EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Medicinal products for human use

Monthly figures — October 2010

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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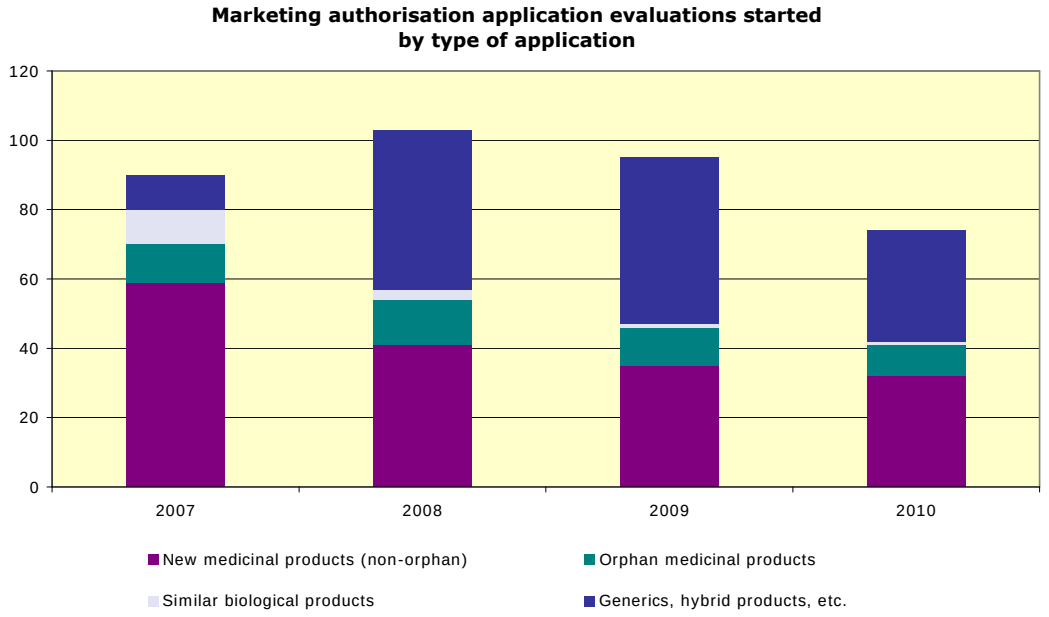
Pre-authorisation: Marketing authorisation applications*	2007		2008		2009		2010	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	59	40	41	40	35	49	**32**	**18**
Advanced therapy medicinal products	na	na	na	na	0	1	**0**	**0**
Advanced therapy Art. 29 transition products	na	na	na	na	0	0	**0**	**0**
Paediatric-use (PUMA) products	0	0	0	0	0	0	**1**	**0**
Well-established use, abridged, hybrid & non-prescription switch products	4	4	16	11	10	14	**8**	**4**
Generic products	6	5	30	4	38	51	**24**	**15**
Similar biological products	10	5	3	6	1	0	**1**	**1**
Total products	**79**	**54**	**90**	**61**	**84**	**114**	**66**	**38**
Orphan medicinal products								
New products	11	11	13	11	11	11	**9**	**3**
Advanced therapy medicinal products	na	na	na	na	0	0	**1**	**0**
Total product applications	**90**	**65**	**103**	**72**	**95**	**125**	**75**	**41**

