EMEA Workshop on the feasibility of Biosimilar monoclonal Antibodies

WELCOME AND KEYNOTE PRESENTATION

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Welcome to a broad range of experts from:

- **Industry - Innovator and Biosimilar**
- **Academia**
- **Scientific Regulators**

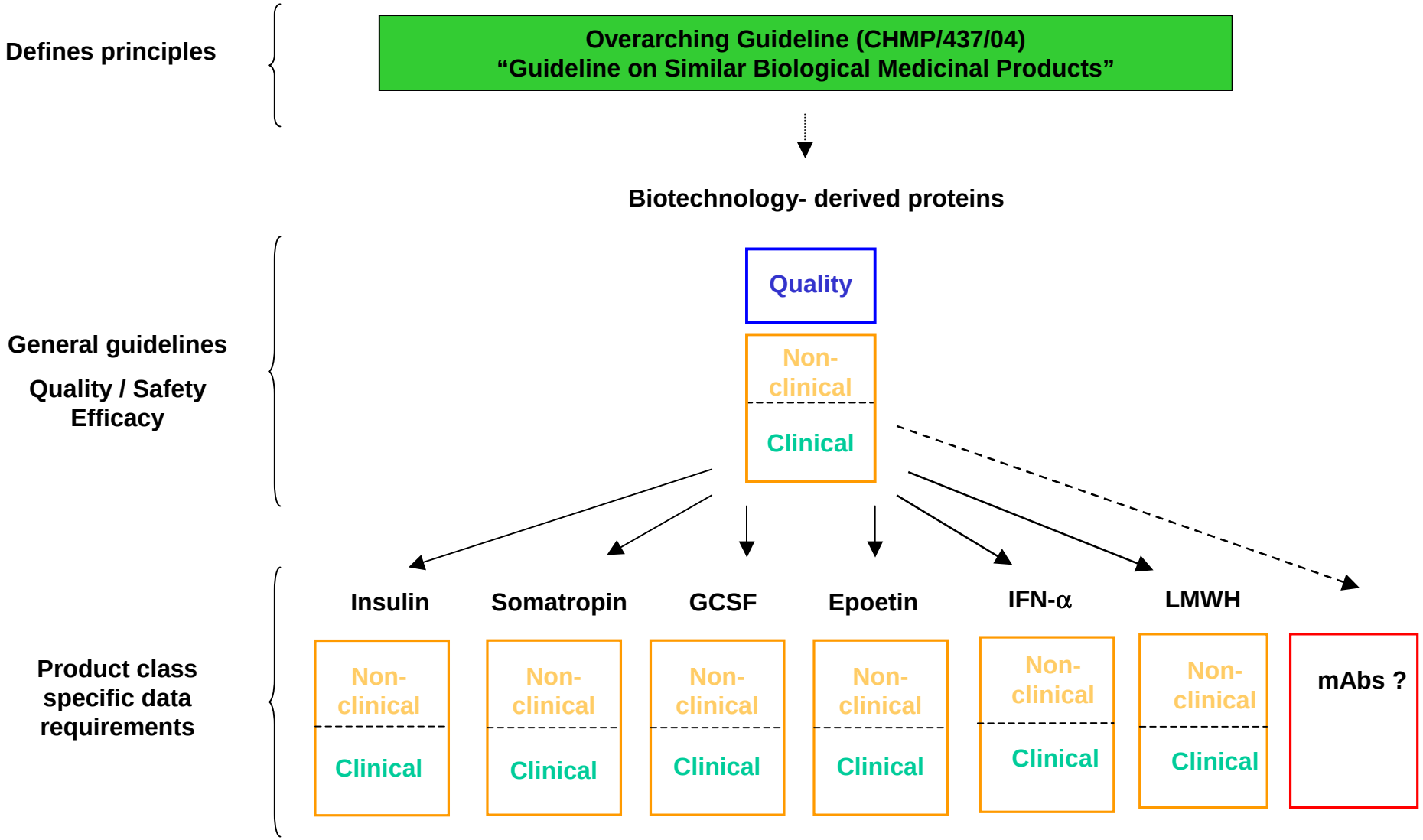
Objective

The objective of this workshop is
to discuss the feasibility and key aspects
of the scientific development and authorisation of monoclonal antibodies
via the Biosimilar regulatory pathway.

