EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Monthly statistics report: September 2023

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*

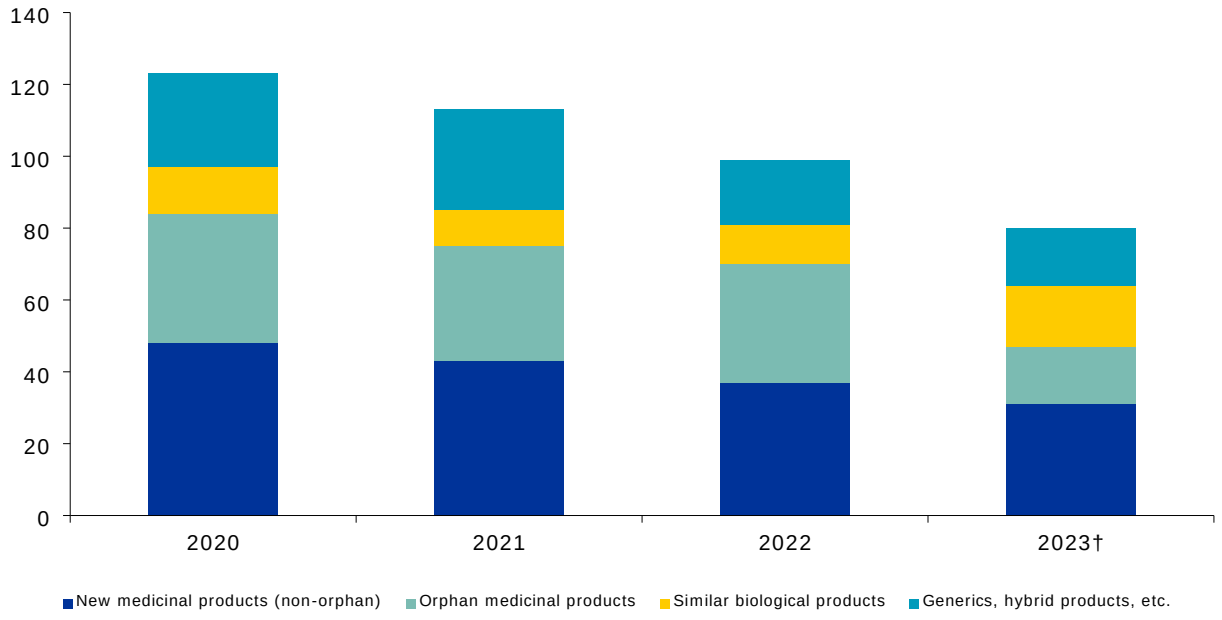
	2020		2021		2022		2023†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	46	39	43	46	35	27	30	22
Advanced-therapy medicinal products	1	0	0	0	0	0	0	0
Paediatric-use (PUMA) products	1	0	0	0	2	0	1	2
Well-established use, abridged, hybrid and informed consent products	10	7	7	6	3	7	3	4
Generic products	16	15	21	12	15	23	13	8
Similar biological products	13	12	10	7	11	10	17	6
Sub-total product applications	87	73	81	71	66	67	64	42
Orphan medicinal products◇								
New products	28	23	29	24	32	19	14	17
Advanced-therapy medicinal products	8	3	3	2	1	6	2	0
Total product applications	123	99	113	97	99	92	80	59

* Finalised applications exclude applications withdrawn prior to opinion.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*

	2020	2021	2022	2023†
Positive opinions (total 1st opinions)	96	92	89	55
- new active substance (NAS)**				28
- conditional marketing authorisation**	13	13	9	5
- under exceptional circumstances**	4	4	5	0
- after accelerated assessment**	6	3	5	3
Negative opinions	3	5	3	4
Applications withdrawn prior to 1st opinion††	16	8	11	13
Applications withdrawn after a 1st opinion (e.g. during re-examination) ††				3
Re-examinations requested	2	4	2	4
Re-examination - Positive opinions	1	0	0	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.

