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# Biosimilars Tendering in Europe: Key Learnings Towards Sustainable Practices

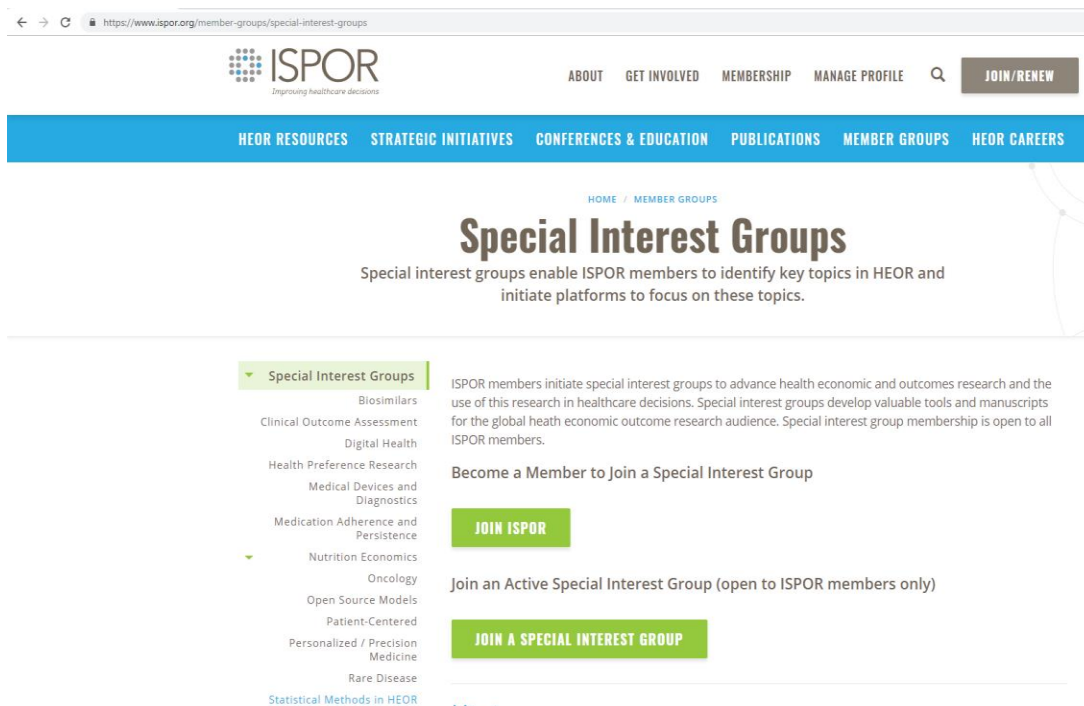
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Group on Biosimilars

