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Information Management Division

Monthly statistics report: March 2019

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*

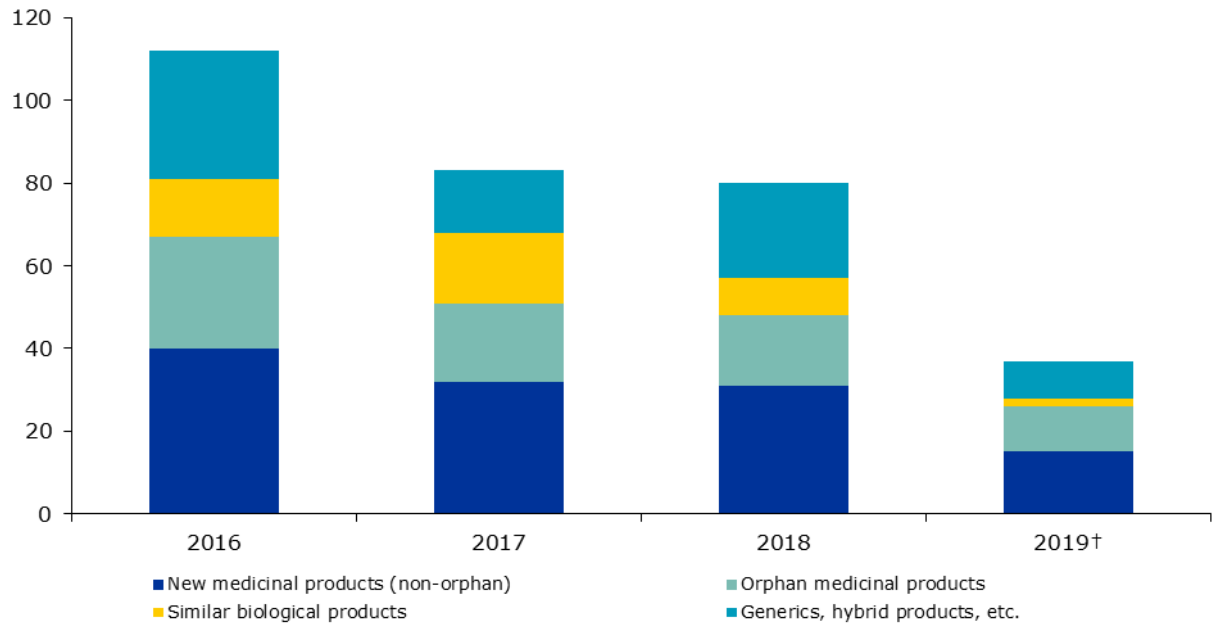
	2016		2017		2018		2019†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	40	28	32	33	31	34	15	7
Advanced-therapy medicinal products	0	0	0	1	1	0	0	0
Paediatric-use (PUMA) products	1	1	2	1	0	2	0	0
Well-established use, abridged, hybrid and informed consent products	7	5	5	6	5	6	4	1
Generic products	24	22	10	22	18	9	5	3
Similar biological products	14	7	17	14	9	15	2	2
Sub-total product applications	86	63	66	77	64	66	26	13
Orphan medicinal products◇								
New products	27	16	19	20	17	20	11	2
Advanced-therapy medicinal products	1	2	4	1	2	3	0	1
Total product applications	114	79	89	101	83	89	37	16

* Finalised applications exclude applications withdrawn prior to opinion.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.

