Pharmacoeconomic potential of Biosimilars

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Agenda

- Lessons from tendering for generics in the Netherlands
- Loss aversion in physicians and patients?
- Biosimilars, lower but sustainable prices?
- Biosimilars, what savings are realistic?

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Tendering: results, risks and opportunities

- *The acquisition of pharmaceuticals based on a competitive bidding process where the contract is granted to the pharmaceutical supplier who offered the best bid following strict criteria* (Leopold 2008)

- Tendering for outpatient generic pharmaceuticals in several EU countries (e.g. Belgium, Denmark, Germany, Malta, Netherlands, Romania, Slovenia)

Tendering: lower prices generics NL

(www.gipdatabank.nl)

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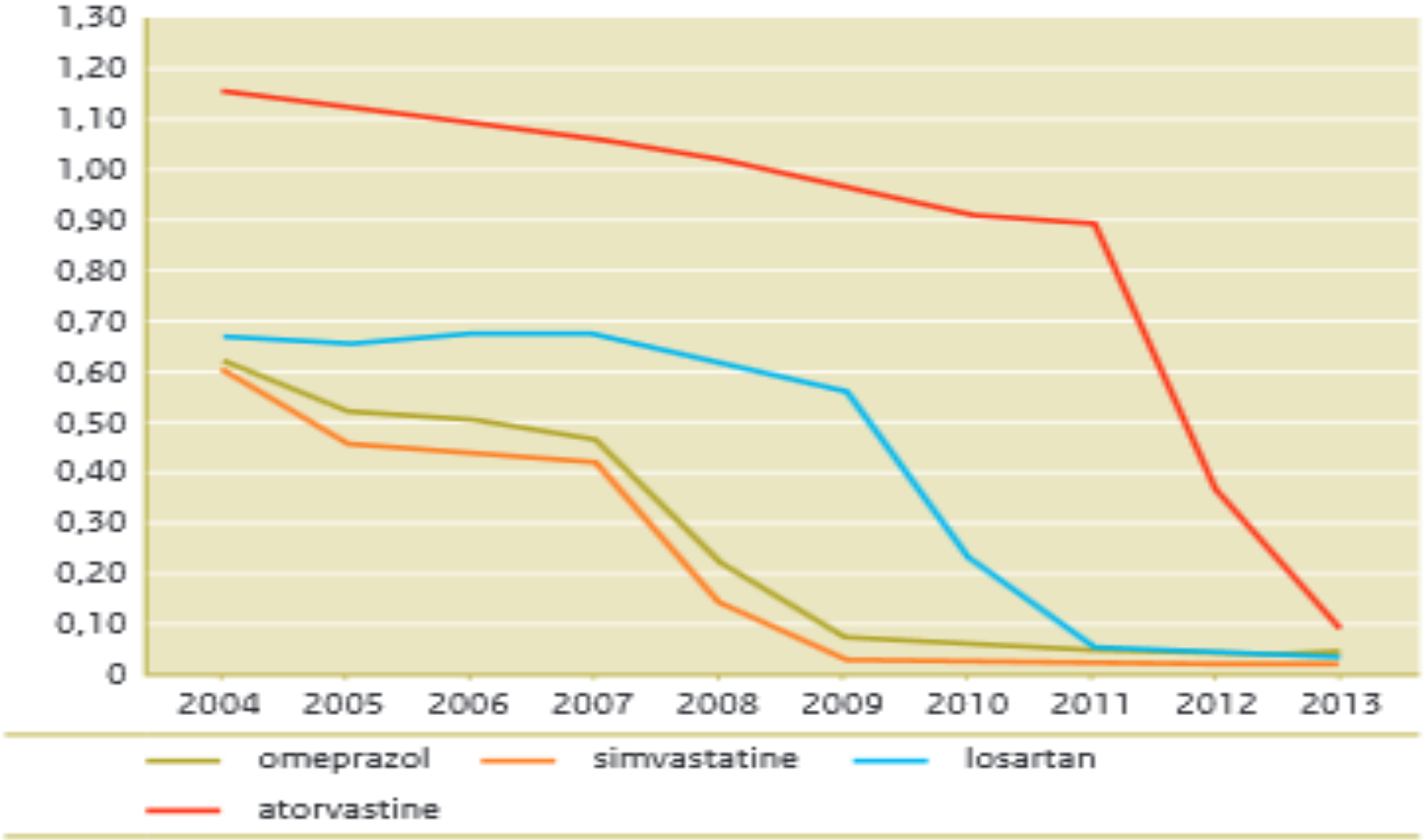
Figuur 3.9 | Prijsondalingen onder invloed van preferentiebeleid generieke geneesmiddelen, 2004-2013

