19 March 2014
EMA/167858/2014
Procedure Management and Business Support Division

Monthly statistics report: February 2014

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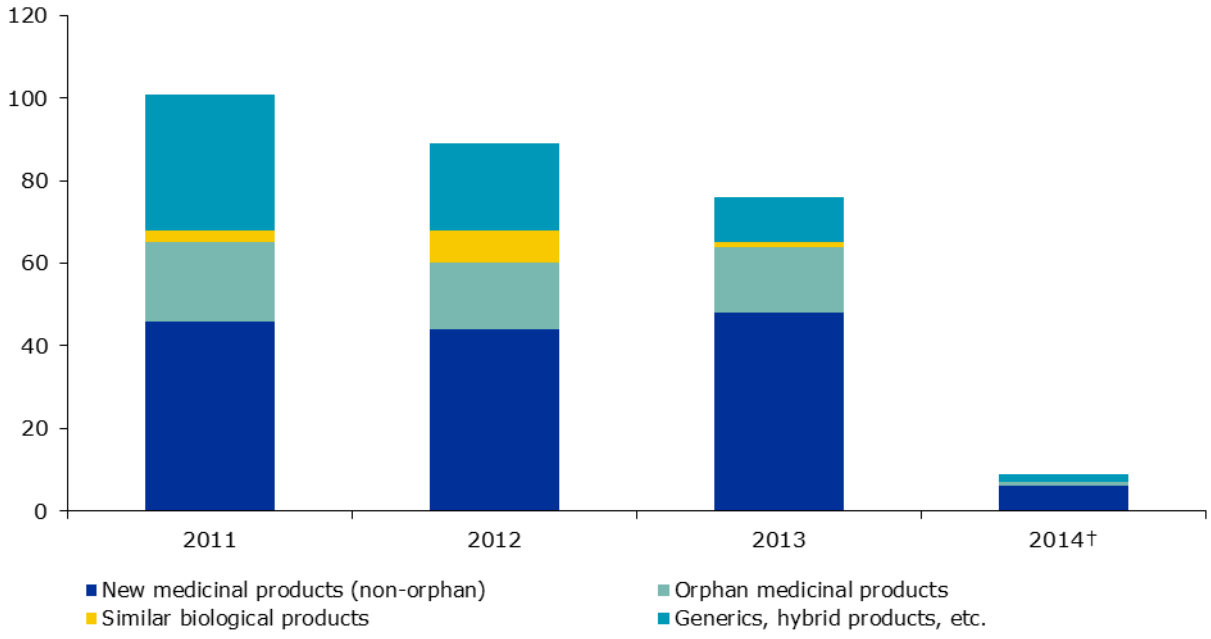
Table 1. Pre-authorisation: Marketing-authorisation applications*

	2011		2012		2013		2014†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	46	37	44	35	48	46	**6**	**8**
Advanced-therapy medicinal products	1	0	1	0	0	2	**0**	**0**
Advanced-therapy Art. 29 transition products	1	0	2	0	N/A	0	**N/A**	**0**
Paediatric-use (PUMA) products	1	1	0	0	1	0	**0**	**1**
Well-established use, abridged, hybrid and non-prescription switch products	8	8	5	6	6	4	**2**	**4**
Generic products	25	34	16	13	5	16	**0**	**2**
Similar biological products	3	0	8	0	1	4	**0**	**1**
Sub-total product applications	**85**	**80**	**76**	**54**	**61**	**72**	**8**	**16**
Orphan medicinal products								
New products	19	11	16	14	16	14	**1**	**4**
Advanced-therapy medicinal products	0	0	2	0	2	0	**0**	**0**
Total product applications	**104**	**91**	**92**	**68**	**77**	**86**	**9**	**20**

* Finalised applications exclude applications withdrawn prior to opinion.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.

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*

	2011	2012	2013	2014†
Positive opinions	87	57	79	**16**
Opinions recommending conditional marketing authorisation**	3	3	4	**0**
Negative opinions	4	8	7	**4**
Opinions after accelerated assessment**	3	0	5	**0**
Applications withdrawn prior to opinion	13	10	8	**1**
Re-examinations requested	5	2	10	**1**

* Outcome of the evaluation leading to an initial opinion, excluding the outcome of a re-examination where applicable.

