5 December 2011
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Product Data Management

Monthly statistics report: October 2011

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*

	2008		2009		2010		2011†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	41	40	35	49	34	21	**41**	**33**
Advanced-therapy medicinal products	n/a	n/a	0	1	0	0	**0**	**0**
Advanced-therapy Art. 29 transition products	n/a	n/a	0	0	0	0	**0**	**0**
Paediatric-use (PUMA) products	0	0	0	0	1	0	**1**	**1**
Well-established use, abridged, hybrid and non-prescription switch products	16	11	10	14	9	6	**7**	**8**
Generic products	30	4	38	51	33	20	**21**	**31**
Similar biological products	3	6	1	0	1	1	**0**	**0**
Sub-total product applications	**90**	**61**	**84**	**114**	**78**	**48**	**70**	**73**
Orphan medicinal products								
New products	13	11	11	11	12	6	**12**	**11**
Advanced-therapy medicinal products	n/a	n/a	0	0	1	0	**0**	**1**
Total product applications	**103**	**72**	**95**	**125**	**90**	**54**	**82**	**84**

* Finalised applications exclude applications withdrawn prior to opinion.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

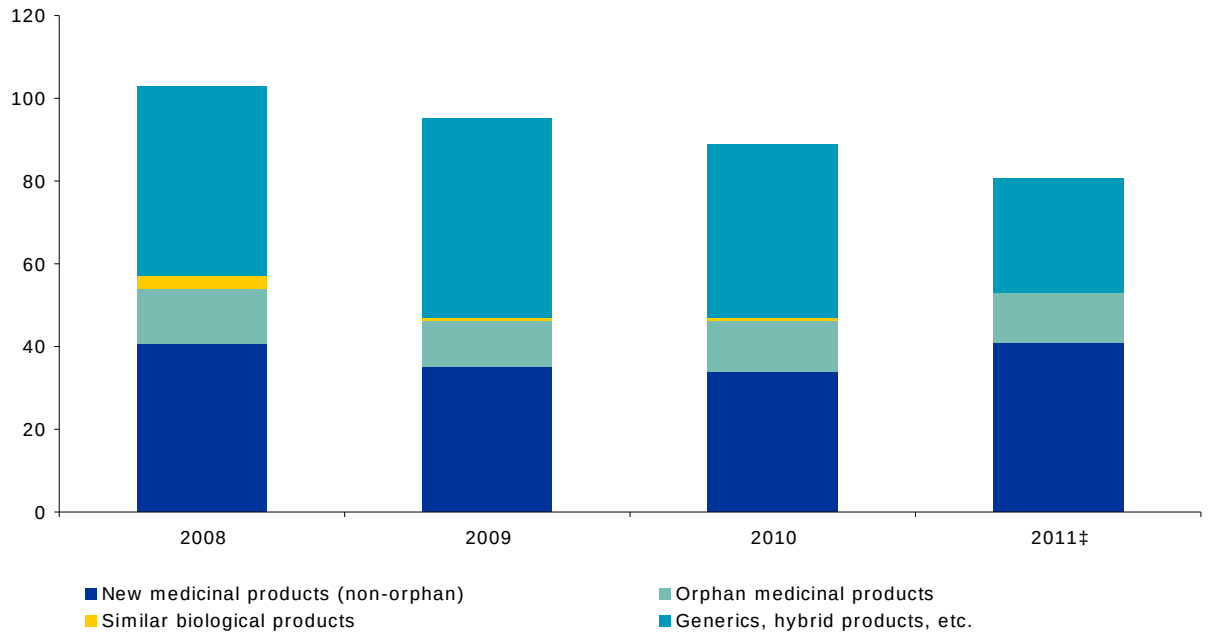

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Table 2. Pre-authorisation: Outcome of the evaluation of marketing authorisation applications

	2008	2009	2010	2011†
Positive opinions*	66	117	51	**80**
Opinions recommending conditional marketing authorisation**	2	1	4	**2**
Negative opinions*	7	8	2	**4**
Applications withdrawn prior to opinion	23	14	12	**12**
Re-examinations requested	9	7	3	**3**
Opinions after accelerated assessment	2	0	1	**4**

* 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.

