DIGESTIVE CANCERS EUROPE

BIOSIMILAR EDUCATION IN METASTATIC COLORECTAL CANCER

BIOS23 Patients Leaders Workshop

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DIGESTIVE CANCERS EUROPE

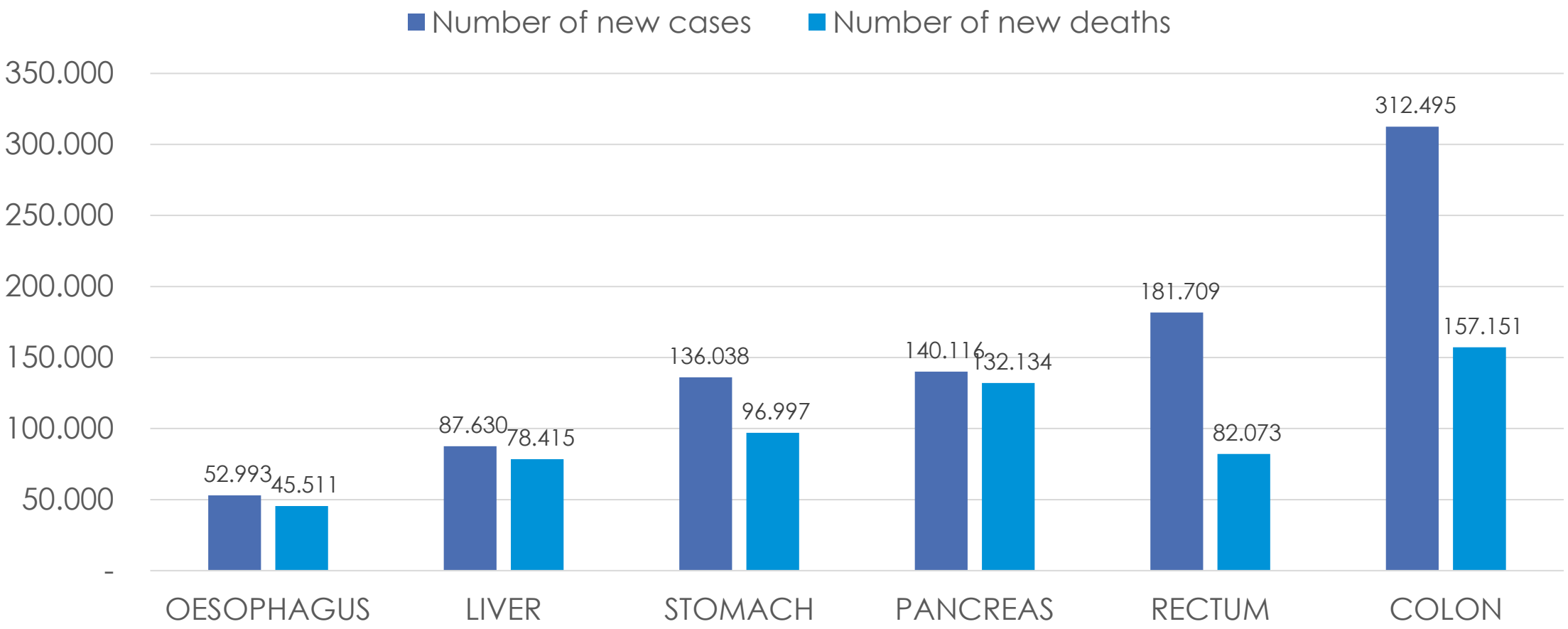
Umbrella organisation of close to 40 national Member Organisations from the WHO European Region

Representing the digestive cancer patient community diagnosed with cancer of the oesophagus, liver, stomach, pancreas, rectum, colon and other rare digestive cancers

Acting on behalf of 900.000 people who get a diagnosis of digestive cancer every year in Europe, as well as the 1,8 million digestive cancer survivors; also representing the families of the 600.000 patients who die every year from digestive cancers

www.digestivecancers.eu

Digestive Cancers in Europe



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European Cancer Information System https://ecis.jrc.ec.europa.eu © European Union, May 2022

The impact on Colorectal Cancer

- Colorectal Cancer is the **third most diagnosed cancer in men** after prostate and lung cancers and the **second one in women** after breast cancer.
- Each year, approximately 500.000 citizens in Europe are diagnosed with CRC, and about 250.000 die from the disease.
- Many of these deaths could be avoided by applying preventive practices and **screening.**
- Detection of CRC at stage 1 is associated **with 90% five-year overall survival**.
- The difference in cost between the early and late stages is probably **tenfold**, between 4.000€ and 40.000.

