CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

CMDh report to PCWP/HCPWP

September 2025

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What is CMDh?

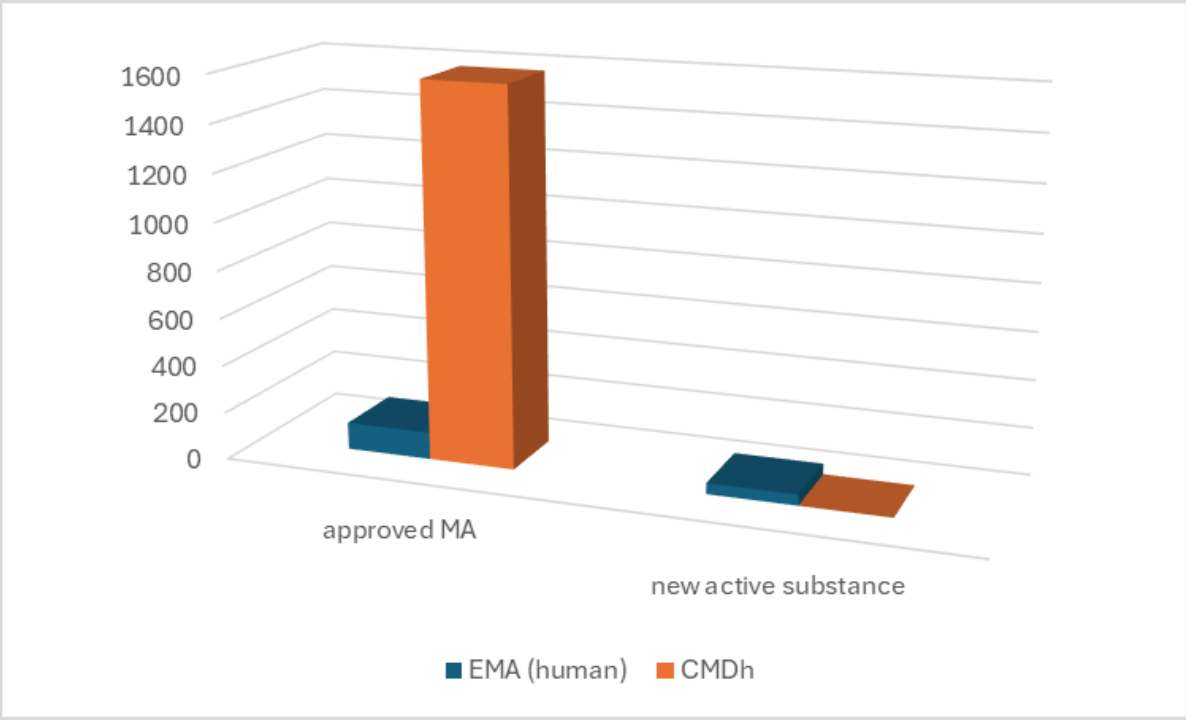
What is CMDh?

Co-ordination Group for **M**utual Recognition and **D**ecentralised Procedures – **h**uman

- **Unique network of cooperation** between **the national competent authorities (NCA)**, where every NCA contributes
- Established in legislation (Article 27 of Directive 2001/83/EC)
- CMDh activities cover a variety of issues related to new applications, variations, renewals and pharmacovigilance activities, preparation of guidance documents, Q&A...for **nationally authorised products**
- The main goal is to ensure **consistent and unified product information and marketing authorisation procedures for medicinal products in the EU**
- CMDh does not have PCs or HCPs representatives, but their voice is reflected earlier in the PRAC procedures (referrals, PSUSAs..), where CMDh is a final decision maker (provided only nationally authorised products are in scope)
- CMDh website: https://www.hma.eu/human-medicines/cmdh/about-cmdh.html

Medicinal products authorised in the EU

- In Europe no medicinal product may be placed on the market unless a Marketing Authorization has been issued by the national competent authorities of European Member State **(NCA)** or by the European Medicines Agency **(EMA)**/European Comission (**EC**).
- Regulatory authorities - **EMA** and all **NCAs** play a crucial role in the evaluation and supervision of medicines, for the benefit of public health in the European Union (EU), where **EMA** focus is on **innovative medicines**, whereas **NCAs** – connected via **CMDh** – mainly deal with **generic medicines,** very important for sustainability of health systems.



