GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

STAKEHOLDER EVENT ON BIOSIMILAR MEDICINAL PRODUCTS
BRUSSELS, 13 DECEMBER 2022

Building trust in oncology biosimilars: clinical practice
Perspective from an oncology clinician

Rosa Giuliani
ESMO Director of Public Policy

The views expressed are the personal views of the presenter and may not be understood or quoted as being made on behalf of or reflecting the position of others

DECLARATION OF INTERESTS

Speaker, consultancy, advisory role (non remunerated)
Apogen, Roche, Mylan, Lilly, Pfizer, Novartis, Medicines for Europe, mAbxience, European Access Academy
Research funding paid to Institution: MSD; Novartis

ESMO Board member 2020-2022
Director of the ESMO Public Policy 2020-2022
Chair of the ESMO Global Policy Committee
Member of the ESMO EU Policy Committee
Member of the ESMO Cancer Medicine Committee

Member of WHO-DECIDE health hub
Former stakeholder pool HTA (EC)
EUnetHTA stakeholder pool

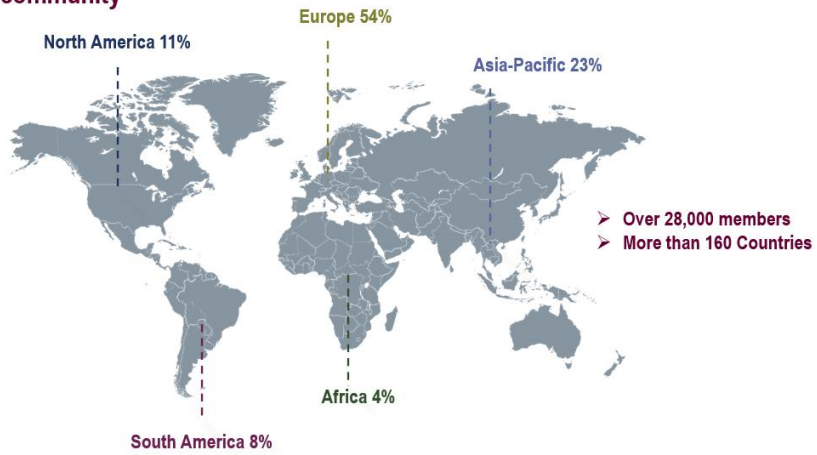
Co-chair of the Healthcare Professional Working Party of the European Medicines Agency (EMA)
Former core member of the EMA Scientific Advisory Group-Oncology (2012-2021)
Member of the EMA Cancer Medicine Forum