** Included in the figures for positive opinions.

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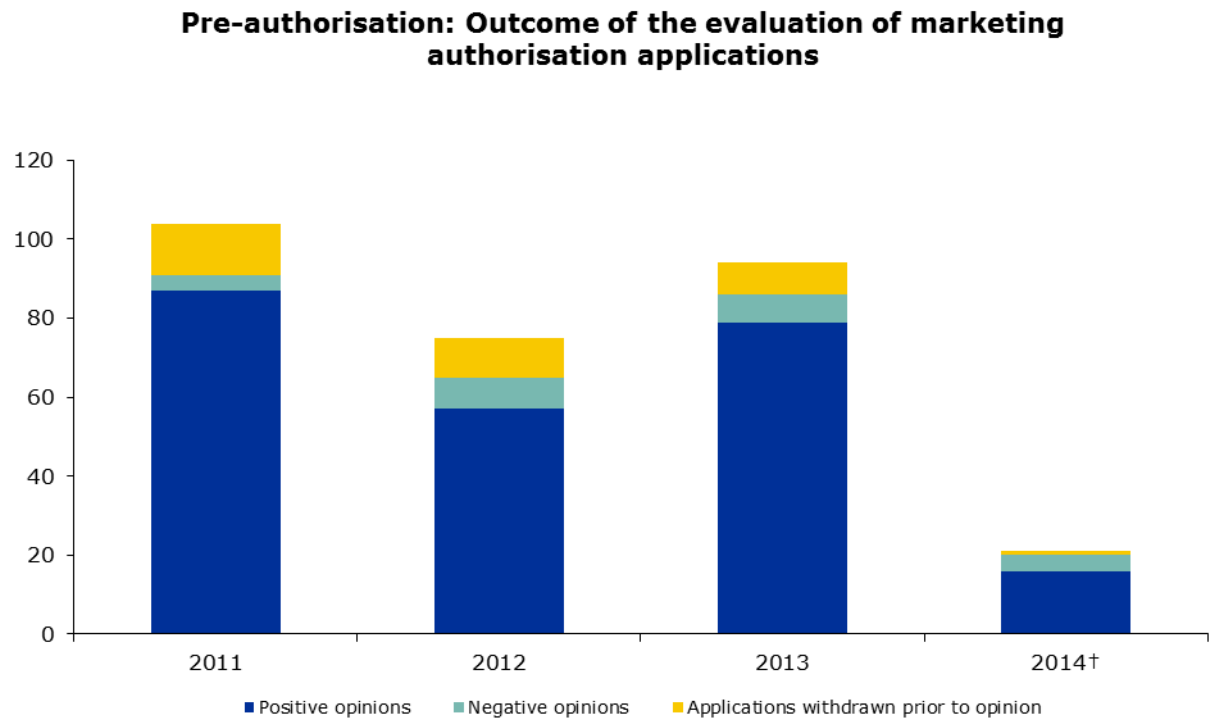

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Table 3. Scientific services

	2011		2012		2013		2014†	
	Started	Finalised	Started	Started	Started	Finalised	Started	Finalised
Compassionate-use opinions	0	0	0	0	2	2	**0**	**0**
Art. 58 (WHO) scientific opinions	1	0	1	2	1	1	**0**	**1**
Opinions on ancillary medicinal substances in medical devices*	3	2	0	2	3	1	**0**	**0**
Plasma master file (includes initial certification, variations and annual re-certification)	30	37	22	28	19	13	**0**	**6**
Vaccine antigen master file	0	0	0	0	0	0	**0**	**0**

* 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

	2011		2012		2013		2014†	
	Received	Finalised	Received	Finalised	Received	Finalised	Received	Finalised
Type IA variations	2,875	2,847	2,889	2,798	2,922	2,886	**399**	**310**
Type IB variations	1,260	1,193	1,468	1,416	1,958	1,597	**281**	**340**
Type II variations	873	918	1,012	906	961	946	**233**	**176**
Extensions of marketing authorisation	31	24	16	17	16	18	**2**	**2**
Grouped applications*	61%	61%	63%	61%	61%	61%	**55%**	**59%**
Multi-product Type IA groups	99	101	111	108	119	118	**15**	**14**
Worksharing variation applications	112	115	120	123	123	112	**33**	**26**
Annual reassessments	18	16	16	14	18	16	**0**	**4**
Renewals**	67	62	76	77	98	77	**33**	**15**

* Excluding groups in worksharing or multi-product Type IA groups

** Includes renewals of conditional marketing authorisations.

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