30<sup>th</sup> November 2021

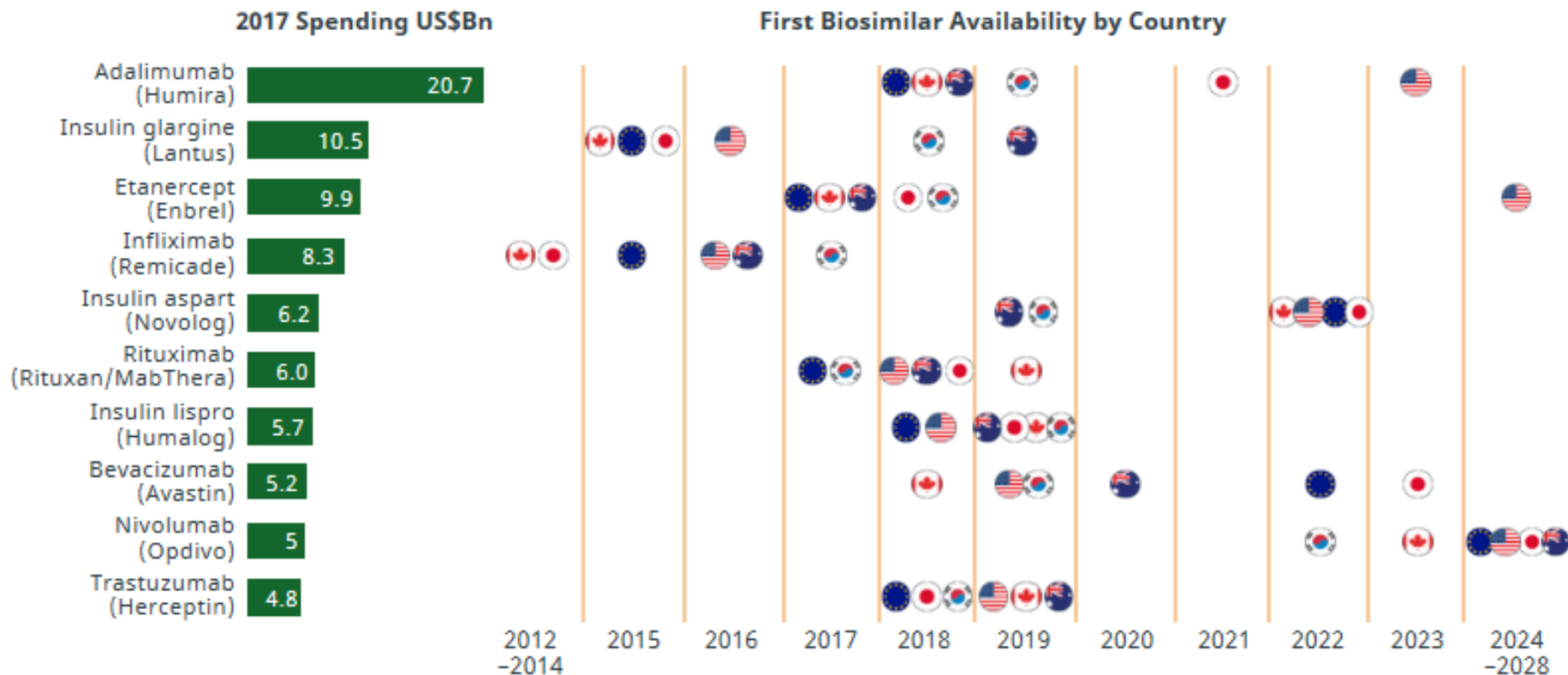
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# Differing approaches in leveraging biosimilar competition

- Biosimilar **uptake varies between countries**, regions and settings (hospital vs retail), and is affected by **differences in market entry frameworks and purchasing mechanisms**
- Dynamic competition is key to **ensuring long-term benefits** from biosimilar competition
  - Requires a combination of **supporting stakeholder adoption** and ensuring the development of **sustainable market access practices**, namely at **tendering level**
  - Opportunities exist to further develop **tender practices** and find new ways to assist involved stakeholders in this, towards **fully realising the promise of biosimilars**

## Aim of today's forum

- Share insights on **procurement/tender practices** of biosimilars across **Europe**:
  - Identify **best practices** that can support **sustainable** and **long-term competition**
  - Exchange of views on **learnings and opportunities** from current practices, and **key recommendations** for an optimal tender design to guarantee long-term patient access to biosimilars

## Speakers

- **Catarina Lopes Pereira**, PharmD, MSc, MBA, Chair-elect of the ISPOR Special Interest Group (SIG) on Biosimilars; Global Market Access Manager, Medac GmbH (moderator)
- **Liese Barbier**, PhD, PharmD, MSc, Postdoctoral researcher, KU Leuven, MABEL fund; Co-chair of member engagement of the ISPOR SIG on Biosimilars
- **Jackie Vanderpuye-Orgle**, PhD, Vice President, Parexel; Past-chair of the ISPOR SIG on Biosimilars
- **Ilan Akker**, MSc, Senior Officer, Dutch Authority for Consumers & Markets

