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Medicinal products for human use

Cumulative figures (year to date): January 2011

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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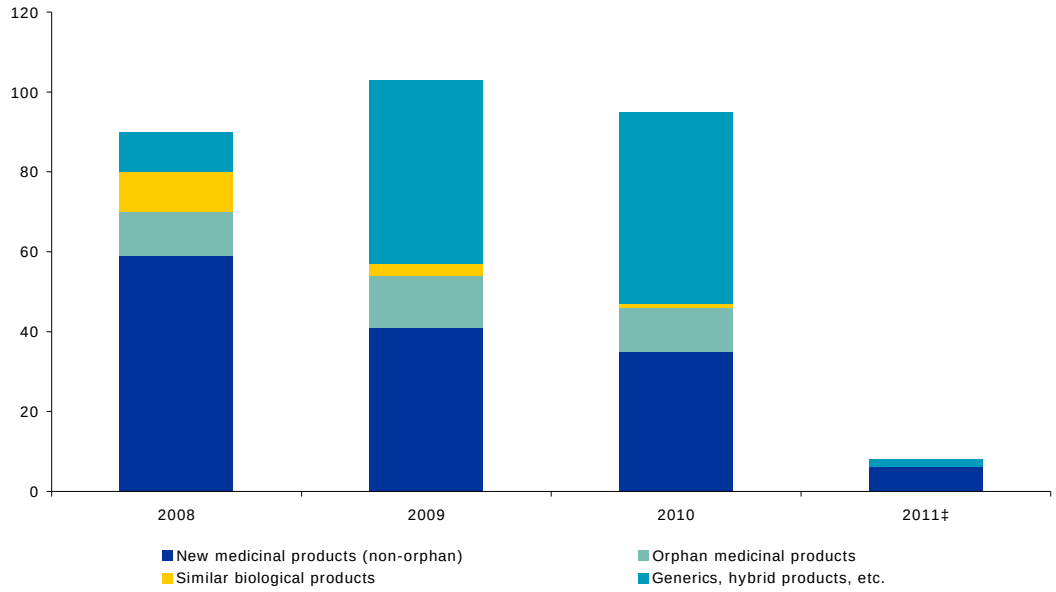
Cumulative figures (year to date): January 2011

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	**6**	**7**
Advanced therapy medicinal products	na	na	0	1	0	0	**0**	**0**
Advanced therapy Art. 29 transition products	na	na	0	0	0	0	**0**	**0**
Paediatric-use (PUMA) products	0	0	0	0	1	0	**1**	**0**
Well-established use, abridged, hybrid & non-prescription switch products	16	11	10	14	9	6	**1**	**1**
Generic products	30	4	38	51	33	20	**1**	**0**
Similar biological products	3	6	1	0	1	1	**0**	**0**
Total products	**90**	**61**	**84**	**114**	**78**	**48**	**9**	**8**
Orphan medicinal products								
New products	13	11	11	11	12	6	**0**	**0**
Advanced therapy medicinal products	na	na	0	0	1	0	**0**	**0**
Total product applications	**103**	**72**	**95**	**125**	**90**	**54**	**9**	**8**

* Finalised applications exclude applications withdrawn prior to opinion

‡ The figures for the current year are cumulative, year to date. The figures for preceding years show the total for the entire year

Marketing authorisation application evaluations started by type of application



‡ The figures for the current year are cumulative, year to date. The figures for preceding years show the total for the entire year

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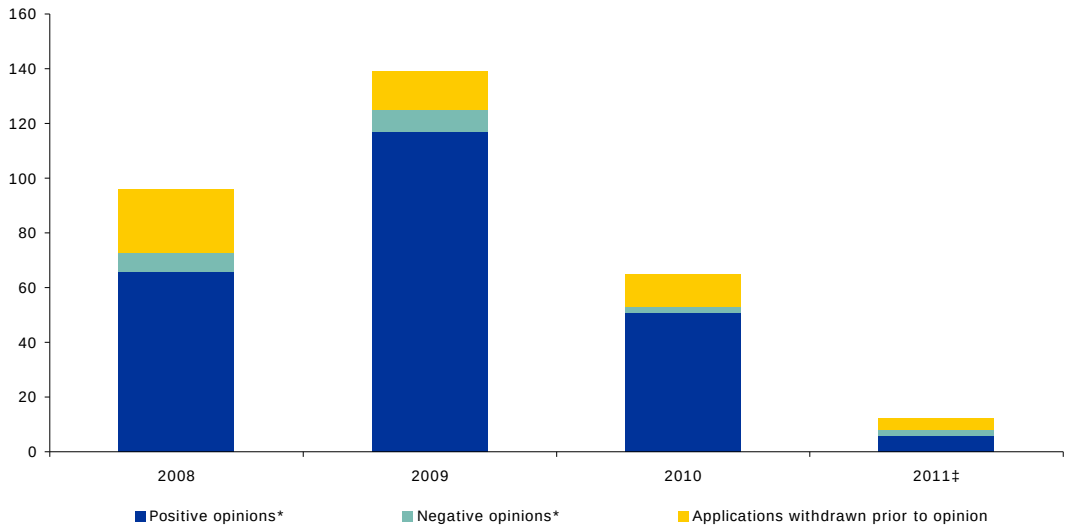
Pre-authorisation: Outcome of the evaluation of marketing authorisation applications				
	2008	2009	2010	2011‡
Positive opinions*	66	117	51	**6**
Opinions recommending conditional marketing**	2	1	4	**0**
Negative opinions*	7	8	2	**2**
Applications withdrawn prior to opinion	23	14	12	**4**
Re-examinations requested	9	7	3	**0**
Opinions after accelerated assessment	2	0	1	**0**

* Only the final outcome in case of the re-examination of an opinion under Art. 9(2) of Regulation (EC) No. 726/2004 is reported
** Included in the figures for positive opinions
‡ The figures for the current year are cumulative, year to date. The figures for preceding years show the total for the entire year

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



* Only the final outcome in case of the re-examination of an opinion under Art. 9(2) of Regulation (EC) No. 726/2004 is reported
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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	**0**	**0**
Opinions on ancillary medicinal substances in medical devices*	1	0	0	1	3	0	**0**	**0**
Plasma master file (includes initial certification, variations and annual re-certification)	19	23	23	23	22	19	**0**	**2**
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 00/70/EC as regards medical devices incorporating stable derivates of human blood or plasma and Directive 2001/14/EC

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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	1579	1360	**74**	**117**
Type IB variations	445	462	470	412	1093	852	**56**	**132**
Type II variations	981	877	1186	1142	966	942	**56**	**82**
Extension of marketing authorisations	37	35	24	31	29	26	**0**	**1**
Percentage of variations submitted in grouped notifications/applications†	N/A	N/A	N/A	N/A	51%	38%	**52%**	**63%**
Multi-product Type IA groups	N/A	N/A	N/A	N/A	41	31	**7**	**7**
Worksharing variation applications	N/A	N/A	N/A	N/A	111	58	**9**	**14**
Annual reassessments	24	24	21	17	19	20	**0**	**1**
Renewals*	65	59	46	54	67	27	**5**	**3**

* Includes renewals of conditional marketing authorisations
† Excluding groups in worksharing or in multi-product Type IA groups
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Post-authorisation: Variations, renewals and annual reassessments