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Payers' price & market access policies supporting a sustainable biosimilar medicines market

Final report

September, 2016

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Outline

- **Project objective and approach**
- Background: Mapping of market-specific pricing & market access policies
- Definition and assessment of sustainability in the biosimilar medicines market
- Conclusions
- Principles for a sustainable biosimilar medicines market for payer communication
- Appendix

Project objectives

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Overall objective

Assess the latest landscape of biosimilar medicines and understand the impact of pricing & market access policies on different parameters such as biosimilar medicines uptake and price in order to derive recommendations supporting a sustainable biosimilar medicines market

Key project goals

- **Analysis of current pricing & market access policies**
  - Provide an overview of current biosimilar medicines pricing and market access policies for markets in scope
  - Assess impact of policies on market uptake and price of selected biosimilar medicines (e.g., filgrastim & epoetins)
- **Analysis of savings and sustainability**
  - Estimate savings achieved by competition of biosimilar medicines
  - Understand the requirements for a sustainable biosimilar medicines market from a payer perspective
  - Analyze different procurement/purchasing practices with regard to their medium-/long-term sustainability, including ROI for biosimilar medicines companies and potential implications
  - Explore how discounts affect different parameters such as savings and patient access
  - Define the 'principles' policy models should fulfill to support sustainable biosimilar medicines business
- **Analysis of patient/health outcomes**
  - Understand the effect of biosimilar medicines competition on access and treatment guidelines as well as health outcomes
- **Synthesis of results and development of final report & payer communication**

Scope


France


Germany


Italy


Spain


UK


Norway


Poland

Source: Simon-Kucher & Partners

Overall project approach

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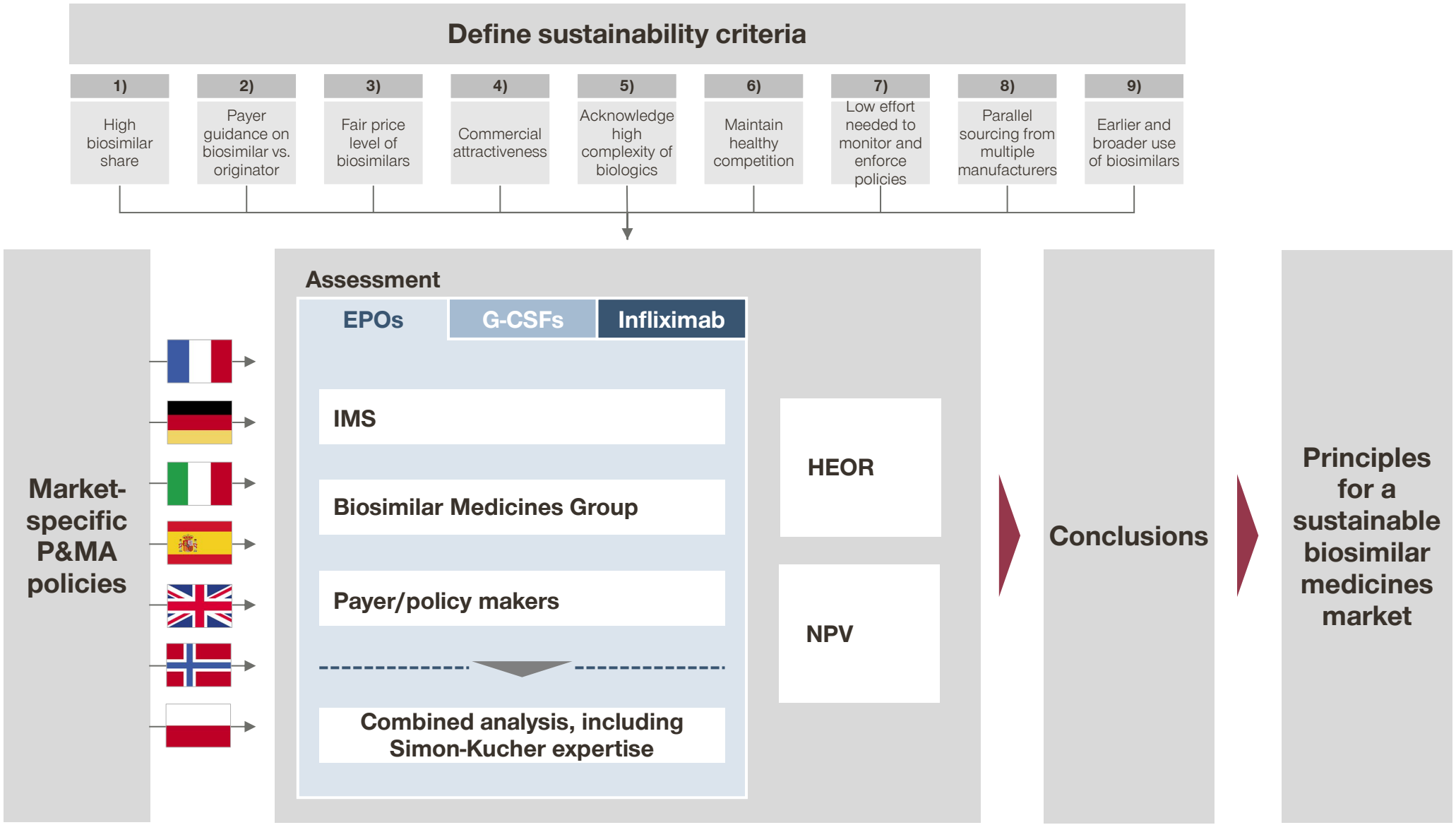

Source: Simon-Kucher & Partners

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As a crucial prerequisite for the upcoming analysis, Simon-Kucher mapped the market-specific biosimilar medicines pricing & market access policies

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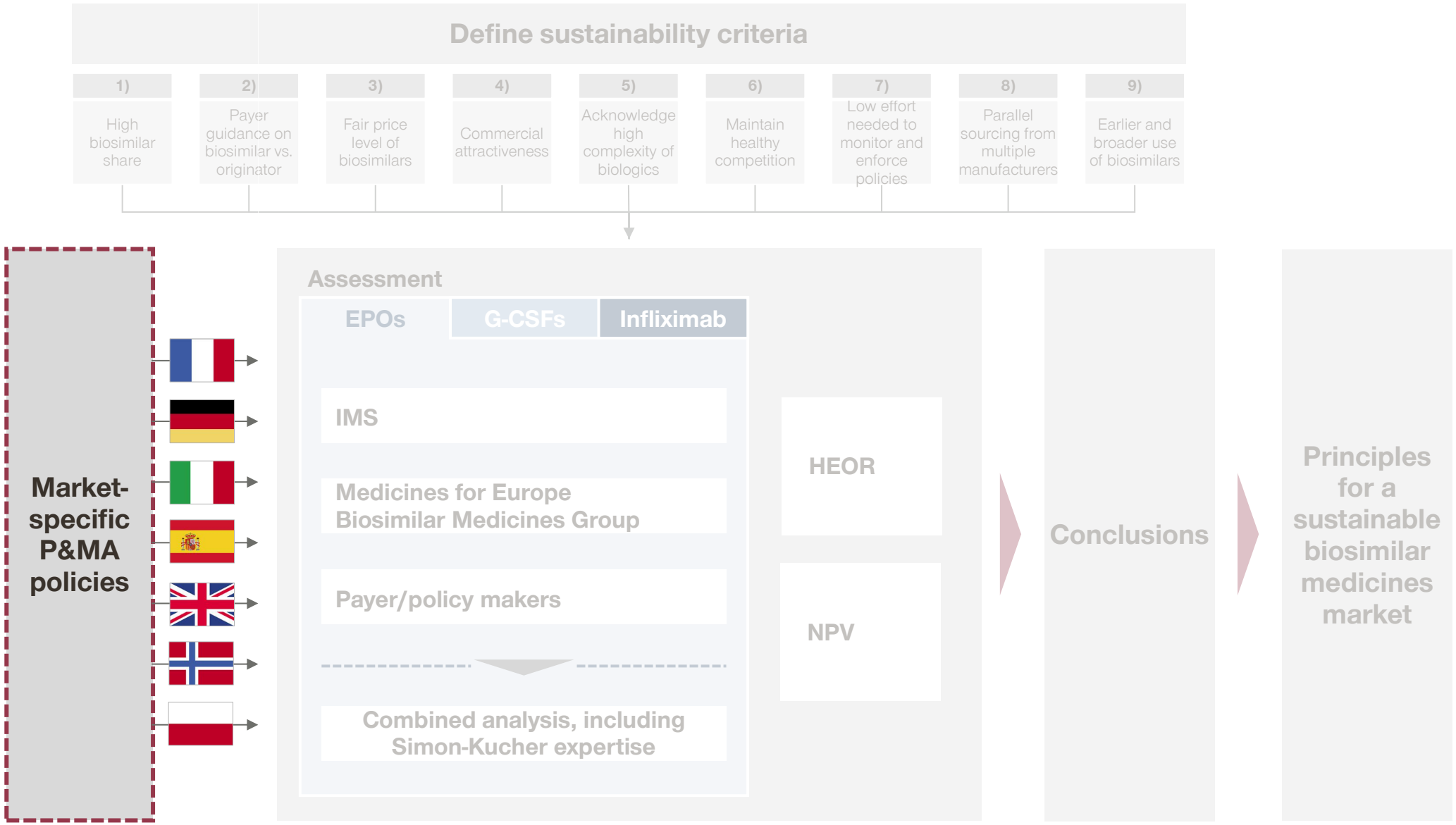

Source: Simon-Kucher & Partners

Payer policies and their influence on price development and uptake of biosimilar medicines in France

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Payer tools and policies

General P&MA regulations

- **Pricing & market access process:** Same process as for innovative medicines. However, chance of shortened TC review, same SMR level as originator, ASMR V by default
- **Hospital setting (T2A/retrocession list)**
  - Mandatory price cut of originator medicine (at least -10%)
  - Biosimilar price must be equal to or lower than originator price
  - Same dispensation status for biosimilar and originator medicines
- **Retail setting**
  - Mandatory price cut of originator medicine (-15 to -20%)
  - Biosimilar medicine needs to price at -25 to -35% relative to innovator's initial price

Drug procurement

- No active payer tools for epoetin, filgrastim and somatropin by payers; price is the main driver for biosimilar access[1]
- **Tenders:**
  - AP-HP[2] initially planned to perform a mixed single lot tender for infliximab, but in the end announced they would give the originator to pre-treated patients and thus align with ANSM[3] guidelines at that time
  - UniHA[4] decided to conduct a tender with two lots, one for previously treated patients and one for naïve patients (due to ANSM recommendation at that time not to switch patients)
- **Gainsharing:** Hospitals have an incentive to purchase T2A products at low prices, as difference between the reimbursement tariff and the price actually paid are split between hospitals and Social Security

Drug prescription

- ***No tools currently in place***
- **Hospital level:** No incentives for physicians to prescribe biosimilars (physicians typically base prescription decision on the hospital formulary)
- **Treatment switching:** ANSM does not formally exclude any interchangeability during treatment. To avoid uncontrolled exchange, interchangeability may be considered provided certain conditions are respected

Drug dispensation

- **Substitution of originator/biosimilar:** 2014 French Social Security Financing Law: Planned to be allowed under certain conditions (naïve patients only, same "similar biologic group" as defined by ANSM and prescribing physician has not explicitly prohibited the substitution → However, final implementation of law still depending on decree from the French Council of State)

Source: Simon-Kucher & Partners; [1] Hospital: dependent on type of hospital (public or private): tendering or direct negotiation with manufacturers; community pharmacy: purchasing from wholesalers or manufacturers at the fixed CEPS price or lower based on negotiations/tenders; [2] l'Assistance publique-hôpitaux de Paris (large hospital purchasing group); [3] National Agency for Medicine and Health Product Safety; [4] Union des hôpitaux pour les achats (large hospital purchasing group)

Payer policies and their influence on price development and uptake of biosimilar medicines in Germany

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	Payer tools and policies
General P&MA regulations	▪ **Pricing & market access process:** AMNOG process does not apply for biosimilar medicines ▪ **Biosimilar pricing:** Free pricing for biosimilar medicines (however, major discount vs. originator medicine expected) ▪ **Originator pricing:** No specific rules/regulations, however, if an FRP group is created, the originator's list price will usually be adjusted to the FRP level to be fully reimbursed ▪ **FRP group:** Composed of originators and biosimilars and is created on a case-by-case basis (e.g., observed with epoetins)
Drug procurement	▪ **Rebate contracts:** Rebate contracts reduce the net price to sick funds. Rebate contracts especially for infliximab in place, other biosimilar medicines (epoetins, filgrastims and somatropins) fractionally covered (market relevance is seen to be rather low here). ▪ **Open-house contracts:** Open-house contracts have been implemented especially for infliximab and etanercept, asking for a predefined relative rebate. All therapies entering the contract are considered to be cost-effective and recommended as economic treatment option ▪ **Therapy advice:** In place for epoetins and infliximab (however, no recommendation for usage to be restricted beyond label). The rather outdated therapy advice for infliximab so far does not account for the subsequently launched less expensive biosimilar medicines
Drug prescription	▪ **Biosimilar quotas:** Put in place by regional physician associations (KVs) in cooperation with sick funds (target agreement on biosimilar prescription shares, encourage economical prescribing). The level of quotas varies between KVs ▪ **Prescribing budget:** Sick funds and regional KVs negotiate a specialty-specific prescribing budget. Physicians need to prescribe rationally to avoid economic audits potentially leading to paybacks ▪ **Treatment initiation & switching:** No regulations on initiation/switching of biosimilar medicines therapies (physician bears the full responsibility)
Drug dispensation	**Automatic substitution at pharmacy level:** ▪ If prescribed by INN, pharmacists are not authorized to dispense the medicine but have to consult the prescribing physician ▪ If the biosimilar medicine is prescribed by brand name it can still be substituted by another biosimilar medicine in the case of similar bio-identity (as stated in the "Apothekenrahmenvertrag,"[1] i.e. biosimilars manufactured by the same company e.g., for Remsima® and Inflectra®)

Source: Simon-Kucher & Partners

[1]Section 129, subsection 1 of the Fifth Book of the German Social Code (SGB V) in connection with the framework agreement between the National Association of Statutory Health Insurance Funds and the German Pharmacists' Association on the supply of medicinal products in the version of 1 February 2011, which is based on section 129, subsection 2 of SGB V.

Payer policies and their influence on price development and uptake of biosimilar medicines in Italy

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	Payer tools and policies
General P&MA regulations	▪ **Pricing & market access process:** Same pricing & market access procedure as for originator medicine ▪ **Biosimilar pricing:** AIFA requests a minimum price reduction of 20% vs. originator medicine ▪ **Originator pricing:** No mandatory discount for originator medicines after LoE (however, AIFA started renegotiating prices of originator medicines where reimbursement has not yet been filed for biosimilar medicines)
Drug procurement	▪ **Tenders:** – For treatments of experienced patients, a specific lot is reserved for the originator medicine – Biosimilars for somatropin, epoetin, filgrastim, and infliximab are currently purchased in regional or local/hospital tenders – However, following the launch of infliximab biosimilar, Tuscany set up a tender without distinction between naïve patients and experienced patients. As a result, Inflectra® is the only available option for infliximab in Tuscany. A physician who wants to prescribe Remicade® (or Remsima®) has to fill out a specific form
Drug prescription	▪ **Biosimilar quotas:** – Quotas/usage guidelines (regional & local) are already in place for existing biosimilars (filgrastim, somatropin, epoetin) in Tuscany, Veneto and Campania. However, quotas are not binding and so far real-life prescribing is not fully compliant with them – Definition of biosimilar quota is likely to differ from region to region ▪ **Mandatory INN prescription:** Does not apply to biosimilar medicines, since they are not considered equivalent products (biosimilar medicines excluded from transparency list), i.e. physicians are being asked to prescribe via brand name ▪ **Treatment initiation:** Different regional/local (hospital) guidelines/recommendations may apply e.g., biosimilar quotas for naïve patients or use of biosimilar medicines in all naïve patients (however, final decision still lies with prescribing physician) ▪ **Treatment switching:** No guidance from public institutions (AIFA), but heavily discussed between clinicians/pharmacists
Drug dispensation	**Automatic substitution at pharmacy level:** ▪ **Originator:** Not possible due to diversity of biosimilar/biologic medicines ▪ **Biosimilars:** Currently excluded from the transparency lists that would support substitutability between equivalents

Source: Simon-Kucher & Partners

Payer policies and their influence on price development and uptake of biosimilar medicines in Spain

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	Payer tools and policies
General P&MA regulations	▪ **Pricing & market access process:** Same pricing & market access procedure as for originator medicines (however, process is typically shortened) ▪ **Originator pricing:** No mandatory discounts after LoE/biosimilar entry beyond (mandatory) creation of FRP group ▪ **FRP group:** For originator and biosimilar medicines after LoE/biosimilar entry (however, given the purchasing system in place for hospital drugs the FRP price is not very relevant). Expected discounts for originator and biosimilar: -25 to -30%
Drug procurement	▪ **Regional/local tenders:** Originator and biosimilar medicines are mainly purchased via mixed tenders for naïve patients ▪ **Direct purchasing:** Patients already under treatment are mainly treated with originator medicines, usually purchased directly from the manufacturer
Drug prescription	▪ **Biosimilar quotas:** Currently not in place. However, the region of Madrid is considering applying biosimilar quotas, given the good examples of Germany. If implemented, other regions will likely follow ▪ **Regional drug evaluation:** Regions issue clinical regional evaluations on new medicines, with the objective of driving and standardizing physicians' prescriptions, and notifying them of less expensive alternatives ▪ **Budget targets:** Regions/hospitals set a budget cap per patient (and per pathology), and physicians need to prescribe rationally in order to avoid cost-cutting measures (e.g. cutting personal expenses) ▪ **Therapeutic equivalence:** Some regions (like Andalusia) defined anti-TNFs to be therapeutic equivalents (composed of originators and biosimilar medicines) to encourage economic prescribing ▪ **Treatment switching:** No regulations on switching stable patients from originator medicine to the respective biosimilar medicine (physician bears the full responsibility)
Drug dispensation	▪ **Automatic substitution not possible:** At the hospital pharmacy, the pharmacist needs to dispense the commercial name prescribed by the physician. Biosimilar medicines are to be prescribed by brand name[1]

Source: Simon-Kucher & Partners
1 ORDER SCO / 2874/2007, of September 28,

Payer policies and their influence on price development and uptake of biosimilar medicines in the United Kingdom

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Payer tools and policies

General P&MA regulations

- **Pricing & market access process:**
  - Standard pricing and market access process applies
  - NICE issued its latest guidance and advice on biosimilars medicines in January 2015, saying that biosimilar medicines should be either subject to MTA[1] together with the originator medicine or to less prescriptive 'evidence summaries'
- **Originator pricing:** No defined pricing rules after launch of biosimilar medicines
- **Biosimilar pricing:** Free pricing for biosimilar medicines – included under and indirectly controlled by PPRS[2] regulation

Drug procurement

- **Four regional tenders:** Originator/biosimilar medicine placed in the same tender only if considered interchangeable:
  - Simple molecules are considered substitutable – single lot tender (e.g. EPO)
  - Complex molecules are not considered substitutable – separate tender for naïve and patients already under treatment (e.g. G-CSF, infliximab)
- **Gainsharing:** Purpose to reward economical prescribing. Savings through cost-effective prescribing are split between the CCG (funding) and the hospital (prescribing). However, not yet commonly implemented due to the complexity of splitting the generated savings

Drug prescription

- **Therapeutic guidance:**
  - Treatment initiation: NICE recommends starting treatment with the cheapest option. This is a significant opportunity for biosimilar medicines as they are likely to be able to achieve a lower ICER[3]
  - Treatment switching: No national rule – depends on specific product/case. In 2015, two NHS trusts successfully implemented pilot projects with selected hospitals to enforce controlled switching (for Crohn's disease patient for infliximab)
  - In general, CCGs have started to issue statements encouraging the use of biosimilar medicines, however, physicians still have certain therapeutic flexibility
- **Prescribing restrictions:** E.g. secondary care prescription of originator medicine also applies to biosimilar medicines

Drug dispensation

- **Automatic substitution of originator/biosimilar:**
  - Not possible, NICE recommends prescribing by brand name ('biosimilar medicines should be considered as medicines in their own right rather than generic versions of a branded originator medicine')
  - In the event that the branded biologic or biosimilar medicine prescribed by the clinician is unavailable, the dispensing pharmacist must contact the prescribing clinician to seek advice on appropriate short-term alternatives

Source: Simon-Kucher & Partners; [1] Multiple Technology Appraisal; [2] Pharmaceutical Price Regulation Scheme; [3] Incremental cost-effectiveness ratio

Payer policies and their influence on price development and uptake of biosimilar medicines in Norway

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Payer tools and policies

General P&MA regulations

- **Pricing & market access process:** Biosimilar medicines follow the same pricing & market access pathway as other pharmaceutical products
- **Biosimilar pricing:**
  - 9% mandatory discount required vs. originator list price in order to be listed by the Norwegian Drug Procurement operation (LIS)
  - However, as of today, the 'stepped price model' which applies for generic medicines is not valid for biosimilar medicines as they are not seen as interchangeable with the originator medicines

Drug procurement

The status of biosimilar medicines in the pricing & market access process in Norway is not yet clearly defined

- **National tender:**
  - Hospital purchasing is performed by LIS via price-sensitive national tender processes
  - Prices that are achieved in the tender process are usually considerably lower compared to the pharmacy purchasing price (PPP)
  - Several manufacturers and their offered prices will be listed, but usually the majority of prescriptions will go to the least expensive offer due to recommendation by LIS special group committee (in cooperation with renown physicians/KOLs)

Drug prescription

- **Treatment initiation:** Treatment options for treatment-naïve patients based on the outcome of the tender process
- **Treatment switching:**
  - Switching patients to biosimilar medicines is allowed and meanwhile common practice among physicians
  - Infliximab: Efficacy and safety data when switching patients from Remicade® (originator) to Remsima® (biosimilar) is currently being assessed in a clinical study sponsored by the Norwegian Health Ministry ('NORSWITCH' study)
  - Intent of the 'NORSWITCH' study is to support the idea that biosimilar medicines are being seen as interchangeable. However, there is already broad consensus among experts and prescribing physicians that interchangeability is given

Drug dispensation

- **Automatic substitution of originator/biosimilar:** Not allowed

Source: Simon-Kucher & Partners

Payer policies and their influence on price development and uptake of biosimilar medicines in Poland

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Payer tools and policies

General P&MA regulations

- **Pricing & market access process:** Biosimilar medicines treated like generic medicines throughout pricing & market acess process (AOTMiT and TC are skipped, and HTAs are not carried out)
- **Originator pricing:** According to the 2012 Reimbursement Act, medicines losing exclusivity must decrease their price by 25% when re-applying for reimbursement at LoE (however, not always observed in reality, due to likely confidential contracting agreements)
- **Biosimilar pricing:** Mandatory discount of 25% vs. the originator's reimbursement price
- **FRP group:**
  - Drugs within the same INN or different INN but similar therapeutic effects and mode of administration are automatically classified into FRP groups (including originator and biosimilar medicines)
  - Filgrastim, epoetin, somatropin and infliximab have been categorized into FRP groups

Drug procurement

- **Hospital setting:**
  - Hospital medicine procurement through tenders with price as the main criterion
  - NHF[1] funds hospital medicines up to FRP limit, thus encouraging biosimilar medicine procurement (if it is the cheapest)
  - No "cash" gainsharing for hospitals, but more patients can be treated within the existing budget of the respective drug program
- **Retail setting:**
  - No impact of payers on purchasing process, mainly influenced by physician/patient due to co-payment

Drug prescription

- **Treatment switching:** Only guidance on national level for the example of infliximab: The Minister of Health stated that any exchange within the scope of drugs containing infliximab at any level of therapy is permissible

Drug dispensation

- **Substitution of originator/biosimilar:**
  - Retail setting[2]: Both, originator and biosimilar medicines are substitutable (pharmacist is obliged to inform patients about cheaper biosimilar medicines and if requested, dispense). Co-payment incentivizes patients to request the cheapest option
  - Hospital setting: Substitution is limited (usually only one product available for a particular active substance)

Source: Simon-Kucher & Partners; [1] National Health Fund; [2] Physician can explicitly prohibit substitution at pharmacy level on the particular prescription

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- **Definition and assessment of sustainability in the biosimilar medicines market**
  - **Definition of 'Sustainability Criteria'**
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Simon-Kucher & Biosimilar Medicines Group defined multiple criteria reflecting a sustainable biosimilar medicines market from the perspective of payers and manufacturers

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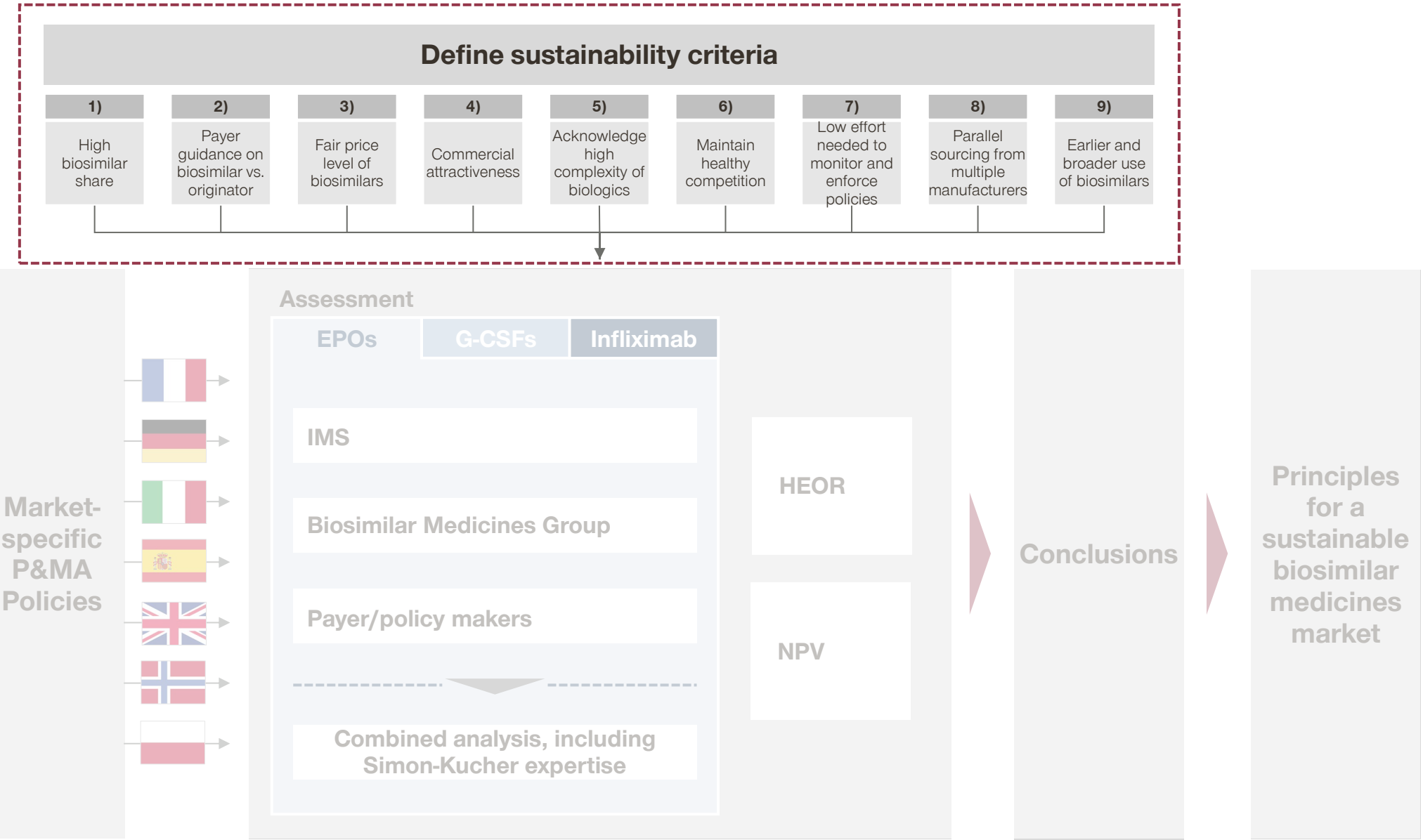

Source: Simon-Kucher & Partners

While the analysis covers both internal and external factors affecting sustainability of the biosimilar medicines market, the recommendations focus mostly on external factors

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Factors affecting sustainability of the biosimilar medicines market

External factors,
i.e. payers' biosimilar medicines policies

- Payer rules define the action space of all biosimilar manufacturers in a particular market environment, such as mandatory price cuts
- Decisions that biosimilar manufacturers do not have any direct influence on

Covered in analysis	✓
Covered by recommendations	✓

Internal factors,
i.e. manufacturers' behavior

- Management decisions made by the biosimilar manufacturers themselves within a particular market environment, such as voluntary price decreases or market exit
- Artefacts, i.e. clearly irrational behavior will ideally be excluded from analysis

Covered in analysis	✓
Covered by recommendations	✗

Recommendations can only be directional since they depend on the specific business case

Source: Simon-Kucher & Partners ✓ = Yes ✗ = No

Ideally, sustainability criteria would reflect both manufacturer and payer perspectives

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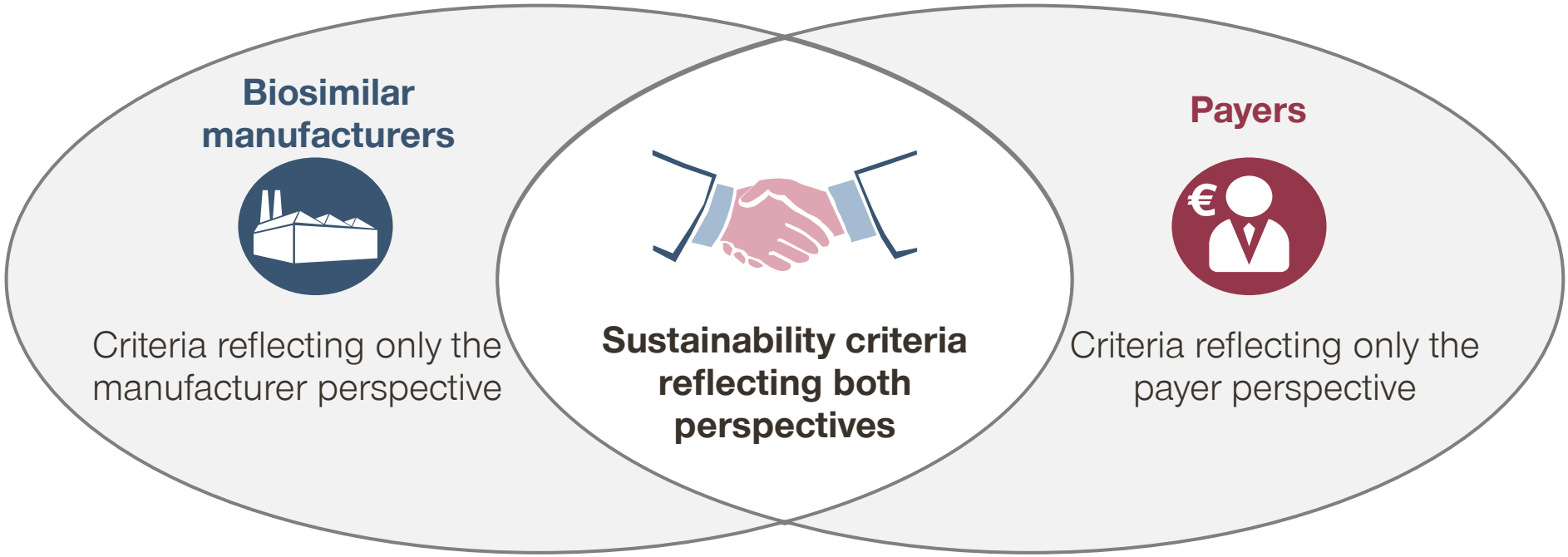

Source: Simon-Kucher & Partners

How would the different stakeholders describe the ideal sustainable biosimilar market?

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Biosimilar manufacturers

*"A sustainable biosimilar market is a **predictable** market supporting the **co-existence** of biosimilar manufacturers and a **price-volume combination that enables continuous investment in further innovation**."*

Payer

*"A sustainable biosimilar market is a market in which biosimilars **create financial savings without jeopardizing the current treatment standards.**[1]"*

Criteria for a sustainable biosimilar market were defined that find <u>acceptance among both stakeholder groups</u>, payers and manufacturers

Source: Simon-Kucher & Partners; [1]Payers' interpretation of sustainability only applicable to markets within project scope (France, Germany, Italy, Spain, UK, Norway, Poland) and might deviate in other countries

Criteria are designed to reflect how both payers and manufacturers view the ideal sustainable biosimilar medicines market

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? Which criteria best describe a sustainable biosimilar medicines market?