Biosimilar development in the EU

- **Legislation**
  - Directive 2001/83/EC, as amended (2004/27/EC) Article 10.4
- **Structures**
  - Biosimilar Task Force (2004-2007) (EMEA transversal group - regulatory / legal / quality / safety / efficacy / PhV competences)
  - Biosimilar Working Party (BMWP) (est. 2005, multidisciplinary)
- **Implementation**
  - Initial guidance (2Q 2004)

Current Biosimilar Guidelines – Summary



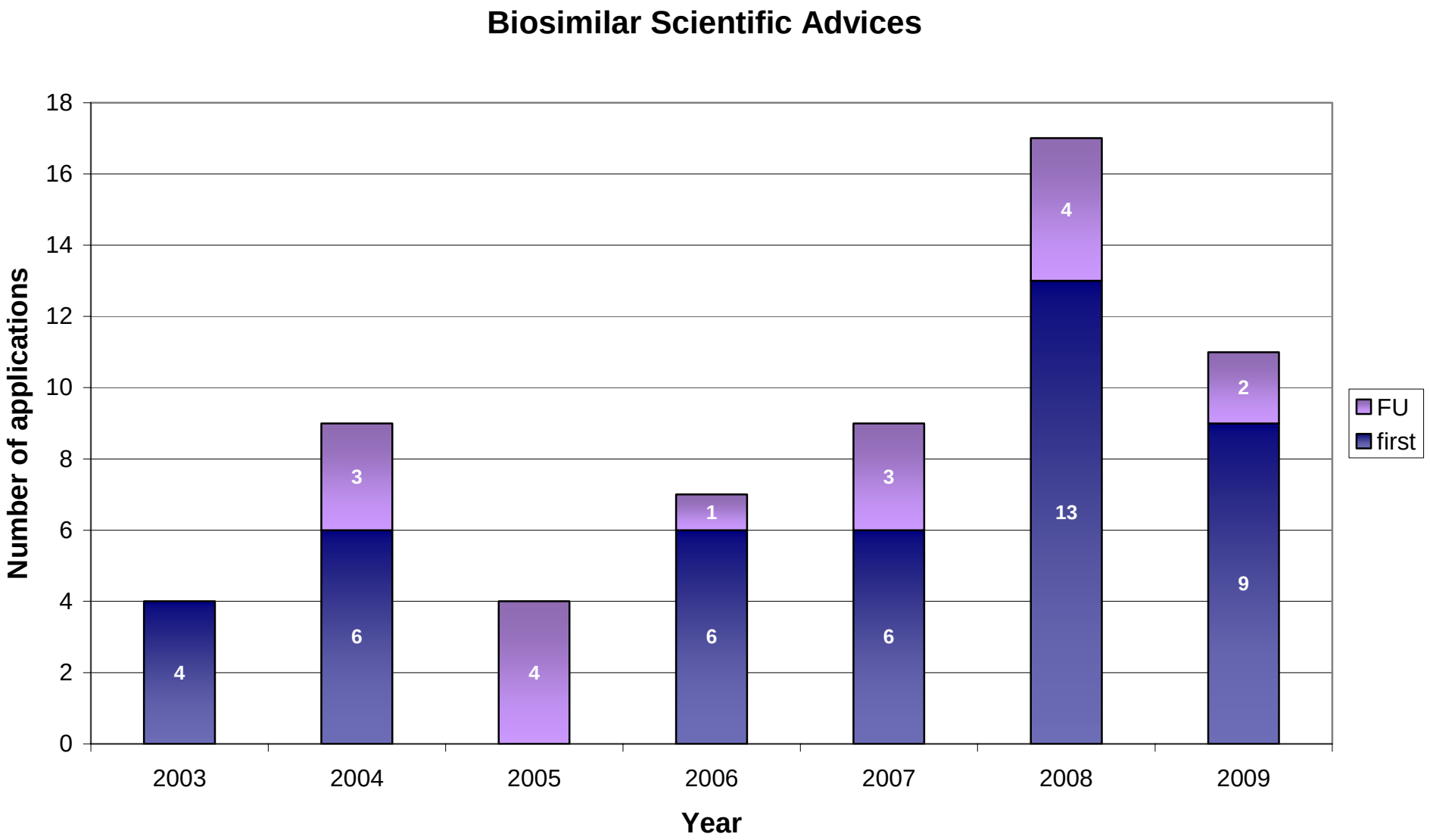
Products evaluated CHMP

– First Scientific Advice for Biosimilar development (2003)

