# Chair's Introduction


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# EU: ATMP MAA Activity, 2011

**Initial Evaluation of MAA for ATMP**

| | 2009 | 2010 | 2011 | 2012 | Total |
|---|---|---|---|---|---|
| Submitted | 3 | 1 | 2 | 2 | 8 |
| Positive draft Opinion | 1 | 0 | 1[!] | 1[!] | 3 |
| Negative draft Opinion | 1[*] | 0 | 1 | 0 | 2 |
| Withdrawals | 1 | 1 | 0 | 0 | 2 |

* Application subsequently withdrawn
[!] Re-examination opinion (Glybera)

**EMA/CAT submissions 2011**

- CellSeed Inc – Corneal repair (confirmed)
- Genzyme - MACI (not yet confirmed)

# EU: ATMP MAA Activity, 2012

| International non-proprietary name (salt, ester, derivative, etc.) / Common Name | Therapeutic area[1] |
|---|---|
| Aclidinium (bromide) | Medicines for obstructive airway diseases |
| Aflibercept | Antineoplastic medicines<br>Ophthalmologicals |
| Autologous cultured chondrocytes | Other medicines for disorders of the musculo-skeletal system |
| Autologous oral mucosal epithelial cells | Ophthalmologicals |
| Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF | Immunostimulants |
| **Avanafil** | **Urologicals** |
| Budesonide/salmeterol | Medicines for obstructive airway diseases |
| Ceftaroline fosamil | Antibacterials for systemic use |
| Colestilan | Other therapeutic medicines |
| Copper (64 Cu) (chloride) | Various (radiolabelling) |
| Crizotinib | Antineoplastic medicines |
| **Cultured autologous chondrocytes on hyaluronan based scaffold** | **Other medicines for disorders of the musculo-skeletal system** |

MACI, Genzyme

Cellseed, CellSeed Inc.

Provenge, Dendreon

Hyalograft C, Anika Therapeutics

dvanced Biologicals

# EU: MAA Outcomes
## To November 2012

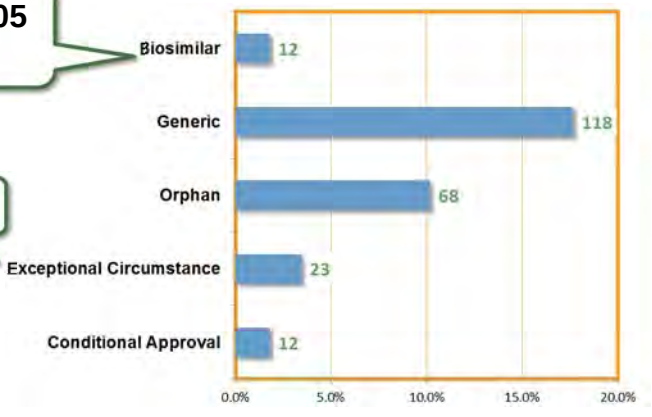
| | 2009 | | 2010 | | 2011 | | 2012† | |
|---|---|---|---|---|---|---|---|---|
| | Started | Finalised | Started | Finalised | Started | Finalised | Started | Finalised |
| **Non-orphan medicinal products** | | | | | | | | |
| New products | 35 | 49 | 34 | 21 | 46 | 37 | **41** | **30** |
| Advanced-therapy 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 | **5** | **6** |
| Generic products | 38 | 51 | 33 | 20 | 25 | 34 | **18** | **13** |
| Similar biological products | 1 | 0 | 1 | 1 | 3 | 0 | **8** | **0** |
| **Sub-total product applications** | **84** | **114** | **78** | **48** | **85** | **80** | **74** | **49** |
| **Orphan medicinal products** | | | | | | | | |
| New products | 11 | 11 | 12 | 6 | 14 | 11 | **19** | **11** |
| Advanced-therapy medicinal products | 0 | 0 | 1 | 0 | 0 | 1 | **0** | **0** |
| **Total product applications** | **95** | **125** | **90** | **54** | **99** | **91** | **93** | **60** |

# Centrally Authorised (EMA) Products

- 667 Centrally Authorised Products (Dec 2012)

**Since Nov 2005 (7 years)**

**Glybera**








# EMA ATMP Scientific Advice Procedures

| Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs | | | | | |
|---|---|---|---|---|---|
| | 2009 | 2010 | 2011 | 2012 | Total |
| Submitted | 1 | 0 | 0 | 1 | 2 |
| Adopted | 0 | 1 | 0 | 1 | 2 |

| Scientific advice procedures on ATMPs | | | | | |
|---|---|---|---|---|---|
| | 2009 | 2010 | 2011 | 2012 | Total |
| Discussed* | 25 | 30 | 36 | 29 | 120 |

* Most scientific advices for ATMPs are discussed by the CAT at 2 time points during the SA procedure