SECTION

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# 1

**Liese Barbier**

**Biosimilar tendering in  
Europe: current practices  
and avenues for more  
sustainable approaches**

# Agenda

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- Short introduction & some context
- Current tender landscape in Europe
- Avenues for more sustainable approaches
- Take home messages



# Tendering – a key driver in biosimilar competition & adoption

- In-patient biologicals including biosimilars are largely procured via tenders across Europe
- Driver for adoption + enabler of savings





Article

# Off-Patent Biologicals and Biosimilars Tendering in Europe—A Proposal towards More Sustainable Practices

Liese Barbier <sup>1,\*</sup> , Steven Simoens <sup>1</sup> , Caroline Soontjens <sup>1</sup>, Barbara Claus <sup>2</sup>, Arnold G. Vulto <sup>1,3</sup> and Isabelle Huys <sup>1</sup>

## Aims

- To explore the **application and design of tenders** for off-patent biologicals and biosimilars
- To identify **learnings and best-practices** according to expert-interviewees
- To formulate **recommendations** in support of sustainable biosimilar tender practices

## Methods

- **Survey** among hospital pharmacists and procurers across Europe
- **Expert-interviews** with purchasers and suppliers in a selection of EU countries

# Biosimilar tendering – current landscape

- **Variability in organization and design of tenders**
  - Central vs regional vs group vs hospital individual
  - Single vs multiple winner
  - Price vs price + qualitative criteria
- **Experience** of hospitals and purchasers **varies**

