



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

Monthly statistics report: September 2016

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.



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

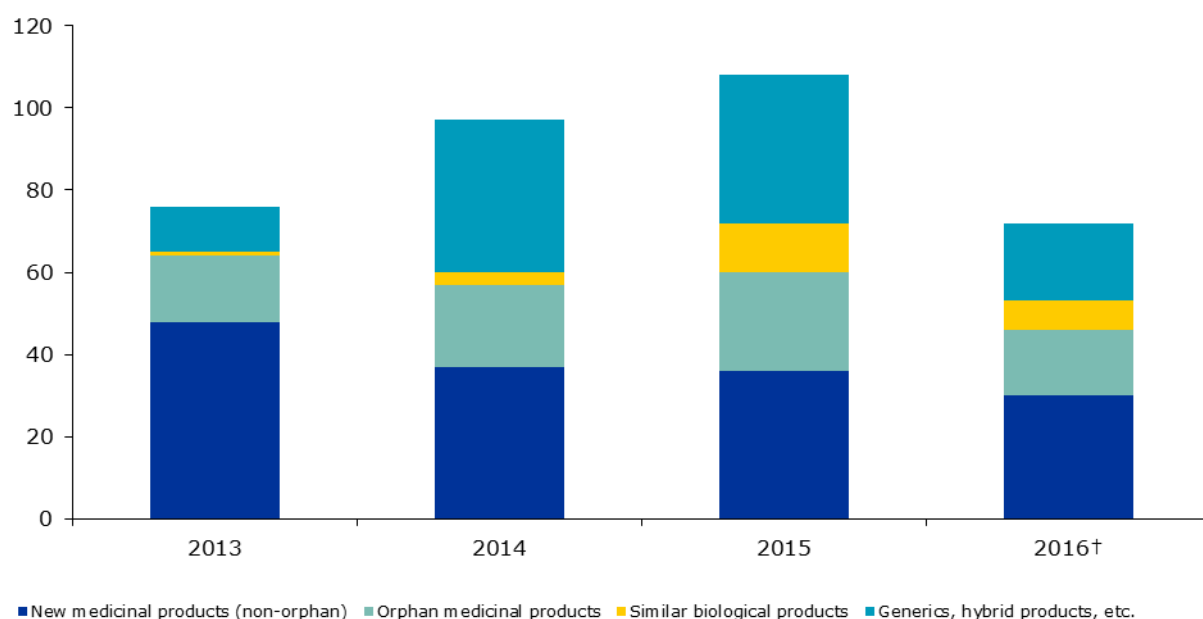
	2013		2014		2015		2016 [†]	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	48	46	37	42	36	41	30	20
Advanced-therapy medicinal products	0	2	1	0	0	1	0	0
Paediatric-use (PUMA) products	1	0	0	1	1	0	0	1
Well-established use, abridged, hybrid and informed consent products	6	4	12	15	8	7	2	4
Generic products	5	16	25	6	28	25	17	15
Similar biological products	1	4	3	3	12	2	7	3
Sub-total product applications	61	72	78	67	85	76	56	43
Orphan medicinal products[◇]								
New products	16	14	20	17	24	20	16	11
Advanced-therapy medicinal products	2	0	1	1	1	1	1	2
Total product applications	79	86	99	85	110	97	73	56

* Finalised applications exclude applications withdrawn prior to opinion.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*

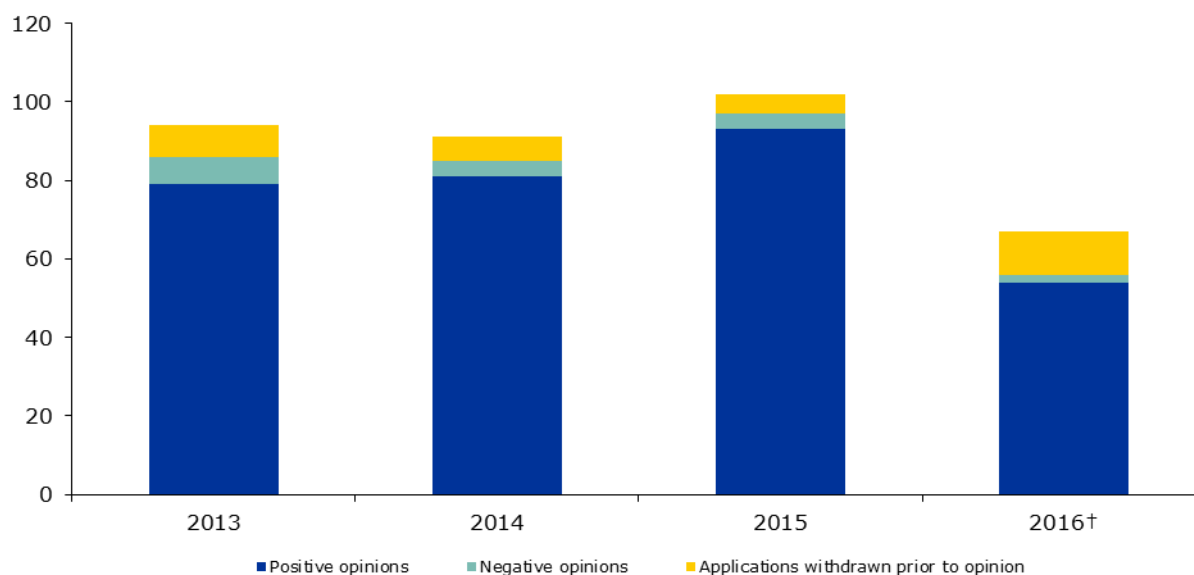
	2013	2014	2015	2016 [†]
Positive opinions	79	81	93	54
Opinions recommending conditional marketing authorisation**	4	4	3	4
Opinions under exceptional circumstances**	3	1	3	1
Negative opinions	7	4	4	2
Opinions after accelerated assessment**	5	7	5	8
Applications withdrawn prior to opinion	8	6	5	11
Re-examinations requested	10	5	1	2
Re-examination - Positive opinions	3	1	0	2

* 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

	2013		2014		2015		2016 [†]	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	2	2	1	1	0	0	0	0
Art. 58 (WHO) scientific opinions	1	1	1	1	1	1	0	1
Opinions on ancillary medicinal substances in medical devices*	3	1	0	1	1	1	0	0
Plasma master file (includes initial certification, variations and annual re-certification)	19	13	16	16	17	19	15	19

* 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

	2013		2014		2015		2016 [†]	
	Started	Started	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	2,922	2,886	2,969	2,854	2,829	2,849	2,249	2,245
Type IB variations	1,958	1,597	1,886	1,986	1,954	1,838	1,458	1,525
Type II variations	961	946	1,151	1,103	1,168	1,097	808	837
Extensions of marketing authorisation	16	18	16	15	14	15	19	11
Annual reassessments	18	16	18	18	16	20	14	13
Renewals*	98	77	100	121	71	75	74	67

* 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

