Preparing future roles for patients in EMA committees PRAC-CHMP

Focus on the CHMP

General Pharmaceutical Legislation Revision

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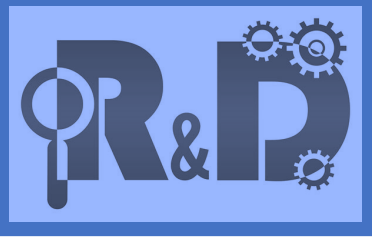
CHMP (main) roles

Development

CHMP and its WPs contribute to the R&D of medicines, by:

- providing SA to developers
- preparing scientific guidelines and regulatory guidance to help pharmaceutical companies prepare applications
- cooperate with international partners on the harmonisation of regulatory requirements



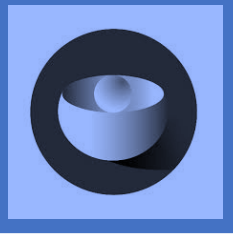
Evaluation

Centralised procedures

- Assessment of EU-wide marketing authorisation applications
- Modifications or extensions ('variations') to an existing MA
- Considering the recommendations of the PRAC (medicines on the market) and when necessary, recommending to EC changes to a medicine's MA, or its suspension or withdrawal from the market

Referral procedures

- Evaluates medicines authorised at national level referred to EMA for a harmonised position across the EU



Agenda 24-27/02/2025 CHMP meeting 82 pages

106 agenda points for decision or for information – 4 days

if 9 hours / day: 20 min per agenda point

https://www.ema.europa.eu/en/documents/agenda/agenda-chmp-meeting-24-27-february-2025_en.pdf

- **Oral explanations (8)**
  - Pre-authorisation procedure oral explanations (3)
    - Insulin human – diabetes mellitus, donanemab for Alzheimer's disease, atropine for myopia 3-18 yo
  - Re-examination procedure oral explanations (3)
    - Cinainu for alopecia aerata children adolescents – Keytruda pembrolizumab – Kizfizo temozolomide neuroblastoma
  - Post-authorisation procedure oral explanations (2)
    - Calquence aclabrutinib for leukaemia – Prevymis letermovir for CMV infection
- **Initial applications (35)**
  - Initial applications; Opinions (4)
  - Initial applications - List of outstanding issues (Day 180; Day 120 if accelerated (17)
  - Initial applications; List of questions (Day 120; Day 90 if accelerated (7)
  - Update on on-going initial applications for Centralised procedure (2)
  - Re-examination of initial application procedures under Article 9.2 (2)
  - Initial applications in the decision-making phase (1)
  - Withdrawals of initial marketing authorisation application (2)

Agenda 24-27/02/2025 (2)

- Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008 **(12)**
  - Opinions (6)
  - Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 180 list of outstanding issues (1)
  - Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008; Day 120 List of question (5)
- Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008 **(22)**
  - Opinions or Requests for supplementary information (20)
  - Update on on-going Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008 (1)
  - Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008 (1)

Agenda 24-27/02/2025 (3)

- Medical devices **(4)**
  - Ancillary medicinal substances - initial consultation (1)
  - Companion diagnostics - initial consultation (3)
- Pre-submission issues **(4)**
- Post-authorisation issues **(9)**
- Referral procedures **(1)**
  - Community Interests - Referral under Article 31 of Directive 2001/83/EC (1)
- Pharmacovigilance issues **(1)**
- Inspections **(4)**
- Organisational, regulatory and methodological matters **(6)**
  - PRAC, PDCO, BWP, NRG, SAWP, SAG

Commission' views - Revision of the General Pharmaceutical Legislation

(12) The structure and operation of the various bodies should be designed in such a way as to take into account the need … for **adequate involvement of civil society.** They should establish and **develop appropriate contacts with representatives of patients and healthcare professionals**.

Current EMA structure: in some cases up to 5 scientific committees are involved in assessing a single medicinal product. Need for simplification to two main Committees, CHMP and PRAC

CAT, COMP, PDCO, HMPC to be reorganised in the form of WPs expertise-based, who will give input to the CHMP, PRAC and CMDh. WPs: a majority of experts appointed by the MS, based on their expertise, and of external experts

The CHMP and PRAC will consist, like today, of experts from all MS. In the CHMP, the voice of patients will be strengthened by appointing patient representatives to this committee for the first time.

Article 146

• Scientific Committees – General provisions

• Committees, their WPs and SAGs should

establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use, in particular patient and consumer organisations and healthcare professionals' associations

• Working groups (?) of patients, consumers, HCPs

Established by the Agency.

Fair representation of healthcare professionals, patients and consumers covering a wide range of experience and disease areas, including orphan, paediatric and geriatric diseases and advanced therapy medicinal products, and a broad geographical range

• Rapporteurs and civil society

Rapporteurs appointed by the scientific committees may, on an advisory basis, establish contacts with representatives of patient organisations and healthcare professionals' associations relevant to the therapeutic indication of the medicinal product for human use

Article 148

- Committee for Medicinal Products for Human Use shall be composed of the following:

- (a)

One member and one alternate member appointed by each Member State

- (b)

Four members and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the EP, in order to represent healthcare professionals

- (c)

Four members and four alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the EP, in order to represent patient organisations

(organisations, or patients?)

Article 163

• Contacts with civil society representatives

• Management Board

The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the healthcare professions

• How?

These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission

Possible roles for patients as CHMP members (in addition to opinions / voting)

Probably not as rapporteur, but more:

- To witness how opinions are made and to explain it to patients and their organisations
- To help identifying patients (ED, SAG, OE, Documents)
- To lead early dialogues (sharing work between 8)
- To discuss whether PPE studies are needed (conditional MA, post authorisation studies..), to comment on PED submitted, to encourage PED submission
- To explain difficult CHMP opinions to POs before and after the publication of the EPARs
- To encourage third party interventions / questions
- Other roles? Your views?

Other questions / challenges

1. With other committees changed to WPs, will the CHMP formally adopt more opinions / make more decisions?
2. CHMP / SAWP and CABs
3. Voting rights

For some Member States, the voice of patients doesn't count

Comments from Eurordis' DITA task force members March 2024

1. *Are you seriously expecting volunteers to dedicate all that time for free as it limits the possibility of individuals to be available for all those roles ?*
2. *Could this be an opportunity to have patient experts in their disease areas involved in CHMP meetings? We cannot be expected to have knowledge of all the diseases for which an opinion is discussed.*
3. *We could think of a mediation link between the permanent CHMP patient members and the patient experts of their disease who need to provide input in the evaluation.*

How to prepare and estimate what it means to be a patient @ CHMP? A proposal

STEP

Each group of 2: 2 meetings
= 8 meetings in total (12 months)

STEP

Report to PCWP/HCPWP on the estimated workload and possible recommendations (profiles?)

STEP

4 groups of 2 observers (1 patient, 1 HCP)
Among PCWP / HCPWP members
As done for PhVWP/PRAC

STEP

To highlight tasks of importance at CHMP

STEP

To share the workload? 4 members, 106 opinions = 26 each
Or to follow all 106 opinions, to discuss them with the other 3?

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Thank you!

Questions?