Emergence of Biosimilar Medicines

The Biosimilar Company Point of View

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Belgium Federal Parliament
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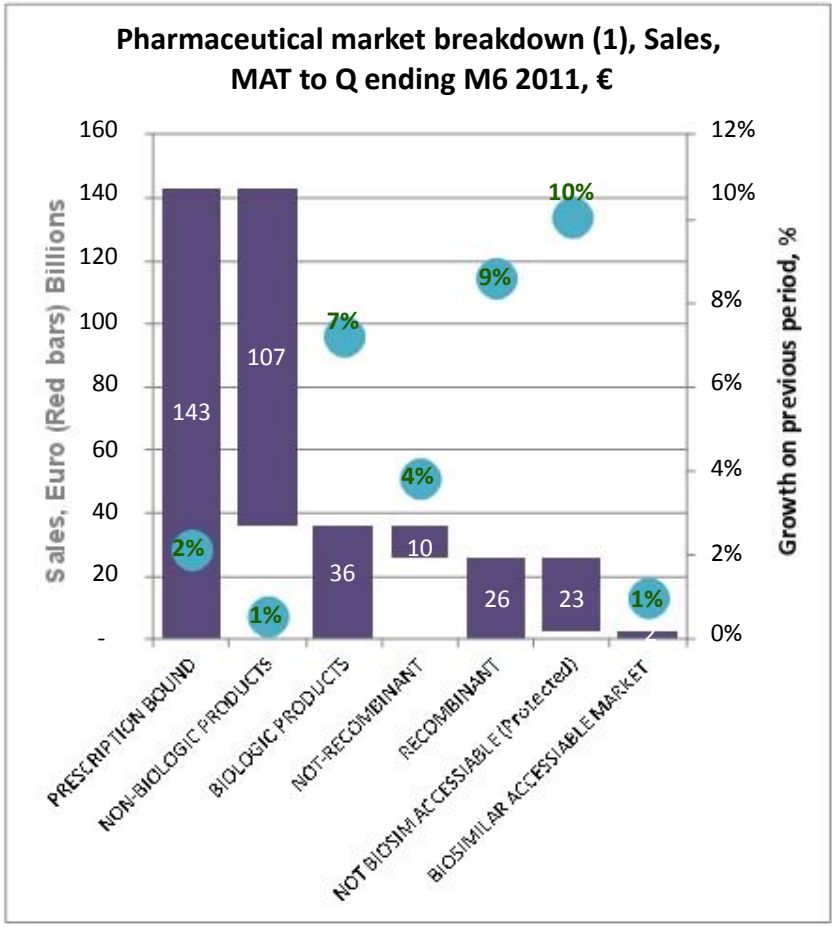
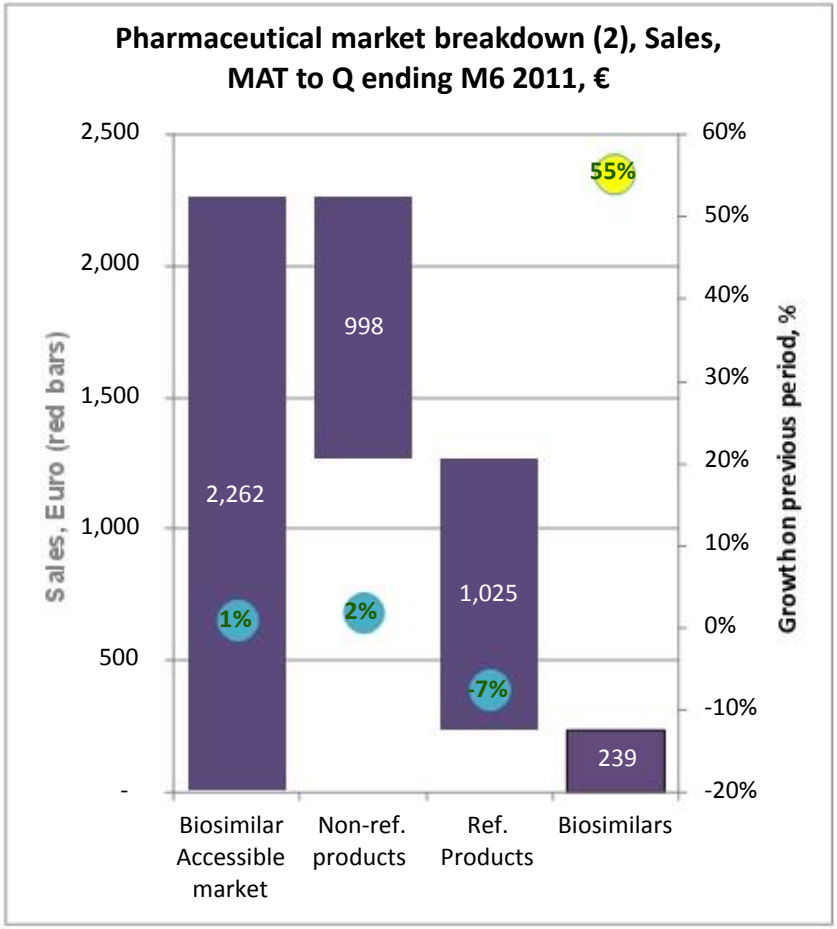
Hospira