1 = 1 EURO



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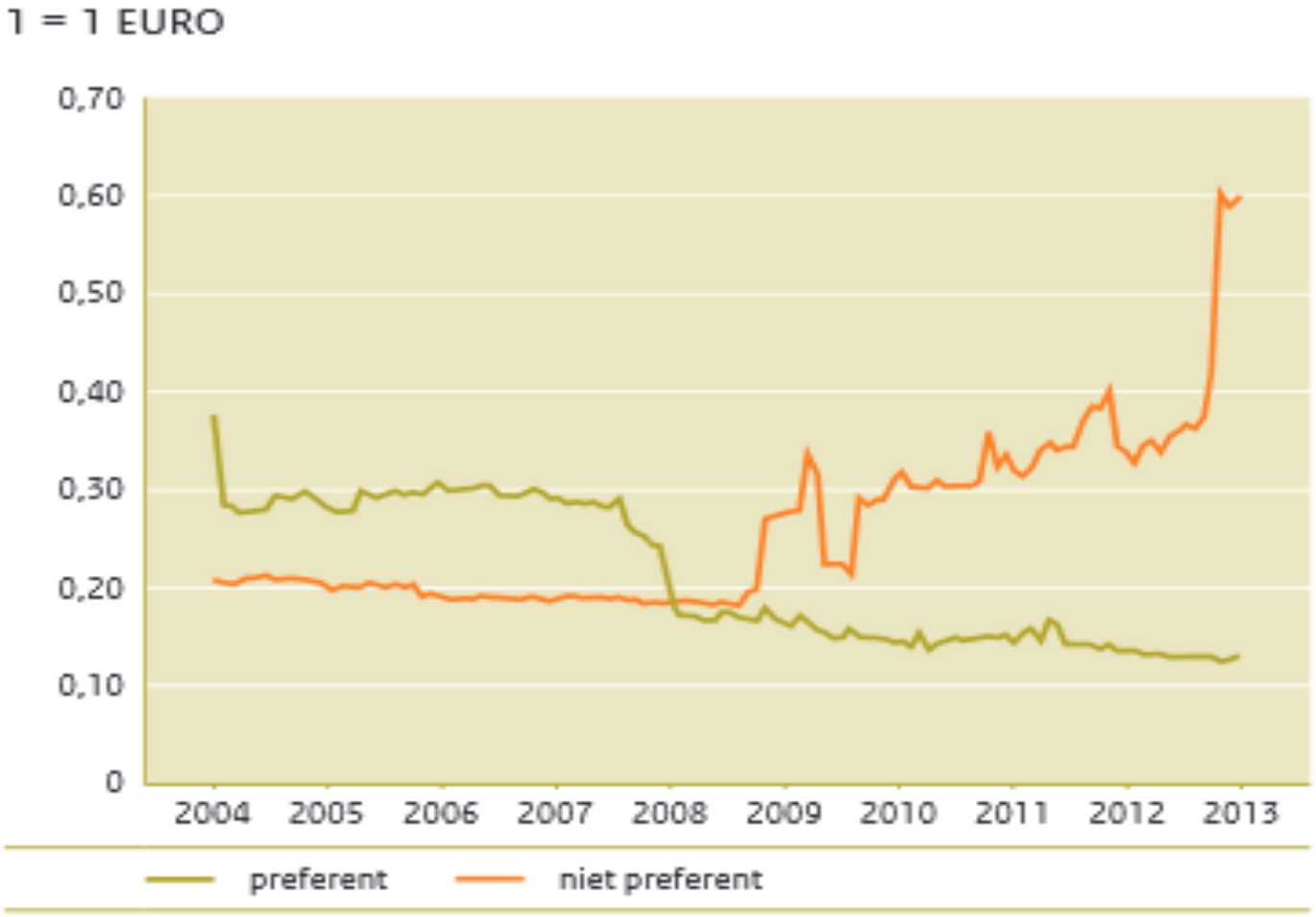
Price per generic DDD, tendered vs not, Netherlands



