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Stakeholders and Communication Division

Revised framework of interaction between EMA and healthcare professionals and their organisations

Annex II: EMA activities where healthcare professionals are involved

To achieve its mission, the European Medicines Agency (the Agency or EMA hereafter) works with thousands of experts who serve the Agency's scientific committees, working parties and scientific assessment teams. The great majority of these experts are healthcare professionals who are made available to the Agency, among others, by the national competent authorities of the EU and EEA.

The present document aims to provide an overview of the activities that support the work of the Agency existing structures with additional input from real clinical practice as well as the areas where healthcare professionals, as civil society representatives, and a well identified stakeholder group, engage with the work of the EMA.

These activities include:

- participation in governance of the Agency via the Management Board;
- inclusion in scientific committees as members;
- contributions on disease and product-specific questions via Scientific Advisory Groups (SAG) and Experts Groups (EG); and consultation by the EMA scientific committees;
- consultation on guidelines and policies;
- review of documents destined for the healthcare professionals;
- dissemination of information;
- participation in workshops, networks and research projects.

1. Non product-specific involvement in EMA activities

Where healthcare professionals are invited on non-product specific matters such as those described below, they are considered to be representing healthcare professionals' organisations.

1.1. EMA Management Board (MB)

The Management Board has a supervisory role with general responsibility for budgetary and planning matters, the appointment of the Executive Director and the monitoring of the Agency's performance ([Rules of Procedure](#))².

Two healthcare professionals sit on the [Management Board](#)²: one representative of doctors' organisations and once representative of veterinarians' organisations.

1.2. European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals Organisations (HCPWP)

While the EMA has engaged in dialogue with healthcare professionals since its inception, a formal working party, European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals Organisations (HCPWP), was established in June 2013. The Agency engages with healthcare professionals via a network of over 30 European **healthcare professionals' organisations** (called eligible organisations). The HCPWP is a core group of representatives from these eligible organisations that provide recommendations to the EMA and its Human Scientific Committees on **all** matters of direct or indirect interest to healthcare professionals in relation to medicines and to monitor the progress of interaction between the Agency and healthcare professionals ([Mandate](#))³.

The HCPWP meetings focus on a wide range of issues, including EU-wide initiatives/legislation, t EMA core activities and projects, interaction with patients, academia and the EMA human scientific committees and working parties, information on medicines to healthcare professionals, and overall EMA communication activities. It is also a platform to share information and best practices amongst healthcare professionals' organisations on activities started by eligible organisations.

Three meetings for the HCPWP are organised on average annually, several of these are combined with the Patients and Consumer Working Party (PCWP).

Healthcare professionals' representatives are predominantly identified via an eligible organisation for the following activities:

1.3. Involvement in workshops, conferences, webinars, etc.

Healthcare professionals are invited to most EMA workshops and increasingly are involved as speakers within the sessions.

Some examples of workshops include [Workshop on collaboration with general practitioners/family physicians](#), [Information session on biosimilars](#), [Workshop on the development of new medicinal products for the treatment of ulcerative colitis and Crohn's disease](#), [Workshop on medicines shortages](#) and [Pharmacovigilance Stakeholders Forum](#).

1.4. Written consultations addressing issues related to real clinical practice

In line with the EMA framework for interaction with healthcare professionals, it is possible for a scientific committee, working party or drafting group to request additional input from relevant organisations on general matters (not product-specific consultations). The purpose of such consultations is to gather valuable input on certain aspects of clinical practice and standards of care that can support the scientific bodies on its further discussions related with on-going evaluations or guideline development.

1.5. Targeted expert groups

In the context of the implementation of the EMA framework of interaction with healthcare professionals' organisations, the Agency is striving to reinforce and promote the **engagement with general practitioners**. The main aim is to support the creation of more awareness amongst GPs on how they can better inform regulatory discussions on benefit-risk evaluation of medicines and promote the alignment of regulatory decisions with the reality of clinical practice.

1.6. Bilateral interactions

There were also cases where healthcare professional organisations contacted the Agency to ask for input or address their concerns. These resulted in bilateral interactions between specialists within EMA and the organisations' representatives.

2. Product-specific involvement in EMA activities

Where healthcare professionals are consulted on product-specific matters, they are involved as individual experts and are required to complete the same documents as all other experts prior to attending the meeting at EMA. These documents include the Confidentiality Agreement, Declaration of Interests and curriculum vitae.

2.1. EMA scientific committees

In addition, healthcare professionals are represented in three of the six human scientific committees at the EMA. The Committees that include healthcare professionals are listed below. Activities performed by healthcare professionals in these committees include the assessment of paediatric investigation plans; the assessment of the quality, safety and efficacy of advanced-therapy medicinal products (ATMPs) and the assessment and monitoring of safety issues for medicines.

