IGBA Contribution: Pricing implications of policies on biosimilar cancer medicines

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Part I-

- **Summary of IGBA recommendations at the 1st Fair Pricing Forum**
- **Barriers to market, impacting the price of biosimilar medicines**
- **EU experience**
  - Market penetration
  - National policies in EU Member States

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Summary of IGBA reactive statement at the 1st WHO Fair Price Forum (Amsterdam, 2017)

Recommendations towards a sustainable health care system

The IGBA would like to put forward a few ideas deemed relevant to optimise costs of medicines and that encourages the WHO to support:

- Stimulating generic and biosimilar medicines competition via uptake measures and removal of barriers, allowing competition to start on day 1 after patent expiry
- Advancing global development of generic/complex generic and biosimilar medicines
- Harmonising and simplifying registration and marketing authorization maintenance
- Sharing of information between Medicines Regulatory Authorities
- Supporting mutual recognition of Good Manufacturing Practices (GMP) inspections
- Ensuring balanced IP/regulatory incentives
- Supporting the introduction of a manufacturing/export waiver during the patent term extension period
- **https://bit.ly/2H7VuMX**

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Barriers to market, impacting price of biosimilar medicines

- **Regulatory barriers i**ncreasing development costs
  - divergent requirements, duplication of studies, including clinical studies, which are unnecessary and hence unethical, lacking the concept of global comparator, approval delays
- **Legal barriers**/"patent thickets" increasing delay and triggering exorbitant legal/litigation costs; examples of successful invalidations below
  - Samsung Bioepis invalidates Herceptin patent in Korea (March 2019)
  - Celltrion wins patent suit in Japan over biosimilar trastuzumab (Nov. 2018)
  - The Hague judges completely rejected Hoffmann-La Roche's claims in the Netherlands (source juve PATENT)
- **Market barriers** like misinformation/scaremongering by interested parties, manipulation of tender procedures (two lots: one for the originator, one for the biosimilar), originators negotiating long tenders (2 years) just before biosimilars entry, international reference pricing, "rebate traps"
- **Barrier in WHO Prequalification pilot procedure** for trastuzumab and rituximab ("marketed" condition)

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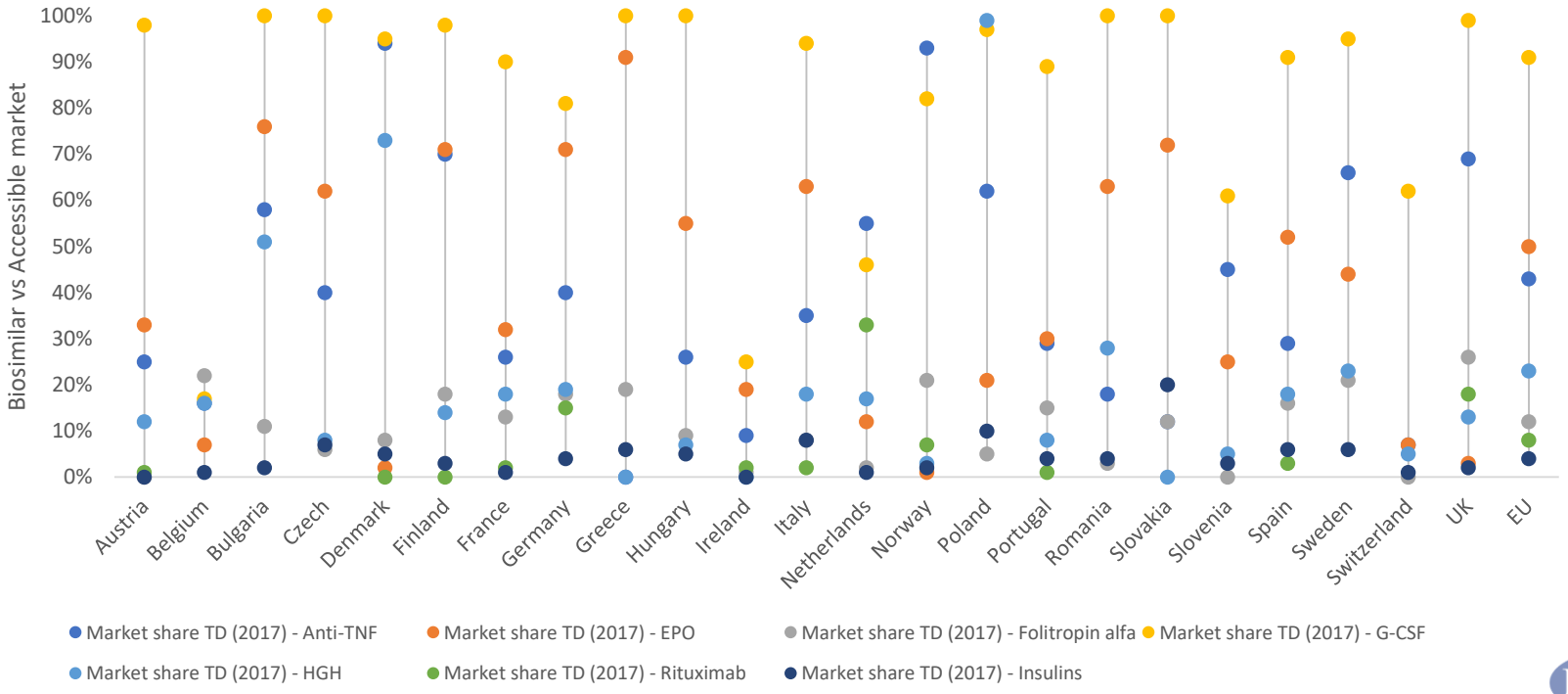
Use of biosimilar medicines in EU varies greatly by country and therapeutic area



