15 March 2024
EMA/117755/2024
Human Medicines Division

Monthly statistics report: February 2024

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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

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

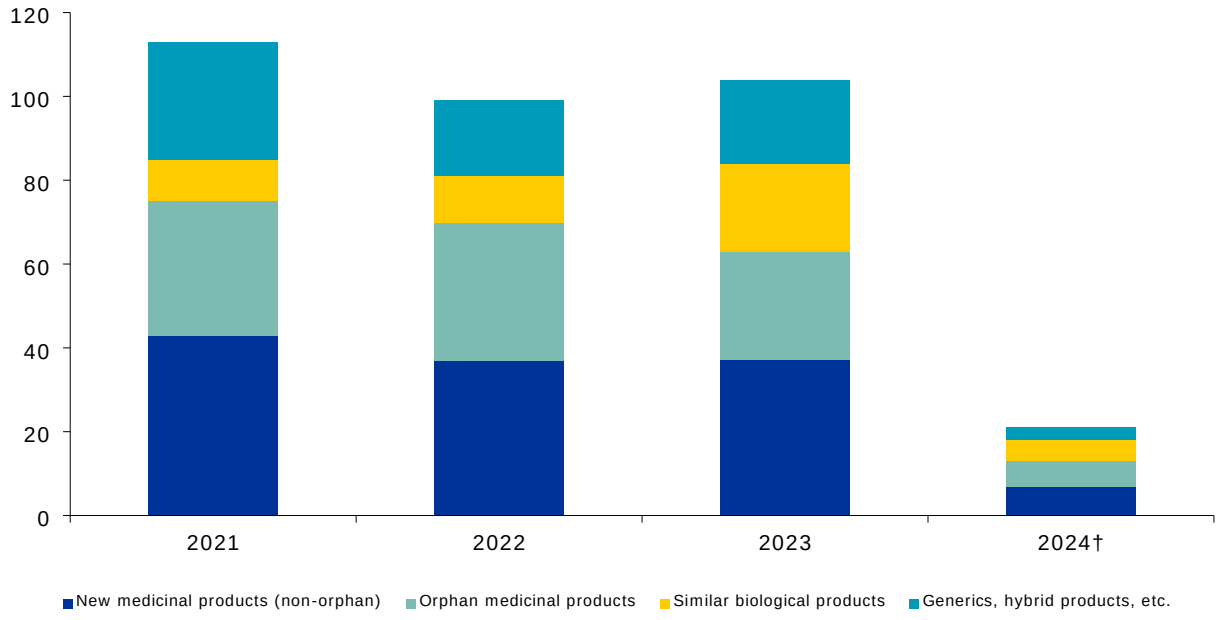
	2021		2022		2023		2024†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	43	46	35	27	35	26	6	6
Advanced-therapy medicinal products	0	0	0	0	1	0	0	0
Paediatric-use (PUMA) products	0	0	2	0	1	2	1	0
Well-established use, abridged, hybrid and informed consent products	7	6	3	7	4	4	0	0
Generic products	21	12	15	23	16	14	3	3
Similar biological products	10	7	11	10	21	8	5	1
Sub-total product applications	81	71	66	67	78	54	15	10
Orphan medicinal products◇								
New products	29	24	32	19	23	25	6	5
Advanced-therapy medicinal products	3	2	1	6	3	1	0	0
Total product applications	113	97	99	92	104	80	21	15

* Finalised applications exclude applications withdrawn prior to opinion.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*

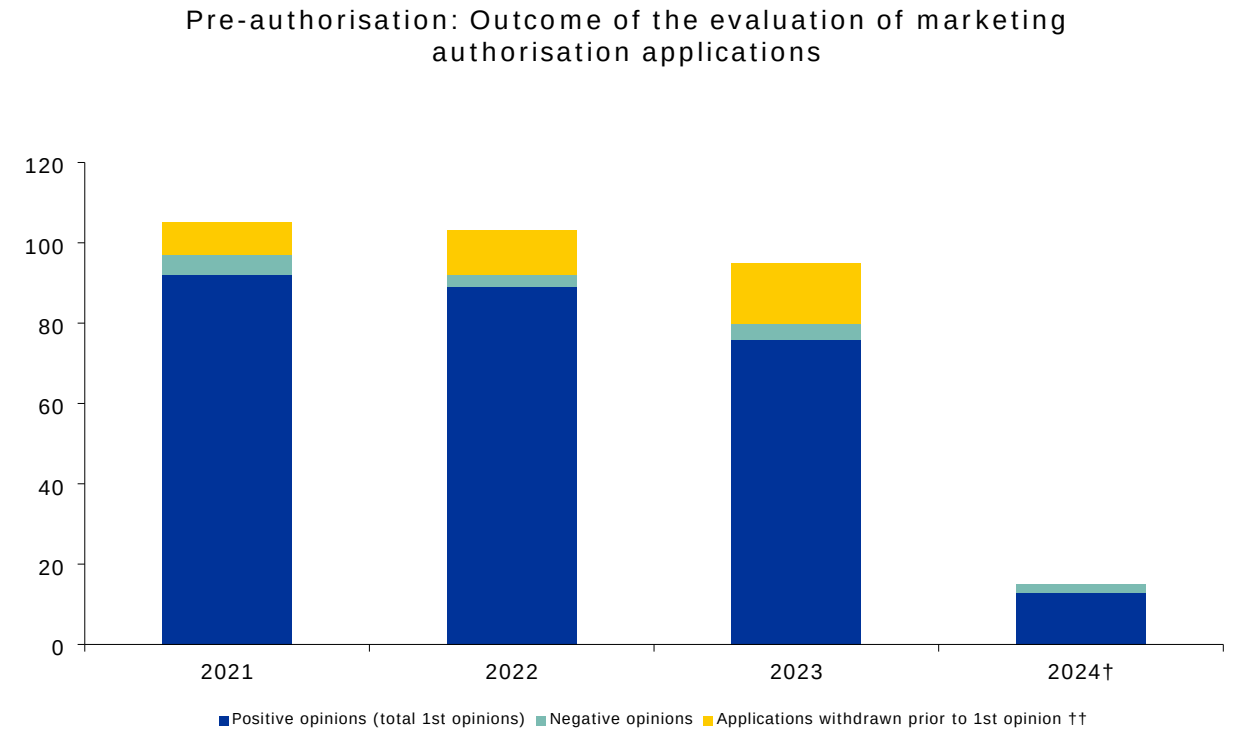
	2021	2022	2023	2024†
Positive opinions (total 1st opinions)	92	89	76	13
- new active substance (NAS)**			40	7
- conditional marketing authorisation**	13	9	7	2
- under exceptional circumstances**	4	5	1	1
- after accelerated assessment**	3	5	3	0
Negative opinions	5	3	4	2
Applications withdrawn prior to 1st opinion††	8	11	15	0
Applications withdrawn after a 1st opinion (e.g. during re-examination) ††			3	0
Re-examinations requested	4	2	4	2
Re-examination - Positive opinions	0	0	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.

