V. Future of Biosimilar Market/Long-Term Sustainability

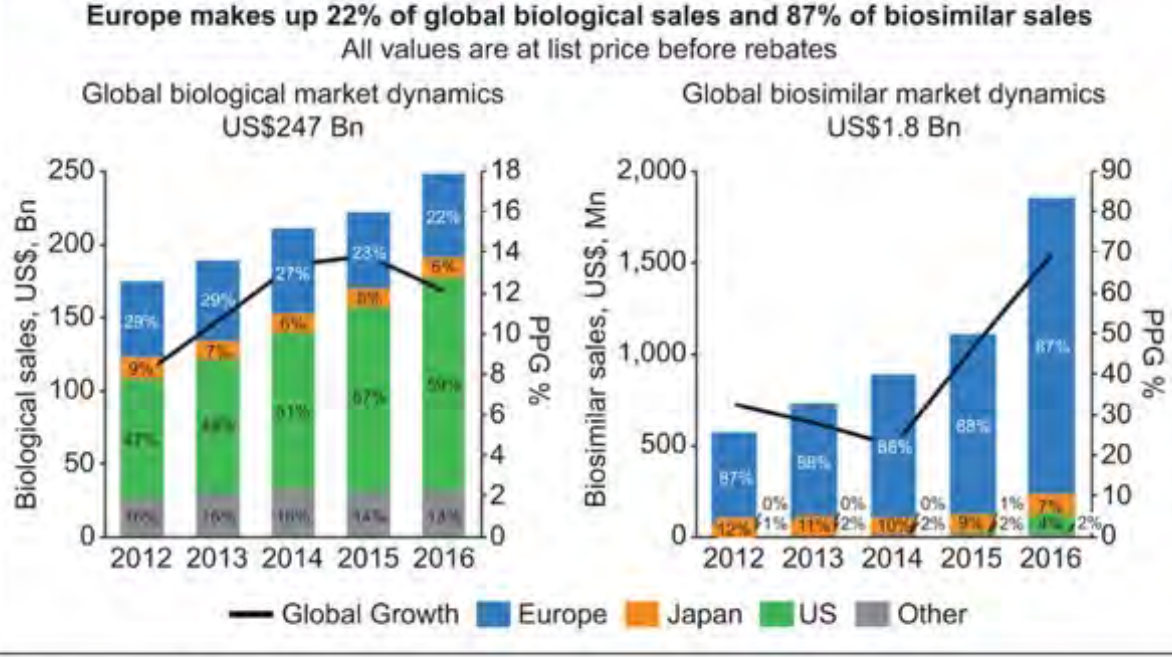
Europe: the Leader in Biosimilar Approval and Commercialization

- First biosimilar regulatory framework (2004)
- Largest biosimilar market in the world, about 60% of the global biosimilar market. As of October 2020, 54 biosimilars of 15 originator biological medicines have marketing authorization in Europe. (46 unique products, under different brands)
- Biosimilar market share as high as 91% for older products (before the approval of the first monoclonal antibody biosimilar in 2013) and as high as 43% for newer products (approved post-2013)
- European countries, with their large biosimilar markets and diverse healthcare systems, serve as valuable examples of different approaches to biosimilar policy.

Biosimilar Competition in Europe

- US has +50% share of BIOLOGICS market
- Europe had 90% of BIOSIMILARS market 2012-2016
- US now has 29 approved biosimilars, 20 on market
- Europe's share of biosimilar market dropping to around 60%

Figure 1: Biosimilar competition in Europe



PPG: previous period growth.
Source: IQVIA.

KPMG/Medicines for Europe Analysis (March 2019) Found Wide Variation Among Countries and Therapeutic Areas:

Total Biosimilar Volume: Denmark: 63%; UK: 45%; Germany 40%; France 34%, Belgium and Switzerland tied at 14%.

Filgrastim/Pegfilgrastim: 16 European countries had > 90% biosimilar utilization in 2018, Ireland was just 27%.

