EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The HCPWP vis-à-vis the Agency's structure and activities

Roles and responsibilities of the HCPWP members

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Medical Information Sector – Public Information and Stakeholder networking

Aims of the framework

Support the Agency in order to access the best possible **independent expertise** and obtain information on the current use of medicines in **real clinical practice**

Contribute to a more efficient and targeted **communication** to healthcare professionals, to support their role in the safe and rational use of medicines

Enhance healthcare professional organisations' **understanding** of the role of the EU medicines Regulatory Network

Network of European healthcare professional organisations

1 The HCPWP vis-à-vis the Agency's structure and activities

Implementation of the framework - Action plan

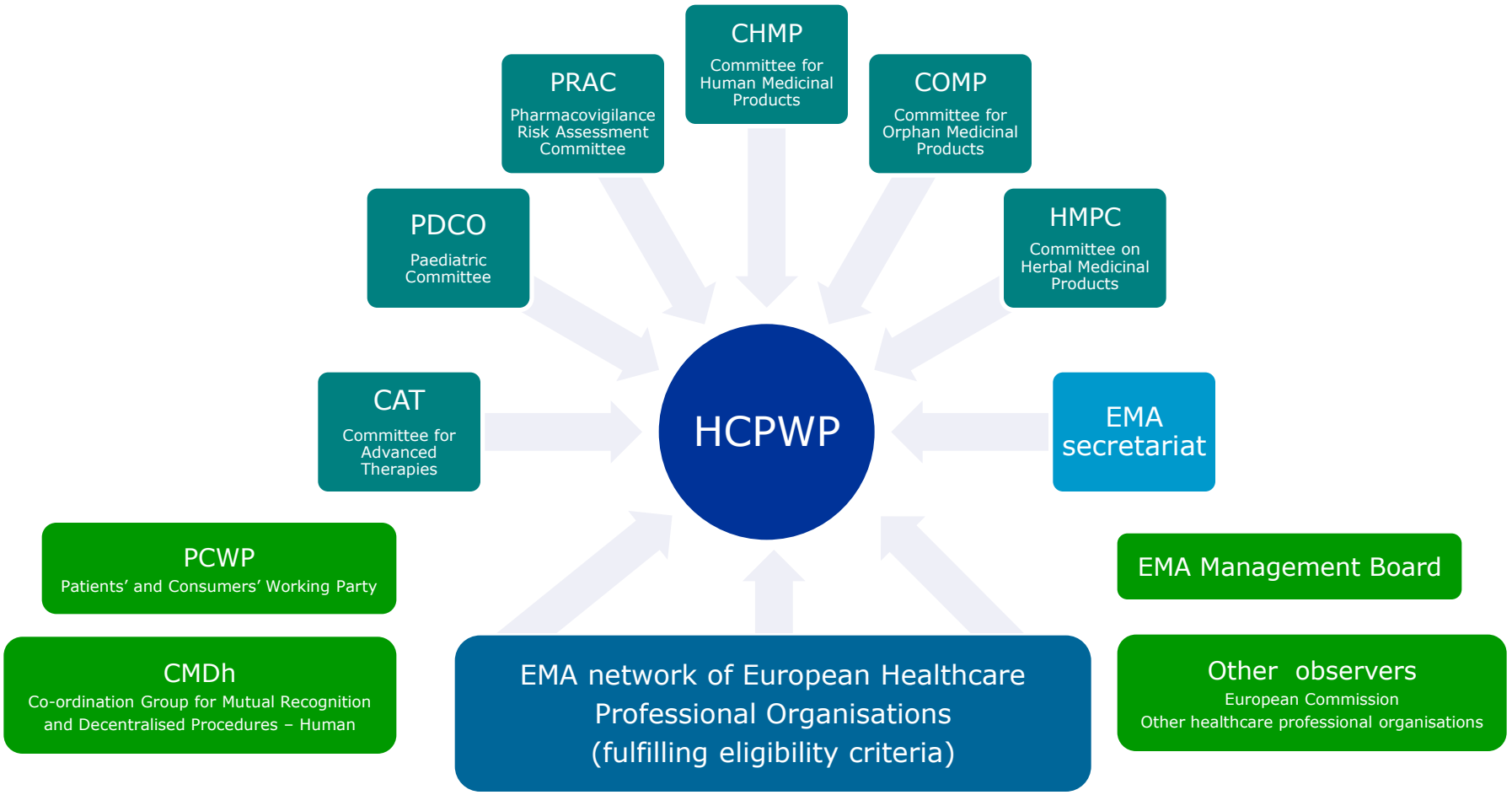
- Enable the network of European healthcare professional organisations (HCPOs) as a valuable source of independent expertise
- Continue to develop specific dialogue and interaction with HCPOs on information produced by the Agency
- Increase awareness and promote input on EMA guidelines
- Facilitate HCPOs input and contribution to the implementation of new legislation
- Establish a network of European healthcare professional organisations
- Establish the EMA Healthcare Professionals Working Party (HCPWP) and ensure its full operation
- Monitor and increase transparency on the involvement of HCPOs in the Agency's activities