Colorectal Screening In Europe - Digestive Cancers Europe

Why this project was needed?

- Bevacizumab **first biosimilar** approved for CRC treatment
- Need for **proper communication** with patients
- **Misconception** that biosimilars are of less quality because of their lower price
- **Support HCP** in delivering the message

About the Project (I)

Objectives

- Improving patients and healthcare professionals' **education on biosimilars**
- Enhancing colorectal cancer **patients' role in the decision-making** process of their treatment
- **Facilitating the communication** between healthcare professionals and patients around biosimilars
- *To achieve these objectives, we worked with a multistake-holder expert group: patients, patient advocates, clinicians, nurses, industry representatives, health economists, hospital pharmacists from EU countries*

Final Outcomes

- An **information brochure** about biosimilars for patients with colorectal cancer
- A **checklist for healthcare professionals** with questions patients with colorectal cancer may have around biosimilars
- **Short presentations** for healthcare professionals around basic concepts regarding biosimilars
- A short **video** to support communication around biosimilars between a patient and a clinician
- **Social Media Toolkit** for the Biosimilars Awareness Week

https://biosimilars.education.digestivecancers.eu

BIOSIMILARS EDUCATION
by DIGESTIVE CANCERS EUROPE

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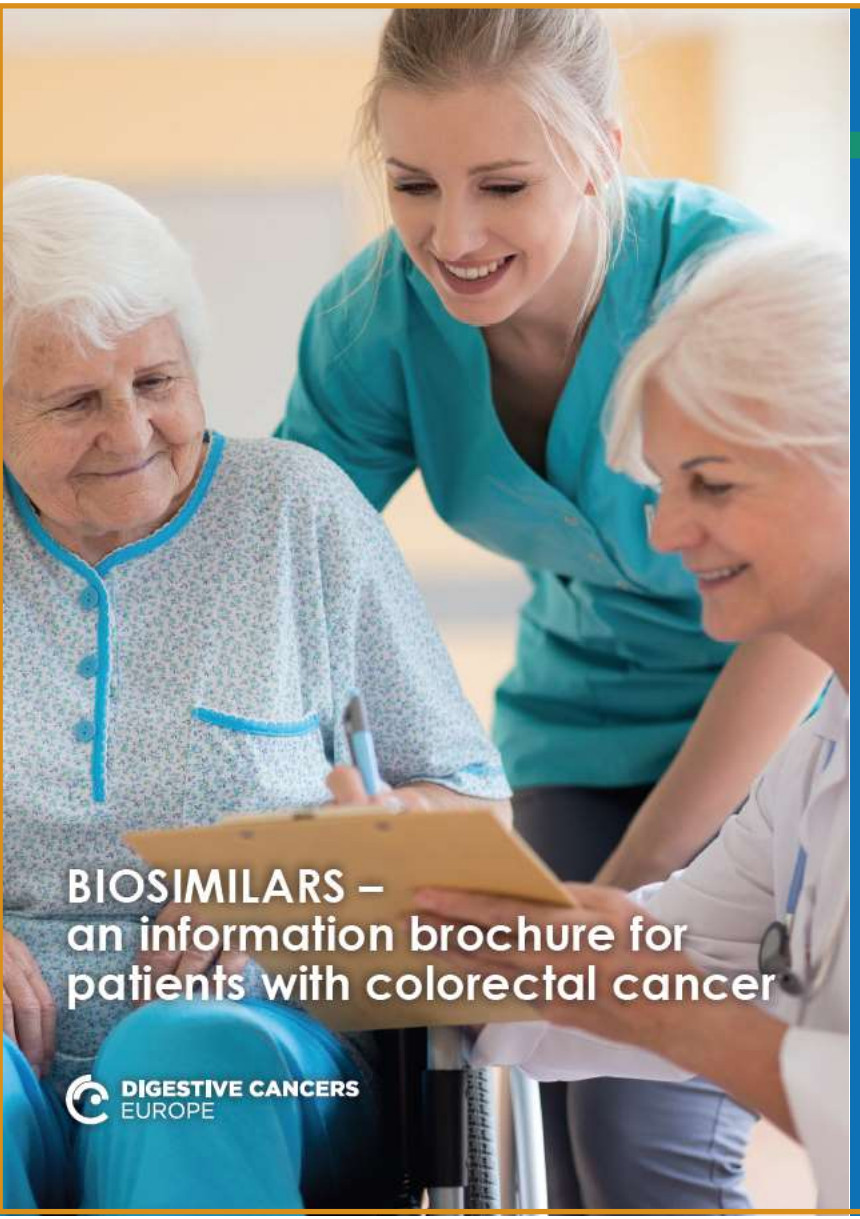
WHAT ARE
BIOSIMILAR MEDICINES?