Anti-TNF biosimilars (adalimumab, etanercept and infliximab), Norway and Denmark had 81% and 96% biosimilar uptake, respectively, while every other country's utilization was less than 50% .

Variations are influenced by government involvement, reimbursement structures and tender procurement policies.

ASBM Whitepaper: "Policy Recommendations for a Sustainable Biosimilars Market: Lessons from Europe"

- Generics and Biosimilars Initiative Journal (GaBI Journal). Published in: Volume 9 / Year 2020 / Issue 2
- Authors: Michael S Reilly, Esq, Professor Philip J Schneider, MS, FASHP, FASPEN, FFIP
- Analyzed the different approaches to biosimilar policy across Europe
- **OBJECTIVE: identify principles which can be applied to develop an efficient and sustainable biosimilar market.**

Paper examined findings and recommendations of five previous studies and reports on biosimilar sustainability in Europe:

2014: GfK Market Access/European Generics Association (EGA) (now Medicines for Europe)

2015: European Federation of Pharmaceutical Industries and Associations (EFPIA)

2016: Simon & Kucher/ Medicines for Europe report: "Payers' price & market access policies supporting a sustainable biosimilar medicines market."

2018: IQVIA; Advancing Biosimilar Sustainability in Europe; commissioned and funded by Pfizer.

2019: Patch Consilium study "Towards a sustainable European market for off-patent biologics", commissioned and funded by EFPIA.

medicines for europe
better access. better health.

efpia
European Federation of Pharmaceutical Industries and Associations

IQVIA

The "Gold Standard": Six Principles

1. Policies should be designed to **incentivize and reward innovation** in all types of biologicals.
2. Healthcare financing must take into account **societal benefits derived from biological medicines,** as well as the **unique characteristics of biologicals**.
3. Procurement practices **must provide for multiple suppliers** and a minimum term of 12 months.
4. **Physicians must have autonomy to choose the most appropriate medicine for their patient, including making decisions on switching, which must also be consented to by the patient; no automatic substitution.**
5. Mandatory **brand- name prescribing** to avoid unintended switches and a **robust pharmacovigilance system** to report adverse drug reactions (ADRs).
6. **Policies with potential to undermine sustainability, such as measures which induce biosimilar uptake or promote preferential treatment, thereby limiting physician choice, should be avoided.**

"Must-Haves": Three Principles

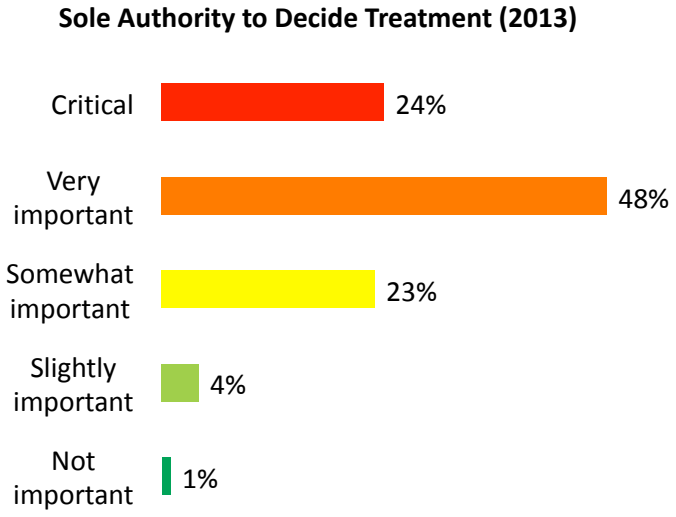
1. Physicians should have the **freedom to choose between off-patent originator biologicals and available biosimilars** and to act in the best interest of their patients based on scientific evidence and clinical experience.
2. Tenders should be designed to include **multiple value-based criteria beyond price**, e.g. education, services, available dose strengths, and **provide a sufficient broad choice** (multi-winner tenders versus single-winner tenders) to ensure continuity of supply and healthy competition.
3. A **level playing field** between all participating manufacturers is the best way to foster competition; mandatory discounts which place artificial downward pressure on manufacturers do not engender a sustainable market environment.