Expression of interested

- There are currently 23 healthcare professional organisations eligible to work with the Agency because they fulfil the Agency's criteria

- Of these, 18 have formally expressed their interest in the membership of the EMA Working Party with Healthcare Professionals
- The creation of the working party is currently in progress and we will communicate the outcome to all candidate organisations

HCPWP composition



EUROPEAN MEDICINES AGENCY

Scientific Coordination Board

HCP input

CAT | CHMP | COMP | HMPC | PDCO | PRAC

CMDh

HCP input

HCP input

Working Parties

HCP input

- Quality
- Safety
- Scientific advice
- Biologics

Others
Biostatistics
Pharmacokinetics
Pharmacogenomics
Biosimilar
Blood products
Geriatrics
Rheum./Immuno.
Gastroenterology
(…)
As necessary

Scientific Advisory Groups (SAGs)

HCP input

- Vaccines
- Oncology
- HIV/ Antiviral
- Diabetes/ Endoc.
- CVS
- Neurology
- Anti-infectives
- Psychiatry
- Diagnostics

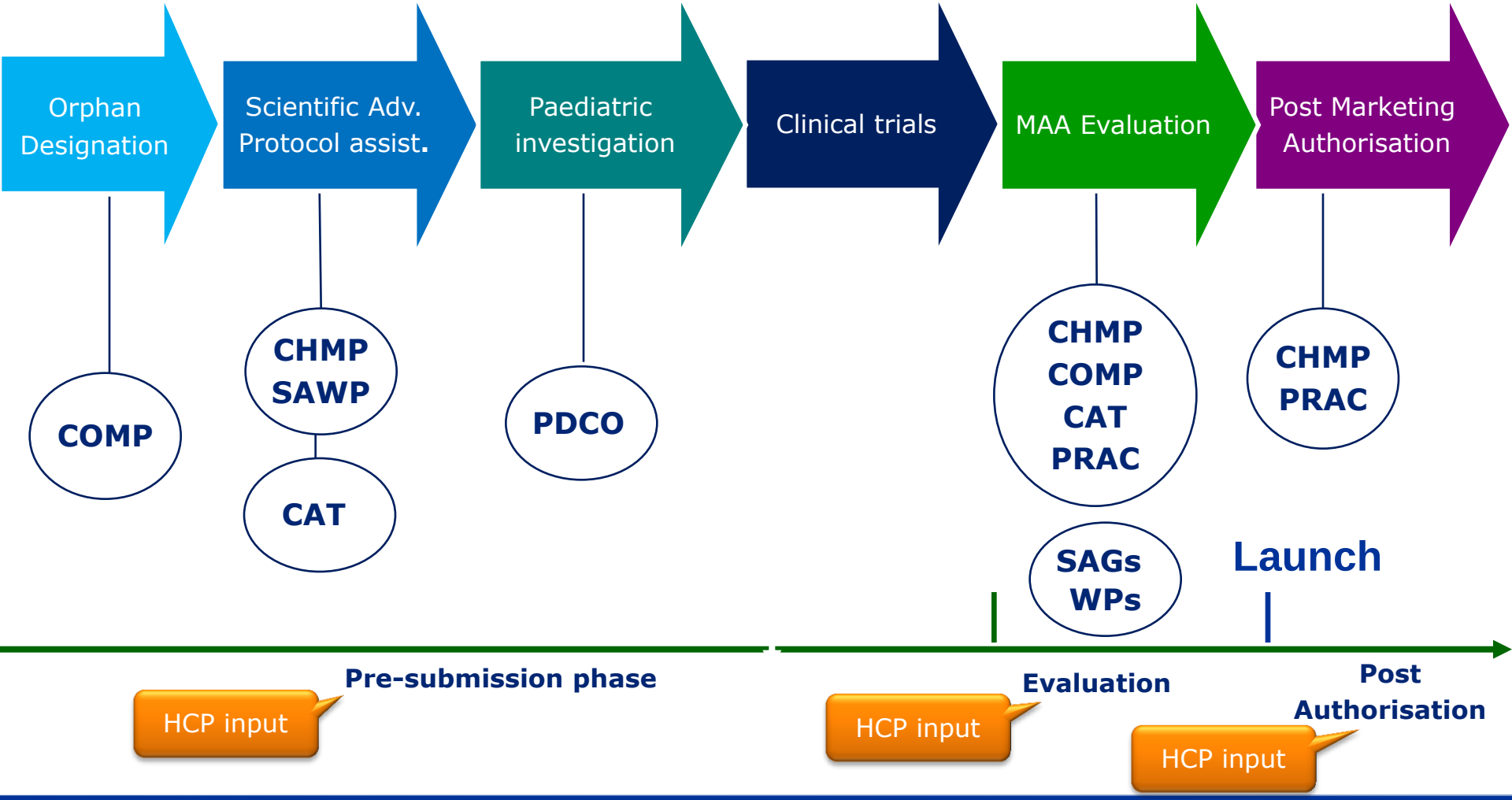
And other ad-hoc expert groups

HCP input

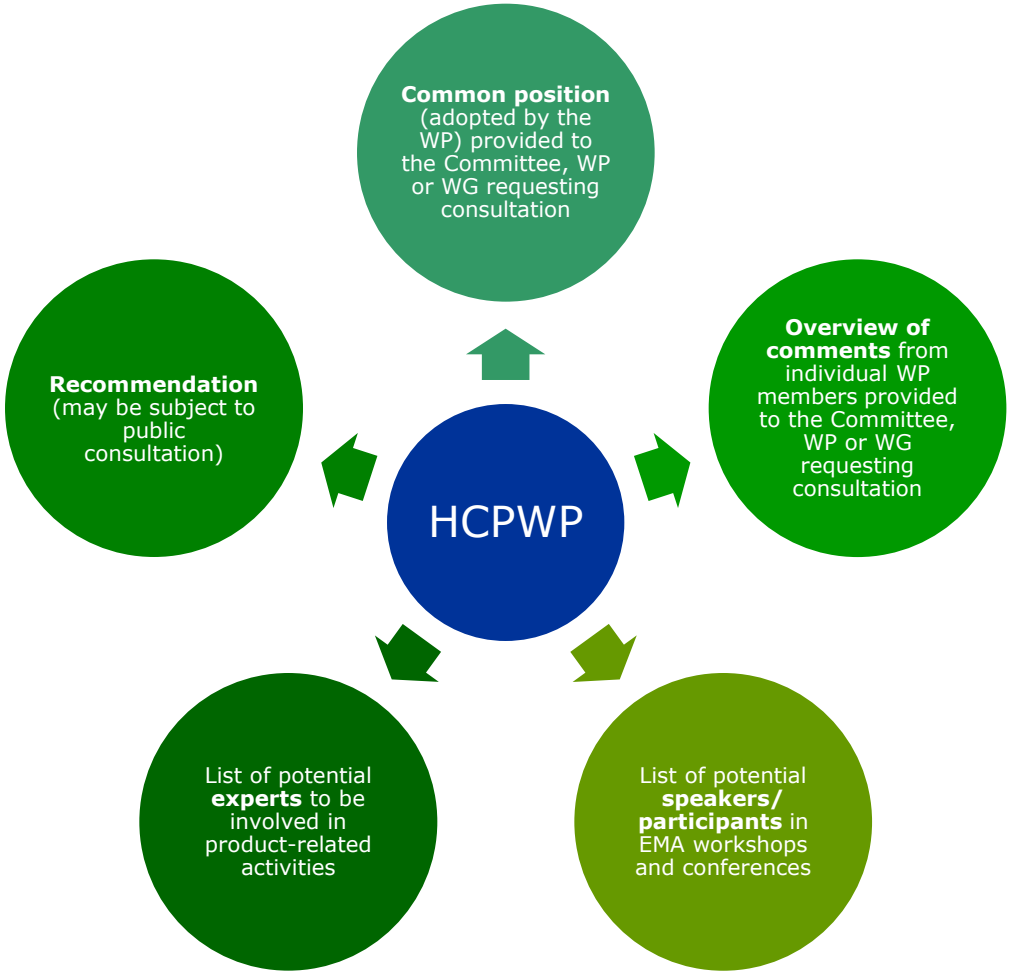
Other Groups

- Working Group on Quality Review of documents (QRD)
- SmPC Advisory Group
- EudraVigilance Users Group
- Others…

Input throughout product life-cycle



HCPWP output



HCP input (I)

- HCPWP – can be consulted as a WP by Committees and WPs on a particular matter (e.g. concept papers; draft guidelines; EMA policies)
  - If topic relevant to majority of members, WP provides common position (have to be adopted by the WP)
  - Otherwise, relevant WP members respond individually and overview of comments provided to the Committee or WP requesting consultation
  - At this level we are looking for input from the member organisation on the basis of what they can collect from their own membership, as much as possible.

HCP input (II)

