Chair's Introduction

Christopher A Bravery

cbravery@advbiols.com

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* Application subsequently withdrawn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 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

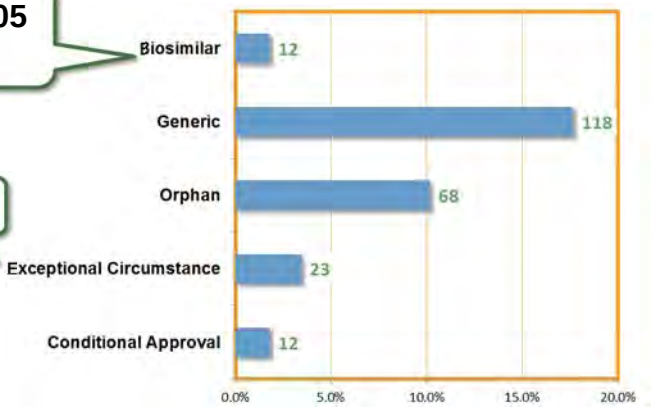
	2009		2010		2011		2012†	
	Started	Finalised	Started	Finalised	Started	Finalised	Started	Finalised
Non-orphan medicinal products								
New products	35	49	34	21	46	37	**41**	**30**
Advanced-therapy medicinal products	0	1	0	0	1	0	**2**	**0**
Advanced-therapy Art. 29 transition products	0	0	0	0	1	0	**0**	**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:

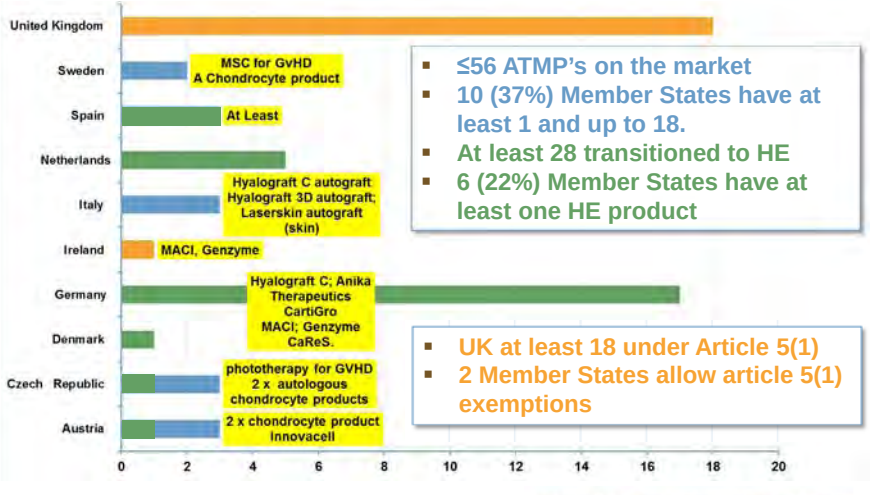
- How many products are legally on the market of each Member State?
- Which of the products legally on the market are prepared on a routine
- basis?
- Which of the products legally on the market fall under the hospital exemption?
- Criteria applied for products under the hospital exemption.


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**