



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2015
EMA/845920/2015
Information Management Division

Monthly statistics report: November 2015

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*

| | 2012 | | 2013 | | 2014 | | 2015 [†] | |
|---|-----------|-----------|-----------|-----------|-----------|-----------|-------------------|-----------|
| | Started | Finalised | Started | Finalised | Started | Finalised | Started | Finalised |
| Non-orphan medicinal products | | | | | | | | |
| New products | 44 | 35 | 48 | 46 | 37 | 42 | 25 | 34 |
| Advanced-therapy medicinal products | 3** | 0 | 0 | 2 | 1 | 0 | 0 | 1 |
| Paediatric-use (PUMA) products | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 0 |
| Well-established use, abridged, hybrid and non-prescription switch products | 5 | 6 | 6 | 4 | 12 | 15 | 8 | 7 |
| Generic products | 16 | 13 | 5 | 16 | 25 | 6 | 22 | 24 |
| Similar biological products | 8 | 0 | 1 | 4 | 3 | 3 | 4 | 2 |
| Sub-total product applications | 76 | 54 | 61 | 72 | 78 | 67 | 60 | 68 |
| Orphan medicinal products[◇] | | | | | | | | |
| New products | 19 | 11 | 16 | 14 | 20 | 17 | 21 | 18 |
| Advanced-therapy medicinal products | 0 | 0 | 2 | 0 | 1 | 1 | 1 | 1 |
| Total product applications | 95 | 65 | 79 | 86 | 99 | 85 | 82 | 87 |

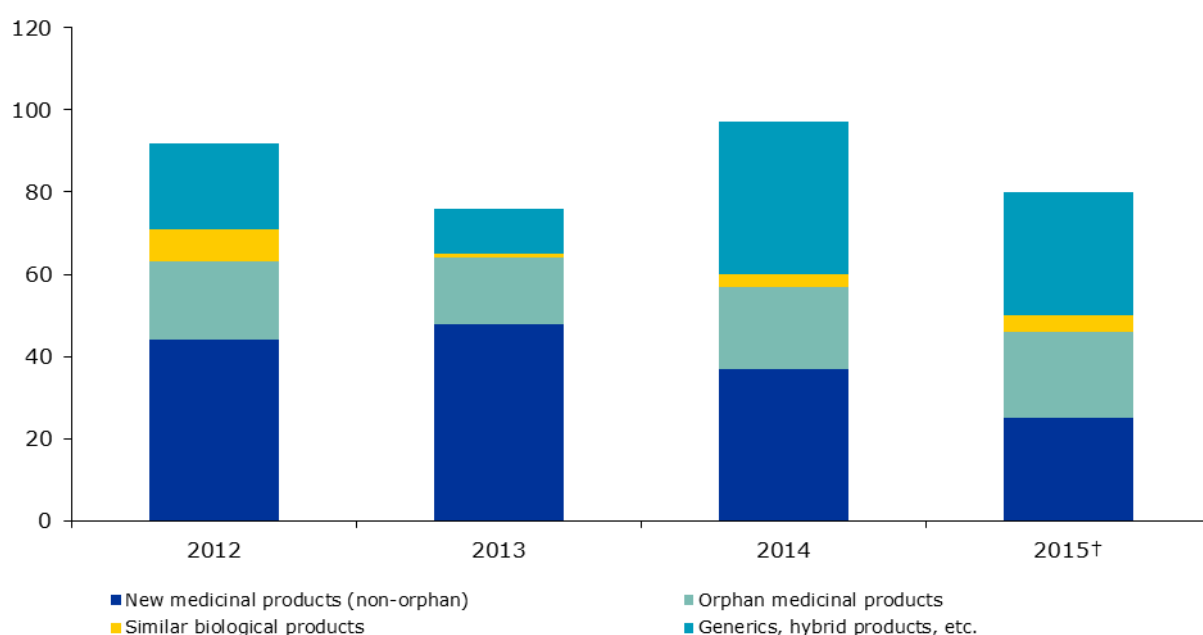
* Finalised applications exclude applications withdrawn prior to opinion.

** 2012 figures include two Article 29 transition products.

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

◇ These figures reflect the orphan status of the medicinal products at the time of the CHMP opinion. EMA's Committee for Orphan Medicinal Products (COMP) then assesses whether the orphan designation should be maintained.

