BIOSIMILAR MEDICINAL PRODUCTS

Seventh Multistakeholder Event

13 December 2023

#HealthUnion

European Commission

Introductory note

Rainer Becker, Director SANTE D (Medical Products and Innovation), European Commission

Agenda

09.30 – 09.45 **Introductory note**

09.45 – 10.00 **Patient perspectives on biosimilars**

10.00 – 10.30 **The impact of biosimilar competition in Europe**

10.30 – 11:00 *Coffee & networking break*

11.00 – 12.30 **Upcoming losses of exclusivity in the biologics pipeline:** addressing the challenges and lack of biosimilar competition

12.30 – 13.30 *Networking lunch*

13.30 – 15.00 **Disparities in biosimilar uptake and access:** opportunities across countries, regions and sectors

15.00 – 15.15 *Coffee & networking break*

15.15 – 16.15 **Product formulation and administration:** consequences for patients, healthcare professionals and systems

16.15 – 16.30 **Closing words**

European Commission

Agenda – Part I

09.30 – 09.45 Introductory note

Rainer Becker, Director SANTE D (Medical Products and Innovation), European Commission

09.45 – 10.00 Patient perspectives on biosimilars

Ljiljana Vukota, Secretary-General NGO “Everything for Her”

10.00 – 10.30 The impact of biosimilar competition in Europe

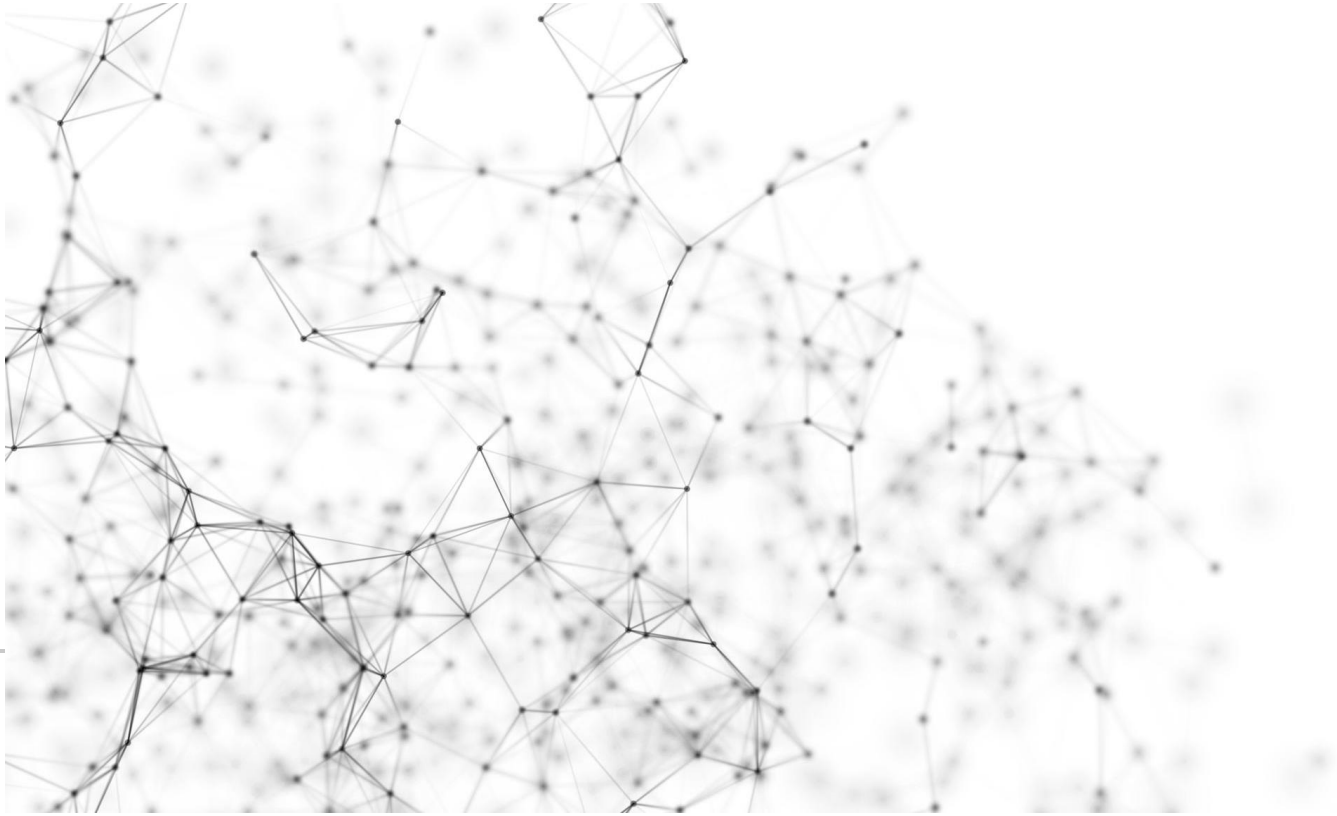
Per Troein, VP, Strategic partners, IQVIA

Max Newton, Global supplier & association relations, IQVIA

10.30 – 11:00 *Coffee & networking break*

European Commission

Patients journey and experience with the use of biosimilars



Ljiljana Vukota, mag. psih.

CSO EVERYTHING for HER, Croatia

The key to successful treatment and good outcomes

Early detection of malignant disease

Precise diagnosis

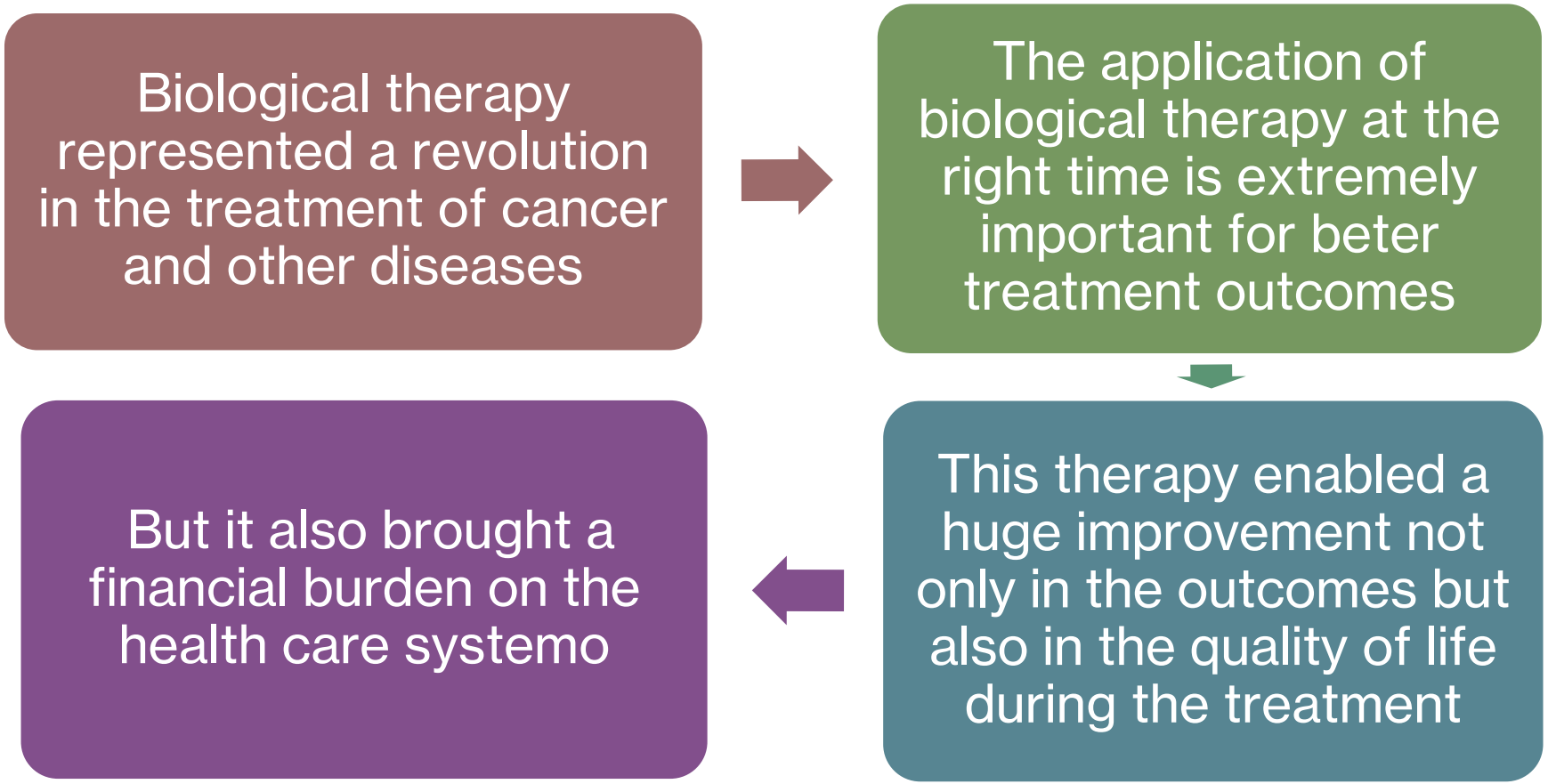
Multidisciplinarity

Timely, optimal and personalized treatment

Availability of effective therapeutic options

Supportive treatment

Biološka terapija



Similar is not the same

- The arrival of biosimilar drugs was followed by skepticism and concern from some experts
- This was also reflected on the patient community
- We mixed it up with the term generic drugs and were confused by the word "similar" because similar is not the same
- There was a lot of mistrust and it took some time to get to know what a biosimilar medicine is, how safe it is and most of all whether it is equally effective

Biosimilars – what we realized later?

- Enable a wider coverage of patients in curative and supportive therapy
- The use of biosimilar drugs is not about just saving money at the expense, but about rational and responsible management of resources in health sistem
- Creating space for the introduction of new therapeutic options, increasing availability
- Today, many patients do not even know that they are taking a biosimilar drug, or if they do, they do not question their trust in such a drug
- However, it is still necessary to inform patients about the value of biosimilars to patients and to the system

Https://www.Halmed.Hr/lijekovi/informacije-o-lijekovima/bioloski-i-bioslicni-lijekovi/

The presence of biosimilars in Croatia

Breast cancer
trastuzumab, filgrastim, pegfilgrastim

Cervical cancer
bevacizumab

Chronic lymphocytic leukemia
rituksimab, filgrastim, pegfilgrastim

Kidney disease
epoetini

Diabetes
inzulin glargin

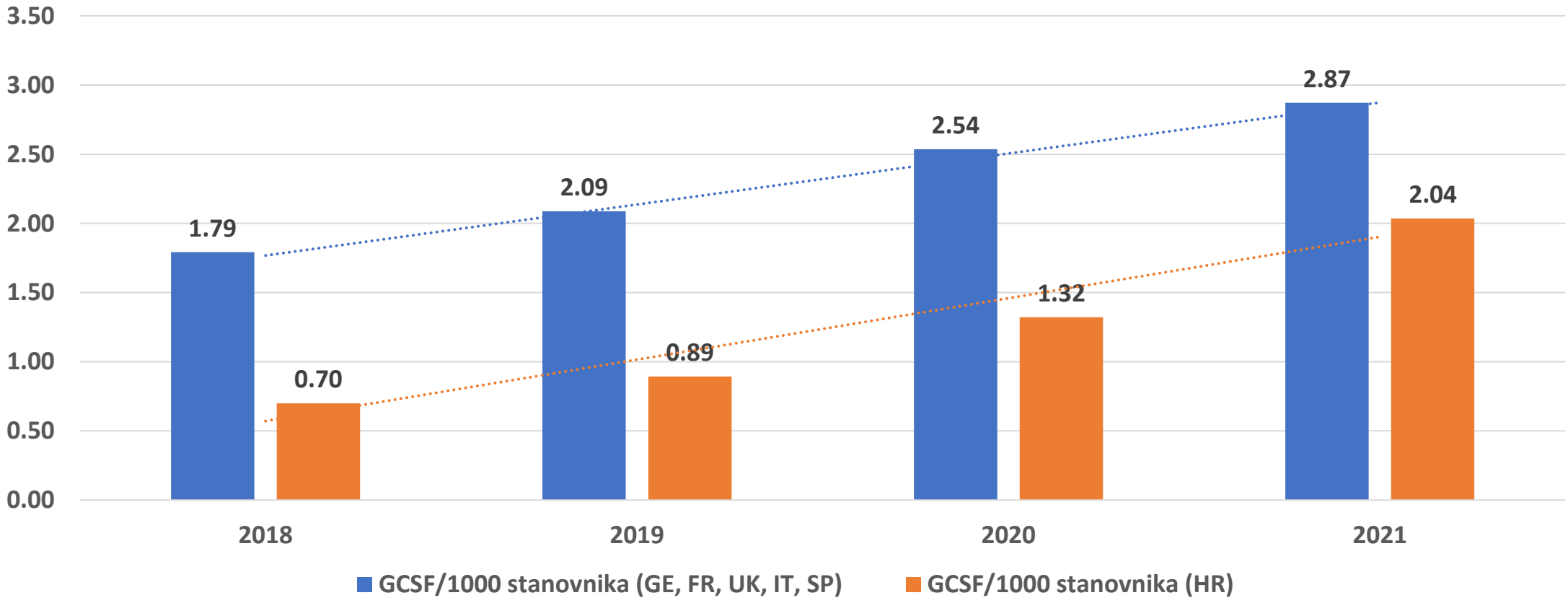
Crohn's disease
infliksimab, adalimumab

Ulcerative colitis
infliksimab

Arthritis
adalimumab, etanercept, infliksimab

Osteoporosis
teriparatid

Primjena GCSF-a per capita 2018-2021



Podaci IMS IQUVIA 2018-2021.

Access

- One of the big problems in the treatment of cancer patients is the availability of drugs
- Differences in availability are visible between countries, but also between regions within a single country
- Biosimilars help reduce these differences
- The fact of where the patient lives should not affect the availability of the best treatment options

Experts and patients should be…

- Experts and the healthcare system should be more open to biosimilar medicines
- Patients should be well informed
- Patient trust in doctors and the healthcare system is key
- The emphasis is not on savings but on economic efficiency and availability
- Patients need safe and effective medicines, and these do not always have to be the most expensive ones

The patient journey

- My journey and the journey of most oncology patients starts from this kind of room
- Biosimilars can make that journey easier
- They help us withstand toxic chemotherapy
- Effective treatment is available to many patients thanks to biosimilars

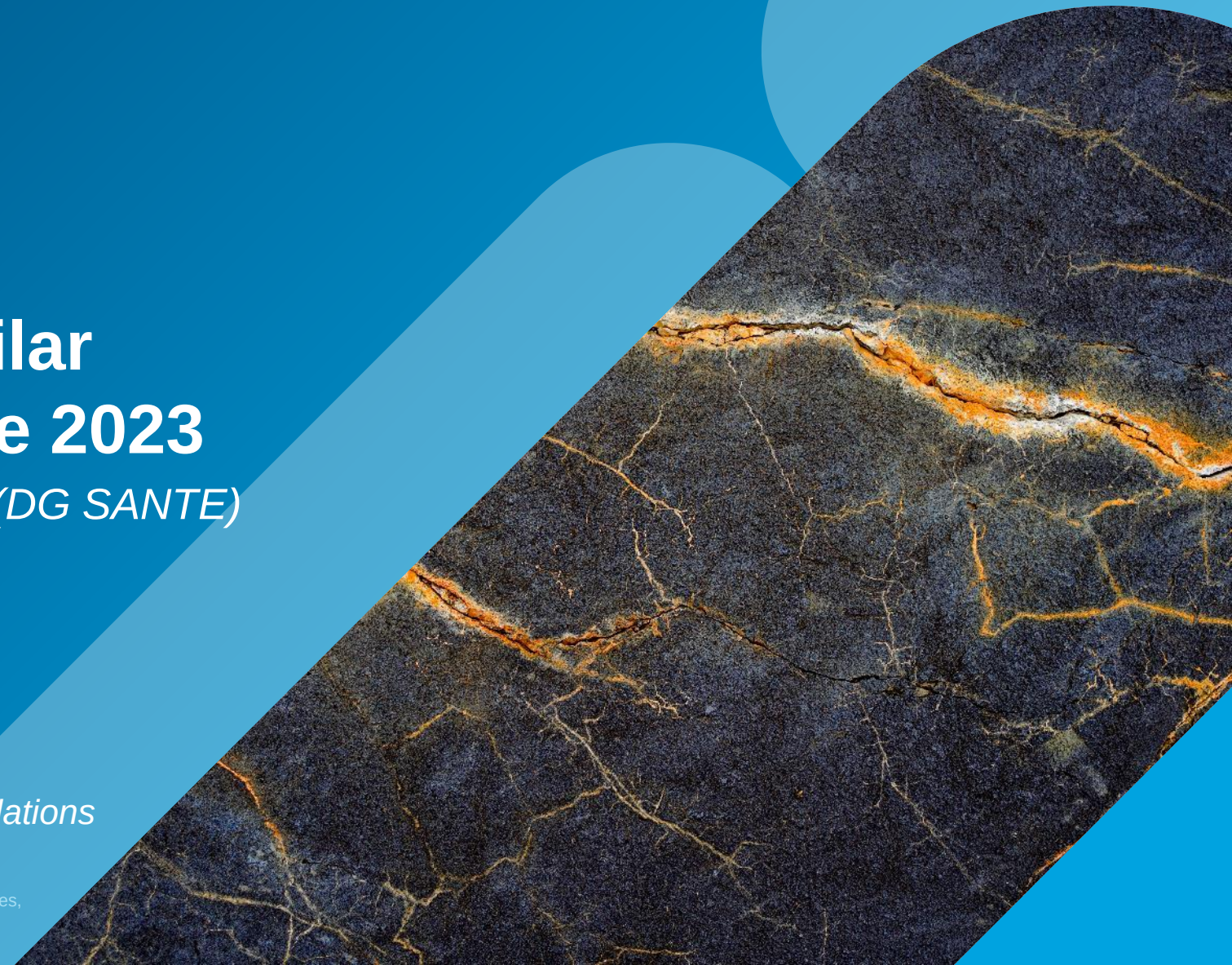
The patient's message

1. The use of biosimilar drugs increases their **pharmacoeconomic availability** and enables the arrival of **new therapeutic options**
2. Application in supportive treatment **increases the number of treated patients**, which can be seen in the example of therapy for the prevention of febrile neutropenia
3. The **choice of therapy** should remain in the hands of the prescribing physician
4. It is difficult to imagine the use of the most toxic cytostatics drugs without supportive therapy - it is important for **adherence** and **treatment outcomes**
5. They helped numerous patients in Croatia, Europe and the world

Thank you!

The Impact of Biosimilar Competition in Europe 2023

Prepared for European Commission (DG SANTE)



Per Troein, *VP, Strategic Partners*
Max Newton, *Global Supplier & Association Relations*

Disclaimer:

This 2023 report has been prepared by IQVIA independently as a public service without industry or government funding with initial contributions on defining the KPIs from EFPIA, Medicines for Europe, and EuropaBio.

The observations have been developed solely by IQVIA based on the data and analyses performed. The information and views set out in this report are those of its authors.

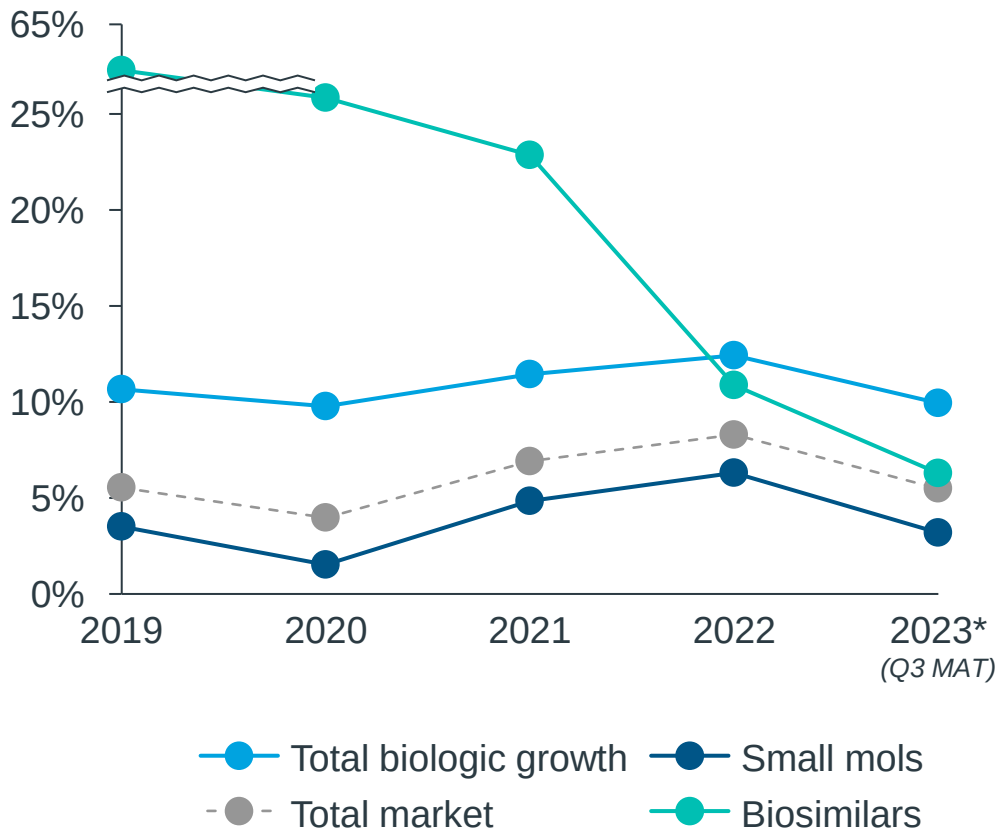
Agenda

+ **Introduction**
+ Methodology and the Country & Therapy Area KPIs
+ IQVIA's 5 Observations in 2023

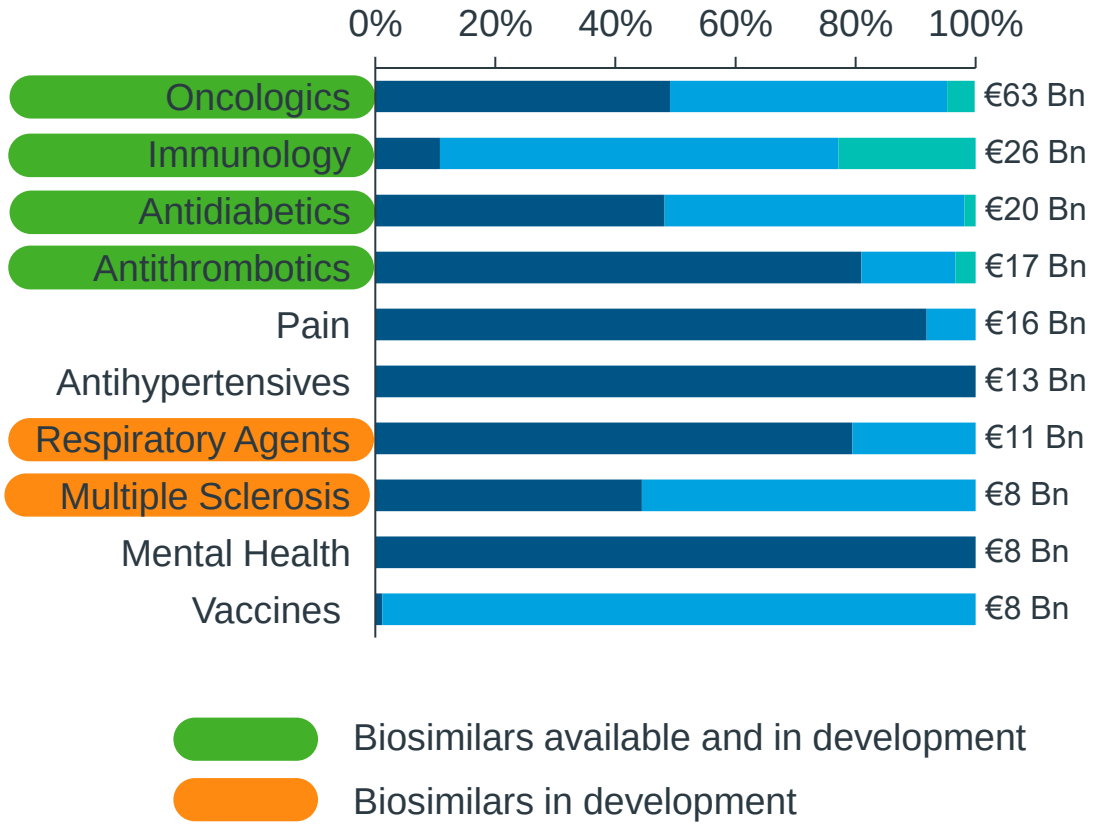
The biologics market continues to grow faster than non-biologics

The highest spend therapy areas are biologic dominated and already have biosimilar competition

Year-over-year spending growth (*EU, €*)