Biosimilar medicines or biosimilars are biological medicines that contain essentially the same active substance as their originator. Although minor differences may exist, a biosimilar matches the originator in terms of quality, safety and efficacy.

All originator biological medicines are patented. This means that once launched, for a period of time that varies, no other product with the same active substance can enter the market. When this term of exclusivity rights expires, new products with the same active substance can gain market access. These new biologics must comply with the same stringent regulatory requirements and are known as biosimilars.

BIOSIMILARS AND
COLORECTAL CANCER (CRC)

The first biosimilar was approved by EMA in 2006, and since then biosimilar production and approval have grown. Currently more than 70 biosimilars have been approved by EMA, and we now have more than 15 years of positive experience with biosimilar use. In 2017, the first biosimilars for the treatment of patients with lymphoma (rituximab) and breast cancer (trastuzumab) were approved.



BIOSIMILARS – an information brochure for patients with colorectal cancer

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When colorectal cancer (CRC) has metastasised (cancer cells have spread from the colon into or other organs), a combination of chemotherapy with either **immunotherapy** or **targeted therapy** can be used as a treatment option. Immunotherapy and many types of targeted therapy rely on biologics.

What are biologics?

Biologics are big molecules produced in living cells or organisms. They have a complicated structure and are complex to manufacture.

How are biologics regulated in the European Union?

As with every medicine in Europe, each biologic undergoes rigorous and strict procedures that check and ensure the medicine's safety and efficacy.
In the European Union (EU):

A biologic is developed

A biologic must meet EMA's **regulatory requirements**, by showing that:
- ✓ it is safe for the patient
- ✓ it has the expected beneficial effect

A biologic is granted **market authorisation**

EMA continuously checks and monitors the **safety** and **effectiveness** of biologics

Efficacy: *a term that means that the medicine has the expected beneficial effect under ideal conditions (before it becomes approved)*

Effectiveness: *a term that means that the medicine has the expected effect under real-world conditions (after it becomes approved)*

European Medicines Agency: *the EU body responsible for the evaluation and supervision of all medicinal products*

Market authorisation: *the permission granted to medicinal products to become available in the EU*

Regulatory requirements: *a set of strict procedures that each medicine in Europe must meet before being approved by EMA*

Safety: *a term means that the risk that may arise from the use of the medicine is negligible compared to the therapeutic benefit*

What are biosimilars?

All **innovative** - or **originator** - medicines are **patented**, which means that during a specific period (~15–20 years) no other product with the same active substance can enter the market. When this term of exclusivity rights expires, new products with the same active substance can gain market access. This can only happen when the new products comply with the same strict regulatory requirements imposed by EMA.

In the case of biologics, these new products are known as **biosimilars** to differentiate them from the initial-patented biologics that are known as **originators. The active substance of a biosimilar is essentially the same as the originator's active substance, and the biosimilar matches the originator in terms of safety and efficacy, assessed and approved by EMA.**

Biosimilars and colorectal cancer

The first biosimilar was approved by EMA in 2006, and since then biosimilar production and approval have grown. Currently more than 70 biosimilars have been approved by EMA, and we now have more than 14 years of positive experience with biosimilar use. In 2017, the first biosimilars for patients with lymphoma (rituximab) and breast cancer (trastuzumab) were approved.