IQVIA. *The Impact of Biosimilar Competition in Europe*. (2018).

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Overall EU experience with cancer biosimilar medicines

- Approved: Filgrastim (7), pegfilgrastim (5), Epoetin (5), trastuzumab (5), rituximab (6), bevacizumab (1)
- Biosimilars introduce price competition, which will dramatically change the oncology landscape
  - ex.: National Health Service England (NHSE) has driven adoption of biosimilars in oncology
    - Rituximab 87,8% after 12 months, trastuzumab even faster
- Like in other therapeutic areas, biosimilars improve the sustainability and affordability of cancer treatment and mitigate drug shortages

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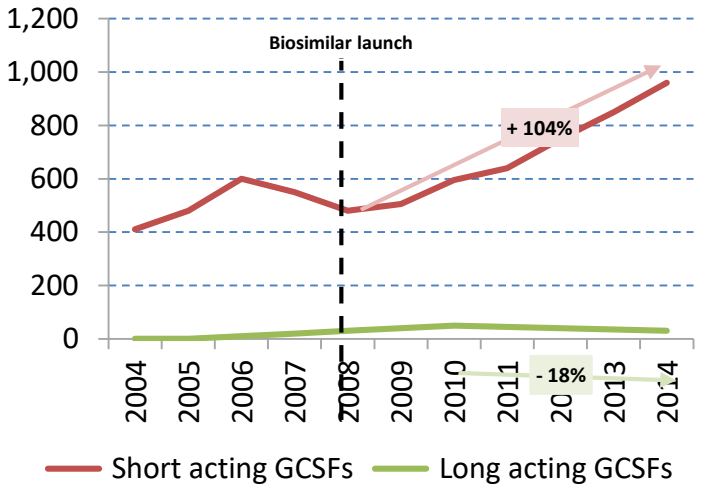
Positive ex. UK: biosimilar filgrastim enabled increased patient access at an earlier stage of the therapy cycle

Filgrastim uptake in the UK

Standard Units (K)



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

- NICE guideline adapted after biosimilar filgrastim introduction
- Filgrastim also recommended for primary prophylaxis of neutropenia
- filgrastim short-acting increased by 104% between 2009 and 2014

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

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Positive ex: Introduction of biosimilars led to revision of prescribing/clinical guidelines

Acknowledging revised cost-effectiveness of a given treatment

- The originator was authorised however not used in a certain indication (in the label)

Remove existing prescription limitations / Introduce authorisation process for less cost-effective option

- Prescription subject to authorisation
- Failure of another treatment (secondary treatment)

Southern healthcare region

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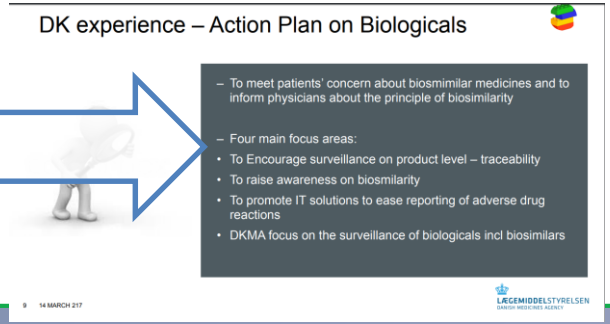
Positive ex.: information on biosimilar medicines as therapeutic alternative

National Position on Physician-led switching

Link: Overview of positions on EU physician-led switching for biosimilar medicines

National/Targeted Information campaign

National Plan/Ambition



UK: https://bit.ly/2z47vzu
FR: https://bit.ly/2Dwalgw
DK: https://bit.ly/2Ic9Zkh

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Positive ex.: Health Care Professionals Initiatives to accompany patient-physician dialogue

Hospital Pharmacists guideline on introducing biosimilar medicines in the hospital

https://bit.ly/2UvOr8I

ESN
EUROPEAN SPECIALIST NURSES ORGANISATIONS

European Specialised Nurses guideline on introducing biosimilar medicines in the hospital

https://bit.ly/2HZWpQ4

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Positive ex.: Italian Procurement law

- new tender within 60 days of first biosimilar market entry
- no “naïve patients only” rule
- AIFA recognizes interchangeability between biosimilar medicines
- Physicians at the center of decision process of their choice.