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CMDh deals with MRP/DCP procedures

- CMDh examines questions relating to a marketing authorisation of **medicinal products authorised in two or more Member States** in accordance with **MRP/DCP**

Mutual Recognition Procedure (MRP)

- Used when a medicine is already nationally authorized in one EU country. Other member states "mutually recognize" the existing approval

Decentralized Procedure (DCP)

- Used when the medicine hasn't been approved in any EU state.
- One Reference Member State (RMS) leads the assessment, involved Concerned Member States (CMS) contribute with comments, questions, etc.

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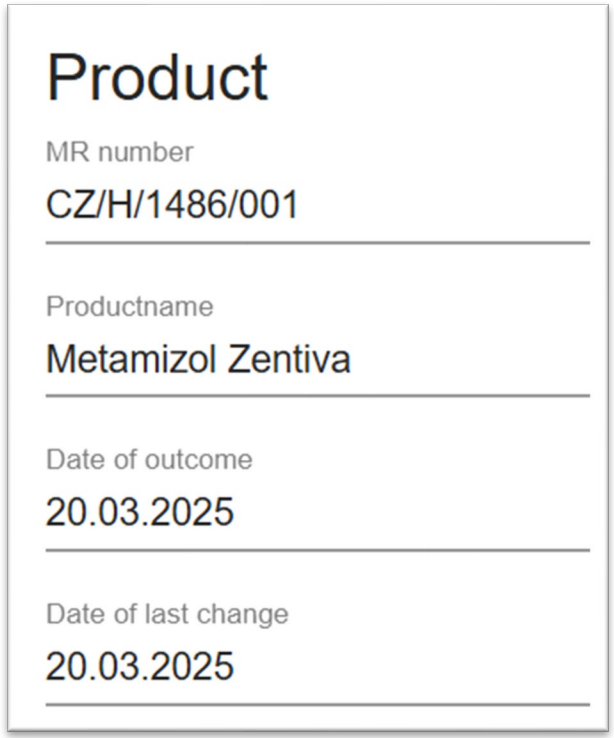
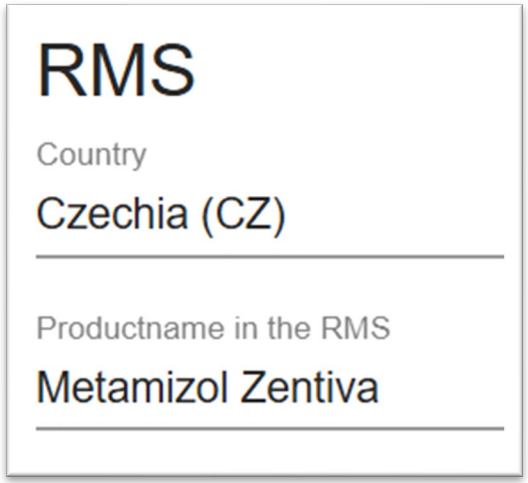
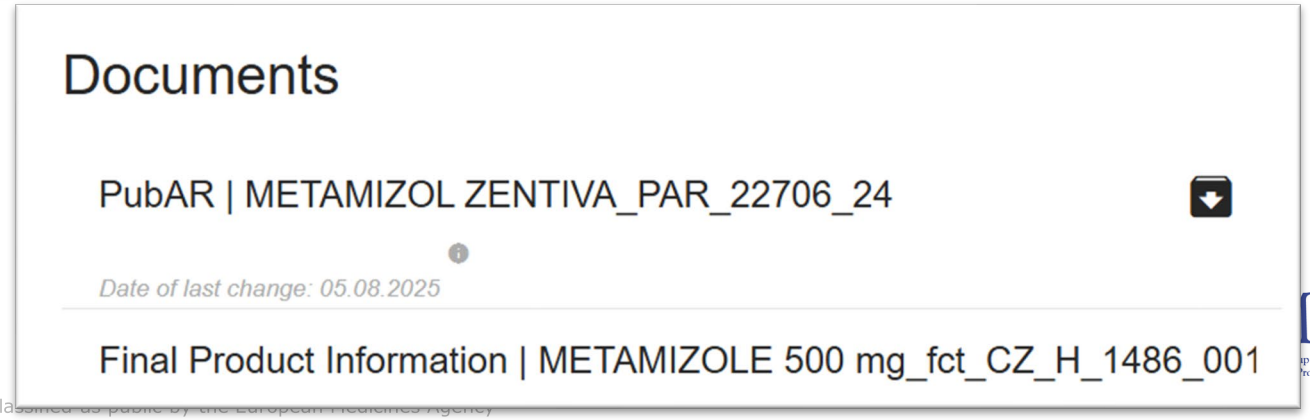
Where can you find details on medicines authorised via MRP/DCP?