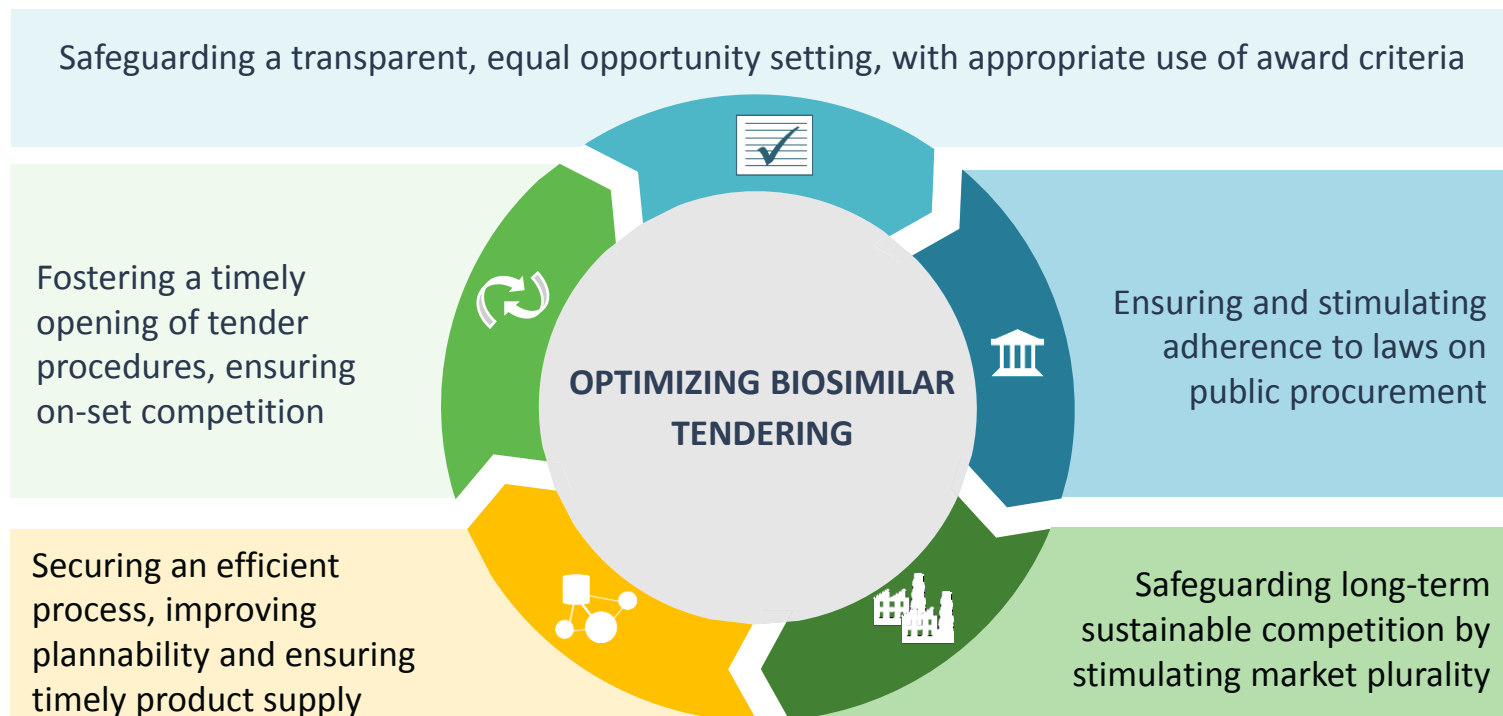


# Biosimilar tendering – current landscape

- **A number of challenges**
  - Focus on short-term savings
  - Existence of originator favouring practices
  - Difficulties with differentiating between products beyond price, need for guidance
- **Complex balance** optimizing short-term savings & creating a sustainable competitive market environment



# Biosimilar tendering – 5 avenues for optimization



# Biosimilar tendering – 5 avenues for optimization

## General considerations

- Different **actors** have all a role to fulfil
- **No one-size fits all solution** – overarching recommendations to be implemented and adapted to national context and maturity of tender system
- Some recommendations may **not** be **limited to** tender practices for off-patent biologics and biosimilars



Transparent procedure with predefined set of rules and pathway, adhered to throughout the process:

- Criteria besides price that add value to the contract: MEAT
- Transparent, non-discriminatory and equal treatment
  - Careful formulation
  - Related and proportionate to the subject-matter
  - Driving actual benefits and proportionally rewarded
  - Timely & transparent info about which criteria will be applied, their relative weight and how these are scored



Timely opening of tenders: avoid delays in competition and market opportunity for biosimilars

- In advance preparation
  - Coordination timing and duration of procedures for products with biosimilar competition
  - Horizon scanning
- No continuous re-opening with every new competitor entering the market
  - Combination of immediate shorter-term tender upon market entry of first biosimilar competitor(s), and subsequent longer tender
  - A differentiated, product-specific approach in determining the appropriate term for opening a tender
- Financial stimulus for purchasers to organize tenders, aligning purchaser and healthcare system perspective
- Tender duration between 12 and 24 months





The rules on public procurement should be **adhered to** and **stakeholders motivated** to do so:

- **Feedback** to purchasing bodies on performance and **steering measures** where needed
- **Auditing, investigating** signals of anti-competitive conduct and if needed taking appropriate **measures**
- **Reviewing of financing structures** of purchaser bodies and involved stakeholders
  - Removing disincentives / incentives favouring a specific product
  - Installing incentive schemes that are aligned with overall healthcare benefits
- Stimulating **physician adherence** to tender outcome
  - Involvement in procedures, e.g. in the Drug & Therapeutic committee
- **Up-to-date guidelines** for biosimilar use, lowering practical barriers and stakeholder uncertainty



Increasing **predictability** and **plannability** for the supplier:

- Setting accurate **estimates of volume** to be supplied, **timely communication** regarding the timing of tender procedures and making use of suitable **lead times**
- Supply issues: **penalties proportionate** to contract value and cause
- Opening procedures throughout the year



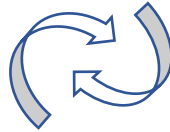
Procurement practices taking a **long-term** view, tailored to supporting market sustainability, with **competition** of multiple suppliers and **savings over the longer term**