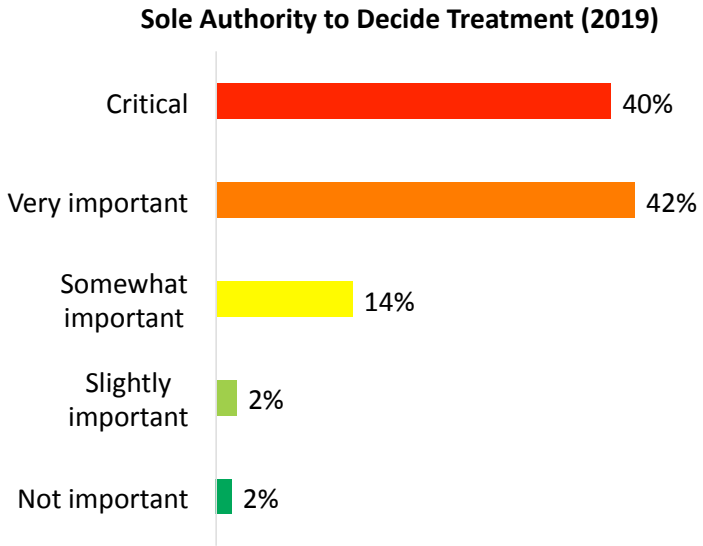
These principles were consistent the findings of ASBM's 2019 European Physician Survey discussed earlier…

Importance of Sole Treatment Decision Authority Has Increased Since 2013

Q: "How important is it to you to have the sole authority to decide, together with your patients, the most suitable biologic medicine for their disease?" (n=579)

A strong majority of respondents (82%) feel that it is either "Very Important" or "Critical" for them to decide which biologic medicine is dispensed to their patients, an increase (from 72%) in 2013 survey.