- The MRI Product Index includes **medicines approved nationally** in the EU Member States **according to the MRP or DCP procedure**
- https://www.hma.eu/human-medicines/mri-product-index.html







CMDh composition, interaction with EMA

- **27 members** appointed by the **EU Member States** (for a renewable period of 3 years)
- **2 members** from **EE-EFTA** States → NO and IS (LI is represented by AT)
- CMDh members represent the position of their national agencies and vote as needed, must ensure the link between the CMDh and their national agencies (including providing feedback on the conclusions of the discussions in the CMDh within their NCAs).
- The **CMDh secretariat** from EMA
- Very **close collaboration with EMA** in many different areas:

  EMA staff participates in the meetings regularly,

  depending on the topic discussed
- Plenary meetings every month except in August
- CMDh members can be accompanied by national experts

CMDh Agenda

1. **INTRODUCTION** (Declaration of interests, agenda and minutes...)

2. **ORGANISATIONAL ISSUES / REPORTS FROM OTHER MEETINGS** (CMDh statistics, reports from WP (also PCWP and HCPWP :-), meetings with interested parties, etc.)

3. **GENERAL ITEMS** (CMDh guidance documents, variations, GMP/GCP, Paediatric Regulation, quality issues, MA harmonisations, medical devices, etc.)

4. **GENERIC/HYBRID MARKETING AUTHORISATIONS** (questions on bioequivalence, RefMP, etc.)

5. **REFERRALS** (Referrals to CMDh, PRAC or CHMP)

6. **PHARMACOVIGILANCE** (monthly PRAC report, recommendations on PSURs and PASS, appointment of PSUSA Lead MS and any other topic related to PhV)

7. **BREAK-OUT SESSIONS AND CMDh SCIENTIFIC INPUT TO APPLICATIONS**

8. MISCELLANEOUS

9. OTHER TOPICS AND DATES FOR NEXT MEETING

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CMDh Press release & Minutes

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Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

25 June 2025
EMA/CMDh/203436/2025

Report from the CMDh meeting held on 17-19 June 2025

CMDh outcome on referrals pursuant to Article 31 of Directive 2001/83/EC

Finasteride- and dutasteride-containing medicinal products

On 19 June 2025, the CMDh endorsed measures recommended by EMA's safety committee, PRAC, to minimise the risk of suicidal ideation (suicidal thoughts) with finasteride and dutasteride medicines. Suicidal ideation was confirmed as a side effect of finasteride 1 and 5 mg tablets by the PRAC, following an EU-wide review of available data on these medicines. The frequency of the side effect is

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17 June 2025
EMA/CMDh/211273/2025
Human Medicines Division

Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)

Minutes for the meeting on 20-21 May 2025

- https://www.hma.eu/human-medicines/cmdh/press-releases.html
- https://www.hma.eu/human-medicines/cmdh/agendas-and-minutes.html

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CMDh Priority areas

CMDh Multi-annual Workplan to 2025

Five main priority areas:

1. Availability of essential medicines and coordination during crisis
2. Optimisation of procedures
3. Innovative projects
4. Preparation for legislative changes
5. **Optimisation of communication/relationship/meetings with interested parties and stakeholders:**

The CMDh Communication Strategy should cover all main areas of its activity and influence and is regarded necessary in the following situations:

Among MSs; With EMA, EC.....

Communication with health care professionals and patients

- **currently the challenges are mainly reported via national contacts of HCP/Patient organizations**
- **could we do better?**

