



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 September 2021
EMA/526215/2021
Human Medicines Division

Monthly statistics report: August 2021

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*

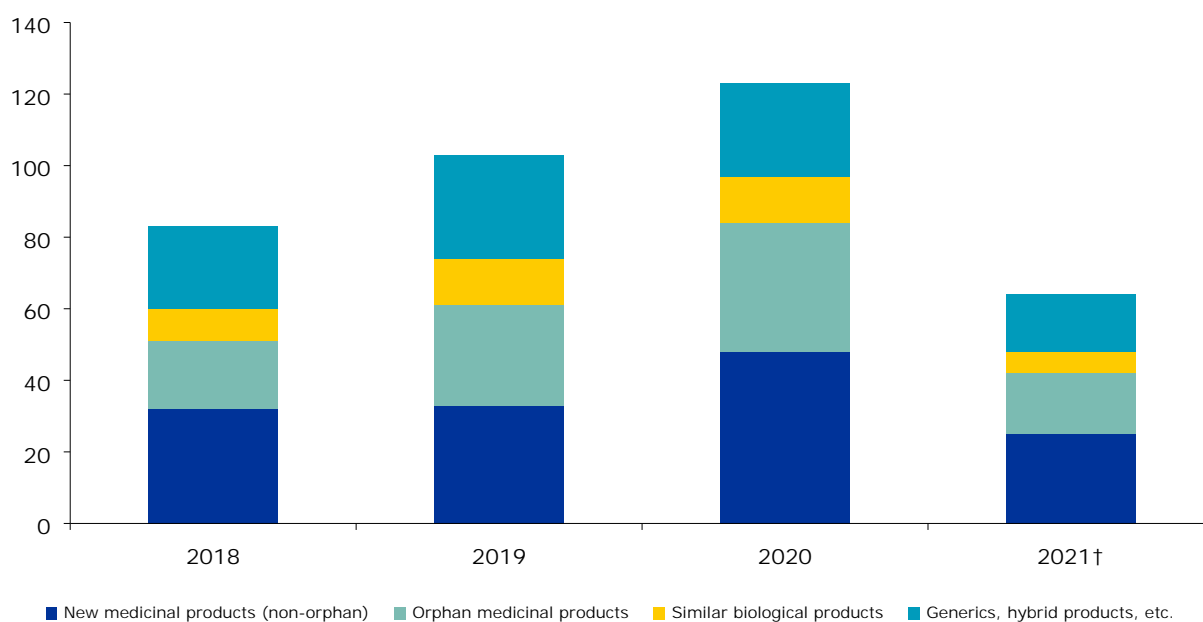
	2018		2019		2020		2021†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	31	34	33	31	46	39	25	24
Advanced-therapy medicinal products	1	0	0	0	1	0	0	0
Paediatric-use (PUMA) products	0	2	0	0	1	0	0	0
Well-established use, abridged, hybrid and informed consent products	5	6	12	8	10	7	5	2
Generic products	18	9	17	15	16	15	11	7
Similar biological products	9	15	13	5	13	12	6	5
Sub-total product applications	64	66	75	59	86	73	47	38
Orphan medicinal products[◇]								
New products	17	20	27	11	28	23	15	14
Advanced-therapy medicinal products	2	3	1	1	8	3	2	2
Total product applications	83	89	103	71	123	99	64	54

* Finalised applications exclude applications withdrawn prior to opinion.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*

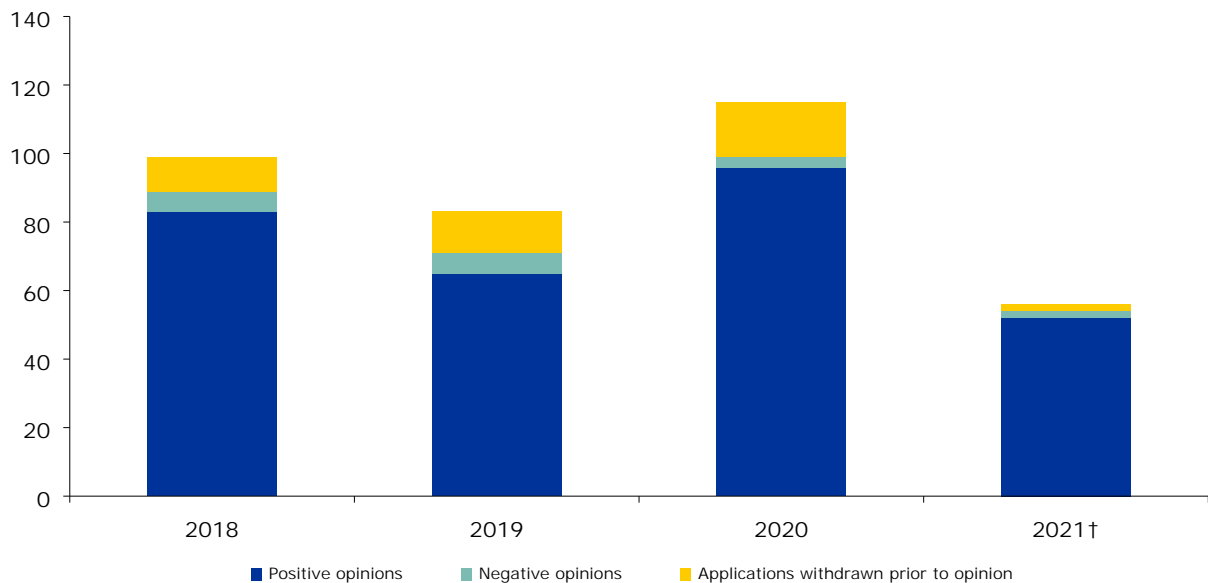
	2018	2019	2020	2021†
Positive opinions	83	65	96	52
Opinions recommending conditional marketing authorisation**	1	8	13	9
Opinions under exceptional circumstances**	3	1	4	2
Negative opinions	6	6	3	2
Opinions after accelerated assessment**	4	3	6	2
Applications withdrawn prior to opinion	10	12	16	2
Re-examinations requested	5	4	2	3
Re-examination - Positive opinions	1	1	1	1

