17 January 2023
EMA/28628/2023
Human Medicines Division

Monthly statistics report: December 2022

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*

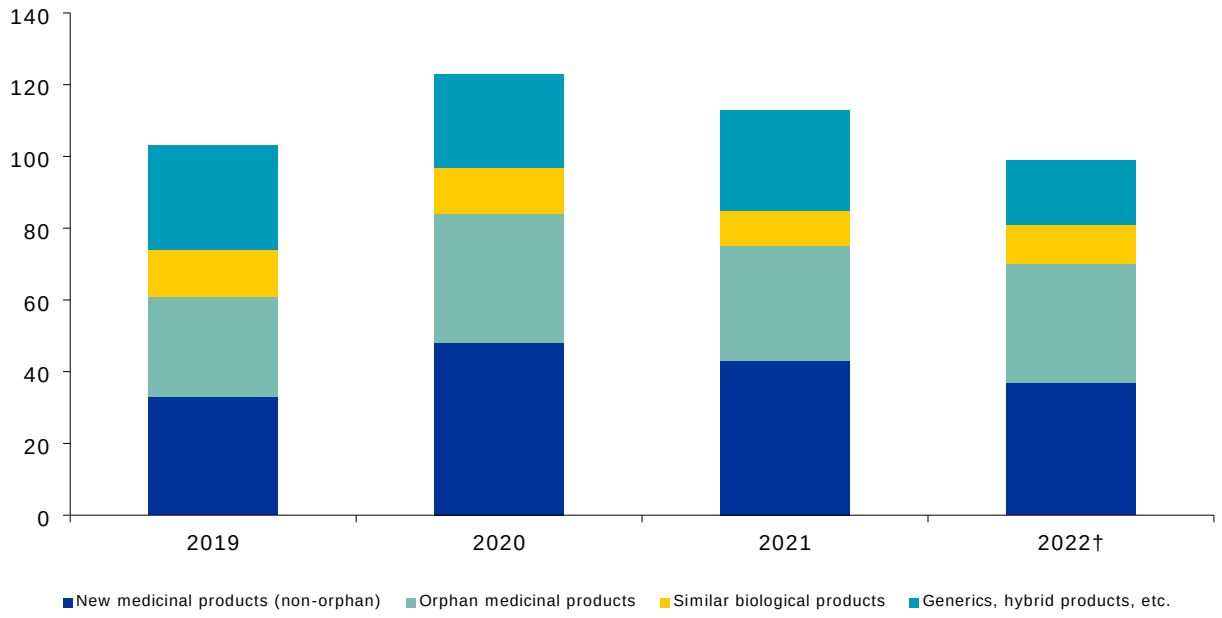
	2019		2020		2021		2022†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	33	31	46	39	43	46	35	27
Advanced-therapy medicinal products	0	0	1	0	0	0	0	0
Paediatric-use (PUMA) products	0	0	1	0	0	0	2	0
Well-established use, abridged, hybrid and informed consent products	12	8	10	7	7	6	3	7
Generic products	17	15	16	15	21	12	15	23
Similar biological products	13	5	13	12	10	7	11	10
Sub-total product applications	75	59	87	73	81	71	66	67
Orphan medicinal products◇								
New products	27	11	28	23	29	24	32	19
Advanced-therapy medicinal products	1	1	8	3	3	2	1	6
Total product applications	103	71	123	99	113	97	99	92

* Finalised applications exclude applications withdrawn prior to opinion.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*

	2019	2020	2021	2022†
Positive opinions	65	96	92	89
Opinions recommending conditional marketing authorisation**	8	13	13	9
Opinions under exceptional circumstances**	1	4	4	5
Negative opinions	6	3	5	3
Opinions after accelerated assessment**	3	6	3	5
Applications withdrawn prior to initial opinion††	12	16	8	11
Re-examinations requested	4	2	4	2
Re-examination - Positive opinions	1	1	0	0