- Stimulating **market plurality** and multiple commercial opportunities for suppliers
  - Multi-winner tender, if sufficiently large scale
  - Division of markets into multiple single-winner opportunities
  - Rotating system between regions or hospitals
- **Regular evaluation** of the market situation and **review of tendering policies** in this context, avoiding market concentration

# In summary



Award on **criteria beyond price**, but ensure appropriate application



Stimulate a **timely opening**, e.g. with horizon scanning



Ensure & stimulate **stakeholder adherence**



Improve **plannability** to safeguard timely product supply



Develop practices with a **long-term market sustainable view**

# Take aways & future outlook

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- Important variation in biosimilar tendering across Europe
- Opportunities to improve tender practices, especially in the context of ensuring competitive dynamics
- Tailoring to local context and maturity of tender system/off-patent biologicals market
- Competition = essential for more sustainable off-patent biologicals markets with improved affordability and accessibility
- Combined approach required: increasing biosimilar acceptance among stakeholders, developing sustainable practices (procurement, incentives,...) to stimulate market plurality
- Shared responsibility: purchasers, suppliers, governments, competition authority, physicians....
- Not only now, but also for the next wave of expected biosimilars

# Thank you!

Questions or input: drop them in the chat or feel free to send me an e-mail

[liese.barbier@kuleuven.be](mailto:liese.barbier@kuleuven.be)

SECTION

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# 2

**Jackie Vanderpuye-Orgle**

**How to move towards a  
sustainable biosimilar  
market in Europe:  
A Delphi Panel Consensus**

# Overview of multistakeholder Delphi Panel

## Rationale

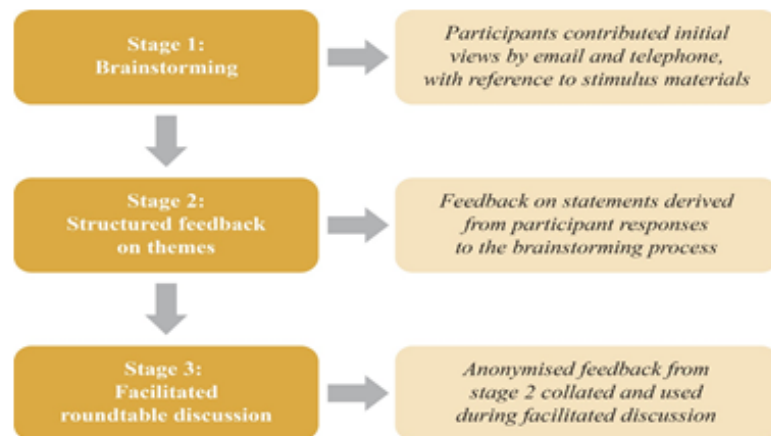
- The biosimilars market is rapidly growing; it is expected to reach US\$23.6 billion (€20 billion) by 2024 with most growth occurring in Europe.
- Biosimilars have the potential to positively impact healthcare systems and budgets, and they could save US\$100 billion (€84.7 billion) over the 5 years.
- To realize this potential, stakeholders need to balance competition and supply chain security to foster a sustainable biosimilars market.
- There is significant variation in the policies for pricing, procurement, and use of biosimilars in the EU.

## Objective

- To examine biosimilar market sustainability in more detail to:
  - establish a multistakeholder definition of biosimilar market sustainability;
  - further identify components of a sustainable biosimilar market; and
  - identify drivers and risks of a sustainable biosimilar market.