Biosimilars are a small but fast growing segment of the pharmaceutical market in the EU

Biosimilar sales are <0.2% of the current pharmaceutical market. Near term expiry on several biological patents will substantially increase the accessible market



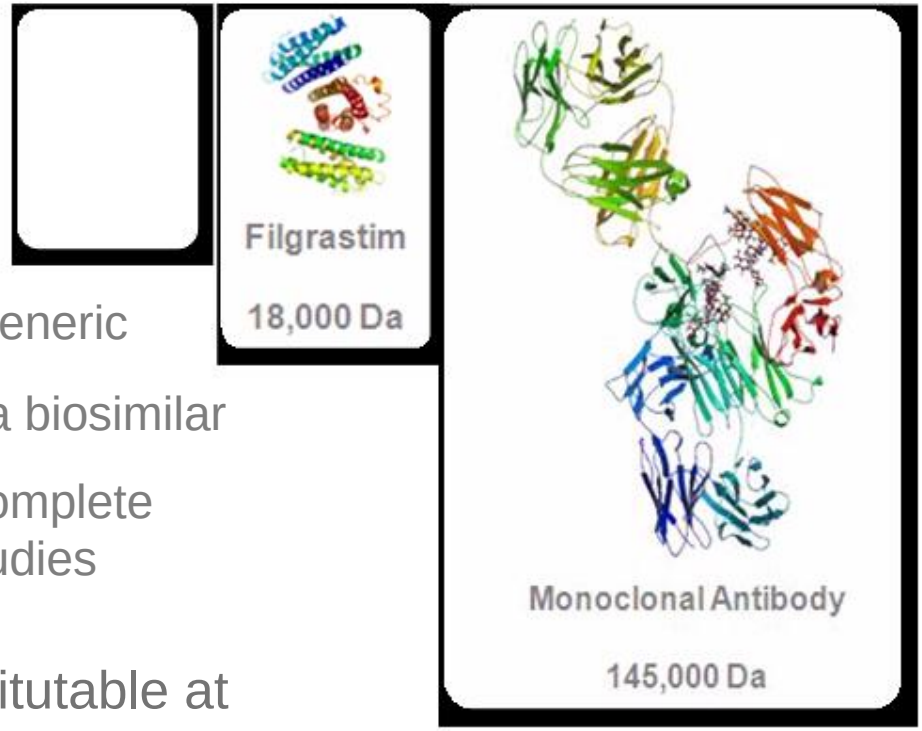


Source: IMS MIDAS to Jun 2011

Biosimilars are not Generics

Biosimilars are more costly to develop than generics and require manufacturers to take considerable risk. The relative cost is expected to be higher than generics.

Biosimilar development is longer, much more costly and riskier than generic development



- <$5M and 3-4 years to develop a generic
- >$100M and 7-8 years to develop a biosimilar
- unlike generics, biosimilars must complete extensive clinical comparability studies