1 WHY BIOSIMILARS ARE RELEVANT TO MY PRACTICE

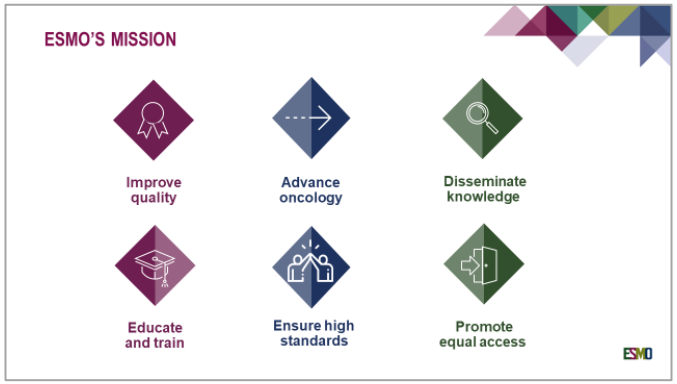
2 HOW DID I BUILD CONFIDENCE

3 NEXT STEPS

ESMO Members
A global community



- Over 28,000 members
- More than 160 Countries



Optimal Cancer Care

Universal Health Coverage

Sustainable Health Systems

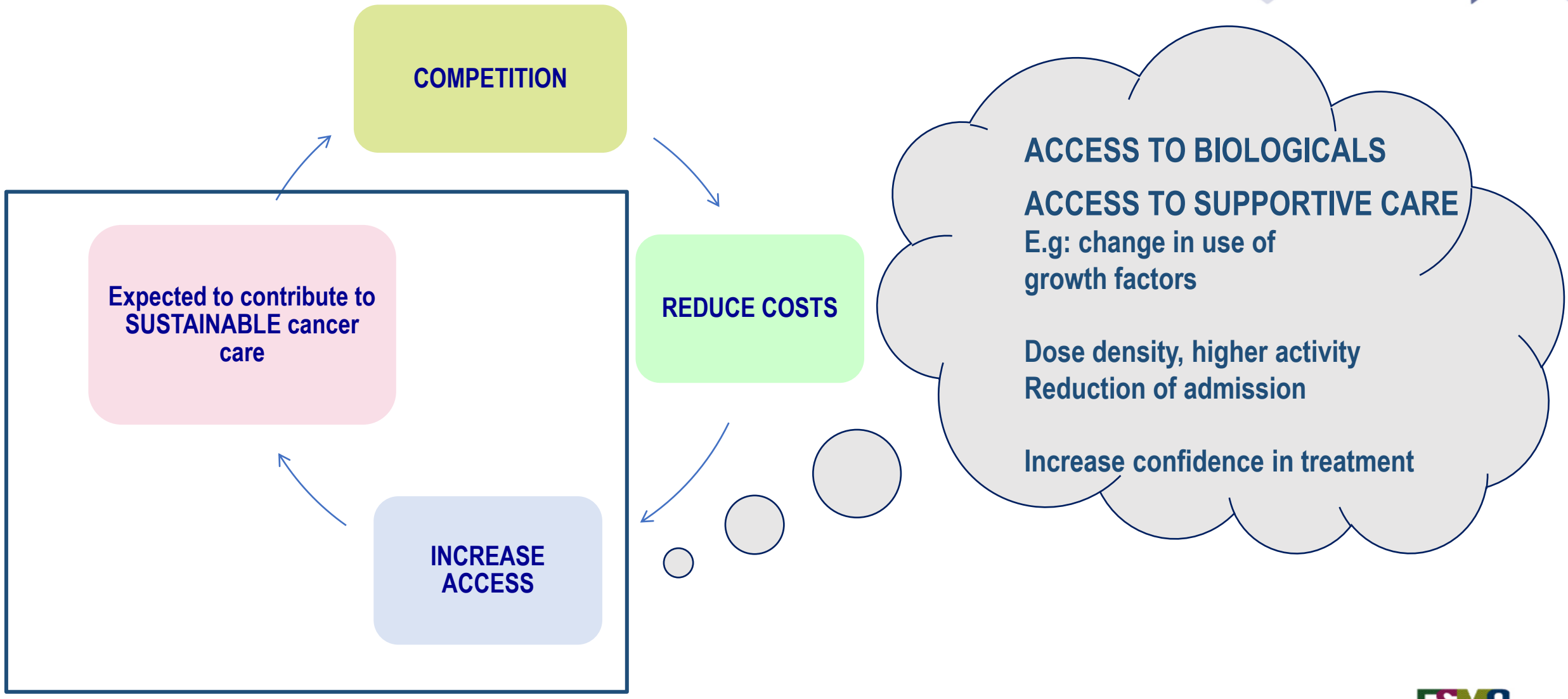
THE ESMO BLUEPRINT TO TACKLE CANCER

PREVENTION	SCREENING	TREATMENT	SURVIVORSHIP
Investing in evidence-based primary prevention policies at national, regional and global levels	Implementing evidence-based screening programmes for secondary prevention of cancer	Diminishing disparities in access to cancer care by harmonising care standards, assessing the clinical benefit of medicines and ensuring availability of all essential medicines	Improving survivorship and providing survivors with the tools and support they need

ACCESS to CARE (continuum)

~~INEQUITIES~~

HCPs perspective: BIOSIMILARS & ACCESS & SUSTAINABILITY



UNDERSTANDING BIOSIMILARS is the RESULT OF SHARING KNOWLEDGE

SCIENCE

REGULATORY EXPERTISE

LEARNED SOCIETIES

EXPERIENCE

CONFIDENCE

The KEY role of learned societies: ESMO in action

Open Access — Review

ESMO Open Cancer Horizons

CrossMark

Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers 2017

POSITION PAPER

VISION

ENGAGEMENT

EDUCATION

Open access — Review

ESMO Open Cancer Horizons

Check for updates

Preparing for the incoming wave of biosimilars in oncology 2018

ESMO Special session @ ESMO 2017 in Madrid
"The incoming wave of biosimilars In oncology"