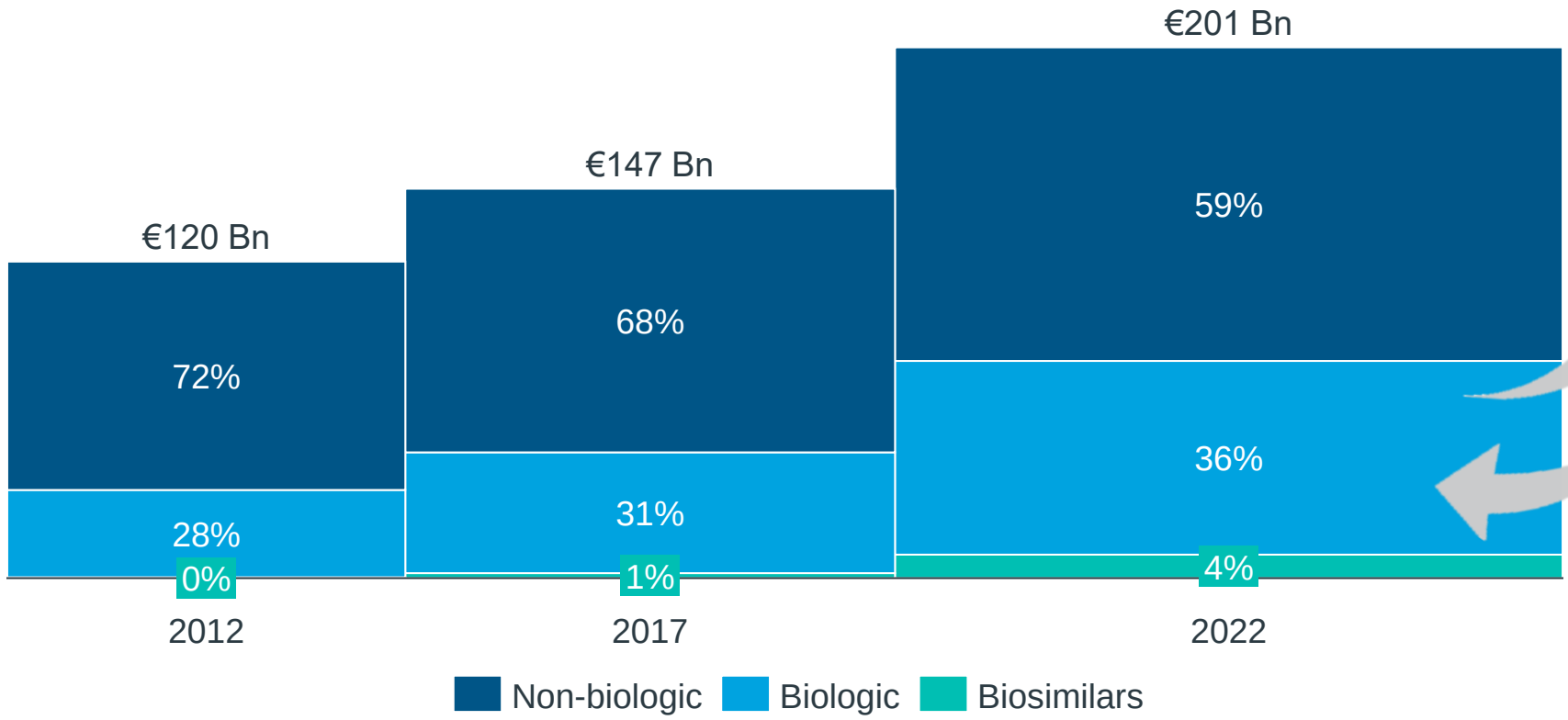
Top-10 leading therapy classes *(€, value)*



Biologics are increasingly important part of expenditure

Biologics represent 40% of current expenditure at list prices making competition critical

Biologics share of EU Pharmaceutical market
(€, billions at list prices)



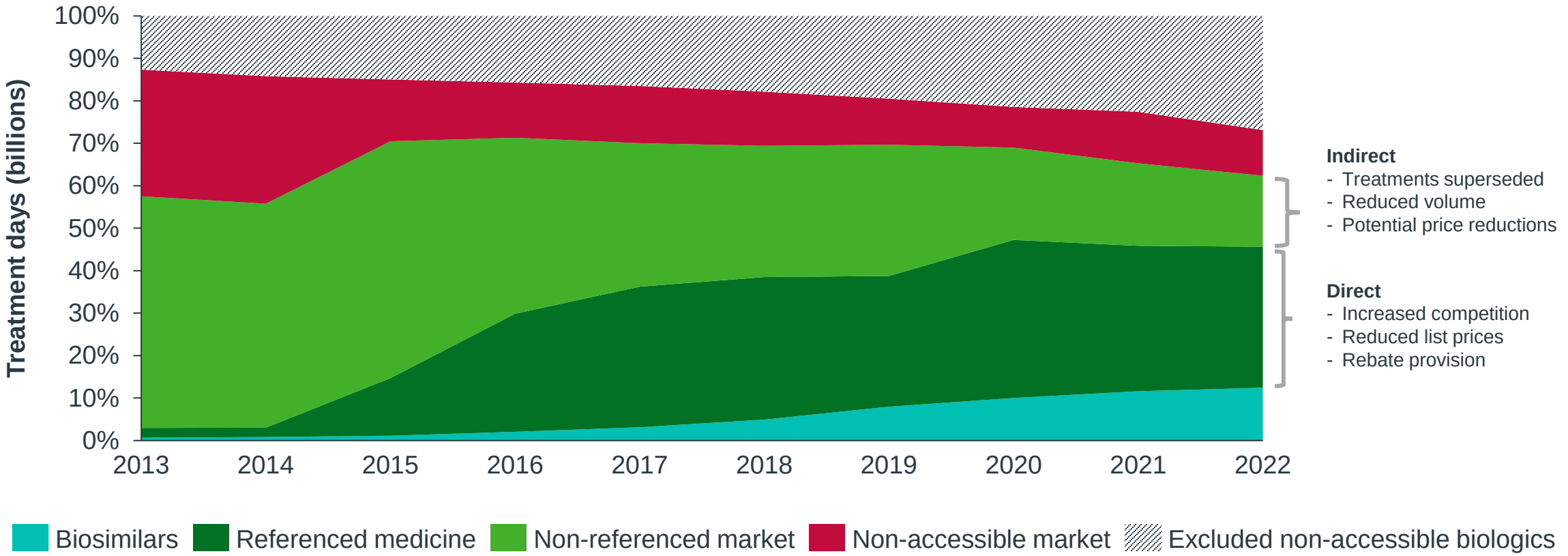
Upward drivers:
Increasing share of new launches are biologics; double digit growth of established brands; complexity and maturation of biologic development; increased demand and prescribing

Downward pressures:
Biosimilar competition; Increased confidential rebates, discounts, and clawbacks

Biosimilars play a significant indirect effect

Presence of biosimilars has an impact beyond the molecule for savings and access

Scope of IQVIA report: 10 key therapy areas
(TD billions, volume)



Agenda

+ Introduction
+ **Methodology and the Country & Therapy Area KPIs**
+ IQVIA's 5 Observations in 2023

10 therapy classes with biosimilar competition are shown

The products are split into 4 categories based on regulatory and protection status

Therapy classes

1. **Human Growth Hormone** (HGH)
2. **Granulocyte-colony Stimulating Factor** (GCSFs)
3. **Epoetin** (EPO)
4. **Anti-Tumour Necrosis Factor** (Anti-TNFs)
5. **Fertility** (Follitropin Alfa)
6. **Insulins**
7. **Oncology**
8. **Low-Molecular-Weight Heparin** (LMWHs)
9. **Parathyroid hormones**
10. **Ophthalmology**

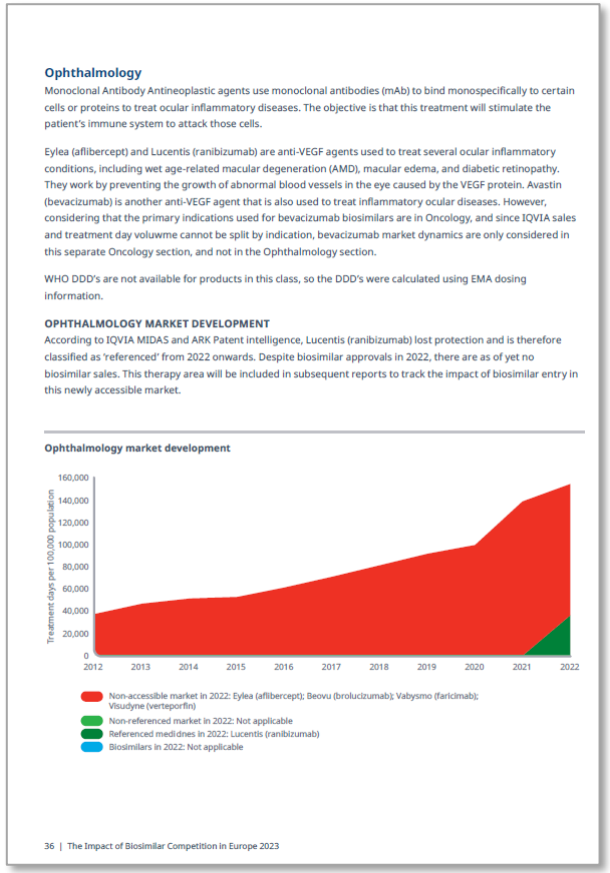
Product categorisation

Description	Key	Other segmentation	
• **Biosimilar Medicinal Product**: Product, granted regulatory approval, demonstrating similarity to the Reference Medicinal Product in terms of quality characteristics, biological activity, safety and efficacy.		**Accessible** market	**Total market:** products within the same ATC3**
• **Referenced Medicinal Product:** Original product, granted market exclusivity at the start of its life, exclusivity has now expired, and the product has been categorised as referenced by having a biosimilar with an EMA-approved marketing authorisation available on a European market.			
• **Non-Referenced Medicinal Product**: Original product, granted market exclusivity at the start of its life, exclusivity has now expired*, and the product has never been categorised as a Referenced Medicinal product by receiving EMA-approved marketing authorisation.			
• **Non-accessible category**: products within the same ATC4 code as the accessible category products. These are typically second-generation products; this category may include products with different dosing schedules and / or route of administration to those in the accessible category, **and** have valid protection status		**Non-accessible** market	

LMWHs: Shown in for the 1st time in 2021; Ophthalmology: Shown for the 1st time in 2022

The report is continually adjusted to reflect latest developments

Information for biosimilar stakeholders



Ophthalmology

Monoclonal Antibody Antineoplastic agents use monoclonal antibodies (mAb) to bind monospecifically to certain cells or proteins to treat ocular inflammatory diseases. The objective is that this treatment will stimulate the patient's immune system to attack those cells.

Eylea (aflibercept) and Lucentis (ranibizumab) are anti-VEGF agents used to treat several ocular inflammatory conditions, including wet age-related macular degeneration (AMD), macular edema, and diabetic retinopathy. They work by preventing the growth of abnormal blood vessels in the eye caused by the VEGF protein. Avastin (bevacizumab) is another anti-VEGF agent that is also used to treat inflammatory ocular diseases. However, considering that the primary indications used for bevacizumab biosimilars are in Oncology, and since IQVIA sales and treatment day voluwme cannot be split by indication, bevacizumab market dynamics are only considered in this separate Oncology section, and not in the Ophthalmology section.

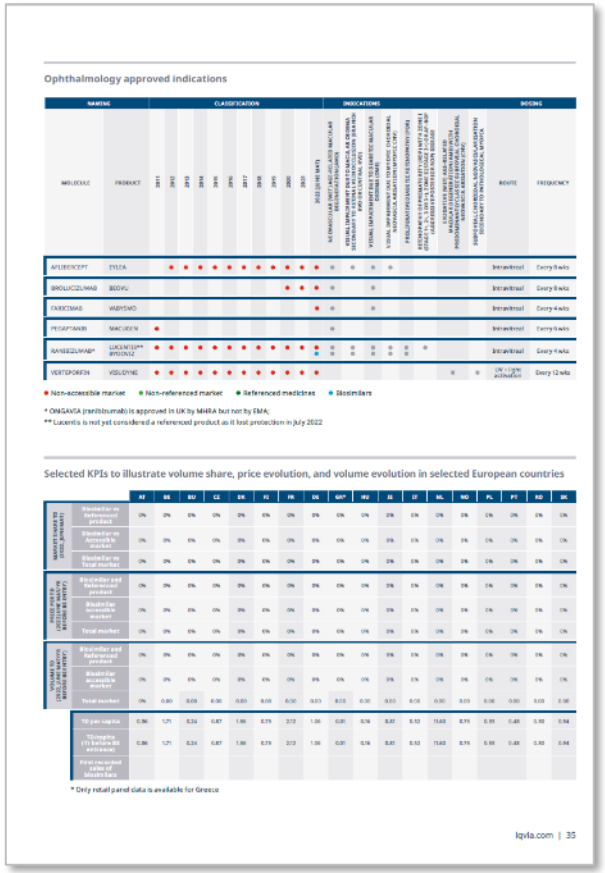
WHO DDD's are not available for products in this class, so the DDD's were calculated using EMA dosing information.

OPHTHALMOLOGY MARKET DEVELOPMENT

According to IQVIA MIDAS and ARK Patent intelligence, Lucentis (ranibizumab) lost protection and is therefore classified as 'referenced' from 2022 onwards. Despite biosimilar approvals in 2022, there are as of yet no biosimilar sales. This therapy area will be included in subsequent reports to track the impact of biosimilar entry in this newly accessible market.

Ophthalmology market development

36 | The Impact of Biosimilar Competition in Europe 2023



Ophthalmology approved indications

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries

iqvia.com | 35

Expanded data period

- Full year 2022 available in the KPI sections

Granularity

- View historical status of products
- Delay to biosimilar entry
- Visibility to 2nd, 3rd, 4th...
- 12-year history of the market

Reading guide

- Available within the document
- Attached in full presentation (below)

Agenda

+ Introduction
+ Methodology and the Country & Therapy Area KPIs
+ **IQVIA's 5 Observations in 2023**

IQVIA's observations (2023)

Key observations on price, volume and market share from historic reports remain as a reference

2015

i. Competition drives down price
ii. The correlation between biosimilars market share and price reduction is weak
iii. Competition can also influence the originator behaviour
iv. Lower prices has the most impact for countries with low initial usage
v. The product profile in classes can explain KPI differences

2016

i. Competition drives down price
ii. The correlation between biosimilars market share and price reduction is weak
iii. Competition can also influence the originator's behaviours
iv. Lower prices increase patient access in countries with low initial usage
v. The product profile in classes can explain KPI differences

2017

i. The entrance of biosimilars increases price competition
ii. In some therapeutic classes, lowering the price of the referenced product can limit the market penetration of the biosimilar
iii. There is a 1st mover advantage in biosimilar markets
iv. Biosimilars have the potential to improve patient access of the total market

2018

i. The entrance of biosimilars increases price competition
ii. Biosimilars have the potential to improve access for the market
iii. In some countries, biosimilars have completely taken over
iv. In some TAs, lowering the price of the referenced product can limit biosimilar penetration
v. The speed of uptake has increased for some more recent biosimilar launches

2019

i. Biosimilar competition has a significant potential impact on overall drug spend
ii. Major products see fast uptake and large price reductions
iii. Originator manufacturers have changed strategy to stay competitive
iv. Access is not yet increasing for all molecules or all countries
v. More is needed to create a sustainable market for biosimilar manufacturers

2020

i. Biosimilar competition continues to offer opportunities to make healthcare savings
ii. Some countries are not increasing usage despite price reductions
iii. The variation of originator response to protection expiry
iv. Several models can work to support competitive markets
v. The real impact of biosimilar competition is just beginning

2021

i. COVID-19 has impacted certain segments of the biologic market
ii. Savings from biosimilar competition at an all-time high
iii. Development of access to biologic medicines remains challenging
iv. The **competition environment in Europe is changing**
v. Ensuring preparedness for the future of biosimilar opportunity

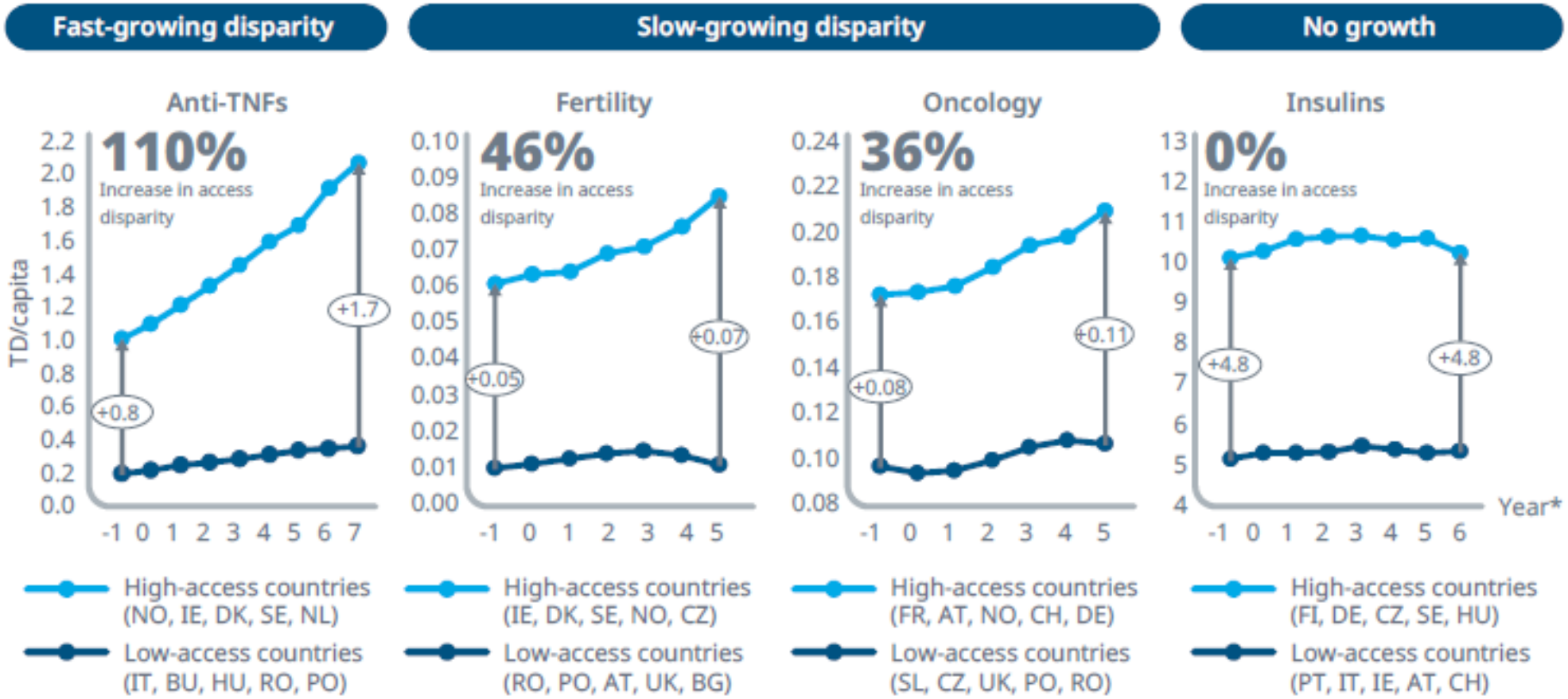
2022

i. Biologic prescribing has rebounded, but macroeconomic challenges loom
ii. The savings from biosimilar competition continues to grow
iii. Access is improving, but a growing disparity is occurring across countries
iv. Not all originators will see competition
v. LOE will triple in the next 5 years versus the previous 5

1. Access to current biologics **signals access challenges** as disparity grows
2. Savings growth has fallen **from list prices due to the LoE opportunity**
3. Guaranteed **savings do not exist for all** classes as the pipeline shows gaps
4. **Policy changes take time** to impact, and are part of a multifactorial environment
5. **A new era** of molecules losing exclusivity show changing dynamics

Access disparity persists between countries

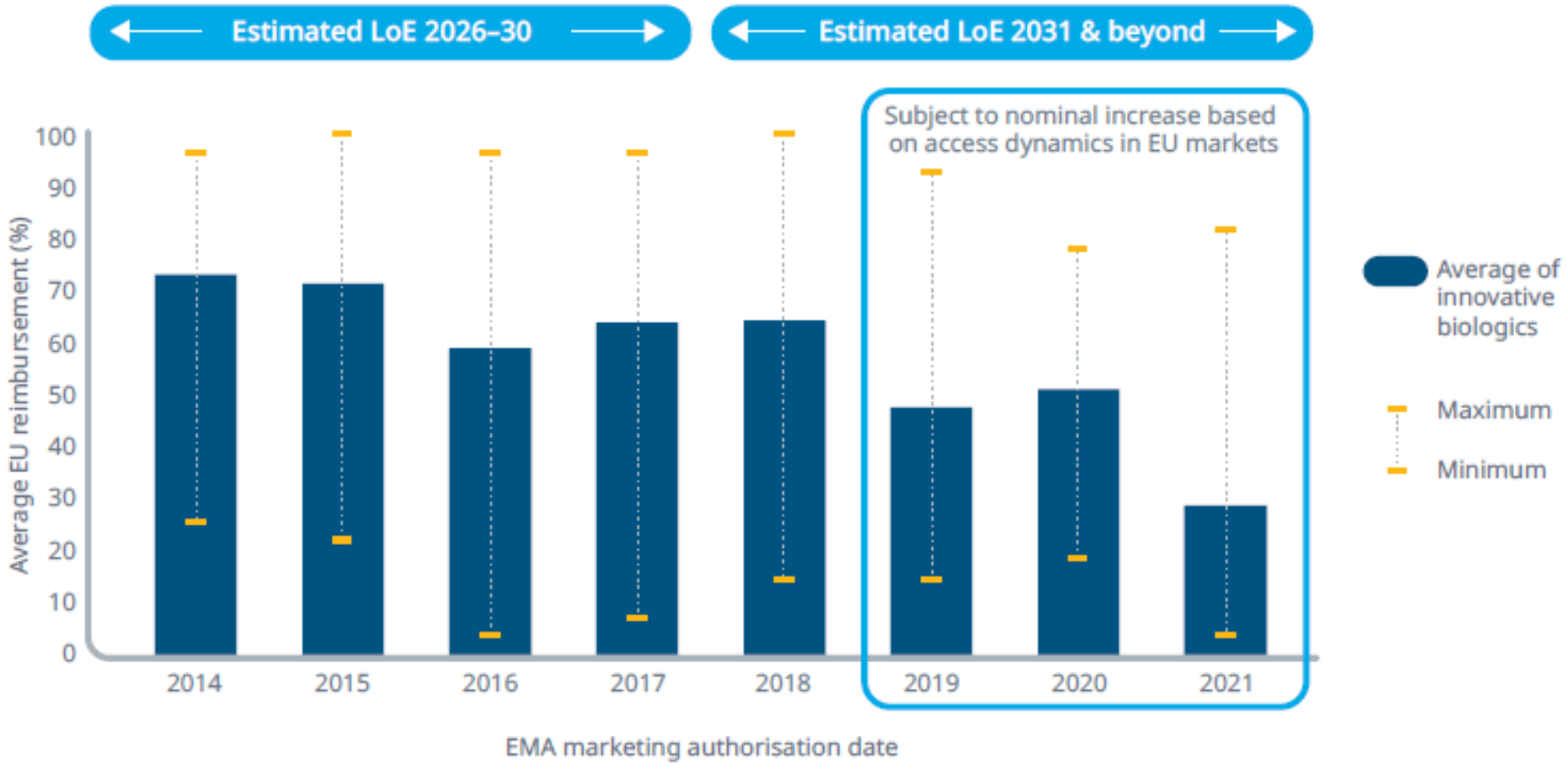
The ability for countries to capitalise on the promise of biosimilar competition has not occurred evenly



*Normalised to the year before first recorded biosimilar sales in each country, to account for markets that are delayed in using biosimilars after loss of patent protection. Notes: Includes TD for all market segments (Non-accessible, Non-referenced, Referenced, Biosimilars); All countries are ranked based on TD/Capita at most recent year and the top-5 and bottom-5 countries includes in this analysis.