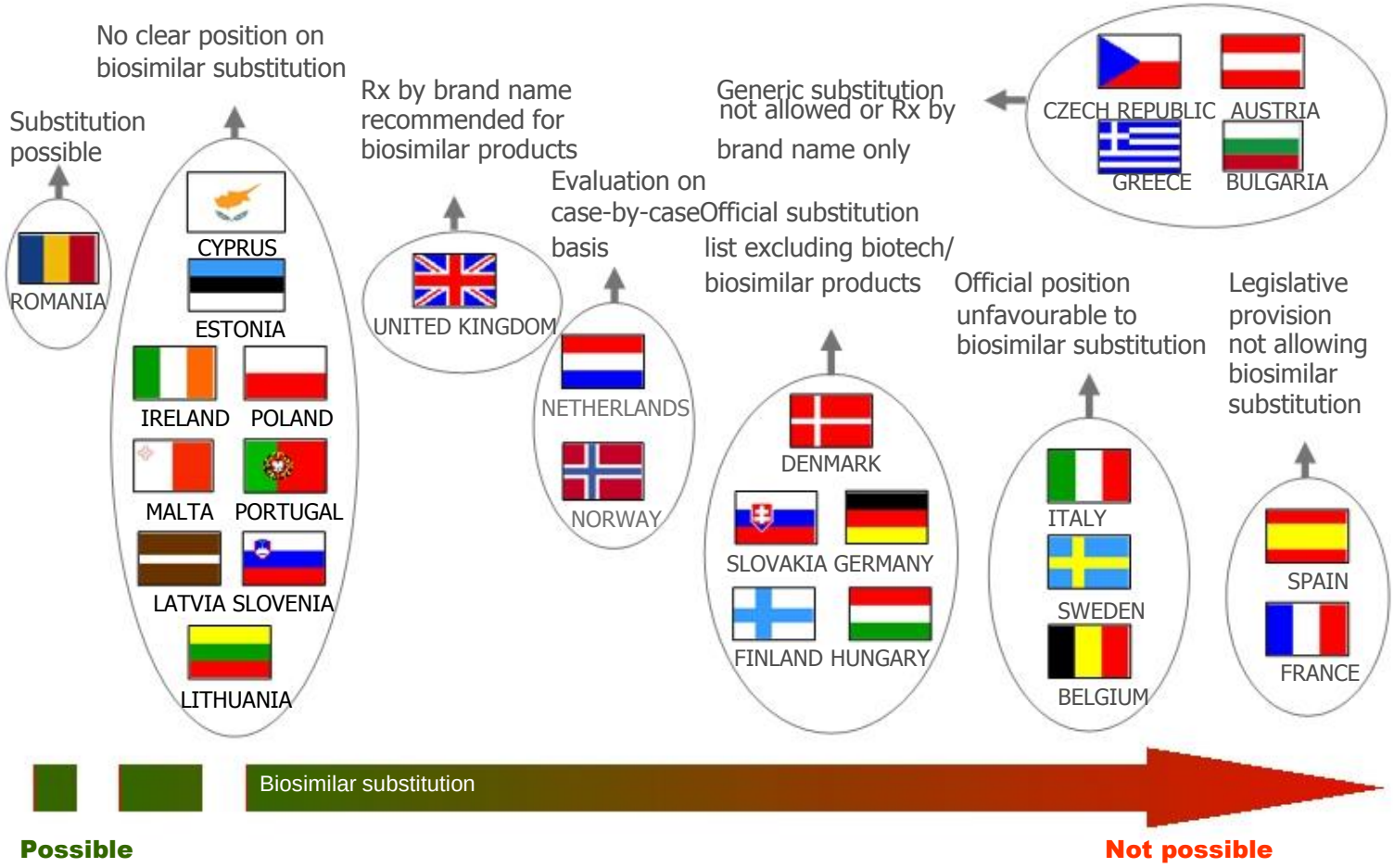
Biosimilars are generally not substitutable at pharmacy level and as a result price is less elastic than with generics

Without guaranteed volume commitment the expected price of biosimilars is expected to be ~20-25% below the reference product

*Molecular weight in Daltons (Da)

Substitution policies and access channel are key factors affecting biosimilar uptake in the EU

Prescribing physicians continue to maintain strong control over brand choice. Understanding the concept of biosimilarity is essential to improving uptake.



Adapted from Schellekens 2011 : http://www.farmaactueel.nl/webcasts/extern/EAHP2011/Powerpoint/Schellekens.pdf

Biosimilar entrants have behaved similarly to proprietary products with slow and steady growth

Since 2006 only 7 biosimilar programs have been approved across 3 therapeutic areas. Uptake of biosimilars has followed a 'proprietary like' trajectory

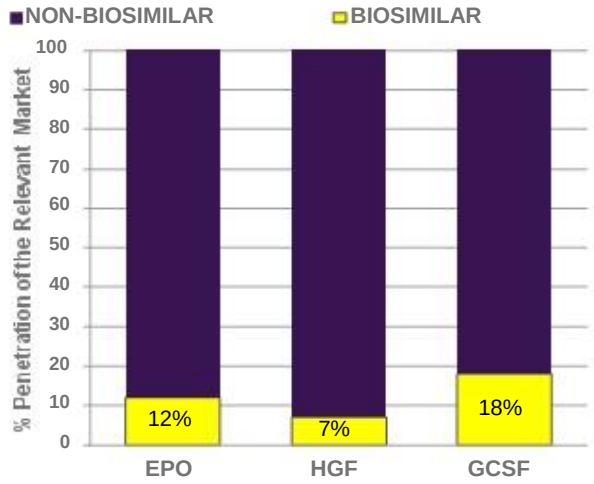
INN	Biosimilar	Company	Reference Product	CHMP Opinion	EU Approval
somatropin	Omnitrope	Sandoz	Genetropin (Pfizer)	Jan-06	Apr-06
somatropin	Valtropin	Biopartners	Humatrope (Lilly)	Feb-06	Apr-06
epoetin alfa	Binocrit	Sandoz	Eprex (J&J)	Jun-07	Aug-07
epoetin alfa	Epoetin Alfa Hexal	Sandoz (Hexal)	Eprex (J&J)	Jun-07	Aug-07
epoetin alfa	Abseamed	Medice	Eprex (J&J)	Jun-07	Aug-07
epoetin zeta	Retacrit	Hospira	Eprex (J&J)	Oct-07	Dec-07
epoetin zeta	Silapo	Stada	Eprex (J&J)	Oct-07	Dec-07
filgrastim	Ratiograstim	Ratiopharm	Neupogen (Amgen)	Feb-08	Sep-08
filgrastim	Tevagrastim	Teva	Neupogen (Amgen)	Feb-08	Sep-08
filgrastim	Filgrastim Ratiopharm	Ratiopharm	Neupogen (Amgen)	Feb-08	Sep-08
filgrastim	Biograstim	CT Arzneimittel	Neupogen (Amgen)	Feb-08	Sep-08
filgrastim	Zarzio	Sandoz	Neupogen (Amgen)	Nov-08	Feb-09
filgrastim	Filgrastim Hexal	Sandoz (Hexal)	Neupogen (Amgen)	Nov-08	Feb-09
filgrastim	Nivestim	Hospira	Neupogen (Amgen)	Mar-10	Jun-10