Biosimilar manufacturers

Payer

1) High biosimilar share
2) Payer guidance on biosimilars vs. originators
3) Fair price level for biosimilar
4) Commercial attractiveness
5) Acknowledgement of high complexity of biologics within P&MA process
6) Maintain healthy competition in the long-term
7) Low effort needed to monitor and enforce policy
8) Parallel sourcing from multiple manufacturers (short-term perspective)
9) Earlier and broader use of biosimilar in additional patient segments

Source: Simon-Kucher & Partners

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To evaluate the defined sustainability criteria, Simon-Kucher analyzed the IMS data for EPO's, G-CSF's and infliximab

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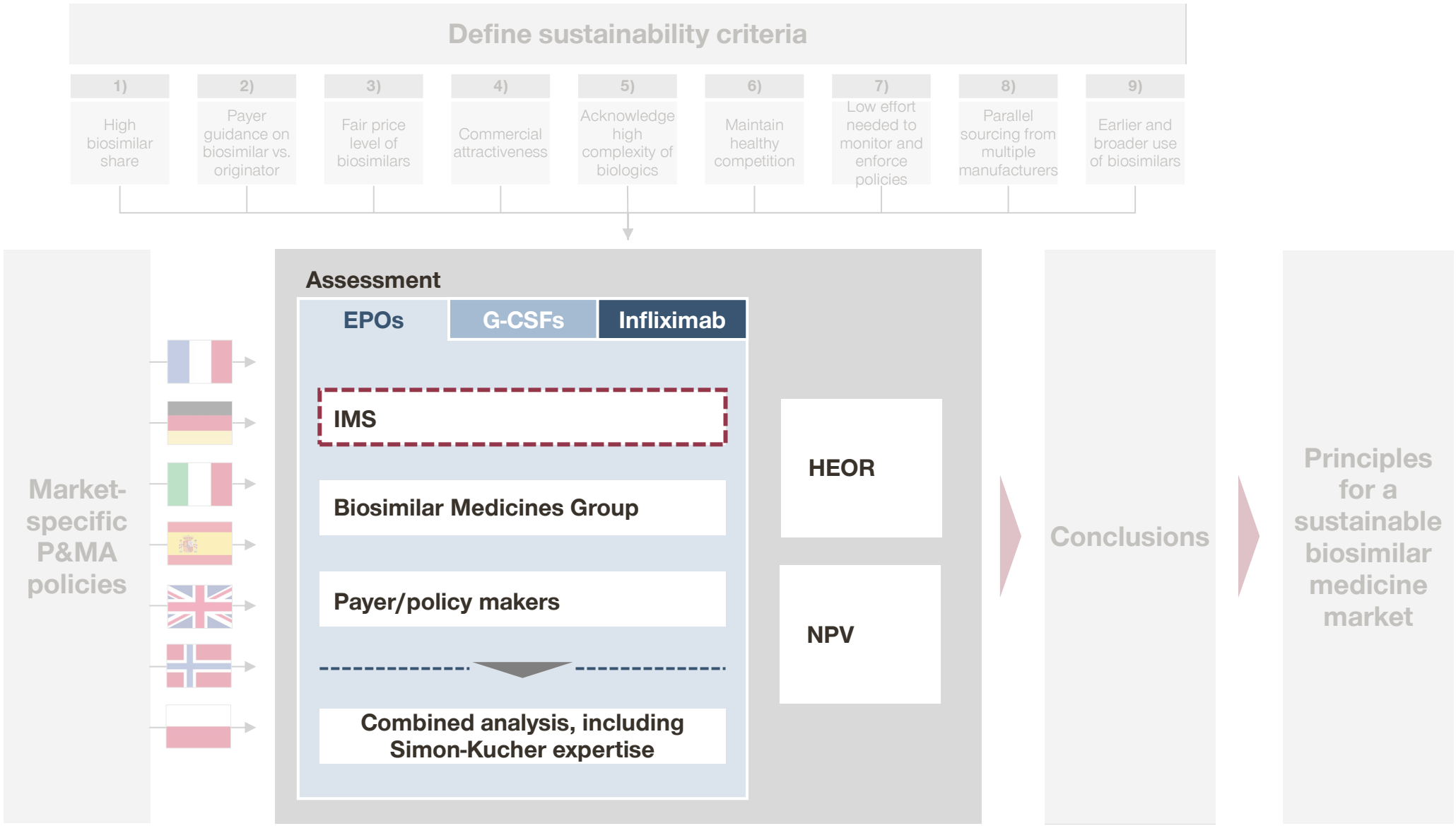

Source: Simon-Kucher & Partners

Four main sustainability criteria were analyzed by means of IMS data

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Evaluation of sustainability criteria with IMS data	
Sustainability criterion	**Primary source**
1) High biosimilar share	✓
2) Payer guidance on biosimilars vs. originators	✗
3) Fair price level for biosimilar	✓ Only on list price level
4) Commercial attractiveness	✗
5) Acknowledgement of high complexity of biologics within pricing & market access process	✗
6) Maintain healthy competition in the long-term	✓
7) Low effort needed to monitor and enforce policy	✗
8) Parallel sourcing from multiple manufacturers (short-term perspective)	✓
9) Earlier and broader use of biosimilar in additional patient segments	✗

✓ = IMS data used as primary source ✗ = IMS data not being used as primary source

Source: Simon-Kucher & Partners; [1] Separate IMS data for hospital and retail setting available

The IMS data set:

Structure:

- Time horizon: 2006–2015
- Market scope: EU-5, Norway, Poland
- Setting[1]: Hospital & Retail
- Product categories: Epoetin, filgrastim, infliximab
- Classification: Reference products, accessible/non-accessible products and biosimilars

Data:

- Epoetin and filgrastim: Yearly treatment days and sales across all markets and manufacturers
- Infliximab: Quarterly data

IMS data: Biosimilar medicines share across markets for epoetin, filgrastim and infliximab to evaluate level of biosimilar medicines uptake

1 **Sustainability criterion:** High biosimilar share

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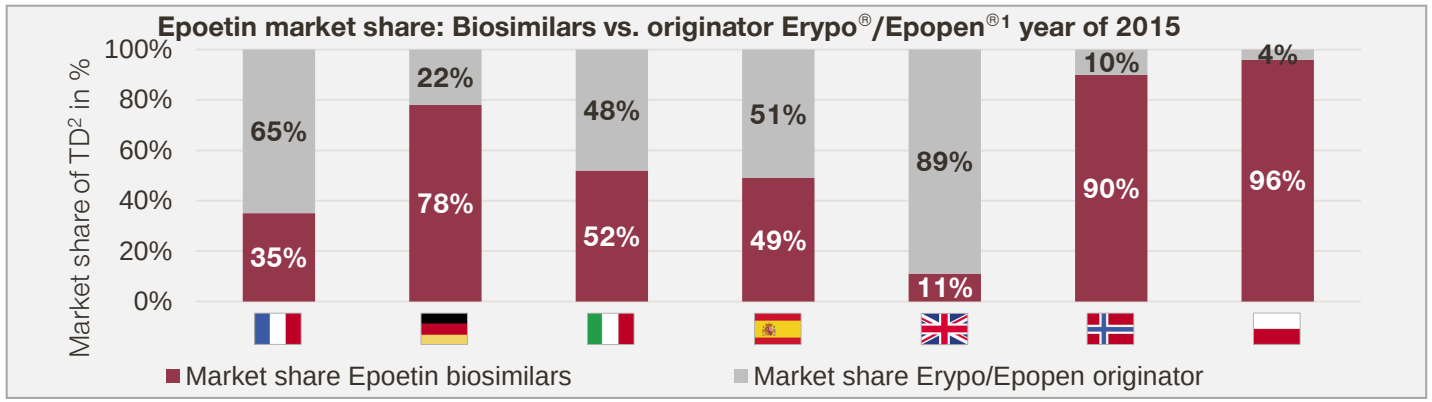

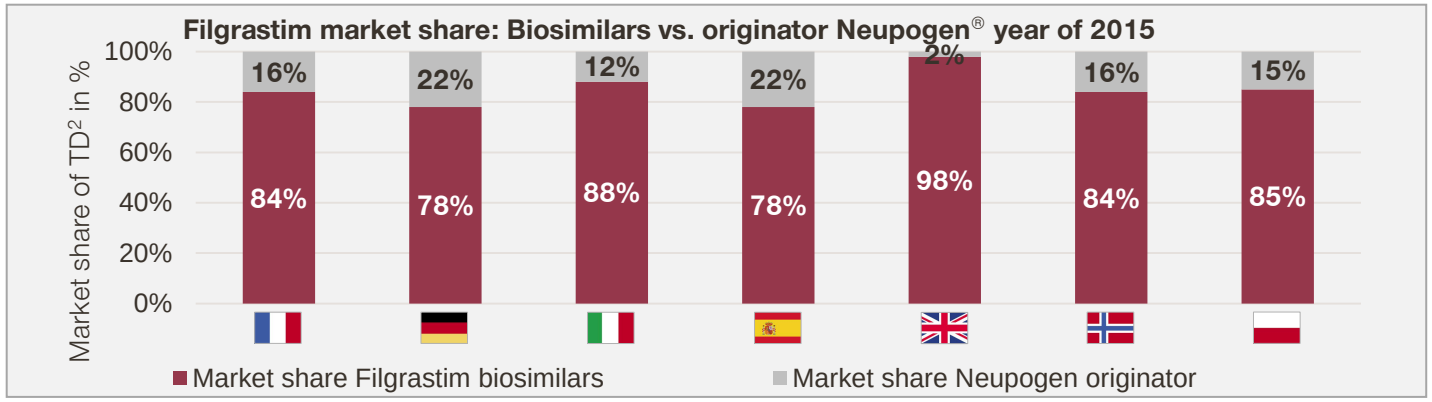

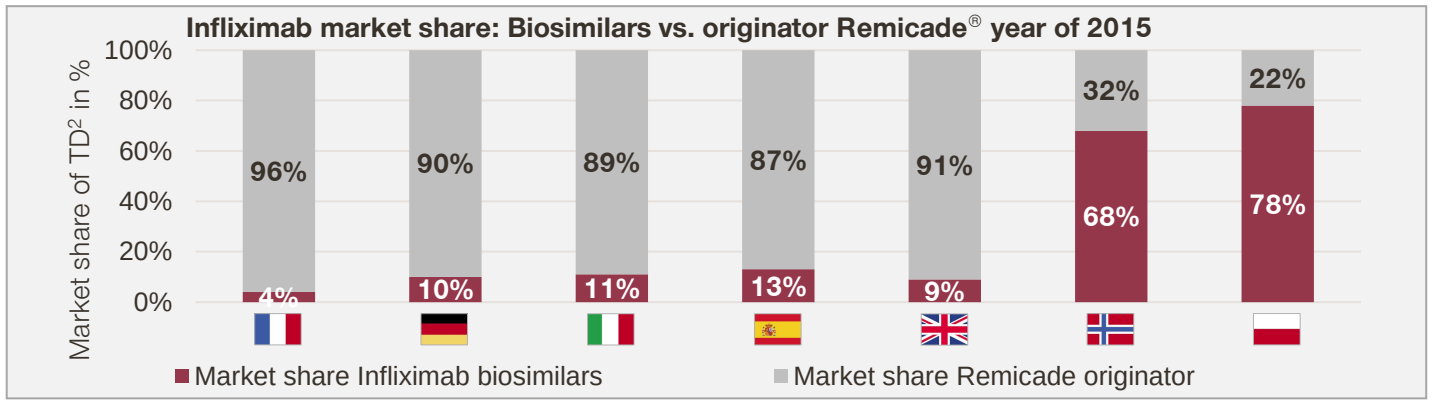

Source: Simon-Kucher & Partners; IMS Health; [1] Epoetin originator = Epopen® in Spain; [2] Treatment days

Key insights:

- : Policies seem to be effective in terms of biosimilar uptake since findings across all three product categories are consistent. This is especially true given the early, high share of infliximab biosimilars
- : High variance regarding biosimilar market shares across product categories is assumed to be driven by:
  - Further (unknown) net price differences
  - Higher prices of filgrastim vs. EPO allowing for additional wiggle room for biosimilar manufacturers when negotiating net prices
  - Higher payer focus on certain indications (e.g. indications with higher budget impact) when enforcing biosimilar policies
  - National differences regarding predominant treatment setting and physician preferences

IMS data: Biosimilar medicines price across markets for epoetin, filgrastim and infliximab to evaluate level of price erosion

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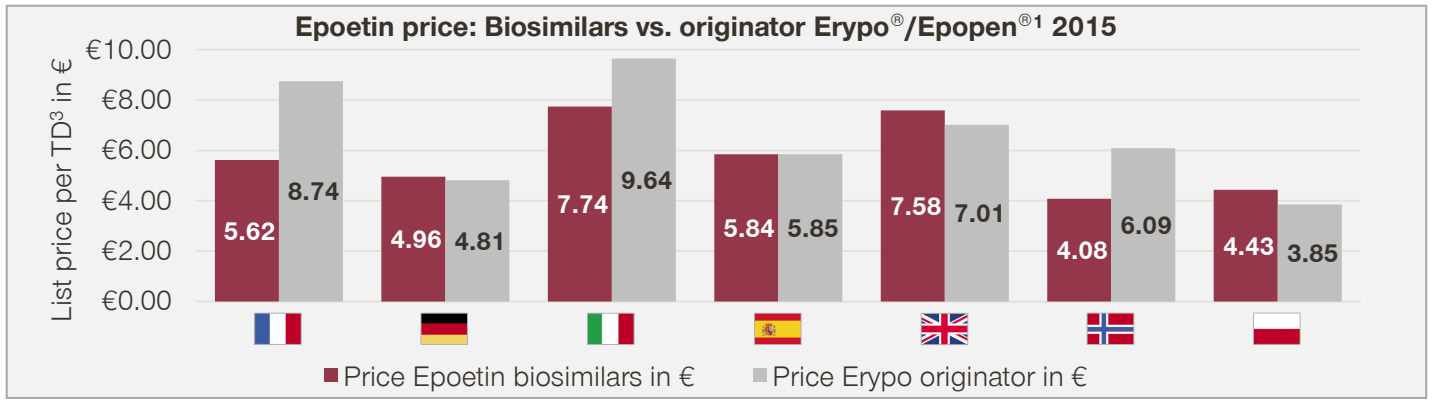

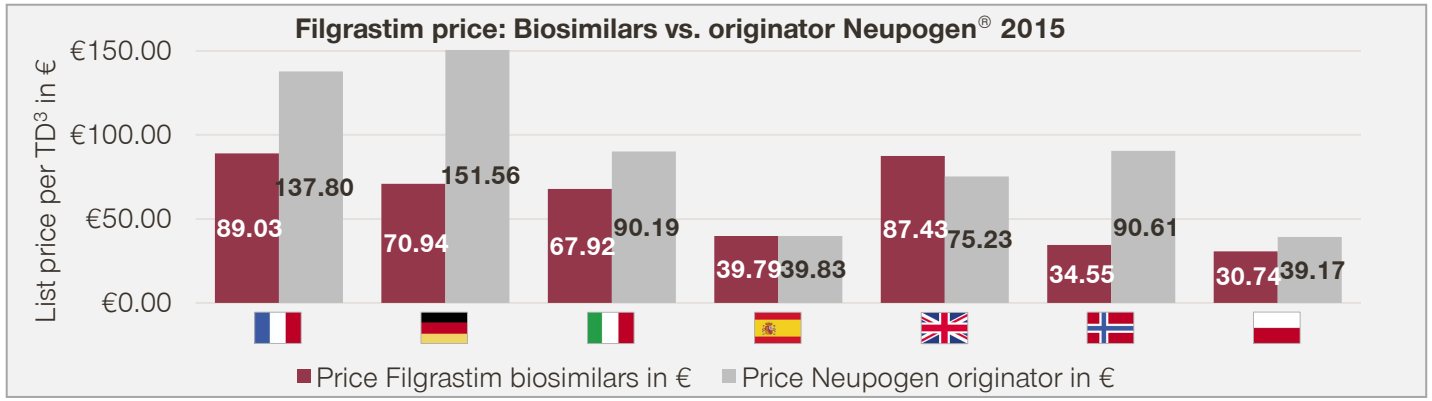

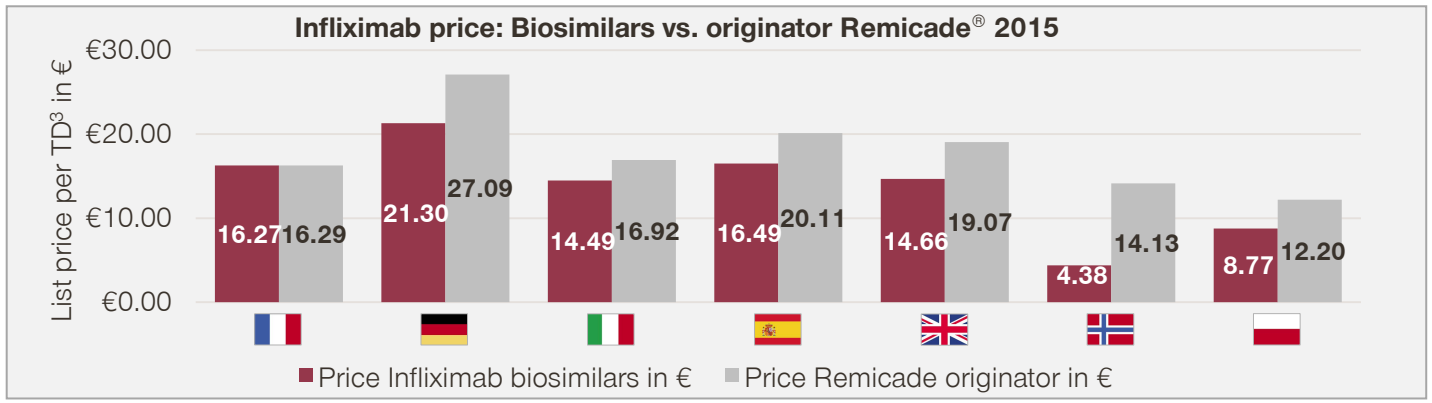

Source: Simon-Kucher & Partners; IMS Health; [1] Epoetin originator = Epopen® in Spain; [2] Similar price relations assessing hospital & retail individually; [3] Treatment day

Shown biosimilar prices reflect:
- Averaged, weighted by TD[3], across retail and hospital setting[2] and all involved biosimilar manufacturers
- **Officially available list prices, not including confidential discounts**

Key insights:

- IT, NO: Biosimilar prices are significantly lower than originator prices across all three product categories
- FR, DE: Biosimilar is priced lower than originator (excl. epoetin in Germany); however, the difference in price strongly varies between epoetins, filgrastim and infliximab
- ES, UK, PL: Biosimilars and originators priced in a similar range

Conclusion:
List price data not overly meaningful except for Italy and Norway where list price differences (biosimilar vs. originator) are substantial, even though additional significant discounts can be found on net level

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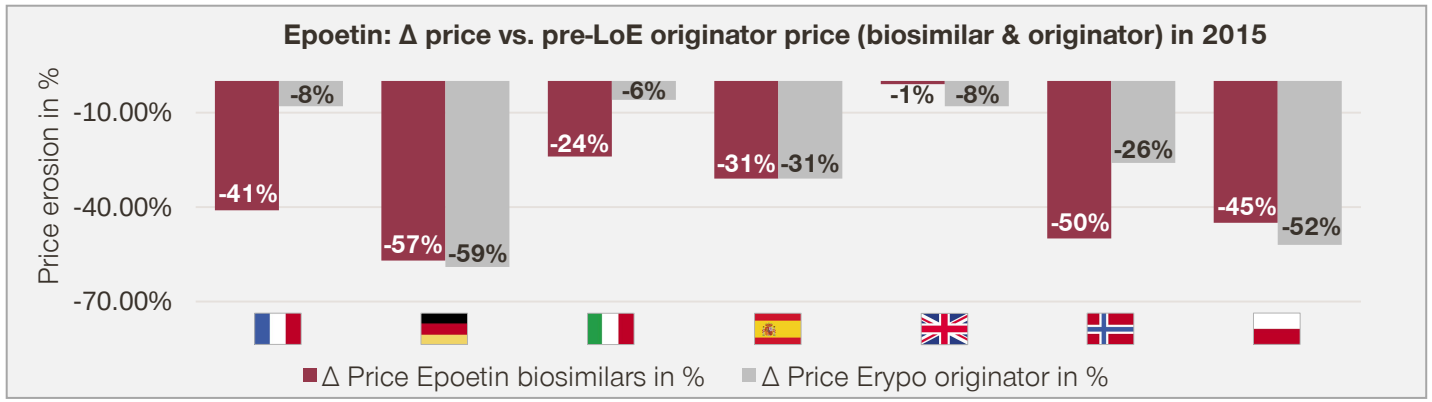
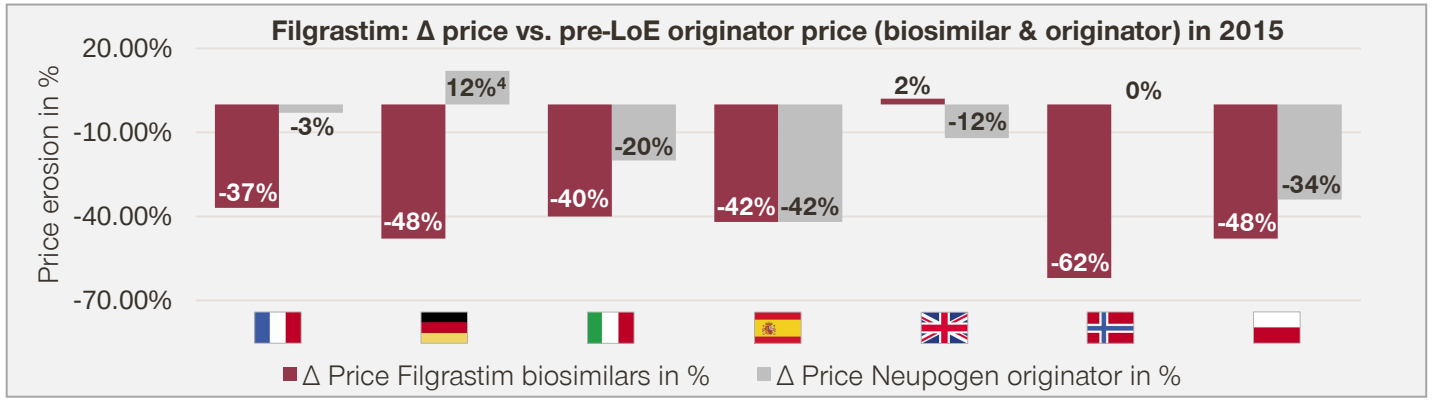
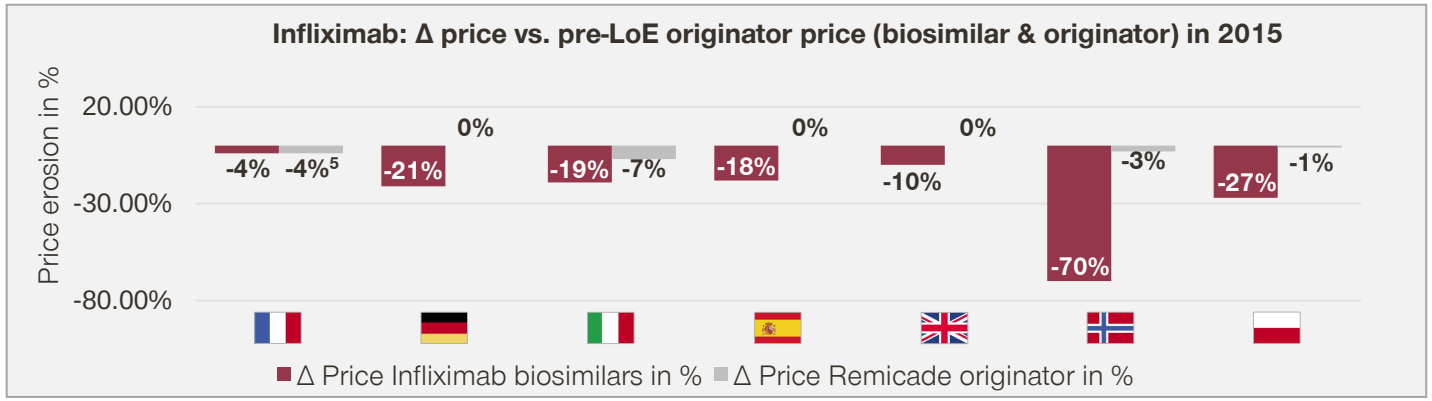
IMS data: Price change of biosimilar and originator medicines since launch for epoetin, filgrastim and infliximab biosimilars







Source: Simon-Kucher & Partners; IMS Health; [1] Epoetin originator = Epopen® in Spain; [2] Similar price relations assessing hospital & retail individually; [3] Treatment day; [4] Price increase of originator may be an artefact due to changes of the mandatory discount in GER over the last years; [5] 10% mandatory price cut after LoE may have not fully materialized in first year after LoE

Shown price changes reflect:
Percentual increase/decrease in weighted, averaged biosimilar prices and originator prices from 2009 to 2015 based on originator price in year before biosimilar launch

Key insights:

- 🇩🇪 🇳🇴 🇵🇱: Prices are significantly eroding across all indications and countries, with highest price differences to originator price prior to biosimilar launch
- 🇩🇪 🇪🇸: Equally leveled price erosions reflect existence of regulating FRP groups (Germany: epoetin)

Conclusion: Significant price erosions on list price level leave noteworthy gap between biosimilar and originator prices

IMS data: Number of active biosimilar medicines manufacturers to evaluate possibility of parallel sourcing (2009–2015)

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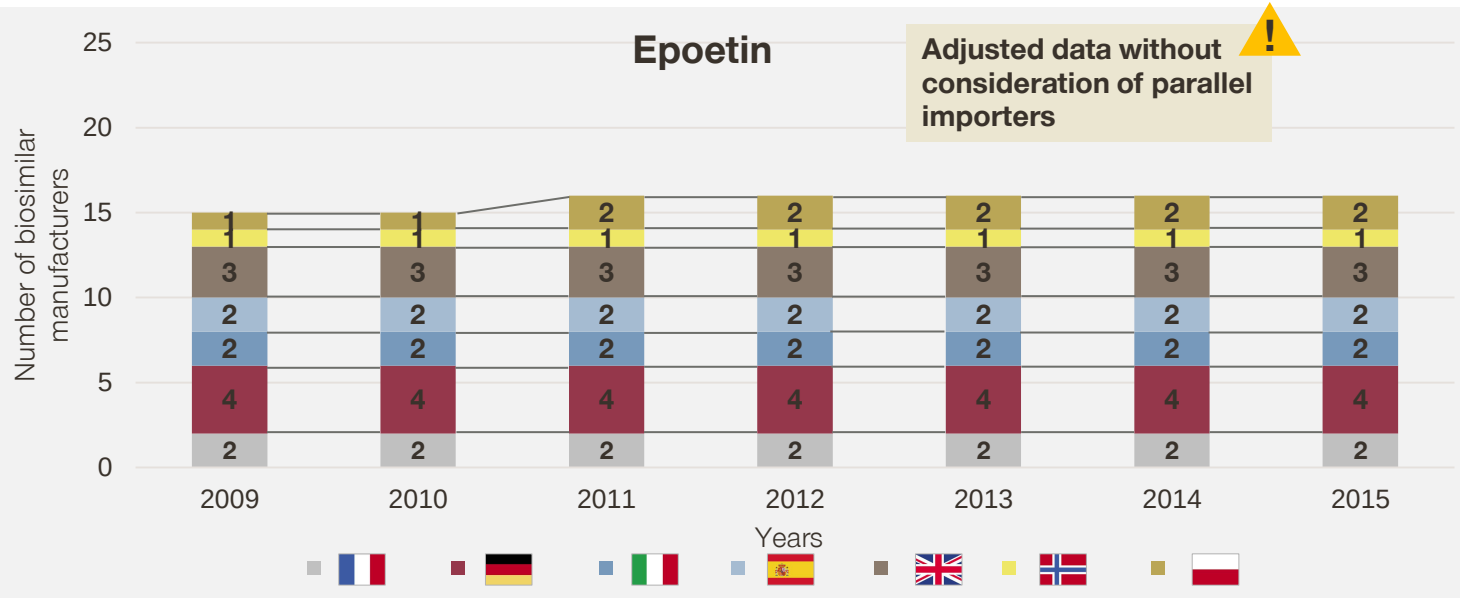

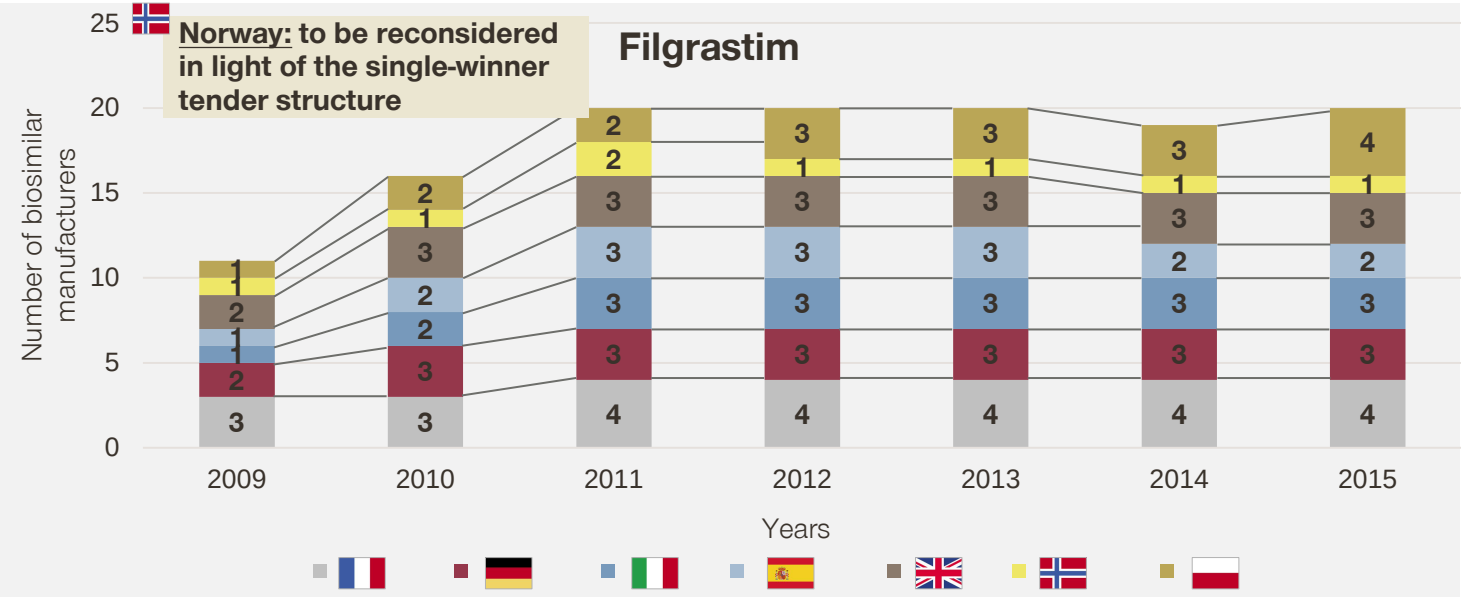

Source: Simon-Kucher & Partners; IMS Health; # = number

Key insights:

With some exceptions, there is a constant absolute number of active biosimilar manufacturers in markets in scope:

- : Highest # of biosimilar manufacturers (epoetin)
- : Rather low # of biosimilar manufacturers observed due to national tender system

Change in # of active biosimilar manufacturers:

- : Slight increase in # of active manufacturers observed for filgrastim
- : # of manufacturers predominantly stable across seven years

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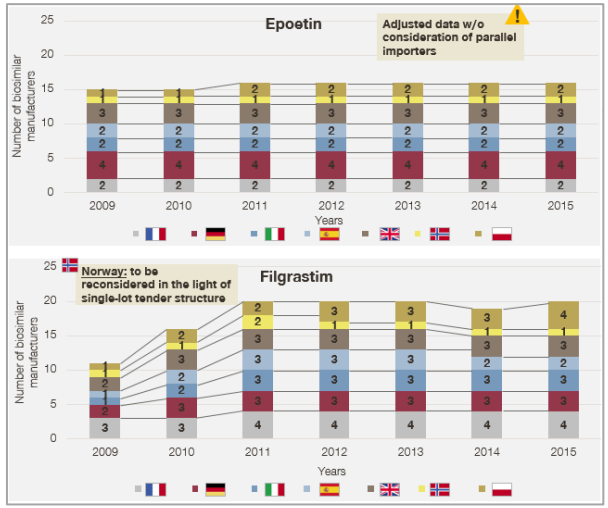
Conceptual

The level of competition for a particular product and market could be measured by calculating an 'index of healthy competition'

a Calculate average # of active biosimilar manufacturers per product & market (2009–2015)



Example:

: On average, 1.7 epoetin biosimilar manufacturers have been active in the market in the observed period of time

×

b Calculate average market activity duration per product and market (2009–2015)

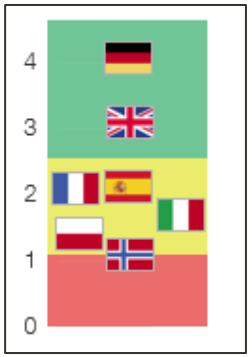
Biosimilar (Epoetin)	Manufacturer	Years							Market activity duration	
		2009	2010	2011	2012	2013	2014	2015	∑ years	%
Abseamed	Medice	✓	✓	✓	✓	✓	✓	✓	7	100% [7÷7]
Binocrit	Novartis	✗	✗	✓	✓	✓	✓	✓	5	71% [5÷7]
Retacrit	Pfizer	✗	✗	✗	✗	✗	✗	✗	0	0%
									Ø 6	Ø 85,5

Example:

: The epoetin biosimilar manufacturers have been actively participating in the market (generating sales) for 85.5% of the observed period (7 years)

=

c Calculate 'index of healthy competition'



Index of healthy competition:

Multiplying the average number of active biosimilar manufacturers with the average duration of market activity, for a particular market & product, will give you the index of healthy competition, serving as a guiding principle to assess the level of competition

Example:

: Epoetin index for healthy competition is calculated by multiplying a × b.
→ 1.7 × 85.5% = 1.45

Source: Simon-Kucher & Partners; # = number

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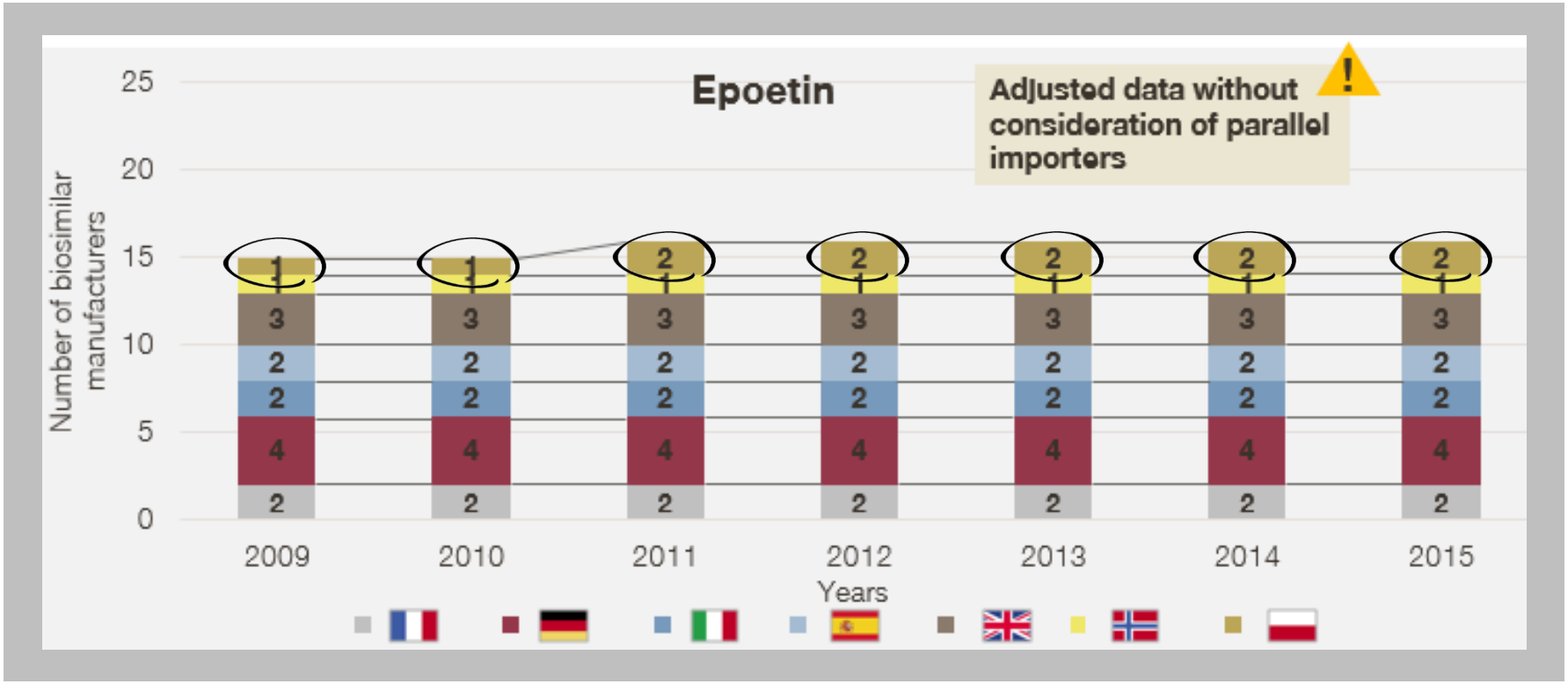
a IMS data: Calculate average number of active biosimilar manufacturers per product and market (2009–2015)

Conceptual



= average of 1.7 biosimilar manufacturers

Example

- Average number of active biosimilar manufacturers: **1.7 biosimilar manufacturers**
- Over the observed period of seven years, on average 1.7 manufacturers have actively been selling biosimilar medicines on the Polish market

Source: Simon-Kucher & Partners

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b IMS data: Calculate average market activity duration per product and market (2009–2015)

Conceptual

Average market activity duration: The average number of years a biosimilar manufacturer actively participates in the market (generating sales) over a defined period of time

Example

Example

Biosimilar (Epoetin)	Manufacturer	Years							Market activity duration	
		2009	2010	2011	2012	2013	2014	2015	∑ years	%
Abseamed	Medice	✓	✓	✓	✓	✓	✓	✓	**7**	100% [7÷7]
Binocrit	Novartis	✗	✗	✓	✓	✓	✓	✓	**5**	71% [5÷7]
									Ø 6	**Ø 85,5**

On average, a Polish epoetin biosimilar manufacturer participates in market activities for 6 years (85.5% of observed period)