* Applicants can request a re-examination. The first four 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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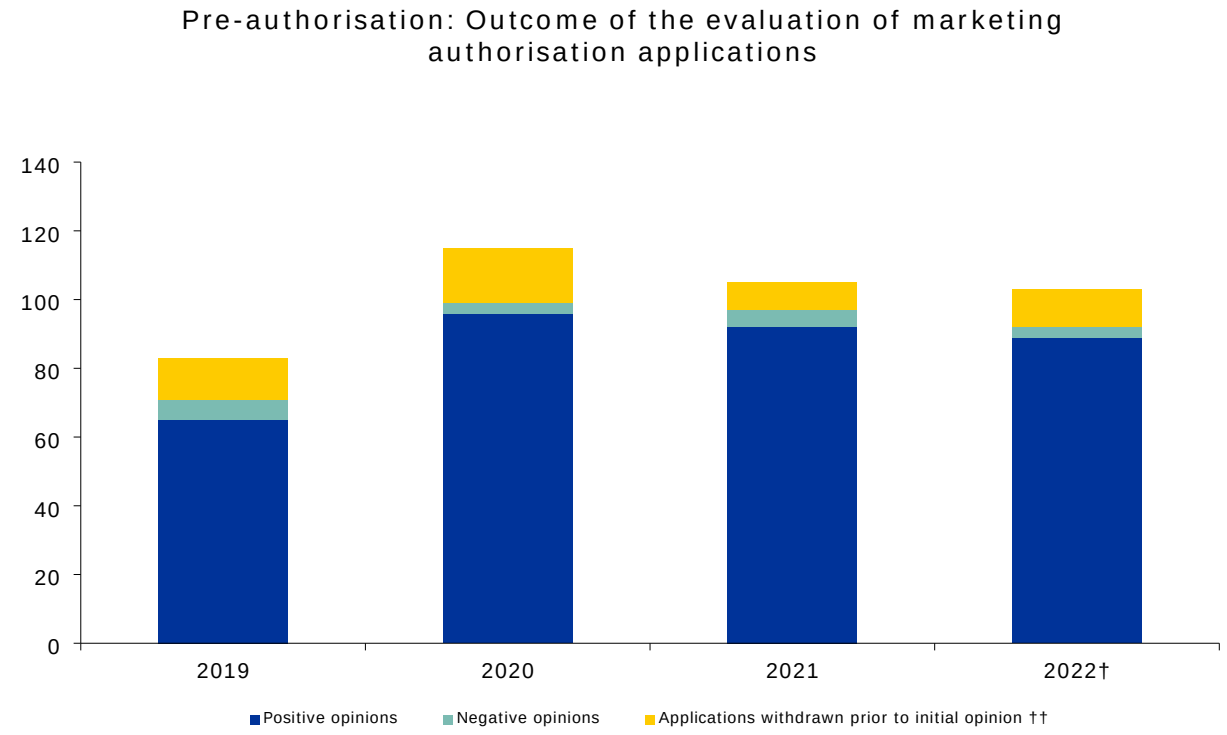
†† Date as per withdrawal letter date. It may first be communicated at the following month's CHMP meeting.



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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

	2019		2020		2021		2022†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	0	0	1	1	0	0	0	0
Art. 58 (WHO) scientific opinions	0	0	0	1	3	0	1	3
Opinions on ancillary medicinal substances in medical devices*	0	0	0	0	0	0	6	3
Plasma master file (includes initial certification, variations and annual re-certification)	17	21	21	20	20	17	17	23

* 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, renewals and annual reassessments

	2019		2020		2021		2022†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	3,886	3,849	3,993	3,925	3,809	3,837	3,586	3,456
Type IB variations	2,425	2,279	2,744	2,725	3,102	2,994	3,354	3,169
Type II variations	1,123	1,108	1,285	1,209	1,390	1,377	1,388	1,373
Extensions of marketing authorisation	27	19	37	29	27	36	31	23
Annual reassessments	25	23	23	24	27	27	27	28
Renewals*	107	85	98	118	123	106	132	129

* Includes renewals of conditional marketing authorisations.

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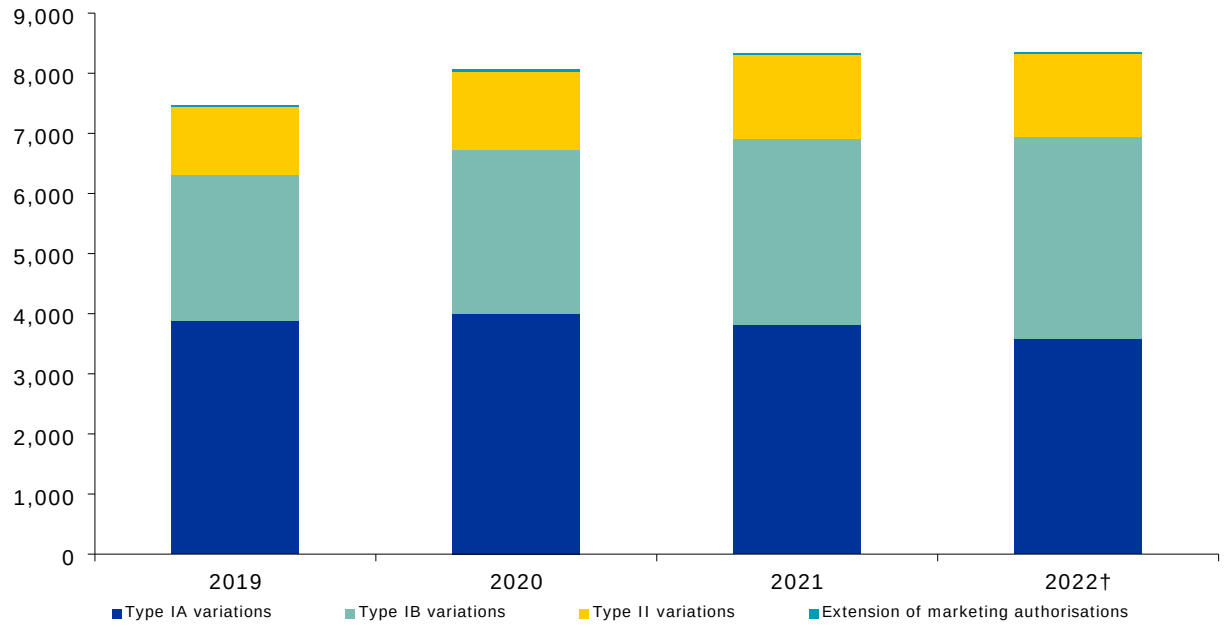
Post-authorisation: Variations, renewals and annual reassessments



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