IGBA Contribution: Pricing implications of policies on biosimilar cancer medicines

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11 April 2019, Johannesburg, South Africa
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
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
Barriers to market, impacting price of biosimilar medicines

- **Regulatory barriers** increasing 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)
Use of biosimilar medicines in EU varies greatly by country and therapeutic area

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

- 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

Filgrastim uptake in the UK

<table>
<thead>
<tr>
<th>Year</th>
<th>Short acting GCSFs</th>
<th>Long acting GCSFs</th>
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<tr>
<td>2004</td>
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<td>2014</td>
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Changes in developments depicted as overall change in % between 2008–2014 (short acting) and 2010–2014 (long acting)

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

Hospital Pharmacists guideline on introducing biosimilar medicines in the hospital

European Specialised Nurses guideline on introducing biosimilar medicines in the hospital
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.
Positive ex.: Measures supporting the clinical use of biosimilar medicines

Quotas/Target Agreements

- Voluntary
- Mandatory

Prescription monitoring

Benefit-sharing schemes
Market Access & Procurement mechanisms

- Internal reference pricing (price based on originator)
- Best-value biologic (preferred biologic)
- Tender (National, Regional, Hospital)
Cost of inaction in Romania—wasteful spending

<table>
<thead>
<tr>
<th>INN</th>
<th>Value (2016)</th>
<th>Value per month (2016)</th>
<th>Value per day (2016)</th>
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<tr>
<td>adalimumab</td>
<td>€ 43,404,811.00</td>
<td>€ 3,617,067.58</td>
<td>€ 118,917.29</td>
</tr>
<tr>
<td>insulin glargine</td>
<td>€ 34,611,225.00</td>
<td>€ 2,884,268.75</td>
<td>€ 94,825.27</td>
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<tr>
<td>etanercept</td>
<td>€ 33,820,417.00</td>
<td>€ 2,818,368.08</td>
<td>€ 92,658.68</td>
</tr>
<tr>
<td>trastuzumab</td>
<td>€ 25,010,189.00</td>
<td>€ 2,084,182.42</td>
<td>€ 68,521.07</td>
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<tr>
<td>rituximab</td>
<td>€ 19,035,275.00</td>
<td>€ 1,586,272.92</td>
<td>€ 52,151.44</td>
</tr>
<tr>
<td>Total</td>
<td>€ 155,881,917.00</td>
<td>€ 12,990,159.75</td>
<td>€ 427,073.70</td>
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Minimum biosimilar discount to enter the market: 20%

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<tr>
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<th>Cost per year:</th>
<th>Cost per month:</th>
<th>Cost per day:</th>
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<tr>
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<td>€ 31,176,383.40</td>
<td>€ 2,598,031.95</td>
<td>€ 85,414.75</td>
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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/organisation, hospital management)
• Education is crucial (new concepts like comparability exercise)
• Sustainable procurement practices—the key to healthy competition
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
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 in 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
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)