* Finalised applications exclude applications withdrawn prior to opinion



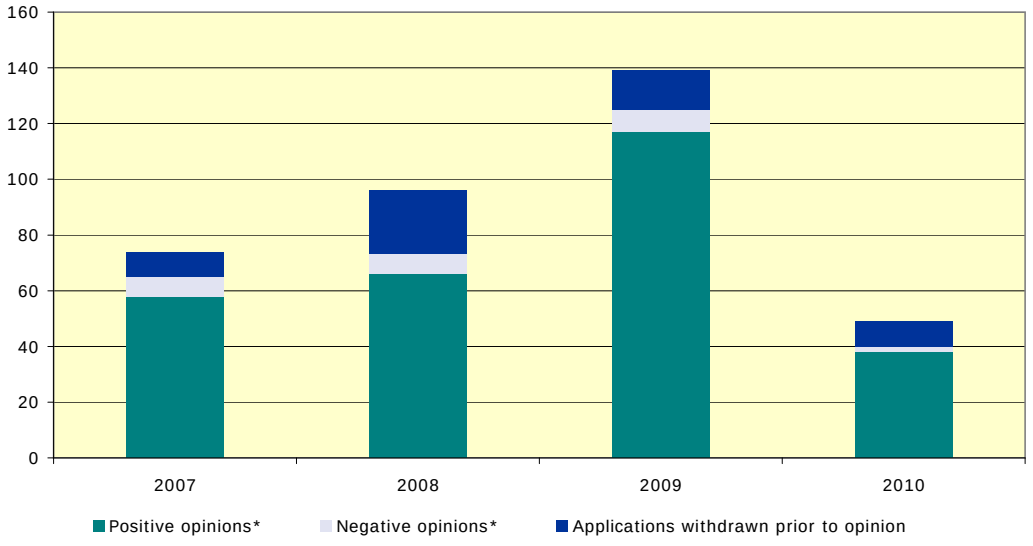
Medicinal products for human use

Monthly figures — October 2010

Pre-authorisation: Outcome of the evaluation of marketing authorisation applications				
	2007	2008	2009	2010
Positive opinions*	58	66	117	**38**
Opinions recommending conditional marketing**	5	2	1	**4**
Negative opinions*	7	7	8	**2**
Applications withdrawn prior to opinion	9	23	14	**9**
Re-examinations requested	5	9	7	**2**
Opinions after accelerated assessment	5	2	0	**1**

* 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

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



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Medicinal products for human use

Monthly figures — October 2010

Scientific services

	2007		2008		2009		2010	
	Received	Finalised	Received	Finalised	Received	Finalised	Received	Finalised
Compassionate-use opinions	0	0	0	0	1	0	**1**	**2**
Art. 58 (WHO) scientific opinions	1	0	0	0	0	0	**0**	**0**
Opinions on ancillary medicinal substances in medical devices*	3	0	1	0	0	1	**3**	**0**
Plasma master file (includes initial certification, variations and annual re-certification)	16	17	19	23	23	23	**15**	**14**
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

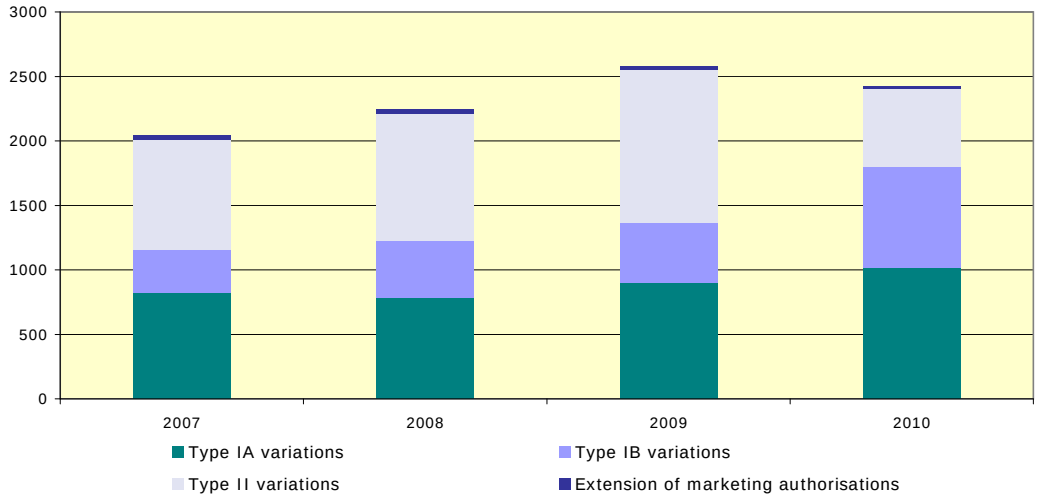
Medicinal products for human use

Monthly figures — October 2010

Post-authorisation: Variations, renewals and annual reassessments

	2007		2008		2009		2010	
	Received	Finalised	Received	Finalised	Received	Finalised	Received	Finalised
Type IA variations	822	820	783	783	897	842	**1017**	**884**
Type IB variations	338	292	445	462	470	412	**779**	**658**
Type II variations	853	777	981	877	1186	1142	**609**	**711**
Extension of marketing authorisations	32	28	37	35	24	31	**21**	**20**
Percentage of variations submitted in grouped notifications/applications†	N/A	N/A	N/A	N/A	N/A	N/A	**49%**	**36%**
Multi-product Type IA groups	N/A	N/A	N/A	N/A	N/A	N/A	**28**	**25**
Worksharing variation applications	N/A	N/A	N/A	N/A	N/A	N/A	**77**	**39**
Annual reassessments	24	25	24	24	21	17	**14**	**17**
Renewals*	46	44	65	59	46	54	**52**	**27**

* Includes renewals of conditional marketing authorisations

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

Post-authorisation: Variations received