New Biosimilar(s) approved

New Originator approved

Biosimilars uptake in the EU started slowly but is improving with each new therapeutic class

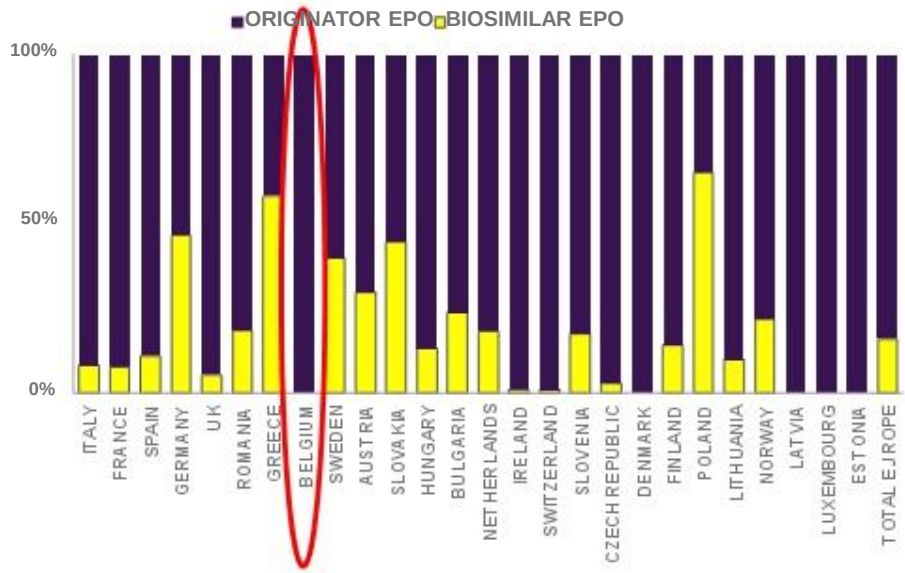
Biosimilar uptake has varied by therapeutic class and by country. Several EU countries have built extensive experience with biosimilars.



	EPO	HGF	GCSF
Relative uptake/year	2.6%	1.2%	5.0%

- Rate of uptake has improved with introduction of new therapeutic classes of biosimilars
- HGF uptake limited by being the first biosimilar and chronic use in paediatric patients
- EPO uptake limited by PRCA concerns, limited indication at launch and heavy price competition among originators
- GCSF uptake limited by concern over use in 'normal' donor indication

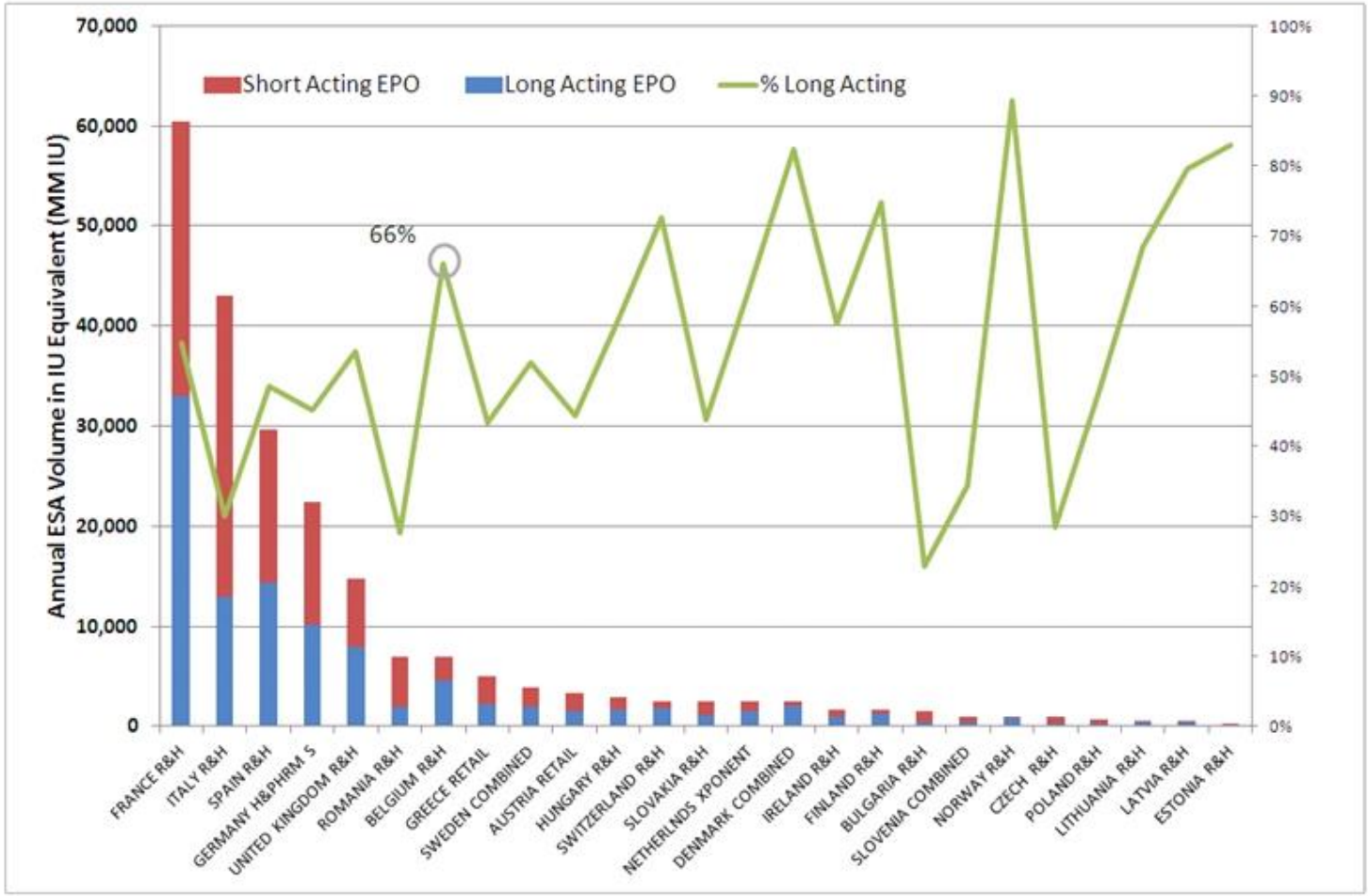
- Variable uptake across EU member states driven by inconsistent P&R processes and in-market price variance
- Payor influence is increasing as clinician confidence grows
- Markets characterised by requiring predominantly prescriber driven or therapeutic tender driven approaches