Access to innovative biologics signals future challenges

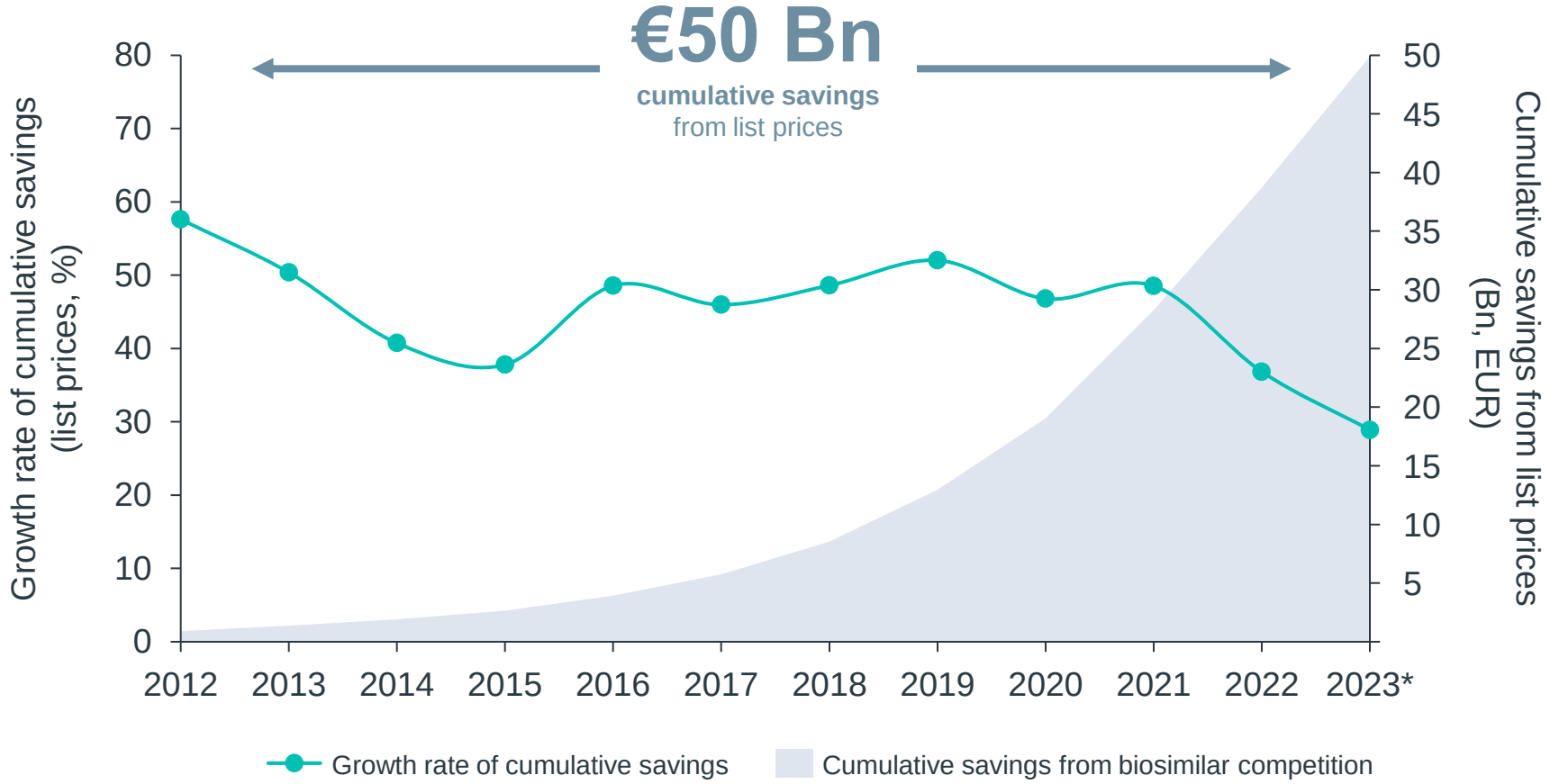
An important consideration is that access rarely increases for products 3+ years after launch



Source: IQVIA EFPIA Patients W.A.I.T. Indicator 2022 Survey (2023).
Notes: European Union average (27 countries). In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE where some hospital products are not covered by the general reimbursement scheme. Some countries did not complete a full dataset and therefore availability may be unrepresentative.

Growth of biosimilar savings from list prices has slowed

This reflects the profile of the LoE opportunity, while there are rebates and opportunities remaining



*Q3 MAT data

Source: IQVIA MIDAS™ data from 2012 – 2023, using Euros at constant exchange rates; Developed using country-level list prices pre- and post-biosimilar entry; Value includes all originator products with approved biosimilars from 2006 – 2023, covering EEA+UK, calculated volume is in treatment days determined by WHO-DDD, and where values are unavailable via Oncology Dynamics Physician Survey (2017) DDD estimates.

Notes: This figure is not equivalent to all savings and is therefore an under-estimate. The data does not include the impact of rebates or discounts, which may have been present prior to the introduction of biosimilars in small quantities and are highly significant post-biosimilar entry as it is based on publicly available list prices.

Uptake for most molecules has delivered on its potential savings

Europe's uptake is not the sole determinant of savings, instead a function of multiple components

Selected KPIs to illustrate biosimilar penetration evolution *(treatment days, %TD)*

	HOSPITAL									MIXED		INSULINS	
	infliximab	etanercept	rituximab	rituximab IV	trastuzumab	trastuzumab IV	pegfilgrastim	bevacizumab	teriparatide	adalimumab	Ranibizumab	Insulin Glargine	Insulin Lispro
UK	96%	87%	83%	95%	20%	82%	92%	66%	94%	90%	64%	15%	1%
Germany	86%	82%	88%	94%	84%	96%	63%	93%	55%	77%	0%	17%	6%
France	82%	56%	73%	97%	45%	99%	86%	99%	43%	51%	1%	30%	0%
Italy	97%	84%	91%	99%	80%	100%	86%	99%	81%	85%	0%	14%	12%
Spain	87%	59%	76%	98%	72%	97%	90%	78%	67%	69%	2%	20%	0%
Netherlands	92%	37%	98%	100%	87%	100%	98%	96%	60%	74%	0%	29%	16%
Denmark	99%	94%	89%	99%	98%	99%	100%	100%	60%	98%	0%	38%	0%
Finland	99%	67%	86%	100%	59%	100%	91%	95%	10%	74%	0%	3%	44%
Norway	99%	92%	96%	100%	96%	100%	100%	92%	89%	93%	9%	32%	2%
Poland	100%	96%	100%	100%	35%	100%	100%	100%	0%	100%	0%	26%	26%
Canada	50%	72%	66%	100%	89%	89%	99%	94%	61%	63%	0%	48%	32%
Japan	29%	51%	79%	79%	71%	71%	0%	35%	77%	14%	26%	50%	22%
US	54%	0%	71%	71%	85%	85%	44%	86%	0%	2%	23%	28%	6%

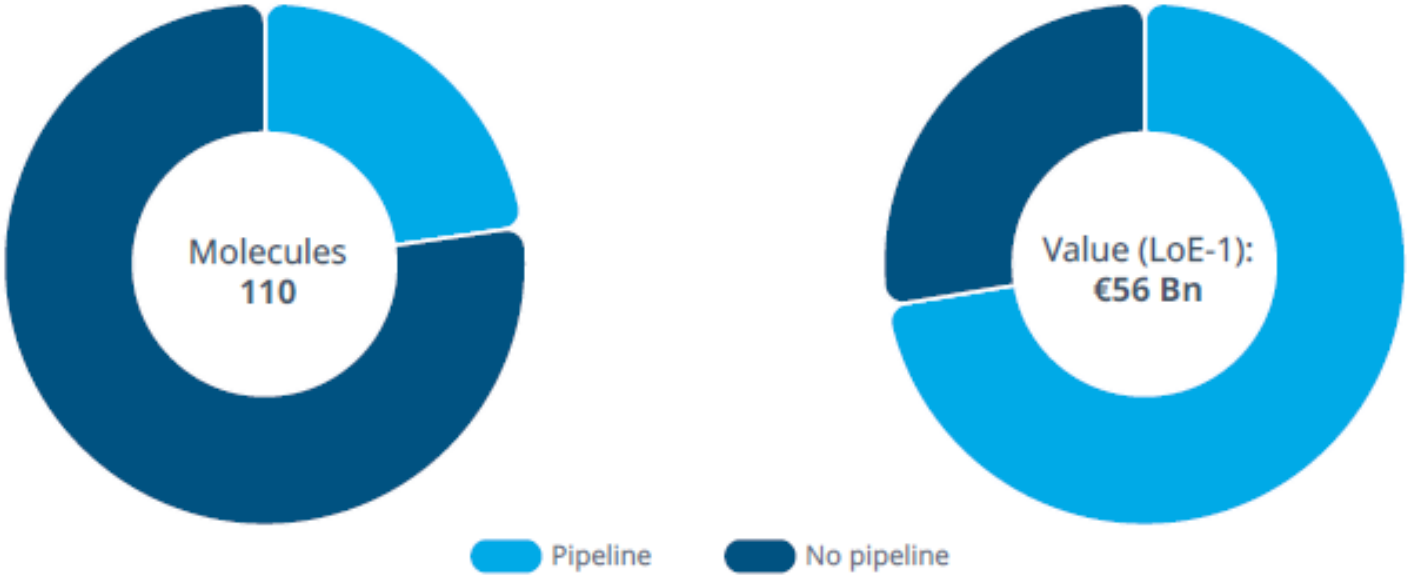
High uptake — Low uptake

Source: IQVIA EMEA Thought Leadership; IQVIA MIDAS QTR June 2023.

Significant numbers of biologics currently do not have a pipeline

The number of biologics is high, but tend to be lower value molecules and should not be overlooked

Products with upcoming LoE by pipeline status *(mols, value, 2023 – 2032)*



High commercial value biologics (high sales, <$1bn)

Oncology medicines (with high comparator costs)

Low commercial value biologics (lowsales, <$500bn)

Orphan biologics (treating small patient groups)

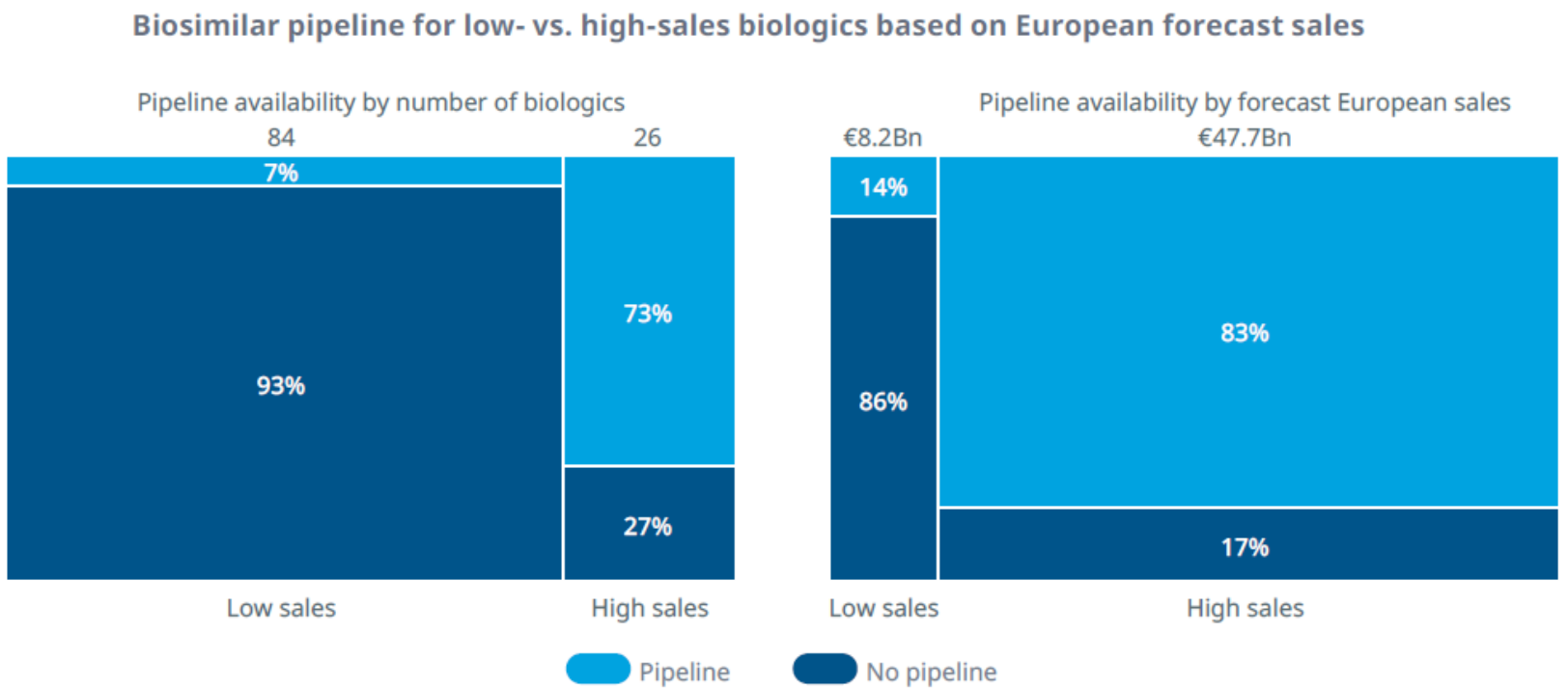
One-off biologic therapies (often orphan molecules)

2nd generation biologics (new formulations of delivery)

Complex biologics (ADCs, C&GT, and oligonucleotides)

The challenge is more acute for low-sales biologics

Only 7% of these molecules are expected to receive competition in the next 10 years

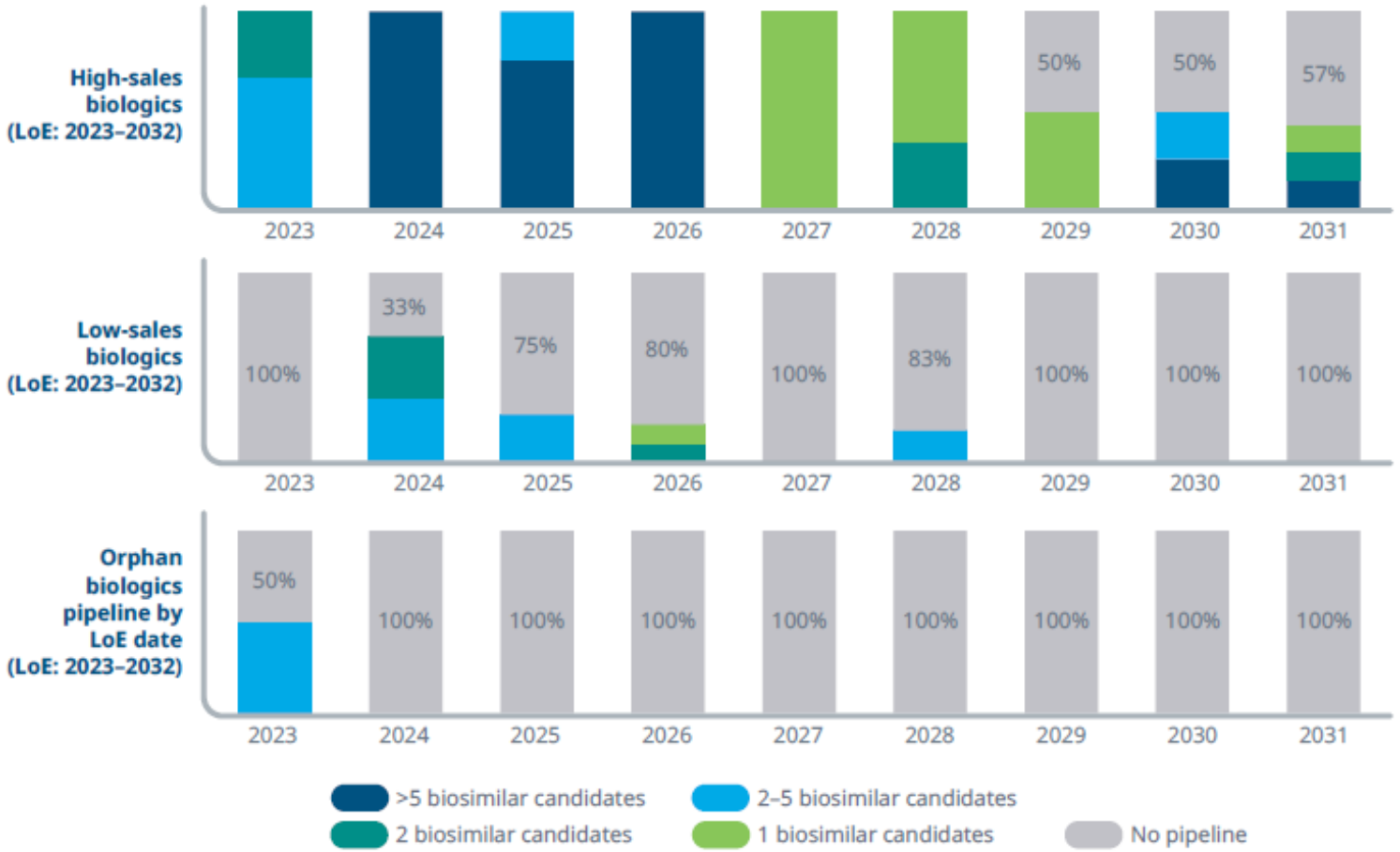


Source: IQVIA MIDAS; IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA Global Biosimilar Database.
Notes: Pipeline data only includes biosimilars in development (Phase I to Phase III, including pre-registration). No approved biosimilar is included in the analysis. Caveat: biosimilar pipeline data is based on publicly available information only. High sales= biologics with over €500Mn in European sales before LoE (LoE-1).; Low sales= biologics with less than €500Mn in European sales before LoE (LoE-1).

Source: IQVIA Institute 'Assessing the biosimilar void: Achieving sustainable levels of competition in Europe' (2023)

Segments of the biologics market are subject to a ‘void’

Biosimilar pipeline for high-sales biologics by LoE date



Source: IQVIA MIDAS; IQVIA Ark Intelligence; IQVIA Forecast Link; IQVIA Global Biosimilar Database. Notes: Pipeline data only includes biosimilars in development (phase I to phase III, including pre-registration). No approved biosimilar is included in the analysis. Caveat: biosimilar pipeline data is based on publicly available information only. High sales= biologics with over €500 in European sales before LoE (LoE-1). No high-sales biologic medicine is expected to lose exclusivity in 2032 (data not shown).

Interchangeability is an important step although others remain

A sustainable market is one optimised to support competition across the framework

ACCESS TO BIOLOGICS

1. Signficant increase to biologics since biosimilar entry*

REGULATORY AND PMA

2. **Regulatory and PMA pathway:** ensuring timely access to biosimilars following EMA approval
3. **Treatment guidelines:** recommending biosimilar use
4. **Switching and substitution policies:** at physicians' discretion while preventing automatic pharmacy substitution

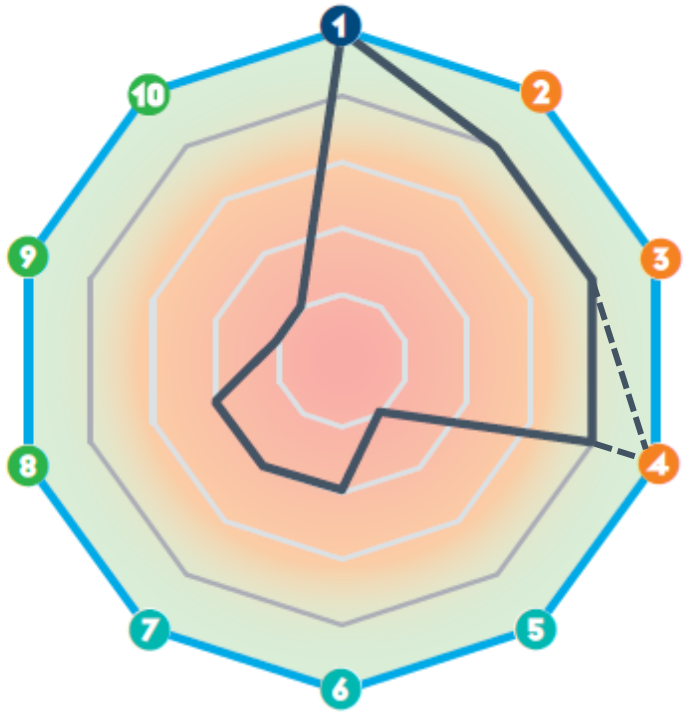
COMPETITIVE PRESSURE

5. **Level of competition:** high level of competition with multiple players
6. **Pricing rules and dynamics:** prices driven by competition only
7. **Procurement:** systems which support competition and drive uptake in the market

INCENTIVES

8. **Patient benefits:** effective benefits encouraging biosimilar use
9. **Provider and prescriber benefits:** effective benefits supporting biosimilar usage
10. **Awareness and education** strong awareness of biosimilar benefits and sustainable practices across stakeholder groups

* Defined as >25% increase in DDD per capita



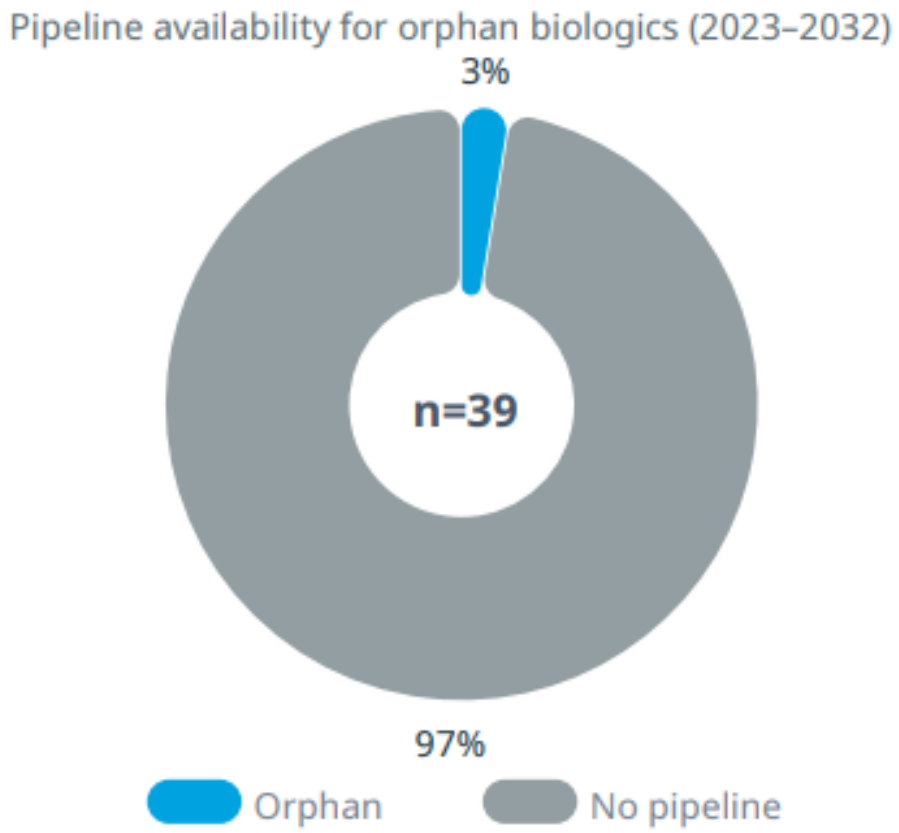
In an ideal **biosimilar market**, all data points lie on the outer-most perimeter

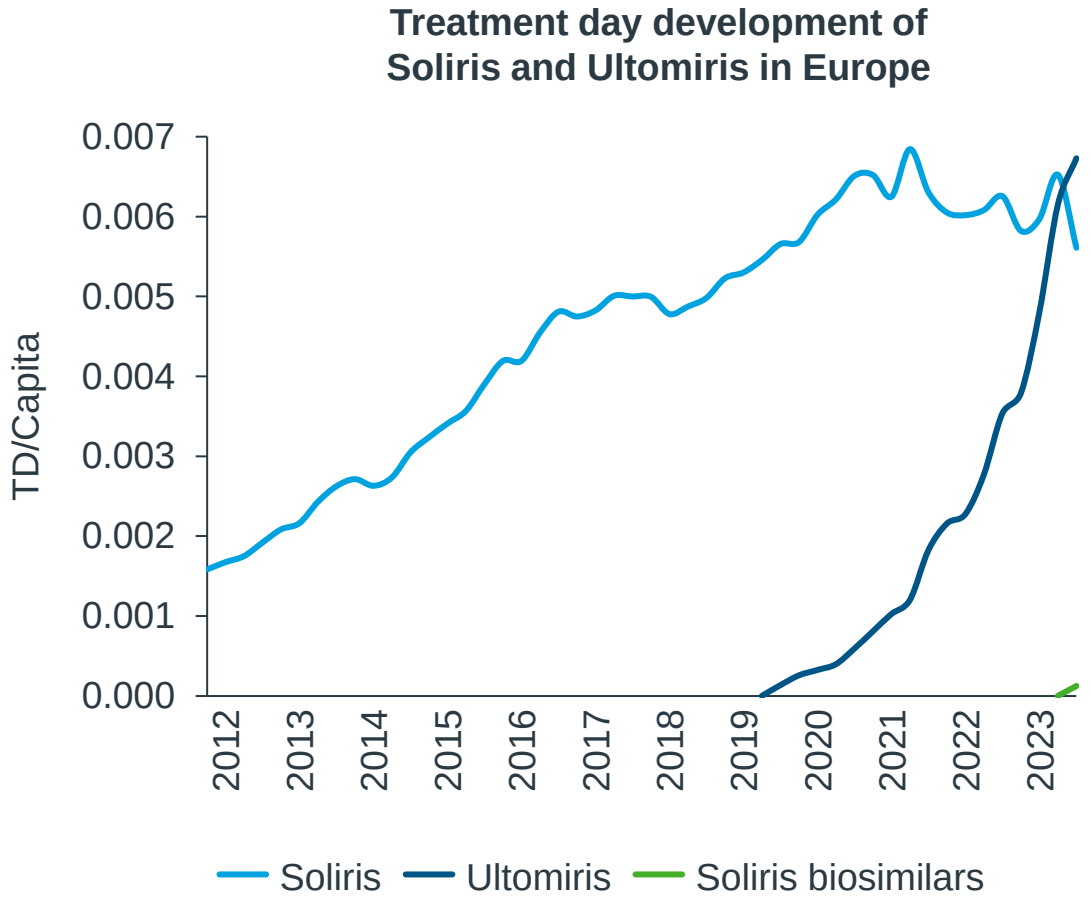
Market A — Ideal market

Not sustainable — Ideal/most sustainable

New classes are losing exclusivity with nuances

Alexion's 2nd generation therapy Ultomiris may impact biosimilar uptake





Future biosimilar waves will have new, and unknown dynamics

Progress continues, but each wave is not the same as the last

		EARLY YEARS ('06 - '11)	EMERGENCE ('11 - '15)	PREPARATION ('16 - '18)	CAPITALIZATION ('19-'21)	OPTIMISATION ('22 - '25)	APEX ('26 - '29)	STRATIFICATION ('30+)
Profile of LoE	EU opportunity	Hundreds of millions	Billions	Tens of billions	Tens of billions	Billions	Tens of billions	Billions
	Therapy areas	hGH, GCSF, EPO	EPOs, anti-TNF (inflix.), insulin	anti-TNFs, insulins, onco., and fertility	anti-TNF (ada), LMWHs, PTH	Ophthalmology, orphan (eculiz.)	Oncology (PD-1s), ophthalmology, orphan	Oncology, orphan medicines
	Molecule size	Few major molecules	Few major molecules	Broadening range	Large molecule and others	Smaller biologics	Large molecules and many others	Smaller biologics and orphans
Market dynamics	Savings	Hundreds of millions	Hundreds of millions	Hundreds of millions	Billions	Hundreds of millions	Billions	Hundreds of millions
	Uptake	Emerging	Increasingly slowly	Variable	High and rapid	High, some variability	High and rapid	Unknown
	Competition	Up to 5 competitors	Up to 5 competitors	Up to 5 competitors	Tens of competitors	Up to 5 competitors to no competitors	Tens of competitors to no competitors	Few competitors to no competitors
	Access	Single digit but variable	Single digit but variable	More than double	More than double	Single digit but variable	Unknown	Unknown
	Tender/ Policy	Single-winner tenders	Single-winner tenders	Multi-winner tenders	Multi-winner tenders	Interchangeability	Unknown	Unknown
	Originator strategy	Differentiation	Differentiation	Price / 2nd Gen. therapies	Price / 2nd Gen. therapies	Price competition and 2nd gen therapies	Price / 2nd Gen. therapies, and combinations	Antibody drug conjugates

Notes: Segments are reflective of the major LoE events within the periods with appreciation for the known variability that exists across markets and molecules; Gen. = generation; ada. = adalimumab; eculiz. = eculizumab; onco. = oncology;
The Impact of Biosimilar Competition in Europe 2023

Thank you!