## Methods

- A modified Delphi process with cross sectional stakeholders
- 11 participants (1 patient advocate, 1 oncologist, 1 rheumatologist, 2 hospital pharmacists, 2 procurement pharmacists, 1 national payer, 2 policy advisers, 1 manufacturer)
- 7 European countries; November 2019





## Consensus statement on market sustainability

- A multistakeholder definition of biosimilar market sustainability
  - A sustainable biosimilar market means that . . . “All stakeholders, including patients, benefit from appropriate and reliable access to biological therapies. Competition leads to a long-term predictable price level, without compromising quality, while delivering savings that may be reinvested.”
- Three key components:
  - Deliver tangible and transparent benefits to the healthcare system
  - Address the needs of all stakeholders
  - Requires collaboration across stakeholders

# Key components of a sustainable biosimilar market

## I. A sustainable biosimilar market must deliver tangible and transparent benefits to the health care system

Biosimilars have the potential to reduce the cost of treatment; this, in turn, strengthens the sustainability of health care expenditure



CONSENSUS

Biosimilar-related savings must be tangible and transparent and should be reinvested efficiently; this may include addressing deficits, and funding innovative therapies, health care or other public services. Biosimilars have the potential to expand access



CONSENSUS

Providers (physicians and pharmacists) incur real costs when transitioning to a new biosimilar; transition should only occur if savings substantially exceed these transition costs and a portion of the savings are used to meet these costs



PHYSICIAN



PHARMACIST

## II. A sustainable biosimilar market must address the needs of all stakeholders

Transitioning between biosimilars causes disruption to patient care and health care services. Unnecessary disruptions (i.e., frequent transitions and/or transitions that do not deliver tangible savings) should be minimized



CONSENSUS

Disruption caused by biosimilar transition may be unavoidable in some therapeutic areas (e.g., acute vs. chronic conditions); however, switch is not advisable if treatment duration is short



PATIENT



PHYSICIAN



PHARMACIST

Disruption and transition costs occur in both hospital and out-of-hospital (including retail and home care) settings; these differences may need to be considered



PHYSICIAN



PHARMACIST

## Key components of a sustainable biosimilar market (cont.)

### III. A sustainable biosimilar market requires collaboration between stakeholders

Policies and practices must encourage trust in biosimilar use among patients through effective communication between stakeholders



CONSENSUS

Language and messaging should be consistent among stakeholders and coordinated nationally



CONSENSUS

Clear guidance from regulators and clinical organisations at European and national levels is required to motivate multiple switches (i.e., following the initial transition from original biological to biosimilar)



PATIENT



PHYSICIAN

- This guidance may benefit from real-world studies (e.g., registry studies)—although not all stakeholders agree that this would be sufficient evidence



PHYSICIAN



PHARMACIST



PAYER

- Research would need to be led by providers (pharmacists and physicians), as there are limited incentives for manufacturers to invest in this research



MANUFACTURER







PHARMACIST



PAYER

## Drivers and risks to sustainability: Competition and incentives

1. Competition is more effective for achieving long-term predictable price level than regulation	
Increased competition leads to more rapid price reduction and, if procurement policies contribute to business continuity, a sustained lower price level	 CONSENSUS*
There is a need to develop better prospective indicators to warn about potential risk of <i>de facto</i> monopoly	 CONSENSUS*
2. There needs to be incentives for investment in future biosimilars	
Continued investment in biosimilar development and market entry is important to generate competition for biological therapies for which no biosimilar is currently available and, to a lesser extent, therapies with biosimilars already available	 CONSENSUS*
3. Governments and pricing bodies need to drive incentives	
These bodies need to supply incentives that enable enough suppliers to survive free market onslaught; this may assure the continuity of long-term competition and sustainable discounts from originator biological therapy price levels	 CONSENSUS*

# Drivers and risks to sustainability: Procurement process

## I. Procurement processes should avoid monopolies and minimize patient and health care system disruption

The emergence of monopolies may lead to higher price levels and/or enhanced supply risks



CONSENSUS

- There are examples of this in generics, although these issues would be more pronounced for biosimilars due to lengthy development and market entry processes



PHARMACIST



POLICY



MANUFACTURER

Procurement design should aim to:

- Prevent predatory behaviour, e.g., by considering factors other than price to avoid aggressive price discounting