Open access — Original research

ESMO Open Cancer Horizons

Check for updates

Knowledge and use of biosimilars in oncology: a survey by the European Society for Medical Oncology 2019

ESMO survey on awareness on Biosimilars launched during ESMO2017 in Madrid. Presented @ ESMO colloquium (ESMO 2018, Munich)

ESMO BIOSIMILARS PORTAL

Biosimilars promote access to innovative cancer medicines

Elisabeth de Vries
Chair of ESMO Cancer Medicines Committee

and the sustainability of health systems

Josep Tabernero
ESMO Past President

Welcome to the ESMO Biosimilars Portal

https://www.esmo.org/Policy/ESMO-Biosimilars-Portal

Science

A collection of resources to understand the science behind biosimilars.

Education

ESMO education material to help stakeholders to better understand biosimilars.

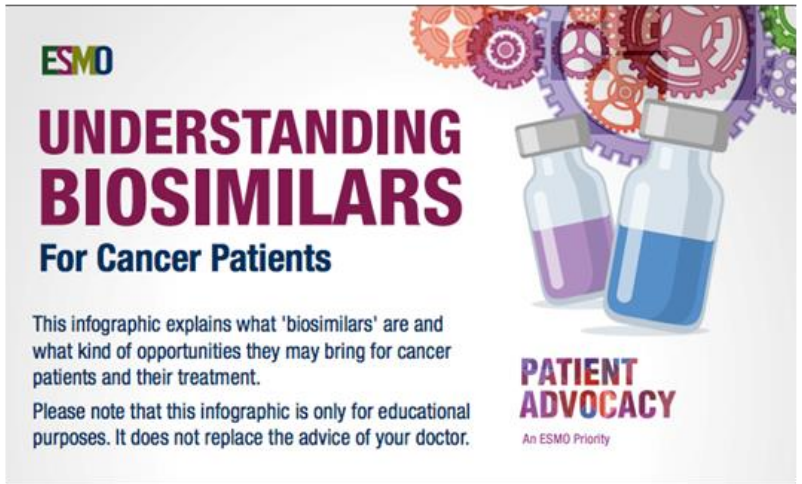
Regulation

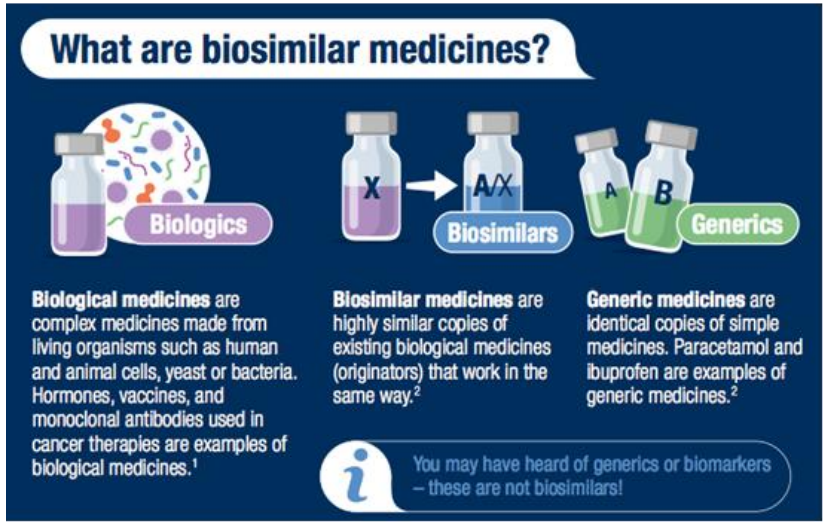
Visit this section to understand how the EMA, the US FDA, and the WHO regulate biosimilars.

