



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Product Data Management

Monthly statistics report: January 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.



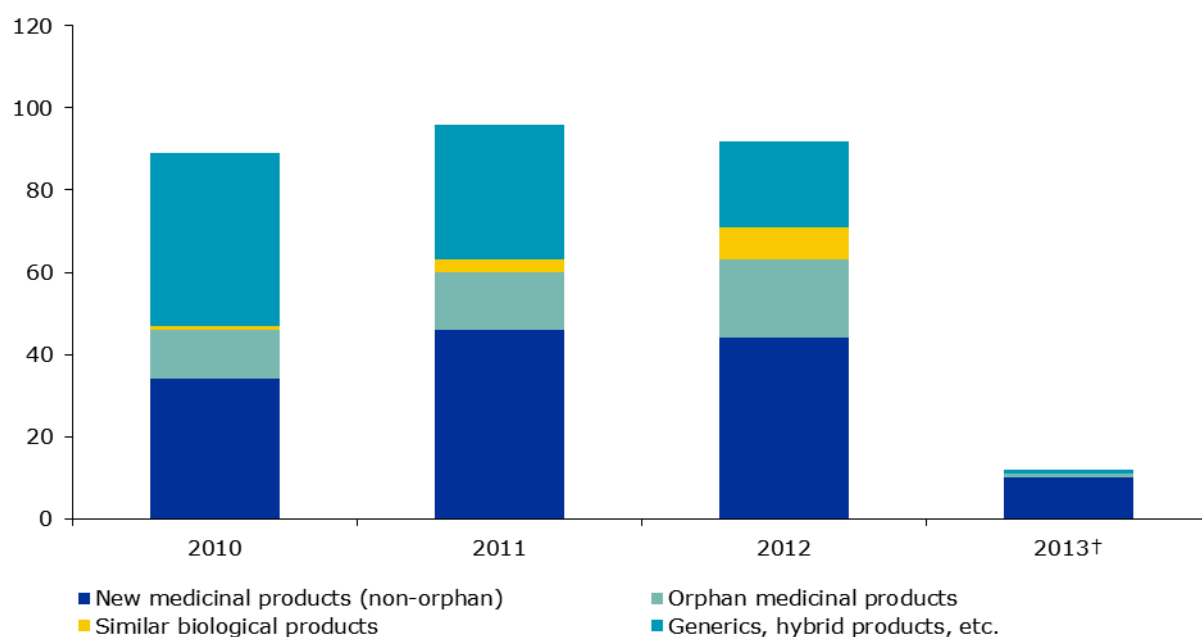
Table 1. Pre-authorisation: Marketing-authorisation applications*

	2010		2011		2012		2013 [†]	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	34	21	46	37	44	35	10	1
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	1	0	0
Well-established use, abridged, hybrid and non-prescription switch products	9	6	8	8	5	6	1	0
Generic products	33	20	25	34	16	13	0	3
Similar biological products	1	1	3	0	8	0	0	0
Sub-total product applications	78	48	85	80	76	54	11	4
Orphan medicinal products								
New products	12	6	14	11	19	11	1	2
Advanced-therapy medicinal products	1	0	0	1	0	0	0	0
Total product applications	90	54	99	91	95	65	12	6

* Finalised applications exclude applications withdrawn prior to opinion.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



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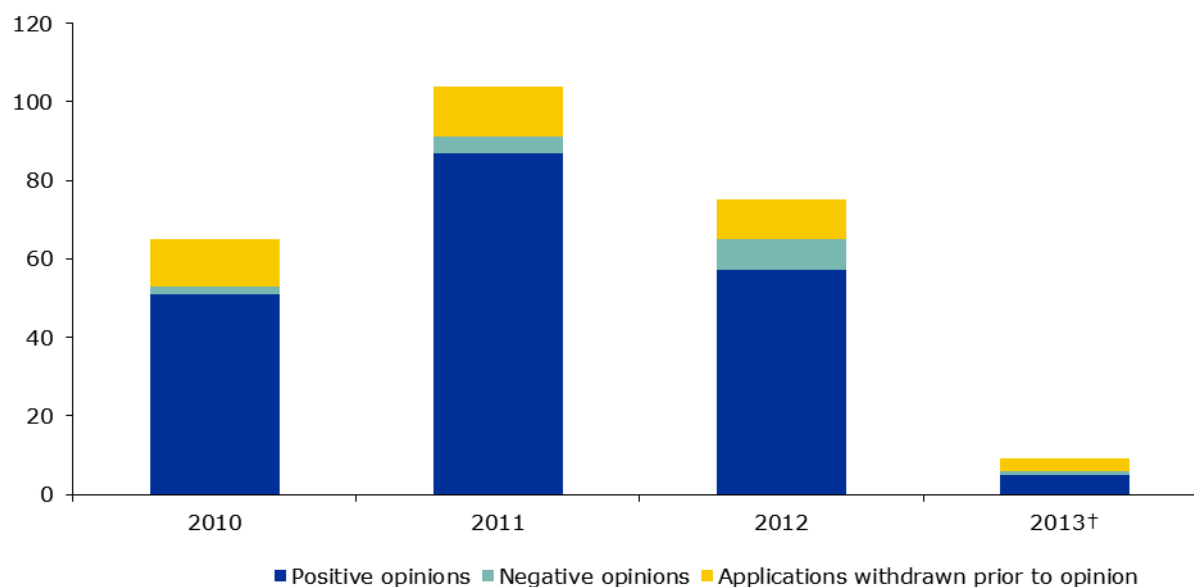
Table 2. Pre-authorisation: Outcome of the evaluation of marketing authorisation applications

	2010	2011	2012	2013 [†]
Positive opinions	117	51	87	5
Opinions recommending conditional marketing authorisation [*]	1	4	3	1
Negative opinions	8	2	4	1
Opinions after accelerated assessment	0	1	0	0
Applications withdrawn prior to opinion	12	13	10	3
Re-examinations requested	7	3	5	2

* 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

	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	0
Plasma master file (includes initial certification, variations and annual re-certification)	22	19	30	37	22	28	0	1
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 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

	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	203	145
Type IB variations	1,093	852	1,260	1,193	1,468	1,416	117	105
Type II variations	966	942	873	918	1,012	906	49	57
Extensions of marketing authorisation	29	26	31	24	16	17	4	1
Grouped applications*	51%	38%	61%	61%	63%	61%	59%	56%
Multi-product Type IA groups	41	31	99	101	111	108	10	7
Work sharing variation applications	111	58	112	115	120	123	6	8
Annual reassessments	19	20	18	16	16	14	1	2
Renewals**	67	27	67	62	76	77	5	3

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

** Includes renewals of conditional marketing authorisations.

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Post-authorisation: Variations, renewals and annual reassessments