NL, volume and price

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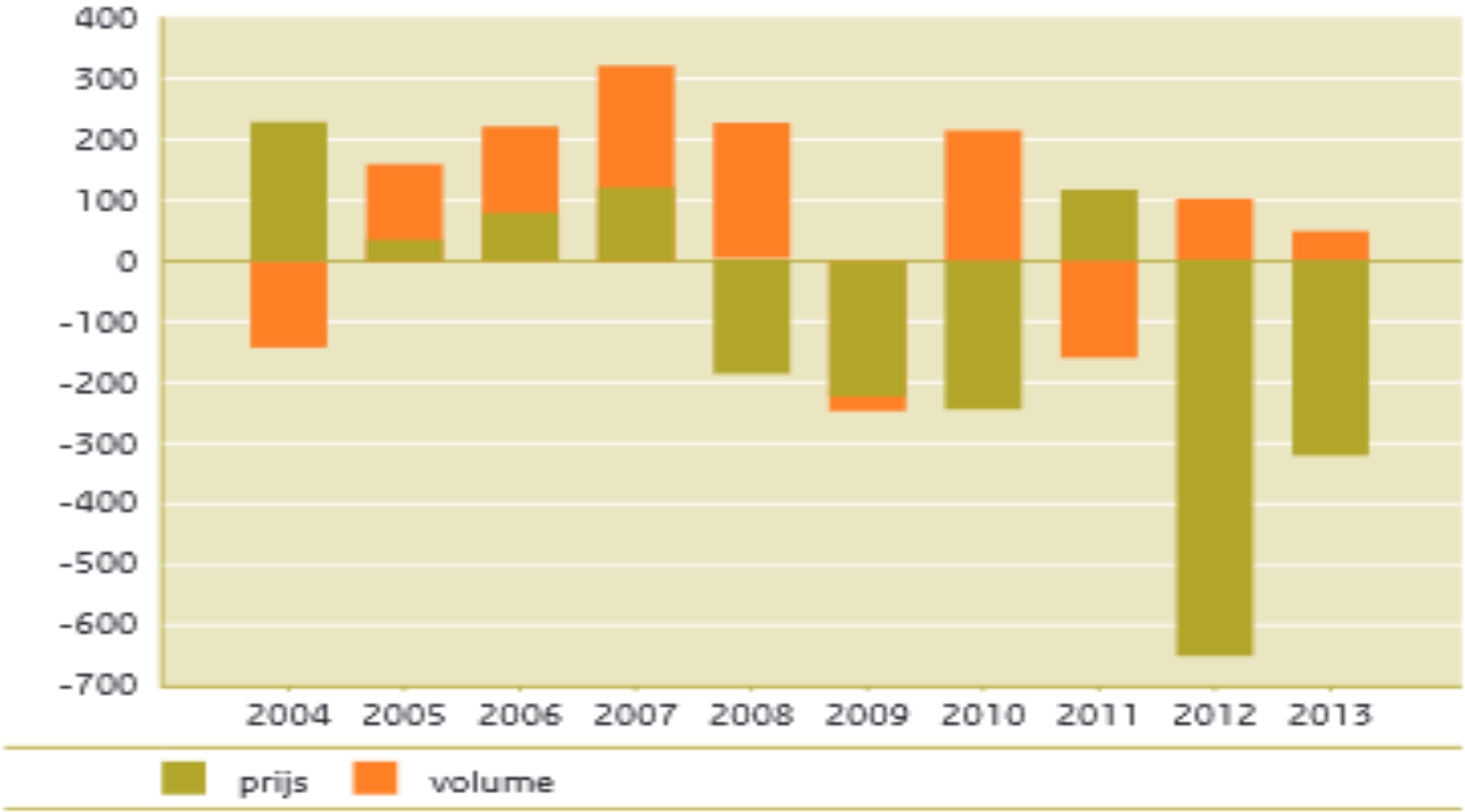
Figuur 3.1 | Farmaceutische zorg: volume- en prijs-component, 2004-2013

1 = 1 MILJOEN EURO



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Results of tendering Netherlands

- Estimated savings in Netherlands 2013: 879 mln euro (Gipeilingen 2013),-> very successful

BUT

- Patients often have to change (package, colour and form of the tablet)
- Production often in low cost countries (eg India) -> Ranbaxy scandal 2014 (manipulation of test results on raw materials).
- Dutch authorities trust test certificates
- Appeal to Dutch health insurers: please pay a bit more for better quality (van Gelder & Vulto, 2014)

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Discussion tendering Netherlands