- HCPWP members can be consulted to identify appropriate experts (or act as individual experts themselves)
  - Experts need to complete DoI and can be involved as individuals in product-specific activities (e.g. Scientific Advice/ Protocol Assistance; SAGs; review of PI; review of DHCs; review of safety communications)
  - At this level, we are looking for the individual's own perspective, based on his/her own clinical experience and background.

HCP input (III)

- HCPWP members can be consulted to identify appropriate speakers/ participants in EMA conferences and workshops
- HCPWP members will be invited to participate in EMA conferences and workshops and provide input either on behalf of HCPWP or on behalf of their own organisation

- HCPWP can develop its own recommendations – these may be subject to public consultation

Mandate and objectives

- Improve the feedback we get on the way medicines are used in clinical practice, so we can make the best-possible decision on their benefit-risk;
- Monitor that we are providing clear and useful information on medicines to healthcare professionals, to support their role as end-users;
- Bring the experience and perspective of healthcare professionals into medicines development and supply;
- Encourage and help professional organisations to cascade information on medicines to their members and their wider constituencies;
- Help healthcare professionals to understand better how the European Union's medicines regulatory network works.

Roles and responsibilities of the HCPWP members (I)

- Reflecting on real-life/ clinical practice implications of regulatory decisions.
- Helping and assisting in decision making so that the best decision is taken.
- Increasing transparency and building confidence and trust in the regulatory process.
- Ensuring credibility by guarantying that scientific regulatory bodies act for the benefit of society.
