



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 October 2012  
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Product Data Management

## Monthly statistics report: September 2012

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.



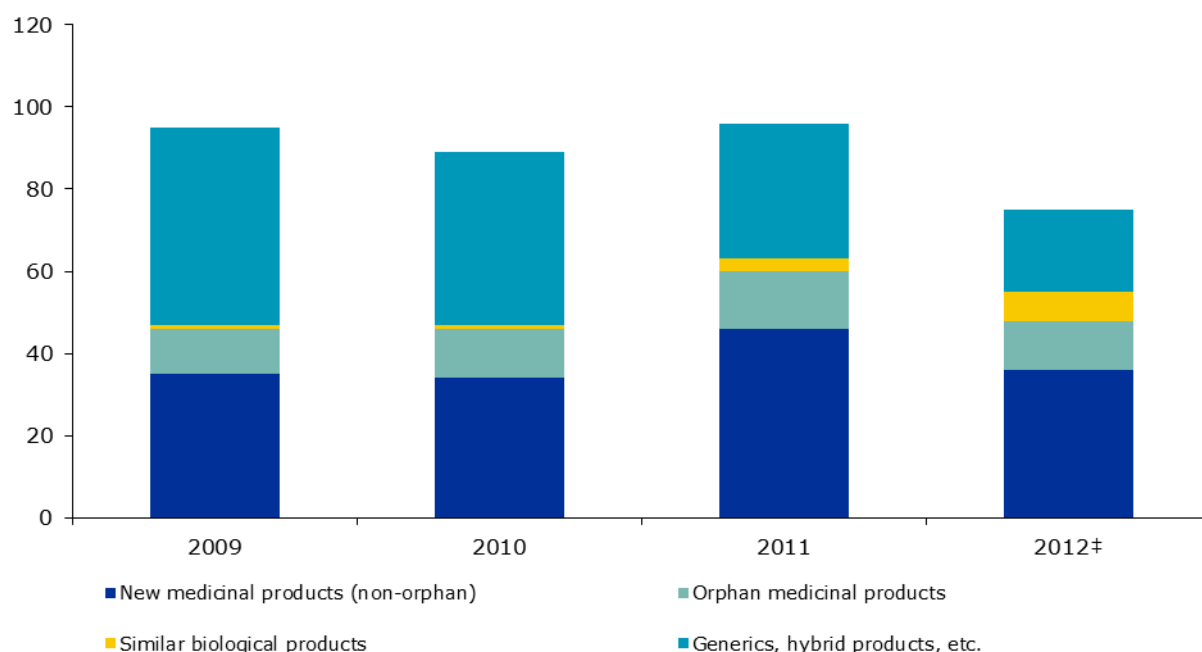
**Table 1.** Pre-authorisation: Marketing-authorisation applications\*

	2009		2010		2011		2012 <sup>†</sup>	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
<b>Non-orphan medicinal products</b>								
New products	35	49	34	21	46	37	36	19
Advanced-therapy medicinal products	0	1	0	0	1	0	2	0
Advanced-therapy Art. 29 transition products	0	0	0	0	1	0	0	0
Paediatric-use (PUMA) products	0	0	1	0	1	1	0	0
Well-established use, abridged, hybrid and non-prescription switch products	10	14	9	6	8	8	4	6
Generic products	38	51	33	20	25	34	16	12
Similar biological products	1	0	1	1	3	0	7	0
<b>Sub-total product applications</b>	<b>84</b>	<b>114</b>	<b>78</b>	<b>48</b>	<b>85</b>	<b>80</b>	<b>65</b>	<b>37</b>
<b>Orphan medicinal products</b>								
New products	11	11	12	6	14	11	12	11
Advanced-therapy medicinal products	0	0	1	0	0	1	0	0
<b>Total product applications</b>	<b>95</b>	<b>125</b>	<b>90</b>	<b>54</b>	<b>99</b>	<b>91</b>	<b>77</b>	<b>48</b>

\* Finalised applications exclude applications withdrawn prior to opinion.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