- SFK report: in 4% of preferent drug prescriptions, the preferred drug is not deliverable
- Health insurer Menzis considers new way of tendering: when patent ends, insurer chooses maximum reimbursed price
- **Every manufacturer** that is willing to deliver for that price can become **a preferred provider**

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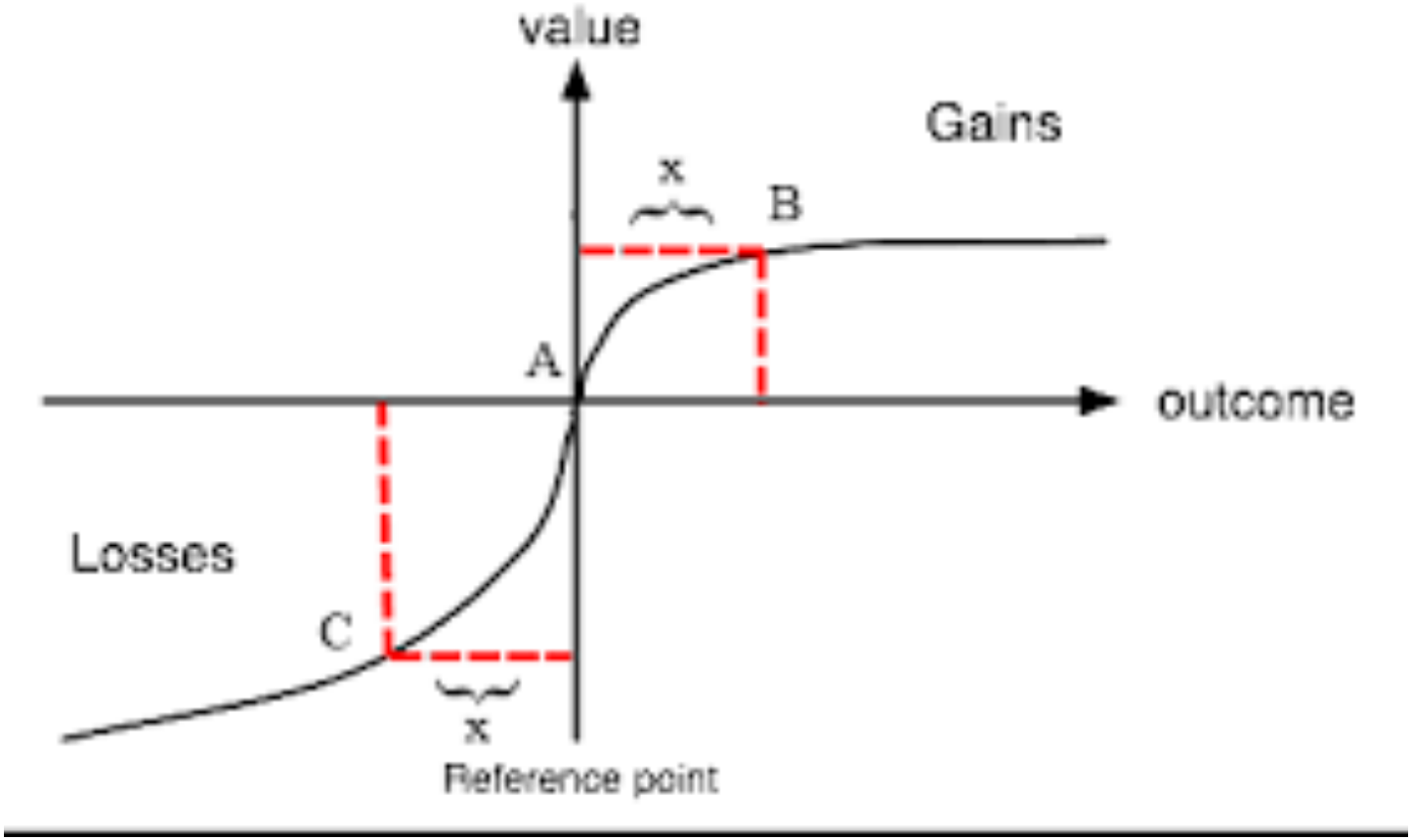
Loss aversion (1)



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Loss aversion (2)

- people are known to form reference points and evaluate outcomes as gains and losses relative to these reference points.
- Moreover, losses as seen from a reference point often 'loom larger' than gains, which is termed loss aversion (Kahneman and Tversky, 1979; Kahneman et al., 1991).