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

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



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

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

Table 3. Scientific services

	2021		2022		2023		2024†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	0	0	0	0	0	0	0	0
Art. 58 (WHO) scientific opinions	3	0	1	3	0	1	1	0
Opinions on Companion Diagnostics medical devices (CDx)			4	3	9	8	2	2
Opinions on ancillary medicinal substances in medical devices*	0	0	2	0	0	2	1	0
Plasma master file (includes initial certification, variations and annual re-certification)	20	17	17	23	18	22	0	3

* 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.

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

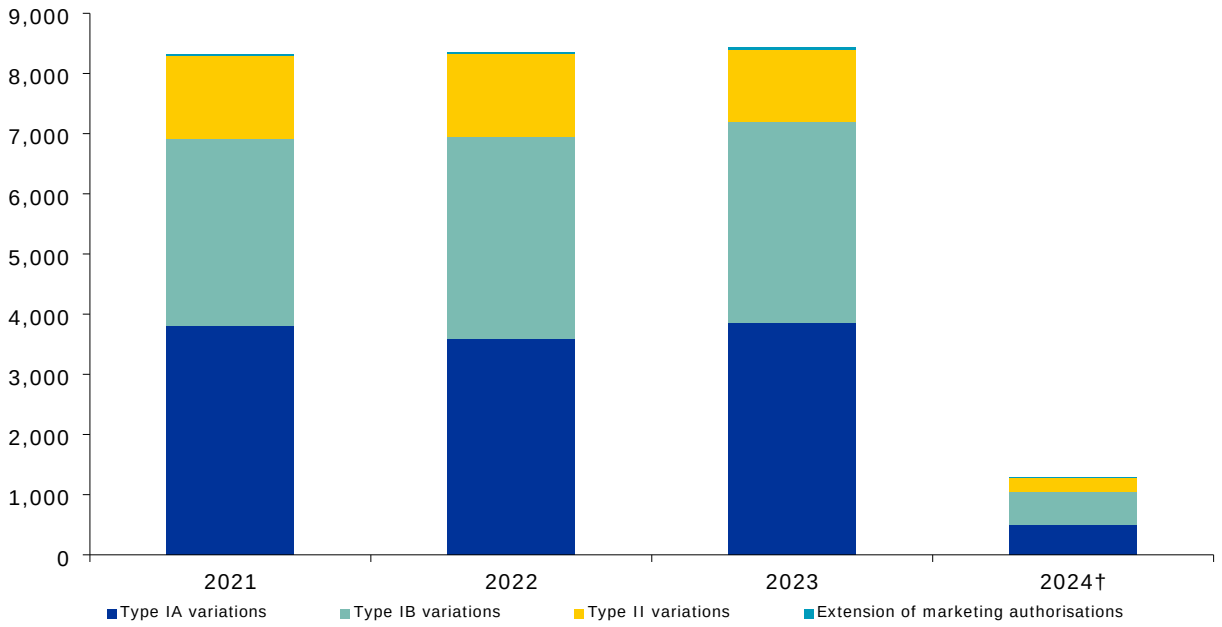
Table 4. Post-authorisation: Variations, renewals and annual reassessments

	2021		2022		2023		2024†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	3,809	3,837	3,586	3,456	3,864	3,883	504	496
Type IB variations	3,102	2,994	3,354	3,169	3,332	3,303	545	549
Type II variations	1,390	1,377	1,388	1,373	1,201	1,131	227	219
Extensions of marketing authorisation	27	36	31	23	43	32	4	7
Annual reassessments	27	27	27	28	33	29	3	11
Renewals*	123	106	132	129	101	116	9	19

* Includes renewals of conditional marketing authorisations.

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

Post-authorisation: Variations, renewals and annual reassessments



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