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Human Medicines Division

Monthly statistics report: April 2025

Medicinal products for human use (cumulative figures for the year to date)

This document provides current information related to the volume and evaluation of marketing authorisation and post-authorisation applications for medicinal products for human use received by the European Medicines Agency.

The purpose is only to provide ongoing factual information. Commentaries and analysis are provided in the Agency's annual reports.

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Table 1. Pre-authorisation: Marketing-authorisation applications*

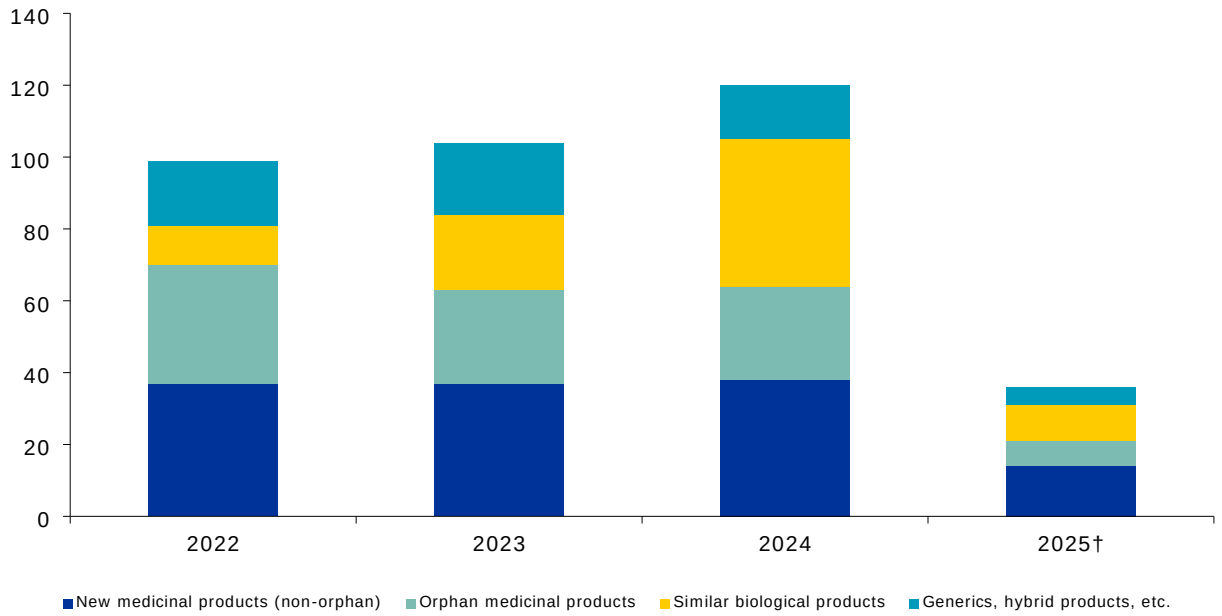
	2022		2023		2024		2025†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	35	27	35	26	33	44	12	10
Advanced-therapy medicinal products	0	0	1	0	2	1	1	0
Paediatric-use (PUMA) products	2	0	1	2	3	2	1	0
Well-established use, abridged, hybrid and informed consent products	3	7	4	4	3	2	5	1
Generic products	15	23	16	14	12	17	0	2
Similar biological products	11	10	21	8	41	28	10	15
Sub-total product applications	66	67	78	54	94	94	29	28
Orphan medicinal products◇								
New products	32	19	23	25	21	25	7	6
Advanced-therapy medicinal products	1	6	3	1	5	0	0	1
Total product applications	99	92	104	80	120	119	36	35

* Finalised applications exclude applications withdrawn prior to opinion.

† Figures for the current year are cumulative, year to date. Figures for preceding years are totals for the year.

◇ These figures reflect the orphan status of the medicinal products at the time of the CHMP opinion. EMA's Committee for Orphan Medicinal Products (COMP) then assesses whether the orphan designation should be maintained.

Marketing authorisation application evaluations started by type of application



† Figures for the current year are cumulative, year to date. Figures for preceding years are totals for the year.

