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Product Data Management

Monthly statistics report:March 2013

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.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

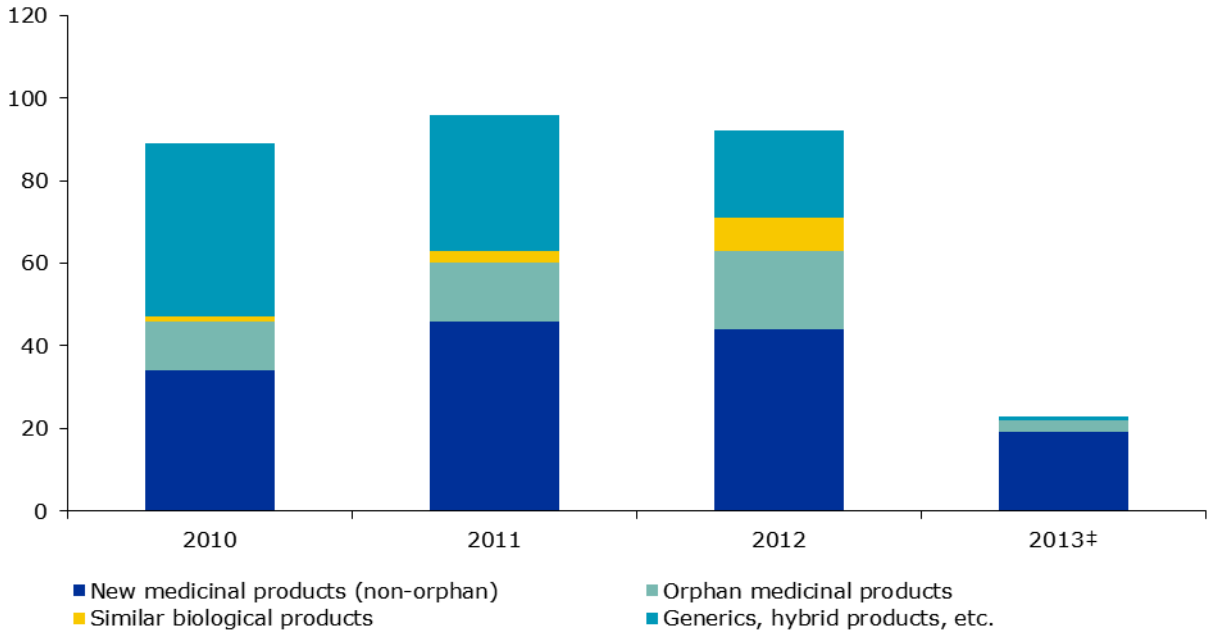
Table 1. Pre-authorisation: Marketing-authorisation applications*

	2010		2011		2012		2013†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	34	21	46	37	44	35	**18**	**8**
Advanced-therapy medicinal products	0	0	1	0	1	0	**0**	**0**
Advanced-therapy Art. 29 transition products	0	0	1	0	2	0	**N/A**	**0**
Paediatric-use (PUMA) products	1	0	1	1	0	0	**1**	**0**
Well-established use, abridged, hybrid and non-prescription switch products	9	6	8	8	5	6	**1**	**1**
Generic products	33	20	25	34	16	13	**0**	**9**
Similar biological products	1	1	3	0	8	0	**0**	**0**
Sub-total product applications	**78**	**48**	**85**	**80**	**76**	**54**	**20**	**18**
Orphan medicinal products								
New products	12	6	14	11	19	11	**2**	**5**
Advanced-therapy medicinal products	1	0	0	1	0	0	**1**	**0**
Total product applications	**90**	**54**	**99**	**91**	**95**	**65**	**23**	**23**

* Finalised applications exclude applications withdrawn prior to opinion.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

	2010	2011	2012	2013†
Positive opinions	51	87	57	**20**
Opinions recommending conditional marketing authorisation*	4	3	3	**1**
Negative opinions	2	4	8	**3**
Opinions after accelerated assessment	1	0	1	**3**
Applications withdrawn prior to opinion	12	13	10	**5**
Re-examinations requested	3	5	2	**4**

* Included in the figures for positive opinions.