✓ = Market involvement ✗ = Market absence

Source: Simon-Kucher & Partners; Ø = average

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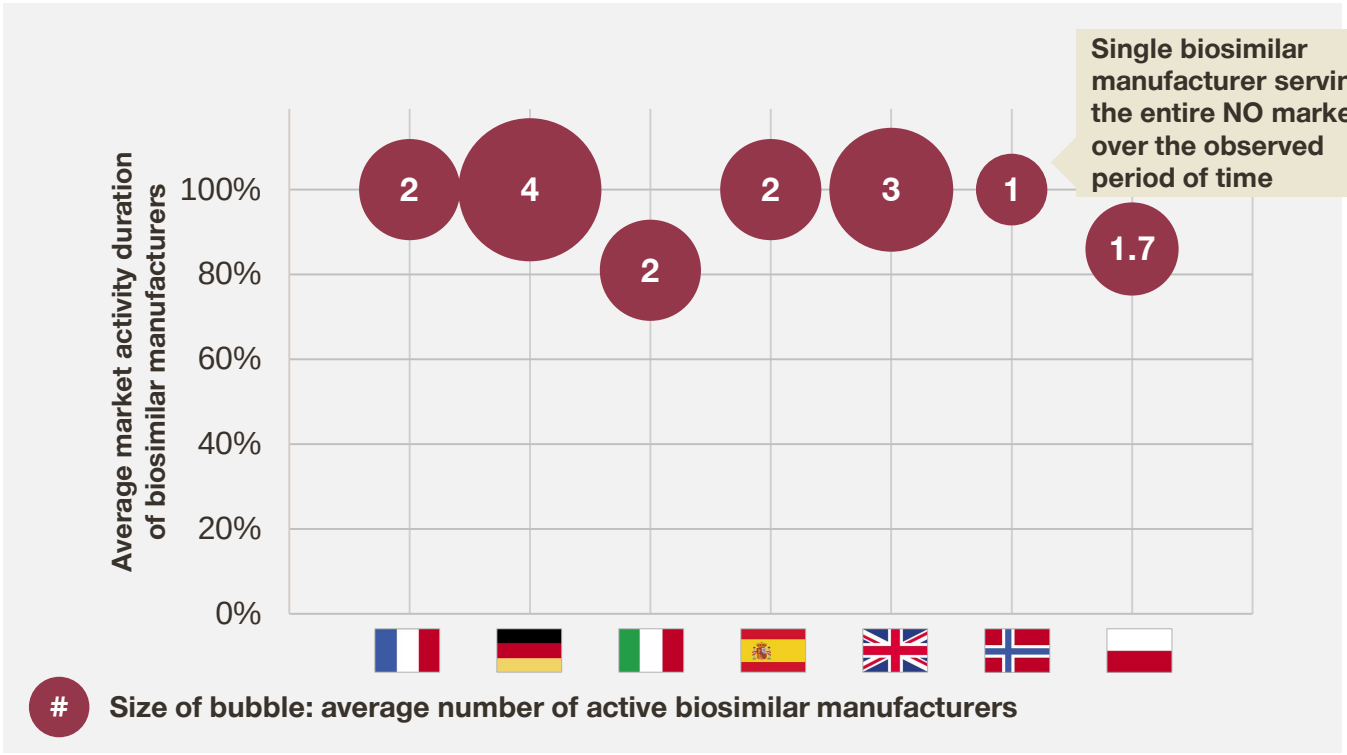
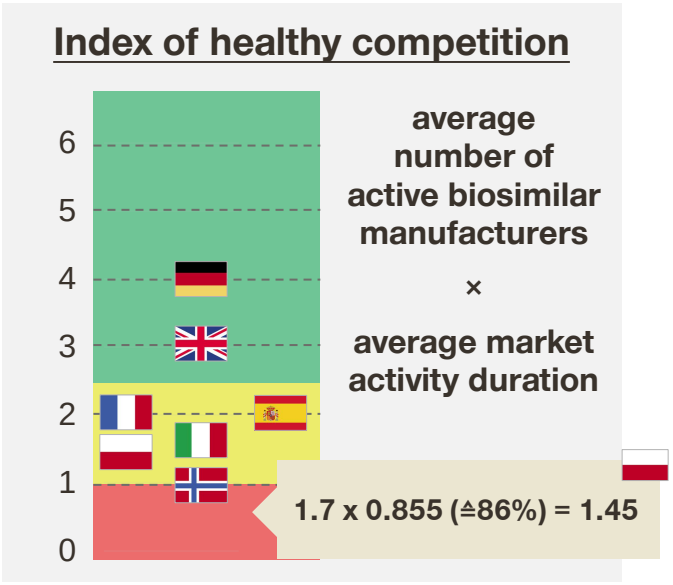
IMS data: 'Index of healthy competition' calculated for biosimilar manufacturers (epoetin) to evaluate level of competition





Market	Index of healthy competition
France	2.00
Germany	4.00
Italy	1.62
Spain	2.00
UK	3.00
Norway	1.00
Poland	1.45

Conclusion:

- On average only 2–3 biosimilar manufacturers are simultaneously active in most of the markets for the observed period
- However, in return, a constant revenue stream is ensured across the observed period of time per manufacturer (each of the participating manufacturers contributes at least 1% of the overall biosimilar volume each year without interruption)
- : One biosimilar manufacturer serving the Norwegian market for the entire observation period does not allow for any competitive behavior throughout the year (indicator for unsustainable biosimilar market)

Source: Simon-Kucher & Partners; IMS Health = Healthy competition = Moderate level of competition = Minor level of competition

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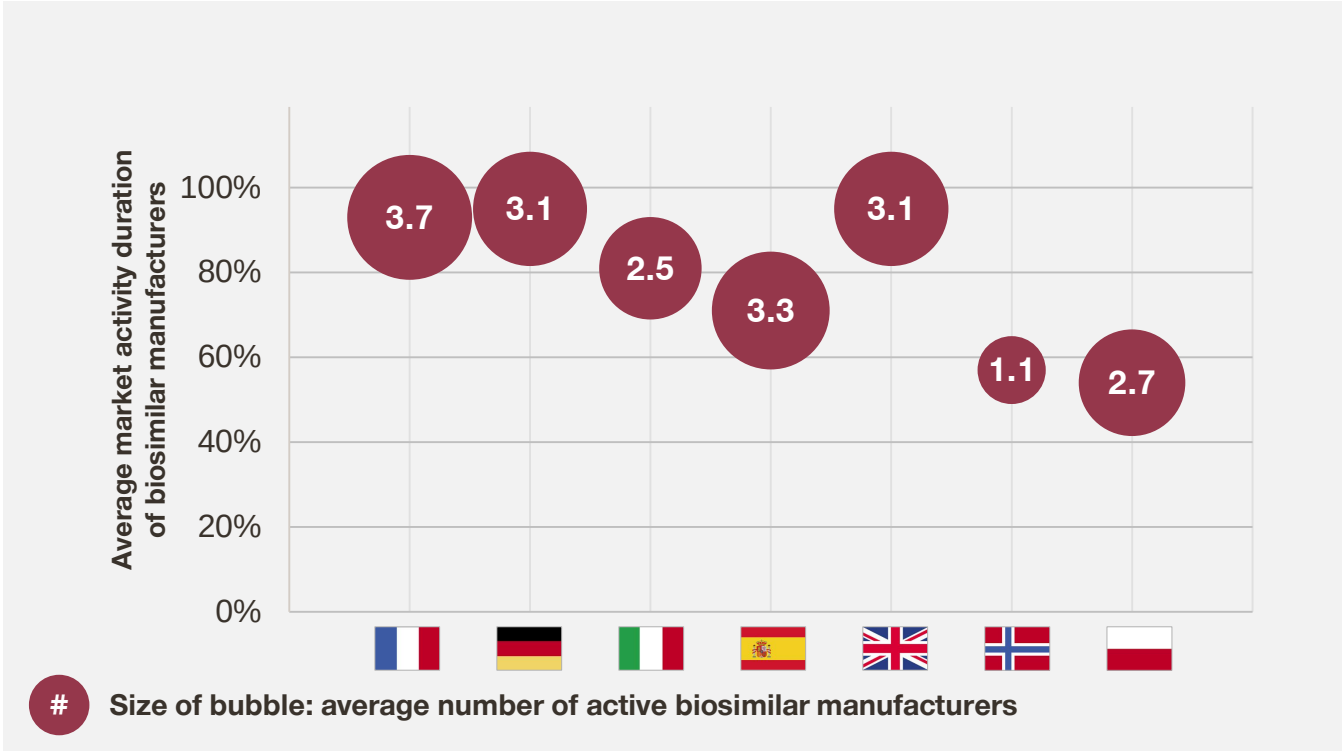
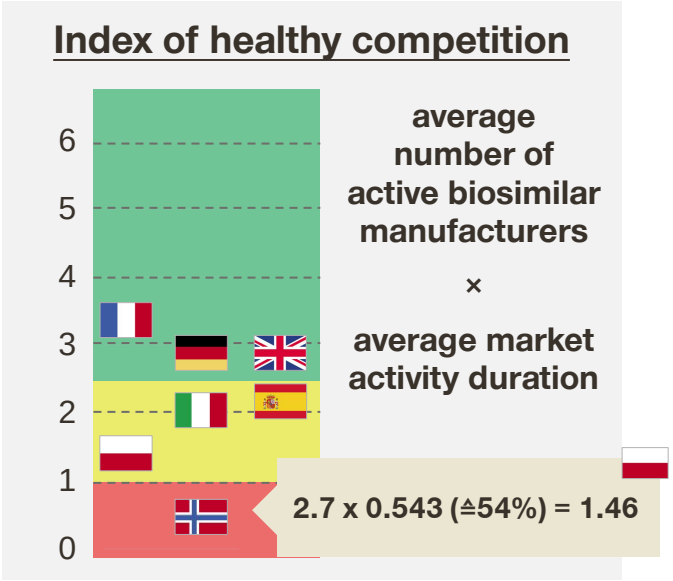
IMS data: 'Index of healthy competition' calculated for biosimilar manufacturers (filgrastim) to evaluate level of competition





Market	Index of healthy competition
France	3.44
Germany	2.95
Italy	2,01
Spain	2.34
UK	2.95
Norway	0.63
Poland	1.46

Conclusion:

- Similar number of filgrastim and epoetin biosimilar manufacturers simultaneously active in the market space. However, filgrastim manufacturers show fewer and less balanced revenue streams compared to epoetin manufacturers manufacturer (each of the participating manufacturers contributes at least 1% of the overall biosimilar volume each year without interruption)
- : Moderate number of biosimilar manufacturer is not balanced by a steady stream of revenue. This may be a risk for sustainability (filgrastim manufacturers have only been generating sales in 60% of the observed period of time, which might reflect a financial risk for future investment decisions of biosimilar manufacturers)

Source: Simon-Kucher & Partners; IMS Health = Healthy competition = Moderate level of competition = Minor level of competition

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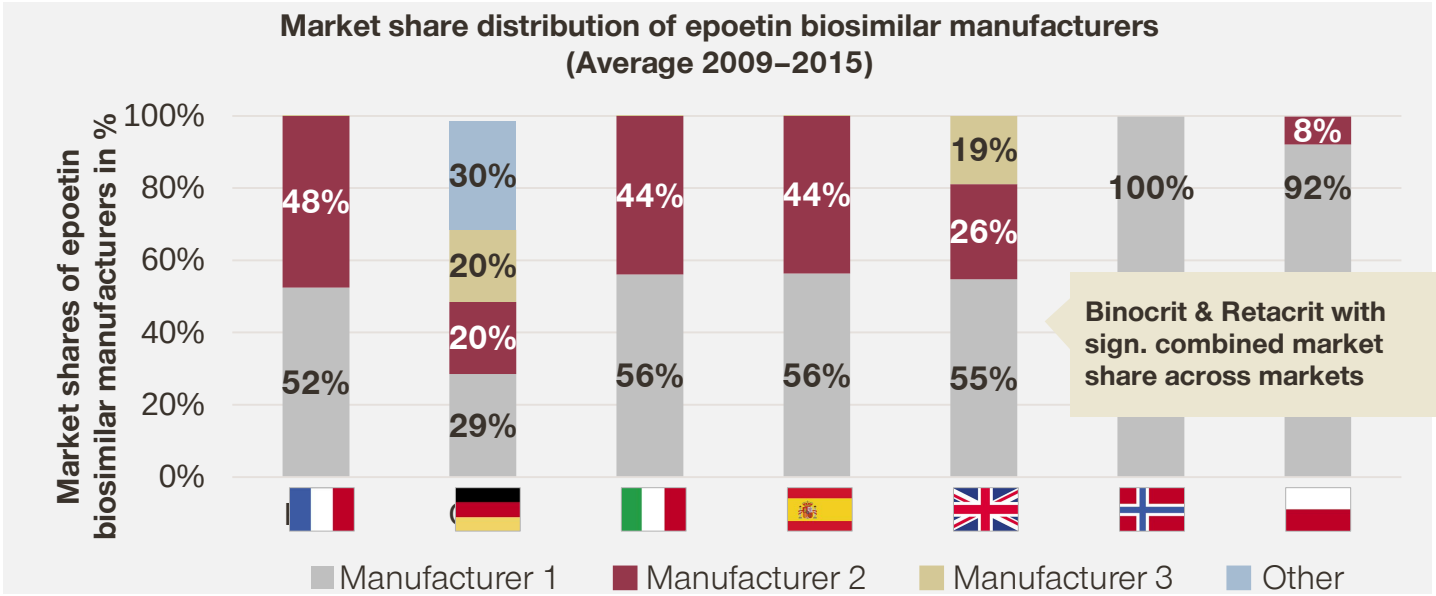
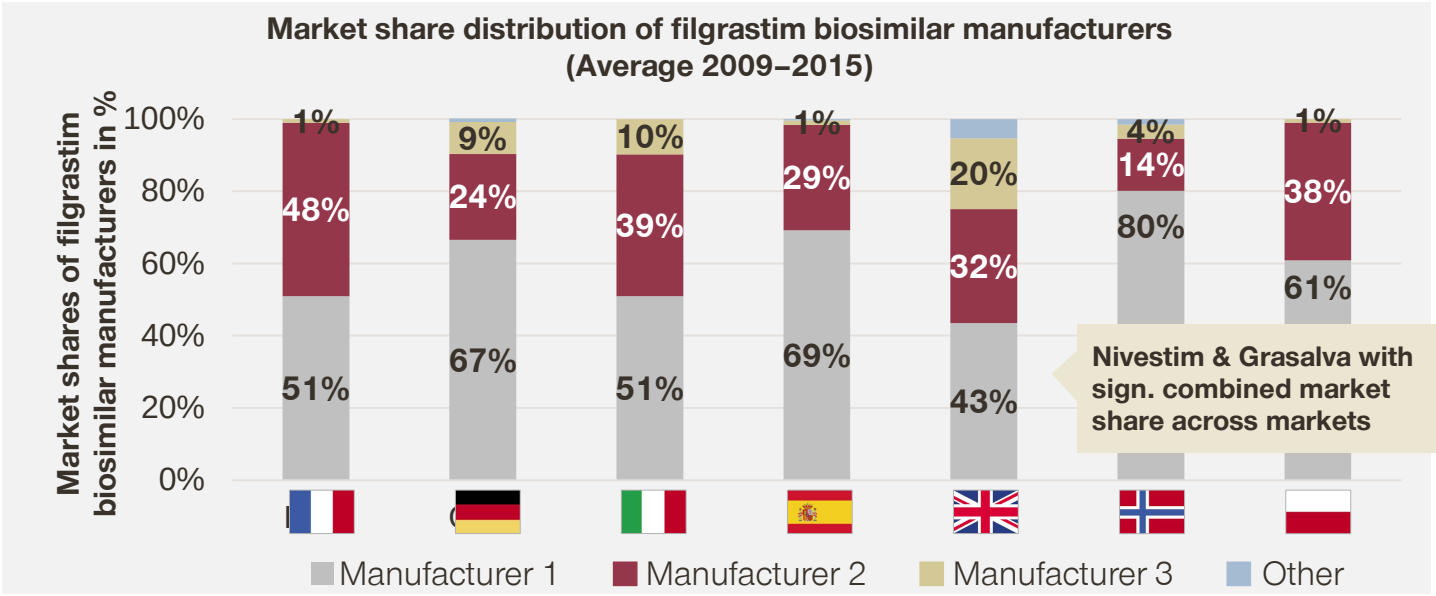
IMS data: Additional analysis of epoetin and filgrastim biosimilar supply split between manufacturers





Source: Simon-Kucher & Partners; IMS health

Conclusion:

- The EU market for epoetin and filgrastim biosimilars is chiefly dominated by two main manufacturers serving the demand of each country (not necessarily the same manufacturers for each market)
- DE, IT, UK: Only 3 markets with noteworthy shares of ≥ 3 biosimilar players for at least 1 product class
  - DE: 4 players in epoetin market; 3 players in filgrastim market
  - IT: 3 players in filgrastim markets
  - UK: 3 players in epoetin and filgrastim market

Shown analysis represents alternative approach to previous assessment of healthy competition (slides 32–33):
Whereas the previous analysis takes into account the average market activity per manufacturer, this analysis shows the average market shares of the manufacturers across seven years

IMS data: Additional analysis of filgrastim biosimilar uptake over time

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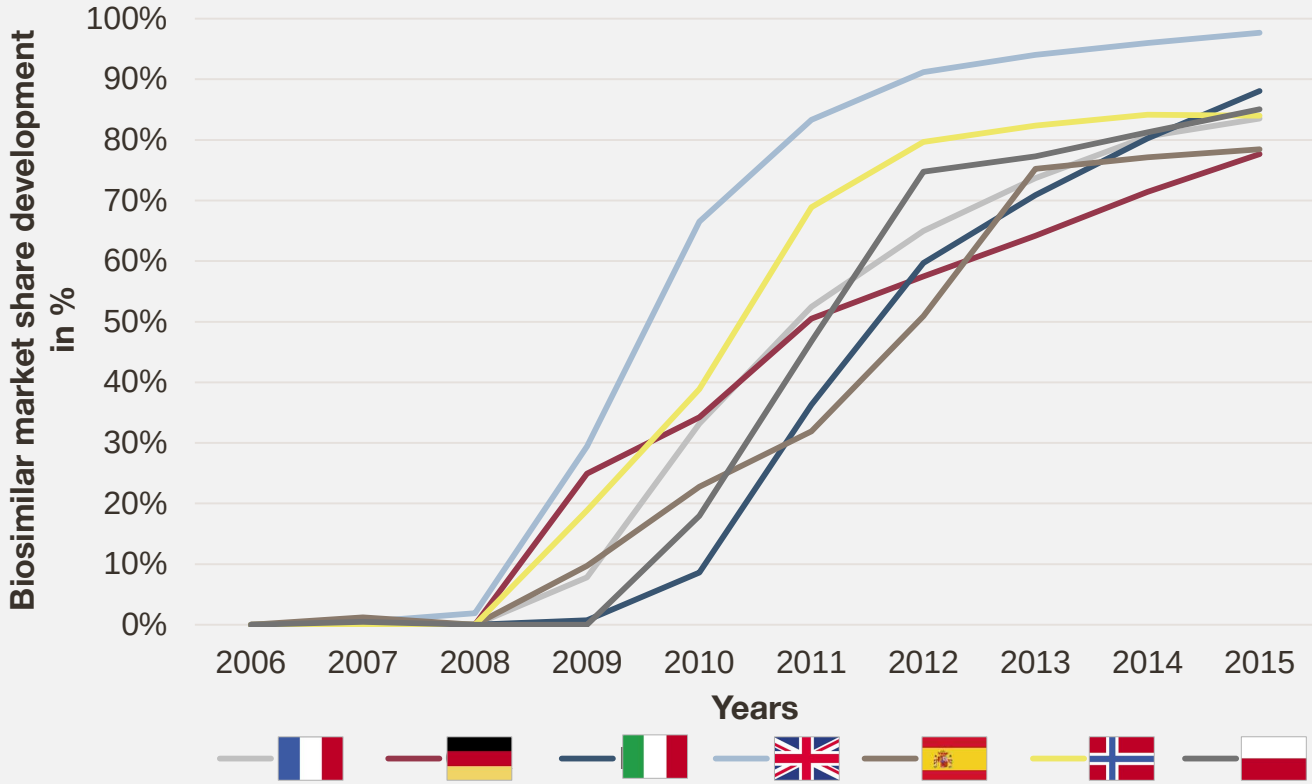

- Biosimilar uptake preliminary tends to differ within the first three years after launch. But from a long-term perspective, all markets tend to achieve a sustainable biosimilar share
- Still, biosimilar manufacturers perceive the initial loss in volume (i.e. volume that was not realized) within the first years after launch as a significant downside
- **Conclusion: In some markets, there is a lost opportunity for manufacturers and payers due to late uptake of biosimilar**

Source: Simon-Kucher & Partners; IMS health

Observation:

- In general, the average biosimilar market share exceeded the originator's share 3 years after the launch of filgrastim biosimilars (2011) across European countries
  - : These markets achieved the fastest biosimilar uptake across markets in scope
- By 2015, the biosimilar market share reached > 80% in most markets
  - : The UK reached a biosimilar share of 98% by 2015, which is the highest share across all analyzed markets

The analysis indicates that there is room for improvement for pricing & market access policies to support a sustainable biosimilar medicines market

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Biosimilar medicines uptake !	▪ On average, it is possible to observe an uptake of up to 80% biosimilar market share ▪ However, some markets show a delay in uptake throughout the first three years after launch compared to other markets, indicating further room for improvement
Parallel sourcing ✓	▪ On average, 2–3 biosimilar manufacturers are simultaneously active over the observed period, guaranteeing market supply ▪ Supply of biosimilar medicines seems to be secured, with only a minimal risk of shortages
Fair biosimilar medicine pricing !	▪ Analysis only based on officially available list prices, not including confidential discounts ▪ The implications of market-specific biosimilar P&MA policies on sustainability (particularly fair price level) cannot be assessed to the full extent, due to lack of available data on net prices

✓ = Pricing & market access policies sufficiently supporting sustainability criterion

! Reconsideration of pricing & market access policies to increase sustainability may be required

Source: Simon-Kucher & Partners

Outline

- Project objective and approach
- Background: Mapping of market-specific pricing & market access policies
- **Definition and assessment of sustainability in the biosimilar medicines market**
  - **Payer and biosimilar manufacturer feedback**
- Conclusions
- Principles for a sustainable biosimilar medicines market for payer communication
- Appendix

Simon-Kucher conducted multiple expert discussions with payers, policy makers and biosimilar manufacturers to assess market-specific P&MA policies and the sustainability criteria

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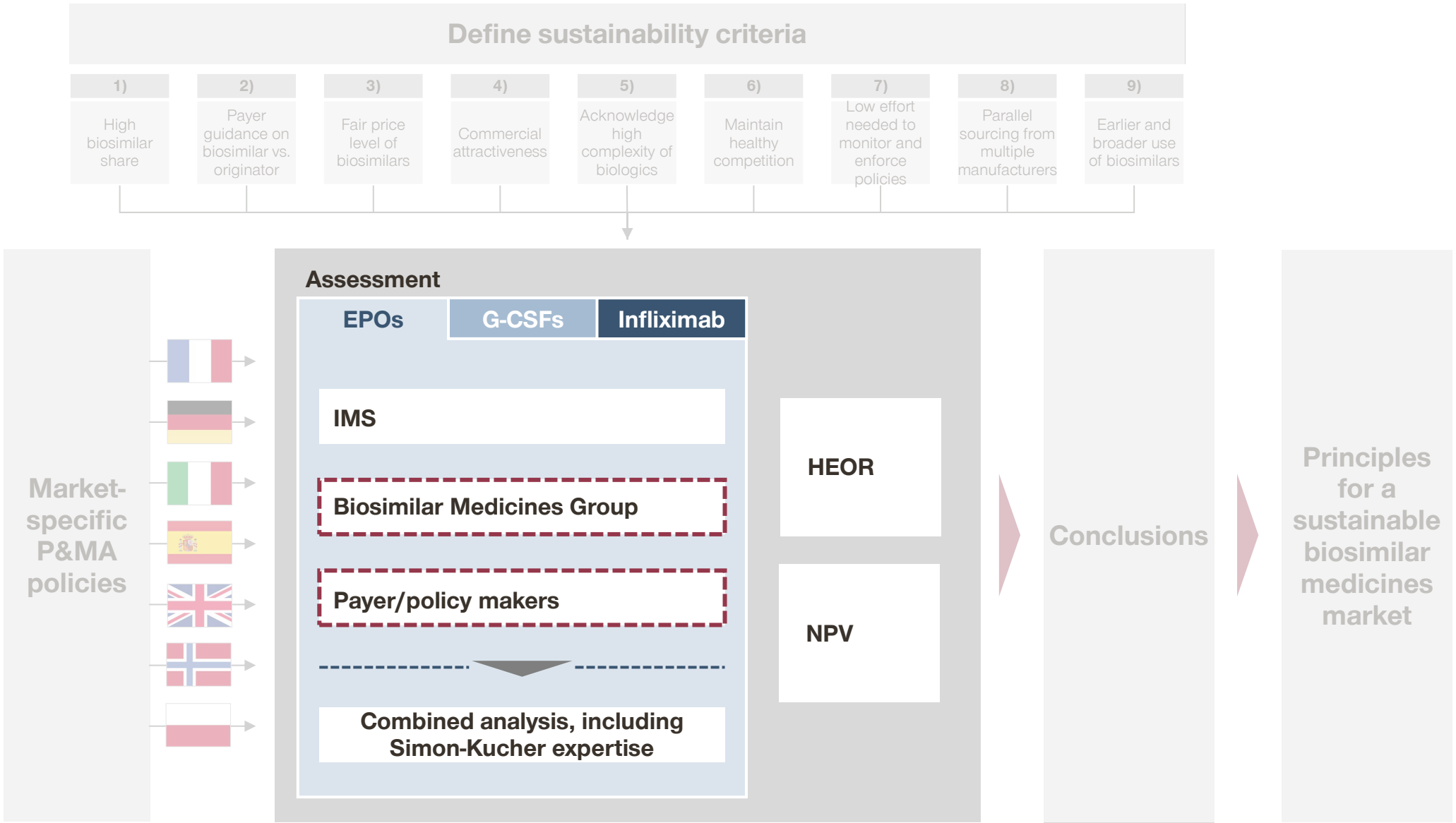

Source: Simon-Kucher & Partners

Both payers and manufacturers see high biosimilar uptake and payer guidance on biosimilar vs. originator medicines as important sustainability criteria

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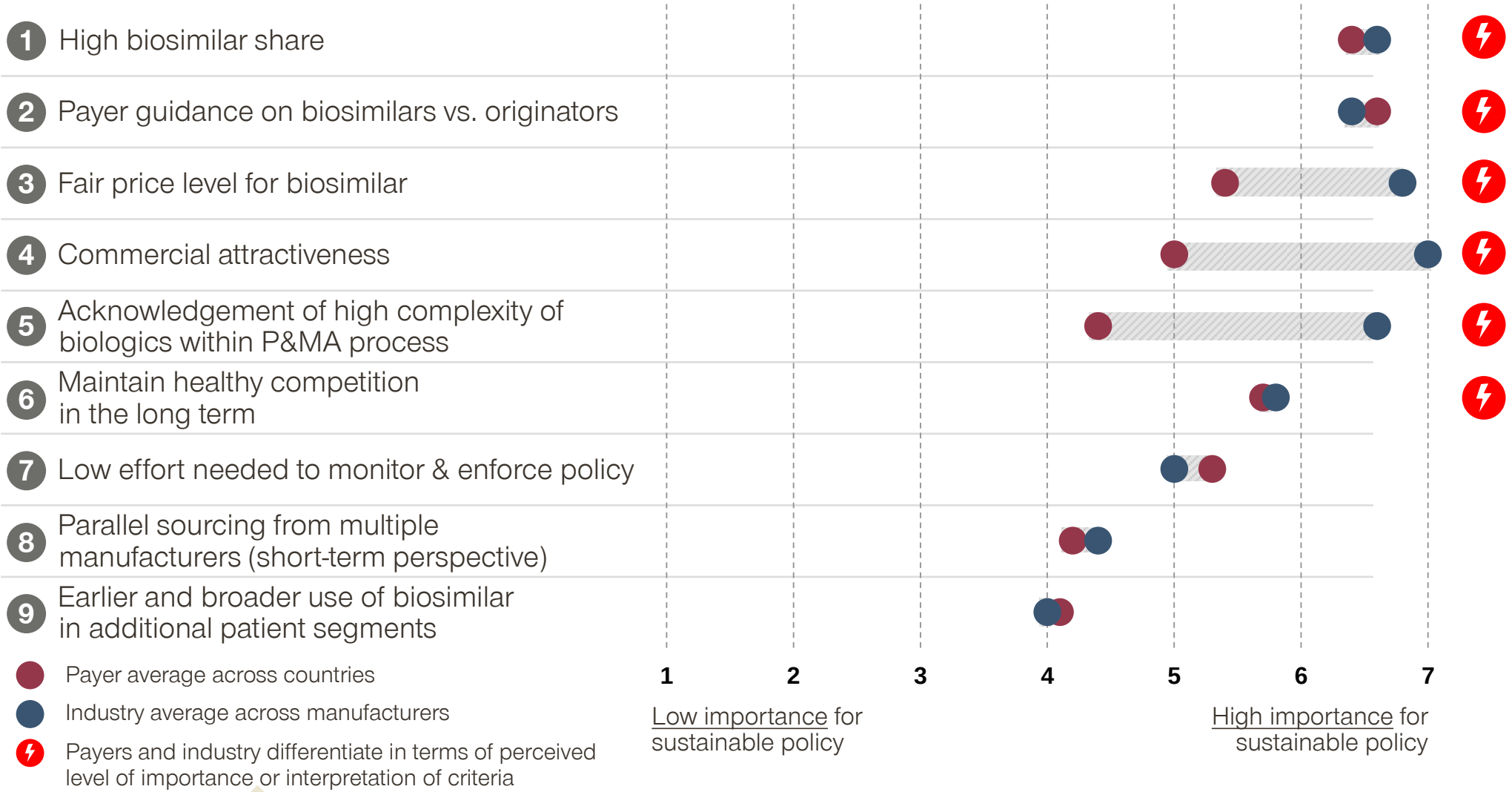
Importance of sustainability criteria from a payer and biosimilar industry point of view



Detailed analysis of criteria 1 - 6 on following slides

Source: Simon-Kucher & Partners

While the biosimilar medicines industry strives for shared business potential among manufacturers, payers are indifferent when it comes to the source of supply

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1 High biosimilar share

Stakeholder incentive behind sustainability criterion
- **Biosimilar industry:** Additional sales
- **Payer:** Budget savings

"A high biosimilar share is a crucial factor, contributing to the commercial attractiveness of the respective market, incentivizing future investments."

"This is the most obvious sustainability criterion: A higher biosimilar share leads to more savings for payers and higher sales for manufacturers – it is a financial win-win situation."

"This criterion is not sustainable if the market-specific healthcare system only favors the usage of one (the cheapest) biosimilar."

"I favor the highest share for the least expensive alternative and this is mostly a biosimilar."

"Only if the biosimilar share is high, will multiple manufacturers be able to participate in the market."

"I can imagine that the biosimilar industry favors a market in which the biosimilar share is split equally among the active manufacturers. However, this is difficult to achieve, especially in the price-driven tender markets."

Stakeholder reaction toward sustainability criterion

Aligned: Importance of high biosimilar share

Not aligned: Distribution of biosimilar share
- Biosimilar industry: Shared business potential (multiple manufacturers)
- Payer: Source of supply often not in focus

Source: Simon-Kucher & Partners

While biosimilar manufacturers expect pricing & market access policies to more intensively drive biosimilar uptake, only few payers see the need to improve current guidance in this respect

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2 Payer guidance on biosimilars vs. originators

Stakeholder incentive behind sustainability criterion
- **Biosimilar industry:** Additional sales
- **Payer:** Budget savings

"Payer guidance is crucial, however, prior to this, payers need to increase the acceptance of biosimilars among physicians."

"A very important sustainability criterion which is constantly being pushed throughout our positioning papers."

"Payers and their national healthcare systems have to feel responsible for encouraging biosimilar uptake."

"I believe the current biosimilar guidelines are in good shape and sufficiently drive biosimilar uptake."

"If the market works well, there is no strong need to put further payer guidance in place."

"Our MoH currently guides physicians to use the least expensive treatment alternative, which usually is a biosimilar. I believe this measure is key and already secures sufficient biosimilar uptake."

Stakeholder reaction toward sustainability criterion

Aligned: Importance of payer guidance on biosimilars vs. originators

Not aligned: Extent of payer guidance required to drive uptake appropriately
- Biosimilar industry: Expect payers to more intensively drive biosimilar uptake via guidance
- Payer: Only few payers see the need to improve current guidance on biosimilars

Source: Simon-Kucher & Partners

Although manufacturers argue for a reasonable price level to cover their investments in biosimilars, payers are mainly interested in generating savings

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3 Fair price level for biosimilars

Stakeholder incentive behind sustainability criterion
- **Biosimilar industry:** Appropriate sales/income
- **Payer:** Budget savings

"Several markets have pricing & market access policies in place, implicitly requiring biosimilar manufacturers to immediately offer high discounts in order to stay in the market (e.g. single-winner tenders). This is not sustainable."

"Other than generics, biosimilars require significant upfront investments which need to be balanced by a reasonable price and an appropriate speed of price erosion."

"There is no such thing as a 'fair price'. A 'fair price' depends on the respective product and market environment. What is considered a fair price may alter based on the number of competitors and the size of the market."

"I perceive a price discount of 40–50% for biosimilars as sustainable (50–70% discount when talking about very successful drugs such as Enbrel, Humira etc.)."

"It's not always the payers asking for high discounts. Often, it's the biosimilar industry itself, offering voluntary price concessions of 50% or higher."

"Payers and biosimilar manufacturers have a very different understanding of a 'fair price level'. However, keep in mind that payers are predominantly interested in the potential savings biosimilars offer."

Stakeholder reaction toward sustainability criterion

Aligned: Both parties must benefit from biosimilar price

Not aligned: Exact level that is then considered to be fair
- Biosimilar industry: Moderate rebates at launch and reasonable price erosion over time
- Payer: High price expectation and influenced by price concessions of manufacturers

Source: Simon-Kucher & Partners

While biosimilar manufacturers try to argue for a fair return on investment, payers do not trust manufacturers' argumentation regarding the commercial business case

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4 Commercial attractiveness

Stakeholder incentive behind sustainability criterion

- **Biosimilar industry:** Coverage of substantial investments
- **Payer:** Maintained competition for future biosimilars

"We need to sustain long-term profits to be able to further invest in future biosimilar research and development."

"Every price discount should be compensated with an appropriate uptake in volume."

"If manufacturers do not perceive a market as commercially attractive, they are not likely to enter it."

"Biosimilars are less complex than one might think: Upfront investments amount to no more than €20–30m. and COGS reflect about 2–4% of the actual BS price. That's why I often refer to biosimilars as 'biogenerics'."

"Our market is commercially attractive – granting a huge uptake for tender winners."

"I agree that investments have to be balanced by income, but can't judge whether, e.g., a 10% ROI[1] is sufficient for manufacturers. But they will never provide us with their real cost structure. And if they did, would we believe them?"

Stakeholder reaction toward sustainability criterion

Aligned: Fair return on investment

Not aligned: Which return on investment would be considered fair

- Biosimilar industry: Upfront expenditures to be balanced by income, supporting continuous investments
- Payer: No trust in manufacturers' argumentation regarding the commercial business case

Source: Simon-Kucher & Partners

Although payers argue that current pricing & market access policies sufficiently take into account the complexity of biologics, manufacturers still see room for improvement

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5 Acknowledgement of high complexity of biologics within P&MA process

Stakeholder incentive behind sustainability criterion

- **Biosimilar industry:** Appropriate compensation for higher upfront investment
- **Payer:** Maintain attractiveness of market for manufacturers

"It is crucial to acknowledge that biologics are complex in many ways: development, production, transportation, supply and storage."

"In Germany and the UK the complexity of biosimilars is already most widely acknowledged."

"Biosimilar pricing & market access policies should be different from generics (lower price cuts) but also different from innovators (shorter time to negotiate prices)."

"Higher complexity of biologics vs. small molecules already being considered throughout our pricing & market access policies – for generics we are expecting much higher discounts."

"Not sure how this reflects a sustainability criterion from a payer perspective."

"Originator manufacturers have already argued that their products are more complex vs. small molecules. So complexity is already being considered in the originators' price, which again is the starting point for biosimilar price negotiations."

Stakeholder reaction toward sustainability criterion

Aligned: Biologic complexity to be considered throughout P&MA policies

Not aligned: Magnitude of influence on P&MA policies

- Biosimilar industry: Pricing & market access policy to stronger appreciate biologic complexity
- Payer: Current pricing & market access policies already take into account biologic complexity

Source: Simon-Kucher & Partners

While the biosimilar industry supports healthy competition to encourage shared business potential among manufacturers, payers mainly see benefit in an increased bargaining power

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6 Maintain healthy competition in the long term

Stakeholder incentive behind sustainability criterion
- **Biosimilar industry:** Shared business potential
- **Payer:** Encourage competitive behavior

"From an industry point of view, I believe that 3–4 active biosimilar manufacturers fulfill the sustainability criterion of a 'healthy competition'."

*"Competition is only healthy if competitors behave in a responsible manner:
In the long run, extraordinary discounts will force competitors out of the market, preventing manufacturers from sharing the market potential."*

"It is difficult to argue for healthy competition from a manufacturer's perspective, because in reality each biosimilar company is striving for market leadership."

"I agree. Multiple manufacturers encourage price competition, assure supply guarantee and increase physician acceptance and awareness of biosimilars."

"Whoever wins the tender wins a lot, that is my philosophy."

"Competitive behavior is important to achieve bargaining power in price negotiations. However, co-existence of multiple biosimilar manufacturers for one active substance is not necessary – it is sufficient if the tender winner serves the market."

