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Information Management Division

Monthly statistics report: October 2015

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*

	2012		2013		2014		2015†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	44	35	48	46	37	42	**25**	**31**
Advanced-therapy medicinal products	3**	0	0	2	1	0	**0**	**1**
Paediatric-use (PUMA) products	0	0	1	0	0	1	**1**	**0**
Well-established use, abridged, hybrid and non-prescription switch products	5	6	6	4	12	15	**8**	**6**
Generic products	16	13	5	16	25	6	**22**	**21**
Similar biological products	8	0	1	4	3	3	**4**	**0**
Sub-total product applications	**76**	**54**	**61**	**72**	**78**	**67**	**60**	**60**
Orphan medicinal products ◇								
New products	19	11	16	14	20	17	**21**	**16**
Advanced-therapy medicinal products	0	0	2	0	1	1	**1**	**1**
Total product applications	**95**	**65**	**79**	**86**	**99**	**85**	**82**	**76**

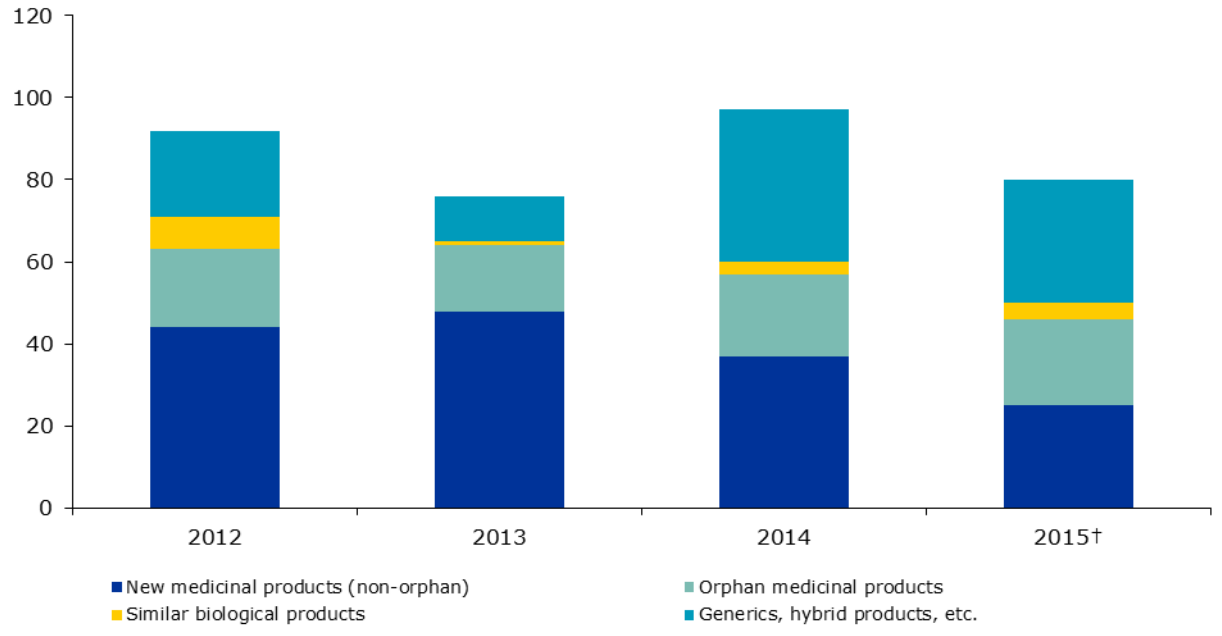
* Finalised applications exclude applications withdrawn prior to opinion.

** 2012 figures include two Article 29 transition products.

† 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.