Contact us for further questions

Per Troein *(per.troein@iqvia.com)*
Max Newton *(maximilian.newton@iqvia.com)*

Final report published January 2023 on **www.iqvia.com/insights**

Agenda – Part II

11.00 – 12.30 **Upcoming losses of exclusivity in the biologics pipeline:** addressing the challenges and lack of biosimilar competition

Moderator: Petra Wilson - Health Connect Partners

Panelists

Yannis Natsis - European Social Insurance Platform (ESIP)

Julie Maréchal-Jamil - Medicines for Europe

Prof. Dr. Wolf-Dieter Ludwig - Standing Committee of European Doctors (CPME)

Dimitrios Athanasiou - Rare Diseases Greece

Steffen Thirstrup - EMA

Interactive Q&A discussion with the audience

12.30 – 13.30 *Networking lunch*

European Commission

Agenda – Part III

13.30 – 15.00 **Disparities in biosimilar uptake and access:** opportunities across countries, regions and sectors

Chair: Johan Pontén (TLV, SE)

Challenges and good practice examples in pricing, reimbursement and demand-side measures to enhance the uptake of biosimilar medicines - Sabine Vogler (GÖG)

How the revision of the EU general pharmaceutical legislation will stimulate broader earlier market entry of biosimilar medicines - Harald Mische (DG SANTE)

What regulators can do to enhance the uptake of biosimilars - Esa Heinonen (HMA BSWG)

Challenges and opportunities for biosimilar uptake specific to the inpatient sector - Despoina Makridaki (EAHP)

Sharing of national best practices and challenges

Chara Kani (EOPPY, EL)

Agnieszka Beer (Ministry of Health, PL)

Interactive Q&A discussion with the audience

15.00 – 15.15 *Coffee & networking break*

European Commission

Challenges and good practice examples in pricing, reimbursement and demand-side measures to enhance the uptake of biosimilar medicines

Sabine Vogler

Head of Pharmacoeconomics Department

Head of WHO Collaborating Centre
for Pharmaceutical Pricing & Reimbursement Policies

7th Multi-stakeholder Event on Biosimilar Medicines

Brussels, 13 December 2023

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

Gesundheit Österreich GmbH

Declaration of interest / Disclaimer

No conflict of interest to declare with regard to the topic of this presentation.

Senior health expert in the Austrian National Public Health Institute (Gesundheit Österreich / GÖG) owned by the Austrian Ministry of Social Affairs, Health, Care and Consumer Protection

Disclaimer:

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WHO Guideline

Recommendations

1. External reference pricing
2. Internal reference pricing
3. Value-based pricing
4. Mark-up regulation across the pharmaceutical supply and distribution chain
5. Promoting price transparency
6. Tendering and negotiation
7. Promoting the use of quality-assured generic and biosimilar medicines
8. Pooled procurement
9. Cost-plus pricing for setting the price of pharmaceutical products
10. Tax exemptions or tax reductions for pharmaceutical products

Strong recommendations for the policy

Conditional recommendation against the policy

Conditional recommendations for the policy

coherence, specificity, clear purpose, transparency, integrated framework, relevance, compliance, collaboration

Eight principles for developing and considering policies

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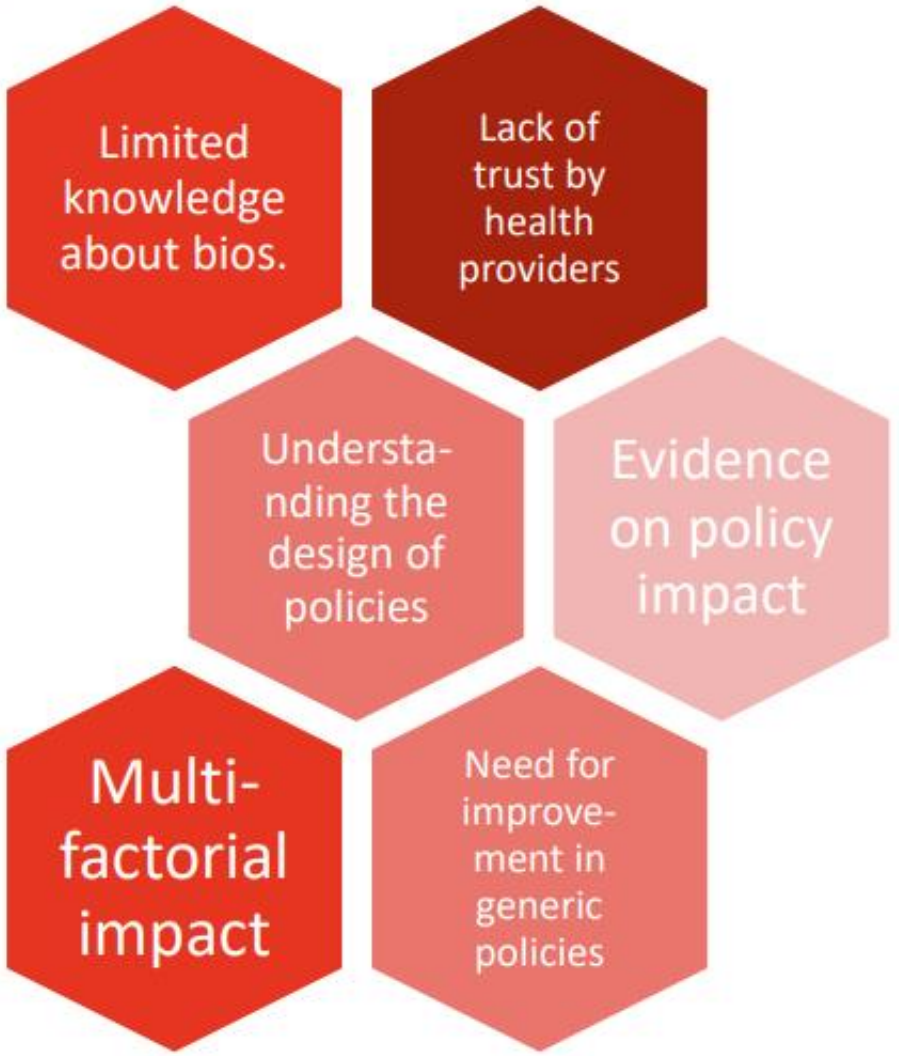
Opportunities and challenges

European leading region in b.

Demonstrated savings

Experience in generic policies



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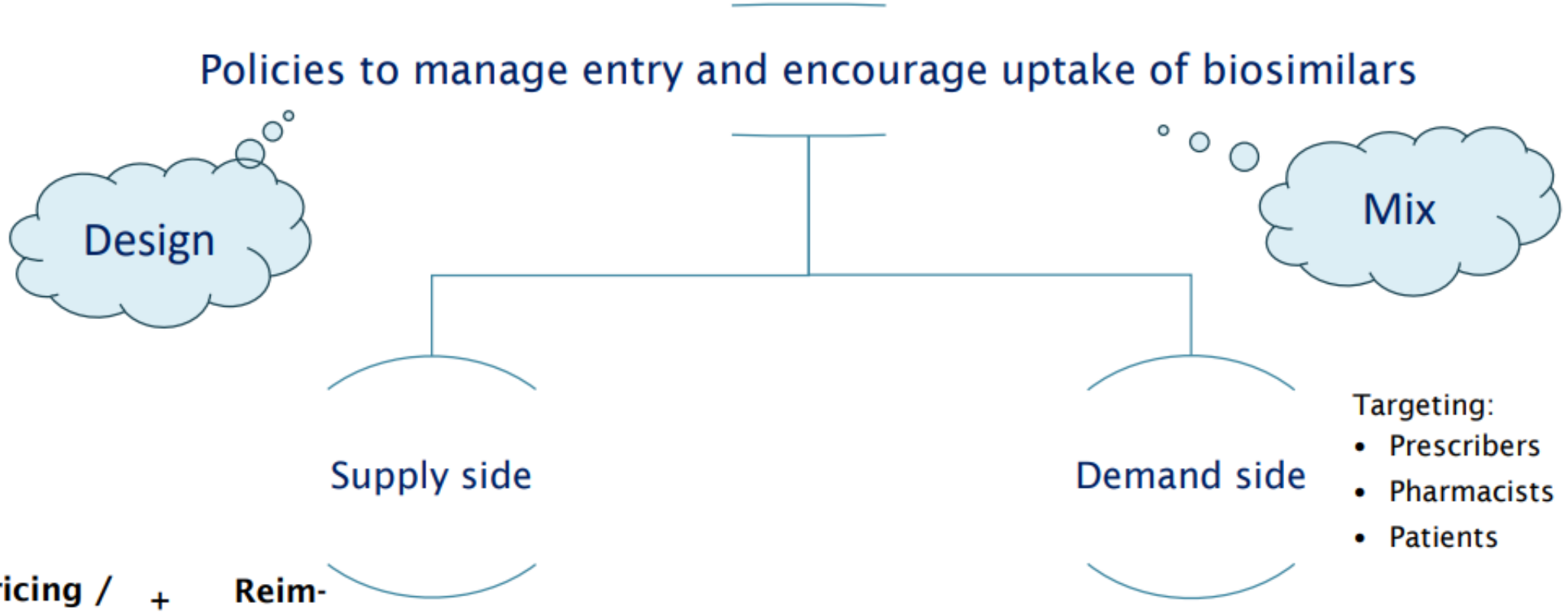
Policies to manage entry and encourage uptake of biosimilars



Pricing / procurement + **Reim-bursement**

Internal referencing pricing
- Price link
- Reference price system

Tendering

Targeting:
- Prescribers
- Pharmacists
- Patients

Educational & capacity-building

Prescribing / dispensing guidelines / recommendations

INN prescribing

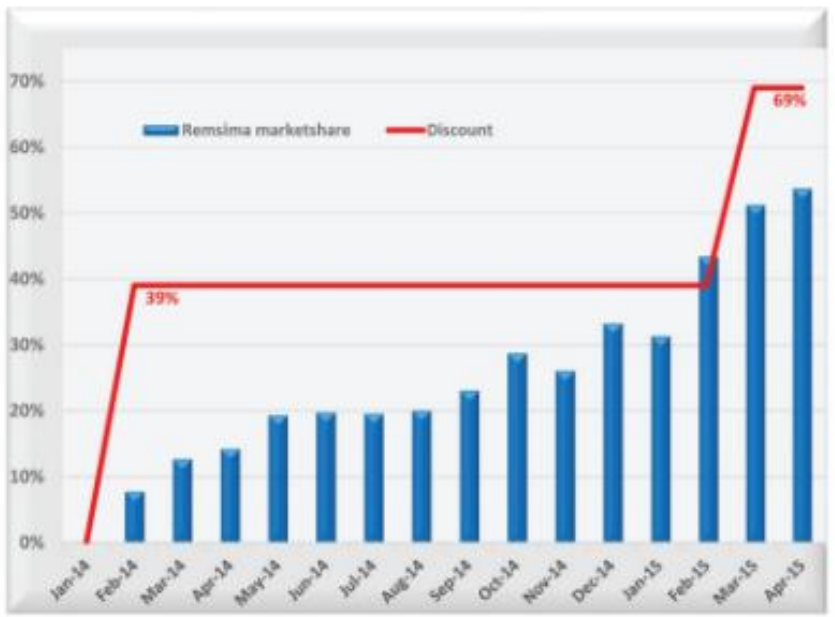
Substitution

Financial incentives (gain-sharing)

Infliximab tendering example from Norway

Savings and improved patient access

Figure 3: Biosimilar performance since launch



Bars show Remsima market share in volume. The line shows the Remsima discount compared with the Remicade tender price.
Source: Farmastat (database with only Norway market data)

Supporting factors:

National tender

National procurement body for hospitals (voluntary)

"H prescriptions"

NOR switch study

Communication and capacity-building

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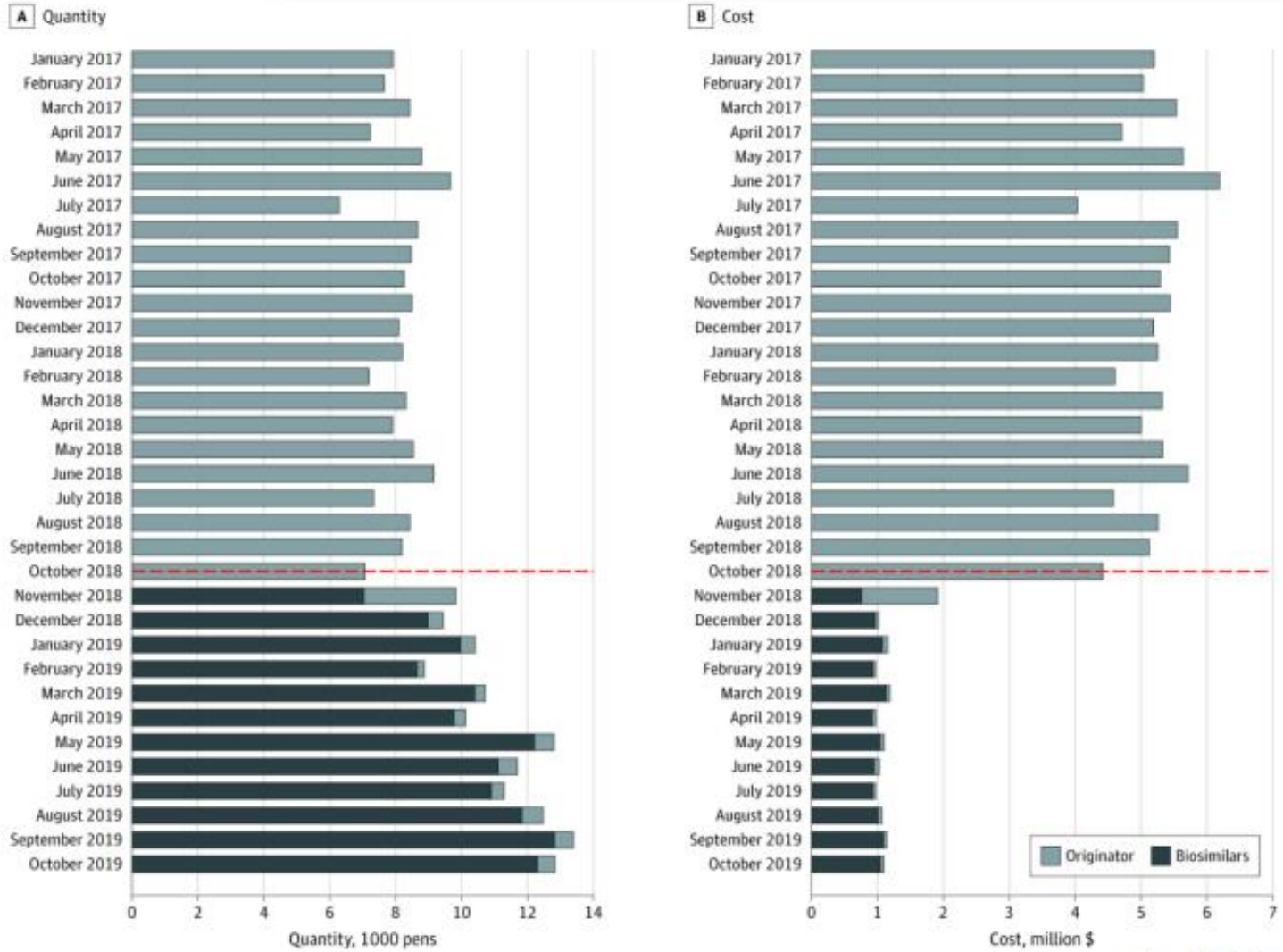
Adalimumab: mandatory switch in Denmark (2019)

90% of adalimumab use switched with 3 weeks

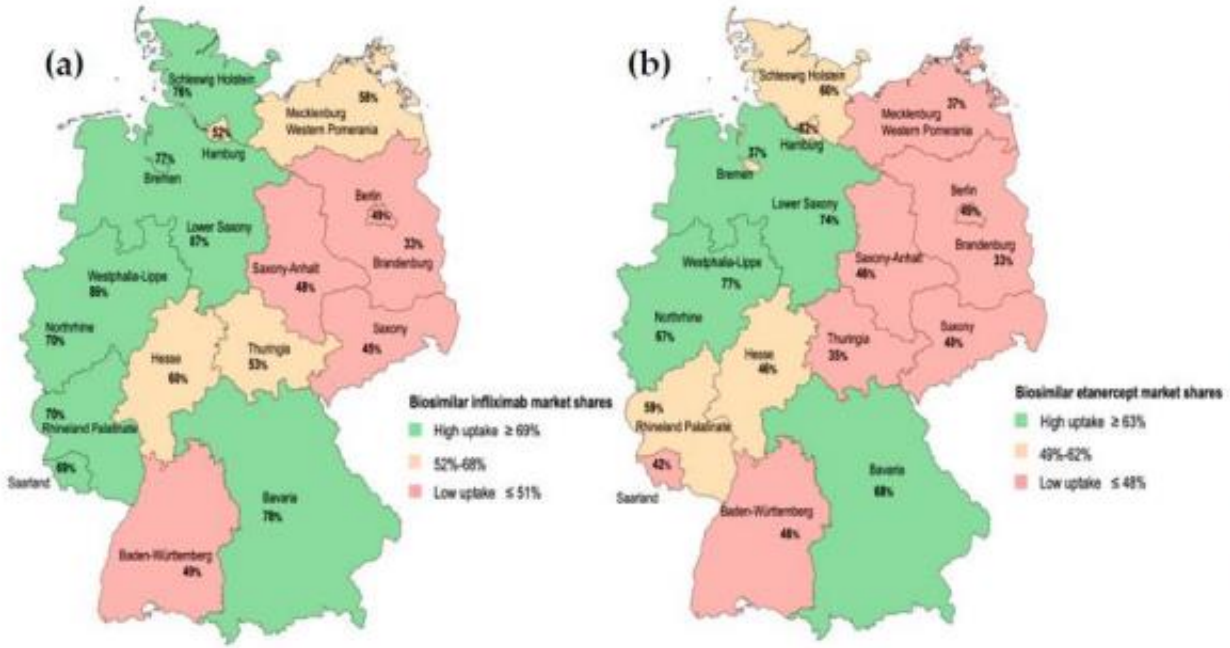
Savings: 1 million DKK per day



Sucess factors:

- National procurement agency AMGROS for all public hospitals
- Clinical staff was prepared
- Biosimilar task force prepared information materials for patients, dialogue with patient organisations
- Recommendation of Danish Medicines Council
- Expectation of savings
- Series of successful negotiations

Differences in the uptake across German regions



https://www.mdpi.com/1424-8247/13/10/324

Market shares of biosimilar infliximab (a) and biosimilar etanercept (b) in Q4/2018

Drivers for use:

Biosimilar prescription quotas:

- Efficient monitoring
- Presence of a sanctioning mechanism

Greater cost-savings potential associated to biosimilars

Gainsharing contracts

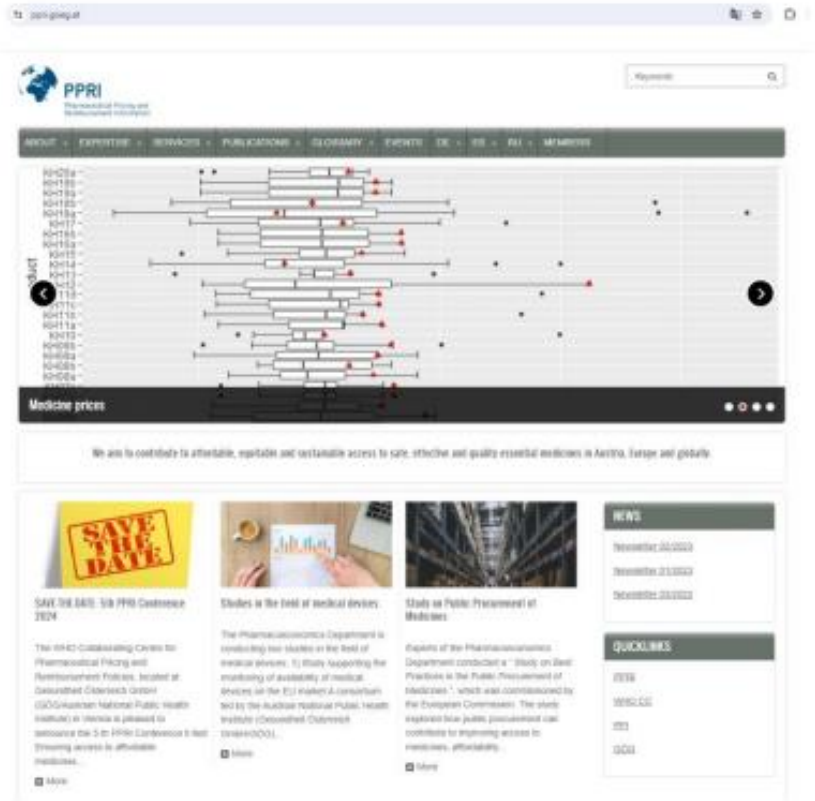
Position statements / guidelines on safety of switching

Efficient communication between stakeholders

Conclusions

- A variety of well-proven policies (P / R & demand-side) for generics exist
- Fewer policies for biosimilar medicines – but increasingly been introduced
- Evidence (mainly from generics) on the importance of the mix of policies
- Need to see studies on impact of specific biosimilar policies (or mix of policies) on access
- Importance of demand-side measures: to ensure trust into and knowledge of biosimilar medicines (communication, capacity-building)
- Changes need to be well prepared

Thank you for your attention!