- Continuously contribute and ask for changes in the system to improve reliability.
- Representing healthcare professionals' interests and providing a "healthcare professional perspective" view, on behalf of those directly affected by regulatory decisions.

Roles and responsibilities of the HCPWP members (II)

- Identifying potential topics which may require or benefit from additional healthcare professionals' consultation.
- Actively contributing to healthcare professionals information and communication related to medicines. Ensure that healthcare professionals and healthcare professionals' organisations can access useful and understandable information.
- Disseminating committees' outcomes when they become public; passing on information to other healthcare professionals and healthcare professionals' organisations.
- Bringing specific expertise from a healthcare professional communication-perspective (e.g. to put safety issues into context), including contribution to the decision on when to communicate.

Roles and responsibilities of the HCPWP members (III)

- Advising and supporting regulators in its dialogue with industry and other stakeholders when identifying areas of medical need for target research.
- Contributing, in a general capacity, to public health (raising awareness, where appropriate, of the impact of regulatory decisions) in the context of their organisation.

The challenges

- Optimising the use of limited resources in the organisations
- Responding within short timelines
- Handling conflicts of interest
- Understanding regulatory jargon
- Finding suitable and available experts

Contacting the EMA

- General queries from healthcare professionals should be sent to
  - info@ema.europa.eu

- For any issues related with the involvement of your organisation in the work of the Agency and/or HCPWP-related matters please use the secretariat's email
  - HCPsecretariat@ema.europa.eu

Over to you!