13 June 2013
EMA/366275/2013
Product Data Management

# Monthly statistics report: May 2013

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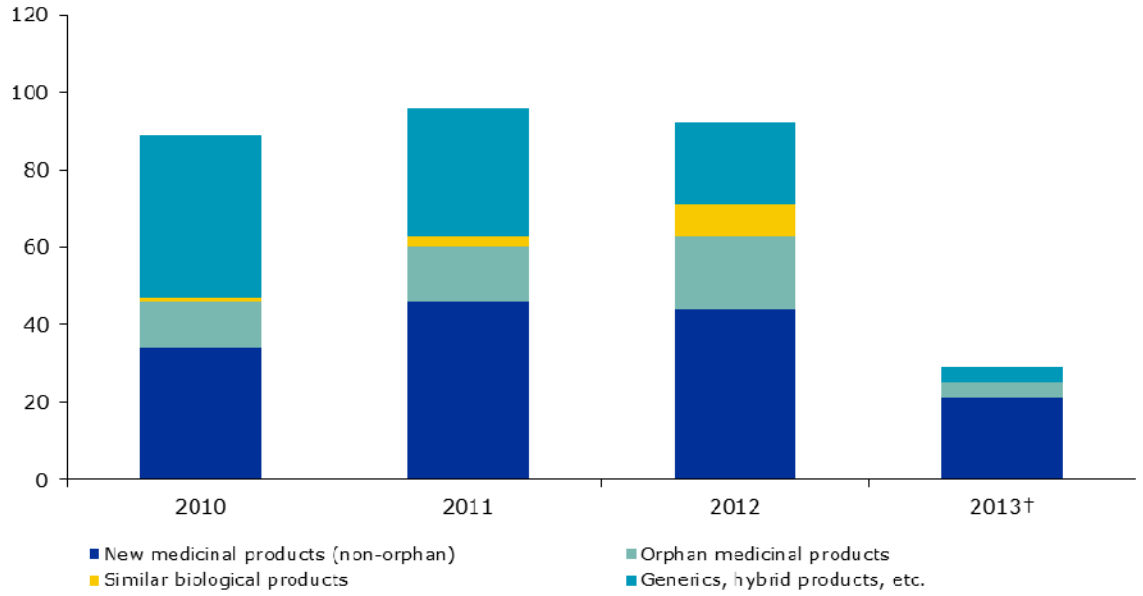
**Table 1.** Pre-authorisation: Marketing-authorisation applications*

| | 2010 | | 2011 | | 2012 | | 2013† | |
|---|---|---|---|---|---|---|---|---|
| | Started | Finalised | Started | Finalised | Started | Finalised | Started | Finalised |
| **Non-orphan medicinal products** | | | | | | | | |
| New products | 34 | 21 | 46 | 37 | 44 | 35 | **21** | **18** |
| Advanced-therapy medicinal products | 0 | 0 | 1 | 0 | 1 | 0 | **0** | **1** |
| Advanced-therapy Art. 29 transition products | 0 | 0 | 1 | 0 | 2 | 0 | **N/A** | **0** |
| Paediatric-use (PUMA) products | 1 | 0 | 1 | 1 | 0 | 0 | **1** | **0** |
| Well-established use, abridged, hybrid and non-prescription switch products | 9 | 6 | 8 | 8 | 5 | 6 | **3** | **1** |
| Generic products | 33 | 20 | 25 | 34 | 16 | 13 | **1** | **12** |
| Similar biological products | 1 | 1 | 3 | 0 | 8 | 0 | **0** | **0** |
| **Sub-total product applications** | **78** | **48** | **85** | **80** | **76** | **54** | **26** | **32** |
| **Orphan medicinal products** | | | | | | | | |
| New products | 12 | 6 | 14 | 11 | 19 | 11 | **4** | **6** |
| Advanced-therapy medicinal products | 1 | 0 | 0 | 1 | 0 | 0 | **1** | **0** |
| **Total product applications** | **90** | **54** | **99** | **91** | **95** | **65** | **31** | **38** |

* Finalised applications exclude applications withdrawn prior to opinion.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**