Stakeholder reaction toward sustainability criterion

Aligned: Importance of competition

Not aligned: Interpretation of competition
- Biosimilar industry: Shared business potential
- Payer: Increase in bargaining power; no specific interest in shared business

Source: Simon-Kucher & Partners

Outline

- Project objective and approach
- Background: Mapping of market-specific pricing & market access policies
- **Definition and assessment of sustainability in the biosimilar medicines market**
  - **Combined analysis of market data, insights from expert discussions and Simon-Kucher expertise**
- Conclusions
- Principles for a sustainable biosimilar medicines market for payer communication
- Appendix

Based on the findings generated from the IMS data and the expert discussions, Simon-Kucher analyzed the impact of market-specific pricing & market access policies on pre-defined sustainability criteria

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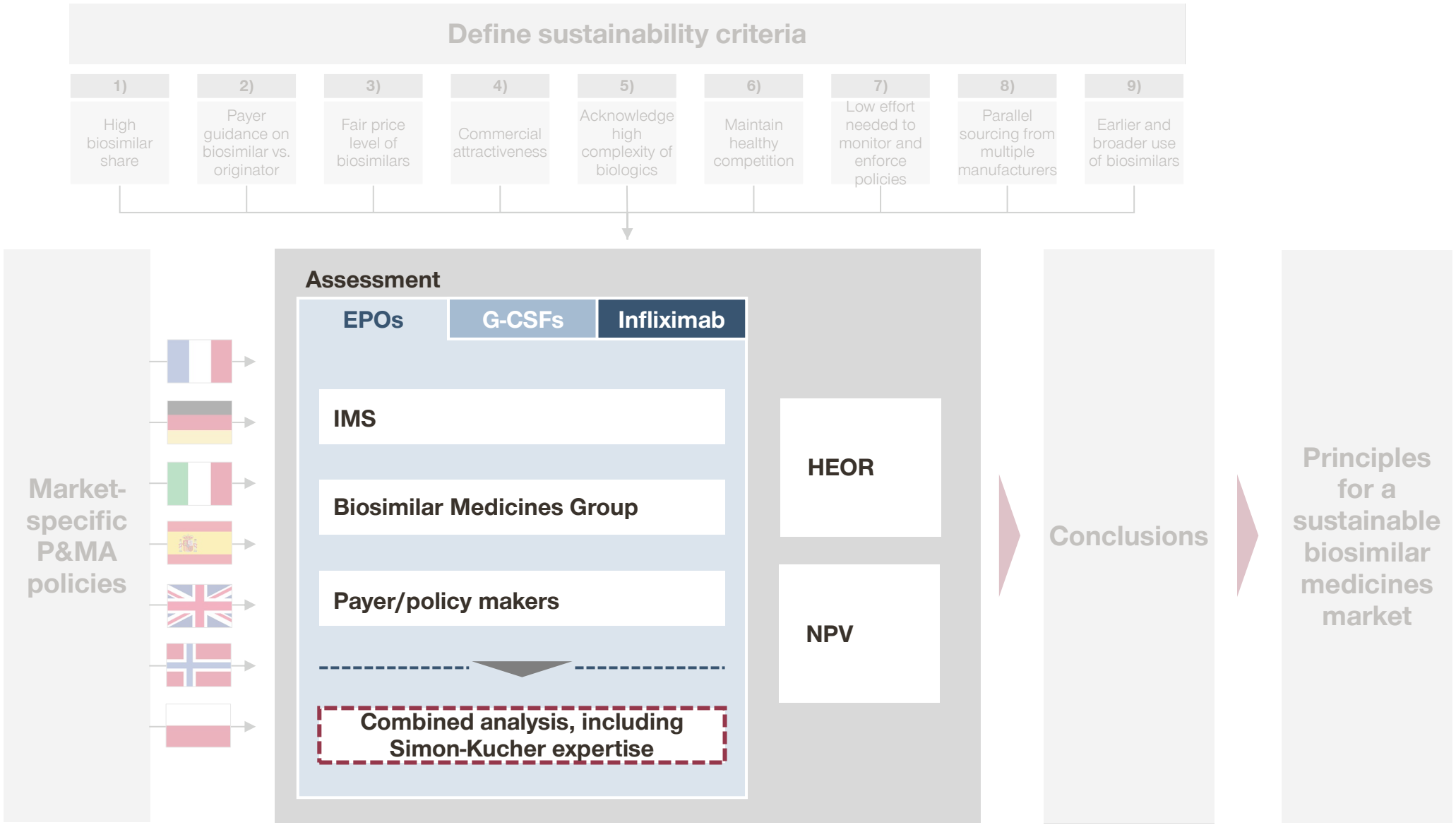

Source: Simon-Kucher & Partners

Germany and the United Kingdom in particular have been mentioned as markets already supporting a sustainable biosimilar business

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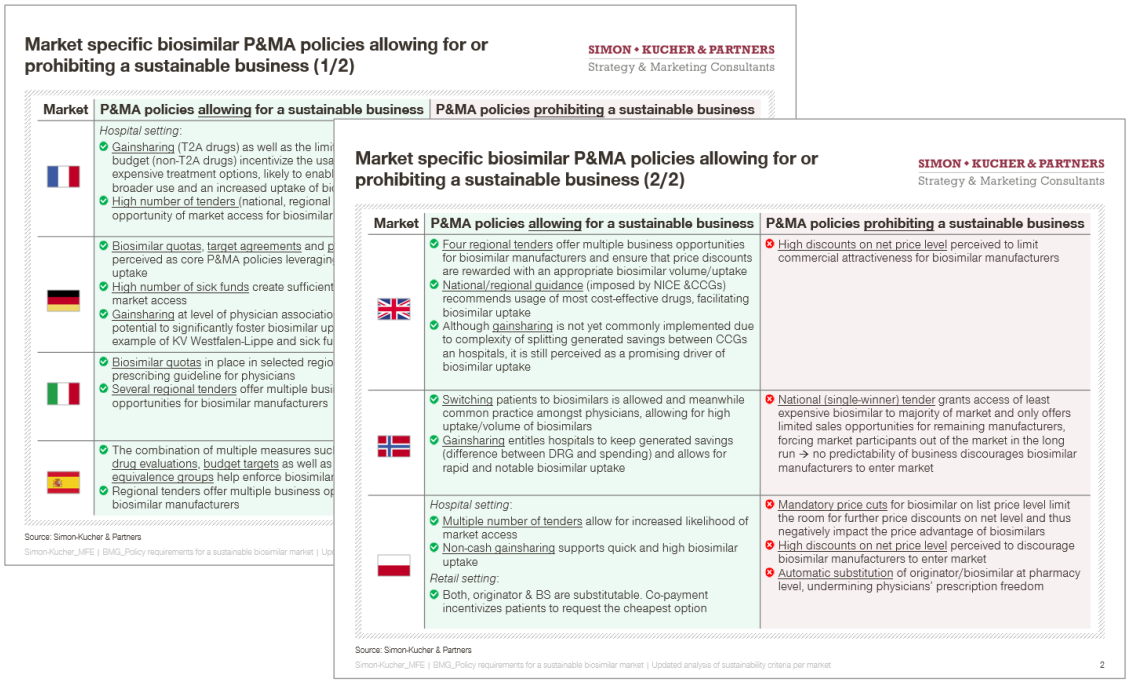

Market specific biosimilar P&MA policies allowing for or prohibiting a sustainable business (1/2)

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Market	P&MA policies allowing for a sustainable business	P&MA policies prohibiting a sustainable business
	Hospital setting: Gainsharing (T2A drugs) as well as the limi budget (non-T2A drugs) incentivize the usa expensive treatment options, likely to enabl broader use and an increased uptake of bi High number of tenders (national, regional opportunity of market access for biosimilar	
	Biosimilar quotas, target agreements and p perceived as core P&MA policies leveragin uptake High number of sick funds create sufficient market access Gainsharing at level of physician associatio potential to significantly foster biosimilar up example of KV Westfalen-Lippe and sick fu	
	Biosimilar quotas in place in selected regio prescribing guideline for physicians Several regional tenders offer multiple busi opportunities for biosimilar manufacturers	
	The combination of multiple measures suc drug evaluations, budget targets as well as equivalence groups help enforce biosimilar Regional tenders offer multiple business op biosimilar manufacturers	

Source: Simon-Kucher & Partners

Market specific biosimilar P&MA policies allowing for or prohibiting a sustainable business (2/2)

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Market	P&MA policies allowing for a sustainable business	P&MA policies prohibiting a sustainable business
	Four regional tenders offer multiple business opportunities for biosimilar manufacturers and ensure that price discounts are rewarded with an appropriate biosimilar volume/uptake National/regional guidance (imposed by NICE &CCGs) recommends usage of most cost-effective drugs, facilitating biosimilar uptake Although gainsharing is not yet commonly implemented due to complexity of splitting generated savings between CCGs an hospitals, it is still perceived as a promising driver of biosimilar uptake	High discounts on net price level perceived to limit commercial attractiveness for biosimilar manufacturers
	Switching patients to biosimilars is allowed and meanwhile common practice amongst physicians, allowing for high uptake/volume of biosimilars Gainsharing entitles hospitals to keep generated savings (difference between DRG and spending) and allows for rapid and notable biosimilar uptake	National (single-winner) tender grants access of least expensive biosimilar to majority of market and only offers limited sales opportunities for remaining manufacturers, forcing market participants out of the market in the long run → no predictability of business discourages biosimilar manufacturers to enter market
	Hospital setting: Multiple number of tenders allow for increased likelihood of market access Non-cash gainsharing supports quick and high biosimilar uptake *Retail setting:* Both, originator & BS are substitutable. Co-payment incentivizes patients to request the cheapest option	Mandatory price cuts for biosimilar on list price level limit the room for further price discounts on net level and thus negatively impact the price advantage of biosimilars High discounts on net price level perceived to discourage biosimilar manufacturers to enter market Automatic substitution of originator/biosimilar at pharmacy level, undermining physicians' prescription freedom

Source: Simon-Kucher & Partners

Simon-Kucher_MFE | BMG_Policy requirements for a sustainable biosimilar market | Updated analysis of sustainability criteria per market 2

Based on the analysis of market-specific pricing & market access policies, the following elements have been identified to effectively support a sustainable biosimilar business:

- No mandatory discounts for biosimilars on list level
- Regional heterogeneity in terms of market access (e.g. multi-winner tenders)
- Volume/uptake as incentive to grant voluntary price concessions on the net level
- Effectively implemented progressive/dynamic biosimilar quotas linked to physician incentives, e.g. via gainsharing (used in many markets, but often not effectively implemented or only fixed quotas)

Markets with biosimilar P&MA policies limiting a sustainable business

Markets with biosimilar P&MA policies supporting a sustainable business

There is still room for improvement → Payers need to introduce more effective biosimilar pricing & market access policies, supporting improved long-term sustainability of the biosimilar business

Source: Simon-Kucher & Partners

Market-specific biosimilar pricing & market access policies supporting or limiting a sustainable business (1/2)

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Market	P&MA policies supporting a sustainable business	P&MA policies limiting a sustainable business
	✓ *Hospital setting:* Gainsharing (T2A drugs) as well as the limited hospital budget (non-T2A drugs) incentivize the usage of less expensive treatment options, likely to enable an earlier and broader use of biosimilars, leading to an increased uptake	✗ ANSM Does not formally exclude interchangeability during treatment (may be considered under certain conditions) ✗ No payer guidance in place for biosimilar mediciness so far ✗ Mandatory price cuts for biosimilar medicines reduce room for further discounts on net level (but also for originator) ✗ *Retail setting*: Mandatory list price discounts not balanced by pricing & market access policies incentivizing prescriptions of less expensive treatment option and thus impeding biosimilar medicine usage and uptake
	✓ Biosimilar target agreements including biosimilar quotas perceived as core pricing & market access policy elements leveraging biosimilar uptake ✓ High number of sick funds create sufficient opportunities for market access (via tendering) ✓ Gainsharing at the physician association level significantly supports the biosimilar uptake (see example of KV Westfalen-Lippe and sick fund Barmer GEK)	✗ Risk of FRP groups to reduce price advantage of biosimilars vs. originator on list level ✗ 'Open-house contracts' with sick funds limit the price advantage of biosimilars vs. originator on net level, as long as there is no additional information on actual cost effectiveness of included therapies ✗ Lack of monitoring and supervision of pricing & market access policies leaves room for improvement, i.e. implementation (information, reporting,, monitoring)
	✓ Biosimilar quotas in place for selected regions, serving as prescribing guideline for physicians (still, quotas are not binding and therefore have not been met in many regions) ✓ Regionality of tenders offer multiple business opportunities for biosimilar manufacturers	✗ Unfavorable procurement measures lead to lack in predictability of business (e.g. single-winner tenders) ✗ Mandatory discounts on list price level limit the wiggle room for biosimilar manufacturers in price negotiations
	✓ The combination of multiple measures such as regional drug evaluations, budget targets as well as therapeutic equivalence groups support biosimilar medicines uptake ✓ Regionality of tenders offer multiple business opportunities for biosimilar manufacturers	✗ Unfavorable procurement measures lead to lack in predictability of business (e.g. single-winner tenders) ✗ Creation of FRP groups limit initial price advantage of biosimilars vs. originator on the list price level

Source: Simon-Kucher & Partners

Market-specific biosimilar pricing & market access policies supporting or limiting a sustainable business (2/2)

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Market	P&MA policies supporting a sustainable business	P&MA policies prohibiting a sustainable business
	✓ Four regional tenders offer multiple business opportunities for biosimilar manufacturers and ensure that price discounts are rewarded with an appropriate biosimilar volume/uptake ✓ National/regional guidance (imposed by NICE &CCGs) recommends using the most cost-effective drugs, facilitating biosimilar medicines uptake ✓ Although gainsharing is not yet commonly implemented (due to complexity of splitting generated savings between CCGs an hospitals), it is still perceived as a promising driver of future biosimilar uptake	✗ Observed high discounts on the net price level seen as limiting commercial attractiveness for biosimilar manufacturers
	✓ Switching patients to biosimilar medicines is allowed and meanwhile common practice among physicians, supporting high uptake/volume of biosimilars ✓ Gainsharing entitles hospitals to keep generated savings (difference between DRG and spending) and allows for rapid and notable biosimilar uptake	✗ National (single-winner) tender grants access of least expensive biosimilar to the majority of markets and only offers limited sales opportunities for the remaining manufacturers, hindering competition in the long run
	*Hospital setting*: ✓ Multiple number of tenders increase the likelihood of market access ✓ Non-cash gainsharing supports quick and high biosimilar uptake	✗ Mandatory price cuts for biosimilars on the list price level limit the room for further price discounts on the net level thus negatively affecting the price advantage of biosimilars ✗ High discounts on net price level seen as discouraging biosimilar manufacturers from entering the market ✗ Automatic substitution of originator/biosimilar at pharmacy level, undermining physicians' prescribing freedom → Polish payers directly transfer generic policies to biosimilars

Source: Simon-Kucher & Partners

Outline

- Project objective and approach
- Background: Mapping of market-specific pricing & market access policies
- **Definition and assessment of sustainability in the biosimilar medicines market**
  - **Qualitative HEOR argumentation**
- Conclusions
- Principles for a sustainable biosimilar medicines market for payer communication
- Appendix

Simon-Kucher generated high-level, qualitative HEOR-based arguments, particularly supporting a sustainable biosimilar business in cost-effectiveness driven markets

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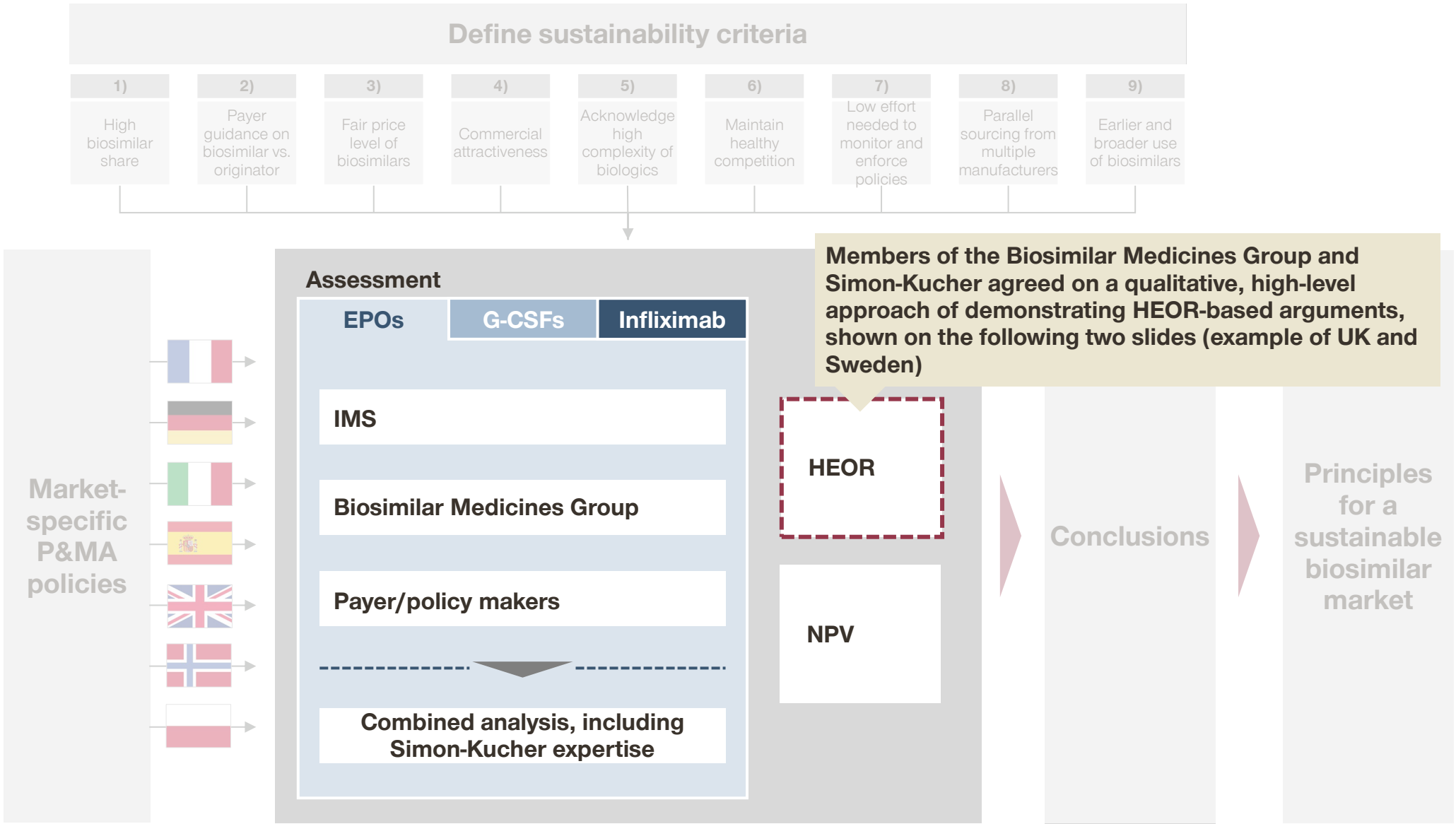

Source: Simon-Kucher & Partners

In Sweden, the availability of less expensive filgrastim biosimilars led to more relaxed prescribing restrictions for physicians, followed by a notable increase in patient access

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Southern healthcare region

Previous situation prior to availability of filgrastim biosimilars

- In order to be allowed to initiate the treatment with filgrastim originator, the opinion / formal approval of three physicians has to be awaited

Current situation with filgrastim biosimilars available

- Launch of filgrastim biosimilars and the associated reduction in treatment costs for G-CSF treatment of febrile neutropenia prompted the regional authorities to relax restrictions on prescribing
- Prescription does not need further authorization

➢ **Uptake of G-CSF increased five-fold in the Southern Healthcare Region, driven by usage of biosimilar filgrastim**

As a result of physicians being given the autonomy to prescribe, one can conclude that the increase was driven by clinical need and consequently, outcomes improved for patients in the region

Source: Simon-Kucher & Partners; IMS Health

Following the launch of less expensive filgrastim biosimilars in the United Kingdom, NICE relaxed the prescribing restrictions for G-CSF, leading to an improved patient access

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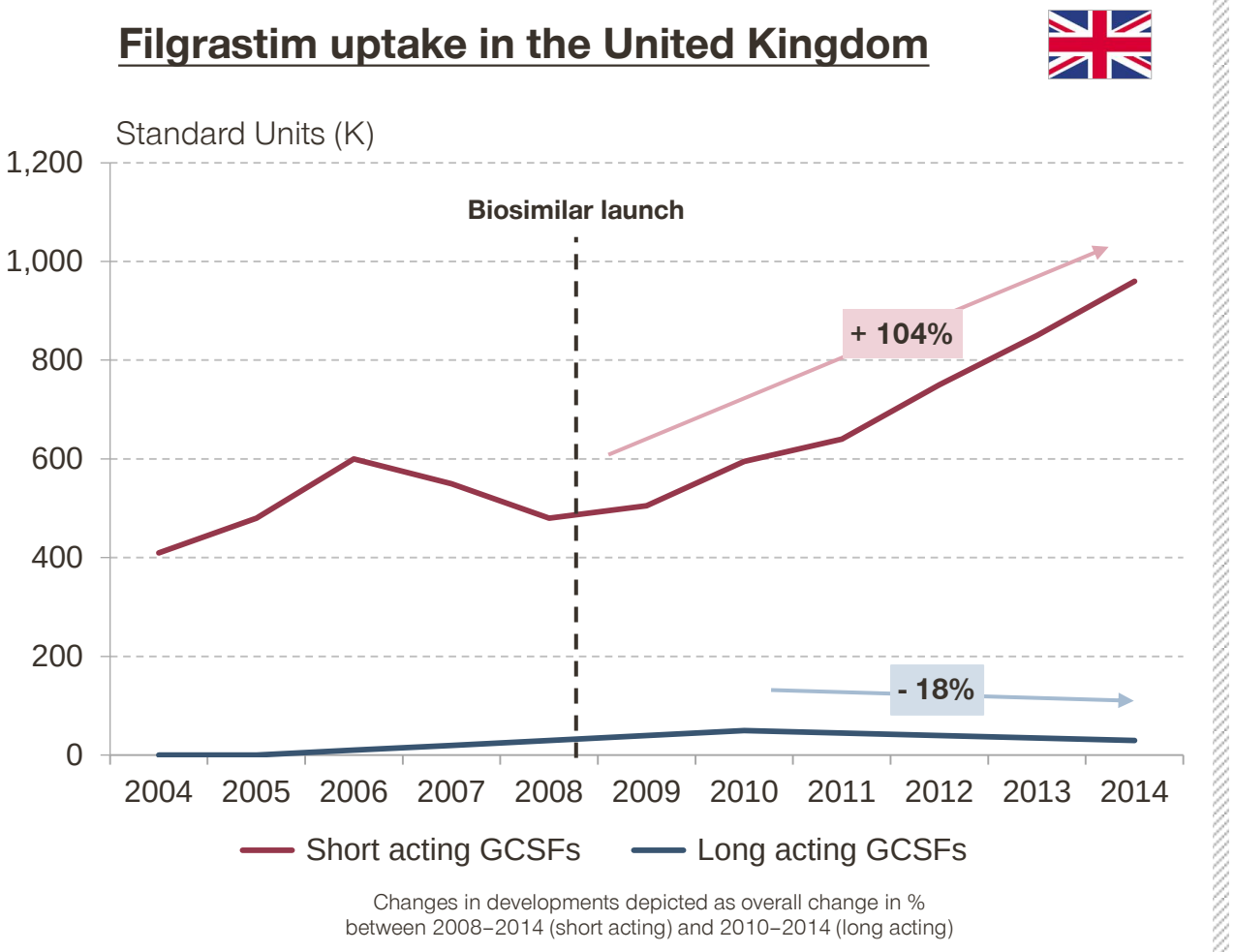
Filgrastim uptake in the United Kingdom



Changes in developments depicted as overall change in % between 2008–2014 (short acting) and 2010–2014 (long acting)

- After biosimilar launch in 2008, NICE guidelines were updated to reflect the improved cost-effectiveness of biosimilar filgrastim vs. alternative treatments
- As a result, G-CSF restrictions have been relaxed and usage is now also recommended for primary prophylaxis of neutropenia (before: secondary prophylaxis only)
- As a consequence, overall clinical use of filgrastim short-acting increased by 104% between 2009 and 2014
- **One can conclude that the launch of biosimilar G-CSF also led to improved patient outcomes, by enabling greater numbers of patients to access these treatments at an earlier stage of the therapy cycle**

This example is specific for filgrastim. Similar experience may not be expected with all other biosimilar medicines that will be launched in the future (i.e. increased uptake may have other reasons)

Source: Simon-Kucher & Partners; IMS Health, MIDAS; IMS Consulting Group, Nov 2015

Agenda

- Project objective and approach
- Background: Mapping of market-specific P&MA policies
- **Definition and assessment of sustainability in the biosimilar market**
  - **NPV analysis**
- Conclusions
- Principles for a sustainable biosimilar market for payer communication
- Appendix

Simon-Kucher conducted a Net Present Value (NPV) analysis to assess the commercial attractiveness of the biosimilar market

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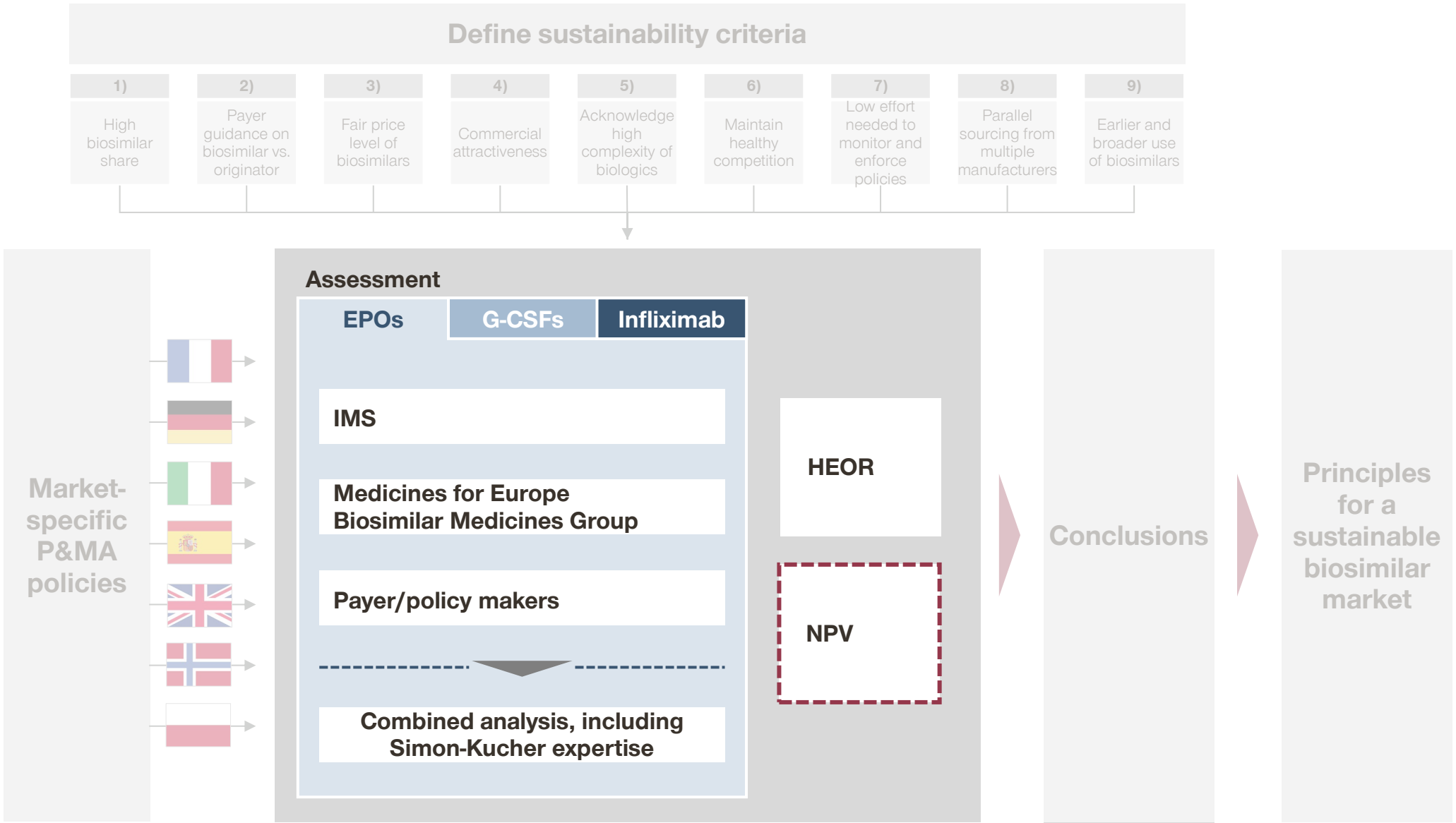

Source: Simon-Kucher & Partners

Methodology of NPV exercise

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1 Agreement on methodology of NPV calculation

- Members of the Biosimilar Medicines Group provided Simon-Kucher with an existing NPV model, developed by a US investment research firm, as a starting point for the analysis
- Based on the assumptions in the existing model (e.g. regarding biosimilar market share, uptake, discount level, etc.), the NPV analysis has been conducted for infliximab while also testing the sensitivity of different input parameters

2 Collection of add. model input from Biosimilar Medicines Group members

- After having signed a non-disclosure agreement, several Biosimilar Medicines Group members were willing to provide Simon-Kucher with their internal assumptions on input variables for infliximab and adalimumab so that a more realistic picture from a manufacturer's perspective could be reflected in the analysis[1]

3 Completion and presentation of actual NPV analysis

- The NPV exercise with internal assumptions provided by Biosimilar Medicines Group members allowed Simon-Kucher to gain valuable insights and for developing their sustainability principles
- Figures resulting from the NPV analysis based on the assumptions provided by Biosimilar Medicines Group member companies will not be shown in the report based on legal advice

This next slides show the NPV results that were calculated based on the existing model input variables, without any model input assumptions collected from the Biosimilar Medicines Group members

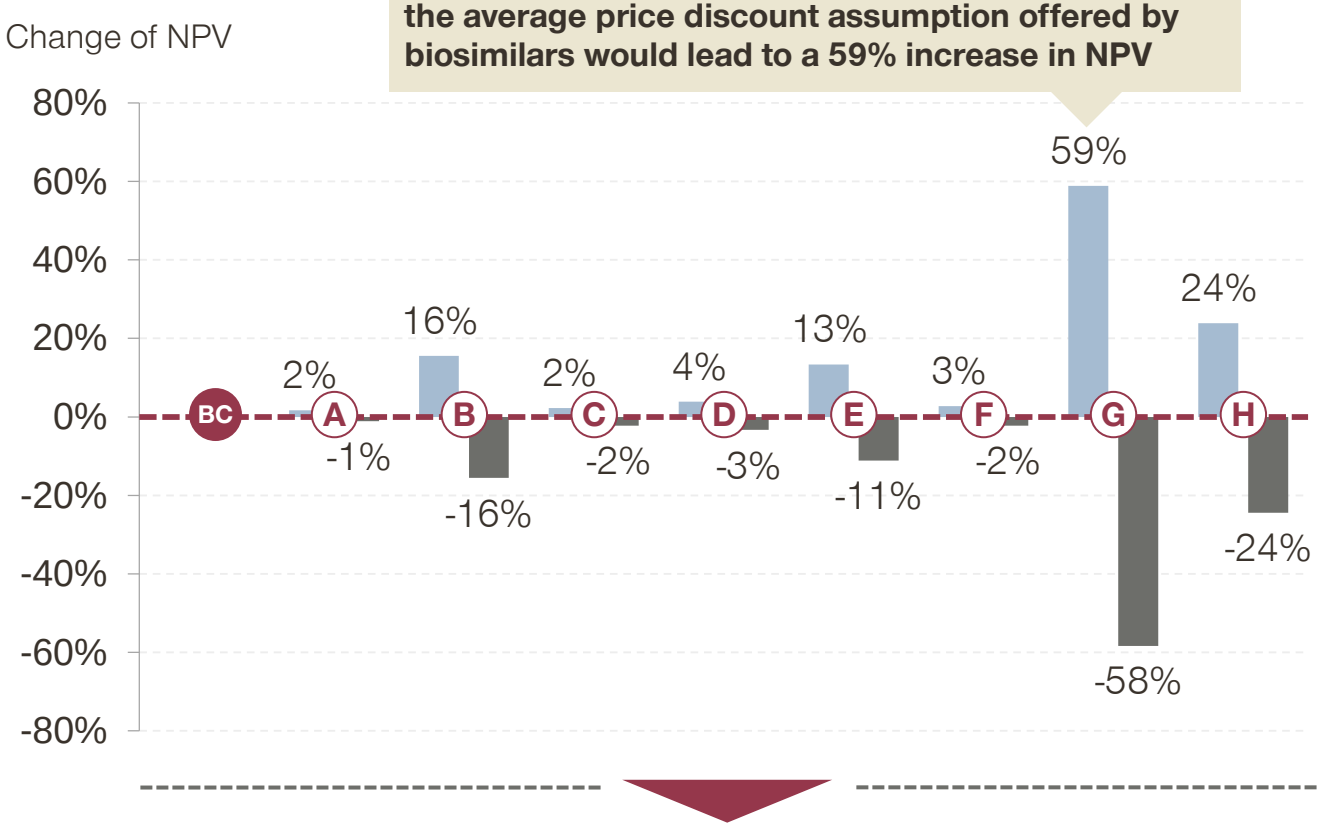
Source: Simon-Kucher & Partners; [1] Simon-Kucher was only permitted to use average numbers for the NPV analysis in case at least four Biosimilar Medicines Group members have provided input to prevent any possibility to reengineer the individual answers

NPV Model – Analysis for infliximab as exemplified case

Scenario overview

Impact of a 10% change (c.p.) of input variables on NPV

A 10% decrease (see bottom table to the right) of the average price discount assumption offered by biosimilars would lead to a 59% increase in NPV



NPV model is most sensitive to the average biosimilar price discount and penetration

BC	**Base-case scenario with assumptions from existing NPV model**
	Varying variable (+10%/-10%)
A	EU upfront investment
B	Share of BS market per BS manufacturer
C	COGS pre/post
D	SG&A
E	Cost of capital
F	Tax
G	Avg. price discount
H	Avg. biosimilar penetration

Source: Simon-Kucher & Partners; All EUR-values in million

Payers' strong influence on price discounts and market share of biosimilars needs to be reflected in the NPV analysis

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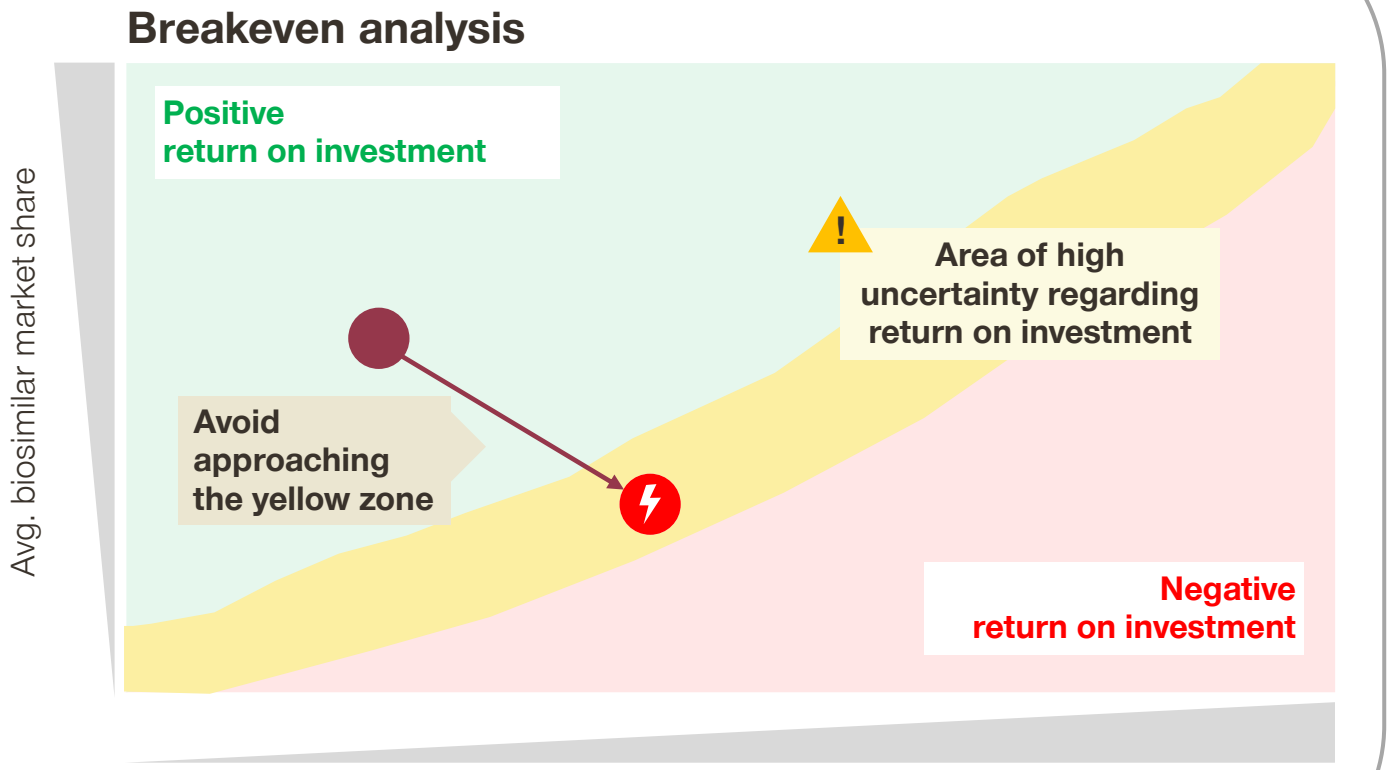
Conceptual example



- The price discount and market share of biosimilar medicines are both highly influenced by payer policies and therefore considered the most relevant input variables in the NPV analysis
- Payers, however, have no effect on upfront investments, COGS, SG&A, etc.

