



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CHMP feedback to PCWP/HCPWP

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CHMP activities with contribution of patients and HCP

- Scientific Advice and Protocol assistance.
- Scientific advisory groups/Ad-hoc expert groups.
- Oral explanations.
- Early contact with patients and HCP for MAA.



Interactions with CHMP activities between 2021 – 2023

Number interactions	CHMP Activity
2021 – 25 (14 meetings) 2022 – 33 (15 meetings) 2023 - 28 patients (15 meetings to date)	Scientific Advisory Groups/ Ad hoc Expert Groups (neurology, oncology, haematology, viral disease)
2021 - 90; 2022 – 79; 2023 – 32	Scientific advice, protocol assistance
2021 – 7 (5 procedures - Evrysdi, Zolgensma, Ozawade, Raylumis, Tecentriq) 2022 – 3 (2 procedure – Miplyffa, Sohonos) 2023 – 5 (3 procedures – Albrioza, Adakveo, Translarna)	Oral explanations



Early contact with patients and HCP organizations (January – October 2023)

Month/year start	Type of Product	# responses from PCO	# responses from HCPO
January 2023	3 orphans; 3 non orphans	6 responses	N/A
February 2023	2 non orphans	2 responses	N/A
March 2023	3 orphans	2 responses	N/A
May 2023	4 orphans; 3 non orphans	3 responses and 1 use of previous response for same indication	5 responses
June 2023	2 non orphans	No responses	2 responses
July 2023	2 orphan; 1 non orphan	2 responses	4 responses as more than one HCPO contacted
August 2023	2 orphans; 4 non orphans	5 responses (1 not for patients)	5 responses - ongoing
September 2023	2 orphans; 2 non orphans	Ongoing	3 responses - ongoing
October 2023	7 orphans; 1 non orphan	Ongoing	Ongoing



Some data on CHMP opinions in 2023



CHMP positive opinions (January – November 2023)

New medicinal products: 70 (including **7** biosimilar products and **9** generics).

- **23** oncology/haematology, **7** CNS, **4** metabolism/endocrinology.
- **3** vaccines (2 RSV and 1 COVID-19) + **1** duplicate of Aflunov. ***First vaccines for prevention of VRS infections (Arexvy and Abrysvo)!***
- **2** PUMAs (sodium thiosulfate and enalapril maleate).
- **22** orphan medicines.

Extensions of the indications: 73



Types of Marketing Authorisations granted

❖ **Standard / Full Marketing Authorisation: 63**

❖ **Non-standard Marketing Authorisations: 7**

- Conditional Marketing Authorisation: **6**
- Under Exceptional circumstances: **1**

- **Conditional Marketing Authorisation (CMA):**
 - **Krazati** (adagrasib): advanced non-small cell lung cancer.
 - **Elrexfio** (elranatamab): relapsed or refractory multiple myeloma
 - **Talvey** (talquetamab): relapsed or refractory multiple myeloma
 - **Columvi** (glofitamab): relapsed or refractory diffuse large B-cell lymphoma
 - **Jaypirca** (pirtobrutinib): relapsed or refractory mantle cell lymphoma
 - **Lytgobi** (futibatinib): locally advanced/metastatic cholangiocarcinoma
- **Under Exceptional circumstances:**
 - **Loargys** (pegzilarginase): hyperargininemia



Thanks for your attention!

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