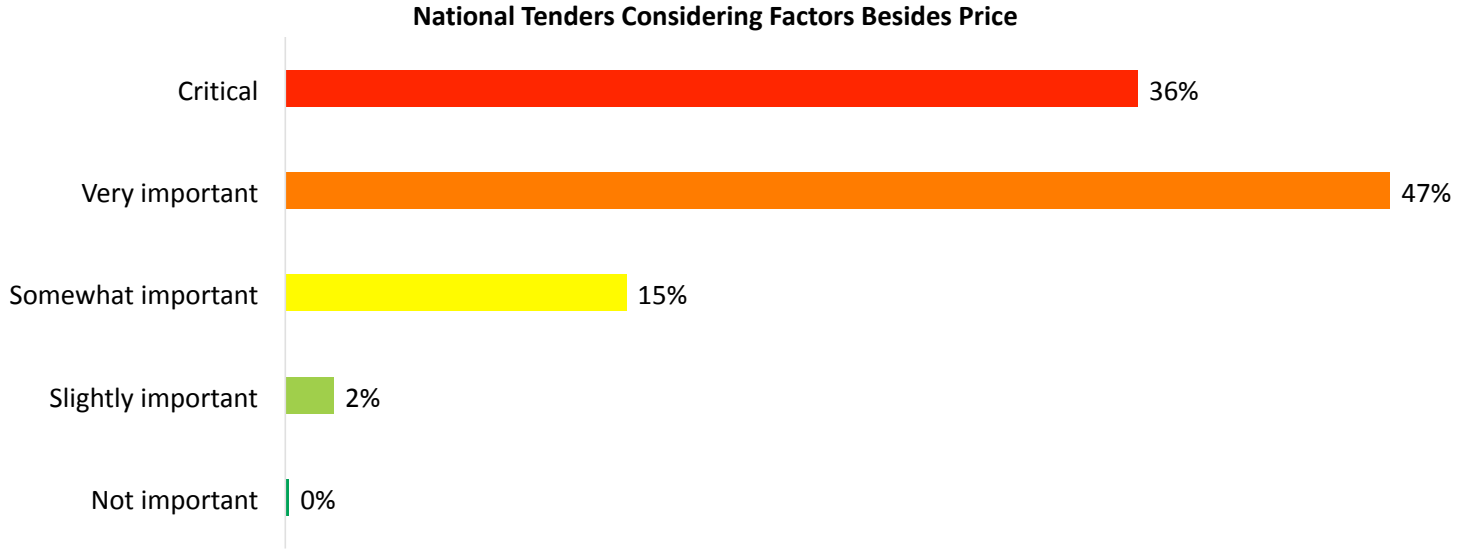




National Tender Design: Factors Besides Price Are Important

"From your perspective, how important is it for factors besides price to be taken into account in national tender offers (e.g. reliability of supply, patient support services, manufacturer reputation)?" (n=579)

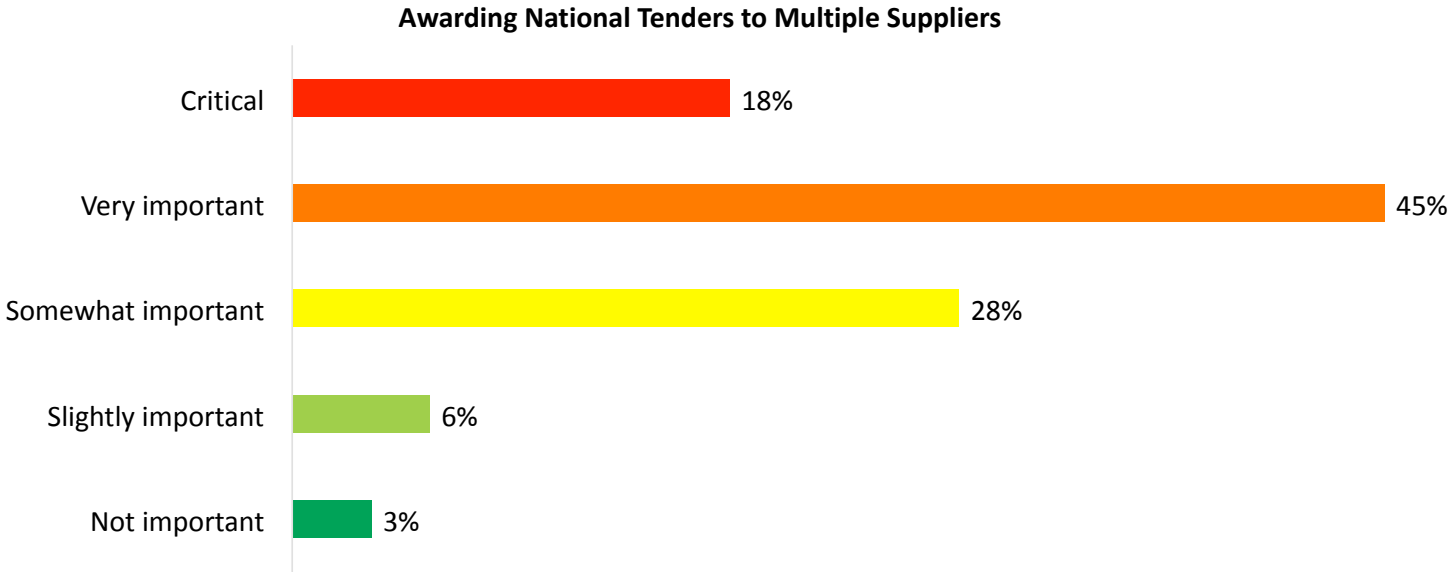
A strong majority of respondents (83%) feel that it is either "Very Important" or "Critical" for national tender offers to consider factors besides price.