Dr. Sabine Vogler
Head of the Pharmacoeconomics Department
Head of the WHO Collaborating Centre
for Pharmaceutical Pricing and Reimbursement Policies

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biosimilars

PPRI Conference, Vienna, 25-26 April 2024
Call for abstracts:
https://ppri.goeg.at/ppriconference2024_abstracts
(deadline: 20 Dec. 2023)

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7th Biosimilar Multistakeholder Event

How the proposed EU pharmaceutical legislation will stimulate market entry of biosimilar medicines

Harald Mische, D2, DG SANTE

EU Pharmaceutical Reform – 26 April

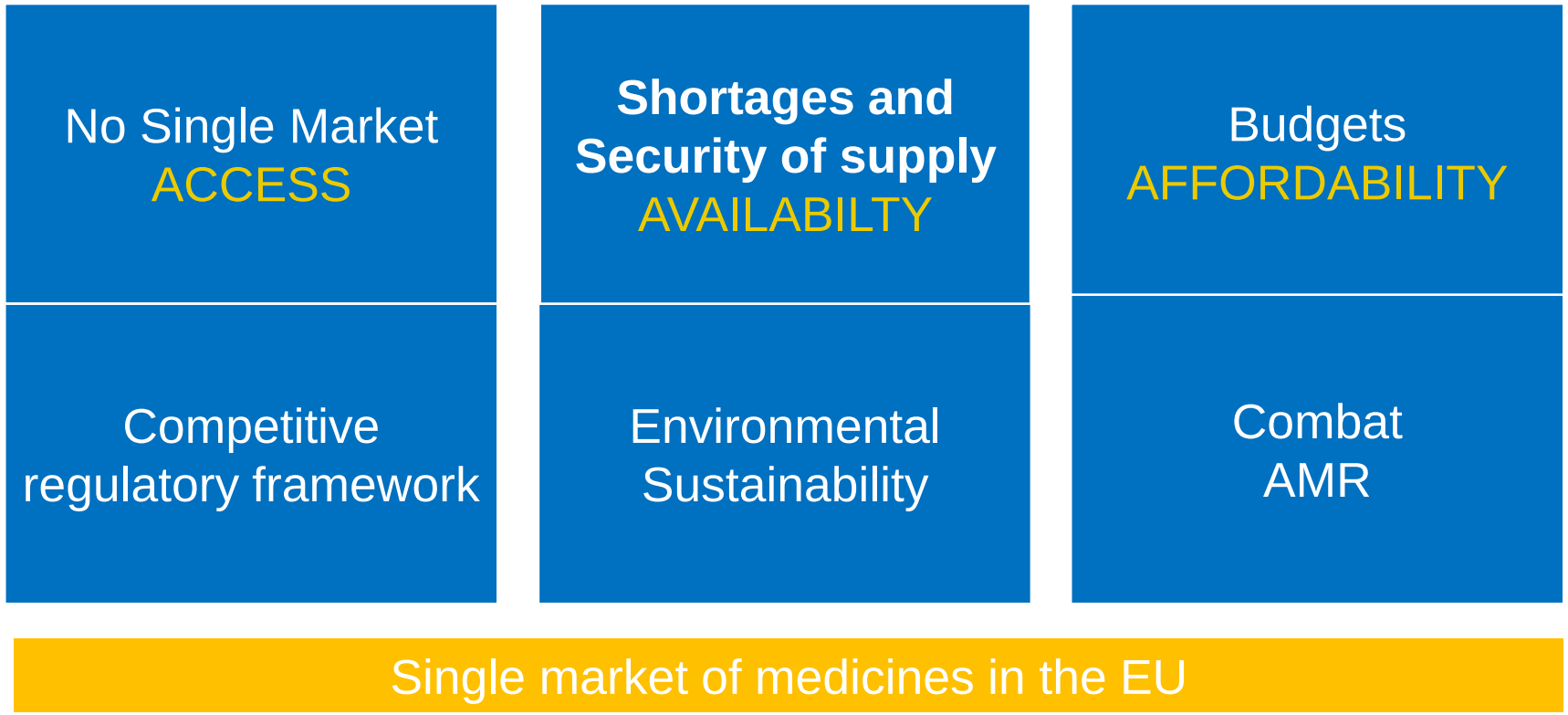
Builds on the **Pharmaceutical Strategy** for Europe (2020)

Supports EU citizens and industry

Addresses **long-standing challenges and public emergencies**

Marks a **European Health Union milestone**

6 Key political objectives



A 4-part package

Chapeau communication

New Regulation

- Specific rules for the most innovative medicines such as orphans, antimicrobials
- Rules on shortages and security of supply
- EMA governance

New Directive

- Placing on the market of all medicines
- Authorisation and labelling requirements
- Strong incentives for access

Council Recommendation on AMR

Measures supporting biosimilars (and generics)

- ✓**Bolar exemption broadened and harmonised** (DIR Art 85)
- ✓**Procedural facilitation of authorisations of generics and biosimilars:**
  - ✓Risk management plan: not required for generics and biosimilars (DIR Art 21)
  - ✓Active substance master file: harmonized EU assessment (DIR Art 25)
  - ✓Additional quality master file: harmonized EU assessment (DIR Art 26)

Measures ct'd

- ✓**Other procedural facilitations (with higher impact on generics and biosimilars):** multi-language packs (DIR Art 74); e-leaflet (DIR Art 63), abolishment of sunset clause and renewal requirement (DIR Art 46)
- ✓**Recognition of interchangeability of biosimilars with biologic reference medicine** (DIR Rec 27)
- ✓**Prohibition of disparagement practices** (DIR Rec 136, Art 176)
- ✓**Repurposing of off-patent medicines** facilitated (DIR Art 84)
- ✓**Modulation of incentives: if purpose of incentive not met, possible earlier market entry of generic and biosimilar medicines** (DIR Art 81)

Thank you

Further information:

https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/making-medicines-more-affordable_en

European Commission

What can regulators do to enhance the uptake of biosimilars

Esa Heinonen, Chair of the HMA Biosimilar Working Group
Senior Advicer, Fimea

Outline

1. Biosimilars as Regulatory Science priority
2. HMA Working group on biosimilars
3. Providing consistent, reliable information to stakeholders
4. Sharing information and best practices
5. Enhance collaboration between various stakeholders

Biosimilars as a Network priority

Promote the availability and support uptake of biosimilars in healthcare systems

- Strategic **communication campaigns** to patient and healthcare professional to **reinforce trust**
- Enhance **training of non-EU regulators in evaluation of biosimilars**
- **Address** regulatory **challenges**

Conclusions of a Stakeholder meeting on biosimilars (during the Finnish EU Presidency 18.9.2019)

- Introduction of biosimilars increases price competition
- Biosimilar market penetration, market shares and availability varies widely both within and between different MSs
- Only few MSs have currently specific policies for promoting biosimilars
- NCAs need to take stronger positions to increasing trust in biosimilars
- The industry highlighted the need for sustainable policy frameworks
- Medicine regulators may need to take new actions in order to realize the full potential of biosimilars in Europe

HMA Biosimilar Working Group (BSWG)

- The Biosimilar Working Group was established during the EU Presidency of Finland (12/2019) first as a pilot and later as an official HMA group.
- Currently 15 agencies [AT, BE, CZ, EE, ES, FI, FR, GE (PEI), GR, IE, IT, LV, NO, SE, SL] participate.
- Secretariat comes for EMA, current chair is Esa Heinonen (Fimea), Vice-Chair Steffen Thirstrup (EMA), scientific secretariat: Niklas Ekman (Fimea), Ingrid Bourges (FAMHP)
- 4-5 TCs annually, one face-to-face meeting

Mission of the HMA Biosimilar Working group (BSWG)

HMA biosimilar working group generates and disseminates tailored information and contributes to training on the quality, efficacy, safety and immunogenicity of biosimilars to **increase confidence in biosimilars** in order to **enhance healthy competition** on the national markets of biologicals.

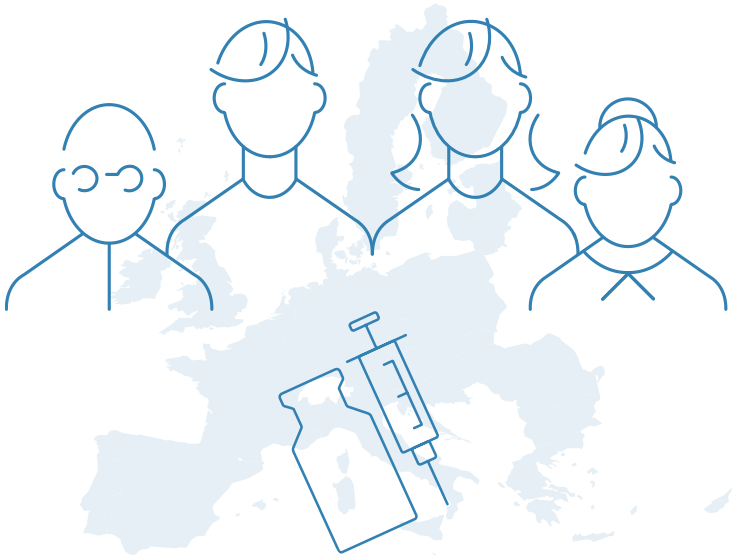
The working group will **support efforts of the NCAs especially in topics outside the EMA mandate**, e.g. informing on interchangeability/substitution and harmonization of NCA messages on biosimilars.

The group keeps HMA updated on the regulatory development in the field of biosimilars.

Ensure consistent information throughout the regulatory network

- **Information on the websites of NCAs:**
  - Analysis was made by Triin Suvi (EE):
    - 10 agencies did not have any information on biosimilars 3/2021.
    - Recommendation on the minimal set of information to the HMA plenary
    - New analysis 9/2023: only 2 agencies lacked the information
- **Information on the EMA website:**
  - 1/2021: Good, gold stardard information on biosimilars, but nothing on interchangeability
  - BSWG made a request that statement on interchangeability should appear
  - Statement published at the EMA website 9/2023

Biosimilar toolkit for Member States (IE, NO, AT, EMA):



HMA Working Group on Biosimilars

- **New modular information pack** on biosimilars targeting healthcare professionals and patients.
- Toolkit available to Member States to support their own communication campaigns – **flexibility based on needs**
- **Including up-to-date EU materials** developed to date
- **New information elements** on:
  - ✓ Biosimilar regulatory **approval process**
  - ✓ **Efficacy and safety** of biosimilars
  - ✓ **Interchangeability**
- ✓ **How to use toolkits**
  - ✓ **Case studies** on uptake of biosimilars resulting in savings

Share information and experiences

- Discuss about the challenges and successes to enhance the uptake of biosimilars and price competition
  - Information campaigns, tendering processes, prescribtion quotas, gain sharing, market situations, access to treatment etc.
- Follow legislative practicies taken in each country
  - Automatic substitution etc.
- Discuss relevant reports (e.g. IQVIA) and articles
- Write articles on biosimilars
- Support regulatory science on biosimilars
- Follow the regulatory changes at global and EU level
  - Future with less requirements for phase III studies

Collaboration between various stakeholders is needed !

- Lack of **unbiased and reliable information is still** a barrier to sustainable uptake
- **Taking seriously** all **concerns** from patients and healthcare professionals is key
- Important to get consistent messages **across the EU to further build trust on biosimilar medicines** regarding also the future changes in regulation (less phase III studies to be required)
- **Sharing best practices of health policies and procuring practices** on biological medicines is important
- An integrative is strategy needed to **gain savings and better access to biological treatments to patients**
- **There is the need to have more collaboration between various regulators (EMA, HMA, HTA bodies, NCAPR, Commission)**

Thanks for your attention!

Questions are welcome

Disparities in biosimilar uptake and access:

Challenges and opportunities for biosimilar uptake specific to the inpatient sector

Despoina Makridaki
Hospital /Clinical Pharmacist
EAHP Director of Professional Development

Nothing to declare

My main interest is the patient's outcome (according to Hippocratic Oath)

- EAHP and relevant Position Papers
- Statement on Interchangeability of biosimilars in the EU
- The role of hospital pharmacists in management of biosimilars
- Discussion on problems regarding biosimilars' uptake
- "Take home" messages

EAHP – European Association of Hospital Pharmacists

*EAHP represents and develops the hospital pharmacy profession within Europe in order to ensure the **continuous improvement of care and outcomes** for patients in the hospital setting.*

36 full member organisations (27 EU & 9 non-EU members)

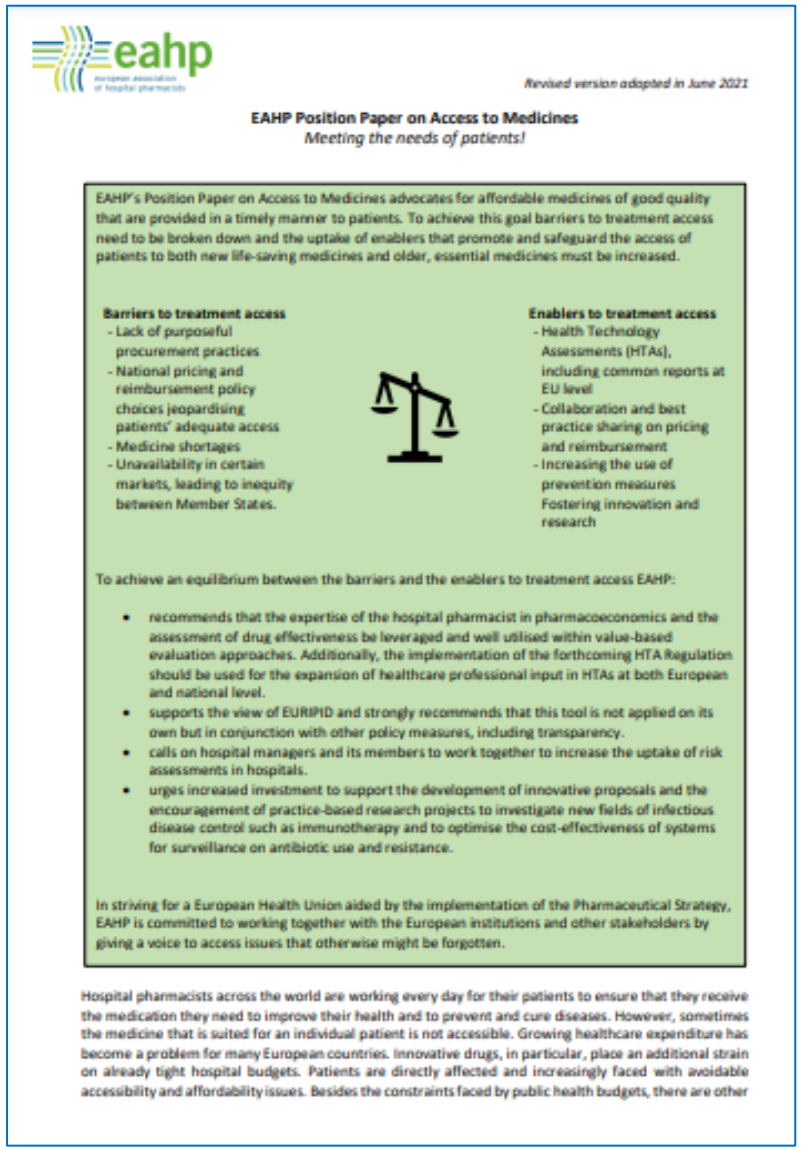
1 international associate member (EFCP)

Representing 27000 hospital pharmacists

eahp european association of hospital pharmacists

making the difference in medication

7th Stakeholder Event on Biosimilar Medicinal Products



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european association of hospital pharmacists

Revised version adopted in June 2021

EAHP Position Paper on Access to Medicines
Meeting the needs of patients!

EAHP's Position Paper on Access to Medicines advocates for affordable medicines of good quality that are provided in a timely manner to patients. To achieve this goal barriers to treatment access need to be broken down and the uptake of enablers that promote and safeguard the access of patients to both new life-saving medicines and older, essential medicines must be increased.

Barriers to treatment access
- Lack of purposeful procurement practices
- National pricing and reimbursement policy choices jeopardising patients' adequate access
- Medicine shortages
- Unavailability in certain markets, leading to inequity between Member States.

Enablers to treatment access
- Health Technology Assessments (HTAs), including common reports at EU level
- Collaboration and best practice sharing on pricing and reimbursement
- Increasing the use of prevention measures Fostering innovation and research

To achieve an equilibrium between the barriers and the enablers to treatment access EAHP:

- recommends that the expertise of the hospital pharmacist in pharmacoeconomics and the assessment of drug effectiveness be leveraged and well utilised within value-based evaluation approaches. Additionally, the implementation of the forthcoming HTA Regulation should be used for the expansion of healthcare professional input in HTAs at both European and national level.
- supports the view of EURIPID and strongly recommends that this tool is not applied on its own but in conjunction with other policy measures, including transparency.
- calls on hospital managers and its members to work together to increase the uptake of risk assessments in hospitals.
- urges increased investment to support the development of innovative proposals and the encouragement of practice-based research projects to investigate new fields of infectious disease control such as immunotherapy and to optimise the cost-effectiveness of systems for surveillance on antibiotic use and resistance.

In striving for a European Health Union aided by the implementation of the Pharmaceutical Strategy, EAHP is committed to working together with the European institutions and other stakeholders by giving a voice to access issues that otherwise might be forgotten.

Hospital pharmacists across the world are working every day for their patients to ensure that they receive the medication they need to improve their health and to prevent and cure diseases. However, sometimes the medicine that is suited for an individual patient is not accessible. Growing healthcare expenditure has become a problem for many European countries. Innovative drugs, in particular, place an additional strain on already tight hospital budgets. Patients are directly affected and increasingly faced with avoidable accessibility and affordability issues. Besides the constraints faced by public health budgets, there are other

EAHP Position Paper on Access to Medicines

- Advocates for **affordable medicines of good quality** that are provided in a timely manner to patients.
- Recommends that the expertise of the hospital pharmacist in pharmacoeconomics and the assessment of drug effectiveness be well utilised within value-based evaluation approaches.
- Urges increased investment to support the **development** of innovative proposals and the encouragement of practice-based research projects to **investigate new fields** of disease control .and innovative treatments.
- EAHP is **committed to working together with the European institutions and other stakeholders** (e.g. participation in **public consultations for revision of legislation, shortages management, clinical trials** etc), by giving a voice to access issues.

EAHP Position Paper on Procurement

“ Procurement of medicines is the indispensable requirement of ensuring an efficient supply of medicines in hospitals.

The responsible use of medicine is directly linked to the availability, safety, quality and efficacy of medicines in the hospital.

Procurement of medicines should therefore take into account not only the volume and price, but also incorporate medicines policy, risk and safety management as well as operational choices for the hospital and the larger health ecosystem.”

EAHP and Health Technology Assessment

Hospital pharmacists have the ethical duty to ensure that patients are provided with access to the most appropriate treatment, and especially to those essential for improving their health.

<u>EU-HTA Regulation promotes development of pan-European initiatives to create:</u>

Real-World-Evidence infrastructure

New early-dialogue opportunities

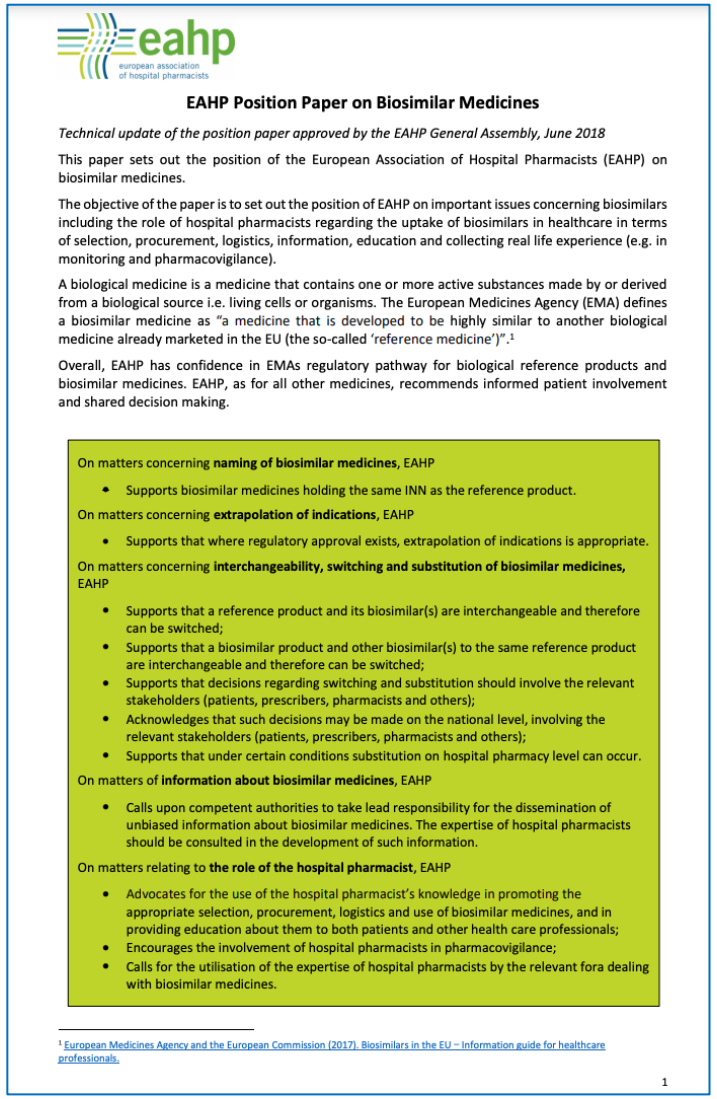
Timely and effective access advanced healthcare for all EU patients

EAHP participated in **EUnetHTA and AdHopHTA** and is currently regular member of **EU-HTA Stakeholder Network.**

Position Paper on Biosimilar Medicines

(Adoption from GA in June 2018, updated in June 2023)

- Naming of biosimilar medicines
- Extrapolation of indications
- Interchangeability, switching and substitution of biosimilar medicines
- Information on biosimilar medicines
- The role of the hospital pharmacist



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EAHP Position Paper on Biosimilar Medicines

Technical update of the position paper approved by the EAHP General Assembly, June 2018

This paper sets out the position of the European Association of Hospital Pharmacists (EAHP) on biosimilar medicines.

The objective of the paper is to set out the position of EAHP on important issues concerning biosimilars including the role of hospital pharmacists regarding the uptake of biosimilars in healthcare in terms of selection, procurement, logistics, information, education and collecting real life experience (e.g. in monitoring and pharmacovigilance).

A biological medicine is a medicine that contains one or more active substances made by or derived from a biological source i.e. living cells or organisms. The European Medicines Agency (EMA) defines a biosimilar medicine as "a medicine that is developed to be highly similar to another biological medicine already marketed in the EU (the so-called 'reference medicine')".[1]

Overall, EAHP has confidence in EMAs regulatory pathway for biological reference products and biosimilar medicines. EAHP, as for all other medicines, recommends informed patient involvement and shared decision making.

On matters concerning **naming of biosimilar medicines**, EAHP

- Supports biosimilar medicines holding the same INN as the reference product.

On matters concerning **extrapolation of indications**, EAHP

- Supports that where regulatory approval exists, extrapolation of indications is appropriate.

On matters concerning **interchangeability, switching and substitution of biosimilar medicines,** EAHP

- Supports that a reference product and its biosimilar(s) are interchangeable and therefore can be switched;
- Supports that a biosimilar product and other biosimilar(s) to the same reference product are interchangeable and therefore can be switched;
- Supports that decisions regarding switching and substitution should involve the relevant stakeholders (patients, prescribers, pharmacists and others);
- Acknowledges that such decisions may be made on the national level, involving the relevant stakeholders (patients, prescribers, pharmacists and others);
- Supports that under certain conditions substitution on hospital pharmacy level can occur.

On matters of **information about biosimilar medicines**, EAHP

- Calls upon competent authorities to take lead responsibility for the dissemination of unbiased information about biosimilar medicines. The expertise of hospital pharmacists should be consulted in the development of such information.

On matters relating to **the role of the hospital pharmacist**, EAHP

- Advocates for the use of the hospital pharmacist's knowledge in promoting the appropriate selection, procurement, logistics and use of biosimilar medicines, and in providing education about them to both patients and other health care professionals;
- Encourages the involvement of hospital pharmacists in pharmacovigilance;
- Calls for the utilisation of the expertise of hospital pharmacists by the relevant fora dealing with biosimilar medicines.

[1] European Medicines Agency and the European Commission (2017). Biosimilars in the EU – Information guide for healthcare professionals.

1

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

19 September 2022
EMA/627319/2022

Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

The EU experts on biosimilar medicines (Biosimilar Medicines Working Party or BMWP) and the Heads of Medicines' Agencies (HMA) Biosimilar Working Group have drafted a joint statement explaining the rationale for considering biosimilars approved in the EU as interchangeable from a scientific perspective. This statement has been endorsed by the Committee for Medicinal Products for Human Use (CHMP) and the Biologics Working Party (BWP).

Joint EMA-HMA statement on interchangeability:

Biosimilars approved in the EU are interchangeable

Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect.

HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product.

Decisions regarding substitution (the practice of dispensing one medicine instead of another medicine without consulting the prescriber), are not within the remit of the EMA and are managed by individual member states.

Interchangeability decision by hospital pharmacists: ensuring **patient safety** and **saving valuable resources**

Approved biosimilars have demonstrated comparable efficacy, safety and immunogenicity compared with their reference products (5). Thus, EU experts consider that when approval for a biosimilar is granted in the EU, additional systematic switch studies are not required to support the interchangeability at prescriber level.

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7th Stakeholder Event on Biosimilar Medicinal Products

Role of the hospital pharmacist

Support of patients & other healthcare professionals on the use of biosimilars: reference products and their biosimilar(s) are interchangeable and therefore can be switched.

Provided that the considerations of the prescriber, the pharmacists and the patient are taken into account.