- This may explain why individuals tend to be very risk averse and stick to their **status quo, the originator drug**.

- More experimental research needed to estimate AMOUNT of loss aversion in physicians and patients

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Biosimilars: lower, but sustainable prices?

- In October 2014 biologic medicines accounted for 27% of pharma sales in Europe (IMS Health, 2014)

- Annual growth rate sales biologics: 5.5% (2013)
- (total market grew 1.9%)

Prominent biosimilars:

- EPO (dialysis, oncology);
- Somatropin (human growth hormone);
- G-CSF (certain cancers);
- Anti-TNF (RA, psoriasis, Crohn's disease)
- Insuline Glargyline (Diabetes).

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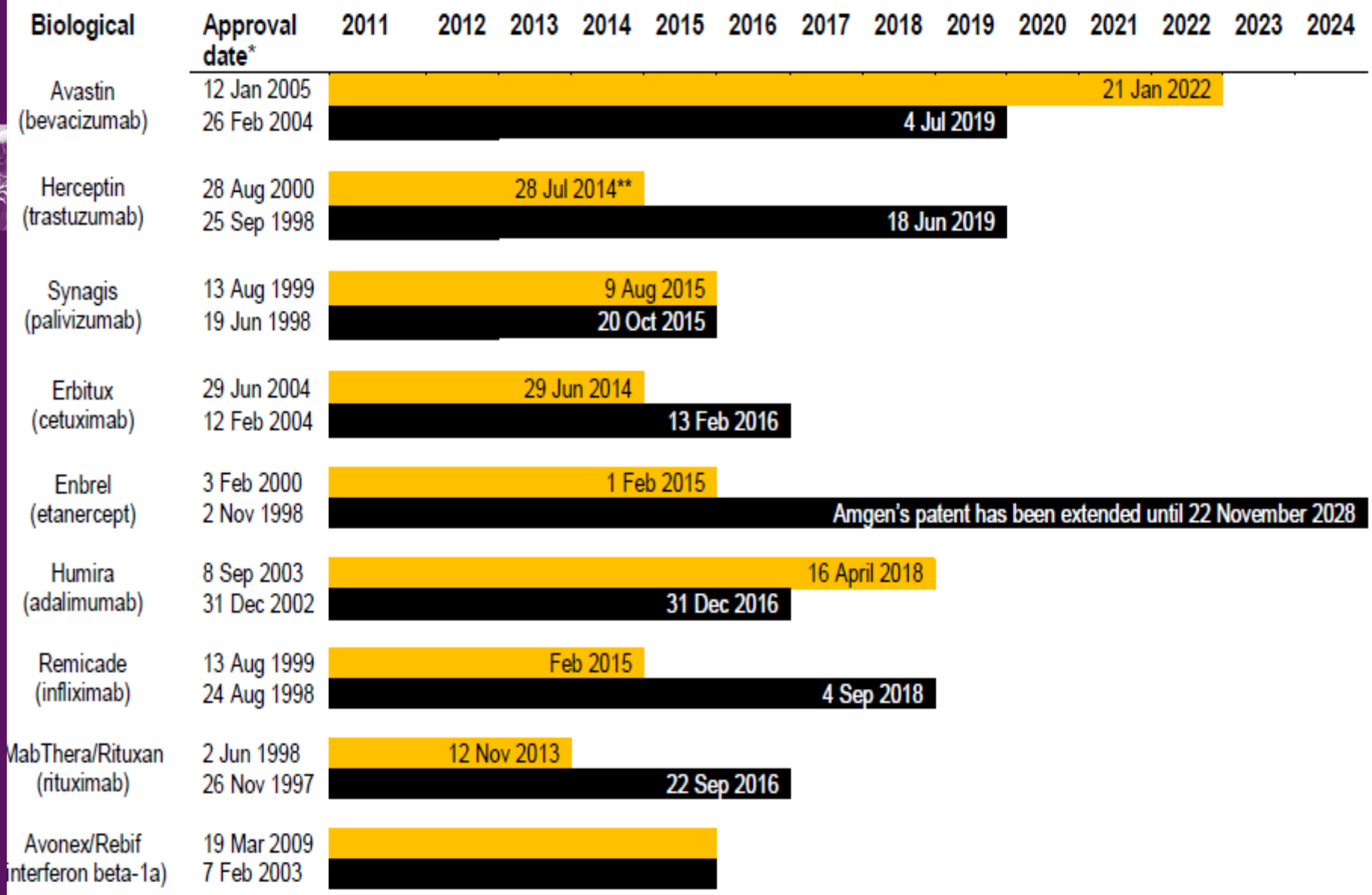
Biological
Approval date*
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
Avastin (bevacizumab)
12 Jan 2005
26 Feb 2004
21 Jan 2022
4 Jul 2019
Herceptin (trastuzumab)
28 Aug 2000
25 Sep 1998
28 Jul 2014**
18 Jun 2019
Synagis (palivizumab)
13 Aug 1999
19 Jun 1998
9 Aug 2015
20 Oct 2015
Erbitux (cetuximab)
29 Jun 2004
12 Feb 2004
29 Jun 2014
13 Feb 2016
Enbrel (etanercept)
3 Feb 2000
2 Nov 1998
1 Feb 2015
Amgen's patent has been extended until 22 November 2028
Humira (adalimumab)
8 Sep 2003
31 Dec 2002
16 April 2018
31 Dec 2016
Remicade (infliximab)
13 Aug 1999
24 Aug 1998
Feb 2015
4 Sep 2018
MabThera/Rituxan (rituximab)
2 Jun 1998
26 Nov 1997
12 Nov 2013
22 Sep 2016
Avonex/Rebif
Interferon beta-1a)
19 Mar 2009
7 Feb 2003