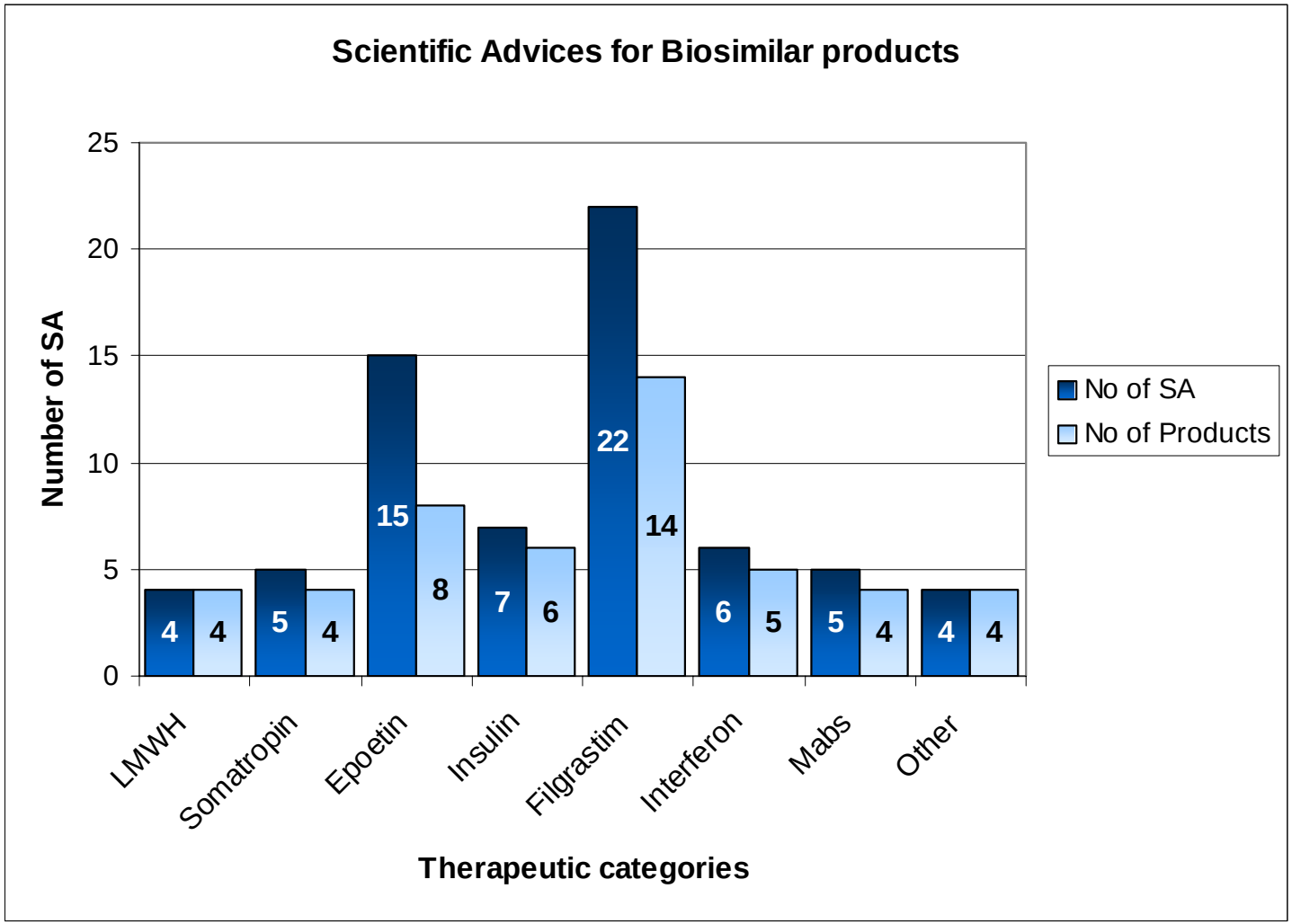
– First positive Biosimilar CHMP opinion (2006 Omnitrope)

– First marketed Biosimilar in the European Union (2006)