Input variables for NPV analysis

Variables influenced by biosimilar payer policy:

- Infliximab biosimilar price discount vs. originator Remicade
- Infliximab biosimilar market share vs. total infliximab market

Variables kept constant throughout analysis:

- Upfront investment costs (R&D)
- Cost of Goods Sold (COGS)
- Sales, General and Administrative costs (SG&A)
- Taxes *(not applicable if manufacturer does not achieve any profit)*

Cost of capital to be varied between 0–10% for purpose of analysis

Source: Simon-Kucher & Partners

Outline

- Project objective and approach
- Background: Mapping of market-specific pricing & market access policies
- Definition and assessment of sustainability in the biosimilar medicines market
- **Conclusions**
- Principles for a sustainable biosimilar medicines market for payer communication
- Appendix

Based on the overarching analysis of a sustainable biosimilar business, Simon-Kucher drew seven main conclusions

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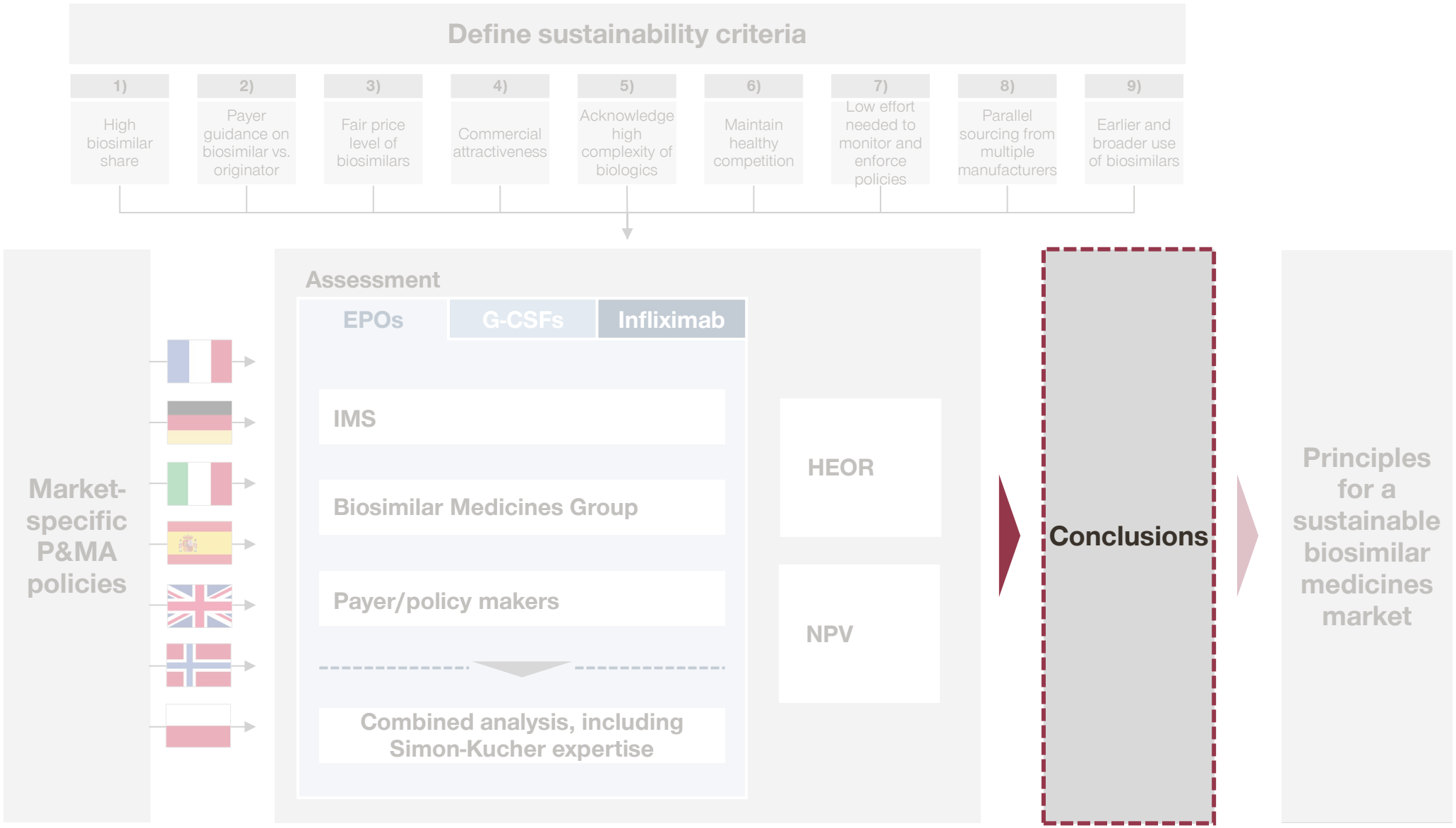

Source: Simon-Kucher & Partners

Overview of high-level findings from payer and manufacturer discussions

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1	Most payers feel adequately informed about biosimilar medicines and perceive the evidence supporting interchangeability to be sufficient
2	While payers strive for short-term savings, biosimilar manufacturers aim for sustainable financials in the long run
3	Payers from DE and the UK as well as manufacturers agree that especially DE and the UK already have pricing & market access policies in place that effectively support a sustainable biosimilar medicines market – even though they still see further room for improvement
4	**Both, payers and biosimilar manufacturers agree that in multiple active market players lead to an environment of healthy competition (however, this obviously also depends on the specific molecule)** ▪ Industry perspective: Multiple active manufacturers seen as supporting sustained long-term commercial attractiveness per manufacturer ▪ Payer perspective: Payers favor competition as a basis for their bargaining power. This necessary level of competition is seen achievable with more than 2 manufacturers
5	**Payers and manufacturers agree that physician support and education is a crucial lever to increase biosimilar medicines acceptance and uptake** ▪ Physicians are seen as one of the main drivers for biosimilar uptake. Since they would promote biosimilar uptake, the potential requirement for automatic biosimilar biosimilar at pharmacy level would be significantly reduced ▪ Example: 'Biolike' initiative in Germany (agreement between KV Westfalen-Lippe and sick fund Barmer GEK: contract focuses on physicians as lever → physicians who achieve a certain biosimilar quota are eligible to bill additional services for their patients)
6	Gainsharing is perceived as the most effective pricing & market access policy in driving biosimilar uptake if physicians see tangible benefits from the generated savings
7	Payers and biosimilar manufacturers agree that a major part of the achieved price reductions in the field of biosimilar medicines today are triggered via voluntary price concession by the industry and not by mandatory price cut rules in the different markets (where applicable)

2 to 7 will be explained in detail on the following slides

Source: Simon-Kucher & Partners

2 While payers strive for short-term savings, biosimilar manufacturers aim for a sustainable business case in the long-run

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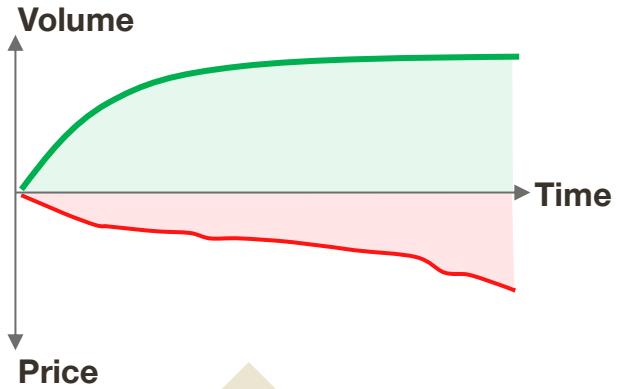
Manufacturers' perspective

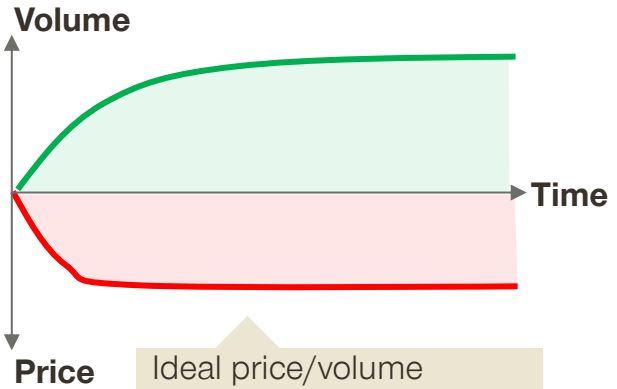
- Biosimilar manufacturers acknowledge that biosimilar medicines are priced below originators but want to limit price erosion especially in the early years (particularly by avoiding mandatory discounts)
- To date, manufacturers argue that offered price discounts and corresponding uptake/volume are often not sufficiently balanced, resulting in non-viable business cases in short-term
- Markets with strongly volatile pricing & market access policies further complicate estimating long-term financial outlooks



Ideal price/volume development from biosimilar manufacturer point of view

Payers' perspective

- Payers aim for high price erosions immediately after biosimilar launch
- Short-term savings are essential to meet annual budget targets
- Payers tend to have high expectations of potential savings, due to their experiences with generics



Ideal price/volume development from payer point of view

Source: Simon-Kucher & Partners

3

Germany and the UK in particular have been mentioned as markets already supporting a sustainable biosimilar business

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P&MA policies allowing for a sustainable business

- Target agreements including biosimilar quotas perceived as core pricing & market access policy elements leveraging biosimilar uptake
- High number of sick funds create sufficient opportunities for market access (e.g. via tendering, open-house contracts)
- Gainsharing at the physician association level significantly supports the biosimilar uptake (see example of KV Westfalen-Lippe and sick fund Barmer GEK)
- Information and education is important for successful implementation

- Four regional tenders offer multiple business opportunities for biosimilar manufacturers and ensure that price discounts are rewarded with an appropriate biosimilar volume/uptake
- National/regional guidance (imposed by NICE & CCGs) recommends usage of the most cost-effective drugs, facilitating biosimilar uptake
- Although gainsharing is not yet commonly implemented (due to complexity of splitting generated savings between CCGs an hospitals), it is still perceived as a promising driver of future biosimilar uptake

Markets with P&MA policies prohibiting a sustainable business

Markets with P&MA policies supporting a sustainable business

There is still room for improvement
→ Payers need to introduce more effective biosimilar pricing & market access policies, supporting improved long-term sustainability of the biosimilar business

Source: Simon-Kucher & Partners

4 Payers and biosimilar manufacturers agree that in general multiple active participants reflect an environment of healthy competition

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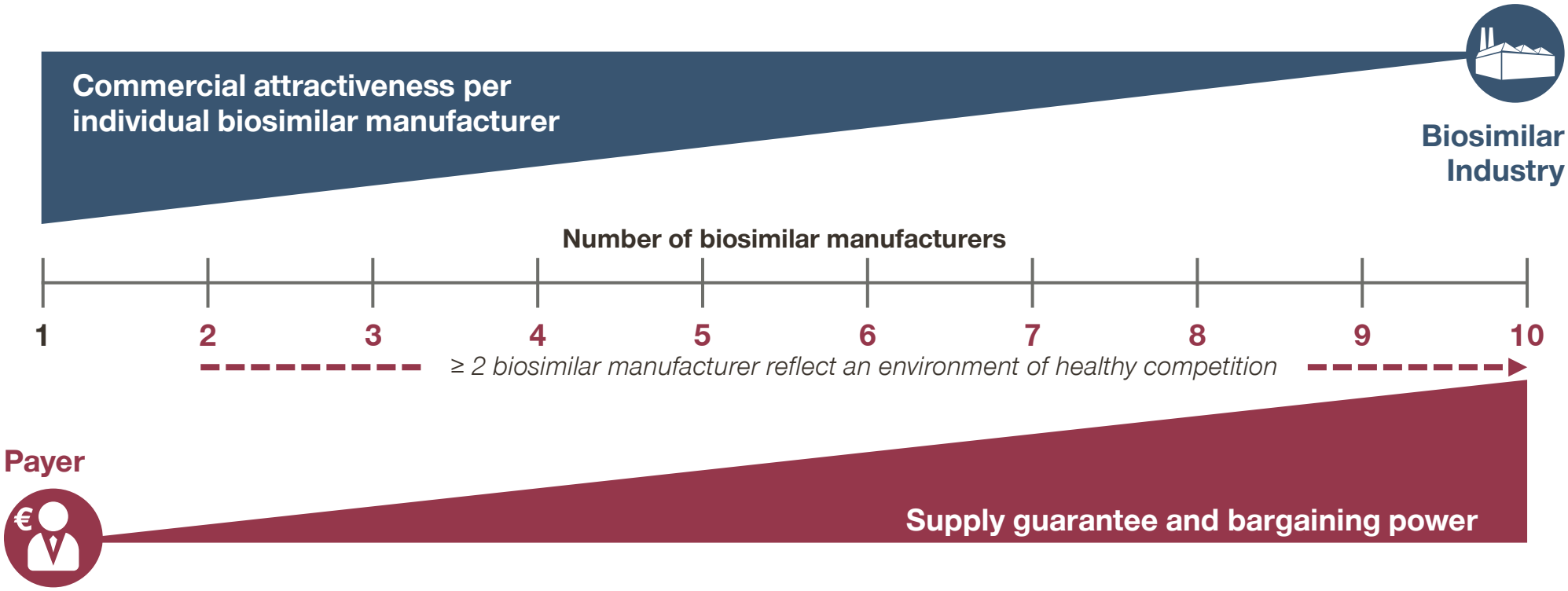

Multiple active biosimilar manufacturers are being considered...

- ...to allow for sustained long-term commercial attractiveness for individual biosimilar manufacturers
- ...as the necessary number of competitors in order to support payers' bargaining power

Source: Simon-Kucher & Partners

5 In Germany, first physician associations have taken initiatives to more effectively encourage physicians to prescribe biosimilars

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‘Biolike initiative’

- ‘Biolike’ is an initiative brought forward by the physician association KV Westfalen-Lippe and the statutory health insurance Barmer GEK, with the overall objective of encouraging physicians to prescribe biosimilars, leading to an enhanced uptake in volume
- Besides foreseeing the provision of detailed information on biosimilars, the agreement between KV Westfalen-Lippe and Barmer GEK focuses on getting physicians to help boost biosimilar uptake: Physicians who achieve a certain biosimilar quota are eligible to bill additional services for their patients

KVWL
Kassenärztliche Vereinigung Westfalen-Lippe

BARMER GEK

Contract on inflammatory bowel disease (IBD)

- The physician association KV Westfalen-Lippe and the statutory health insurance Barmer GEK closed a contract geared toward improving care of IBD patients
- The agreement indicates that patients with ulcerative colitis or Crohn's disease are to be treated with a drug-based therapy of primarily infliximab biosimilars
- Absolute savings generated from prescribing infliximab biosimilar will be equally split between the treating physician and the Barmer GEK

Both, the ‘Biolike initiative’ as well as the contract on IBD help physicians to see tangible benefits from generated savings due to more cost-effective prescribing, leading to an increased biosimilar uptake

Source: Simon-Kucher & Partners

6 Gainsharing has proven to be a successful driver of biosimilar uptake across multiple markets

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Best practice examples: Gainsharing

Increasing impact of gainsharing on biosimilar uptake

Non-cash gainsharing at hospital level

- Fixed drug program/hospital budgets

  Generated savings (e.g., via lower drug acquisition cost) enable more patients to be treated within existing budget and therefore help improve patient care

No 'cash-based' savings, but budget constraints are removed - leading to improved supply for patients

Gainsharing at hospital level

- Hospitals entitled to keep generated savings (difference between DRG and expenditures)
- Hospitals incentivized to purchase T2A products** at low prices: difference between the reimbursement and price paid are split (hospitals, payers)
- Region of Campania: €2.7m savings in H2 2015 from biosimilar use lead to €1.3m being re-allocated to health units. On average, each unit received €165k reward to further invest in patient care

Savings can 'disappear' in hospital overhead, leading to no tangible benefits for treating physicians or directly concerned patients

Gainsharing at level of physician (association)

- Agreement between physicians' association (KV Westfalen-Lippe) and statutory health insurance (Barmer GEK) to improve quality of care of patients with IBD*:
  - **Part of this agreement:** Absolute savings generated from prescribing infliximab biosimilar will be split equally between treating physician and health insurance
- Managed switching program (University Hospital Southampton): Payers benefit from reduced drug bills and providers can re-invest savings in improving patient care

Patients benefit from additional services / facilities, while payers & treating physicians benefit from generated savings

- **Gainsharing is most effective if the physician sees tangible benefits from generated savings (additional services for patients, improved working conditions, etc.)**
- **There is no such thing as a universal gainsharing approach: Gainsharing activities can be designed flexibly and adapted to the structure of the respective national healthcare system**

Source: Simon-Kucher & Partners; *IBD = inflammatory bowel disease; **Biosimilars included in T2A list: epoetin alfa, infliximab, etanercept; filgrastim not included in T2A list

7 In some markets, pricing & market access policies are triggering an unsustainable market environment by encouraging manufacturers to give unusually high price concessions

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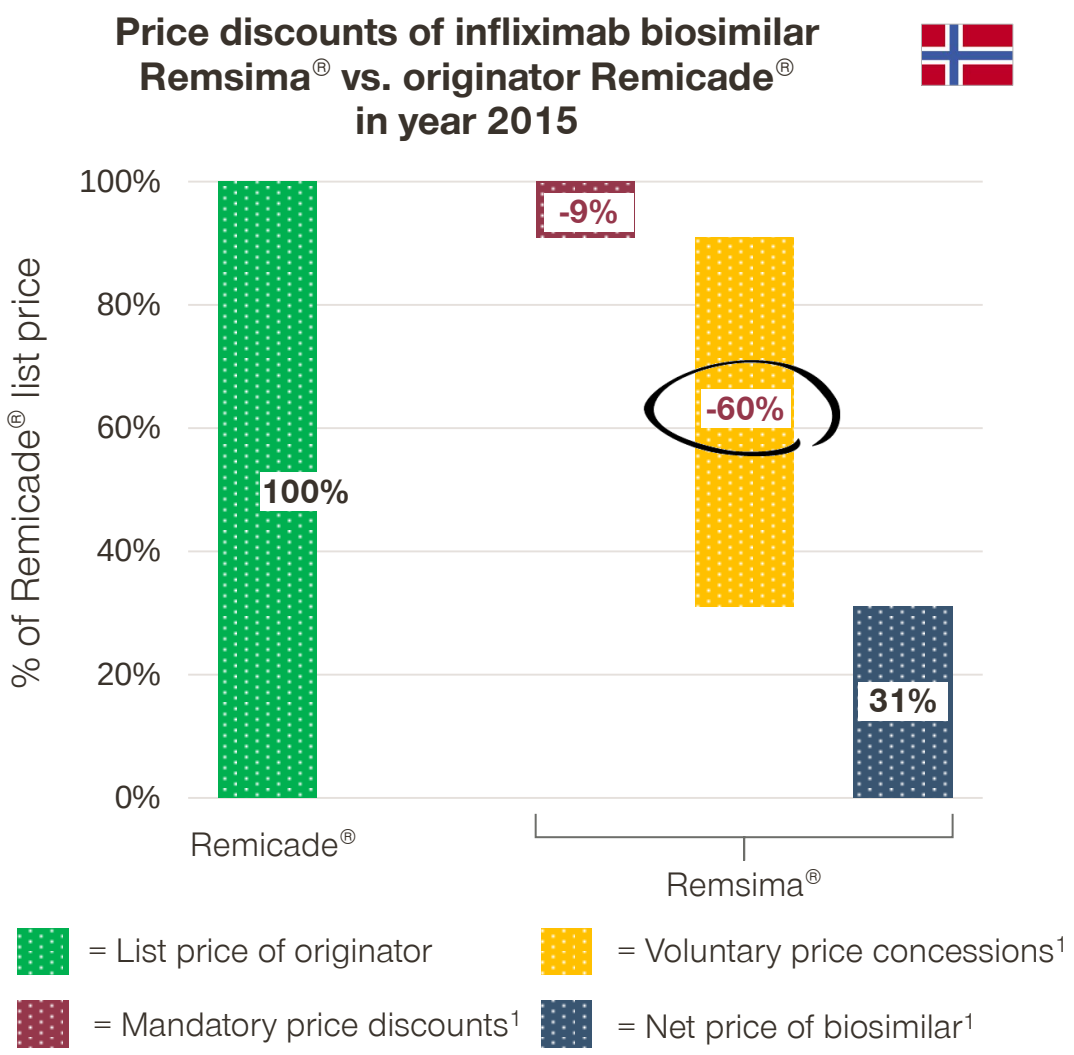

National single-winner tender in Norway drives high voluntary price concessions

- National single-winner tender grants the manufacturer offering the highest discount for a biosimilar preliminary access to the majority of the market
- As the second and third highest bidder will usually not be compensated with a sufficient uptake in volume, manufacturers are pushed to grant high price concessions
- Risk of biosimilar manufacturers not covering their upfront expenditures and potentially not being able to further invest in future biosimilar development
- Similar observations have been made across other EU markets, whenever a contracting decision is involved (e.g., regional tenders, rebate contracts etc.)
- **The latest data for 2016 shows that Norwegian payers have not been able to achieve similar savings compared to 2015 (2016 tender winner offered higher prices vs. 2015), indicating that a lack of competition may also lead to price increases again**

Source: Simon-Kucher & Partners; [1] In percentage of originator list price

Outline

- Project objective and approach
- Background: Mapping of market-specific pricing & market access policies
- Definition and assessment of sustainability in the biosimilar medicines market
- Conclusions
- **Principles for a sustainable biosimilar medicines market for payer communication**
- Appendix

Based on the overall analysis, Simon-Kucher developed fifteen principles for a sustainable biosimilar medicines market

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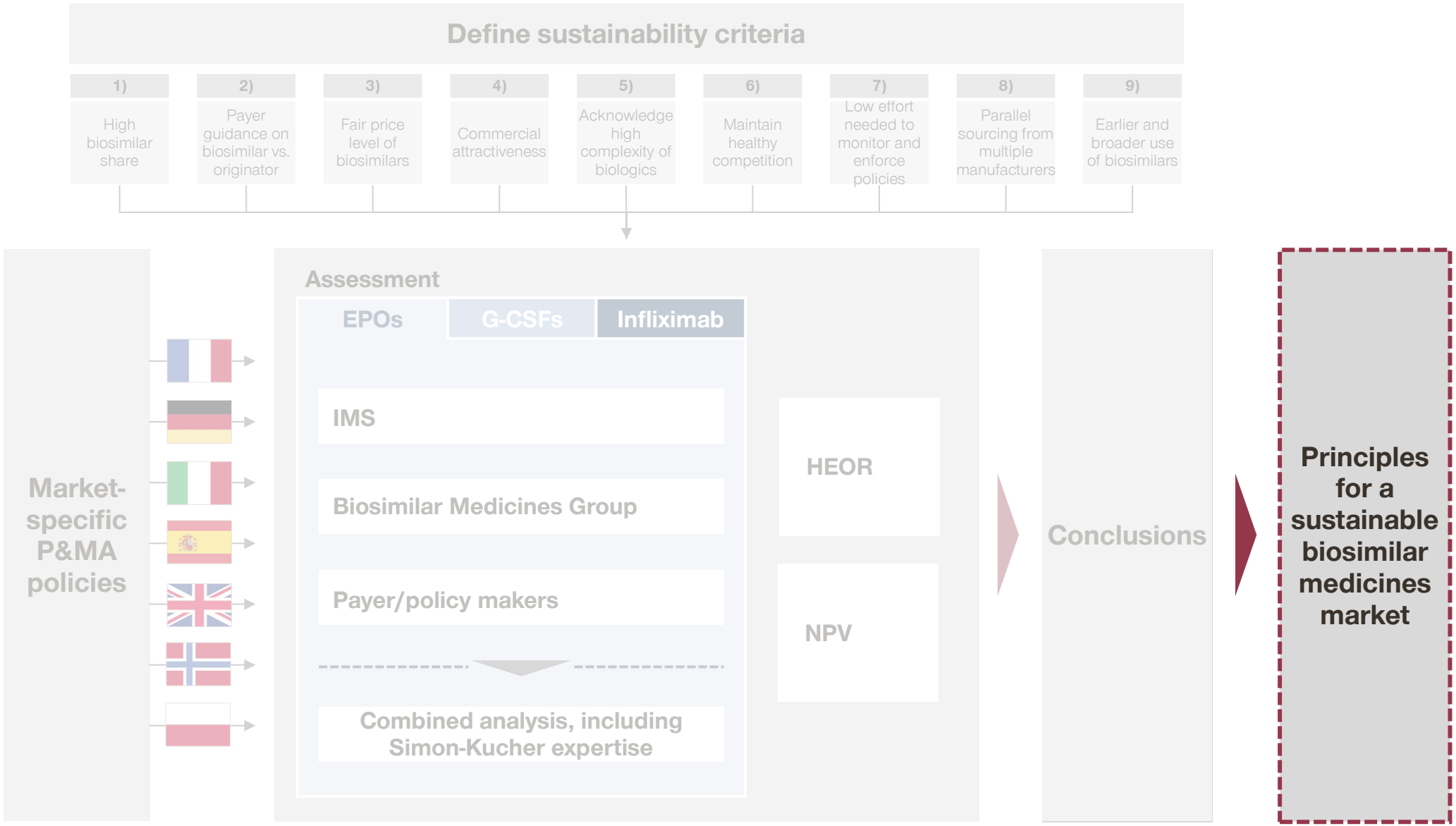

Source: Simon-Kucher & Partners

Targeted principles should be applied to address any discrepancies between the biosimilar industry and payers

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Agreements

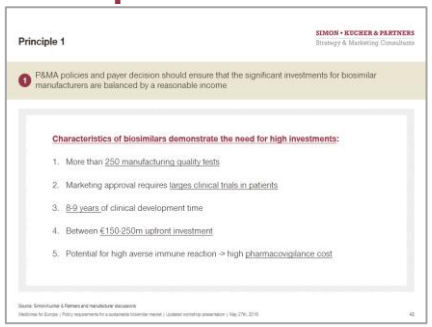
- Long-term savings for the healthcare system
  (due to a fair erosion of prices at an adequate volume of prescribed biosimilars)
- Viable business through healthy competition of several manufacturers
  - Making small changes to the pricing & market access policies over time reduce payers' efforts and increase predictability for the industry
  - Procurement practices that support business potential for several manufacturers at the same time in the same market
  - Prescribing incentivization of less expensive biosimilars vs. their reference products
- Physician education and incentivization to ensure appropriate but cost-conscious prescribing while ensuring quality of care

Discrepancies

- High biosimilar medicines share
  (Not aligned on distribution of biosimilar medicines share)
- Payer guidance on biosimilar vs. originator medicines
  (Not aligned on the extent of payer guidance required to sufficiently drive uptake)
- Fair price level
  (Not aligned on the exact level considered to be fair)
- Commercial attractiveness
  (Not aligned on which ROI would be considered fair)
- Maintain healthy competition (long-term perspective)
  (Not aligned on interpretation of competition)
- Acknowledge high complexity of biologics within pricing & market access process
  (Not aligned on extent of influence on P&MA policies)

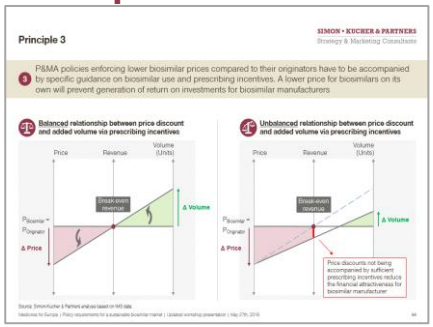
Principles for a more sustainable biosimilar medicines market

Principle 1



Principle 2

Principle 3



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Source: Simon-Kucher & Partners

Story flow of presented principles for a sustainable biosimilar market

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1. **Biologics (including biosimilar medicines) are complex molecules and require a tailored pricing & market access policy** *[see principles 1a, 1b, 1c]*
2. **Biosimilar medicines are very valuable for the healthcare systems since they generate savings and improve patient access** *[see principles 2–4]*
3. **Biosimilar medicines will offer benefits only if there is healthy competition among manufacturers** *[see principles 5–7]*
4. **The basis for healthy competition will be a sustained market attractiveness from a manufacturer & payer perspective** *[see principles 8 – 12]*
5. **Biosimilar medicine policies require appropriate monitoring and maintenance** *[see principle13]*

Source: Simon-Kucher & Partners

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Principle 1a

1a Biologic medicines, including biosimilar medicines, are complex medicines grown in living cells which are used to treat serious conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. The use of biologic medicines should be supervised and carried out by specialist physicians and advanced practitioners. Therefore, respective biosimilar policies should allow physicians to choose from different treatment alternatives.

Pricing & market access policies for biosimilar medicines should allow physicians to have an important role in terms of deciding on which biologic medicine to prescribe

Drug procurement:

- Ensure a sufficient number of biologic medicines (originator and biosimilar) are available to physicians so that prescription decisions are based on clinical reasons

❗ Single-lot tenders will favor the least expensive biologic, significantly reducing the physician's flexibility to prescribe

Drug dispensation:

- The pharmacist should always take the physicians' prescribing decision into consideration. As such, substitution at the pharmacy level should not take place by default

Source: Simon-Kucher & Partners

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Principle 1b

1b Pricing & market access policies and payer decisions should ensure that the significant investments for biosimilar manufacturers are balanced by a reasonable income

Characteristics of biosimilar medicines demonstrate the need for high investments:

1. May take up to 9 years of development time
2. More than 250 manufacturing quality tests
3. Marketing approval may require comparative clinical trials in patients where applicable
4. Significant upfront investment; can be in the range of €150m to €250m
5. Rare potential for high averse immune reaction for biologic medicines in general → Comprehensive post-marketing surveillance/pharmacovigilance program required

Source: Simon-Kucher & Partners and manufacturer discussions

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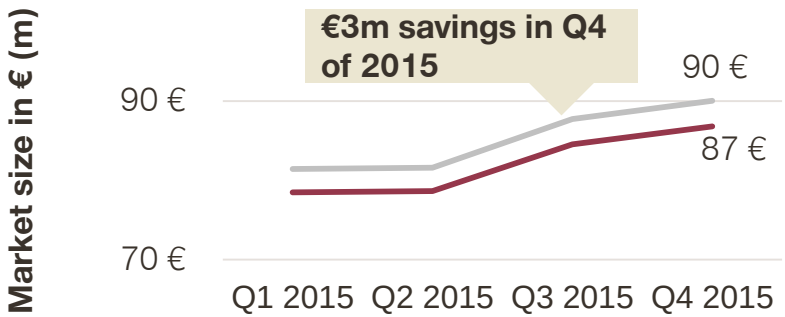
Principle 2

2 Biosimilar medicines have generated considerable savings over the past years and have therefore alleviated budget constraints in the French public healthcare system. Savings for infliximab in 2015 alone account for a double-digit million figure.

Analysis based on list prices; net price savings effect assumed to be significantly higher

Base case scenario

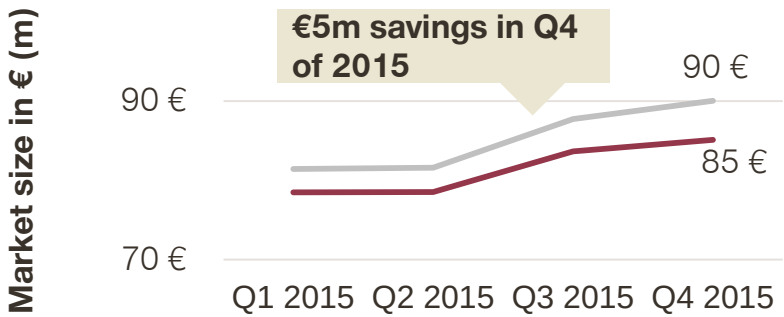


Accumulated savings (2015):

€12m

Discount scenario

Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2015):

€15m

Source: Simon-Kucher & Partners analysis based on IMS data

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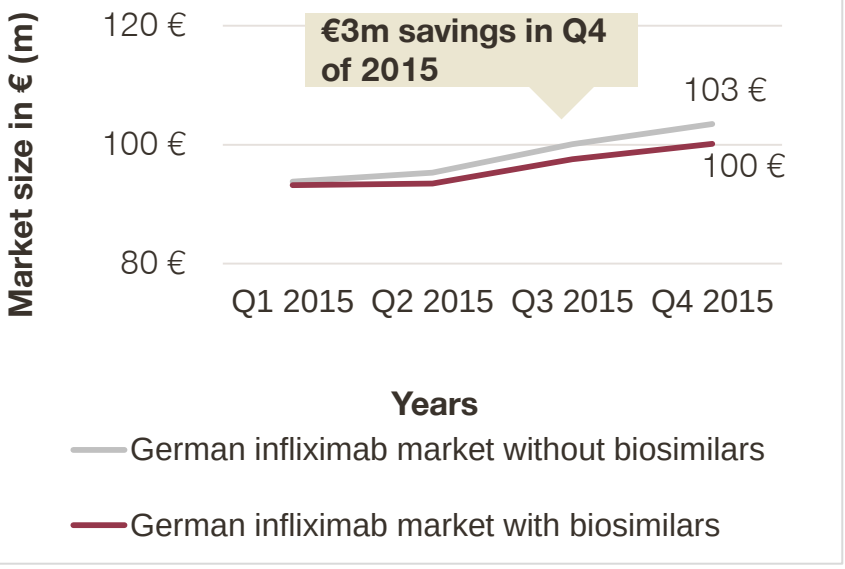
Principle 2

2 Biosimilar medicines have generated considerable savings over the past years and have therefore alleviated budget constraints in the German public healthcare system. In 2015 alone, infliximab was able to save millions

Analysis based on list prices; net price savings effect assumed to be significantly higher

Base case scenario

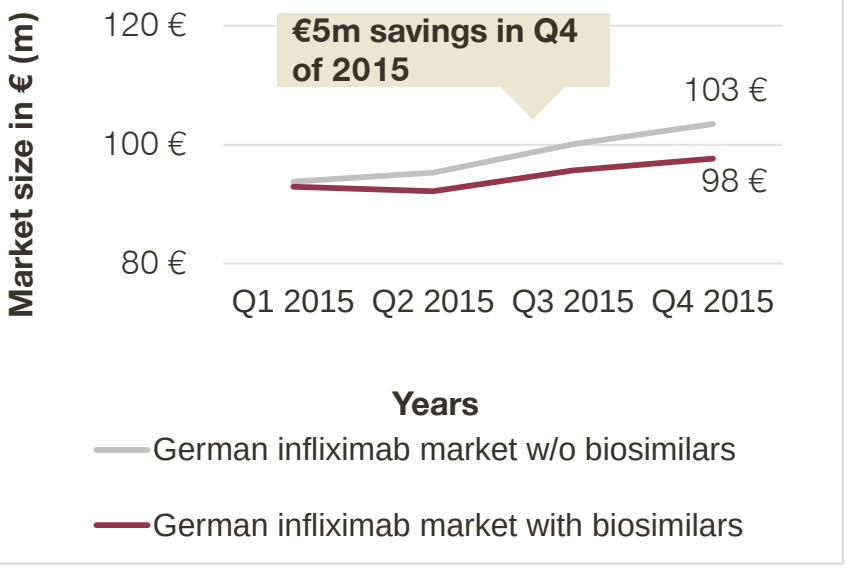


Accumulated savings (2015):

€8m

Discount scenario

Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2015):

€14m

Source: Simon-Kucher & Partners analysis based on IMS data (including inpatient and outpatient data)

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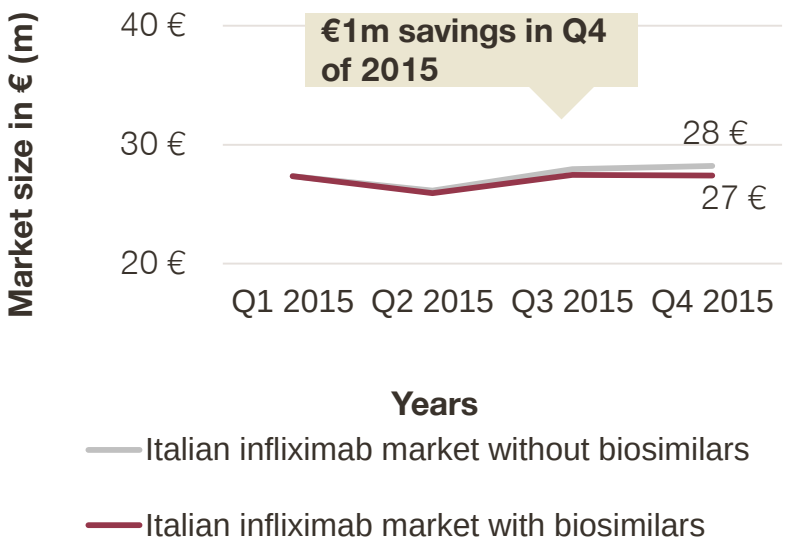
Principle 2

2 Biosimilar medicines have generated considerable savings over the past years and have therefore alleviated budget constraints in the Italian public healthcare system. Savings for infliximab in 2015 alone account for a single-digit million figure.