Expertise in

- Pharmacology
- Evidence interpretation
- Appropriate selection
- Procurement

Hub of information

- Uptake
- Good use
- Evidence base
- Switching & substitution

Provision of advice for

- Hospital committees → ***Local Procurement procedures***
- Other healthcare professionals
- National and international bodies → ***Central tendering procedures***
- Patient organisations

Maximizing biosimilar uptake – Enablers

- **Procurement and reimbursement models**
  - •Inclusion of physicians and pharmacists is key
  - •Local, regional, national tenders should avoid ‘winner takes it all’ approach (shortages, supply chain robustness)
  - •Reference pricing is a viable option. Formation of such reference groups promotes non-medical switch and substitution

- **Healthcare professionals (HCPs)**
  - •Source of unbiased information (real data)
  - •Certified educational and training programs for HCPs (Physicians, Hospital Pharmacists).
  - •Smart procurement mechanisms incorporate Hospital Pharmacists (HPs) input and dedication to serve the patient
  - •Patient education and empowerment

- **Harmonization of procedures**
  - •Patient, Provider and HCP support with uniform assessment and motivation procedures

Barriers in Biosimilars' Uptake (non-exhaustive)

- New therapies **highly expensive** and **non predictable**
- **Limited Closed budgets** for hospital pharmaceutical expenditure
- **Different Clawback mechanisms** make the industry weaker to respond in crisis
- Data show **lower rate of entrance of new biosimilars** in the pharmaceutical market for the immediate and near future
- **Shortages** often occur due to problems in production or in the supply chain
- **Assessment procedures are not uniform in all EU Member States**
- **Need for patient awareness campaigns and educational strategies**

Food for thought - Take Home Messages

- **Barriers should be faced in a common and collaborative way.**
- Active communication platforms are necessary to exist among all relevant stakeholders **Authorities, Industry, HCPs, Patients plus carers**
- **The holistic approach networking** should be combined by availability of **proper budget and human resources,** to ensure improved results.
- **Harmonization of procedures can support the industry to invest in Biosimilars' development and indication extrapolation,** *as they show to lose interest gradually.*
- **HCPs' and Patients' certified education and training** is very important to allow smooth flow of change.

Food for thought - Take Home Messages

- **EU and National Policies for Medicines** should incorporate **the expertise and scientific knowledge of specialized HCPs** , and not only numeral indexes, to design and implement **uniform procedures** that maximize uptake of biosimilars.
- Improving biosimilar uptake in hospital settings, should be prioritized as *a measure to increase access to therapies for the society, now that interchangeability issues are defined by the new legislation.*
- **HPs are catalysts in preventing and identifying barriers** that block access to patients , ensuring that **the needs of each patient are satisfied and management of valuable resources for health systems in Europe is performed in a beneficial way.**

EAHP Position Paper on Medicines shortages

EAHP Position Paper on Access to Medicines

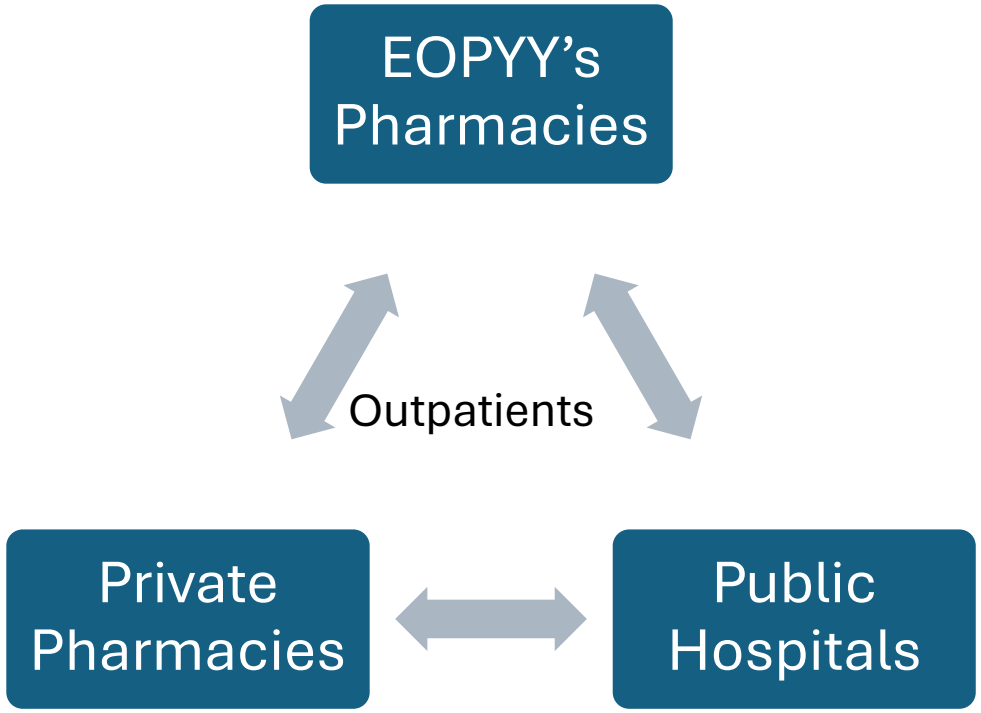
Thank you for your attention!

Despina.Makridaki@eahp.eu

Sharing of national best practices and challenges
The case study of Greece

- Chara Kani, Pharmacist, MSc, PhD
- Head of the Medicines Division
- EOPYY (National Organization for Healthcare Services Provision)

National system overview for medicinal products



EOPYY's –Public Hospital's Pharmacies

- ❑ Included in the Positive List for High Cost Medicinal Products
- ❑ Directly from MAHs
- ❑ Baseline purchase price: ex-factory price- 13,3%
- ❑ Exempted from co-payment

Private Pharmacies

- ❑ Wholesaler and pharmacist profit
- ❑ Reference pricing system based on ATC4/ DDD (heparins, insulins are excluded)
- ❑ Co-payment mainly based on the disease

National system overview for medicinal products

- **Mandatory INN prescription**

❑ Implemented through e-prescription from 2012

❑ Private pharmacies: The pharmacist should dispense the product with the lowest price

❑ EOPYY pharmacies: The pharmacist should dispense the product with the lowest purchased by EOPYY price

❑ Public Hospital pharmacies: Procurements through E.K.A.P.Y. (national authority for central procurements and for implementing agreements from the Negotiation Committee)

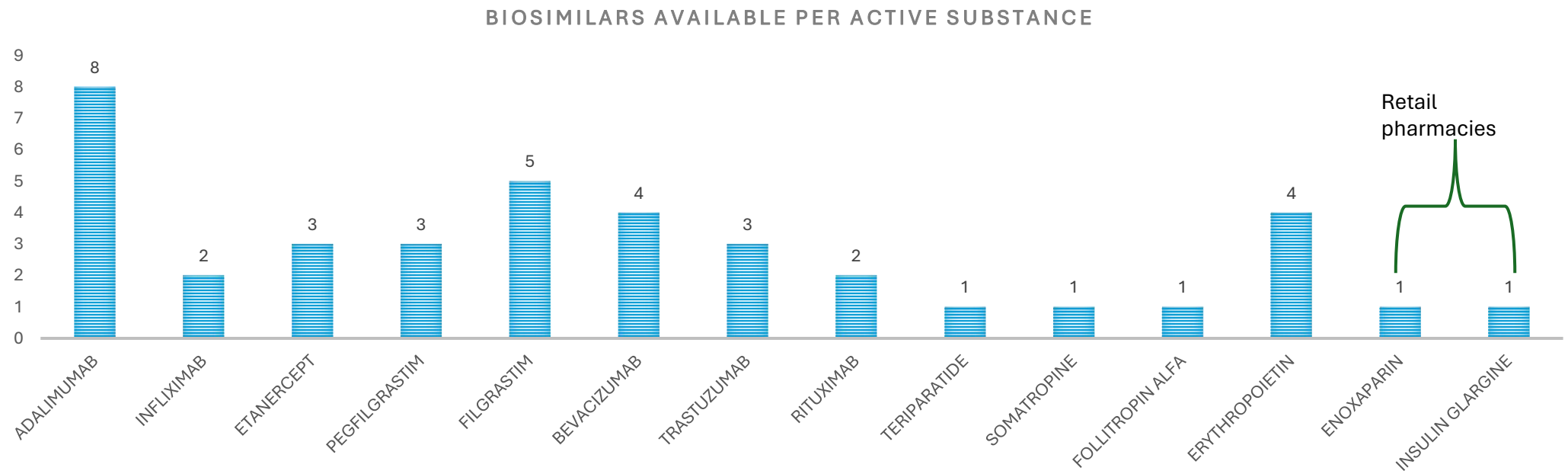
- **National Guidelines on biosimilars**

❑ Issued by the National Medicines Agency on 2018

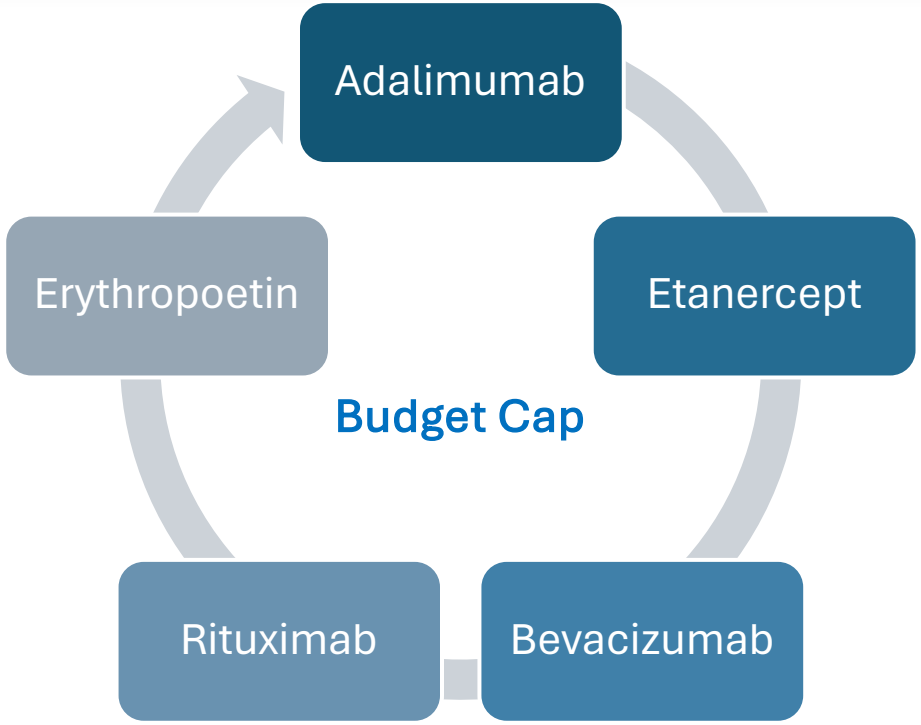
❑ Refers to interchangeability and is based on the physician's decision

❑ Substitution is not allowed in the level of pharmacies (EOPYY + private pharmacies)

National biosimilars overview



National biosimilars overview



- Products not included in budget usually remain in the Positive List as last line treatment
- Framework agreements are applicable for biosimilars through the Negotiation Committee

The case of biosimilars –Pricing/Reimbursement

- **Basic pricing rules**

❑ External Reference Pricing

❑ The average price of the two different lowest prices in Eurozone countries

❑ Biosimilars receive a price based on the above-mentioned rule

- **Health Technology Assessment /Negotiation Procedure**

❑ Abridged assessment for biosimilars (1 month maximum)

❑ Data assessed: available clinical data, epidemiology, budget impact

❑ If biosimilar's price (ex-factory) is lower than the reference product price a positive opinion might be issued without the opinion of the negotiation committee

Main challenges

- **Differences between retail and EOPYY/Hospital market**
  - ❑ Greater penetration of biosimilars
  - ❑ Established procedure for taking advantage of the competition
  - ❑ Retail market is depending on the retail price
- **Procedure for starting naïve patients with biosimilars**
  - ❑ According the national framework substitution is not allowed
  - ❑ More difficult to be implemented in the primary health sector due to availability
  - ❑ Develop a framework to start with an active substance with biosimilars in an ATC4 category
- **Differences in devices needed for the administration**

Future actions

- **Revision on national guidance on biosimilar interchangeability/ substitution**

❑ Different approach between initiation and maintenance phase

- **Revision on national framework on pricing**
- **Revision on national framework for HTA on biosimilars**
- **Communication strategy for biosimilars to all relevant stakeholders**

Thank you for listening!

Biosimilar medicinal products - best practices and challenges

Stakeholder Event on Biosimilar Medicinal Products - biosimilar uptake and access disparities

13.12.2023 r.

Agnieszka Beer

Ministry of Health – Poland

Possibility of exchanging one medicine for another that is expected to have the same clinical effect

Biosimilar medinces in Poland – most often areas

Costs on biosimilars in relations to the entire reimbursement

Potential of biosimilar medicines

Interchangeability of biosimilar medicines in Poland

Possibility of exchanging one medicine for another (drug stores, hospital treatment)

Patient has to be informed about possibility of exchanging a prescribing drug for another (visible note in every drug store) – profits for patients (different names of drugs = different prices)

Two examples of enoxaparinum

DRUG	RETAIL PRICE	COST FOR PATIENT	REIMBURSEMENT	FREE FOR
Clexane, 80 mg/0,8 ml, in packs of 10's	48,89	18,15	30,74	Children Pregnant women Adults 65+
Neoparin, 80 mg/0,8 ml, in packs of 10's	37,94	7,20	30,74	Children Pregnant women Adults 65+

1 EUR = 4,3327 PLN, 30.11.2023

Expenses on biosimilar medicinal products vs. general reimbursement

Biosimilars vs. Originals in Poland – costs [EUR]

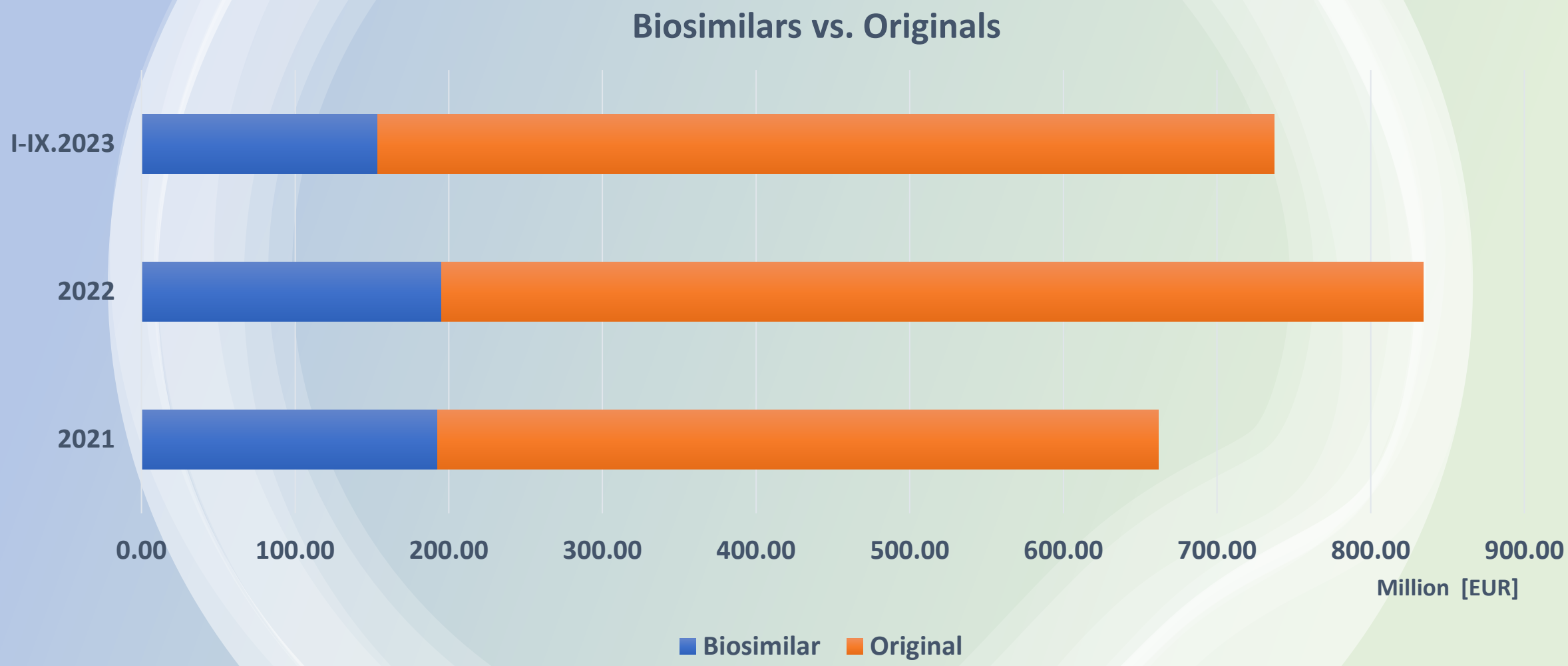
Category / Year	2021	2022	I – IX.2023
CHEMOTHERAPY:			
Biosimilar	56 994 752,78	69 675 225,03	60 094 415,03
Originial	1 428 147,49	25 196,65	8 674,15
DRUG THERAPY:			
Biosimilar	135 781 434,92	125 786 866,10	93 678 799,47
Original	467 462 010,59	638 515 087,39	583 350 429,54
TOTAL AMOUNT:	661 666 345,78	834 002 375,17	737 132 318,19

All reimbursed drugs

Category / Year	2021	2022	I-IX.2023
Chemotherapy	114 527 252,03	116 426 313,50	94 169 680,37
Drug therapy	1 186 468 673,37	1 497 115 322,60	1 344 056 603,33
TOTAL AMOUNT:	1 300 995 925,41	1 613 541 636,09	1 438 226 283,70

1 EUR = 4,3327 PLN, 30.11.2023

Biosimilars vs. Originals in Poland – costs [EUR]



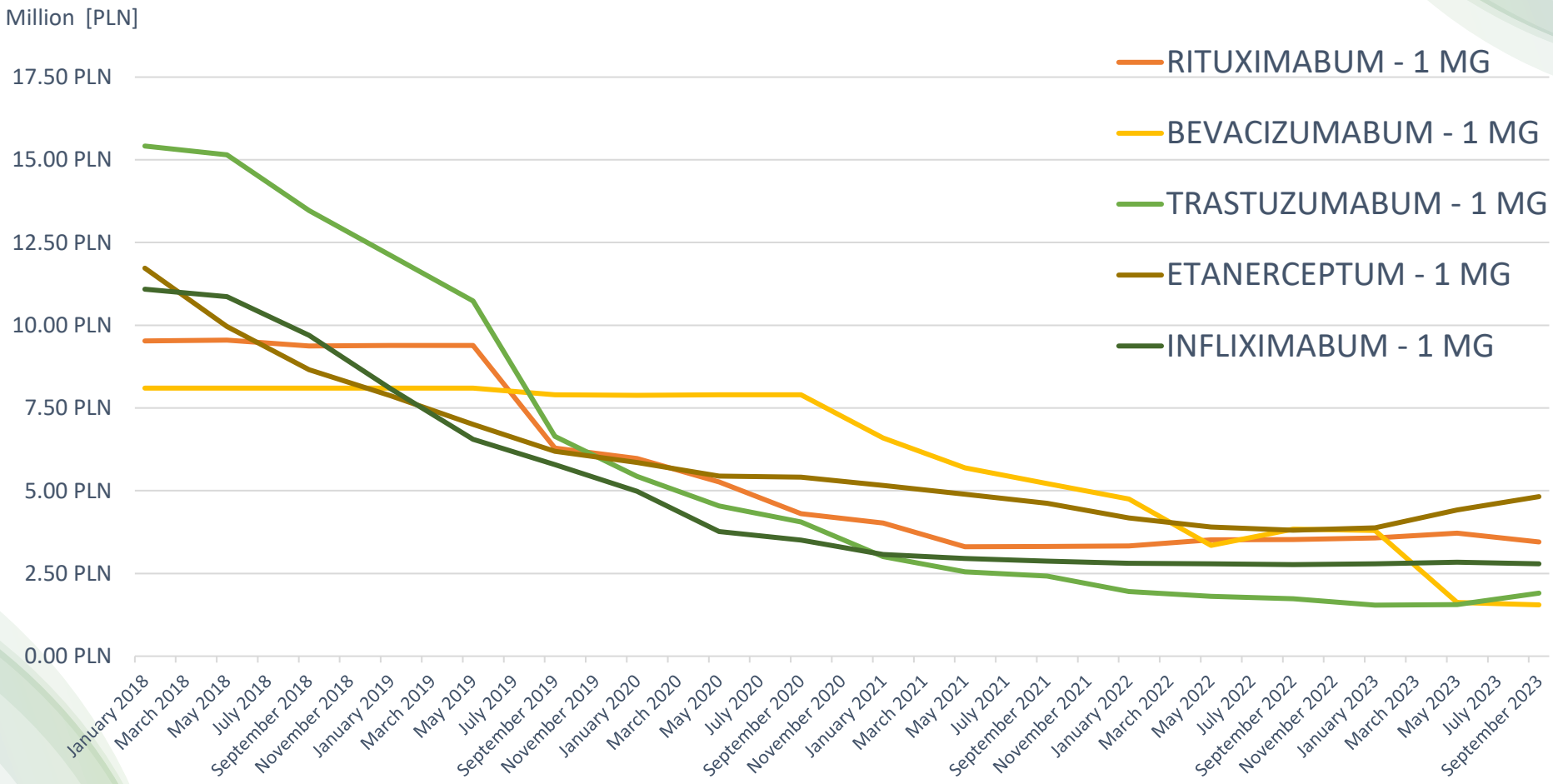
Difference in price

DRUG	PACKAGE	ORIGINAL BIOLOGICAL DRUG	CHEAPEST BIOSIMILAR DRUG REIMBURSED
		SELLING PRICE	SELLING PRICE
transtuzumab	150 mg	572,39	193,81
rituksimab	500 mg	1 306,11	553,35
bewacyzumab	400 mg	1 089,39	462,85
adalimumab	80 mg	524,67	325,92
etanercept	200 mg	853,97	438,53
infliksimab	100 mg	451,73	159,25

1 EUR = 4,3327 PLN, 30.11.2023

ACTIVE SUBSTANCE	PRICE DROP
transtuzumab	34%
rituksimab	42%
bewacyzumab	46%
adalimumab	62%
etanercept	51%
infliksimab	35%

Average cost of settlement of chosen biosimilars by the public payer



Decrease in therapy costs/medical expenses – *trastuzumabum (i.v.)*

2018

reimbursement of biosimilar (Kanjinti)

2021

% share of reimbursed units (mg) of the original drug: 0.08%

% share of reimbursed units (mg) of biosimilar drugs: 99.92%

Reimbursement of biosimilar medicinal products – benefits

- savings for the public payer
- increase in price competitiveness in tender procedures
- increasing access to a given therapy
- the processing of reimbursement applications is efficient, making the therapy available in the shortest possible time

Difficulties and challenges – patent protections

Herceptin, Trastuzumabum – a new form of application

Phesgo, Pertuzumabum + Trastuzumabum – two active substances in one product instead of two different products

Xarelto, Rywaroksaban - extension of indication (paediatric)

Polish drug market is based on biosimilar & generic access

Thank you for your attention!

a.beer@mz.gov.pl

Agenda – Part IV

15.15 – 16.15 **Product formulation and administration:** consequences for patients, healthcare professionals and systems

Chair: Carlos Martin Saborido (Ministry of Health, ES)

Regulatory aspects of biosimilar formulation and administration - René Anour (EMA BWP)

Biosimilar formulation and administration: Transformative Opportunities and Challenges - Adrian van den Hoven (MfE)

Reinvesting biosimilar savings to the benefit of patient access and administration – Bernard Duggan (HSE, IE)

Role of pharmacists - Ana Soldo (HLJK, HR)

Interactive Q&A discussion with the audience

16.15 – 16.30 **Closing words**

European Commission

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Regulatory aspects of biosimilar formulation and administration

Dr. René Anour, AGES,

Chair EMA Biosimilar Medicinal Products Working Party

How we handle formulation differences in Europe

All is fine – if it does not affect clinical performance

Bundesamt für Sicherheit im Gesundheitswesen
BASG

- Selected according to state of the art technology
- **does not need to be identical** to that of the reference medicinal product
- Suitability (e.g. stability, compatibility, interaction with excipients) to be demonstrated
- Potential impact on efficacy/safety appropriately justified

Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1), EMA/CHMP/BWP/247713/2012

How about the Device?

In general, the same applies – but less specific

Bundesamt für Sicherheit im Gesundheitswesen
BASG

- Different container/closure system (including material in contact with medicinal product) possible
- Impact on efficacy and safety appropriately justified
- **Challenge: To be marketed device not in development**

Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1), EMA/CHMP/BWP/247713/2012

Interchangeability not automatically for the Device

Aspects of formulation/device might be reflected in PI

Bundesamt für Sicherheit im Gesundheitswesen
BASG

The interchangeability statement relates to the **active substance**

Does not cover potential issues related to the handling of different administration devices (e.g. the need for patient training when using a new device)

Interchange only after careful consideration of the product information.

Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

Example 1 – Biosimilar Eculizumab

Excipient „Sorbitol“ as source for discussion

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BASG

- First Biosimilar Candidate for Soliris
- Comparability on all levels demonstrated.
- Formulation contains Sorbitol (as opposed to originator)
- Issue for patients with Fructose Intolerance (as opposed to originator)

Should indications be modified?

Instead of raising doubts regarding biosimilarity …

Adapted PI and Pharmacovigilance measures

Bundesamt für Sicherheit im Gesundheitswesen
BASG

- Contraindications for fructose intolerant patiens and babies/children below 2 (Section 4.3. of the PI)
- Pharmacovigilance Measures: included in the Risk Management Plan
- educational materials: physician's guide, patient's/parent's information brochure, and patient safety card.