In Italy, AIFA position clarifies that biological and biosimilar medicines cannot be considered *sic et simpliciter* as generic products.

While considering that the choice of treatment remains a clinical decision entrusted to the prescriber, the latter is also entrusted with the task of contributing to an appropriate use of resources for the sustainability of the healthcare system and the correct patient information on the use of biosimilars.

As demonstrated by the regulatory authorization process, the risk-benefit ratio of biosimilars is the same as that of the reference originators. **For such reason, AIFA considers biosimilars as interchangeable products with the correspondent reference originators. This consideration holds true for *naïve* patients as for patients already under treatment.**

Moreover, in view of the fact that the process of evaluation of biosimilarity it is conducted by the EMA and the national regulatory authorities at the highest level of knowledge scientific and based on all available evidence, are not necessary further comparative assessments carried out at regional or local level.

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Positive ex.: Measures supporting the clinical use of biosimilar medicines

Quotas/ Target Agreements

Prescription monitoring

- Voluntary
- Mandatory

Benefit-sharing schemes

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Market Access & Procurement mechanisms

Internal reference pricing (price based on originator)

Best-value biologic (preferred biologic)

Tender (National, Regional, Hospital)

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Cost of inaction in Romania-wasteful spending

INN	Value (2016)[1]	Value per month (2016)	Value per day (2016)
adalimumab	€ 43,404,811.00	€ 3,617,067.58	€ 118,917.29
insulin glargine	€ 34,611,225.00	€ 2,884,268.75	€ 94,825.27
etanercept	€ 33,820,417.00	€ 2,818,368.08	€ 92,658.68
trastuzumab	€ 25,010,189.00	€ 2,084,182.42	€ 68,521.07
rituximab	€ 19,035,275.00	€ 1,586,272.92	€ 52,151.44
Total	**€ 155,881,917.00**	**€ 12,990,159.75**	**€ 427,073.70**

Minimum biosimilar discount to enter the market[2]: **20%**

Cost of inaction		
Cost per year: € 31,176,383.40	Cost per month: € 2,598,031.95	Cost per day: € 85,414.75

Source: IQVIA. Medicines for Europe - Generics and Biosimilars Report. (2017). - Medicines for Europe. Market Review – European Biosimilar Medicines Markets 2017. (2017).

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PART II-Conclusions

- Cancer is one of the world's greatest global health challenges
- Cancer treatment remains unaffordable for many patients worldwide, who lack adequate insurance coverage
- Biosimilar medicines support
  - greater access (patients currently denied access to expensive biologicals will have the chance to receive treatment),
  - earlier access (supportive cancer care success story with filgrastim),
  - broader access (innovative medicines),
  - hence better health outcomes
- Multi-stakeholder approach/interaction/collaboration needed (doctors, pharmacists, nurses, patient/organization, hospital management)
- Education is crucial (new concepts like comparability exercise)
- Sustainable procurement practices-the key to healthy competition

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Part II: IGBA Recommendations to WHO

- WHO
  - to adapt the prequalification procedure to enable further access to trastuzumab and rituximab to patients worldwide
    - IGBA will present detailed position to WHO
  - to further promote competition through implementation of its biosimilar guidelines and to foster a true global biosimilar development framework
    - IGBA will work with WHO on a global framework under a Memorandum of Understanding under development
  - to support information and education on biosimilar medicines

Patients are desperately waiting

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THANK-YOU!

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About IGBA

- Founded in March 1997 as the International Generic Pharmaceutical Alliance
- Renamed **International Generic and Biosimilar medicines Association (IGBA)** in September 2015
- Legally incorporated in Geneva, Switzerland I 2015
- Admitted as Assembly Member of ICH in June 2016
- Maintains constant dialogue with the WHO, WTO, WIPO, ICH and other national, regional and international bodies

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Members

- IGBA is committed to promoting generic and biosimilar medicines worldwide, and consists of the following associations:

  - Association for Accessible Medicines (AAM-United States)
  - Canadian Generic Pharmaceutical Association (CGPA-Canada)
  - Generic and Biosimilar Medicines Southern Africa (South Africa)
  - Indian Pharmaceutical Alliance (IPA-India)
  - Japan Generic Medicines Association (JGA-Japan)
  - Jordanian Association of Pharmaceutical Manufacturers (JAPM-Jordan)
  - Medicines for Europe (Europe)
  - Taiwan Generic Pharmaceutical Association (TGPA-Taiwan)

  The generic and biosimilar medicines associations of Australia, Brazil, Malaysia, Mexico and Saudi-Arabia are Associate Members.

- In addition, IGBA includes:
  - Biosimilars Canada
  - Biosimilars Council (AAM Division)
  - Biosimilar Medicines Group (Medicines for Europe Sector Group)

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