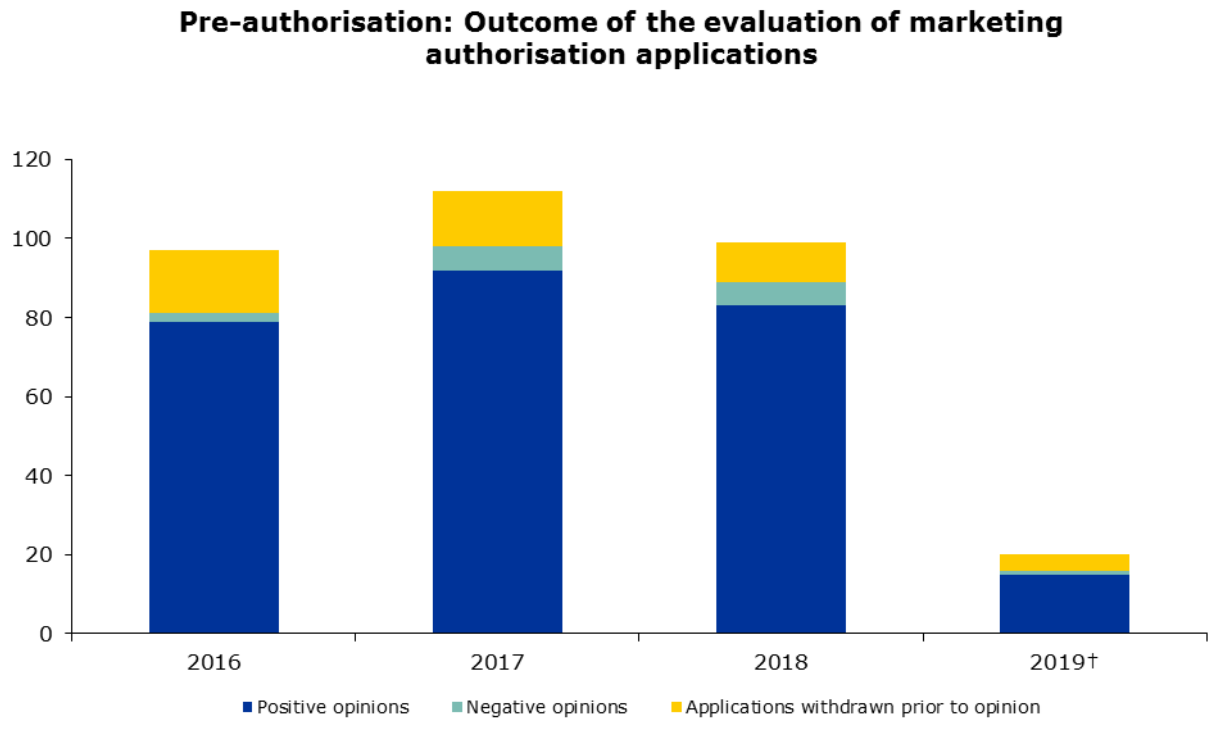
Table 2. Pre-authorisation: Outcome of the evaluation of marketing authorisation applications*

	2016	2017	2018	2019†
Positive opinions	79	92	83	15
Opinions recommending conditional marketing authorisation**	7	3	1	4
Opinions under exceptional circumstances**	1	2	3	1
Negative opinions	2	6	6	1
Opinions after accelerated assessment**	7	7	4	1
Applications withdrawn prior to opinion	16	14	10	4
Re-examinations requested	2	5	5	1
Re-examination - Positive opinions	2	0	1	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.

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



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

Table 3. Scientific services

	2016		2017		2018		2019†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	0	0	0	0	0	0	0	0
Art. 58 (WHO) scientific opinions	0	1	1	0	1	1	0	0
Opinions on ancillary medicinal substances in medical devices*	0	0	2	1	0	1	0	0
Plasma master file (includes initial certification, variations and annual re-certification)	19	22	22	24	19	18	3	7

* 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

	2016		2017		2018		2019†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	3,019	2,934	3,080	3,069	3,433	3,347	1,090	1,041
Type IB variations	2,000	1,988	2,054	1,975	2,164	2,063	494	604
Type II variations	1,185	1,131	1,133	1,116	1,119	1,041	304	341
Extensions of marketing authorisation	25	16	21	25	20	19	6	5
Annual reassessments	25	19	19	22	22	22	5	5
Renewals*	107	89	94	90	90	101	29	19

* Includes renewals of conditional marketing authorisations.

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