriatrics*
- 6 organisations **did not select** cluster 5 *(ESR; EULAR; ESNO; EFIM; EAU; PGEU)*

For discussion: Would this topic interest more organisations?

How can you/your organisation contribute?

EUROPEAN MEDICINES AGENCY



- Actively shaping the program by suggesting sessions and speakers
- Bringing the organisation's perspective
- Discussing possible ways forward from the HCPs' point of view
- Collecting data/input
- Reflecting on training needs

- Other: 1 organisation *(geriatrics)*

What is it you want to take back home from HCPWP meetings?

EUROPEAN MEDICINES AGENCY

General overview of ongoing initiatives	• 8 organisations + COMP
How to link EMA projects/ initiatives/ activities to areas where my organisation is already involved in, to create more interest and engagement within my organisation	• 6 organisations
Select initiatives in which my organisation could have an active interaction with regulators and provide a meaningful contribution	• 5 organisations
Reflect if there are initiatives where HCPWP members can join forces / benefit from each other's strengths more	• 5 organisations

For discussion:

- Where can we strike the right balance between general overview and level of detail?
- What do you need to take action on options 2, 3 and 4?

Is there a role for the HCPWP to help identify how advances/changes in healthcare practice and clinical research relate to EMA's work in the evaluation and monitoring of medicines?

- 4 organisations are not sure
- 8 organisations + COMP replied with a 'yes'

- **How?**
  - HCPWP **working groups** could prepare **position papers**
  - Some HCP organisations have **infrastructures able to run registries** for both pharmacovigilance and early access.
  - HCP organisations can provide specific **suggestions of world renown experts** that may be useful for the evaluation and monitoring of medicines
  - See the **nurses perspective** of application of medicines
  - The **priority in healthcare** is now the **high number of very old frail people and their medicines**
  - **Identify a few priorities** (it can be a disease or a group of diseases - like rare diseases - or a type of innovative medicine - like precision medicine - or something like electronic information or use of data collected about medicines). Then it would be possible to **organise specific working groups or workshops** followed by a discussion during a HCPWP meeting

For discussion: On what? What should trigger it?

For discussion: How?

- **How?**
  - Bringing the **real world clinical practice** to the regulatory system so that EMA and its committees are guided on the needs of patients and HCP and be stricter or more open depending on the expectations of the final users of the new medicines. All the efforts of assessing a new medicines are lost when the product and the product information are out of the reality. The same relates to the access of patients to new medicines and the differences in criteria between EMA and national HTA bodies.

For discussion: On what?

  - **Sharing of best practices**, sharing of **evidence coming out of practice**.
  - Even though EMA might not always be empowered to act on the discussions, there is a **position of influence that the EMA and the HCPWP can use** e.g. in relation to the disconnect between approval and availability.

For discussion: How? On what?

Do you see a value in running a similar analysis/discussion as this one on a periodic basis to help identify well in advance issues of interest?

- 11 organisations + COMP replied with a ‘yes’

Other suggestions/comments

EUROPEAN MEDICINES AGENCY

Discussions to identify issues and possibilities for both EMA and its partners are crucial. However, not all participants are equipped to provide profound input.
This is high-level content with often limited experience in both clinical practice as research. It might be worth to consider a careful selection of the participants.

Please listen to the arguments of the geriatricians and start as soon as possible a "geriatric committee".


Thank you!