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

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

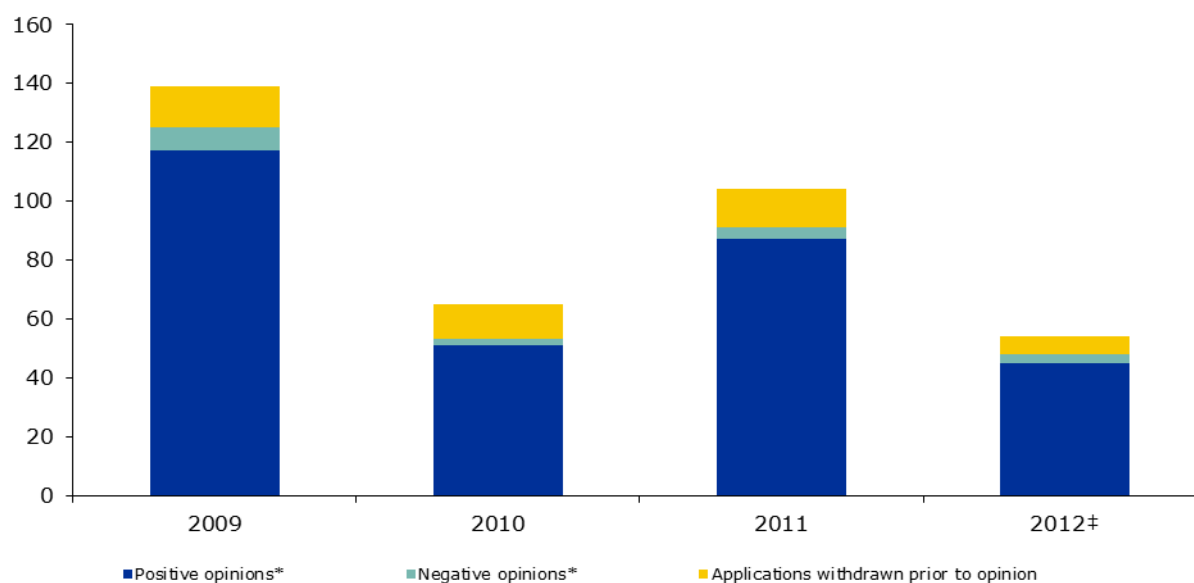
	2009	2010	2011	2012 <sup>†</sup>
Positive opinions*	117	51	87	<b>45</b>
Opinions recommending conditional marketing authorisation**	1	4	3	<b>3**</b>
Negative opinions*	8	2	4	<b>3</b>
Applications withdrawn prior to opinion	14	12	13	<b>6</b>
Re-examinations requested	7	3	5	<b>2</b>
Opinions after accelerated assessment	0	1	0	<b>1</b>

\* 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. As adopted in February (1) and July (2)

<sup>†</sup> 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**



\* 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.

<sup>†</sup> Figures for the current year are cumulative, year to date. Figures for preceding years are totals for the year.

**Table 3.** Scientific services

	2009		2010		2011		2012 <sup>†</sup>	
	Received	Finalised	Received	Finalised	Received	Finalised	Received	Finalised
Compassionate-use opinions	1	0	1	2	0	0	0	0
Art. 58 (WHO) scientific opinions	0	0	1	0	1	0	1	2
Opinions on ancillary medicinal substances in medical devices*	0	1	3	0	3	2	0	1
Plasma master file (includes initial certification, variations and annual re-certification)	23	23	22	19	30	37	16	19
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.

<sup>†</sup> 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

	2009		2010		2011		2012 <sup>†</sup>	
	Received	Finalised	Received	Finalised	Received	Finalised	Received	Finalised
Type IA variations	897	842	2,057	1,711	2,875	2,847	<b>2,129</b>	<b>2,063</b>
Type IB variations	470	412	1,093	852	1,260	1,193	<b>1,163</b>	<b>1,118</b>
Type II variations	1,186	1,142	966	942	873	918	<b>798</b>	<b>678</b>
Extensions of marketing authorisation	24	31	29	26	31	24	<b>11</b>	<b>15</b>
Percentage of variations submitted in grouped notifications/applications*	N/A	N/A	51%	38%	61%	61%	<b>63%</b>	<b>61%</b>
Multi-product Type IA groups	N/A	N/A	41	31	99	101	<b>79</b>	<b>75</b>
Worksharing variation applications	N/A	N/A	111	58	112	115	<b>100</b>	<b>95</b>
Annual reassessments	21	17	19	20	18	16	<b>7</b>	<b>11</b>
Renewals**	46	54	67	27	67	62	<b>52</b>	<b>61</b>

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

\*\* Includes renewals of conditional marketing authorisations.

<sup>†</sup> Figures for the current year are cumulative, year to date. Figures for preceding years are totals for the year.

### Post-authorisation: Variations, renewals and annual reassessments