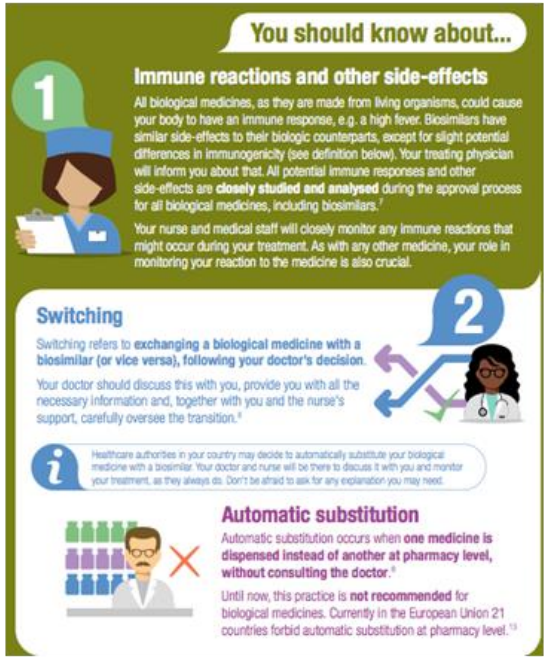
Patient Resources

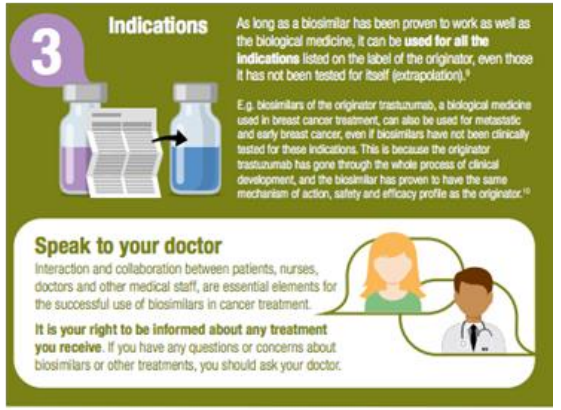
A series of resources produced by ESMO and independent sources to address patient concerns regarding biosimilars.