Source: IMS MIDAS to Jun 2011

Use of long acting EPO in Belgium is higher than in the majority of EU member states

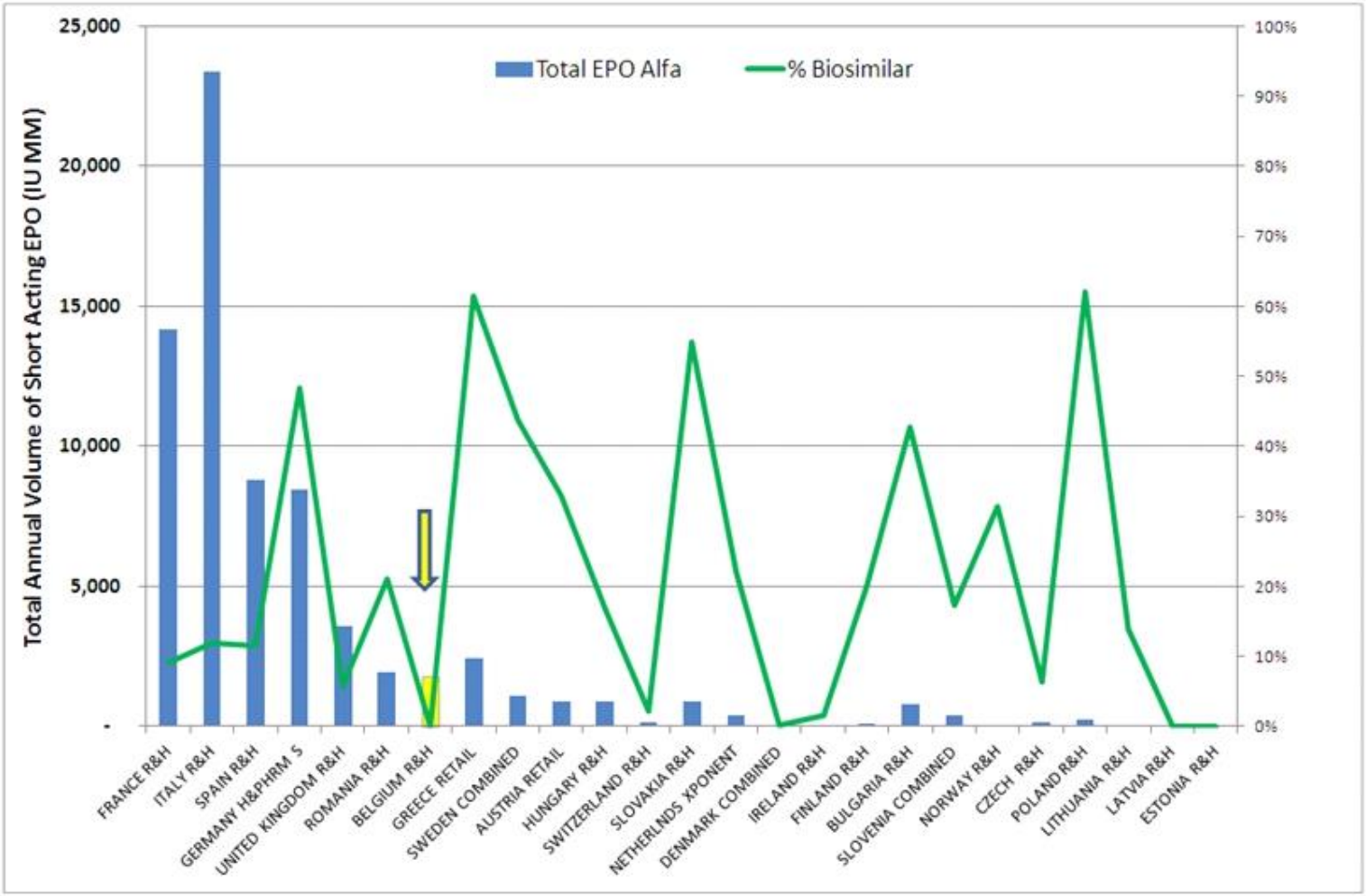
Around 2/3rds of EPO use in Belgium is with long acting brands. The opportunity for use of biosimilar short acting EPO is limited compared to other EU markets.



