8 February 2018
EMA/85286/2018
Information Management Division

Monthly statistics report: January 2018

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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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

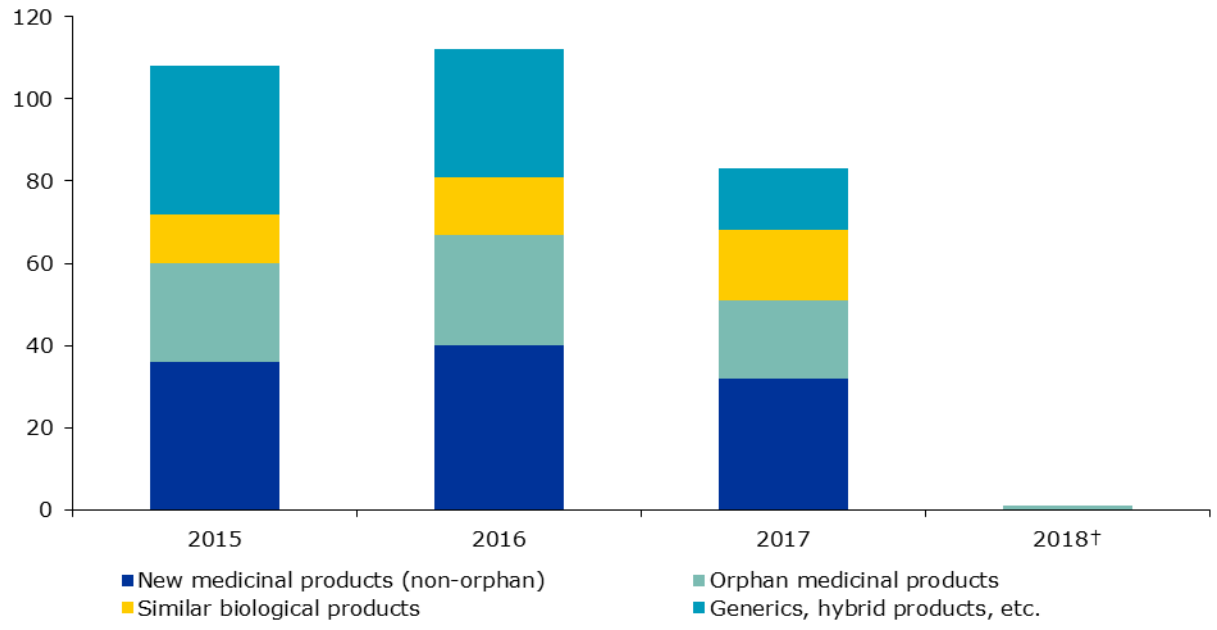
	2015		2016		2017		2018†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	36	41	40	28	32	33	0	6
Advanced-therapy medicinal products	0	1	0	0	0	1	0	0
Paediatric-use (PUMA) products	1	0	1	1	2	1	0	0
Well-established use, abridged, hybrid and informed consent products	8	7	7	5	5	6	0	0
Generic products	28	25	24	22	10	22	0	0
Similar biological products	12	2	14	7	17	14	0	1
Sub-total product applications	85	76	86	63	66	77	0	7
Orphan medicinal products◇								
New products	24	20	27	16	19	20	1	1
Advanced-therapy medicinal products	1	1	1	2	4	1	0	0
Total product applications	110	97	114	81	89	98	1	8

* Finalised applications exclude applications withdrawn prior to opinion.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.

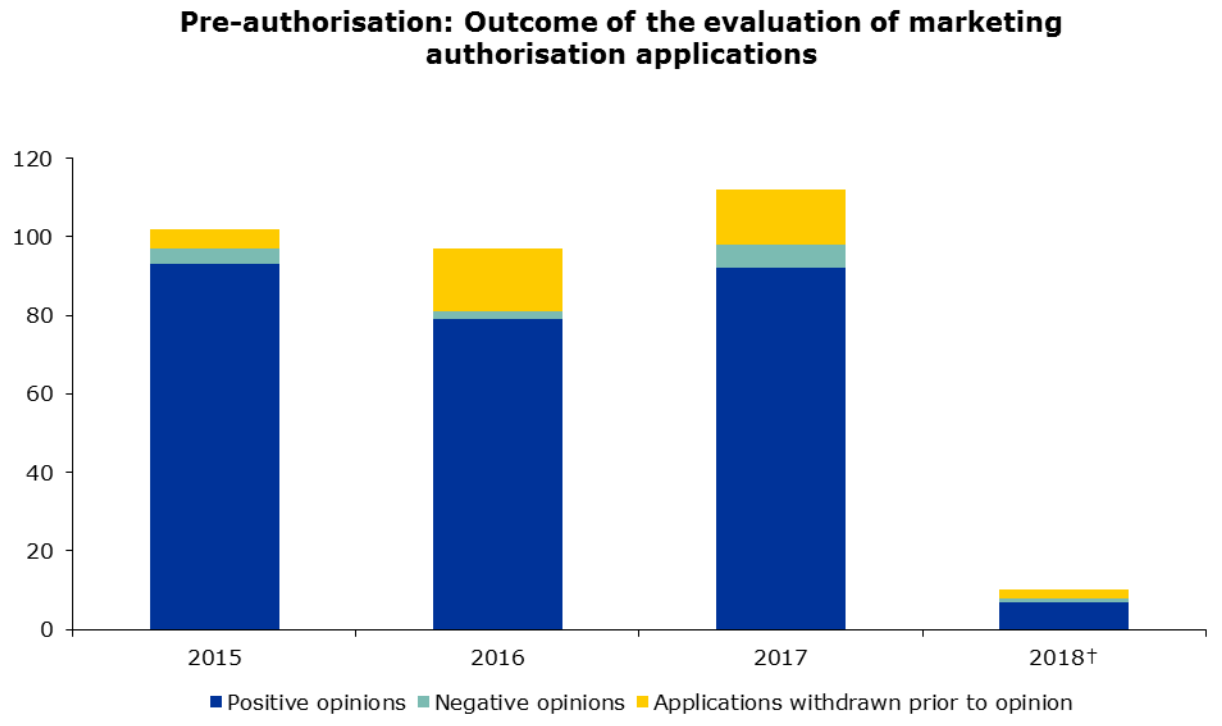
Table 2. Pre-authorisation: Outcome of the evaluation of marketing authorisation applications*

	2015	2016	2017	2018†
Positive opinions	93	79	92	7
Opinions recommending conditional marketing authorisation**	3	7	3	0
Opinions under exceptional circumstances**	3	1	2	1
Negative opinions	4	2	6	1
Opinions after accelerated assessment**	5	7	7	1
Applications withdrawn prior to opinion	5	16	14	2
Re-examinations requested	1	2	5	0
Re-examination - Positive opinions	0	2	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.

† 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

	2015		2016		2017		2018†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	0	0	0	0	0	0	0	0
Art. 58 (WHO) scientific opinions	1	1	0	1	1	0	1	0
Opinions on ancillary medicinal substances in medical devices*	1	1	0	0	2	1	0	1
Plasma master file (includes initial certification, variations and annual re-certification)	17	19	19	22	22	24	1	1

* 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

	2015		2016		2017		2018†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	2,829	2,849	3,019	2,934	3,080	3,069	236	208
Type IB variations	1,954	1,838	2,000	1,988	2,054	1,975	174	194
Type II variations	1,168	1,097	1,185	1,131	1,133	1,116	82	92
Extensions of marketing authorisation	14	15	25	16	21	25	0	1
Annual reassessments	16	20	25	19	19	22	2	1
Renewals*	71	75	107	89	94	90	4	4

* 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.