* 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.

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

Pre-authorisation: Outcome of the evaluation of marketing authorisation applications



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

Table 3. Scientific services

	2018		2019		2020		2021 [†]	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	0	0	0	0	1	1	0	0
Art. 58 (WHO) scientific opinions	1	1	0	0	0	1	3	0
Opinions on ancillary medicinal substances in medical devices*	0	1	0	0	0	0	0	0
Plasma master file (includes initial certification, variations and annual re-certification)	19	18	17	21	21	20	9	16

* 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 derivatives 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.

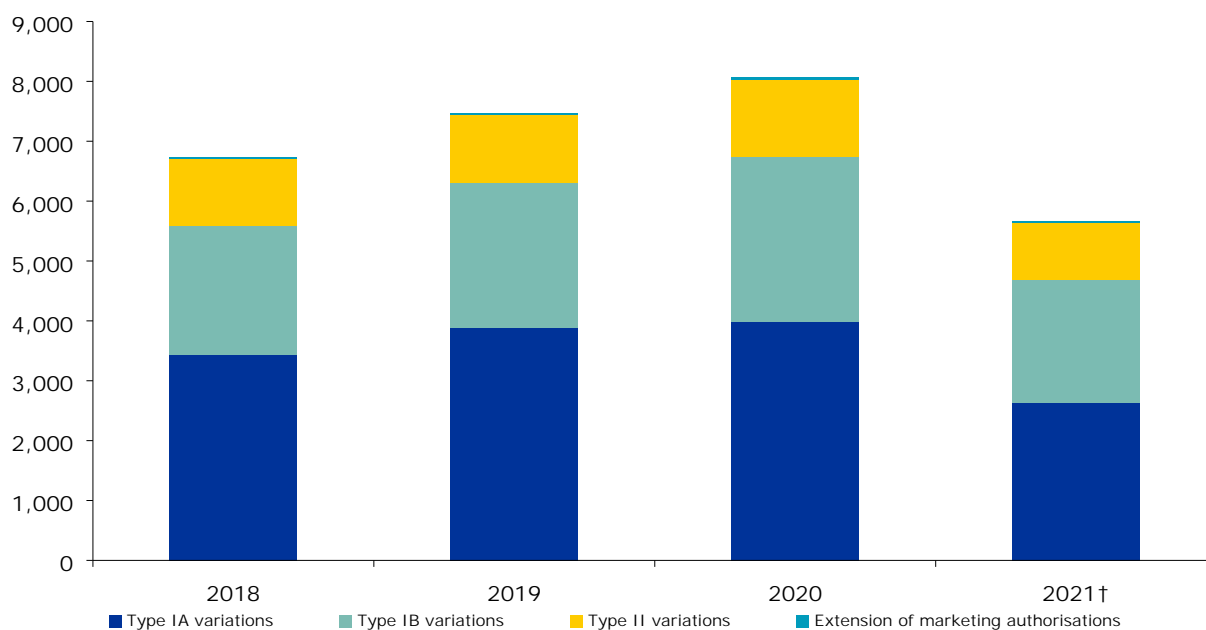
Table 4. Post-authorisation: Variations, renewals and annual reassessments

	2018		2019		2020		2021 [†]	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	3,433	3,347	3,886	3,849	3,993	3,925	2,633	2,697
Type IB variations	2,164	2,063	2,425	2,279	2,744	2,725	2,054	1,894
Type II variations	1,119	1,041	1,123	1,108	1,285	1,209	958	849
Extensions of marketing authorisation	20	19	27	19	37	29	19	21
Annual reassessments	22	22	25	23	23	24	15	15
Renewals*	90	101	107	85	98	118	73	58

* 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.