(European Medicines Agency: Information for the package leaflet regarding fructose and sorbitol used as excipients in medicinal products for human use; EMA/CHMP/460886/2014).

Example 2: Biosimilar Etanercept

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Omission of a vial causes discussions

- Originator (Enbrel) has a specific pediatric container (vial, 10mg) as well as PFS with 25 and 50mg
- Biosimilar developer does not produce the vial for pediatric use
- Biosimilarity to Originator shown throughout development
- Indications „untouched“
- Note in 4.2 of SmPC: *A 10 mg vial strength may be more appropriate for administration to children with JIA below the weight of 25 kg.*

biosimilar medicines
better access. better health.

Biosimilar formulation and administration: Transformative opportunities and challenges

Adrian van den Hoven

Director General

Medicines for Europe

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Biosimilars Drive Innovation in Medicines and the Delivery of patient care

- Loss of Exclusivity ignites innovation dynamics
- Regulatory, Market Frameworks and Clinical Practice face adaptive challenges
- Multi-stakeholder approach to Biosimilar policy shaping remains highly relevant to achieve access to invaluable therapeutic options

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Innovation does not stop at Loss of Exclusivity (LoE)

Perspective of LoE acts as an incentive for innovative companies to develop new medicines

IP environment & Clinical experience (originator) shape and feed into biosimilar medicines development

- Manufacturing process
- Product safety profile
- (Ease of use) Device considerations
- Healthcare Workforce organisation and storage considerations
- Patient adherence

Source: Perspectives on the availability of innovative medicines, IQVIA, 2023, https://www.iqvia.com/library/white-papers/perspectives-on-the-availability-of-innovative-medicines

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Diabetes Care – Transformative Evolution

Insulin and insulin analogues constitute a successful example of continuous innovation impacting patient treatment pathways and organization of care

Recombinant human forms

IV administration

Better controlled potency
Sustained production capacity

~~**Inhaled forms**~~

Short & Long-acting forms

SC administrations

Improved management of hypoglycaemia
Lower number of injections
Organisation of Nursing Care

On-body continuous glucose monitoring and Insulin pump
Companion Apps
Smart pens

Tight control of glycemia
Remote follow up for diabetes teams

Source: History of Insulin, Cleste C. et al (2012) Journal of community Hospital Internal Medicines Perspectives

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Biosimilar-led Improvements and Innovation

Illustrative examples

Biosimilar Product Properties

- Stability at Room Temperature
  - Bevacizumab biosimilar
- Improved administration device
  - Follitropin biosimilar
- Formulation: Reduced immunogenicity
  - Etanercept biosimilar

Biosimilar medicine Use

- New mode of administration
  - Infliximab Biosimilar SC
- Companion Diagnostic or App
  - Pegfilgrastim biosimilar
- Repositioning
  - Infliximab biosimilar

Originator Evolution

- New mode of administration
  - Opdivo® SC
- New formulation
  - Humira® high-concentration
- Companion diagnostic or App
  - REMORA study
- Next generation medicine
  - Ultomiris® (Soliris®)
- Extension of Indication Repositioning
  - Anti-TNF therapy in Covid-19

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What could it mean for Patients and the Organisation of Care?

Patient Health Outcomes

- Patient Disease management & Quality of Care
- Patient Empowerment (access to health data)
- Adherence to Treatment
- Ambulatory, Home Care, Remote Monitoring
- Improved patient journey (eg 1st line biologic therapy)

Organisation of Care

- Hospital Pharmacy organization (Cold Storage Management)
- Availability and Management of multiple Therapeutic options
- Digitalisation of Healthcare
- Shift in Health Workforce Resources allocation
- Shift in Point of care organisation

What are the important considerations ?

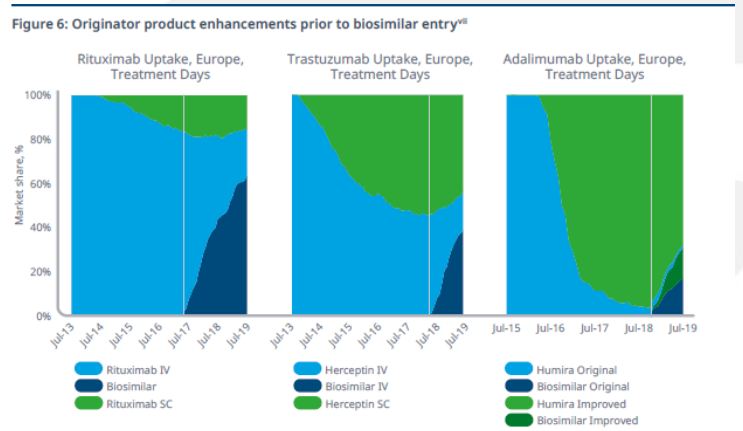
Innovative vs Incremental innovation vs evergreening – How substantiated are the claims?

- A shift to a newer form of the originator shortly before LoE can have a significant impact on the 'accessible market'[1]

How will the choice of medicine affect its use and the organization of care and how easily could it be undone?

- Shifting to SC from IV means change to HCP/nursing workforce and hospital 'bed space' allocation
- Switching consideration (HCP & patient information & education)

Will the investment and development risk be rewarded ?



Cardiff Hospital experience

- Limited rituximab SC
- IV biosimilar savings used for nurses-led remote administration center

Paediatric infliximab repositioning to 1st-line intervention

- Specific treatment paradigm

Source: **1.** IQVIA – The impact of Biosimilar Competition in Europe (2019)

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Encouraging Value Adding Innovation on Biosimilar medicines for Better Outcomes

Multi-stakeholder approach

Identify opportunities: patient outcomes, healthcare infrastructures and workforce management needs	**Incentives:** Regulatory framework P&R	**Horizon scanning** Health economic considerations & Health Technology Management	**Pro-Competitive** market policies Active monitoring of **Competition dynamics**	**Healthcare Community** Impact on **organization of care**/workforce **Education, Information**

patients • quality • value • sustainability • partnership

biosimilar medicines
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- Loss of Exclusivity ignites innovation dynamics: massive opportunity for improved outcomes thanks to improved use of existing biologics
- Regulatory, Market Frameworks and Clinical Practice face adaptive challenges: Pharma Reform an opportunity
- Multi-stakeholder approach to Biosimilar policy shaping remains highly relevant to achieve access to invaluable therapeutic options

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Thank you!

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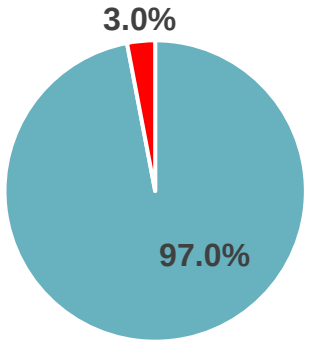
Reinvesting Biosimilar Savings to the Benefit of Patient Access and Administration

Bernard Duggan B Sc (Pharm), Dip Health Econ, Dip Project Management
Chief I Pharmacist, HSE-Medicines Management Programme

Medicines Management Programme

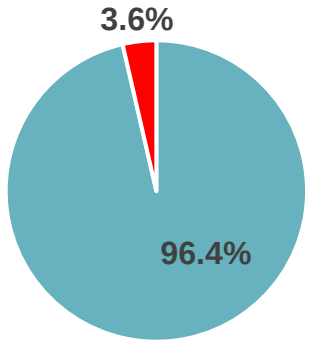
The challenge!!!

Adalimumab – June 2019



Biosimilar medicine available since November 2018

Etanercept – June 2019



Biosimilar medicine available since September 2016

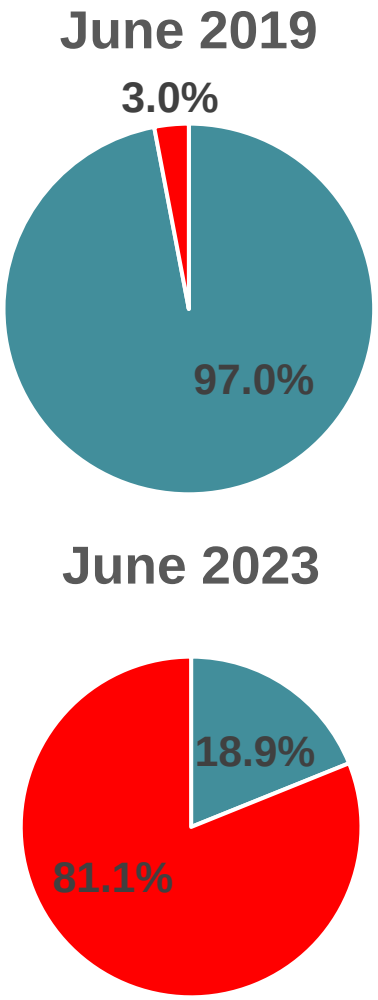
- National framework agreements with industry mandated 30% reduction in price of reference medicine upon biosimilar launch
- Automatic substitution of biosimilar medicines not permitted
- Clinicians not embracing availability of biosimilar medicines

Medicines Management Programme

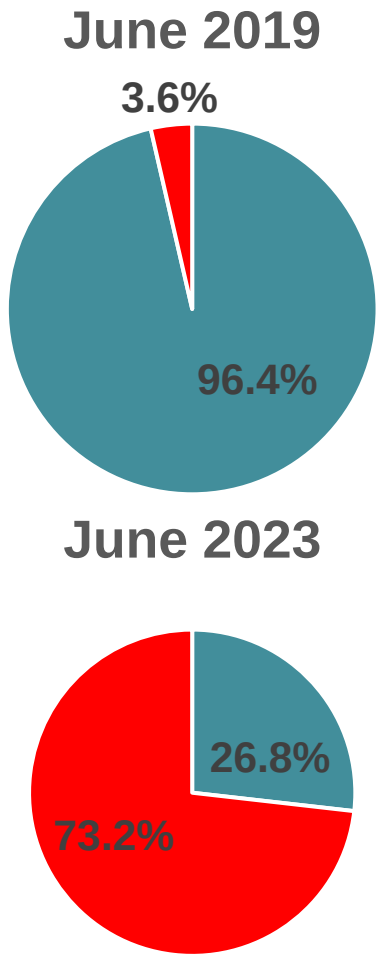
Disclaimer:
The views and opinions expressed in this presentation are those of the authors and do not necessarily represent official policy or position of HSE-MMP

The result

Adalimumab



Etanercept



Health Technology Management (HTM)

HTM refers to measures being put in place to enhance the safe, effective and cost-effective use of medicines thereby controlling utilisation and expenditure

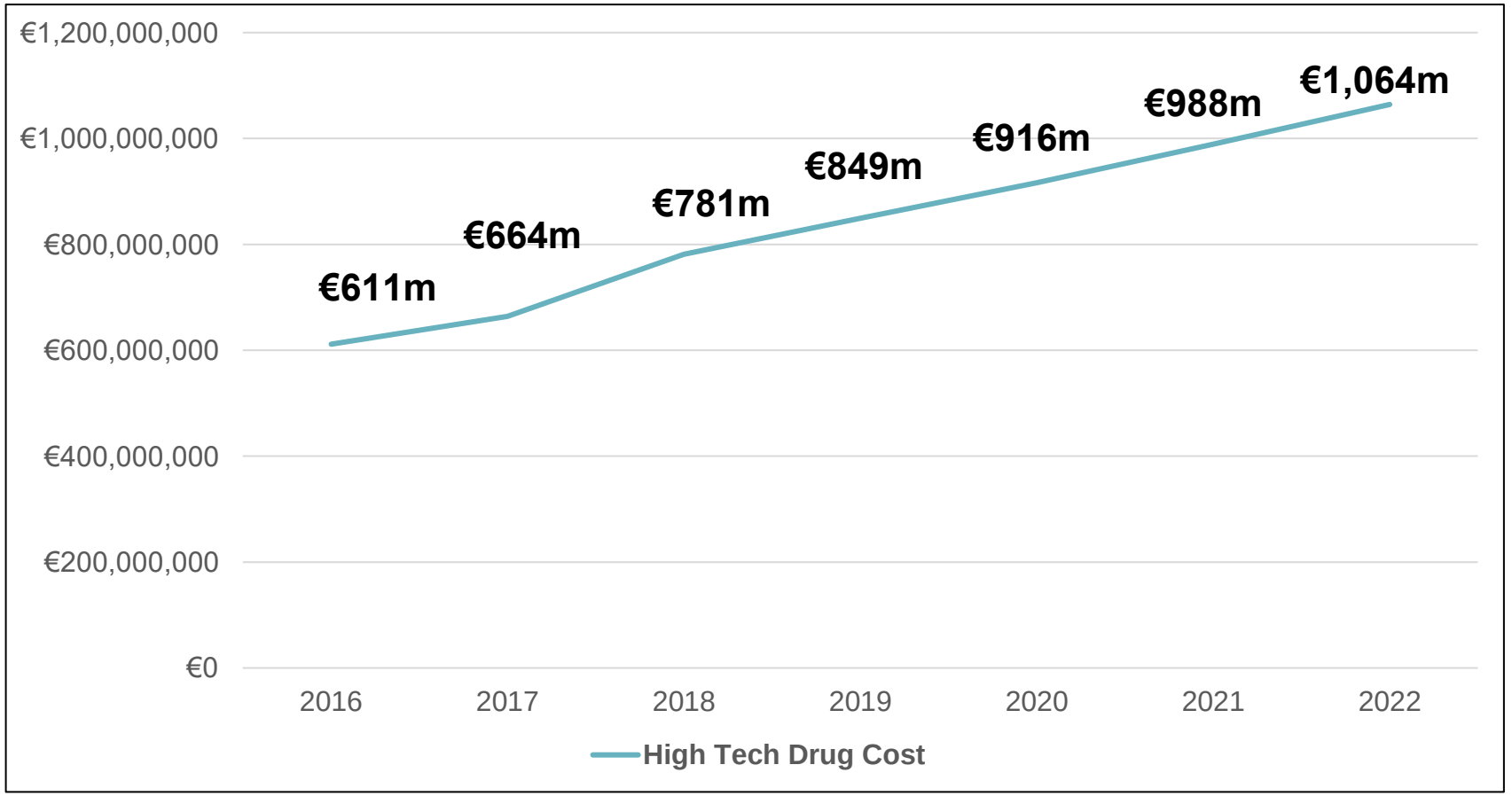
Reimbursement Application Systems

Managed Access Protocols (MAPs)

Best-Value Biological (BVB)/Best-value medicine (BVM) initiatives

Medicines Management Programme

High Tech Arrangement



Medicines Management Programme

MMP Roadmap

- Outlines criteria for identification of BVB medicines
- Formal consultation phase
- Submissions from stakeholders, including MAHs

HSE-Medicines Management Programme

Preferred Drugs

MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting

A biosimilar medicine (or 'biosimilar') is a biological medicine that is highly similar to an existing biological medicine (reference medicine) that has already been authorised for use in the European Union.[1] In January 2016, the HSE-Medicines Management Programme (HSE-MMP) highlighted the potential for biosimilars to significantly reduce drug expenditure and facilitate greater access to such treatments.[2] On the introduction of a biosimilar to the Irish market, the 2021 Framework Agreement on the Supply and Pricing of Medicines provides for an automatic price reduction of 37.14% for patent-expired, non-exclusive biological medicines. In addition to this price reduction, a rebate of 12.5% is applied.[3] Potential savings to the health service will only be realised by fostering a competitive biological medicine market.

Biosimilars must demonstrate that there are no clinically meaningful differences relative to the reference biological medicine in order to be approved by the European Medicines Agency (EMA). The evidence acquired over ten years of clinical experience with biosimilars demonstrates that they can be used as safely and effectively in all their approved therapeutic indications as their reference biological medicines. There has been a significant increase in the utilisation of biosimilars in Ireland since 2019; as of January 2022, 72% of patients in receipt of adalimumab 40 mg and 65% of patients in receipt of etanercept 25/50 mg under the High Tech Arrangement received a biosimilar medicine.

The MMP aims to identify best-value biological (BVB) medicine(s)[1] [using the criteria outlined below] within various therapeutic classes, including at a molecular level. Various supports will be made available to clinicians to enhance uptake of the BVB medicines. A collaborative approach involving clinicians, pharmacists, nurses, patients and the health service is required to implement utilisation of BVB medicines.

Regulatory bodies, including the EMA and the Health Products Regulatory Authority (HPRA), have published guidance and information for healthcare professionals and patients in relation to biosimilars. A clinician, in consultation with their patient, may switch a reference biological medicine to a biosimilar medicine (or vice versa).[4] Pharmacist-led substitution of biological medicines is not permitted under the Health (Pricing and Supply of Medical Goods) Act 2013.[5]

Evaluation Process

The MMP will evaluate the therapeutic areas where there is potential to identify BVB medicines to support their safe, effective and cost-effective use. The MMP will publish an evaluation report, in which the recommended BVB medicines will be identified.

A number of criteria may be considered by the MMP in identifying BVB medicine(s), including:

1. Acquisition cost
2. Therapeutic indications
3. Formulation considerations
4. Product range including pack sizes and strengths available
5. Product stability including storage requirements
6. Administration devices
7. Patient factors
8. Expenditure in the therapeutic area and potential for cost efficiencies
9. Clinical guidelines
10. Security of supply to the Irish Market
11. Utilisation and clinical experience with the biological medicine
12. Any other relevant factors with respect to the particular INN

[1] In some cases, there may be biosimilar medicines and/or hybrid medicines available of a reference biological medicine. In these circumstances, the MMP may identify a best-value medicine (BVM).

March 2022 1 Version 3

Medicines Management Programme

Medicines Management Programme

Best-Value Biological Medicines:

Tumour Necrosis Factor-α Inhibitors on the

High Tech Drug Scheme

Preferred Drugs
THE RIGHT CHOICE, RIGHT NOW.
MEDICINES MANAGEMENT PROGRAMME

Approved by:	Prof. Michael Barry, Clinical Lead, Medicines Management Programme (MMP).
Date approved:	02/05/2019
Version:	1.0

Medicines Management Programme

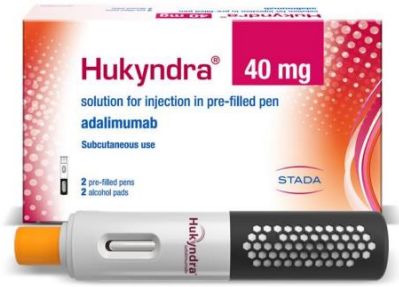
BVB Medicines – Adalimumab & Etanercept

Adalimumab

Amgevita®

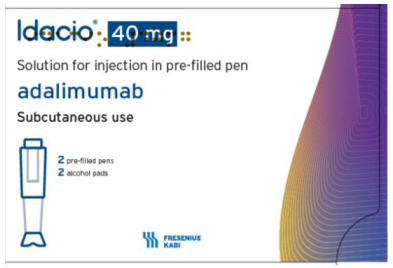
Imraldi®

Yuflyma®



Hukyndra®

Benepali®



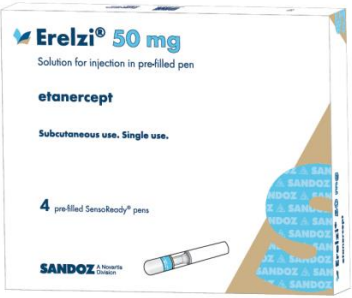
Idacio®

Hulio®

Hyrimoz®

Humira®

Etanercept



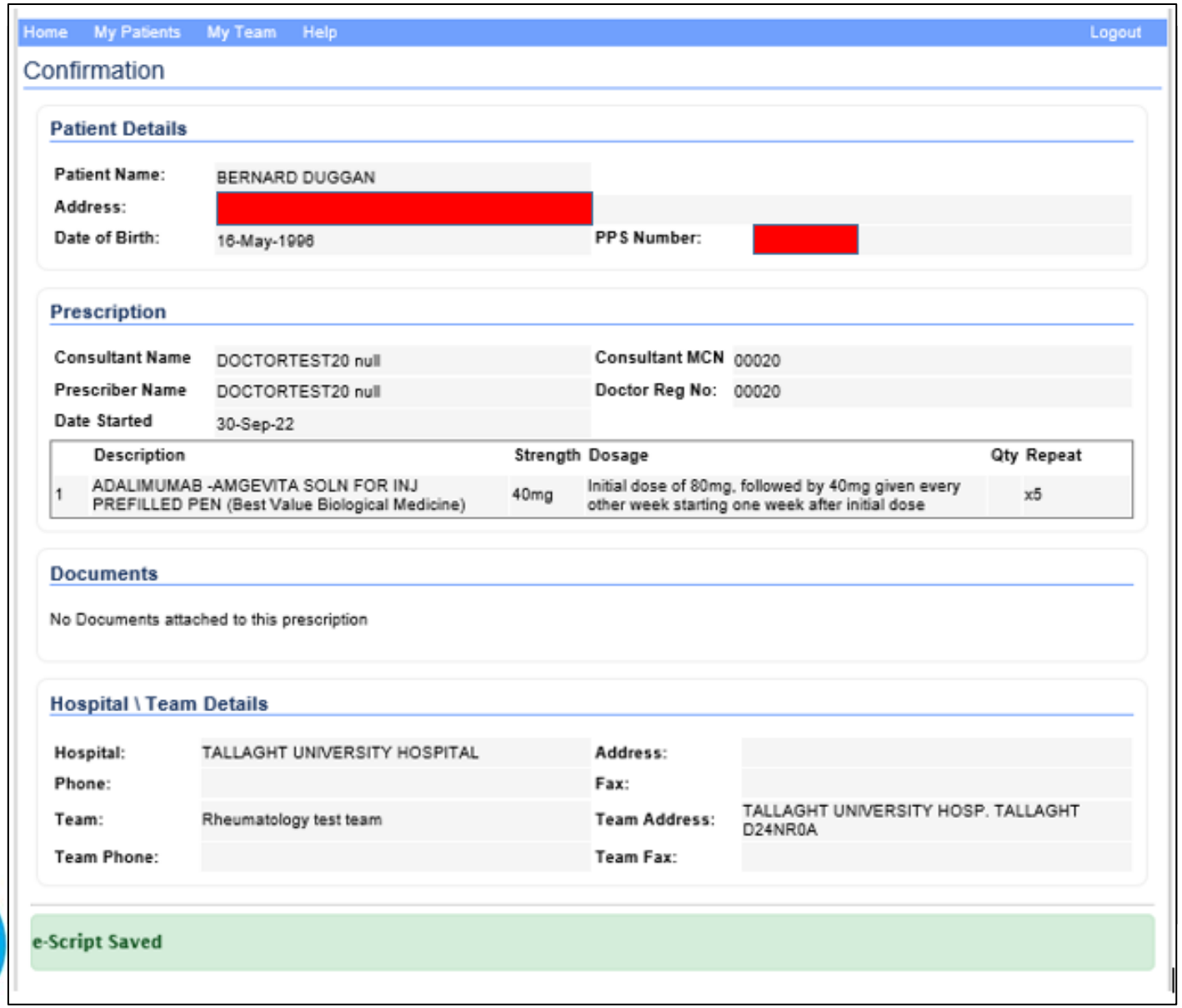
Erelzi®

BVB Medicines: Implementation

- **High Tech Hub**
- Gainshare arrangement
- Policy for new patients
- Site visits to provide information sessions
- Resources for clinicians and their team
- Collaboration with stakeholders
  - National Clinical Programmes
  - Patient Support Groups

Medicines Management Programme

High Tech Hub



Home My Patients My Team Help Logout

Confirmation

Patient Details

Patient Name:	BERNARD DUGGAN		
Address:	[redacted]		
Date of Birth:	16-May-1996	PPS Number:	[redacted]

Prescription

Consultant Name	DOCTORTEST20 null	Consultant MCN	00020
Prescriber Name	DOCTORTEST20 null	Doctor Reg No:	00020
Date Started	30-Sep-22		

	Description	Strength	Dosage	Qty	Repeat
1	ADALIMUMAB -AMGEVITA SOLN FOR INJ PREFILLED PEN (Best Value Biological Medicine)	40mg	Initial dose of 80mg, followed by 40mg given every other week starting one week after initial dose		x5

Documents

No Documents attached to this prescription

Hospital \ Team Details

Hospital:	TALLAGHT UNIVERSITY HOSPITAL	Address:	
Phone:		Fax:	
Team:	Rheumatology test team	Team Address:	TALLAGHT UNIVERSITY HOSP. TALLAGHT D24NR0A
Team Phone:		Team Fax:	

e-Script Saved

Medicines Management Programme

BVB Medicines: Implementation

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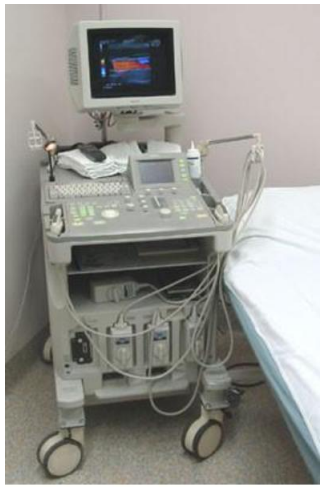
Medicines Management Programme

Gainshare Arrangement

- Prescribing of BVB medicines by clinical teams will result in efficiencies for the Health Service.
- Gainshare arrangement whereby €500 of savings accruing per patient will be made available to the clinical team responsible for the saving.
- Savings made when Consultant-led team initiate a new patient on, or switch them to a BVB medicine.
- Savings are used to fund service delivery and enhancements for the benefit of patients.