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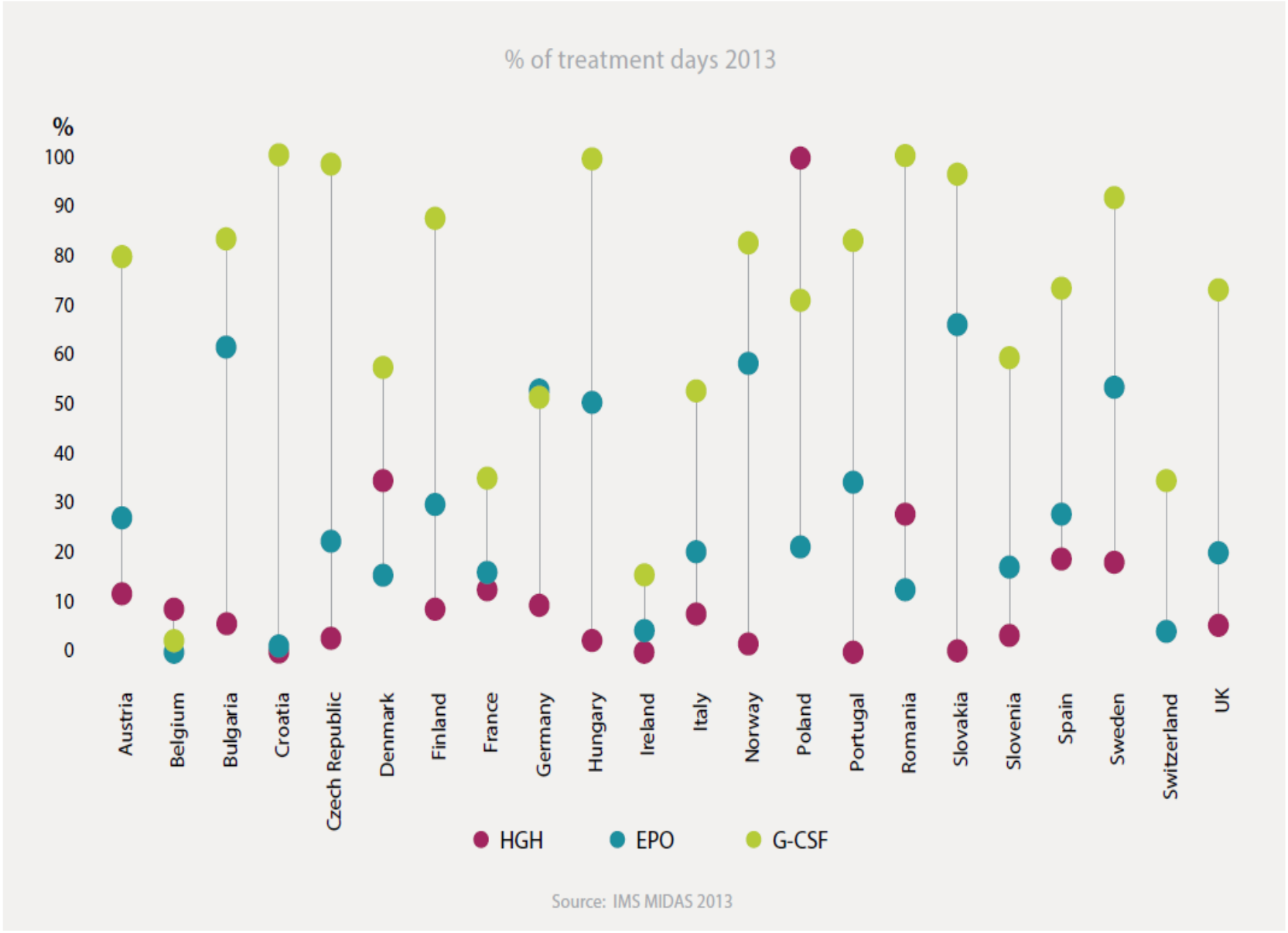
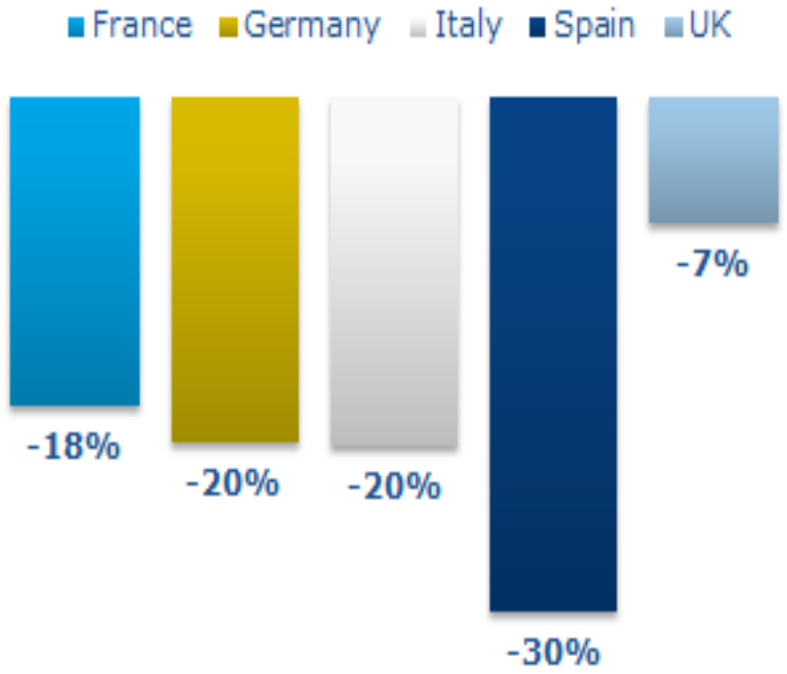
Biosimilar penetration: 3 examples