Source: IMS MIDAS to Jun 2012

Belgium has not taken advantage of the introduction of biosimilar EPO to help reduce cost

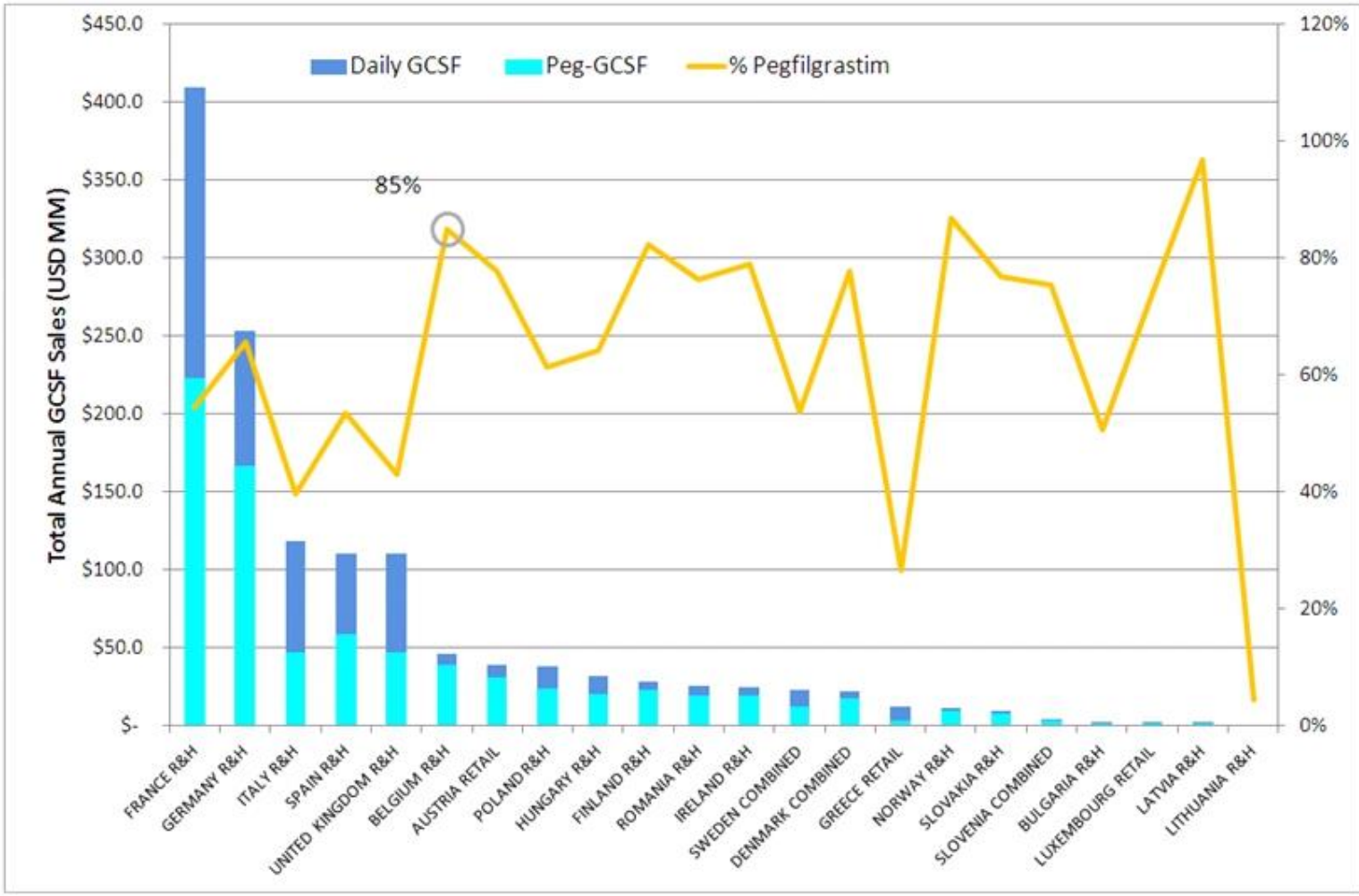
Belgium uses ~€16M ($20M) of epoetin alfa per year. Currently no biosimilar epoetin alfa is used.