- [PDCO](#)⁴ - Paediatric Committee
- [CAT](#)⁵ - Committee for Advanced Therapies
- [PRAC](#)⁶ - Pharmacovigilance and Risk Assessment Committee

Committees also include healthcare professionals in providing input within benefit-risk discussions, for example, via participation in scientific advisory groups and ad-hoc expert group meetings and ad-hoc consultations of committees and their working parties. Healthcare professionals also participate on the development of new/revised EMA guidelines.

2.2. Scientific Advisory/ad hoc Expert Group meetings

Scientific Advisory Groups (SAGs) are convened at the request of the Committee for Medicinal Products for Human Use (CHMP) or Pharmacovigilance and Risk Assessment Committee (PRAC) to deliver answers, on a consultative basis, to specific questions addressed to them ([mandate](#))⁷. Currently eight SAGs exist for specific areas.

Healthcare professionals are involved in SAG meetings in order to support scientific discussions related with the evaluation of new marketing authorisation applications and changes in indications of already approved medicines. The agency calls upon individual experts to participate in SAG meetings and bring additional expertise on clinical practice in various domains.

When the issues refer to a therapeutic area for which no specific SAG has been constituted, an **ad-hoc expert group** is organised that follows the SAG mandate. To illustrate, EMA created the Geriatric Expert Group (GEG) ([mandate](#)), which provides scientific advice to the CHMP and the European Medicines Agency secretariat on issues related to older people.

Healthcare professionals also participate in SAGs and ad-hoc expert group meetings specifically convened in the context of safety referrals.

2.3. Written consultations

The purpose of this type of consultation is to gain a better understanding of whether specific elements of the product information and package design (e.g. labelling; expression of strength; posology recommendations; instructions for use; colour differentiation strategy) are sufficiently clear. Furthermore there is a focus on whether additional risk minimisations measures (e.g. key messages to include in educational materials) can reduce potential risk of medication errors in the context of clinical practice reality and facilitate the appropriate and safe use of the medicinal product under assessment.

3. Communication

3.1. Review of documents destined for the public:

The EMA is responsible for providing information about medicines authorised via the centralised procedure, which includes information directed to stakeholders. During the preparation of this information, the Agency interacts with healthcare professionals' organisations to ensure that the communication is adequately formulated and comprehensible to the target audience.

Healthcare professionals are asked to provide their views on several types of documents, such as:

- **Summary of Product Characteristics (SmPC)**, which is a key part of the marketing authorisation of all medicines authorised in the European Union and the basis of information for healthcare professionals on how to use a medicine safely and effectively.
- **Safety communications**, which refer to documents that are specifically addressed to the public, patients and healthcare professionals on authorised medicinal products and that convey an important (emerging) message relating to the product (e.g. a product is withdrawn or suspended for safety reasons, has a new contraindication or warning, or there is a product defect).
- **Direct healthcare professional communications** (DHPCs), that are usually disseminated by one or a group of marketing authorisation holders for the respective medicinal product(s) or active substance(s),
- **Shortages catalogue** contains information on medicine shortages that affect or are likely to affect more than one European Union (EU) Member State.

3.2. Risk communication

A main focus of the Agency's communication policy is to inform stakeholders of key safety information that the Agency produces. EMA public information on 'start of safety referrals' as well as 'summary of recommendations' are written specifically with the intention to target patients and healthcare professionals, and the Agency's policy is to disseminate these communications at the time of their publication to the key EU organisations in the field. Healthcare professionals regularly contribute to the shaping of the risk communication.

3.3. Consultations

Healthcare professionals are consulted on guidance and policy documents via the EMA website as well as targeted emailing to ensure to capture the input of this group. In addition, healthcare professionals can be consulted on an ad-hoc basis on product-specific topics linked to the prevention of medication errors, such as educational and packaging materials.

Healthcare professionals are consulted along with patients and other experts, in closed workshops, on the guidelines for the clinical investigation of disease-specific medicinal products (e.g. Duchenne Muscular Dystrophy, Cystic fibrosis...)

3.4. Human Medicines Highlights (HMH) newsletter

A monthly newsletter addressed primarily to organisations representing patients, consumers and healthcare professionals provides a summary of key information relating to medicines for human use published during the previous month by the EMA.

3.5. EMA website

The homepage of the EMA website contains a feed of all of the Latest Information and Press Releases.

Under the News and Events tab a scrolling feed of 'What's New' also provides links to monthly information and Press Releases.

3.6. Healthcare professionals pages

[Healthcare professionals](#) have a dedicated area in the Partners and Networks section of the website providing information on Agency activities where healthcare professionals are involved, how they can get involved, which organisations are currently involved with the EMA as well as training and supporting key documents for these activities.

3.7. Send a Question and Social media

Healthcare professionals, patients and the public in general can request information directly to the EMA from the home page using the Send a Question form.