Average Price differential between originator and biosimilars by country



Source: PRICENTRIC™ - January 2013 data

Methodology: calculation based on Eprex®, Neupogen® and Genotropin® current ex-factory price per unit versus their lowest biosimilar, using 2 different strengths by brand

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Biosimilars, how low will they go (1)?

Difficult to predict future price reductions (& uptake)

- For a new biosimilar producer -30% probably possible;
- For original biological producer that recouped R&D costs, maybe 60-70% possible?
- Switching policy (biologicals -> biosimilars)
- Tendering for biosimilars?
- Dilemma for government: very low prices attractive, but good to have a few biosimilars in each class.

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Biosimilars, how low will they go (2)?

Rough suggestion:

- Government (preferably EU) offers a lump sum (a la prize fund) for first and second biosimilar in a class to recoup development costs;
- when first and second biosimilar on the market: tendering price with about 60-70% reduction,
- gives about equal playing field for biological and biosimilars

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What savings are realistic

- Savings depend on:
- uptake biosimilars and price reduction (as compared to the biological price before patent expiry)
- Uptake: **all new patients** on biosimilars
- Norway: by tendering price reduction 70% feasible

- Rough guess: NL 2019:
  - TNF alfa blockers -> about 10% cost reduction in 1st year (45 mln euro), increasing in subsequent years
- If switching patients on treatment allowed

Discussion

- Biosimilars: huge potential for savings in health care expenditure
- Reluctance explainable?
- Future savings very uncertain (price & uptake)
- Tendering attractive for biosimilars?
- best road to lower but sustainable prices?