** Included in the figures for positive opinions.

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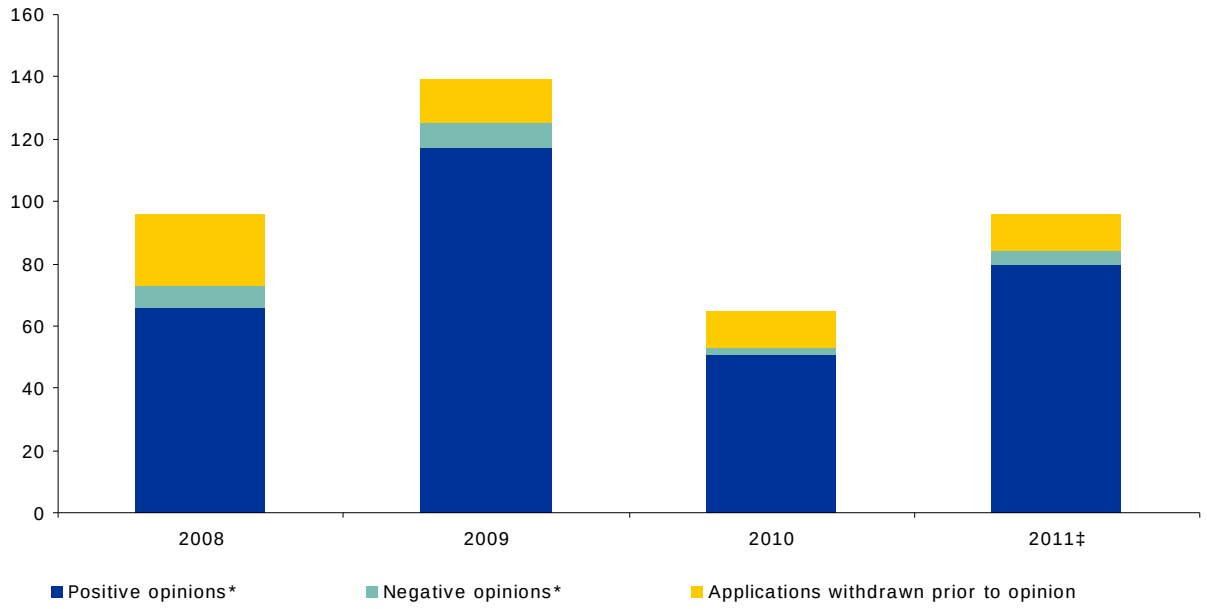
Pre-authorisation: Outcome of the evaluation of marketing authorisation applications



* 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.

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

Table 3. Scientific services

	2008		2009		2010		2011†	
	Received	Finalised	Received	Finalised	Received	Finalised	Received	Finalised
Compassionate-use opinions	0	0	1	0	1	2	**0**	**0**
Art. 58 (WHO) scientific opinions	0	0	0	0	1	0	**1**	**0**
Opinions on ancillary medicinal substances in medical devices*	1	0	0	1	3	0	**3**	**2**
Plasma master file (includes initial certification, variations and annual re-certification)	19	23	23	23	22	19	**23**	**26**
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

	2008		2009		2010		2011†	
	Received	Finalised	Received	Finalised	Received	Finalised	Received	Finalised
Type IA variations	783	783	897	842	2,057	1,711	**2,441**	**2,375**
Type IB variations	445	462	470	412	1,093	852	**975**	**979**
Type II variations	981	877	1,186	1,142	966	942	**711**	**783**
Extensions of marketing authorisation	37	35	24	31	29	26	**27**	**23**
Percentage of variations submitted in grouped notifications/applications*	n/a	n/a	n/a	n/a	51%	38%	**60%**	**60%**
Multi-product Type IA groups	n/a	n/a	n/a	n/a	41	31	**83**	**79**
Worksharing variation applications	n/a	n/a	n/a	n/a	111	58	**89**	**99**
Annual reassessments	24	24	21	17	19	20	**12**	**10**
Renewals**	65	59	46	54	67	27	**46**	**51**

* 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