Analysis based on list prices; net price savings effect assumed to be significantly higher

Base case scenario

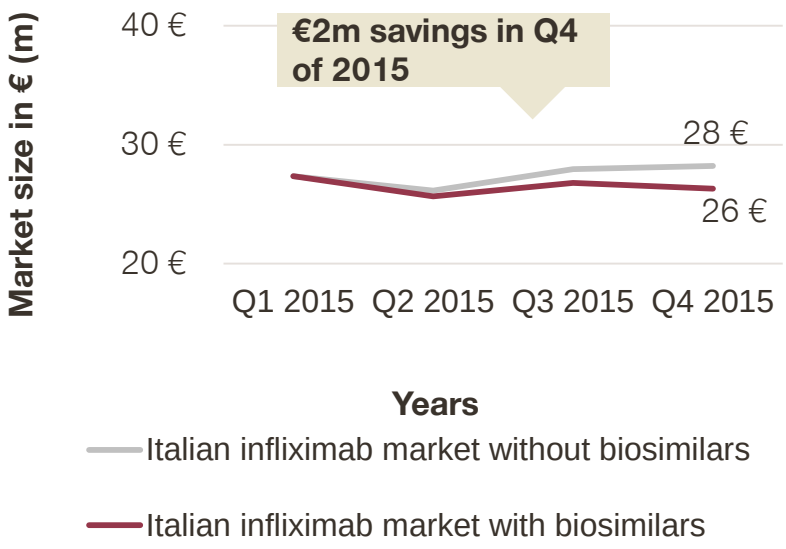


Accumulated savings (2015):

€2m

Discount scenario

Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2015):

€4m

Source: Simon-Kucher & Partners analysis based on IMS data

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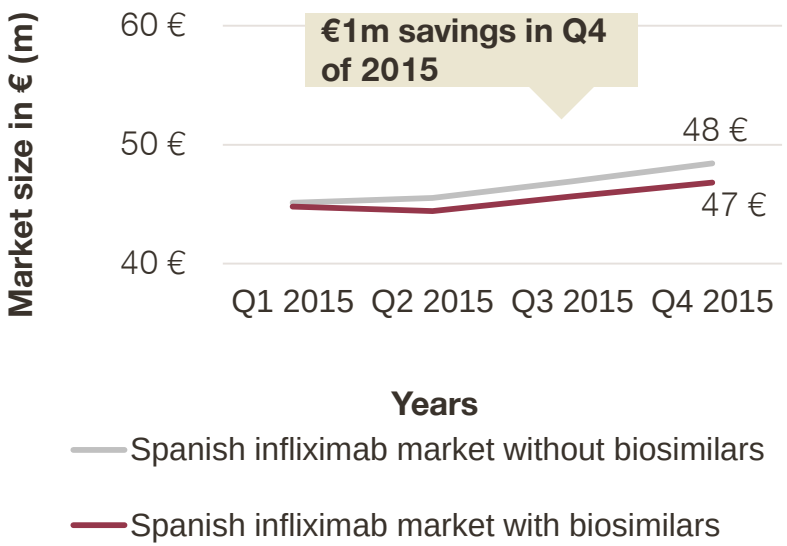
Principle 2

2 Biosimilar medicines have generated considerable savings over the past years and have therefore alleviated budget constraints in the Spanish public healthcare system. Savings for infliximab in 2015 alone account for a single-digit million figure.

Analysis based on list prices; net price savings effect assumed to be significantly higher

Base case scenario

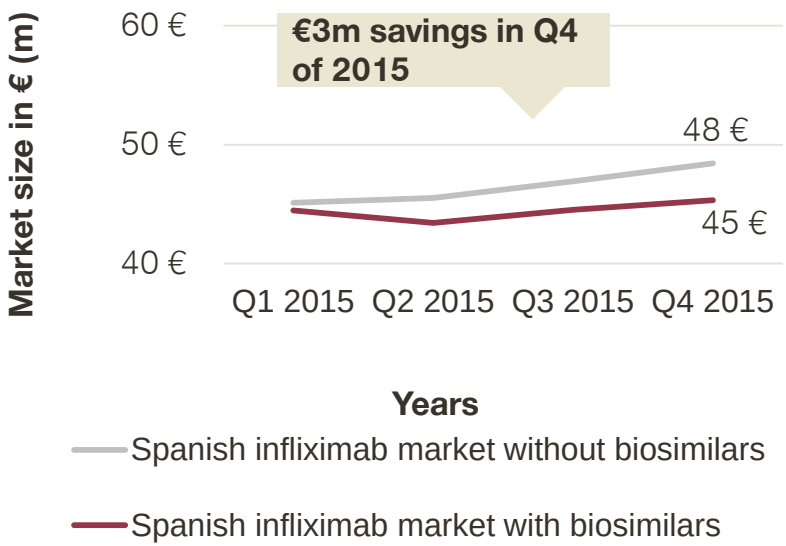


Accumulated savings (2015):

€4m

Discount scenario

Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2015):

€8m

Source: Simon-Kucher & Partners analysis based on IMS data

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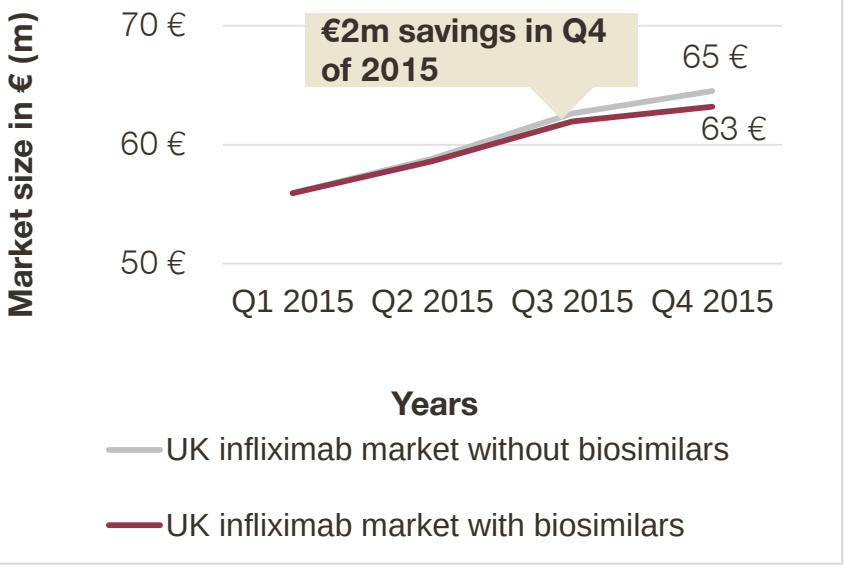
Principle 2

2 Biosimilar medicines have generated considerable savings over the past years and have therefore alleviated budget constraints in the UK public healthcare system. Savings for infliximab in 2015 alone account for a single-digit million figure.

Analysis based on list prices; net price savings effect assumed to be significantly higher

Base case scenario

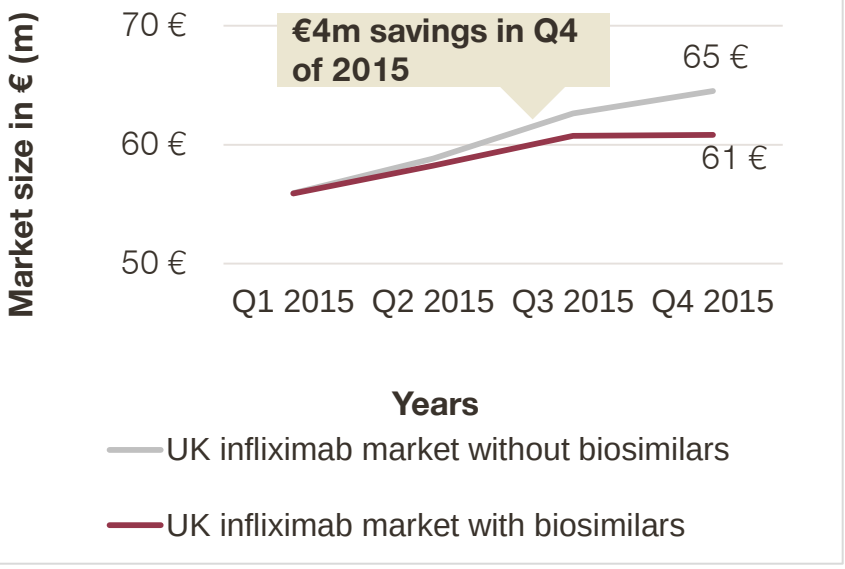


Accumulated savings (2015):

€2m

Discount scenario

Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2015):

€6m

Source: Simon-Kucher & Partners analysis based on IMS data

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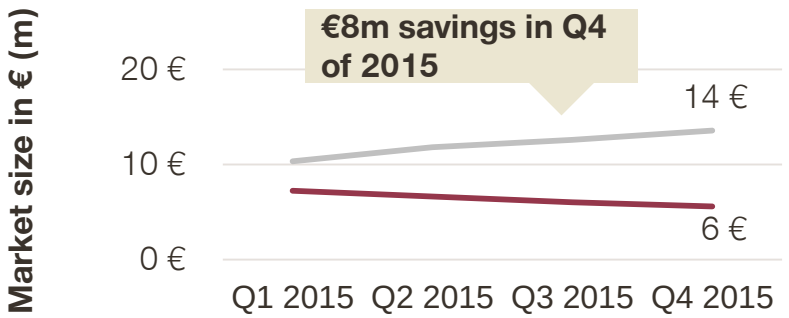
Principle 2

2 Biosimilar medicines have generated considerable savings over the past years and have therefore alleviated budget constraints in the Norwegian public healthcare system. Savings for infliximab in 2015 alone account for a double-digit million figure.

Analysis based on list prices; net price savings effect assumed to be significantly higher

Base case scenario

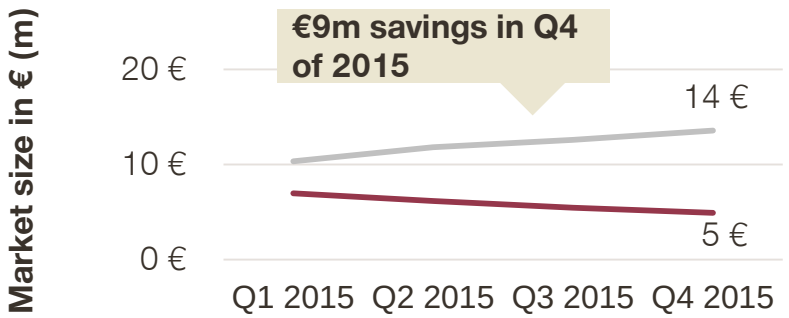


Accumulated savings (2015):

€23m

Discount scenario

Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2015):

€25m

Source: Simon-Kucher & Partners analysis based on IMS data

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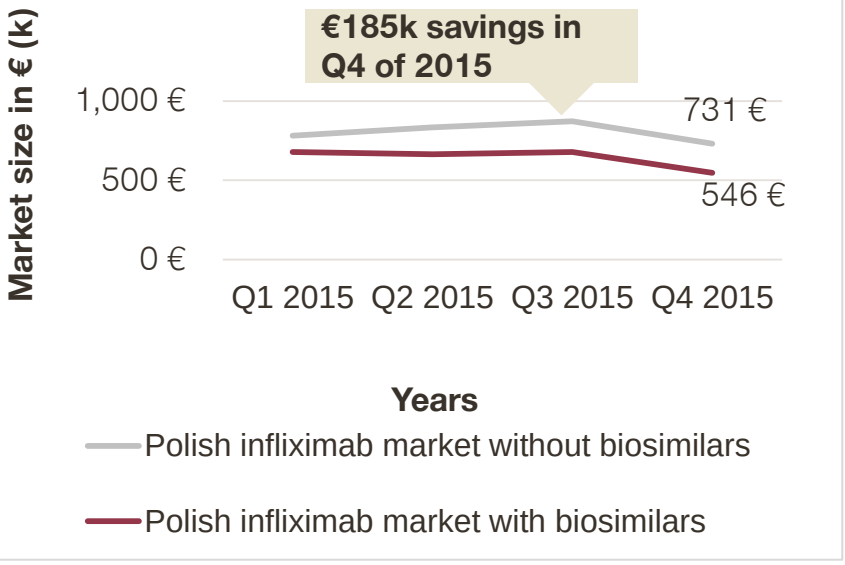
Principle 2

2 Biosimilar medicines have generated considerable savings over the past years and have therefore alleviated budget constraints in the Polish public healthcare system. Savings for infliximab in 2015 alone account for a single-digit million figure.

Analysis based on list prices; net price savings effect assumed to be significantly higher

Base case scenario

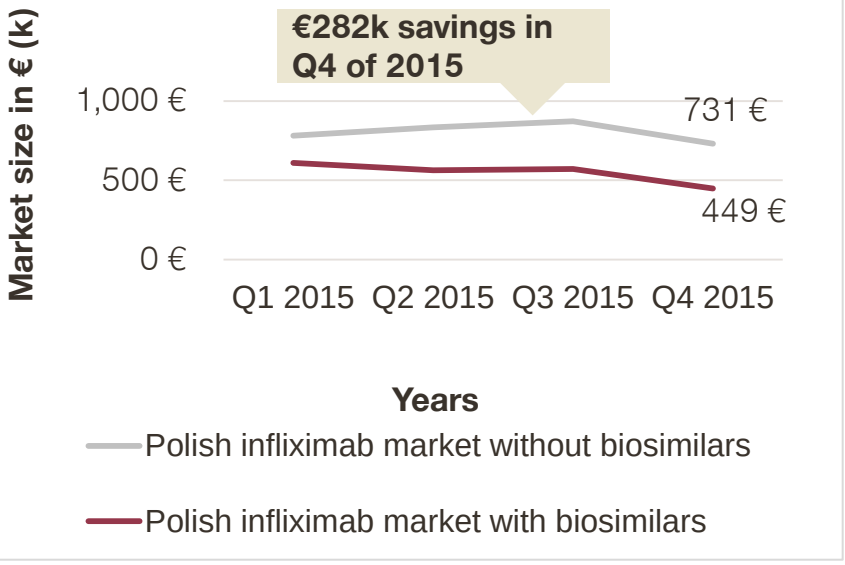


Accumulated savings (2015):

€1m

Discount scenario

Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2015):

€1m

Source: Simon-Kucher & Partners analysis based on IMS data

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Principle 3.1

3 Their competitive drug acquisition cost makes it possible for biosimilar medicines to reach an acceptable ICER in situations where originator cannot. As a consequence, biosimilar medicines support improved patient access to certain therapeutic areas compared to the originator medicine.

Example 1: Infliximab

Ankylosing spondylitis patients covered by EMA label

2015

2015 NICE guidance recommends **use of infliximab biosimilar medicines in** adults with non-radiographic axial spondyloarthritis

According to 2008 NICE guideline, infliximab (originator) should **not be used at all**

2008

Example 2: Epoetin

Treatment-induced anemia patients with cancer covered by EMA label

2014

According to 2014 NICE guideline, epoetin **is both clinically and cost-effective**

According to 2008 NICE guideline, epoetin is clinically effective for cancer treatment-induced anaemia, **but not cost-effective**

2008

- The NICE Committee noted that the companies marketing biosimilar versions of infliximab/epoetin had presented **new ICERs**, in response to the appraisal consultation document, using lower prices for their products to reflect the tendering process that was taking place during the consultation period
- As a result the cost-effectiveness of infliximab/epoetin was within the range considered to be a **cost-effective use of NHS resources**

Source: Simon-Kucher & Partners; www.NICE.org.uk

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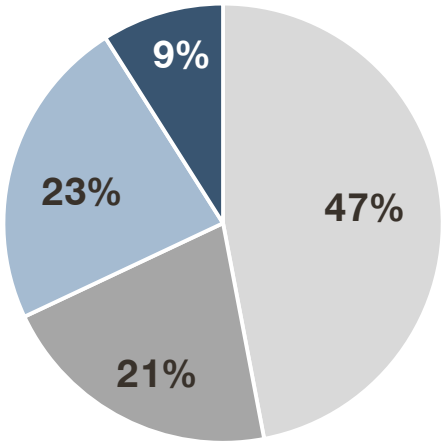
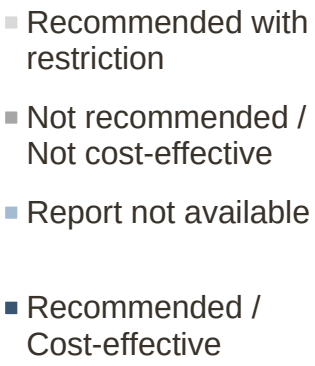
Principle 3.2

3 Their competitive drug acquisition cost makes it possible for biosimilar medicines to reach an acceptable ICER in situations where originators cannot. As a consequence, biosimilar medicines support improved patient access to certain therapeutic areas compared to the originator medicine.

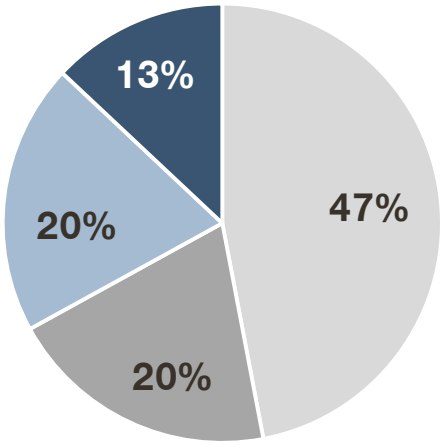
NICE appraisals of biologics



68%



SMC appraisal of biologics



67%

Cost-effectiveness cited as driver for restricted or negative decisions*

Source: Simon-Kucher & Partners; Sandoz: ISPOR 18th Annual European Congress; based on 7 biologics having biosimilars (one under EMA review) and 15 bestselling biologics expected to have a biosimilar within the next 5 years & covering 106 licensed indications

*Apart from the absence of dossier submission, restricted indication requested by the manufacturer or restriction related only to prescription limited to specialists when summary of product characteristics includes specific supervision by a specialists or when no rationale available (one page advice or reference to unpublished advice of NICE advice (for SMC), i.e, 22 SMC indications, and 55 NICE indications

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Principle 4.1

4 Improved access (within the existing label) for biologic medicines due to the availability of less expensive biosimilar medicines supports better health outcomes.

Southern healthcare region

Previous situation prior to availability of filgrastim biosimilars

- In order to be allowed to initiate the treatment with filgrastim originator, the opinion / formal approval of three physicians has to be awaited

Current situation with filgrastim biosimilars available

- Launch of filgrastim biosimilars and the associated reduction in treatment costs for G-CSF treatment of febrile neutropenia prompted the regional authorities to relax restrictions on prescribing
- Prescription does not need further authorization

➢ **Uptake of G-CSF increased five-fold in the Southern Healthcare Region, driven by usage of biosimilar filgrastim**

With physicians given the freedom to prescribe, one could conclude that this increase was driven by clinical need and that consequently outcomes improved for patients in the region

Source: Simon-Kucher & Partners; IMS Health

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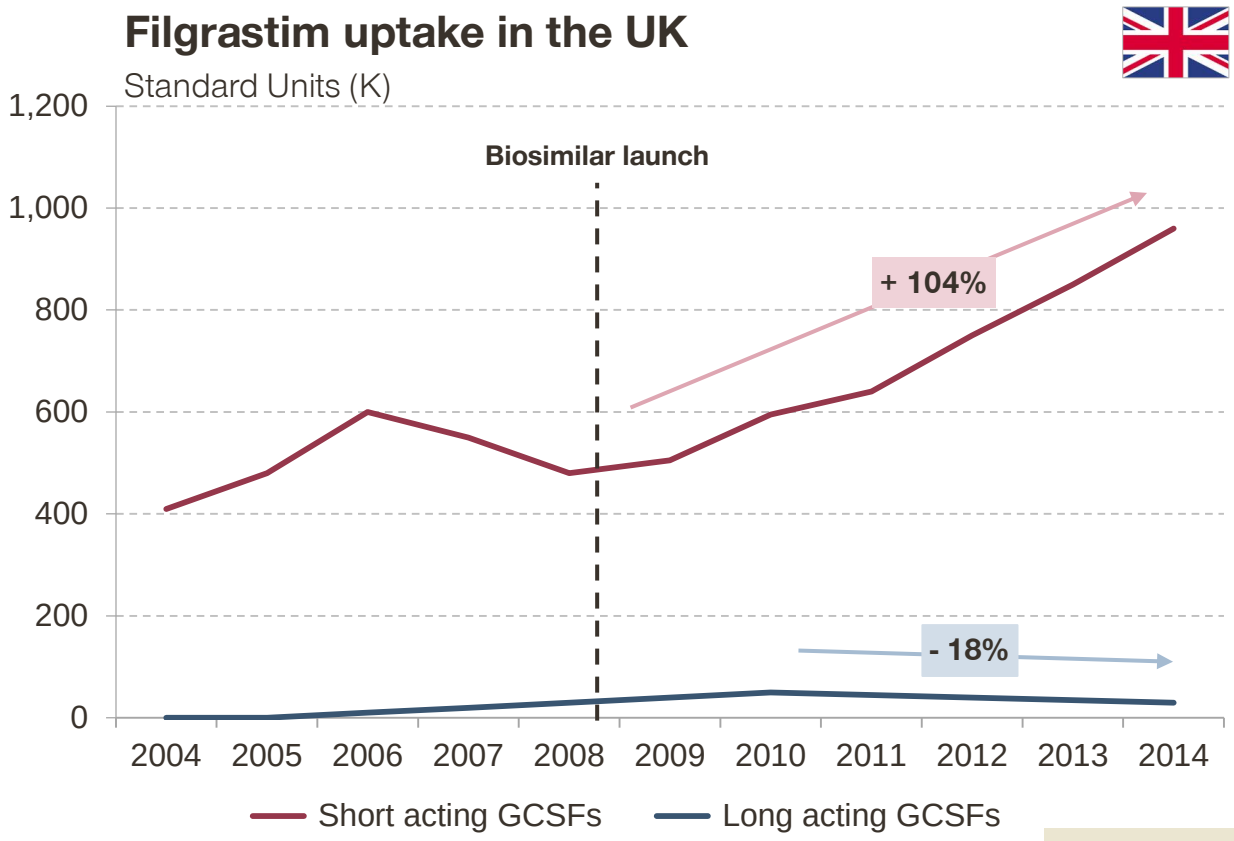
Principle 4.2

4 Improved access (within the existing label) for biologic medicines due to the availability of less expensive biosimilar medicines supports better health outcomes.



Changes in developments depicted as overall change in % between 2008–2014 (short acting) and 2010–2014 (long acting)

- After biosimilar launch in 2008, NICE guidelines were updated to reflect the improved cost-effectiveness of biosimilar filgrastim vs. alternative treatments
- As a result, G-CSF restrictions have been relaxed and usage is now also recommended for primary prophylaxis of neutropenia (before: secondary prophylaxis only)
- As a consequence, overall consumption of filgrastim short-acting increased by 104% between 2009 and 2014
- **One can conclude that the launch of biosimilar G-CSF also led to improved patient outcomes, by enabling greater numbers of patients to access these treatments at an earlier stage of the therapy cycle**

This example is specific for filgrastim. Similar experience may not be expected with all other biosimilar medicines that will be launched in the future (i.e. increased uptake may have other reasons)

Source: Simon-Kucher & Partners; IMS Health, MIDAS; IMS Consulting Group, Nov 2015

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Principle 5

5 Pricing & market access policies, and tenders specifically, should ensure a continuous market participation of several biosimilar manufacturers in order to maintain healthy competition.

Win-win situation due to continuous market participation of multiple biosimilar manufacturers

Payer

- Short-term supply guarantee
- Budget savings due to competition triggering price decreases
- Maintain interest of manufacturers to keep market participation
- Better predictability of business
- Healthy co-existence of several suppliers

Biosimilar industry

Example: Pharmadialog for generic medicines (agreement between industry and payers/policy makers)

- Increased risk of supply guarantee has been observed with current procurement measures (e.g. rebate contracts)
- As a consequence industry and payers/policy makers have agreed that future procurement measures need to further support parallel supply from multiple manufacturers of generic and biosimilar medicines

Source: Simon-Kucher & Partners

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Principle 6

6 Tender decisions should not be based only on price. They should also reflect a value-based approach, taking into consideration multiple influencing factors apart from price (such as supply guarantee, provision of education or other value added services) to support sustained benefits from biosimilar medicines.

Tender scorecard as decision instrument

Purchasing criteria	Manufacturer 1	Manufacturer 2	Manufacturer 3
Price	~		
Supply guarantee	✓		
Provision of education	✗		
Value added services	✓		
...	...		
Overall rating	~		

✓ = Purchasing criterion fulfilled
~ = Purchasing criterion partially fulfilled
✗ = Purchasing criterion not fulfilled

- Value-based tendering involves decision criteria other than price and is being introduced in the tendering process in markets such as the UK, Finland, Norway and Sweden
- Recent outcome of 'Pharmadialog' in Germany:
  Alignment between industry and payers/policy makers on the fact that future procurement measures need to more strongly consider supply guarantee and thus leave room for multiple manufacturers, especially in the field of generic medicines, but also targeting future biosimilar medicines procurement decisions

Source: Simon-Kucher & Partners

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Principle 7

7 Countries in which the biosimilar policy limits the room for simultaneously active market participants are hindering parallel sourcing. Such policies negatively affect the country's ability to guarantee short-term medical supply for their patients.

Regional single-lot tenders

- Market observations have shown that manufacturers that make the best offer (in terms of price) are not always able to sufficiently serve the market, e.g. during peak demand
- As a consequence, a supply shortage can occur due to lack of multiple sourcing as a consequence of the single-lot tender structure

Risk of supply shortage

Multiple-lot tender*

	Bidding volume	Supplying manufacturer
1st bidder	500,000 units	Manu. 1
2nd bidder	250,000 units	Manu. 2
3rd bidder	150,000 units	Manu. 3
4th bidder	100,000 units	Manu. 4
Total volume	1 million units	

Supply guarantee via multiple manufacturers

Source: Simon-Kucher & Partners; * Multiple-lot tender not necessarily relevant in all markets

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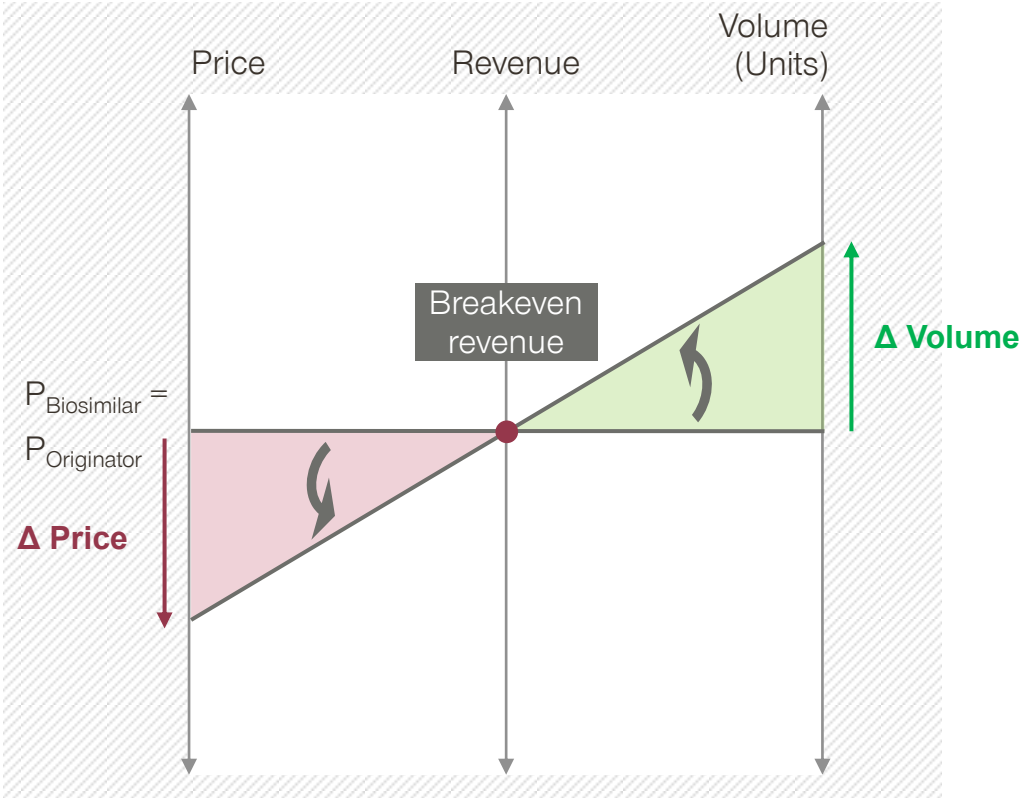
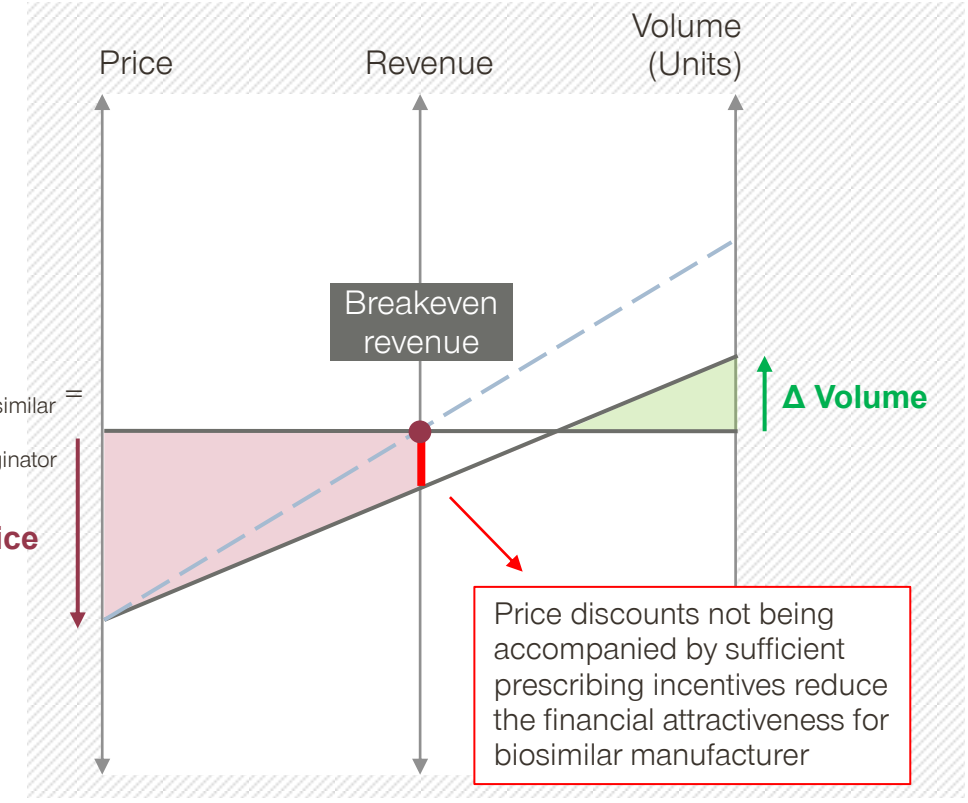
Principle 8.1

8 Pricing & market access policies enforcing lower biosimilar prices compared to their originators have to be accompanied by specific guidance on biosimilar use and prescribing incentives. A lower price for biosimilar medicines on its own will prevent generation of return on investments for biosimilar manufacturers.

Balanced relationship between price discount and added volume via prescribing incentives



Unbalanced relationship between price discount and added volume via prescribing incentives



Source: Simon-Kucher & Partners analysis based on IMS data

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Principle 8.2

8 Pricing & market access policies enforcing lower biosimilar prices compared to their originators have to be accompanied by specific guidance on biosimilar use and prescribing incentives. A lower price for biosimilar medicines on its own will prevent generation of return on investments for biosimilar manufacturers.

Breakeven situation	
Price per unit	€10
Sold units	10
Resulting revenue	**€100**

Balanced relationship between price discount and added volume via prescribing incentives

Balanced situation	
Price per unit	€5
Sold units	20
Resulting revenue	**€100**

Resulting revenue ≥ breakeven revenue

Unbalanced relationship between price discount and added volume via prescribing incentives

Unbalanced situation	
Price per unit	€5
Sold units	12
Resulting revenue	**€60**

Resulting revenue < breakeven revenue

Source: Simon-Kucher & Partners analysis based on IMS data

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Principle 9

9a Mandatory price discounts that are not linked to a certain volume compensation do not offer biosimilar manufacturers a sustainable market environment.

9b Biosimilar manufacturers may grant price concessions voluntarily if they can expect to be compensated with an appropriate amount of sold units in exchange.

9c Provided that 9b) applies, mandatory price cuts are not essential to create savings to the healthcare system.

Source: Simon-Kucher & Partners

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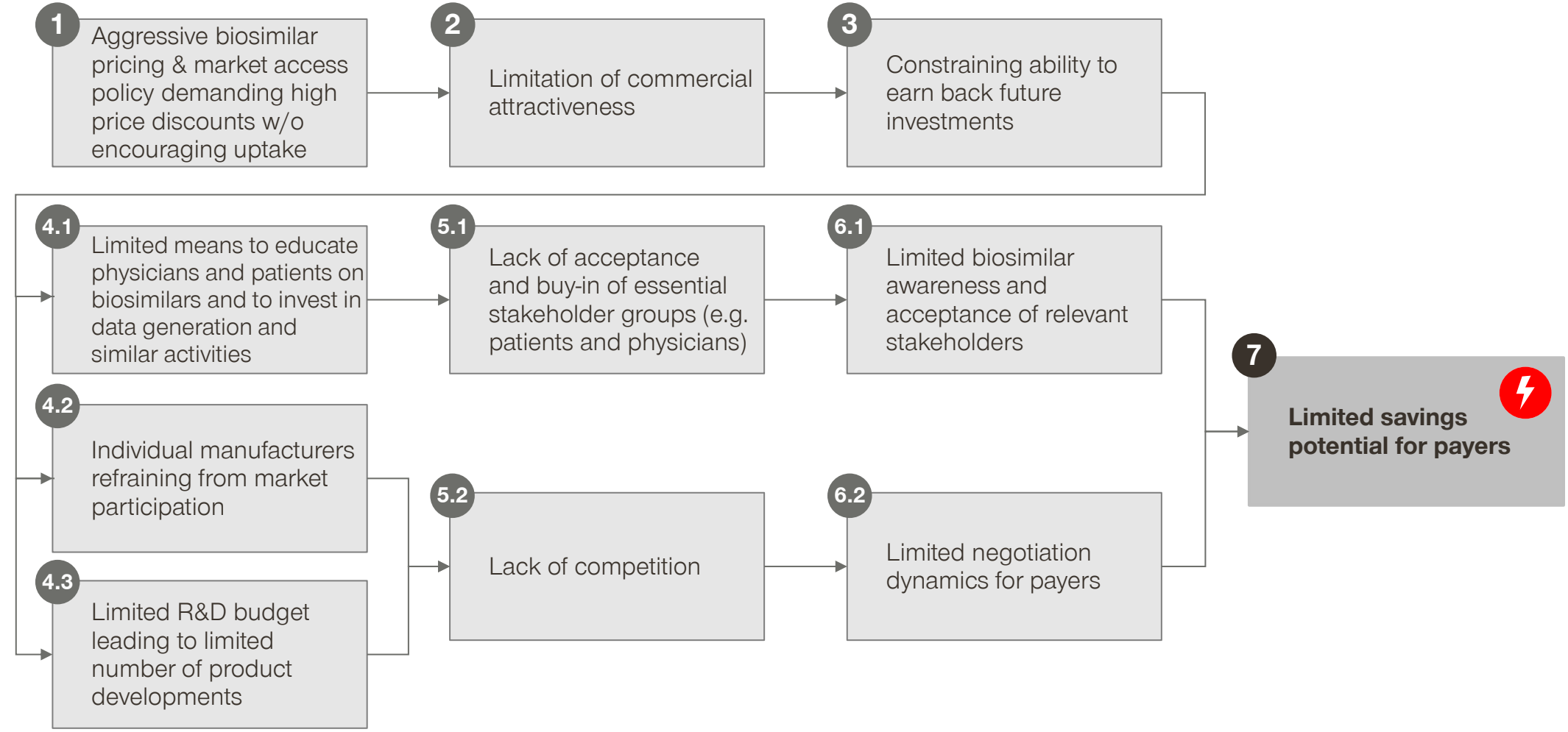
Principle 10

10 A pricing & market access policy that does not allow for commercial attractiveness for biosimilar manufacturers will reduce competition in the long run and thus negatively impact the likelihood for payers to generate savings



Source: Simon-Kucher & Partners

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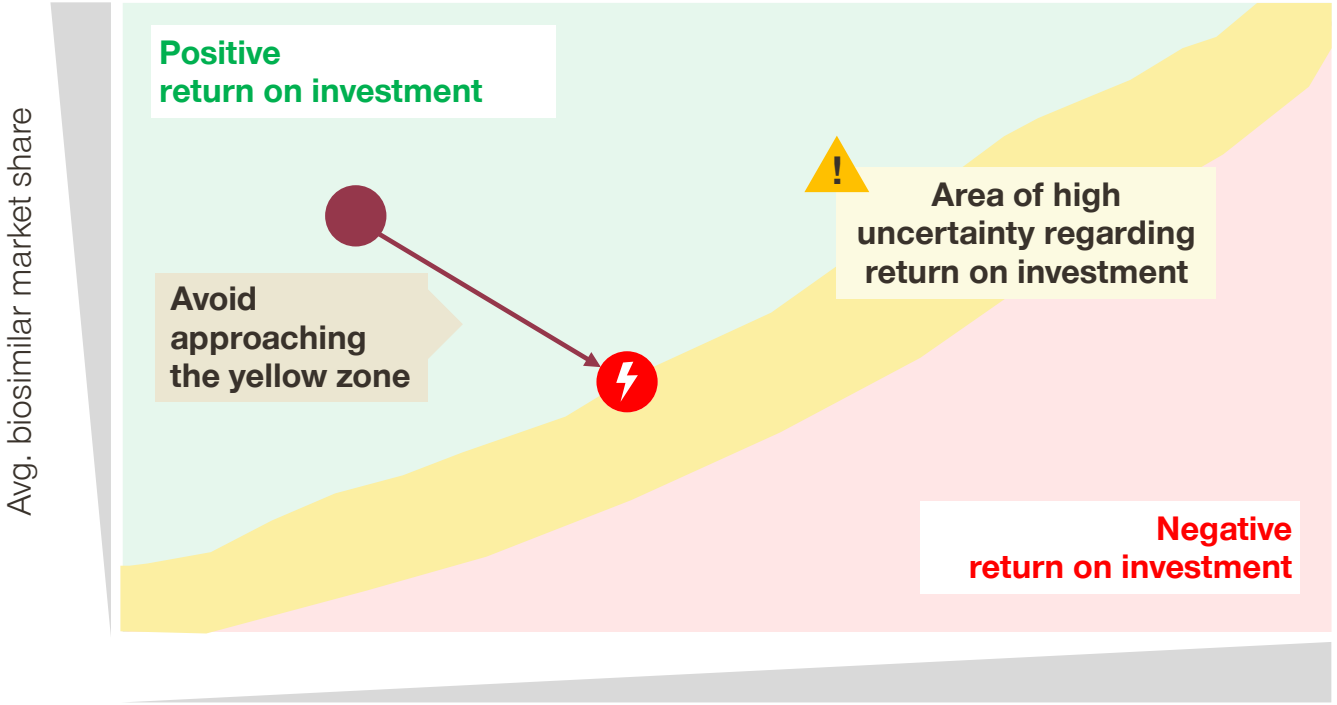
Principle 11

11 Unfavorable combinations of price erosion and volume uptake for biosimilar medicines will not support a sustainable biosimilar business potential in the medium and long-term.