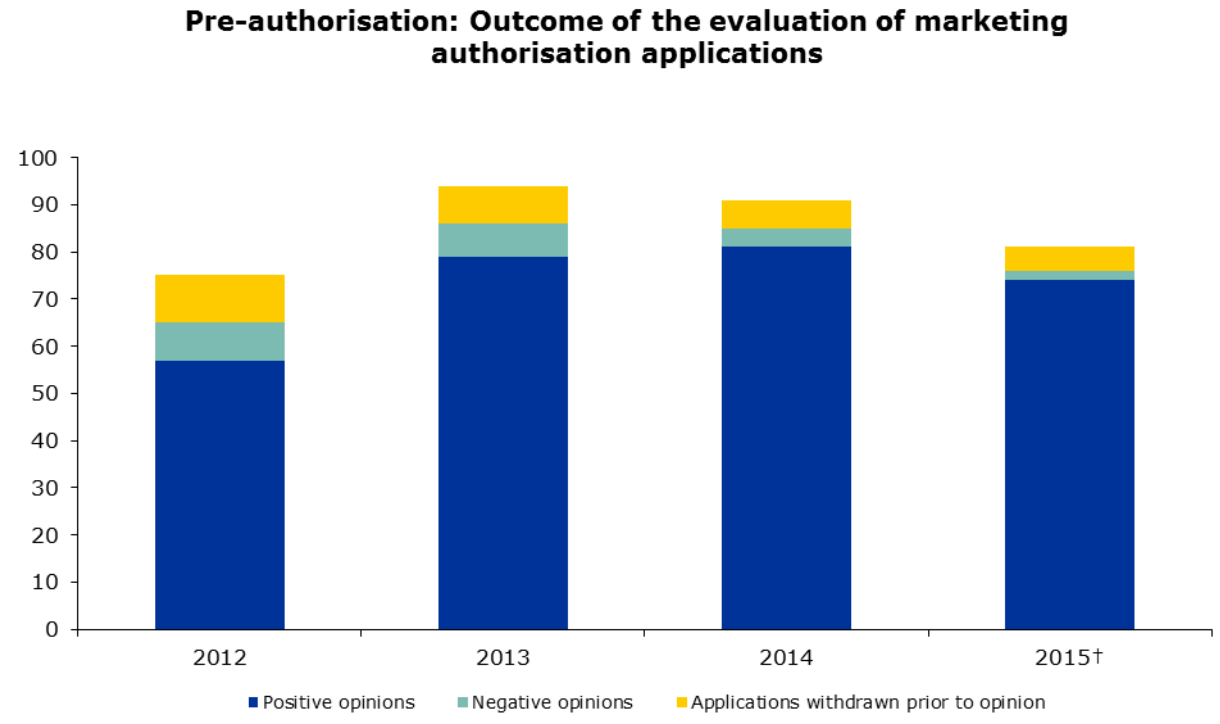
Table 2. Pre-authorisation: Outcome of the evaluation of marketing authorisation applications*

	2012	2013	2014	2015†
Positive opinions	57	79	81	**74**
Opinions recommending conditional marketing authorisation**	3	4	4	**2**
Opinions under exceptional circumstances**	0	3	1	**3**
Negative opinions	8	7	4	**2**
Opinions after accelerated assessment**	1	5	7	**5**
Applications withdrawn prior to opinion	10	8	6	**5**
Re-examinations requested	2	10	5	**1**
Re-examination - Positive opinions	1	3	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

	2012		2013		2014		2015†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Compassionate-use opinions	0	0	2	2	1	1	**0**	**0**
Art. 58 (WHO) scientific opinions	1	2	1	1	1	1	**1**	**1**
Opinions on ancillary medicinal substances in medical devices*	0	2	3	1	0	1	**1**	**1**
Plasma master file (includes initial certification, variations and annual re-certification)	22	28	19	13	16	16	**15**	**17**

* 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

	2012		2013		2014		2015†	
	Started	Started	Started	Finalised	Started	Finalised	Started	Finalised
Type IA variations	2,889	2,798	2,922	2,886	2,969	2,854	**2,245**	**2,271**
Type IB variations	1,468	1,416	1,958	1,597	1,886	1,986	**1,486**	**1,513**
Type II variations	1,012	906	961	946	1,151	1,103	**917**	**945**
Extensions of marketing authorisation	16	17	16	18	16	15	**12**	**12**
Annual reassessments	16	14	18	16	18	18	**14**	**13**
Renewals*	76	77	98	77	100	121	**60**	**53**

* Includes renewals of conditional marketing authorisations.

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