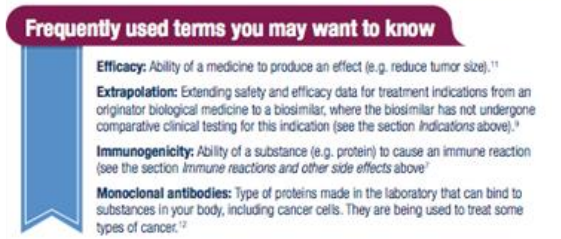
Patients' support





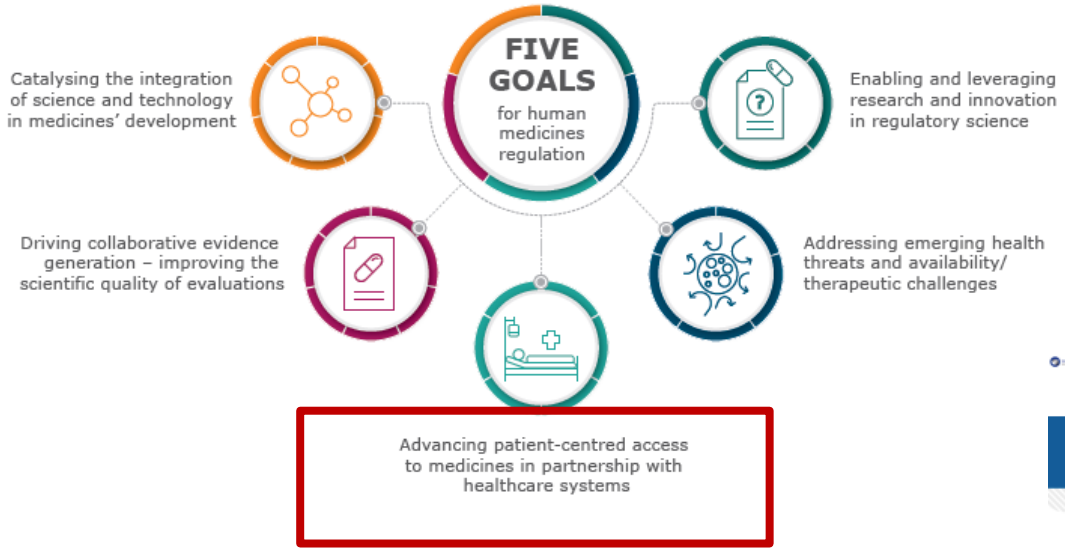


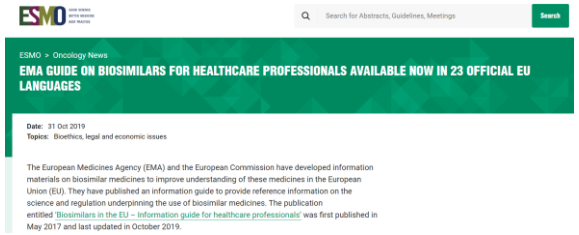


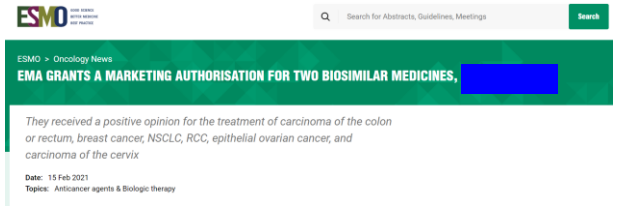


ESMO

COOPERATION with EU BODIES







Promote the availability and support uptake of biosimilars in healthcare systems

Further develop strategic communication campaigns to healthcare providers and patient organisations to reinforce trust and confidence;

Enhance training of non-EU regulators in the evaluation of biosimilars

Address regulatory challenges in manufacturing e.g., statistical assessment of CQAs in the comparability exercise and the evolution of multisource biologicals/biosimilars;

Further develop the biosimilar framework, adapting the clinical part of the development to the latest scientific knowledge concerning the comparability assessment.

And now confidence is at the extent that...

v. personal position

WHY are we still discussing the role of biosimilars and how to build confidence?

Biosimilars (as their originator) changed the natural history of many cancers

SCIENCE

Is the phase III trial validation needed?

Regulatory experience and technological advances
(high performing analytical tools)