Scientific Advice - Biosimilars



Scientific Advice - Biosimilars

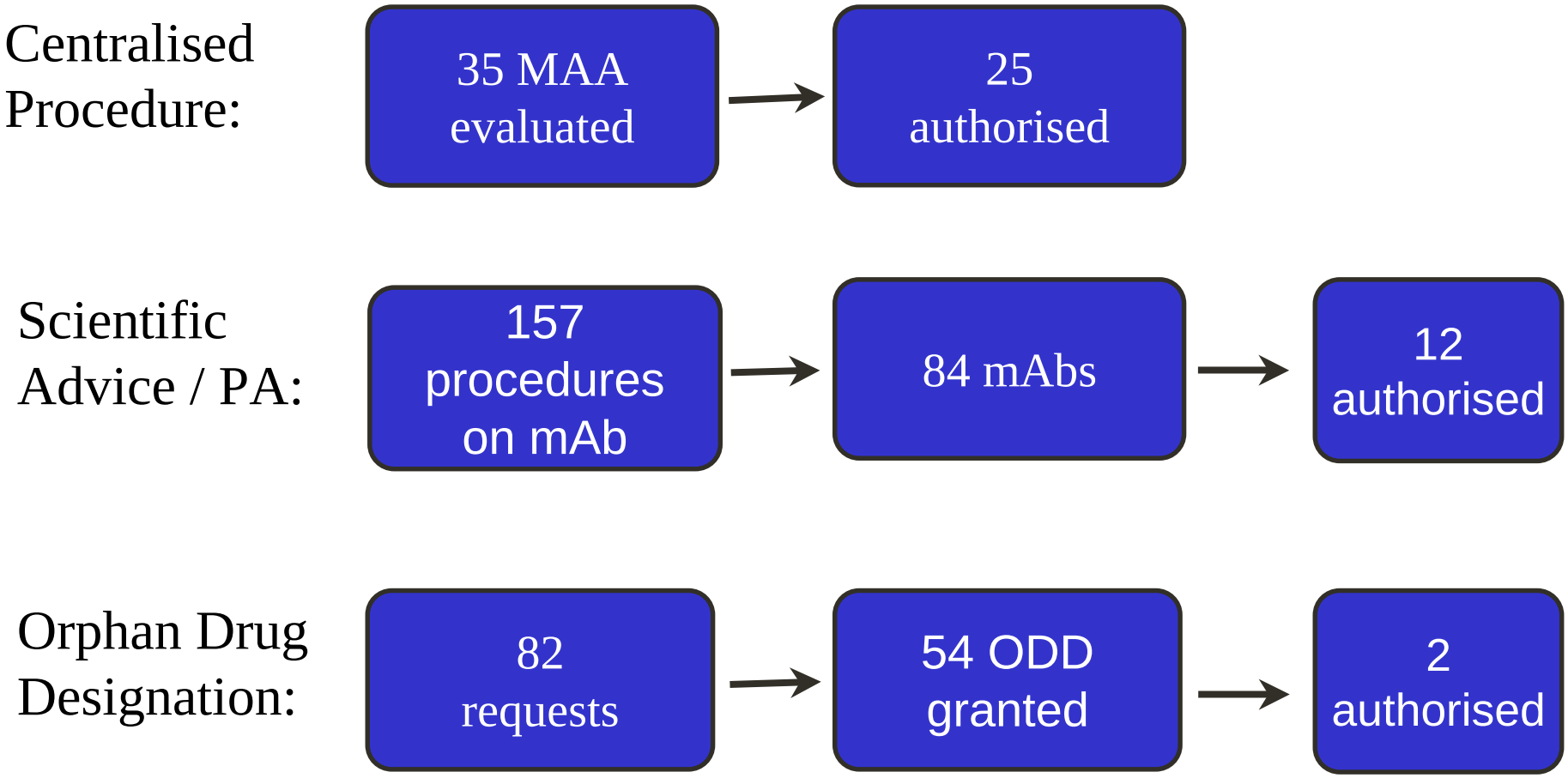


Other refers to follitropin, PTH and blood factor biosimilars

Biosimilar MAA Procedures (Status - June 2009)

1	Omnitrope (somatropin)	Sandoz	**Authorised**
2	Valtropin (somatropin)	Biopartners	**Authorised**
3	Alpheon (interferon alfa)	Biopartners	Negative
4	Binocrit (epoetin alfa)	Sandoz	**Authorised**
5	Epoetin alfa Hexal (epoetin alfa)	Hexal	**Authorised**
6	Abseamed (epoetin alfa)	Medice	**Authorised**
7	Silapo (epoetin zeta)	Stada	**Authorised**
8	Retacrit (epoetin zeta)	Hospira	**Authorised**
9	Insulin Marvel Short (human insulin)	Marvel Life Sci'	Withdrawn
10	Insulin Marvel Intermediate (human insulin)	Marvel Life Sci'	Withdrawn
11	Insulin Marvel Long (human insulin)	Marvel Life Sci'	Withdrawn
12	Filgrastim Ratiopharm (filgrastim)	Ratiopharm	**Authorised**
13	Ratiograstim (filgrastim)	Ratiopharm	**Authorised**
14	Biograstim (filgrastim)	CT Arzneimittel	**Authorised**
15	Tevagrastim (filgrastim)	Teva	**Authorised**
16	Filgrastim Hexal (filgrastim)	Hexal	**Authorised**
17	Zarzio (filgrastim)	Sandoz	**Authorised**

EMEA Experience with monoclonal Antibodies (mAbs)



Summary

- Biosimilar MAA portfolio and related guidelines continue to grow
- Increasing interest in the development of Biosimilars
  (Scientific Advices)
- EMEA gained comprehensive experience for certain types of monoclonal antibodies
- EU Regulators experience important reference for other territories (Japan (first marketed Biosimilar), Canada, WHO, Malaysia, US)