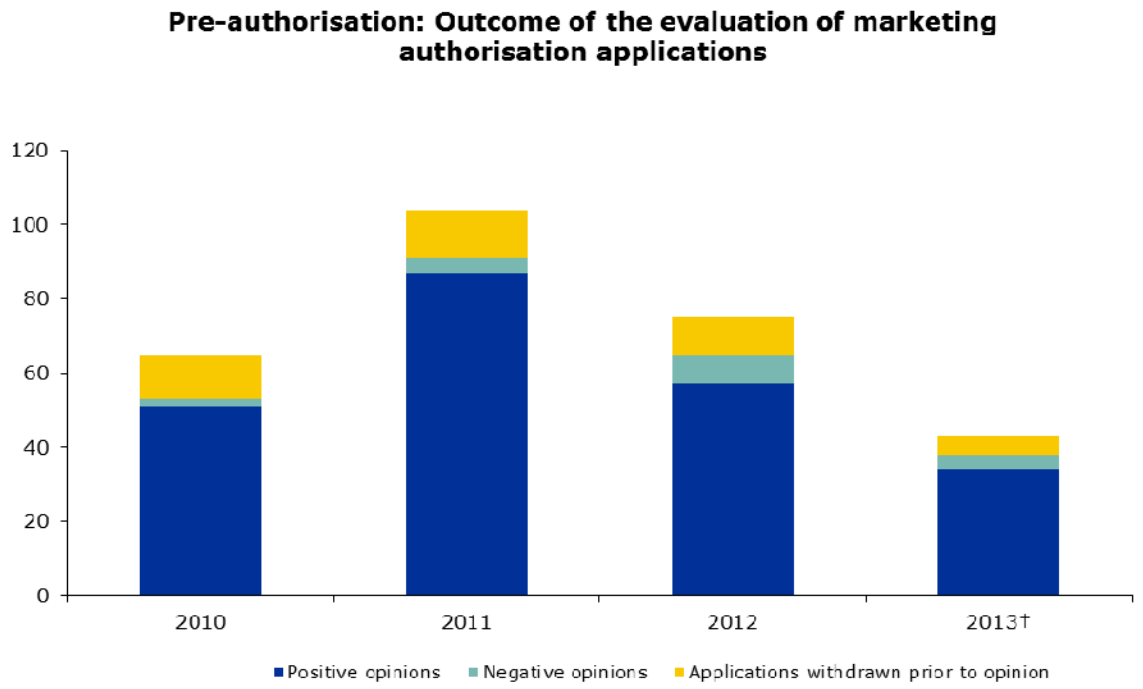

† Figures for the current year are cumulative, year to date. Figures for preceding years are totals for the year.

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

| | 2010 | 2011 | 2012 | 2013† |
|---|---|---|---|---|
| Positive opinions | 51 | 87 | 57 | **34** |
| Opinions recommending conditional marketing authorisation* | 4 | 3 | 3 | **2** |
| Negative opinions | 2 | 4 | 8 | **4** |
| Opinions after accelerated assessment* | 1 | 0 | 1 | **3** |
| Applications withdrawn prior to opinion | 12 | 13 | 10 | **5** |
| Re-examinations requested | 3 | 5 | 2 | **8** |

* Included in the figures for positive opinions.

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




* 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

| | 2010 | | 2011 | | 2012 | | 2013† | |
|---|---|---|---|---|---|---|---|---|
| | Started | Finalised | Started | Started | Started | Finalised | Started | Finalised |
| Compassionate-use opinions | 1 | 2 | 0 | 0 | 0 | 0 | **0** | **0** |
| Art. 58 (WHO) scientific opinions | 1 | 0 | 1 | 0 | 1 | 2 | **0** | **0** |
| Opinions on ancillary medicinal substances in medical devices* | 3 | 0 | 3 | 2 | 0 | 2 | **1** | **1** |
| Plasma master file (includes initial certification, variations and annual re-certification) | 22 | 19 | 30 | 37 | 22 | 28 | **5** | **8** |
| 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

| | 2010 | | 2011 | | 2012 | | 2013† | |
|---|---|---|---|---|---|---|---|---|
| | Received | Finalised | Received | Finalised | Received | Finalised | Received | Finalised |
| Type IA variations | 2,057 | 1,711 | 2,875 | 2,847 | 2,889 | 2,798 | **1,228** | **1,137** |
| Type IB variations | 1,093 | 852 | 1,260 | 1,193 | 1,468 | 1,416 | **673** | **627** |
| Type II variations | 966 | 942 | 873 | 918 | 1,012 | 906 | **363** | **427** |
| Extensions of marketing authorisation | 29 | 26 | 31 | 24 | 16 | 17 | **5** | **8** |
| Grouped applications* | 51% | 38% | 61% | 61% | 63% | 61% | **62%** | **64%** |
| Multi-product Type IA groups | 41 | 31 | 99 | 101 | 111 | 108 | **48** | **43** |
| Worksharing variation applications | 111 | 58 | 112 | 115 | 120 | 123 | **51** | **43** |
| Annual reassessments | 19 | 20 | 18 | 16 | 16 | 14 | **5** | **6** |
| Renewals** | 67 | 27 | 67 | 62 | 76 | 77 | **30** | **24** |

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

** Includes renewals of conditional marketing authorisations.

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