SCIENCE

Phase III trials never added crucial information about

The most impressive enabler: equal access

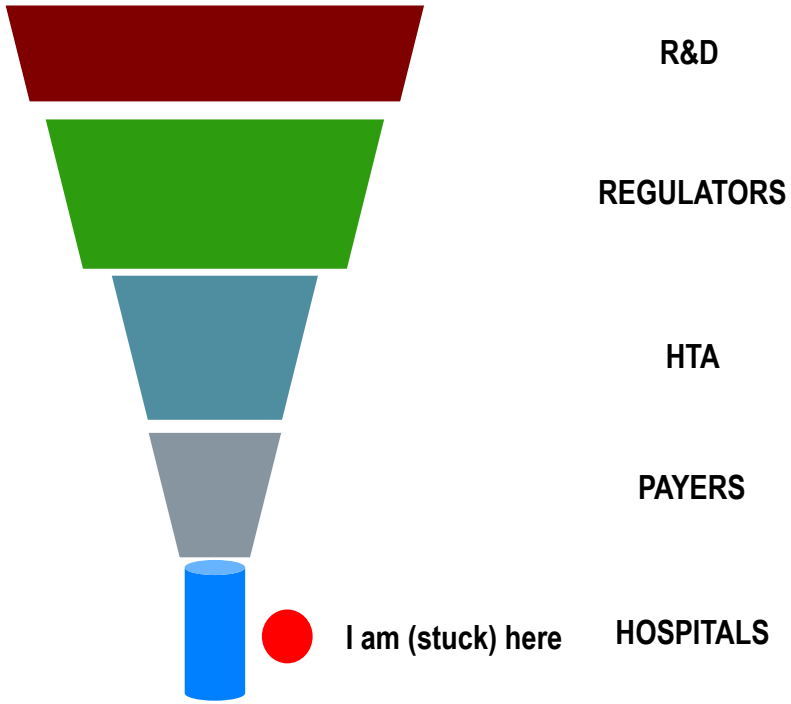
FAIRNESS

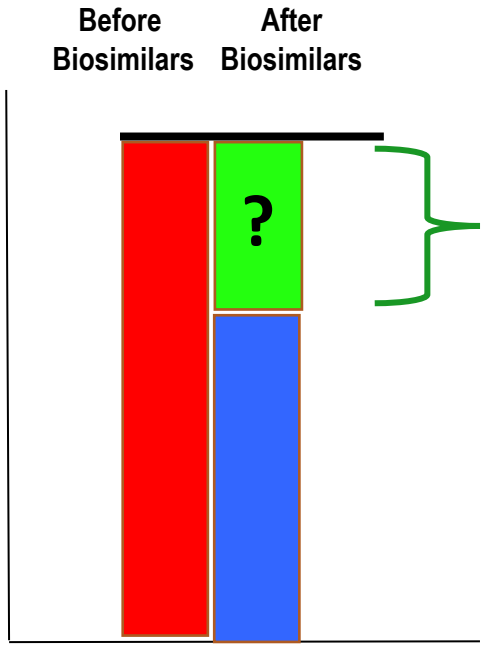
Transparency in benefit sharing plans may play as enabler

Beneficiary: patients and consumers

TRANSPARENT Re-ALLOCATION of RESOURCES

The "FUNNEL" effect





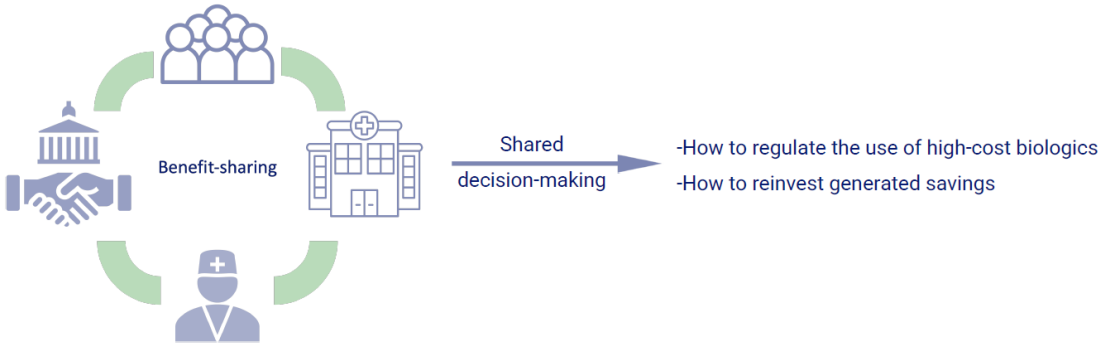
Adapted from Steinar Madsen, Biosimilar Medicines Conference 2017

Cancer services?
Cancer Drugs?
Healthcare system more in general?
Workforce?

Qualitative Analysis of the Design and Implementation of Benefit-Sharing Programs for Biologics Across Europe

Biodrugs, 2022

Teresa Barcina Lacosta[1] · Arnold G. Vulto[1,2] · Adina Turcu-Stiolica[3] · Isabelle Huys[1] · Steven Simoens[1]



TRANSPARENCY at the beginning and during the whole process

Potential outcomes to be achieved via the implementation of benefit-sharing strategies:

1. Improved value for money
2. Aligned interests for stakeholders in health care
3. Active engagement of HCPs and patients
4. Transparent redistribution and reinvestment of savings
5. Leveraged resources to: (1) address the needs of health care systems and societies at large and (2) improve patients' outcomes

Overview of recommendations

Pre-implementation phase—design

→ To present a strong benefit-sharing proposal/business case including:

A comprehensive estimation of the savings potential over the years. This estimation would depend on the evolution of prices and the number of eligible patients

A detailed analysis of resource needs to be covered by the benefit-sharing agreement

→ To establish a reasonable time frame for the agreement based on savings potential, resource needs and the future market availability of other molecules within the therapeutic area