Table 2. Pre-authorisation: Outcome of the evaluation of marketing authorisation applications*

	2022	2023	2024	2025†
Positive opinions (total 1st opinions)	89	76	113	33
- new active substance (NAS)**		40	46	9
- conditional marketing authorisation**	9	7	8	3
- under exceptional circumstances**	5	1	4	0
- after accelerated assessment**	5	3	3	1
Negative opinions	3	4	6	2
Applications withdrawn prior to 1st opinion††	11	15	9	4
Applications withdrawn after a 1st opinion (e.g. during re-examination) ††		3	1	2
Re-examinations requested	2	4	5	1
Re-examination - Positive opinions	0	1	1	0

* Applicants can request a re-examination. The first five rows present the outcome of the evaluation before a re-examination (or a re-consideration). The final row shows the number of changes from a negative to a positive opinion following a re-examination or a re-consideration.

** Included in the figures for positive opinions. Duplicate products, if any, are included in the figures.

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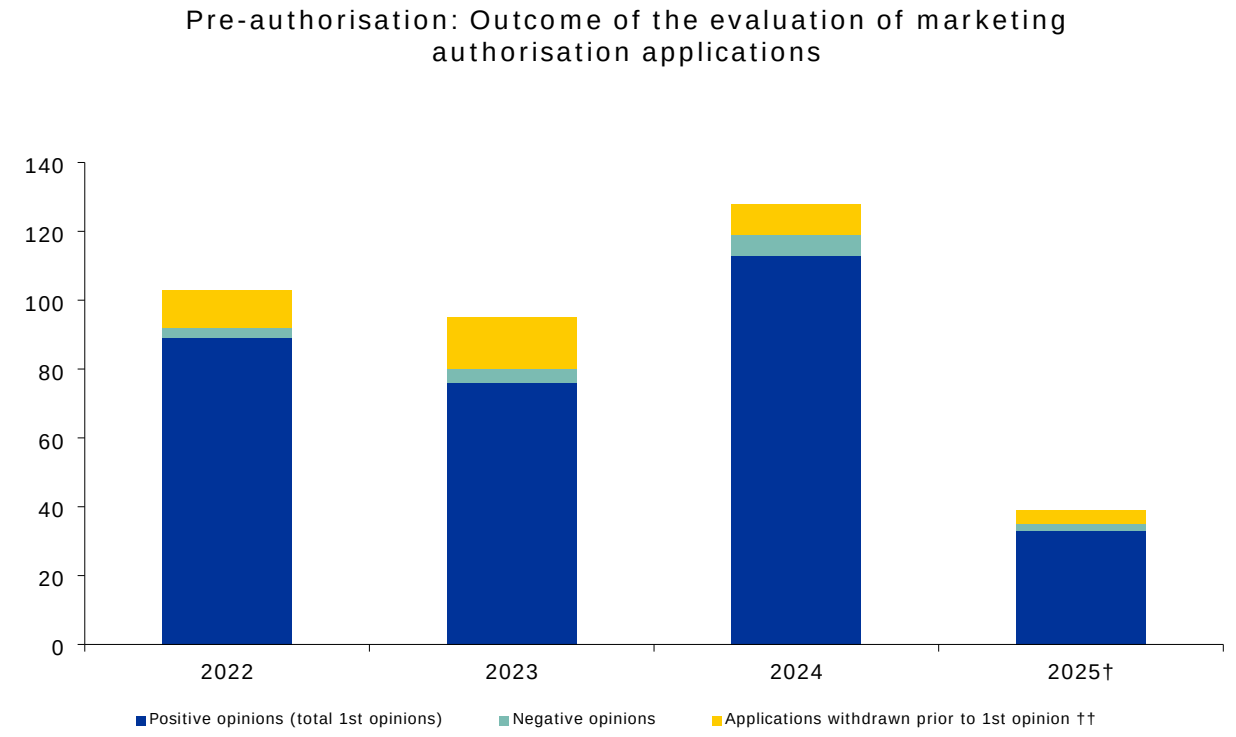
†† Date as per withdrawal letter date. It may first be communicated at the following month's CHMP meeting.