Breakeven analysis



Input variables

- Upfront investment
- EU sales compared to ROW
- COGS
- SG&A
- Cost of capital
- Tax
- Biosimilar market share (and subsequently the share per biosimilar manufacturer)
- Price discount (to originator)

Input variables influenced by payer policy

- Structure of NPV model is validated by financial experts
- Input variables are collated from several biosimilar manufacturers

Source: Simon-Kucher & Partners

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Principle 12

12 Gainsharing has proven to be a successful driver of biosimilar uptake across multiple markets, with benefits for multiple stakeholders – patients, prescribers / decision makers and payers.

Increasing impact of gainsharing on biosimilar uptake

Non-cash gainsharing at hospital level	Gainsharing at hospital level	Gainsharing at level of physician (association)
Fixed drug program/hospital budgets Generated savings (e.g., via lower drug acquisition cost) enable more patients to be treated within existing budget and therefore help improve patient care	Hospitals entitled to keep generated savings (difference between DRG and expenditures) Hospitals incentivized to purchase T2A** products at low prices: difference between the reimbursement and price paid are split (hospitals, payers) Region of Campania: €2.7m savings in H2 2015 from biosimilar use lead to €1.3m being re-allocated to health units. On average, each unit received €165k reward to further invest in patient care	Agreement between physicians' association (KV Westfalen-Lippe) and statutory health insurance (Barmer GEK) to improve quality of care of patients with IBD*: – **Part of this agreement:** Absolute savings generated from prescribing infliximab biosimilar will be split equally between treating physician and health insurance Managed switching program (University Hospital Southampton): Payers benefit from reduced drug bills and providers can re-invest savings in improving patient care
No 'cash-based' savings, but budget constraints are removed - leading to improved supply for patients	Savings can 'disappear' in hospital overhead, leading to no tangible benefits for treating physicians or directly concerned patients	Patients benefit from additional services / facilities, while payers & treating physicians benefit from generated savings

Gainsharing is most effective if the healthcare provider sees tangible benefits from generated savings (additional services for patients, improved working conditions, monetary benefits, etc.)

Source: Simon-Kucher & Partners; *IBD = inflammatory bowel disease; **Biosimilars included in T2A list: epoetin alfa, infliximab, etanercept; filgrastim not included in T2A list

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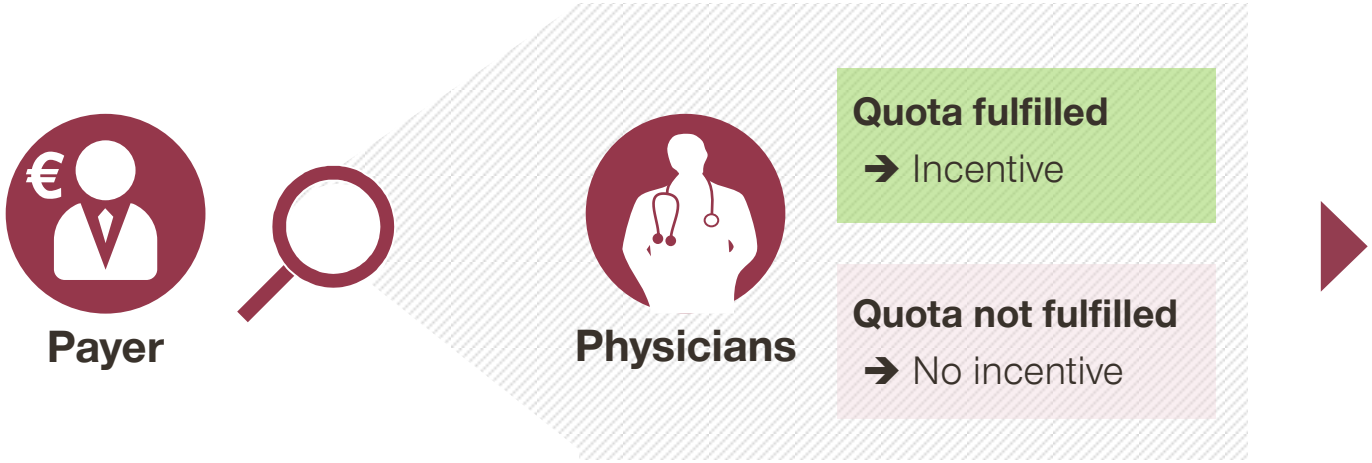
Principle 13

13 Pricing & market access policies are only sustainable if payers are able to ensure close monitoring of their implementation, subsequently incentivizing physician adhere to these policies.

Example:
Implementation of regional biosimilar quotas



Region	Biosimilar quota	Physicians	
		Name	Biosimilar quota
1	50%	A	60%
		B	50%
		C	45%
		D	55%
		E	50%
		...	...
2	*No quota*	X	20%
		Y	25%
		...	...
...	...	...	...

Effectively implemented progressive/dynamic biosimilar quotas linked to physician incentives are more effective than just implementing fixed quotas alone

Source: Simon-Kucher & Partners

Outline

- Project objective and approach
- Background: Mapping of market-specific pricing & market access policies
- Definition and assessment of sustainability in the biosimilar medicines market
- Conclusions
- Principles for a sustainable biosimilar medicines market for payer communication
- **Appendix**

List of abbreviations (1/3)

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Acronym	Explanation
A	
AIFA	Agenzia italiana del farmaco (Italy)
AMNOG	Arzneimittelmarkt-Neuordnungsgesetzes (Germany)
ANSM	National Agency for Medicine and Health Product Safety (France)
AOTMiT	The Agency for Health Technology Assessment and Tariff System
AP-HP	l'Assistance publique-hôpitaux de Paris (large hospital purchasing group in France)
ARS	Agences Régionales de Santé (France)
ASMR	Therapeutic Improvement Rating (France)
B	
BS	Biosimilar
C	
CCG	Clinical Commissioning Group (UK)
CEPS	Economic Committee for Health Products (France)
COGS	Cost of Goods Sold
D	
DRG	Diagnosis-related group
E	
EC	Economic Commission (Poland)
EPO	Epoetin
F	
FRP (Group)	Fixed Reference Price (Group)
FRA	France
G	
G-BA	Gemeinsamer Bundesausschuss (Germany)
GER	Germany

Source: Simon-Kucher & Partners

List of abbreviations (2/3)

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Acronym	Explanation
H	
HEOR	Health Economic Outcomes Research
I	
IBD	Inflammatory bowel disease
ICER	Incremental Cost-Effectiveness Ratio
INN	International Nonproprietary Name
ITA	Italy
K	
KOL	Key Opinion Leader
KV	Kassenäztliche Vereinigung (physician association Germany)
L	
LIS	Norwegian Drug Procurement operation
LoE	Loss of Exclusivity
M	
MoH	Ministry of Health
MTA	Multi technology appraisal

Source: Simon-Kucher & Partners

List of abbreviations (3/3)

SIMON • KUCHER & PARTNERS
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Acronym	Explanation
N	
NHF	National Health Fund (Poland)
NICE	National Institute for Health and Clinical Excellence
NOR/NO	Norway
NPV	Net Present Value
NWA	Norwegian Medicines Agency
N	
P&MA	Pricing and market access
PHMEV	Prescriptions hospitalières (médicamenteuses) retentissant sur l'envelope de ville
POL	Poland
PPP	Pharmacy purchasing price
PPRS	Pharmaceutical price Regulation Scheme (UK)
R	
ROI	Return on investment
S	
SG&A	Selling, General and Administrative Expenses
SMC	Scottish Medicines Consortium
SMR	Medical Benefit Rating (France)
SPA	Spain
T	
TD	Treatment Days
T2A	Diagnosis Related Group Tariffs
TC	Telephone conference or Transparency Council (Poland), or Transparency Commission (France)
U	
UniHA	Union des hôpitaux pour les achats (large hospital purchasing group in France)
UK	United Kingdom
W	
WS	Workshop

Source: Simon-Kucher & Partners

Definitions being used throughout this report

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1 **Biosimilar medicine**	A biosimilar medicine is a biological medicine that is developed to be similar to an existing biological medicine (the 'reference medicine'). The active substance of a biosimilar and its reference medicine is essentially the same biological substance, though there may be minor differences due to their complex nature and production methods. Biosimilar medicines are usually authorized several years after the approval of the reference medicine. This is because the reference medicine benefits from a period of exclusivity, during which biosimilar medicines cannot be authorized.
2 **Interchangeability**	The medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting and in any patient on the initiative, or with the agreement of the prescriber.
3 **Switching**	Decision by the treating physician to exchange one medicine for another medicine with the same therapeutic intent in patients who are undergoing treatment.
4 **Substitution**	Practice of dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber.
5 **Treatment naïve patients**	Patients who have not been treated with the originator (biologic medicine) of a particular active substance
6 **Experienced patients**	Patients who have been previously treated with the originator (biologic medicine) of a particular active substance

Source: Simon-Kucher & Partners; Consensus Information Paper 2013. What you need to know about Biosimilar Medicinal Products

NO example: The high biosimilar uptake in Norway is a result of a unique combination of drivers

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Major drivers for biosimilar uptake

Payer rationale for these drivers

1 National single-lot, multi-winner tender

Healthy competition as lever for high price discounts:
- NO payers show little interest in actively engaging multiple biosimilar manufacturers in market participation
- Payers do not fear losing bargaining power in price negotiations in the long run:
  → *'Manufacturers won't drop out of the market – they are eager to achieve the high volume in Norway'*

2 Gainsharing at the hospital level:
- Almost no market shares for second or third lowest bidder as a consequence

3 High physician acceptance of biosimilars:
- Physician education early on resulted in high price sensitization
- Norwegian payers have not advised against switching – common practice among physicians

Interim results of NORSWITCH study proving interchangeability:
- Payers in NO use this as an additional argument in favor of their current switching practice
  → *'The risk of switching is a myth created by the pharmaceutical industry'*

Source: Simon-Kucher & Partners

Different market scenarios for filgrastim biosimilars in Germany

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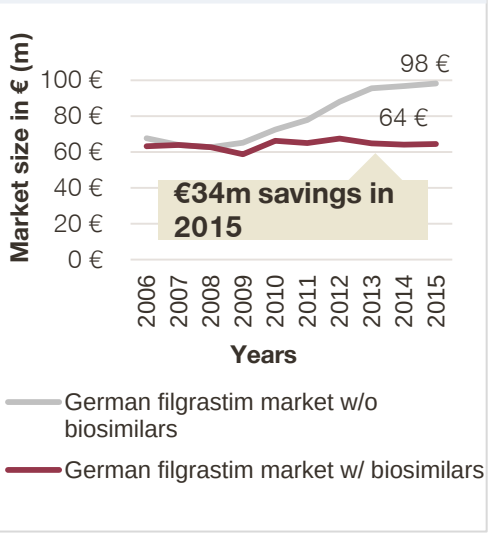
Base case

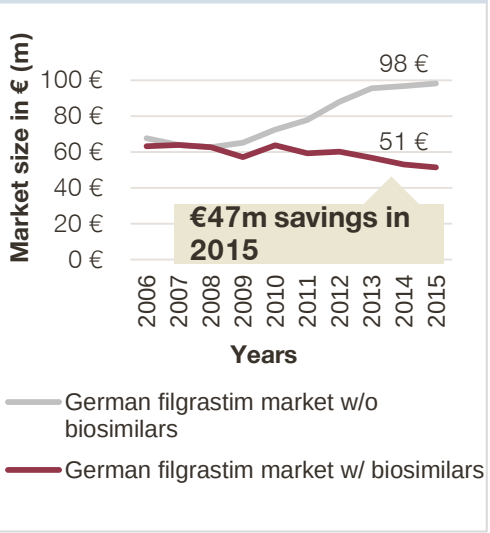
Analysis based on list prices; net price savings effect assumed to be significantly higher



Accumulated savings (2008–2015):

€148m

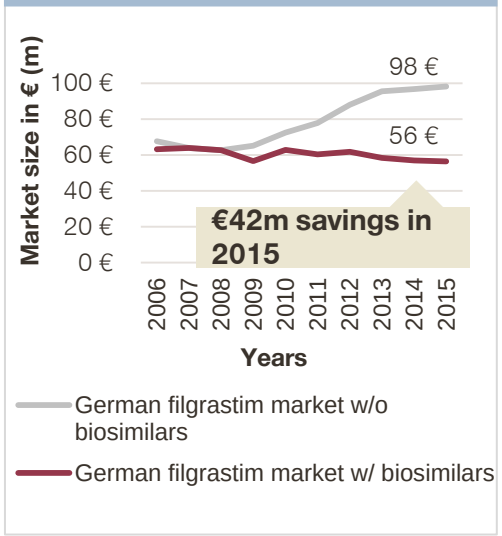
Scenario 1: Higher biosimilar market share (+30%)



Accumulated savings (2008–2015):

€197m

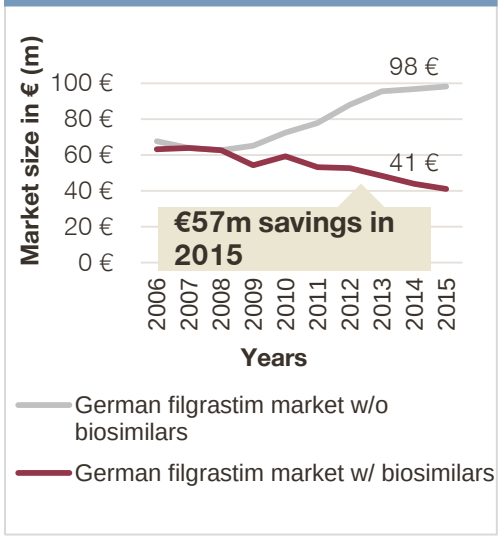
Scenario 2: Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2008–2015):

€185m

Scenario 3: Higher biosimilar market share (+30%) and discount (20%) on list price



Accumulated savings (2008–2015):

€245m

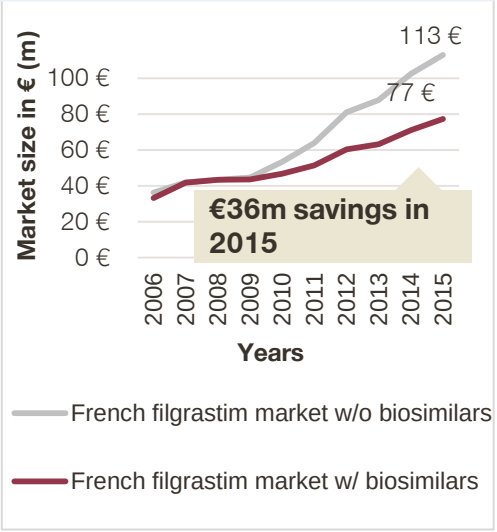
Source: Simon-Kucher & Partners analysis based on IMS data (including inpatient and outpatient data)

Different market scenarios for filgrastim biosimilars in France

SIMON • KUCHER & PARTNERS
Strategy & Marketing Consultants

Base case

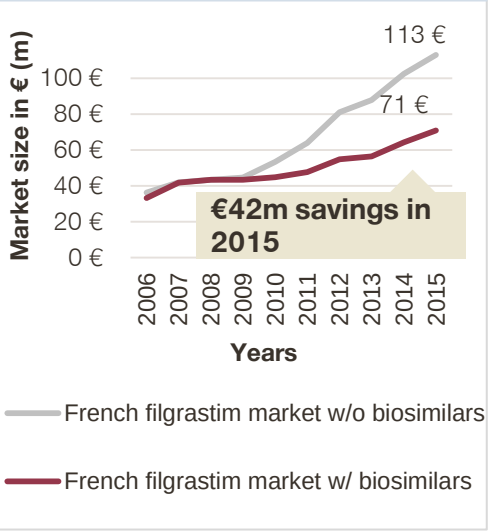
Analysis based on list prices; net price savings effect assumed to be significantly higher



Accumulated savings (2008–2015):

€136m

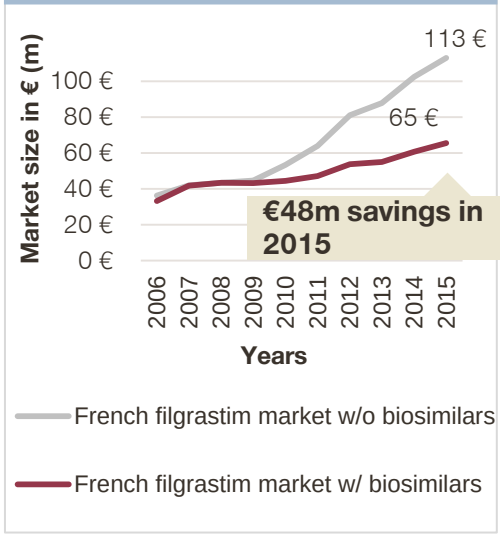
Scenario 1: Higher biosimilar market share (+30%)



Accumulated savings (2008–2015):

€167m

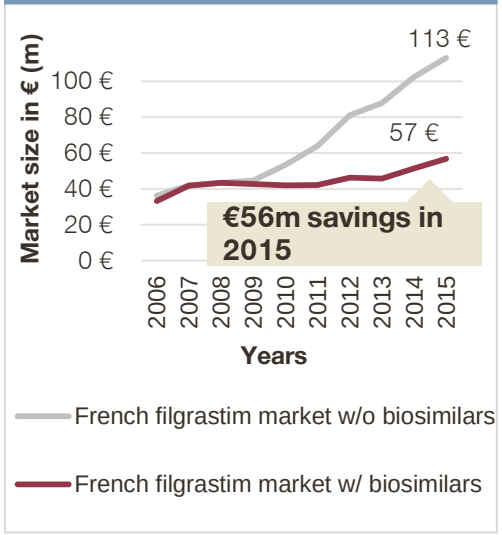
Scenario 2: Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2008–2015):

€179m

Scenario 3: Higher biosimilar market share (+30%) and discount (20%) on list price



Accumulated savings (2008–2015):

€222m

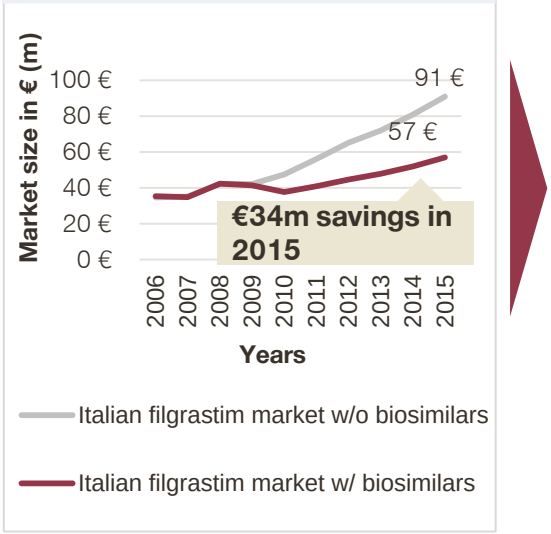
Source: Simon-Kucher & Partners analysis based on IMS data

Different market scenarios for filgrastim biosimilars in Italy

SIMON • KUCHER & PARTNERS
Strategy & Marketing Consultants

Base case

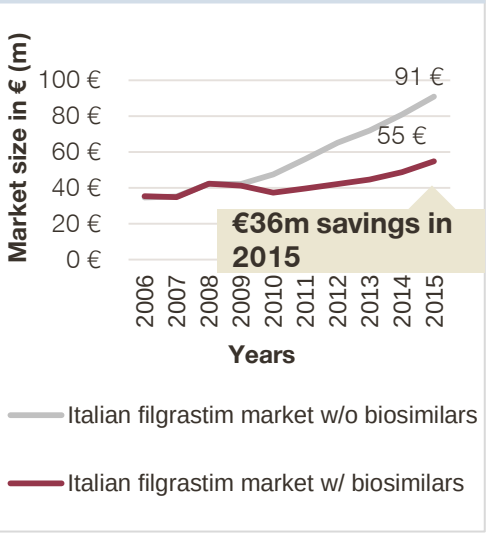
Analysis based on list prices; net price savings effect assumed to be significantly higher



Accumulated savings (2008–2015):

€133m

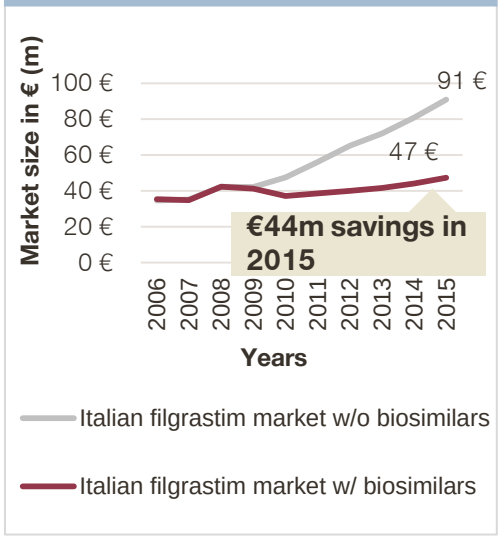
Scenario 1: Higher biosimilar market share (+30%)



Accumulated savings (2008–2015):

€145m

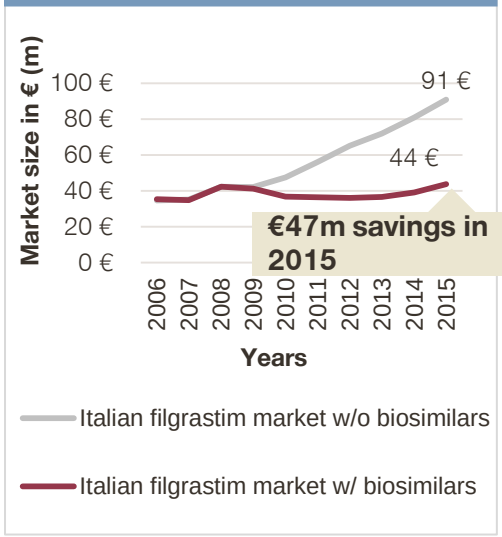
Scenario 2: Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2008–2015):

€164m

Scenario 3: Higher biosimilar market share (+30%) and discount (20%) on list price



Accumulated savings (2008–2015):

€184m

Source: Simon-Kucher & Partners analysis based on IMS data

Different market scenarios for filgrastim biosimilars in Spain

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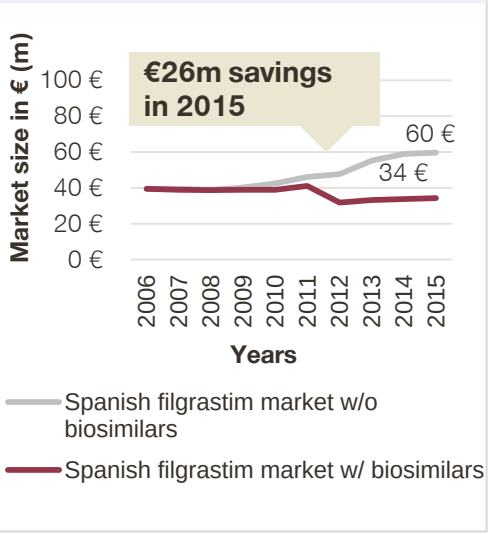
Strategy & Marketing Consultants

Base case

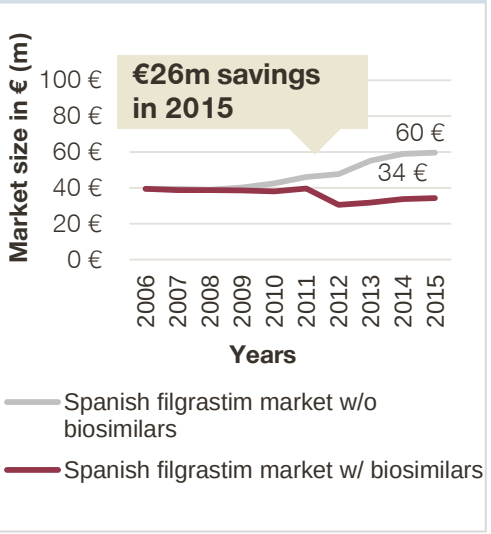
Analysis based on list prices; net price savings effect assumed to be significantly higher



Accumulated savings (2008–2015):

€99m

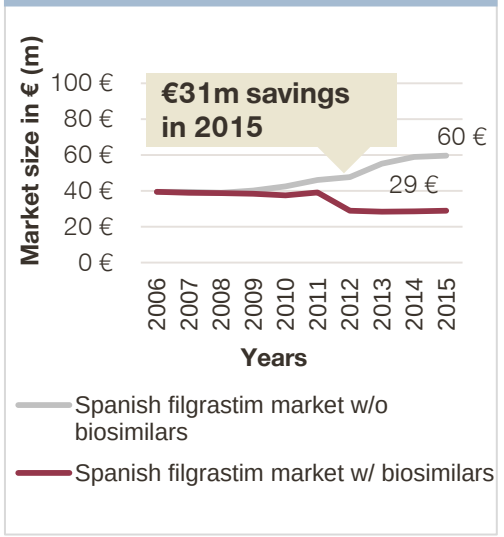
Scenario 1: Higher biosimilar market share (+30%)



Accumulated savings (2008–2015):

€104m

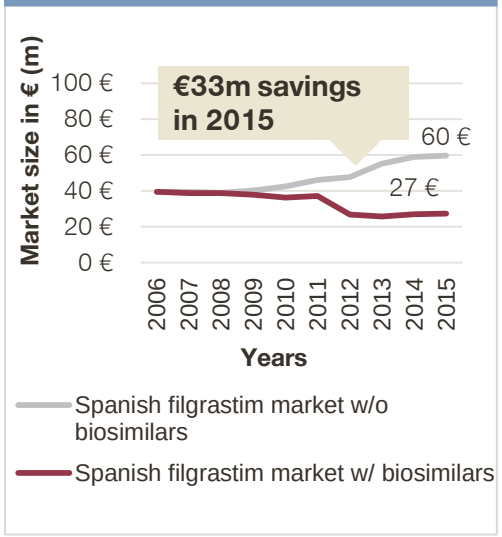
Scenario 2: Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2008–2015):

€121m

Scenario 3: Higher biosimilar market share (+30%) and discount (20%) on list price



Accumulated savings (2008–2015):

€134m

Source: Simon-Kucher & Partners analysis based on IMS data

Different market scenarios for filgrastim biosimilars in UK

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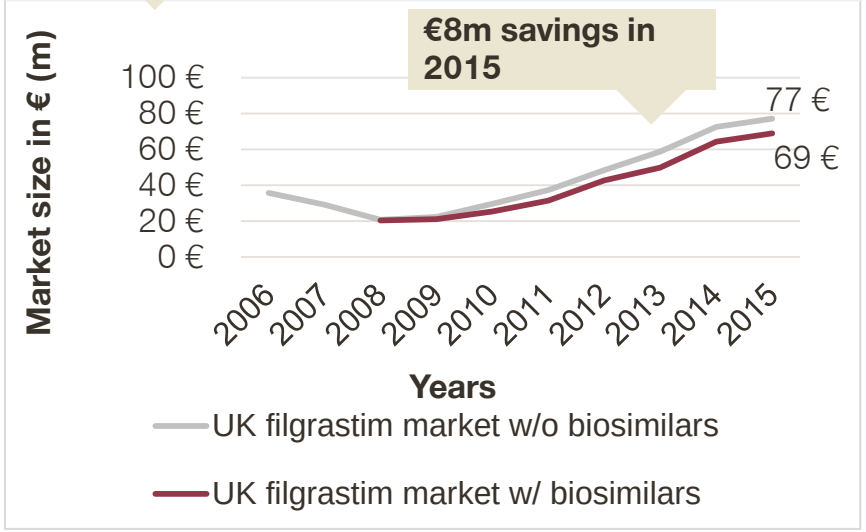
Calculated with originator price in year of biosimilar market entry (2008)

Base case

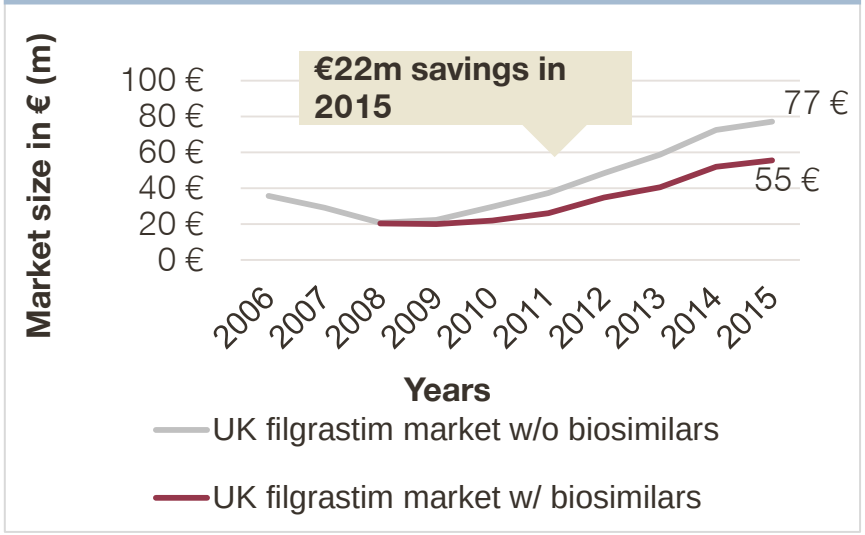
Analysis based on list prices; net price savings effect assumed to be significantly higher



Accumulated losses (2008–2015):

€43m

Scenario 2:
Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2008–2015):

€96m

Source: Simon-Kucher & Partners analysis based on IMS data

Different market scenarios for filgrastim biosimilars in Norway

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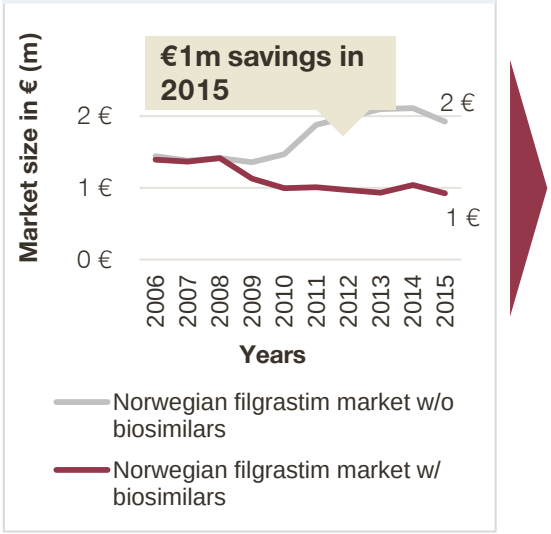
Base case

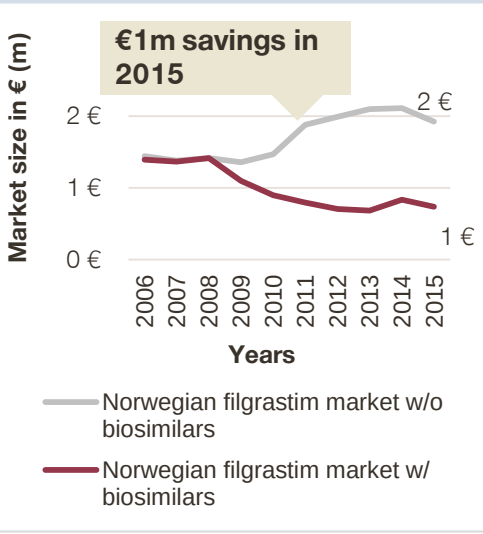
Analysis based on list prices; net price savings effect assumed to be significantly higher



Accumulated savings (2008–2015):

€6m

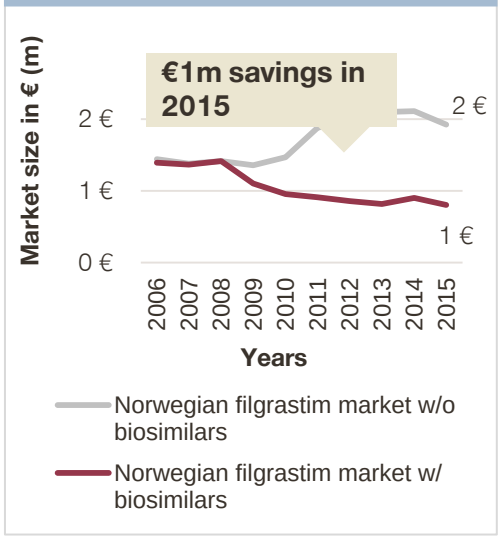
Scenario 1: Higher biosimilar market share (+30%)



Accumulated savings (2008–2015):

€7m

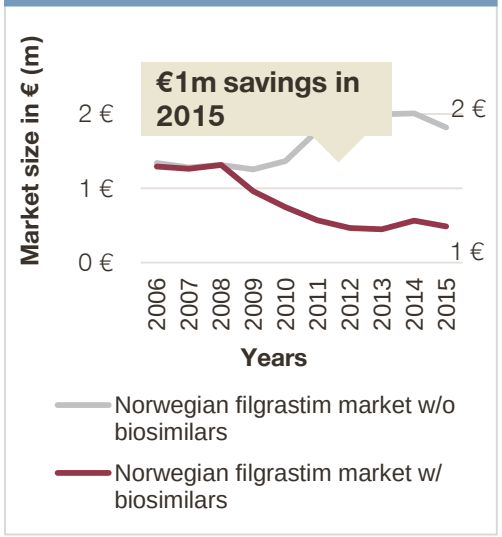
Scenario 2: Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2008–2015):

€7m

Scenario 3: Higher biosimilar market share (+30%) and discount (20%) on list price



Accumulated savings (2008–2015):