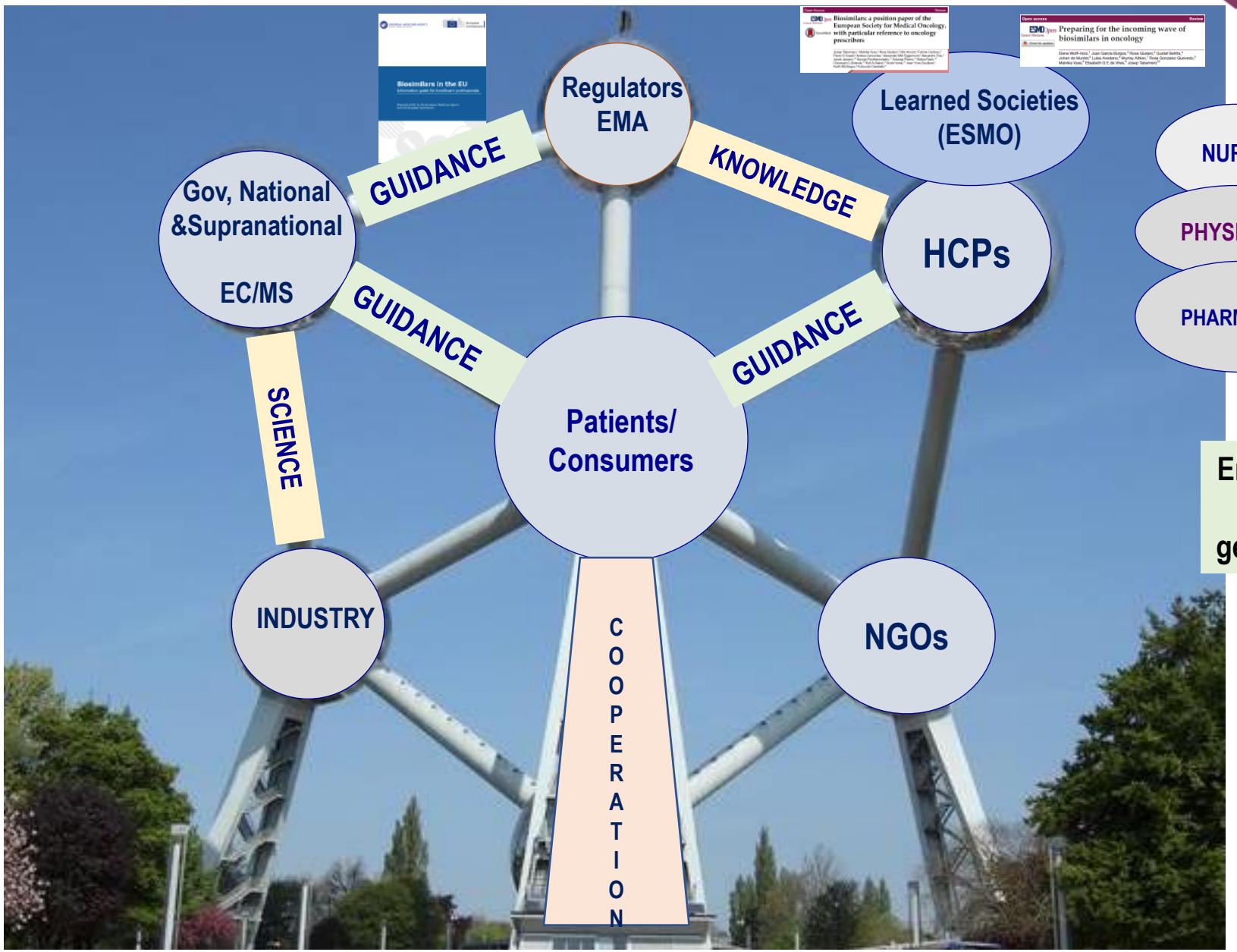
→ To clearly define (in advance) the scope of the benefit-sharing program in terms of uptake and savings objectives, resources reinvestment and expected outcomes

→ To clearly specify (in advance) who would be the direct/indirect beneficiaries of the savings reinvestment process and to establish clear pathways for the redistribution of savings

Experts recommend that a proportion of savings flows back to the clinical departments that participated in the savings generation. These department should provide a proposal for the reinvestment of savings that is impactful for the clinical service and the patients

→ To establish mechanisms able to identify factors that may affect the continuity of benefit-sharing strategies

The Biosimilar Atomium: maintaining confidence



THANK YOU FOR ATTENDING TODAY!

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Thank you for attending this session,
please do not hesitate to send any questions you may have to
esmo@esmo.org
and we will be happy to answer them.