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Information Management Division

Monthly statistics report: August 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.

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

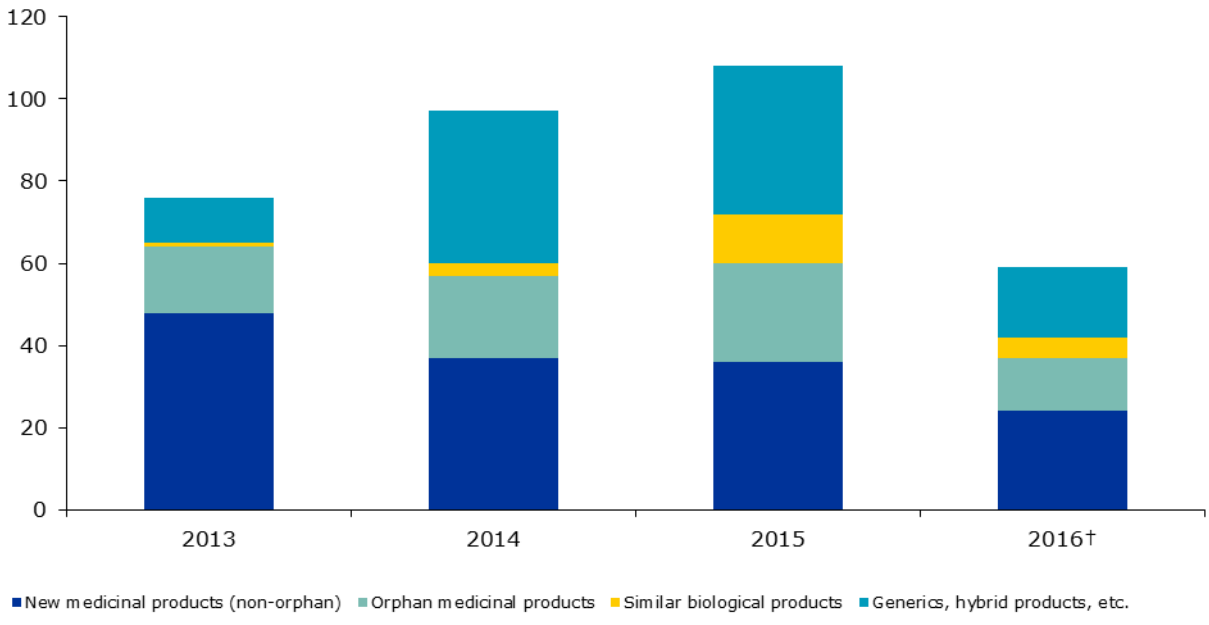
	2013		2014		2015		2016†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	48	46	37	42	36	41	**24**	**17**
Advanced-therapy medicinal products	0	2	1	0	0	1	**0**	**0**
Paediatric-use (PUMA) products	1	0	0	1	1	0	**0**	**1**
Well-established use, abridged, hybrid and informed consent products	6	4	12	15	8	7	**1**	**4**
Generic products	5	16	25	6	28	25	**16**	**11**
Similar biological products	1	4	3	3	12	2	**5**	**3**
Sub-total product applications	**61**	**72**	**78**	**67**	**85**	**76**	**46**	**36**
Orphan medicinal products◇								
New products	16	14	20	17	24	20	**13**	**9**
Advanced-therapy medicinal products	2	0	1	1	1	1	**1**	**2**
Total product applications	**79**	**86**	**99**	**85**	**110**	**97**	**60**	**47**

* Finalised applications exclude applications withdrawn prior to opinion.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	**45**
Opinions recommending conditional marketing authorisation**	4	4	3	**3**
Opinions under exceptional circumstances**	3	1	3	**0**
Negative opinions	7	4	4	**2**
Opinions after accelerated assessment**	5	7	5	**6**
Applications withdrawn prior to opinion	8	6	5	**9**
Re-examinations requested	10	5	1	**2**
Re-examination - Positive opinions	3	1	0	**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.

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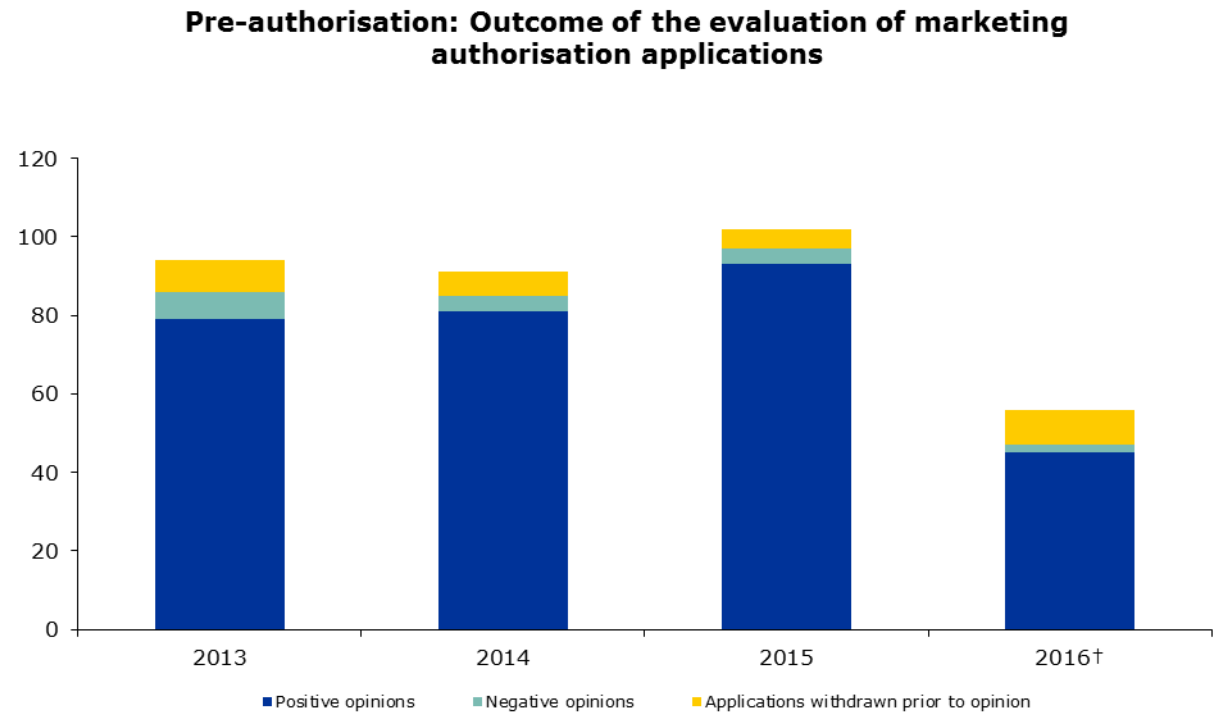

† Figures for the current year are cumulative, year to date. Figures for preceding years are totals for the year.

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	**14**	**18**

* 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

	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	**2,025**	**1,922**
Type IB variations	1,958	1,597	1,886	1,986	1,954	1,838	**1,299**	**1,333**
Type II variations	961	946	1,151	1,103	1,168	1,097	**739**	**673**
Extensions of marketing authorisation	16	18	16	15	14	15	**15**	**9**
Annual reassessments	18	16	18	18	16	20	**11**	**13**
Renewals*	98	77	100	121	71	75	**67**	**55**

* Includes renewals of conditional marketing authorisations.

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