Medicines Management Programme

Gainshare Arrangement



Medicines Management Programme

Gainshare Arrangement

Primary Care Eligibility & Reimbursement Service BVB Gainshare Release Form

Section 1: Hospital Details (Clinical Service)			
Hospital Name			
Hospital Address			
Speciality (complete one /delete others)	Rheumatology	Gastroenterology	Dermatology
Short Description of Project / use of Gainshare (include details of benefits)			
Amount to be released	€		

Section 2: Hospital Bank Details (Hospital)	
Account Name:	
IBAN:	
BIC:	

Section 3: Hospital Funding Release Request (Clinical Service / Hospital Management)			
We request the release of Gainshare to support the specific project outlined above. *We confirm that we understand that the release of these funds is conditional on use for the purpose specified above.*			
Signature:		Signature:	
Date:		Date:	
Consultant Name:		Hospital Manager / Financial Officer:	
MCN		Job Title:	
Email Address:		Email Address:	

Section 4: Clinical Lead Confirmation (Clinical Programme)	
Signature:	
Date:	
Name / Programme:	

Section 5: Gainshare Release (For PCERS Internal Use Only)			
Checklist		BVB Gainshare Release Internal Approval	
Hospital Details	Yes No	Sufficient Funds Accrued	Yes No
Bank Details	Yes No	Department Head Signature:	
Consultant	Yes No	Date:	
Hospital Manager	Yes No	Head of Reimbursement Operations Signature:	
Clinical Lead	Yes No	Date:	

Return to: High Tech Hub, HSE PCERS, J5 Plaza North Road, Finglas, Dublin 11, D11 FXTO
Email: pcrs.hitech@hse.ie

Medicines Management Programme

Gainshare Arrangement

Trevor Duffy
@DrTrevorDuffy

New rheumatology unit #Connolly to be funded entirely by patient contributions. And creates 12 New Inpatient Beds at NO COST. What is this magic? 1/4 @jackfchambers @rodericogorman @PaulDonnellySF @LeoVaradkar @RoisinShortall @sburx @SusanMitchell_ @Damian_Cullen @boucherhayes

Trevor Duffy @DrTrevorDuffy · Jul 4, 2021

Yes @WexGenHosp it's a genius scheme by @MedMgmtProg and @HSELive It provides targeted incentives to patient and clinical groups. Works on #trust that portion of savings made go back to the service. #gainshare Expect if this program works they'll extend to other biosimars

Trevor Duffy @DrTrevorDuffy · Jul 4, 2021
Replying to @DrTrevorDuffy
Funded by Patient contributions through #genius HSE PCRS Gainshare scheme. Patients agree to trial switch to lower cost biological drug and generate €500 donation to rheumatology services. What are the benefits... 2/4

2 3 17

Trevor Duffy @DrTrevorDuffy · Jul 4, 2021
New unit can take over 700 off waiting list with 1. Daily clinics, 2. Urgent review service, 3. Patient education facilities, 4. Primary care support facilities. And there's more...3/4

1 2 25

Trevor Duffy @DrTrevorDuffy · Jul 4, 2021
12 new acute bed spaces created by vacating old space. Major HSE drug savings through alternatives to high cost drugs. Old building given new life with cost of effective renovation. Everyone wins. When it works, it works! 4/4

Medicines Management Programme

BVB Medicines: Implementation

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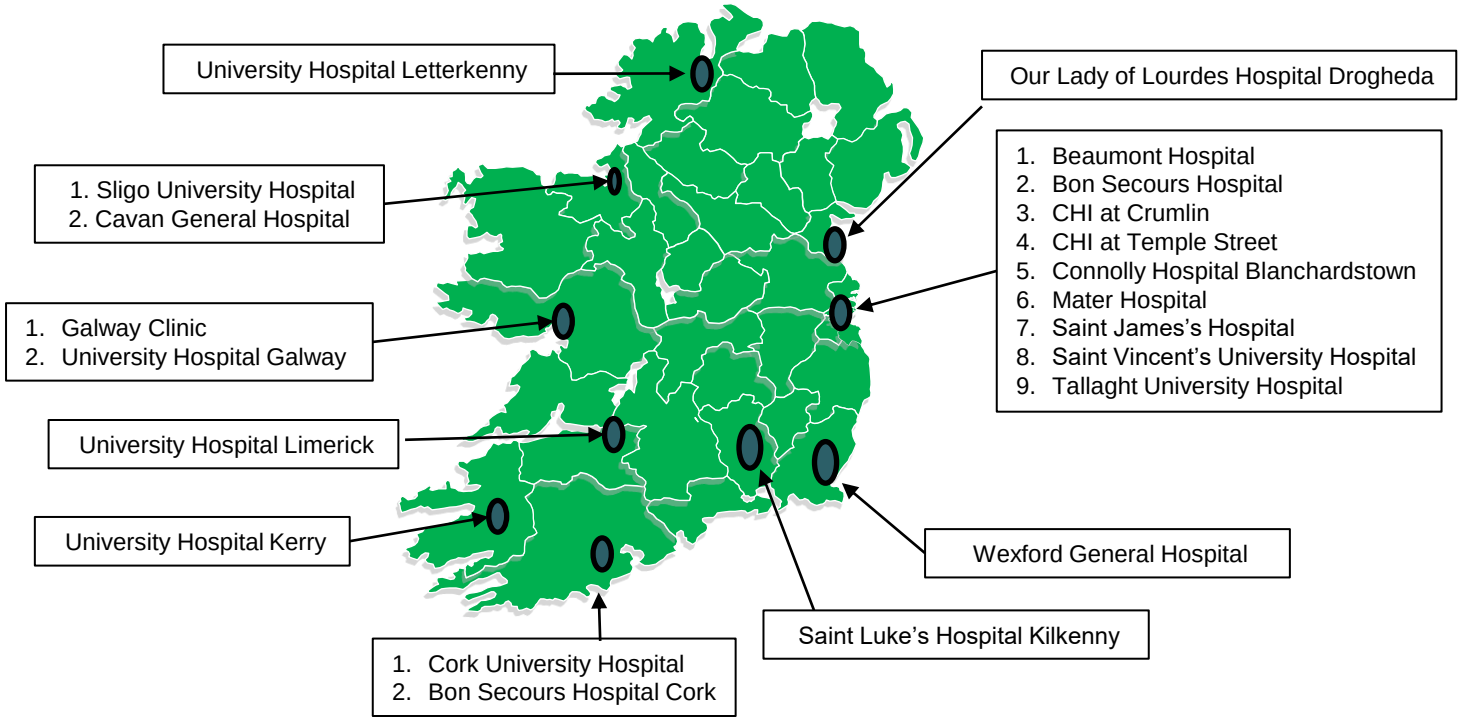
Medicines Management Programme

Information Sessions



Medicines Management Programme

BVB Medicines: Implementation

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Medicines Management Programme

Best-value biological medicines

The Medicines Management Programme has identified best-value biological (BVB) medicines for TNF-α inhibitors under the High Tech Arrangement.

The MMP recommends the following BVB medicines for adalimumab and etanercept:

- Adalimumab:
  - Citrate-containing: Hyrimoz, Idacio
  - Citrate-free: Amgevita, Hukyndra, Hulio, Humira, Imraldi, Yuflyma
- Etanercept: Benepali, Erelzi

Clinicians should give due consideration to the prescription of these agents when prescribing a TNF-α inhibitor. Implementation of the BVB medicines will lead to significant savings for the health service, in the order of millions of euros.

The MMP recommends Humira 80 mg and Yuflyma 80 mg as the BVB medicines for presentations of adalimumab 80 mg solution for injection that are available as self-administered injection devices on the High Tech Arrangement.

The MMP recommends Amgevita as the BVB medicine for presentations of adalimumab 20 mg solution for injection that are available as self-administered injection devices on the High Tech Arrangement. This presentation of adalimumab is predominately used in paediatric patients. The MMP wrote a letter to prescribers in relation to this in May 2021.

Resources to support prescribing of the BVB medicines are located in the Related Files section below:

- Questions and Answers for Healthcare Professionals.
- MMP Product Information Sheets for Amgevita, Benepali, Erelzi, Hukyndra, Hulio, Humira, Hyrimoz, Idacio, Imraldi and Yuflyma
- Contact information for MMP support.
- Contact information for patient support services for Amgevita, Benepali, Erelzi, Hukyndra, Hulio, Humira, Hyrimoz, Idacio, Imraldi and Yuflym
- Templates for switching letters for Benepali and Erelzi

In this section

Medicines Management Programme

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Biosimilars

What is a biosimilar?

Are biosimilar medicines the same as generic medicines?

Biosimilars in Ireland

How are biosimilars administered?

What is a biosimilar?

A biosimilar medicine is a highly similar, but not identical, copy of an originator biologic medicine. A biosimilar contains a version of an active substance of a biologic medicine, which is referred to as the 'reference medicine' or 'originator medicine'.

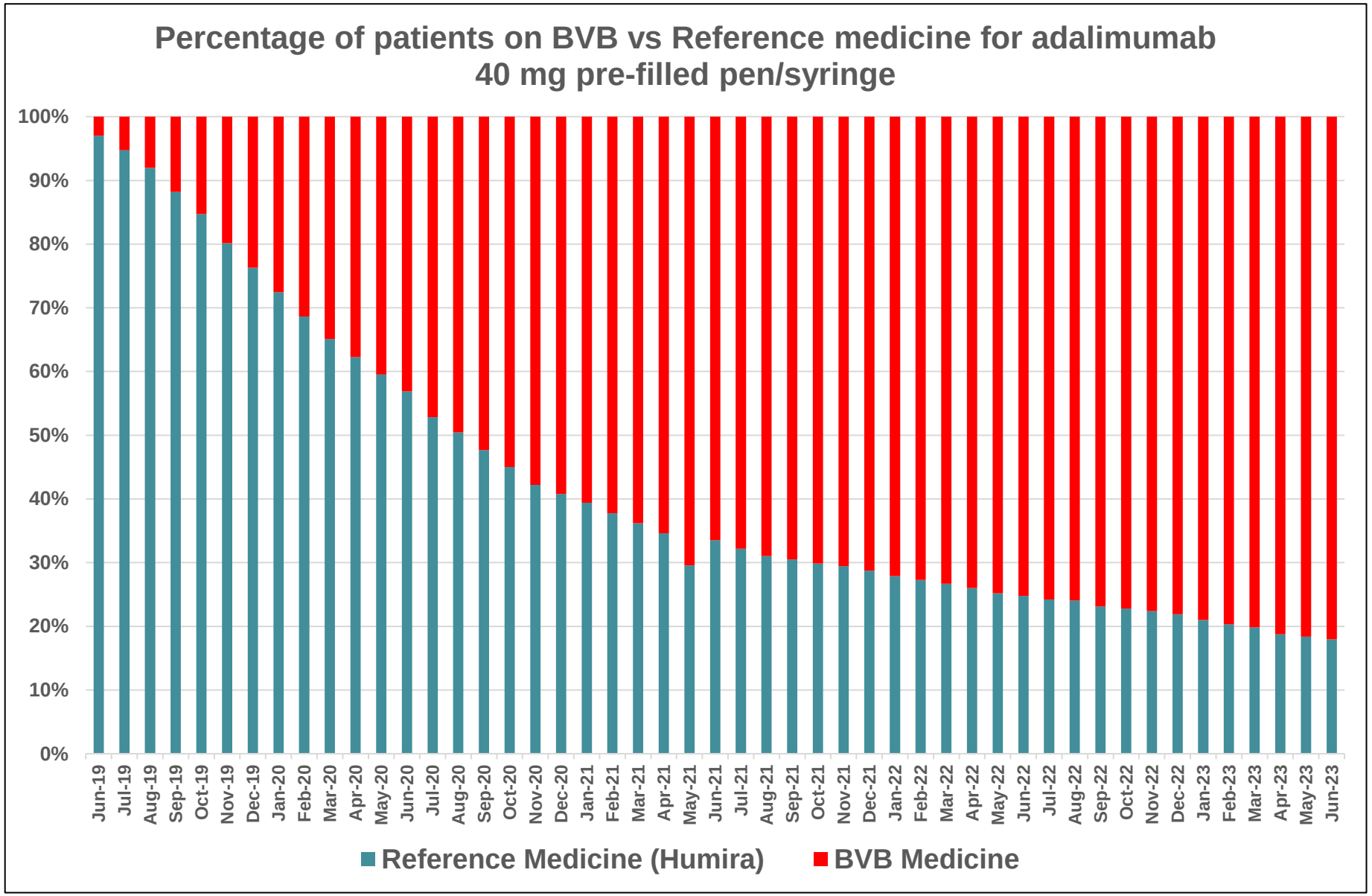
A biosimilar medicine is not an exact copy of its biologic counterpart because of the complex production process needed for these medicines. Like the reference medicine, a biosimilar medicine has a degree of natural variability, due to the biological nature of its ingredients.

However, when approved for use in people by the European Medicines Agency, any differences between a biosimilar and its reference medicine will have been shown not to affect safety or effectiveness.

This means that, in order to be licensed for use in people, a biosimilar medicine has to show that it is as safe and works as well as the originator medicine. All medicines, whether chemical or biological, have to be regulated for safety and approved before being made available to people.

While biosimilars have been used to treat cancer for many years, their use for people with inflammatory conditions like arthritis is relatively new in Ireland. However, this is changing as there is increasing availability of biosimilars for arthritis patients in Ireland.

Medicines Management Programme



Medicines Management Programme

Thank you

Find us on: www.hse.ie/mmp

Email: Bernard.Duggan@hse.ie

@MedMgmtProg

Medicines Management Programme

The role of Pharmacists

Seventh stakeholder event on biosimilar medicinal products
Brussels, 13 December 2023

Ana Soldo, MPharm

Croatian Chamber of Pharmacists

Pharmacies and pharmacists

Pharmacies and pharmacists

Pharmacists represent the **third largest healthcare professional group** globally after nurses and physicians and they are developing **skillset and patient-centred care roles** which can be used in healthcare workforce planning to meet the rising healthcare demand of the ageing population.

Key trends such as population ageing and future public health crises and emergencies can be best addressed by **moving away from traditional hospital-centric models** towards more **patient-centred care services, treating patients as close to their homes as possible.** This can be pursued by expanding community pharmacy services as an integral part of primary care, promoting prevention and better management of long-term conditions, improving accessibility and affordability of health services to help addressing the needs of an ageing population, **while contributing to the health systems fiscal and financial sustainability.**

Where are we now?

Findings from this study indicate that clinicians in the United States and Europe are cautious about biosimilar use and do not predominantly support the use of biosimilars as safe and effective treatment options in patients already receiving bio-originator therapy.

Provider hesitancies deter biosimilar prescribing and use. Biosimilar education can help to increase prescriber comfort and familiarity with biosimilar medicines, inspire prescribing changes, and ultimately drive biosimilar use. However, biosimilar-specific education remains a relatively neglected area of emphasis in the published literature.

This review identifies several topics that clinician-tailored biosimilar education should address to alleviate existing misunderstandings and bridge knowledge gaps altogether. Major areas of focus include thoroughly reviewing the concepts of immunogenicity, extrapolation, and interchangeability.

Future research should explore different health care provider types in greater detail and evaluate practitioners' engagements with patients to ensure that providers can effectively communicate with their patients about biosimilars as a treatment option..

What I can do as a Pharmacist?

- Support that biosimilar medicines should hold the same INN as the reference product;
- Support that where regulatory approval exists, extrapolation of indications is appropriate;
- Support that a reference product and its biosimilar(s) are interchangeable and therefore can be switched;
- Support that a biosimilar product and other biosimilar(s) to the same reference product are interchangeable and therefore can be switched;
- Support that decisions regarding switching and substitution should involve the relevant stakeholders (patients, prescribers, pharmacists and others);

https://www.eahp.eu/sites/default/files/eahp_position_paper_on_biosimilar_medicines_june_2023.pdf

What I can do as a Pharmacist?

- Advocate for the use of the hospital and community pharmacist's knowledge in promoting the appropriate selection, procurement, logistics and use of biosimilar medicines, and in providing education about them to both patients and other health care professionals;
- Encourage the involvement of hospital and community pharmacists in pharmacovigilance;
- Call for the utilisation of the expertise of hospital and community pharmacists by the relevant fora dealing with biosimilar medicines.

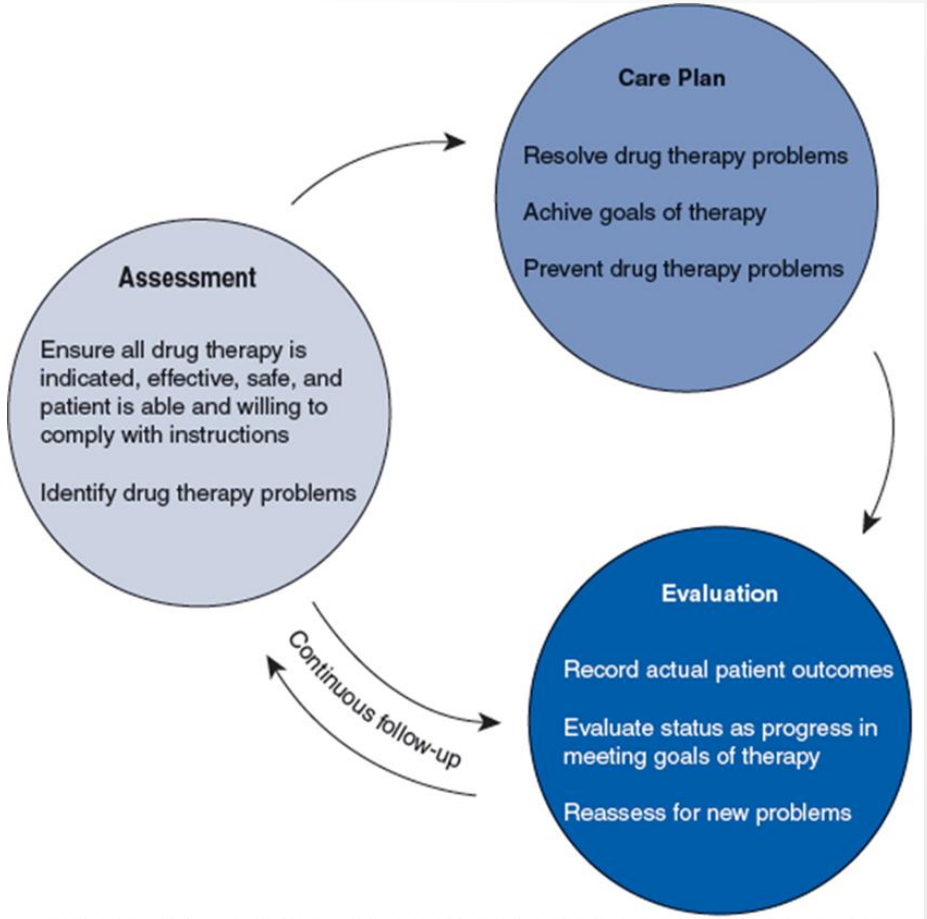
https://www.eahp.eu/sites/default/files/eahp_position_paper_on_biosimilar_medicines_june_2023.pdf

What I can do as a Pharmacist?

- Call upon competent authorities to take lead responsibility for the dissemination of unbiased information about biosimilar medicines. The expertise of hospital pharmacists should be consulted in the development of such information;
- Acknowledge that such decisions may be made at the national level, involving the relevant stakeholders (patients, prescribers, pharmacists and others);
- Support that under certain conditions substitution at hospital pharmacy level can occur.

https://www.eahp.eu/sites/default/files/eahp_position_paper_on_biosimilar_medicines_june_2023.pdf

What I can do as a Pharmacist?



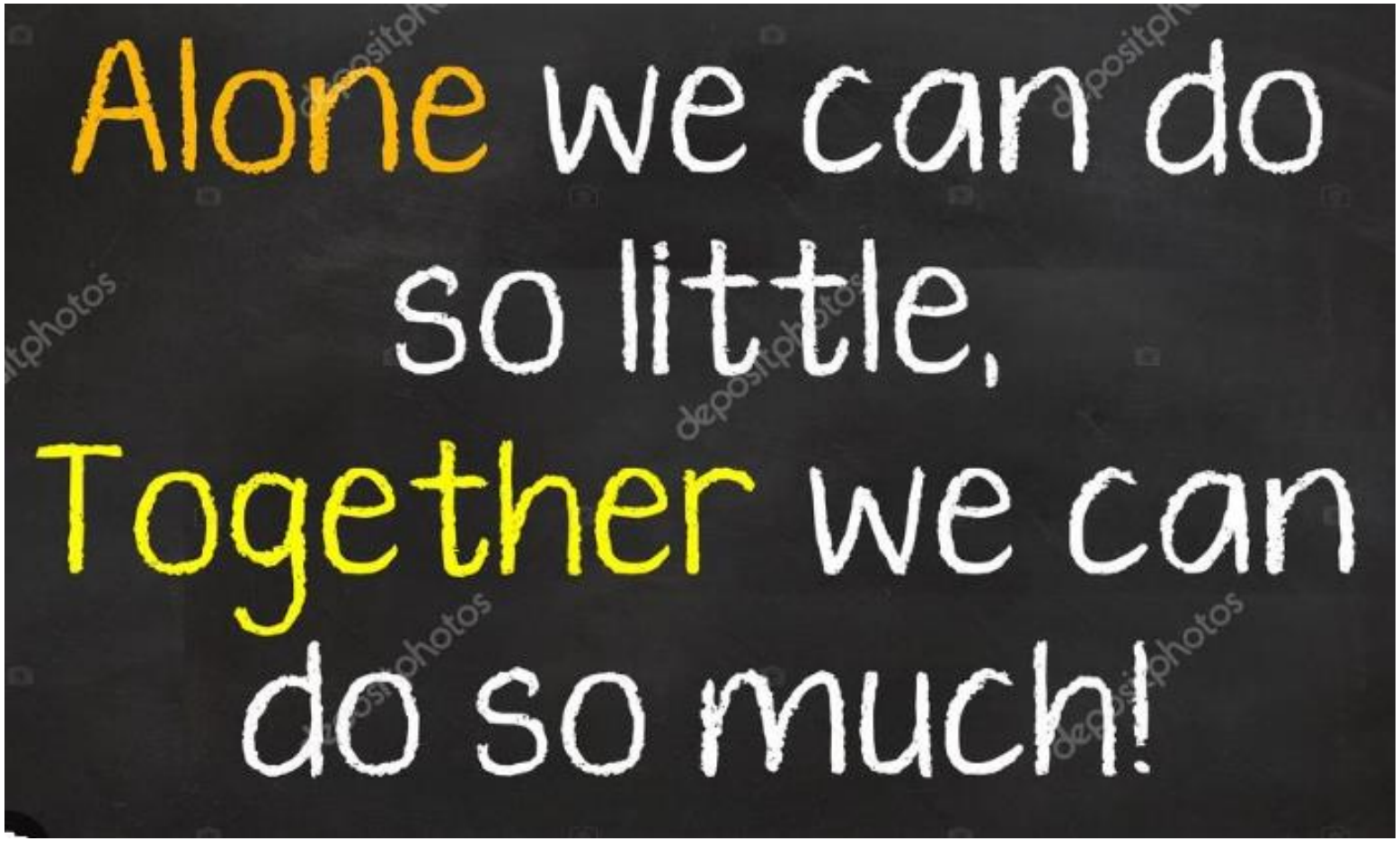
Source: Cipolle RJ, Strand LM, Morley PC: *Pharmaceutical Care Practice: The Patient-centered Approach to Medication Management Services, 3rd Edition*: www.accesspharmacy.com

Croatian experience

- Very slow proces of reimbursement in HZZO - National Health insurance company;
- Professional associations of doctors had a strong opinion on biosimilars;
- The media campaigns casting doubt on the quality of biosimilar medicinal products;
- Patient associations have expressed concern about the arrival of biosimilars on the market;
- The supply of medicines only in hospitals;

What we can do as a Chamber?

- The Chamber participated in all working groups for the drafting of legislation regulating the proscribing and regulation of biosimilar medicinal products in Croatia;
- The Chamber strongly supports extrapolation of indications in HZZO, Croatian health insurance company;
- The Chamber organized education for pharmacists on biosimilars and their importance in treating disease and increasing access to medicines for patients;
- The Chamber organized education for journalists on medicines, their development, registration and safety;
- The Chamber advocates the development of a national policy on medicines that will increase access to treatment for all patients;



ana.soldo@hljk.hr

Conclusions

Thank you

All approved documents will be published on the DG SANTE event website:

https://health.ec.europa.eu/events/biosimilar-medicines-multistakeholder-event-2023-12-13_en

European Commission
Public Health information:
http://ec.europa.eu/health/index_en.htm

@EU_Health

https://ec.europa.eu/health/medicinal-products/pharmaceutical-strategy-europe/making-medicines-more-affordable_en

#EUPharmaStrategy

European Commission