PHARMACIST



PAYER

- Minimize disruption of patient care, based on the needs of individual therapeutic areas, e.g., by setting contract duration that is proportional to duration of treatment



PATIENT



PHYSICIAN

## II. The principles for procurement should be agreed by all stakeholders

There should be a multistakeholder group that sets principles for policy and practice around biosimilar procurement



CONSENSUS

Patients and physicians should have an opportunity for their views to be represented (e.g., in a national forum) and patients should be informed of the rationale behind procurement decisions that impact on their care



PATIENT



PHYSICIAN

There can be no one-size-fits-all approach to procurement, as the structure and characteristics of health care systems vary; however, there should be a consistent approach and a common set of guiding principles



POLICY



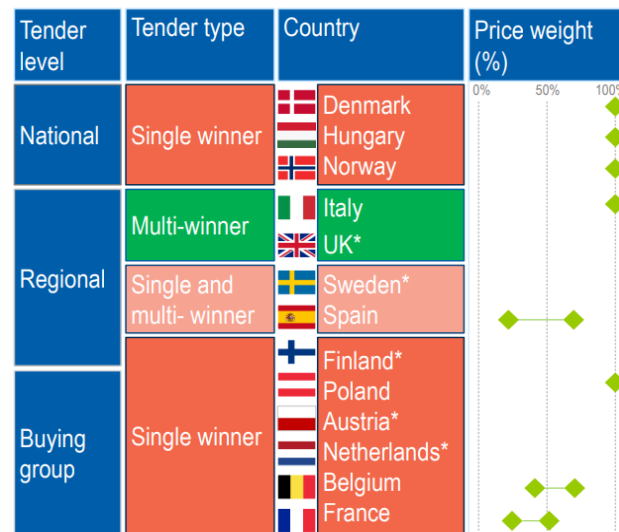
MANUFACTURER

# Supporting literature on sustainable biosimilar procurement in Europe

Vulto et al. led preceding systematic literature review found

- Awarding major market share to a single product may:
  - Limit new entry and continuity of existing manufacturers, and therefore competition for future tenders
  - Enhance supply risk, due to reliance on a single product
- There is significant variation in biosimilar procurement policy/practice
- The two main approaches identified are:
  - Single vs. multi-winner tenders
  - 100% price weight, vs. price plus other criteria

## European Tender Structure and Price Weighting



\*Weightings not available

## Where do we go from here

- Biosimilars have the potential to improve patient access to much needed medicines
- Tendering could minimize/fix the purchasing price thus reducing acquisition costs
- Tendering could also lead to drug shortages and quality trade-offs if not well-administered
- Transparent and clear tender procedures will help foster a sustainable market

### Risk factors

- Products procured through tenders without differentiation concerning value characteristics
- Lowest price criterion defines the tender winner
- Tendering systems are applied for the on- and off-patent drug segments
- No consideration of the quality of the product or reliability of the manufacturer
- High frequency and short duration of tenders
- Single winner tender

### Components of good practice

- An established, accepted, and publicly known process
- An audit trail along the entire decision chain
- Mechanisms such as product value categorization to ensure fairness to all parties
- Encouragement of competition
- Written quotations, along with relevant supporting information, against pre-defined requirements;
- A structure that allows easy comparison of offers
- Selection of multiple winners

