



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2010
EMA/646611/2010

Medicinal products for human use

Monthly figures — September 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.



Medicinal products for human use

Monthly figures — September 2010

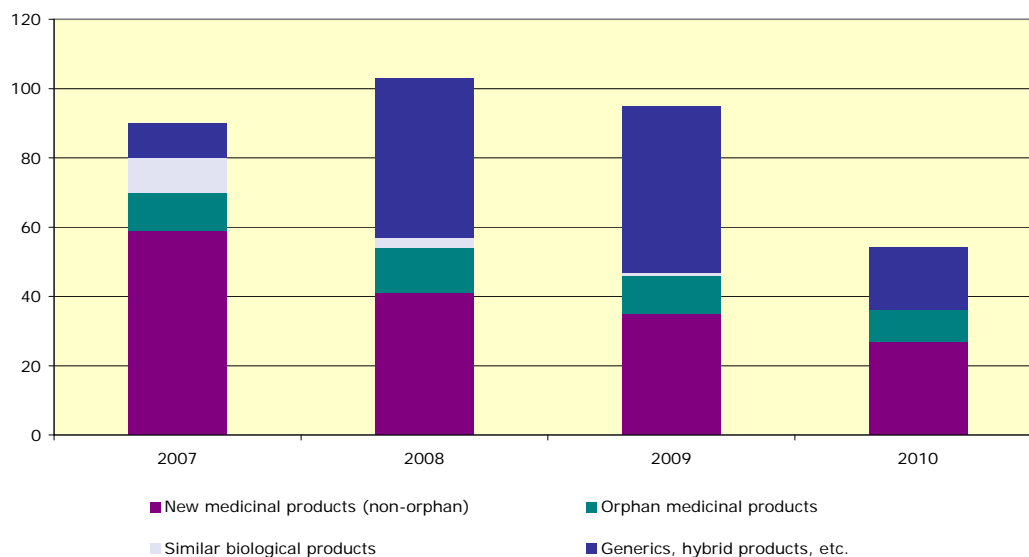
© European Medicines Agency, 2010. Reproduction is authorised provided the source is acknowledged.

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	27	16
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	5	3
Generic products	6	5	30	4	38	51	13	13
Similar biological products	10	5	3	6	1	0	0	1
Total products	79	54	90	61	84	114	46	33
Orphan medicinal products								
New products	11	11	13	11	11	11	9	4
Advanced therapy medicinal products	na	na	na	na	0	0	1	0
Total product applications	90	65	103	72	95	125	55	37

* Finalised applications exclude applications withdrawn prior to opinion

Marketing authorisation application evaluations started by type of application



Medicinal products for human use

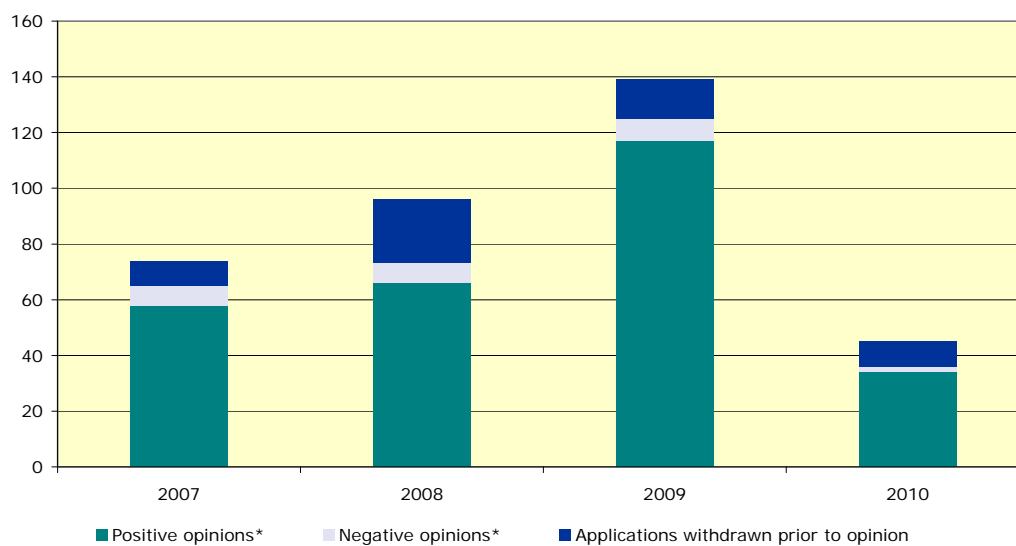
Monthly figures — September 2010

Pre-authorisation: Outcome of the evaluation of marketing authorisation applications				
	2007	2008	2009	2010
Positive opinions*	58	66	117	34
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Applications withdrawn prior to opinion	9	23	14	9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



* 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

Medicinal products for human use

Monthly figures — September 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	1	0
Opinions on ancillary medicinal substances in medical devices*	3	0	1	0	0	1	2	0
Plasma master file (includes initial certification, variations and annual re-certification)	16	17	19	23	23	23	13	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 derivatives of human blood or plasma and Directive 2001/14/EC

Medicinal products for human use

Monthly figures — September 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	953	792
Type IB variations	338	292	445	462	470	412	658	583
Type II variations	853	777	981	877	1186	1142	574	660
Extension of marketing authorisations	32	28	37	35	24	31	19	20
Percentage of variations submitted in grouped notifications/applications [†]	N/A	N/A	N/A	N/A	N/A	N/A	48%	33%
Multi-product Type IA groups	N/A	N/A	N/A	N/A	N/A	N/A	28	22
Worksharing variation applications	N/A	N/A	N/A	N/A	N/A	N/A	72	32
Annual reassessments	24	25	24	24	21	17	11	17
Renewals*	46	44	65	59	46	54	47	27

* Includes renewals of conditional marketing authorisations

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

Post-authorisation: Variations received