€8m

Source: Simon-Kucher & Partners analysis based on IMS data

Different market scenarios for filgrastim biosimilars in Poland

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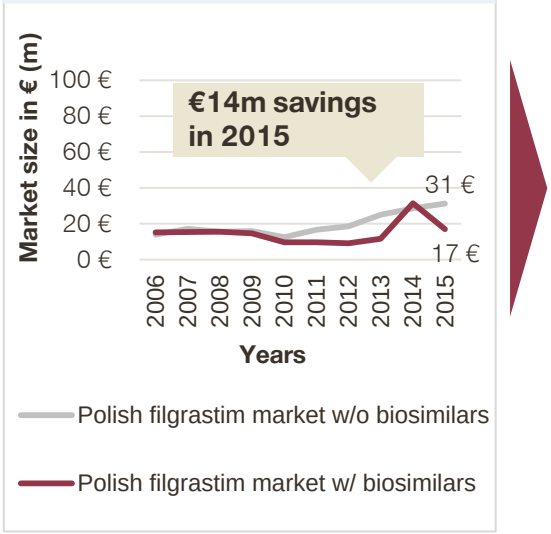
Strategy & Marketing Consultants

Base case

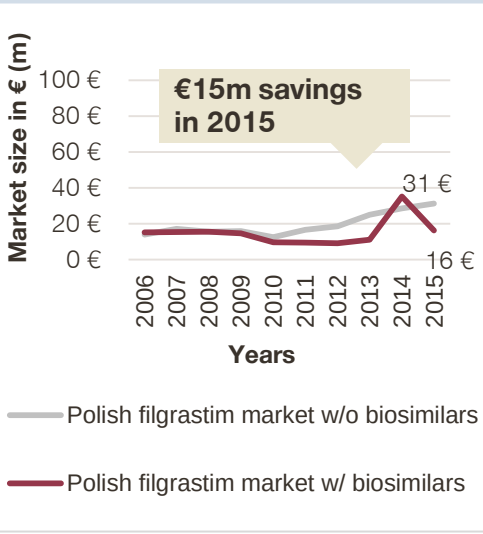
Analysis based on list prices; net price savings effect assumed to be significantly higher



Accumulated savings (2008–2015):

€46m

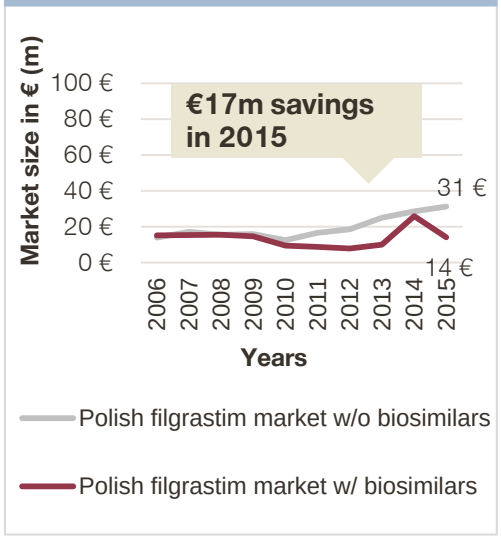
Scenario 1: Higher biosimilar market share (+30%)



Accumulated savings (2008–2015):

€44m

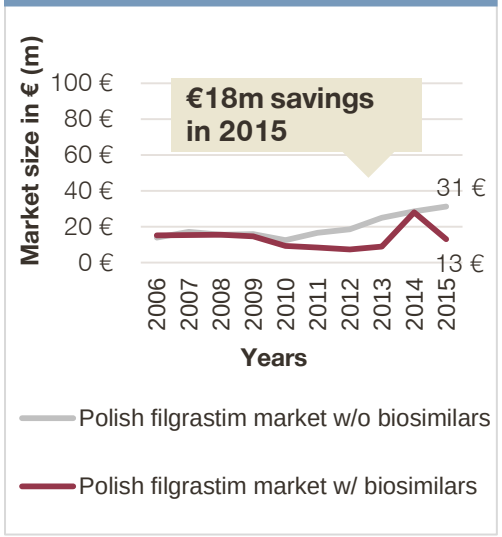
Scenario 2: Actual savings due to assumed biosimilar discount of 20% on top of list price



Accumulated savings (2008–2015):

€58m

Scenario 3: Higher biosimilar market share (+30%) and discount (20%) on list price



Accumulated savings (2008–2015):

€59m

Source: Simon-Kucher & Partners analysis based on IMS data

No payer guidance on biosimilar medicines has been implemented in France so far

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
1) High biosimilar uptake	✗	✓	?	▪ **Filgrastim:** – Initiated (mostly as biosimilar medicine) in hospital; switching may be considered provided certain conditions are respected – Still, patient likely to be kept on same product in retail setting ▪ **Epoetin:** – Prescribed at hospital, utilization largely in retail (hospital budget not affected) – Hospital physicians not encouraged to prescribe biosimilar medicines – Likely strong price competition (originator), limiting biosimilar uptake ▪ **Infliximab:** – Infliximab biosimilar launch too recent to generate and observe significant uptake
2) Payer guidance on biosimilar vs. originator	✗	✗	✗	▪ No tools currently in place to encourage physicians to prescribe biosimilar medicines
3) Fair price level for biosimilars	~	~	?	! **Analysis limited to list prices only:** ▪ Epo and filgrastim: average list price erosion from BS launch until 2016 ~40% ▪ Infliximab biosimilar market not mature enough to draw additional conclusions
4) Commercial attractiveness	✓ *Hospital*	✓	✓	▪ Hospital setting: – In general, payers reward low price offers with volume and uptake potential via hospital tenders – Further, gainsharing (T2A drugs) as well as the limited hospital budget (non-T2A drugs) are incentivizing the usage of less expensive treatment options – However, mandatory price discounts for biosimilar medicines reduce the wiggle room for biosimilars during price negotiations/tenders ▪ Retail setting: No direct link between price and usage/uptake due to lacking incentivization to prescribe less expensive treatment options
	✗ *Retail*	✗	✗	

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible; [1] Agences Régionales de Santé; [2] prescriptions hospitalières (médicamenteuses) retentissant sur l'envelope de ville

Gainsharing at hospital level is expected to support earlier and broader use of biologics due to the lower acquisition costs of biosimilar medicines

SIMON • KUCHER & PARTNERS
Strategy & Marketing Consultants

Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
5) Acknowledge high complexity of biologics within pricing & market access process	✓	✓	✓	▪ Biosimilars: – Hospital setting (T2A/retrocession list): Mandatory price cut of originator medicine (at least -10%) → biosimilar medicine must match or may be lower than originator price – Retail setting: Mandatory price cut of originator medicine (-15 to -20%) → biosimilar medicine needs to price at -25 to -35% relative to innovator's initial price ▪ Lower mandatory discounts required for biosimilar vs. generic medicines are indicating that payers acknowledge the higher complexity of biological medicines including biosimilar medicines
6) Maintain healthy competition	✓	✓	?	▪ Limited number of active manufacturers stayed (constant sales > 1%) in the market for almost 100% of the accessible timeframe for biosimilar medicines
7) Low effort to monitor and enforce policy		✗		▪ No major tools in place in order to encourage physicians to prescribe biosimilars ▪ National, regional and local tender: Perceived as very time-consuming, recurring and complex process, especially as hospitals usually differentiate between naïve and experienced patients in purchasing process (ANSM: switching may be considered provided certain conditions are respected)
8) Parallel sourcing from multiple manufacturers	~	~	?	▪ 2–4 manufacturers have actively supplied the market in parallel ▪ However, only 2 manufacturers shared almost 100% of sales, indicating a duopoly
9) Earlier and broader use of biosimilar in additional patient segments vs. originator	✓ *Hospital*	✓	✓	▪ Hospital inpatient: Gainsharing (infliximab): Hospitals have an incentive to purchase T2A products at low prices, as the difference between reimbursement tariff and the price actually paid are split between hospitals and Social Security (e.g. infliximab). This policy is expected to support earlier and broader usage of biologic medicines due to lower drug acquisition cost after the availability of biosimilar medicines ▪ Hospital inpatient: Non T2A products (epo, filgrastim): Limited budget incentivizes hospitals to purchase and prescribe less expensive treatment options, likely also enabling earlier and broader use of biosimilar medicines ▪ Hospital outpatient: At the regional level, ARS[1] identifies hospitals with high level of expenditures and signs contracts with them to control costs related to drugs prescribed in the hospital for outpatient usage (PHMEV[2]) → less expensive biosimilar mediciness potentially to improve the access situation of biologics ▪ Retail: No incenitivization to use less expensive treatment options
	✗ *Retail*	✗	✗	

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible; [1] Agences Régionales de Santé; [2] prescriptions hospitalières (médicamenteuses) retentissant sur l'envelope de ville

The heterogeneity in terms of market access and payer guidance on biosimilar medicines strongly contributes to a sustainable biosimilar business in Germany

SIMON • KUCHER & PARTNERS
Strategy & Marketing Consultants

Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
1) High biosimilar uptake	✓	✓	✓	▪ Rationale for high biosimilar share (~80%) with epoetin and filgrastim: – BS quotas for epoetin in combination with target agreements, physician's prescribing budget, general price sensitivity of physicians – Filgrastim: short-term/acute therapy enables faster biosimilar uptake (new patients) ▪ Infliximab biosimilar share reached >40% in selected KV regions within the 1st year (e.g. Westfalen-Lippe) supported by biosimilar target agreements including quotas. The higher savings potential compared to epoetin & filgrastim is expected to lead to additional and broader uptake in the near future
2) Payer guidance on biosimilar vs. originator	✓	~	✓	▪ Epoetin, infliximab: – Many KVs introduced target agreements including biosimilar quotas – Infliximab: – Regulator guidance on biosimilar use from Paul-Ehrlich-Institut – Physician education programs sponsored by sick funds and pilot programs targeting physicians supporting increased biosimilar usage – Gainsharing agreement (KV Westfalen-Lippe & sick fund Barmer GEK): savings from biosimilar prescriptions split between physician and sick fund ▪ Filgrastim: – Biosimilar quotas in place only for KVs in Bremen, Bayern, Mecklenburg-Vorpommern and Hessen
3) Fair price level for biosimilars	✓	✓	~	▪ **Analysis limited to list prices only (at least in retail setting):** ▪ ~50–60% list price decrease for epos & filgrastim after > 6 years still considered fair ▪ Infliximab BS price already decreased by 25% since being on the market
4) Commercial attractiveness	✗	✓	✓	▪ The German system is based on voluntary price concessions and rewards low priced offers with volume and uptake potential → commercial attractiveness assumed (especially in the case of filgrastim and infliximab) ▪ FRP group for epoetin reduces the price advantage of biosimilars on list level Lower room for offering further discounts vs. the originator ▪ Still, high number of sick funds create sufficient opportunities for market access (via tendering, open-house contracts)

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

Also, a comparably high number of parallel biosimilar suppliers contribute to a sustainable biosimilar market

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
5) Acknowledge high complexity of biologics within pricing & market access process	✓			▪ Biosimilar medicines are treated equally to their originator medicines (e.g. no mandatory price cuts)
6) Maintain healthy competition	✓	✓	?	▪ Comparably high number of parallel suppliers who were active in the market for 30–60% of the overall observed timeframe
7) Low effort to monitor and enforce policy	✗	✗	✗	▪ Until today, biosimilar quotas have not always been met in many Germany KV regions, indicating room for improvement in terms of monitoring and supervision ▪ Increased monitoring efforts and target agreements required to increase the biosimilar prescribing quota ▪ Filgrastim: There are biosimilar quotas only within the KV regions of Bremen, Bayern, Mecklenburg-Vorpommern and Hessen
8) Parallel sourcing from multiple manufacturers	✓	✓	✓	▪ 3–4 manufacturers shared almost 100% of sales ▪ Infliximab: several biosimilar manufacturers expected to be active in the near future
9) Earlier and broader use of biosimilar in additional patient segments vs. originator	~	~	✗	! Infliximab: 'Praxis specialty' status** of the originator implies that drug cost did not play a major role in the prescribing decision of physicians in the past ▪ In general, no cost-related restrictions in place for epoetin and filgrastim However, physicians' prescribing budget might have led to cost-sensitive prescribing in the past (economic prescribing) → biosimilars might therefore trigger/enable earlier and broader use

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible; ** Praxis specialty = Expensive treatments may be exempted from the physician's quarterly prescribing budget to ensure that physicians do not undertreat patients due to cost

Mandatory discounts for biosimilar medicines at launch limit the room for further price negotiations on the net level in Italy

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
1) High biosimilar uptake	~	✓	?	▪ Low BS share for epos (~50%); high BS share for filgrastim (~90%): – Potential rationale: Different regional BS quotas for both active substances; different level of additional discounts granted in tenders (epos with more competitive originators) ▪ Infliximab biosimilar launch too recent to generate and observe significant uptake
2) Payer guidance on biosimilar vs. originator	✓	✓	✓	▪ Quotas/usage guidelines (regional and local) are in place for existing biosimilar mediciness in Tuscany, Veneto and Campania. However, quotas are not binding and real-life prescribing so far is not fully compliant with them ▪ Definition of biosimilar quota is likely to differ from region to region
3) Fair price level for biosimilars	✓	~	~	**Analysis limited to list prices only:** ▪ Overall list price discounts have been in the range of 20–40%, adding at maximum another 20% points to the already existing mandatory discount of 20% ▪ Further price erosion for infliximab likely in the future due to more competitors expected to enter the market
4) Commercial attractiveness	~	~	~	▪ Most attractive offer wins the tender and is thus rewarded by volume ▪ Regional tenders (for both, hospital and retail setting) offer multiple business opportunities for manufacturers. However, only the least expensive offer wins (single-winner tender) ▪ Tenders will be re-opened upon availability of biosimilar medicines, creating early business opportunity for biosimilar manufacturers ▪ Further, the mandatory price reduction of min. 20% vs. originator is seen as limiting the room for price negotiations for biosimilar manufacturers

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

Regional tenders offer multiple business opportunities for biosimilar manufacturers in Italy

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
5) Acknowledge high complexity of biologics within pricing & market access process	~			▪ Similar mandatory price cut rule applies to generic and biosimilar medicines (however, additionally negotiated discounts are usually much higher for generic medicines) ▪ No transparency list for Class A biologic medicines (originator and biosimilar medicines) ▪ Several position papers of AIFA reaffirmed that biosimilar medicines are not generic medicines ▪ Automatic substitution of the originator (so far) is not possible due to diversity of biosimilar/biologic medicines
6) Maintain healthy competition	~	~	?	▪ Limited number of active manufacturers stayed (constant sales > 1%) in the market for almost 80% of the accessible timeframe for biosimilars
7) Low effort to monitor and enforce policy	✗	✗	✗	! National, regional and local tender: Perceived as very time-consuming, recurring and complex process, especially as hospitals usually differentiate between naïve and experienced patients in purchasing process
8) Parallel sourcing from multiple manufacturers	~	~	?	▪ 2–3 manufacturers have actively supplied the market in parallel ▪ However, only two manufacturers shared almost 100% of sales, indicating a duopoly (which is surprising in the context of multiple regional tenders)
9) Earlier and broader use of biosimilar in additional patient segments vs. originator	✗	✗	✗	▪ No cost-related restrictions beyond label in place for biologics in Iltaly ▪ Additionally, budget savings from prescribing less expensive treatment options is not incentivized → earlier and broader use of biologics unlikely to be triggered via the availability of less expensive treatment alternatives (biosimilars)

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

Multiple payer guidances support the uptake of biosimilar medicines in Spain

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Sustainability of pricing & market access policy per criteria

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
1) High biosimilar uptake	~	✓	?	▪ Low BS share for epos (~50%); high BS share for filgrastim (~80%): – Potential rationales: 1. Filgrastim BS have granted higher absolute discounts & regional drug evaluations make physicians aware of these less expensive alternatives 2. Manufacturers of epo originators are known to have granted substantial discounts for their epoetin products in the past ▪ Infliximab biosimilar launch too recent to generate and observe significant uptake
2) Payer guidance on biosimilar vs. originator	✓	✓	✓	▪ Regional drug evaluation and hospital protocols: Objective is to drive and standardize physicians' prescriptions, and alert them of less expensive alternatives ▪ Budget targets: Regions/hospitals set a budget cap per patient (and per pathology), and physicians need to prescribe rationally in order to avoid cost-cutting measures. Further, hospital pharmacists put significant pressure on physicians to prescribe the respective biosimilar, offering the lowest discounts via tender/direct negotiations ▪ Therapeutic equivalence: Some regions define anti-TNFs to be therapeutic equivalents (comprising originators and biosimilars) to encourage economic prescribing ▪ However, no biosimilar quotas in place yet (however introduction is already planned)
3) Fair price level for biosimilars	~	~	?	! **Analysis limited to list prices only:** ▪ List price discounts in the range of 20–40% ▪ Creation of FRP groups impedes list price advantage of biosimilar vs. originator medicines
4) Commercial attractiveness	~	~	~	▪ Most attractive offer (tender or direct negotiations) is rewarded by volume ▪ Regional tenders offer multiple business opportunities for manufacturers. However, only the least expensive offer wins (single-winner tenders) ▪ However, the creation of FRP groups (including originator and biosimilars) in combination with significant net price cuts by the time of biosimilar launch, limits the cost advantage of biosimilar medicines and thus reduces the competitive advantage in price negotiations ▪ Manufacturers of the originator medicines are willing to offer significant net price discounts, further limiting biosimilar's cost advantage (also with the intention to support price negotiations for more innovative treatment options (package deal))

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

Generic pricing & market access policies such as the creation of FRP groups, limit the commercial attractiveness for biosimilar manufacturers in Spain

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
5) Acknowledge high complexity of biologics within pricing & market access process	✗			▪ Both, generic and biosimilar medicines will be grouped into FRP groups with the originator directly after launch ▪ List price cuts of ~30% (biosimilar medicines) and ~40% (generic medicines) vs. the pre-LoE price of the respective originator medicine can be expected, additionally followed by large discounts on net price level
6) Maintain healthy competition	~	~	?	▪ Both suppliers of epoetin have been in the market for 100% of the observed timeframe ▪ The three suppliers for filgrastim had an average market presence of 75% of the accessible timeframe for biosimilar medicines
7) Low effort to monitor and enforce policy	✗			▪ Regional and local tender: Perceived as time-consuming, recurring and complex process ▪ Regional drug evaluations further increase required efforts for payers to steer physicians' prescribing
8) Parallel sourcing from multiple manufacturers	~	~	?	▪ 2–3 manufacturers have actively supplied the market in parallel ▪ Only two manufacturers shared almost 100% of sales, indicating a duopoly (which is surprising in the context of multiple regional tenders)
9) Earlier and broader use of biosimilar in additional patient segments vs. originator	~	~	~	▪ In general, no cost-related restrictions in place (and also no cost-effectiveness analysis being conducted by payers). However, physicians' budget targets might have led to cost-sensitive prescribing in the past → biosimilar medicines might therefore trigger/enable earlier and broader use ▪ Hospital setting: Lower treatment costs of biosimilar vs. originator medicines lead to loosened usage/prescription controls in hospitals, leading to higher freedom of prescribing for physicians

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

Both, national/regional payer guidances on biosimilar medicines support earlier and broader use in the UK

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
1) High biosimilar uptake	✗	✓	?	▪ Significant deviations in BS share: Epo (only ~10%) vs. filgrastim (almost 100%) – Potential rationale: 1. Higher safety concerns around the epo BS in the UK and epo originators being more competitive on net price level vs. biosimilar medicines than with filgrastim 2. This effect might be further strengthened by gainsharing ▪ Low infliximab biosimilar uptake so far (~10%). Potentially, launch is too recent to allow meaningful observation
2) Payer guidance on biosimilar vs. originator	✓			▪ National guidance: NICE recommends starting treatment with a more cost-effective option. This is a significant opportunity for biosimilar medicines as they are likely to be able to achieve a lower ICER[1] ▪ Regional guidance: CCGs build upon NICE recommendation and particularly point out that biosimilar medicines are to be used over originators due to lower ICER
3) Fair price level for biosimilars	✓	✓	?	**Analysis limited to list prices only:** ▪ Lowest list price erosion for biosimilar and originator medicines across all analyzed markets (~0–10%) ▪ Epos and filgrastim: average biosimilar list prices are even higher than originator prices ▪ However, high discounts are being expected on net price level
4) Commercial attractiveness	✗	✓	✓	▪ Regional tenders generally reward low price offers with volume and uptake ▪ Epoetin: Highly competitive originators limit price advantage of biosimilars on list level and do not allow for sufficient 'wiggle-room' to offer further discounts on net level

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible; [1] Incremental cost-effectiveness ratio

Free pricing of biosimilar medicines at launch strongly contributes to a sustainable biosimilar business in the UK

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
5) Acknowledge high complexity of biologics within pricing & market access process		✓		▪ Biosimilar medicines are treated equally to their originators (e.g. no mandatory price cuts)
6) Maintain healthy competition	✓	✓	?	▪ A relatively high number of active manufacturers stayed (constant sales > 1%) in the market for > 90% of the accessible timeframe for biosimilar medicines
7) Low effort to monitor and enforce policy		~		▪ Regional tender: Perceived as very time-consuming, recurring and complex process
8) Parallel sourcing from multiple manufacturers	~	✓	?	▪ 3–6 manufacturers have actively supplied the market in parallel ▪ Only three manufacturers shared almost 100% of sales (which is surprising in the context of multiple regional/local tenders)
9) Earlier and broader use of biosimilar in additional patient segments vs. originator		✓		▪ Epoetin: After biosimilar medicines entry, 2014 NICE guidelines have been adapted and epoetin has been considered both, clinically effective as well as cost-effective for cancer treatment-induced anemia (before 2014: not considered cost-effective) ▪ Filgrastim: NICE announced filgrastim biosimilars to be cost-effective in 2008, additionally recommending its use in primary prophylaxis (before: secondary prophylaxis only) ▪ Infliximab: 2015 NICE guidance recommends use of infliximab biosimilars in adults with non-radiographic axial spondyloarthritis (before: originator not recommended to be used in this patient population)

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

Gainsharing at the hospital level strongly incentivizes earlier and broader use of biosimilar medicines in Norway

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
1) High biosimilar uptake	✓	✓	✓	▪ Very high biosimilar hare for all three observed product categories ▪ Even the majority of infliximab sales are already generated via biosimilar medicines – Rationale for high BS share and the fast BS uptake: ▪ Natl. tender that grants instant access of the least expensive offer to the majority of the market ▪ LIS special group committee recommends usage of least expensive treatment option and broad consensus amongst experts and prescribing physicians that interchangeability is given ▪ Hospital DRGs allowing for gainsharing if less expensive product is being used
2) Payer guidance on biosimilar vs. originator		✓		▪ Switching patients to biosimilar medicines is allowed and meanwhile common practice among physicians ▪ Infliximab: NORSWITCH study currently ongoing. It's purpose is to support the idea that biosimilar medicines are seen as interchangeable
3) Fair price level for biosimilars	✗	✗	✗	! **Analysis limited to list prices only:** ▪ Highest observed list price erosion across countries for all analyzed products (50–70%) ▪ The "winner-takes-it-all-mentality" triggers manufacturers to offer high discounts in order to secure market access
4) Commercial attractiveness		✗		▪ National tender → Several manufacturers and their offered prices will be listed, but usually the majority of prescriptions will go to the least expensive offer due to recommendation by LIS special group committee → very limited sales opportunities for more than 1 biosimilar manufacturer

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

The national tender does not support shared business potential among multiple biosimilar manufacturers

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
5) Acknowledge high complexity of biologics within pricing & market access process	✓			▪ No mandatory discounts (biosimilar medicines do not fall under the discount regulations for generic medicines referred to as 'stepped price model' and therefore can achieve the same list price as the originator medicine) ▪ As of today, the 'stepped price model' is not applied to biosimilar medicines as they are not seen as interchangeable with the originator medicines
6) Maintain healthy competition	✗	~	?	▪ The "winner-takes-it-all-mentality" further leads to a short supply period for manufacturers if they lose the tender in the next period
7) Low effort to monitor and enforce policy	✓			▪ One national tender is not seen as requiring high efforts ▪ Apart from tenders, no specific cost-containment measures are in place that would require significant effort and monitoring
8) Parallel sourcing from multiple manufacturers	✗	~	?	▪ 2–3 biosimilar manufacturers have been supplying filgrastim in parallel, while epo has only been provided by one biosimilar manufacturer since LoE – Potential rationale for >1 manufacturers serving the filgrastim market: Not all patients can be switched to the tender winning product in the case of a change
9) Earlier and broader use of biosimilar in additional patient segments vs. originator	✓			▪ LIS special group committee recommends usage of the least expensive treatment option (independent of biologic or alternative treatment approaches). Less expensive biosimilar medicines therefore offer the opportunity to replace other alternatives at an earlier stage of the patient disease history (if in line with the label) ▪ Gainsharing at the hospital level incentivizes use of the least expensive treatment option as hospitals are entitled to keep generated savings (difference between DRG and expenditures)

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

Multiple tenders support an increased likelihood of market access for biosimilar medicines in Poland

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
1) High biosimilar uptake	✓	✓	✓	▪ Very high biosimilar share for all three observed product categories ▪ Potential rationale for high biosimilar share and the fast biosimilar uptake: – Hospital setting (mainly epoetin and infliximab): Multiple tenders in combination with non-cash gainsharing (assuming biosimilar medicines being less expensive) – Retail setting (mainly filgrastim): Both, originator and biosimilar medicineare substitutable. Co-payment incentivizes patients to request the cheapest option
2) Payer guidance on biosimilar vs. originator	~	~	✓	▪ Infliximab: – Ministry of Health: Any exchange within the scope of drugs containing infliximab at any level of therapy is permissible (switching) – Several hospital drug programs tend to favor the use of infliximab biosimilars over the originator
3) Fair price level for biosimilars	✗	✗	~	**Analysis limited to list prices only:** ▪ ~45–50% discount for biosimilar observed (initial mandatory discount = 25%) ▪ Even infliximab biosimilar is already granting ~30% discount vs. the originator (pre-LoE price) ▪ Further, high discounts are being expected on the net price level
4) Commercial attractiveness	✓	✓	✓	▪ Hospital tenders with price as the main criterion as well as automatic substitution at the pharmacy level (retail) reward less expensive biosimilar medicines with volume/uptake ▪ Still, mandatory price cuts for the originator and biosimilar medicines on the list price level, limit the room for further price discounts on the net level and thus negatively impact the price advantage of biosimilar medicines

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

High discounts on the list and net price level as well as automatic substitution at the pharmacy level suppress sustainable biosimilar medicines business

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Sustainability of pricing & market access policy per criterion

Sustainability criteria	*Evaluation of criteria*			*Rationale for evaluation of sustainability and further details*
	Epo	*Filgrastim*	*Infliximab*	
5) Acknowledge high complexity of biologics within pricing & market access process	✗			▪ Same pricing & market access rules apply for generic and biosimilar medicines, e.g. automatic substitution at the pharmacy level, limiting the responsibility of physicians when it comes to deciding which biologic medicine (originator/biosimilar) to prescribing (similar to generic medicines)
6) Maintain healthy competition	~	~	?	▪ A relatively low number of active manufacturers stayed (constant sales > 1%) in the market for ~70% of the accessible timeframe for biosimilar medicines
7) Low effort to monitor and enforce policy	~			▪ Hospital tender: Perceived as time-consuming, recurring and complex process ▪ Retail: Automatic substitution at pharmacy level is not requiring significant monitoring efforts
8) Parallel sourcing from multiple manufacturers	~	~	?	▪ 2–3 manufacturers have actively supplied the market in parallel ▪ However, only two manufacturers shared almost 100% of sales, indicating a duopoly
9) Earlier and broader use of biosimilar in additional patient segments vs. originator	✓			▪ Limited hospital budgets might have led to cost-sensitive prescribing in the past → savings from less expensive biosimilar medicines might therefore trigger/enable earlier and broader use (via non-cash gainsharing) if in line with the respective drug program

✓ = Sustainability criterion fulfilled ~ = Sustainability criterion not affected ✗ = Sustainability criterion not fulfilled

Source: Simon-Kucher & Partners; * Only insights into list prices possible

Overview: Full and abbreviated principles for a sustainable biosimilar medicines market (1/2)

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	Full payer messages	Abbreviated payer messages
1a	Unlike generics, which have simple chemical structures, biosimilar medicines are not expected to be identical medicines to the reference products. However, their differences are not clinically meaningful and biosimilar medicines are as safe and effective as the reference product.	Differences between biosimilar medicine and reference product not clinically meaningful
1b	Biologic medicines, including biosimilar medicines, are complex medicines grown in living cells which are used to treat serious conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. The use of biologic medicines should be supervised and carried out by specialist physicians and advanced practitioners. Therefore, respective biosimilar policies should allow physicians to choose from different treatment alternatives.	Maintain physicians' freedom to prescribe
1c	Pricing & market access policies and payer decisions should ensure that the significant investments for biosimilar manufacturers are balanced by a reasonable income.	High investments to be balanced by reasonable income
2	Biosimilar medicines have generated considerable savings over the past years and have therefore alleviated budget constraints across European public healthcare systems.	Biosimilar medicines support sustainability of healthcare budgets
3	Their competitive drug acquisition cost makes it possible for biosimilar medicines to reach an acceptable ICER in situations where originators cannot. As a consequence, biosimilar medicines support improved patient access to certain therapeutic areas compared to the originator.	Improved cost-effectiveness leads to improved patient access
4	Improved access (within the existing label) for biologic medicines due to the availability of less expensive biosimilar medicines supports better health outcomes.	Improved patient access leads to better health outcomes
5	Pricing & market access policies should ensure a continuous market participation of several biosimilar manufacturers in order to maintain healthy competition.	P&MA policies to support for healthy competition

Source: Simon-Kucher & Partners

Overview: Full and abbreviated principles for a sustainable biosimilar market (2/2)

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	Full payer messages	Abbreviated payer messages
6	Tender decisions should not be based only on price. They should also reflect a value-based approach, taking into consideration multiple influencing factors apart from price (such as supply guarantee, provision of education or other value added services) to support sustained benefits from biosimilar medicines.	Tenders should not only focus on price
7	Countries in which the biosimilar policy limits the room for simultaneously active market participants are hindering parallel sourcing. Such policies negatively affect the country's ability to guarantee short-term medical supply for their patients.	Parallel sourcing needed
8	pricing & market access policies enforcing lower biosimilar prices compared to their originators have to be accompanied by specific guidance on biosimilar use and prescribing incentives. A lower price for biosimilar medicines on its own will prevent generation of return on investments for biosimilar manufacturers.	Price discounts to be accompanied by prescribing incentives
9	Mandatory price discounts that are not linked to a certain volume compensation do not offer biosimilar manufacturers a sustainable market environment. Biosimilar manufacturers may grant price concessions voluntarily if they can expect to be compensated with an appropriate amount of sold units in exchange. Provided that this applies, mandatory price cuts are not essential to create savings to the healthcare system	Voluntary price concessions vs. mandatory discounts
10	A pricing & market access policy that does not allow for commercial attractiveness for biosimilar manufacturers will reduce competition in the long run and thus negatively impact the likelihood for payers to generate savings	Commercial attractiveness
11	Unfavorable combinations of price erosion and volume uptake for biosimilar medicines will not support a sustainable biosimilar business potential in the medium and long-term.	Price erosion vs. volume uptake
12	pricing & market access policies are only sustainable if payers are able to ensure close monitoring of their implementation, subsequently incentivizing physician adhere to these pricing & market access policies.	Monitoring/enforcing P&MA policies

Source: Simon-Kucher & Partners

Most payers agree that biosimilars are key to generating financial savings and therefore highly emphasize price as a main criterion in future procurement decisions

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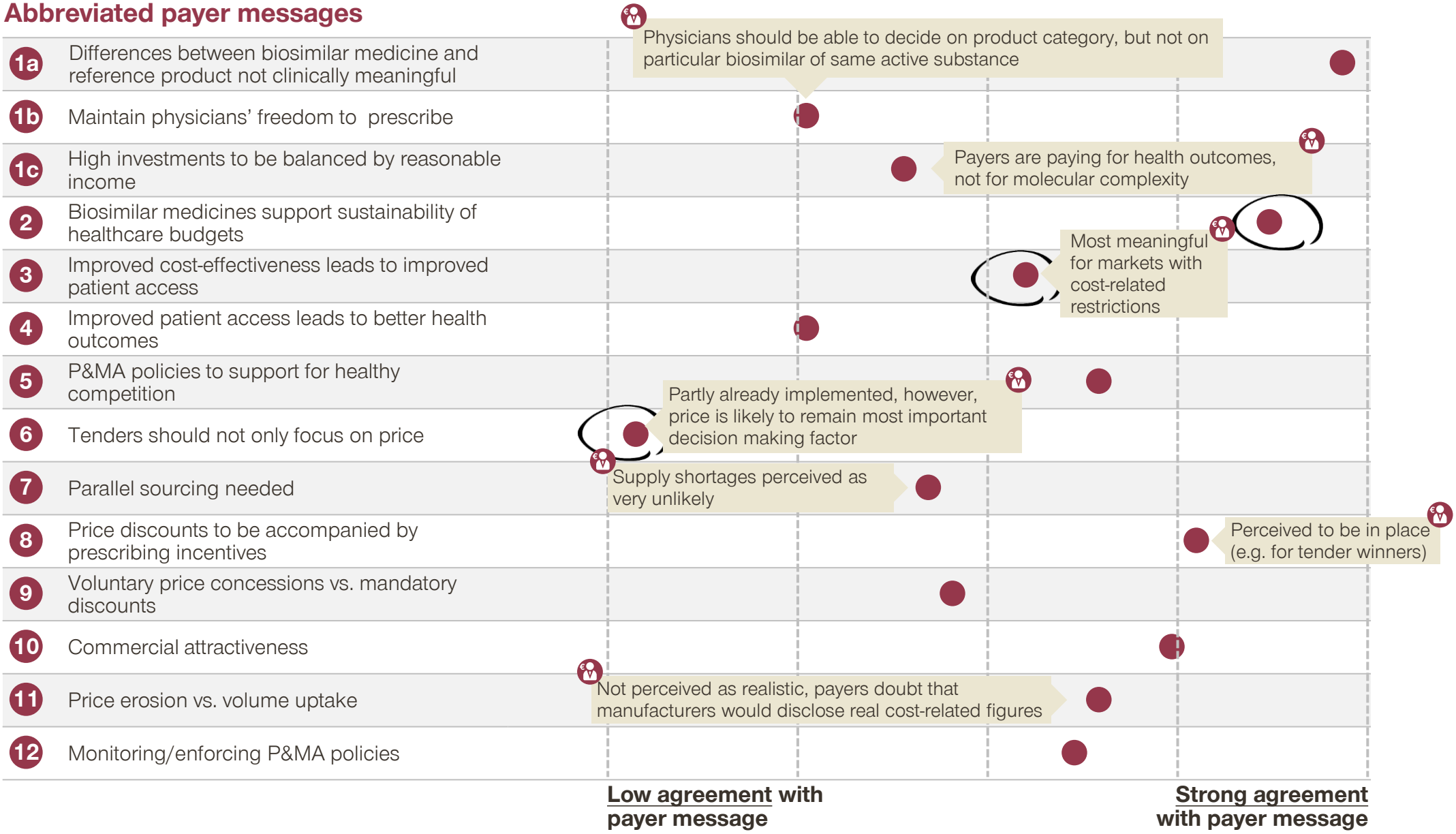
Abbreviated payer messages



Source: Simon-Kucher & Partners = Details on following slide

Especially the idea of introducing balanced score cards for future procurement decision making has not resonated well across payers from most markets

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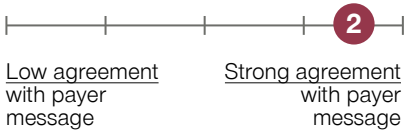
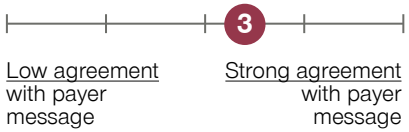
2 **Biosimilar medicines support sustainability of healthcare budgets**



Payer reaction

- *"Biosimilars indeed helped and costs were cut, but not enough to fully finance higher expenditures for innovative drugs."*
- *"Difficult to disagree with that point."*

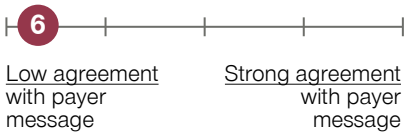
3 **Improved cost-effectiveness leading to improved patient access**



Payer reaction

- *"Not relevant in DE: So far, no cost-related restrictions on prescribing of biologics are in place for the concerned biologics (practice specialty)."*
- *"Earlier and broader use is been observed in my market, especially with infliximab biosimilar. Sales for infliximab biosimilar have increased by 60%, however, we have still achieved 30% savings."*

6 **Tenders should not only focus on price**



Payer reaction

- *"Supply guarantee is already a relevant component in tenders, but criteria is difficult to predict. Still, price is by far the most important criterion. A score card seems unrealistic."*
- *"Only the price counts. Other factors, e.g. supply guarantee and provision of educational materials is part of the contract have to be provided by all the companies. Price is the only factor differentiating the companies."*

Source: Simon-Kucher & Partners