SECTION

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# 3

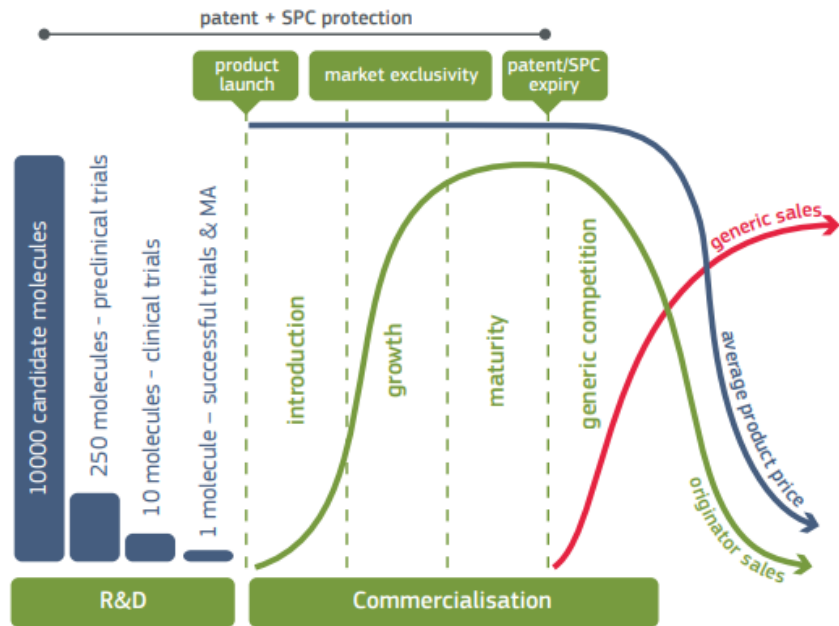
**Ilan Akker**

**Biosimilars and competition  
policy in the Netherlands**



# Life cycle pharmaceutical products

## Big questions:



1. Success in price control?
2. Fair shot biosimilar products?
3. Incentives to invest?

# NL Context – intramural setting

Pharmaceutical  
company



Hospital



Health  
Insurance



# Sector enquiry TNF inhibitors (1/2)

## Why sector enquiry

- Therapeutic equivalence, but limited price competition
- Biosimilar entry successful?
- Includes drugs with highest turnovers in NL

## Results

- Entrance biosimilars > prices go down
- Certain markets, gaining market share stays behind
- Incentive to invest into biosimilars + enter NL market

# Sector enquiry TNF inhibitors (2/2)

- Use lock in to hinder switching
  - Self-administration of the drug
  - Locked in population (rest population and/or bundling)
  - Rebate systems: rest population price expensive



European Pharmaceutical Law Review > [Volume 4 \(2020\), Issue 1](#) > Pages 57 - 66



## A Cure for All Ills? The Effectiveness of Therapeutic and Biosimilar Pharmaceutical Competition in the Netherlands

Ilan Akker, Wolf Sauter

DOI <https://doi.org/10.21552/eplr/2020/1/8>

# Humira case (1/2)

- High stakes
  - Turnover NL > €200 mln/year before patent expiry
  - 4 biosimilar producers ready to enter the NL market Fall 2018
  - Future biosimilar markets
- Rebate system
  - Widely understood switch > rebate 0%
  - Clarification letter AbbVie
  - Varying market response

## Humira case (2/2)

- Analysis
  - Lock in
  - Fair shot biosimilars
  - Effect on long term competition
- Outcome
  - Communication norm, cooperation / communication AbbVie
  - Awareness hospitals, buying groups and health insurances
  - Warning producers for the future

# NL Conclusions Biosimilars

## Price control:

- Successful TNF- $\alpha$ -inhibitors in NL
- Rebate structures & patent issues may delay price decrease
- No entry for orphan biologicals

## Fair Shot

- Requires vigilance for subcutaneous products
- Depends on doctors, hospitals and health insurances
- Problematic for small patient groups?

## Incentives

- Sufficient potential patients
- Timely entrance

# Future biosimilar markets in the Netherlands

## Biosimilar competition NL

- High awareness (hospitals + health insurances)
- Positive attitude to switching
- Competition rules enforced

## ACM Outlook

- Continuing vigilance rebate systems
- Strategies to delay entry



SECTION

# Q&A



**Thank you for your attention and participation!**

**For questions about the Biosimilar Special Interest Group**

**Email us at [BiosimilarSIG@ispor.org](mailto:BiosimilarSIG@ispor.org)**

**Join us!**