Source: IMS MIDAS to Jun 2012

Biosimilar GCSF opportunity in Belgium is limited by a high proportion of peg-filgrastim use

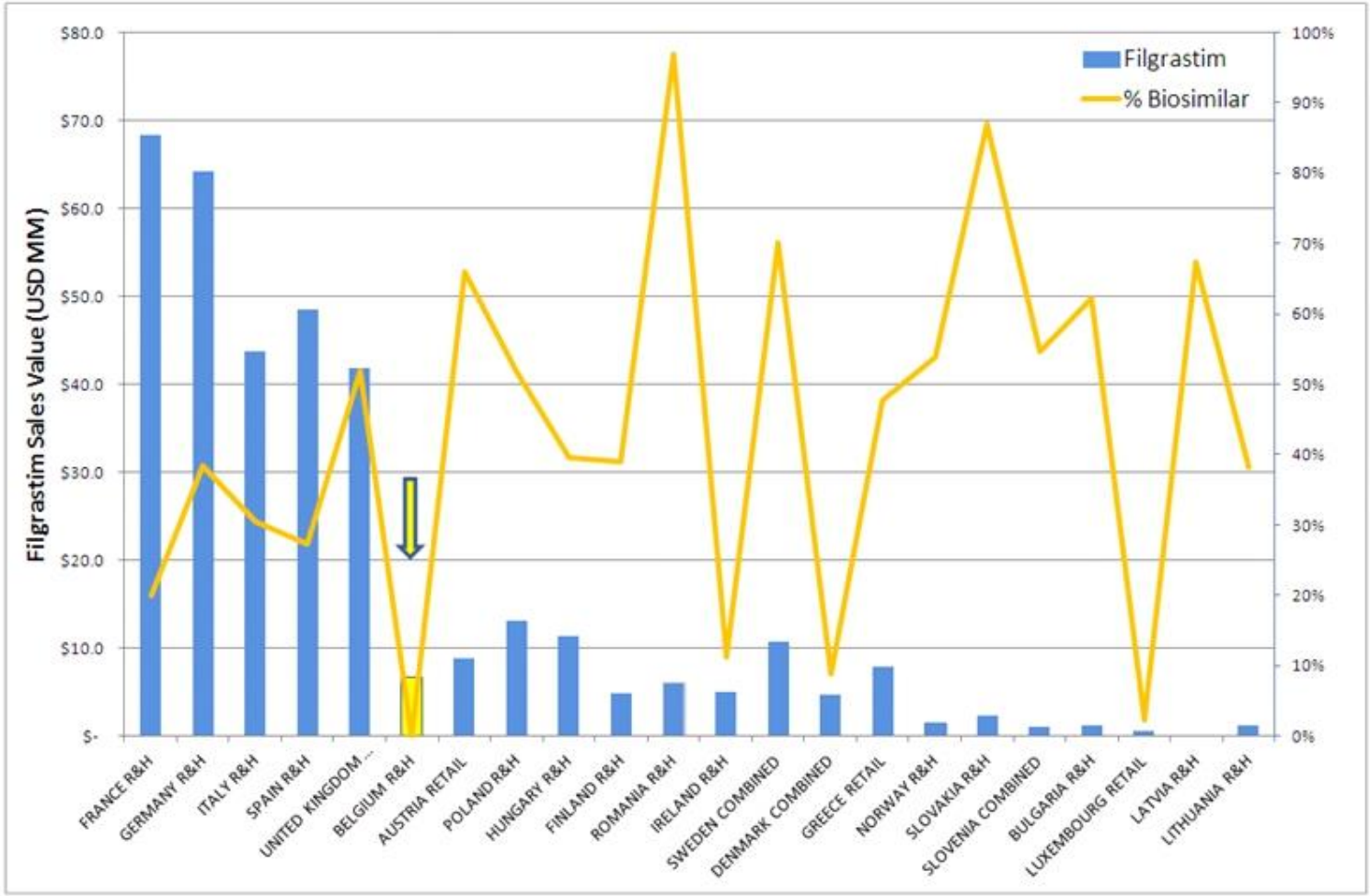
Belgium has a high proportional use of pegylated-GCSF. The opportunity for use of biosimilar daily GCSF is limited compared to other EU markets.



Source: IMS MIDAS to Jun 2012

Unlike most EU countries Belgium has not taken advantage of the introduction of biosimilar GCSF to help reduce cost

Belgium uses ~€5M ($7M) of filgrastim per year. Currently no biosimilar filgrastim is used.