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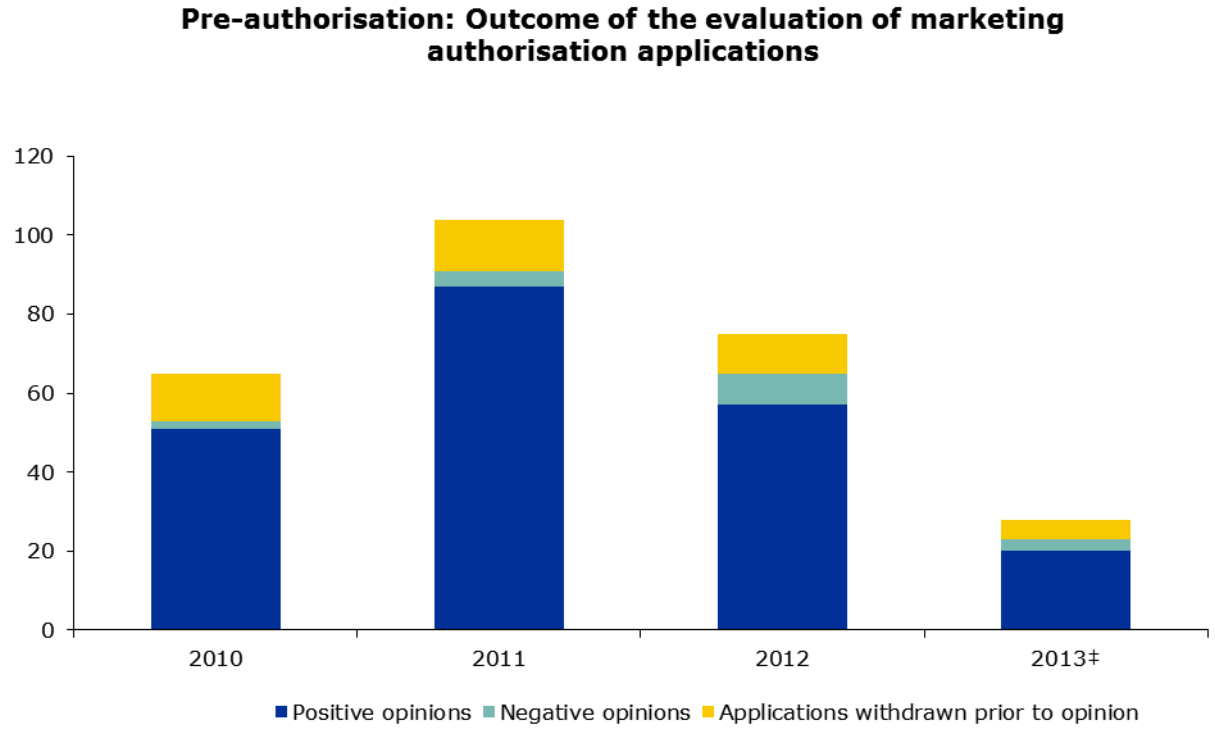

* Only the final outcome in the case of a re-examination of an opinion under Art. 9(2) of Regulation (EC) No 726/2004 is reported.

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Table 3. Scientific services

	2010		2011		2012		2013†	
	Started	Finalised	Started	Started	Started	Finalised	Started	Finalised
Compassionate-use opinions	1	2	0	0	0	0	**0**	**0**
Art. 58 (WHO) scientific opinions	1	0	1	0	1	2	**0**	**0**
Opinions on ancillary medicinal substances in medical devices*	3	0	3	2	0	2	**0**	**1**
Plasma master file (includes initial certification, variations and annual re-certification)	22	19	30	37	22	28	**1**	**4**
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.

† 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

	2010		2011		2012		2013†	
	Received	Finalised	Received	Finalised	Received	Finalised	Received	Finalised
Type IA variations	2,057	1,711	2,875	2,847	2,889	2,798	**747**	**597**
Type IB variations	1,093	852	1,260	1,193	1,468	1,416	**434**	**372**
Type II variations	966	942	873	918	1,012	906	**224**	**225**
Extensions of marketing authorisation	29	26	31	24	16	17	**5**	**5**
Grouped applications*	51%	38%	61%	61%	63%	61%	**66%**	**64%**
Multi-product Type IA groups	41	31	99	101	111	108	**32**	**24**
Worksharing variation applications	111	58	112	115	120	123	**31**	**19**
Annual reassessments	19	20	18	16	16	14	**3**	**6**
Renewals**	67	27	67	62	76	77	**20**	**15**

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

** Includes renewals of conditional marketing authorisations.

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