National Tender Design: Reimbursement of Multiple Products is Important

From your perspective, how important is it for government tenders for biosimilars to be awarded to multiple suppliers? (n=579)

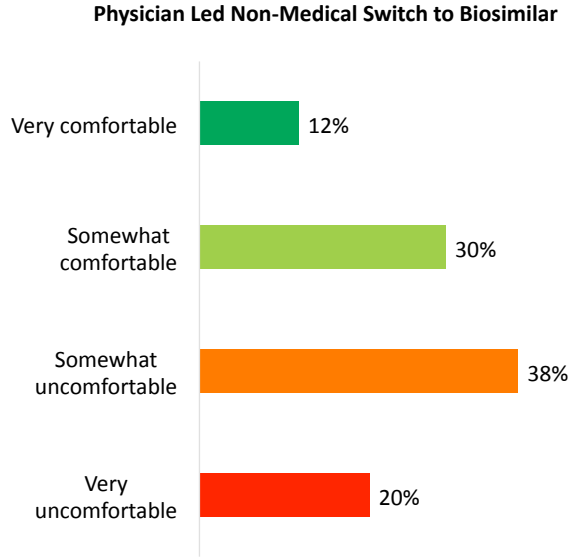
Most respondents (63%) feel that it is either “Very Important” or “Critical” for tenders to be awarded to multiple suppliers.

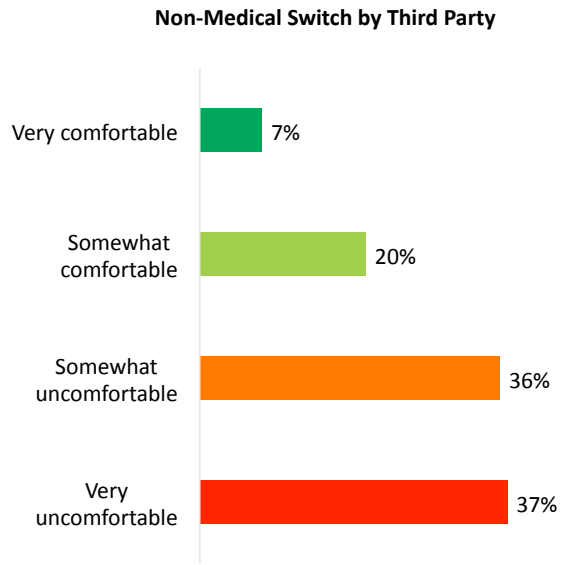


Strong Discomfort With Third-Party/ Non-Medical Switching

Q: "How comfortable are you with switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)
Q: "How comfortable are you with a third party switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)

More than half of prescribers (58%) are uncomfortable with switching their patients to a biosimilar for non-medical reasons. **This percentage increases to 73% when asked about a third party initiating such a switch .**





View the full 2019 European Physician Survey at
www.safebiologics.org/surveys

Across All European Markets, Biosimilars Have:

1. **Increased competition**
2. **Reduced unit cost of both originator and biosimilars** compared to price levels prior to the arrival of biosimilars
3. Increased volume consumption of molecules with biosimilar competition thus **expanding market access** and optimizing patient dosing
4. **Alleviated budget pressures** by providing headroom to fund novel treatment solutions.

Common Principles Across European Markets:

While the policies by which this has been achieved vary between countries, all major European markets share the following principles:

1. Automatic substitution for biologicals is forbidden.
2. All approved biologicals, i.e. originators and their biosimilars, are available on the market and are reimbursed when prescribed.
3. Reimbursement decisions on novel treatment solutions are independent from biosimilar use and uptake.
4. The time from market approval to first product sales for biosimilars is shorter than the time to first sales of novel medicines

Review: "Must-Haves": Three Principles to Promote Sustainability

1. Physicians should have the **freedom to choose between off-patent originator biologicals and available biosimilars** and to act in the best interest of their patients based on scientific evidence and clinical experience.
2. Tenders should be designed to include **multiple value-based criteria beyond price**, e.g. education, services, available dose strengths, and **provide a sufficient broad choice** (multi-winner tenders versus single-winner tenders) to ensure continuity of supply and healthy competition.
3. A **level playing field** between all participating manufacturers is the best way to foster competition; mandatory discounts which place artificial downward pressure on manufacturers do not engender a sustainable market environment.

SafeBiologics

ALLIANCE *for* SAFE BIOLOGIC MEDICINES

Thank You For Your Attention