Source: IMS MIDAS to Jun 2012

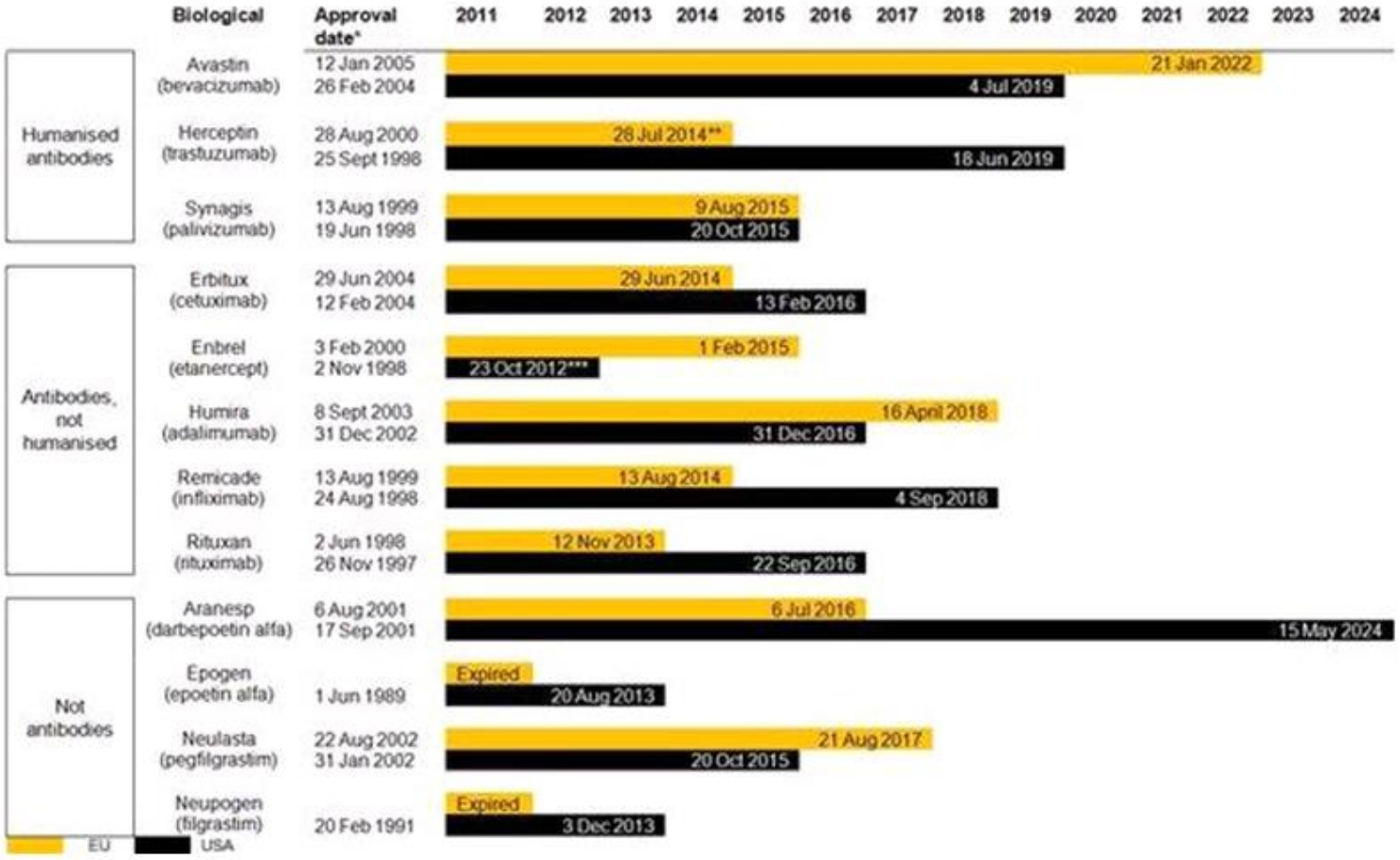
The EMA guideline on biosimilar mAbs paves the way for future approvals

The biosimilar mAb guideline opens a huge opportunity for future cost saving. The mAb market in EU is currently valued at ~$19B and growing at 12% CAGR.

Source : ThePharmaLetter (May 12)

Several high cost mAbs will soon come off-patent

The major biopharmaceuticals coming off patent in the next 10 years are mAbs and are used mainly in areas of oncology or rheumatology.



* EU provides 10 years of data exclusivity, US BPCI Act provides 12 years exclusivity
** In the UK. Other major EU markets follow on 28 August 2015.
*** Aqueous formulation patent runs until 2023, but dry powder biosimilar possible.

Source: Bernstein Research, published at GABI On-Line (Sept 2011)

Summary

- Biosimilars are a small segment in the total pharmaceutical market but are growing strongly
- The EU uptake of biosimilars has been variable between product class, between EU countries and within countries
- Belgium has not embraced the introduction of the first biosimilars
- Substitution practice is the major factor affecting biosimilar uptake
- Other factors affecting uptake include;
  - Physician perception of biosimilars
  - Patient acceptance of biosimilars
  - Local pricing and reimbursement regulation
  - Procurement policies and terms
  - Price differential between reference and biosimilar
- Biosimilar mAbs could provide a major opportunity for cost saving in Belgium

Thank you