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*

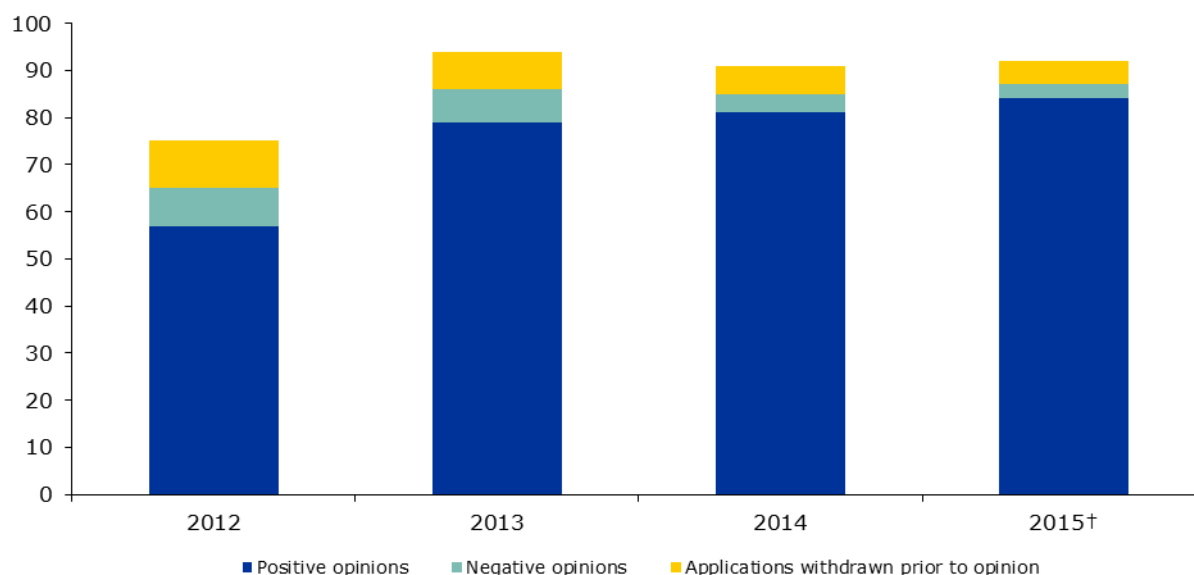
| | 2012 | 2013 | 2014 | 2015 [†] |
|---|------|------|------|-------------------|
| Positive opinions | 57 | 79 | 81 | 84 |
| Opinions recommending conditional marketing authorisation** | 3 | 4 | 4 | 2 |
| Opinions under exceptional circumstances** | 0 | 3 | 1 | 3 |
| Negative opinions | 8 | 7 | 4 | 3 |
| Opinions after accelerated assessment** | 1 | 5 | 7 | 5 |
| Applications withdrawn prior to opinion | 10 | 8 | 6 | 5 |
| Re-examinations requested | 2 | 10 | 5 | 1 |
| Re-examination - Positive opinions | 1 | 3 | 1 | 0 |

* Applicants can request a re-examination. The first four rows present the outcome of the evaluation before a re-examination (or a re-consideration). The final row shows the number of changes from a negative to a positive opinion following a re-examination or a re-consideration.

** 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.

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



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

Table 3. Scientific services

| | 2012 | | 2013 | | 2014 | | 2015 [†] | |
|---|---------|-----------|---------|-----------|---------|-----------|-------------------|-----------|
| | Started | Finalised | Started | Finalised | Started | Finalised | Started | Finalised |
| Compassionate-use opinions | 0 | 0 | 2 | 2 | 1 | 1 | 0 | 0 |
| Art. 58 (WHO) scientific opinions | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 |
| Opinions on ancillary medicinal substances in medical devices* | 0 | 2 | 3 | 1 | 0 | 1 | 1 | 1 |
| Plasma master file (includes initial certification, variations and annual re-certification) | 22 | 28 | 19 | 13 | 16 | 16 | 15 | 17 |

* 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.

[†] 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

| | 2012 | | 2013 | | 2014 | | 2015 [†] | |
|---------------------------------------|---------|---------|---------|-----------|---------|-----------|-------------------|--------------|
| | Started | Started | Started | Finalised | Started | Finalised | Started | Finalised |
| Type IA variations | 2,889 | 2,798 | 2,922 | 2,886 | 2,969 | 2,854 | 2,548 | 2,452 |
| Type IB variations | 1,468 | 1,416 | 1,958 | 1,597 | 1,886 | 1,986 | 1,643 | 1,646 |
| Type II variations | 1,012 | 906 | 961 | 946 | 1,151 | 1,103 | 1,025 | 1,030 |
| Extensions of marketing authorisation | 16 | 17 | 16 | 18 | 16 | 15 | 12 | 13 |
| Annual reassessments | 16 | 14 | 18 | 16 | 18 | 18 | 14 | 19 |
| Renewals* | 76 | 77 | 98 | 77 | 100 | 121 | 71 | 66 |

* Includes renewals of conditional marketing authorisations.

[†] 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