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†† Date as per withdrawal letter date. It may first be communicated at the following month's CHMP meeting.

Table 3. Scientific services

	2022		2023		2024		2025†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	0	0	0	0	0	0	0	0
Art. 58 (WHO) scientific opinions	1	3	0	1	1	0	1	1
Opinions on Companion Diagnostics medical devices (CDx)	4	3	9	8	11	10	2	3
Opinions on ancillary medicinal substances in medical devices*	2	0	0	2	3	1	0	1
Plasma master file (includes initial certification, variations and annual re-certification)	17	23	18	22	20	19	7	9

* Consultation in accordance with Council Directive 93/42/EEC concerning medical devices as amended by Directive 2000/70/EC as regards medical devices incorporating stable derivates of human blood or plasma and Directive 2001/14/EC.

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Table 4. Post-authorisation: Variations (scopes), renewals and annual reassessments

	2022		2023		2024		2025†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	3,586	3,456	3,864	3,883	3,931	3,845	1,077	1,085
Type IB variations	3,354	3,169	3,332	3,303	3,323	3,105	1,110	1,121
Type II variations	1,388	1,373	1,201	1,131	1,333	1,261	394	427
Extensions of marketing authorisation	31	23	43	32	33	36	17	14
Annual reassessments	27	28	33	29	35	38	15	10
Renewals*	132	129	101	116	107	101	42	38

* Includes renewals of conditional marketing authorisations.

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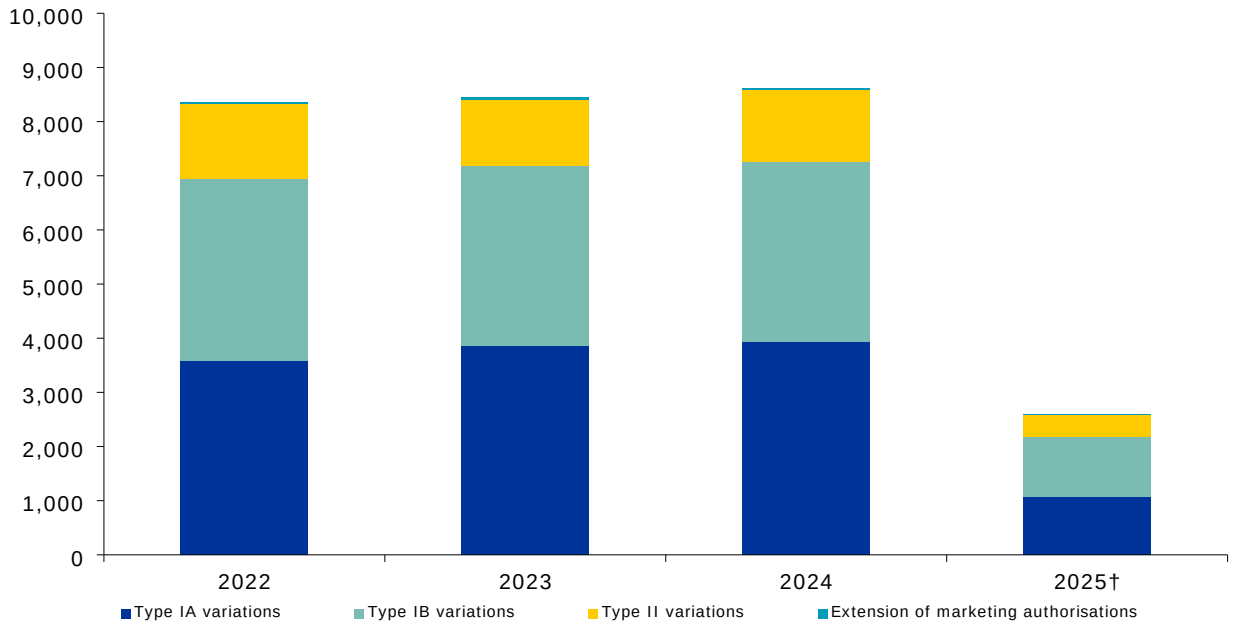
Post-authorisation: Variations, renewals and annual reassessments



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