# EMA HTA Parallel Advice

***Pre-authorisation: scientific advice and protocol assistance EMA centralised procedures***

| | 1995 - 2011 | 2012 | Overall total |
|---|---|---|---|
| Scientific Advice | 1627 | 197 | 1824 |
| Follow-up to Scientific Advice | 400 | 91 | 491 |
| Protocol Assistance | 342 | 46 | 388 |
| Follow-up to Protocol Assistance | 162 | 25 | 187 |
| HTA parallel advice | 8 | 8 | 16 |
| Qualification of novel methodologies | 14 | 14 | 28 |
| | **2553** | **382** | **2935** |

CHMP monthly report: Nov 2012





# EMA/FDA Joint Advice

## To October 2011

| FDA Parallel Scientific Advice | 2006 - 2010 | 2011 | Overall total |
|---|---|---|---|
| Completed | 9 | 5 | 14 |
| **Ongoing** | 0 | 1 | 1 |
| Foreseen | 0 | 2 | 2 |
| | **9** | **8** | **17** |

CHMP monthly report: Oct 2011

| FDA Parallel Scientific Advice | 2006 - 2011 | 2012 | Overall total |
|---|---|---|---|
| Completed | 17 | 1 | 18 |
| | | | |

CHMP monthly report: Nov 2012

# EU Commission Survey results Oct 2012

Member States were requested to provide information on the following points regarding Advanced Therapy Medicinal Products:

- How many products are legally on the market of each Member State?
- Which of the products legally on the market are prepared on a routine
- basis?
- Which of the products legally on the market fall under the hospital exemption?
- Criteria applied for products under the hospital exemption.


EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Health systems and products
Medicinal products – authorisations, EMA

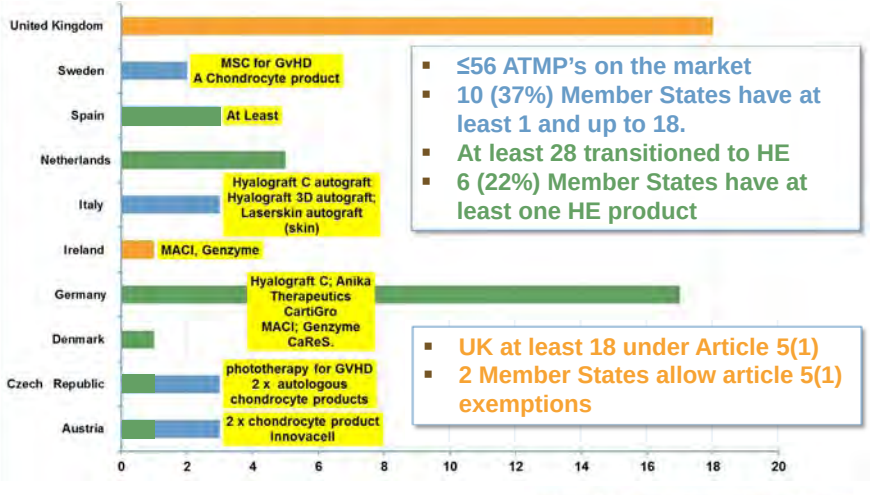
PHARM 608

PHARMACEUTICAL COMMITTEE
22 October 2012





# EU Commission Survey results Oct 2012




- ≤56 ATMP's on the market
- 10 (37%) Member States have at least 1 and up to 18.
- At least 28 transitioned to HE
- 6 (22%) Member States have at least one HE product

- UK at least 18 under Article 5(1)
- 2 Member States allow article 5(1) exemptions

# Looking to the future: Post-MA Activities

| | 2009 | | 2010 | | 2011 | | 2012† | |
|---|---|---|---|---|---|---|---|---|
| | Received | Finalised | Received | Finalised | Received | Finalised | Received | Finalised |
| Type IA variations | 897 | 842 | 2,057 | 1,711 | 2,875 | 2,847 | **2,634** | **2,391** |
| Type IB variations | 470 | 412 | 1,093 | 852 | 1,260 | 1,193 | **1,348** | **1,308** |
| Type II variations | 1,186 | 1,142 | 966 | 942 | 873 | 918 | **879** | **846** |
| Extensions of marketing authorisation | 24 | 31 | 29 | 26 | 31 | 24 | **14** | **21** |
| Percentage of variations submitted in grouped notifications/applications* | N/A | N/A | 51% | 38% | 61% | 61% | **63%** | **61%** |
| Multi-product Type IA groups | N/A | N/A | 41 | 31 | 99 | 101 | **100** | **88** |
| Worksharing variation applications | N/A | N/A | 111 | 58 | 112 | 115 | **108** | **118** |
| Annual reassessments | 21 | 17 | 19 | 20 | 18 | 16 | **11** | **14** |
| Renewals** | 46 | 54 | 67 | 27 | 67 | 62 | **66** | **74** |

- **666 Centrally authorized products**
- **>7 post-auth. Activities/product/year**
- **>1 Type II variation/product/year**