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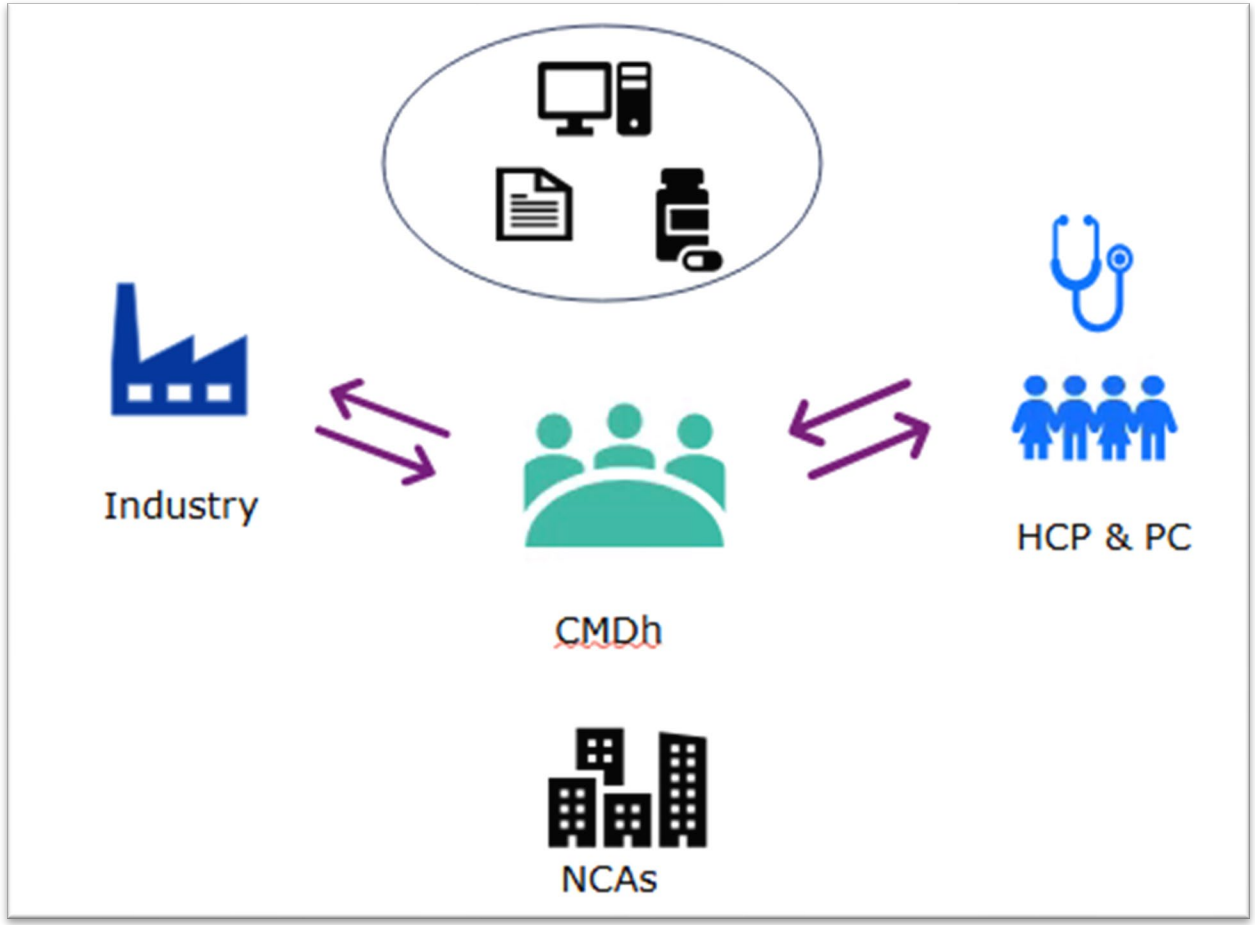
How do the patient and HCP voice reflect on the CMDh day to day work



Current work at the CMDh

Action/activities taken in safeguarding the public health

- Safety information, bringing transparency to all parties to facilitate timely updates of the latest known safety relevant information to all of EU/EEA users so the updated product information can be immediately found in English on the MRI Product index and then in the national languages on NCAs websites.
- In cooperation with PRAC the CMDh take the final decisions on outcome of procedures concerning safety; referral, PSUSA where only nationally authorised products are included. Outcomes such as direct healthcare professional communication (DHPC), patient card, risk minimisation messures (RMM) and product information updates are considered.
- Follow-up nitrosamine impurities, all aspects are evaluated, the work is ongoing the risk of harm vs. availability of medicinal products in all of EU/EEA are closely monitored and action are taken with the patient's safety in mind.

Current work at the CMDh

Bringing updated information to the users and HCP in a fast and timely manner.

- Variation regulation,
- Harmonisation,
- Faster and simultaneous update of product information

Activities taken to heighten availability and prevent shortages of medicinal products in EU/EEA

- RUP reduced timetable - Accelerate approval procedures to help make medicinal product available on market with availability issues.
- Multilingual Packaging - to increase the marked, making the medicine available.

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Current work at the CMDh

New pharma legislation, input via NCA

- Innovation, changes to facilitate a robust information
- Preventing disharmonisation
- Facilitate digitalisation
- Repurposing
- …..

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Thank you

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