RSS feeds, Twitter and YouTube are available to subscribers. The EMA uses these means to communicate up to the minute information on authorisations, consultations (Twitter), newsletters on a range of topics (RSS feeds) as well as to transmit information and training (YouTube).

3.8. Leaflet on healthcare professionals activities at EMA

A [leaflet](#) describing the different ways that healthcare professionals can be and are involved with the EMA has been elaborated and is updated regularly as activities evolve.

3.9. Information exchange

The eligible organisations working with EMA serve as a vital platform for exchange of information.

The EMA consults and informs these groups on relevant Agency activities via targeted emailing. An identified contact person is the recipient of relevant information that is then shared with the members of that organisation.

The eligible organisations support the Agency in providing targeted information in appropriate language to stakeholders and enhance understanding of the regulatory processes.

4. Monitoring / Training

4.1. Monitoring – surveys and feedback on satisfaction

In order to monitor the satisfaction of healthcare professionals who have been involved in any EMA activity, the EMA organises satisfaction surveys every two years. Based on the outcome of these surveys, actions plans are then determined. The results are included within the [annual report](#). EMA is also focused on collecting organisations' testimonies on how/where they see the added-value of the EMA interaction.

4.2. Involvement in EU-wide projects and academic networks

The EMA is involved in several projects in varying capacities. Healthcare professionals are invited to participate as partners, in steering groups, etc.

[ENCePP](#): The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance is a network of over 170 research centres, existing networks and providers of healthcare data, which is coordinated by the European Medicines Agency. A healthcare professional representative forms part of the Interested Parties and Stakeholder group.

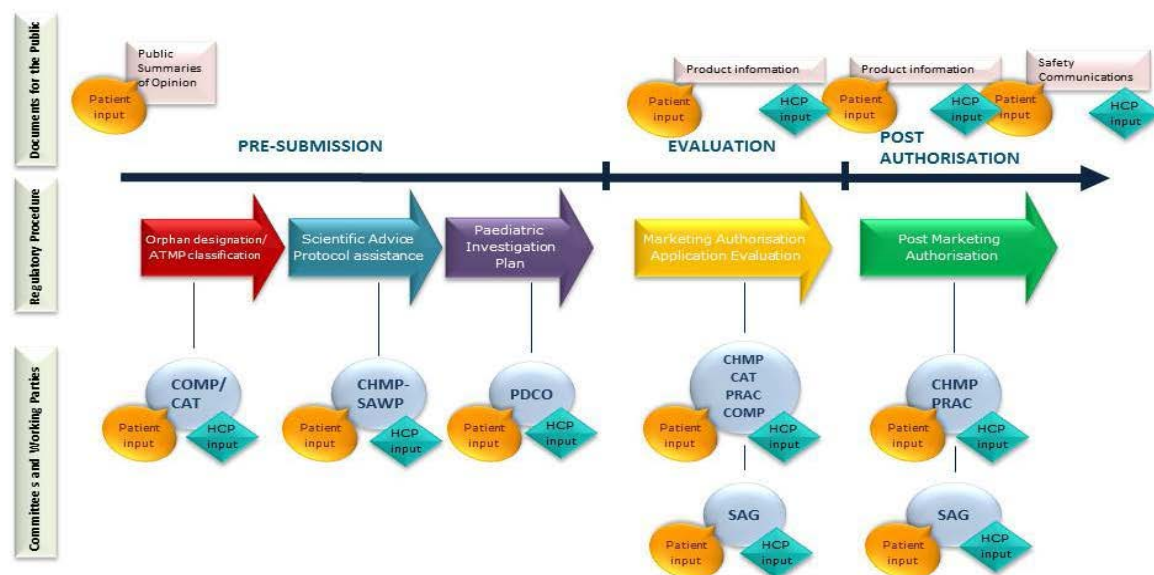
[Enpr-EMA](#): The European Network of Paediatric Research at the European Medicines Agency is a network of research networks, investigators and centres with recognised expertise in performing clinical studies in children. A healthcare professional representative participates its annual workshop.

[EUCTR](#): The European Union Clinical Trials Register enables searches for protocol and results information on interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA) and clinical trials conducted outside the EU / EEA that are linked to European -medicine development. Healthcare professionals were and are still consulted all along the development of this portal regarding aspects from design to information to be included.

References

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6. Regulation (EC) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 on pharmacovigilance of medicinal products for human use <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0001:0016:EN:PDF>
7. Mandate, objectives and rules of procedure for the scientific advisory groups (SAGs) and ad-hoc experts groups:
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Figure 1: Product-specific HCP contributions in the product life cycle



* COMP – Committee for Orphan Medicinal Products; CHMP – Committee for Human Medicinal Products; CAT – Committee for Advanced Therapies; PDCO – Paediatric Committee; SAWP – Scientific Advice Working Party; SAG – Scientific Advisory Group; PRAC – Pharmacovigilance and Risk Assessment Committee; EPAR – European Public Assessment Report