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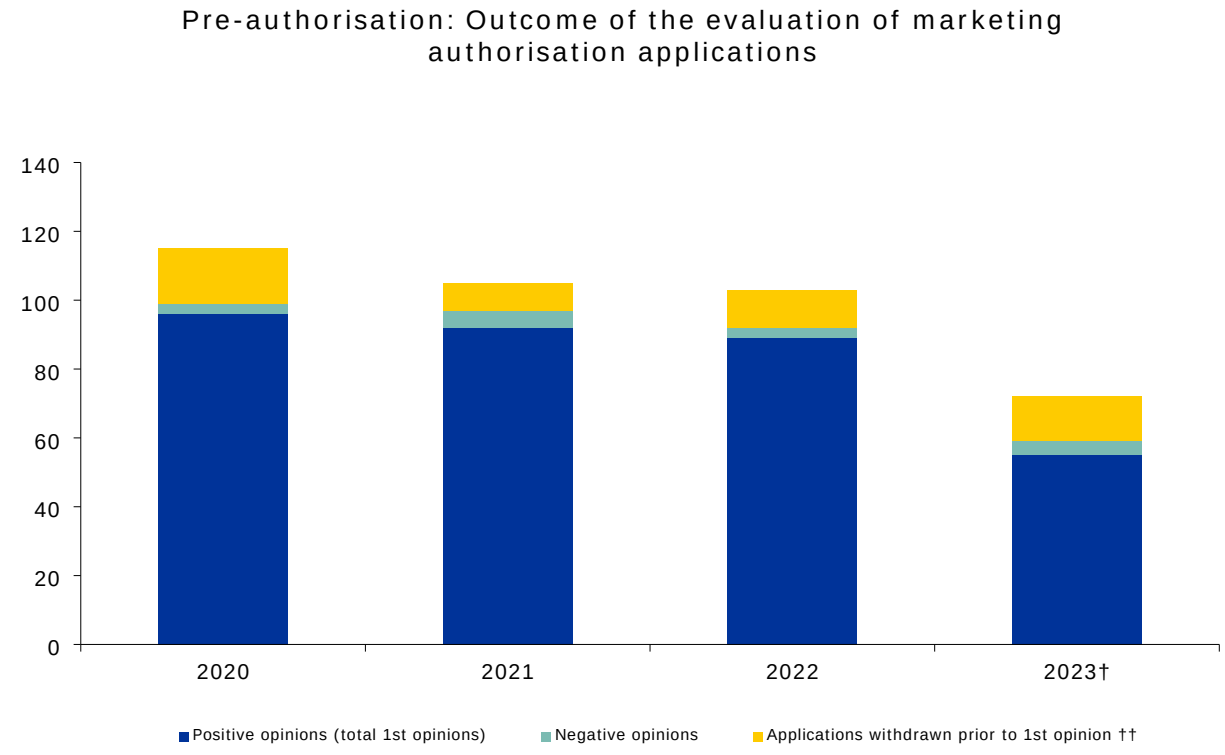
†† Date as per withdrawal letter date. It may first be communicated at the following month's CHMP meeting.



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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

	2020		2021		2022		2023†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	1	1	0	0	0	0	0	0
Art. 58 (WHO) scientific opinions	0	1	3	0	1	3	0	0
Opinions on Companion Diagnostics medical devices (CDx)					4	3	8	4
Opinions on ancillary medicinal substances in medical devices*	0	0	0	0	2	0	0	2
Plasma master file (includes initial certification, variations and annual re-certification)	21	20	20	17	17	23	13	17

* 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

	2020		2021		2022		2023†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	3,993	3,925	3,809	3,837	3,586	3,456	2,911	2,914
Type IB variations	2,744	2,725	3,102	2,994	3,354	3,169	2,519	2,610
Type II variations	1,285	1,209	1,390	1,377	1,388	1,373	832	853
Extensions of marketing authorisation	37	29	27	36	31	23	31	24
Annual reassessments	23	24	27	27	27	28	24	19
Renewals*	98	118	123	106	132	129	75	95

* Includes renewals of conditional marketing authorisations.

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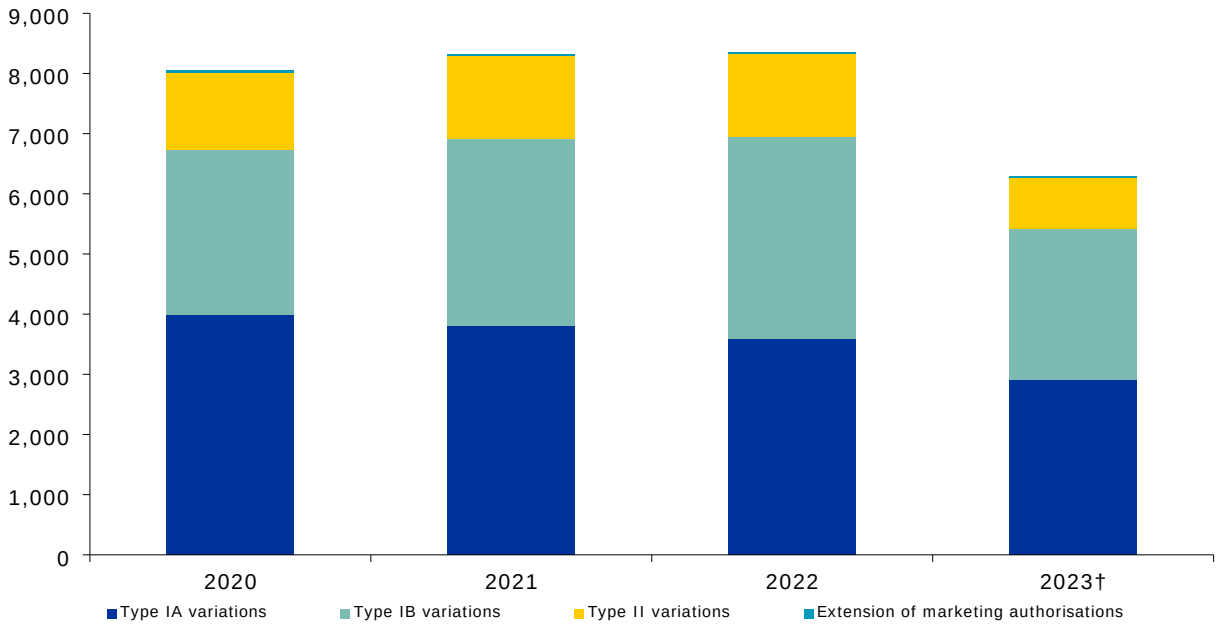
Post-authorisation: Variations, renewals and annual reassessments



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