For patients with metastatic CRC (mCRC), EMA has approved a biological medicine known as **bevacizumab**, which is indicated for the treatment of mCRC in combination with chemotherapy drugs. In addition to the originator, EMA has currently (up until April 2021) approved nine bevacizumab biosimilars that can be used for the treatment of patients with mCRC.

What is the benefit of using a bevacizumab biosimilar?

For a patient, there is no additional treatment benefit or downside to using a (bevacizumab) biosimilar rather than the originator. Both types of products have undergone rigorous testing and comply with the same strict, high-standard safety and efficacy criteria set by EMA (discussed above). However, as with all biosimilars, the availability of bevacizumab biosimilars to European health systems and hospitals offers several advantages for the patient community and society, as they contribute to more **sustainable** and **affordable** healthcare systems.

- ► funding new, innovative treatments for patients, using released resources to improve patient support programs, hiring additional nurses in the hospital, or investing in new treatment and researchthey offer the opportunity for more patients to have access to biological treatments
- ► helping reduce the waiting time to be treatedhelping reduce the waiting time to be treated
- ► more patients to have access to biological treatments

BIOSIMILARS –

A guide for healthcare professionals to address any questions patients with colorectal cancer may have on biosimilars

1. What are biological medicines?

Biological medicines, also called biologics, are big molecules that are produced in living cells or organisms. They have a complicated structure and are complex to manufacture. In digestive cancers, biologics are used as **immunotherapy** and **targeted therapy treatments**.

A biologic with an active substance not previously used to treat any disease is known as an **originator**. Originators are patented, and when the patent expires, usually after some 15–20 years, other new products with the same **active substance** can enter the market. These new products are known as **biosimilars**.

2. What are biosimilars?

A **biosimilar** is a biological medicine that has essentially the same active substance and the same indication as the originator. Biosimilars match their originators in terms of quality, safety and efficacy.

3. Are biosimilars as safe and effective as the original medicines?

Yes! Biosimilars are as **safe** and **effective** as the originators. Biosimilars are assessed by the **European Medicines Agency (EMA)**, the EU body responsible for the evaluation and supervision of medicinal products, are approved if they comply with the same strict regulatory requirements applied to all biological medicines.

4. How is the safety and efficacy of biosimilars ensured?

The EMA monitors the **safety and efficacy** of biosimilars before approval and then continuously. Over the last 15 years, the EU monitoring system for safety concerns has not identified any differences in severity or frequency of treatment-related side effects between biosimilars and originators.

5. Are biosimilars the same as generics?

No. **Generics** have a simple structure and contain exact copies of chemically made active substances. Unlike generics, all biologics, including biosimilars, are made in living cells, so no two batches of any biologic are the same. This is normal and tightly controlled. Both biosimilars and generics are versions of brand-name products with the same efficacy and safety.

6. How long have biosimilars been on the market and how many biosimilars have been approved for colorectal cancer?

EMA has currently approved more than 70 biosimilars (up until September 2021).

When it comes to the treatment of metastatic colorectal cancer (mCRC), EMA initially approved a biologic originator with an active substance called **bevacizumab**. Currently, EMA has approved seven bevacizumab biosimilars (up until September 2021).

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VIDEO

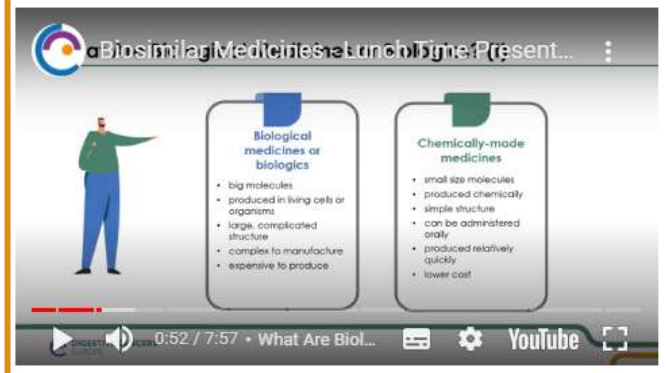
ABOUT COMMUNICATION AROUND BIOSIMILARS

ENGLISH

ESPAÑOL

VIDEO

PRESENTATIONS



Biosimilar Medicines - Lunch Time Presentation Part I

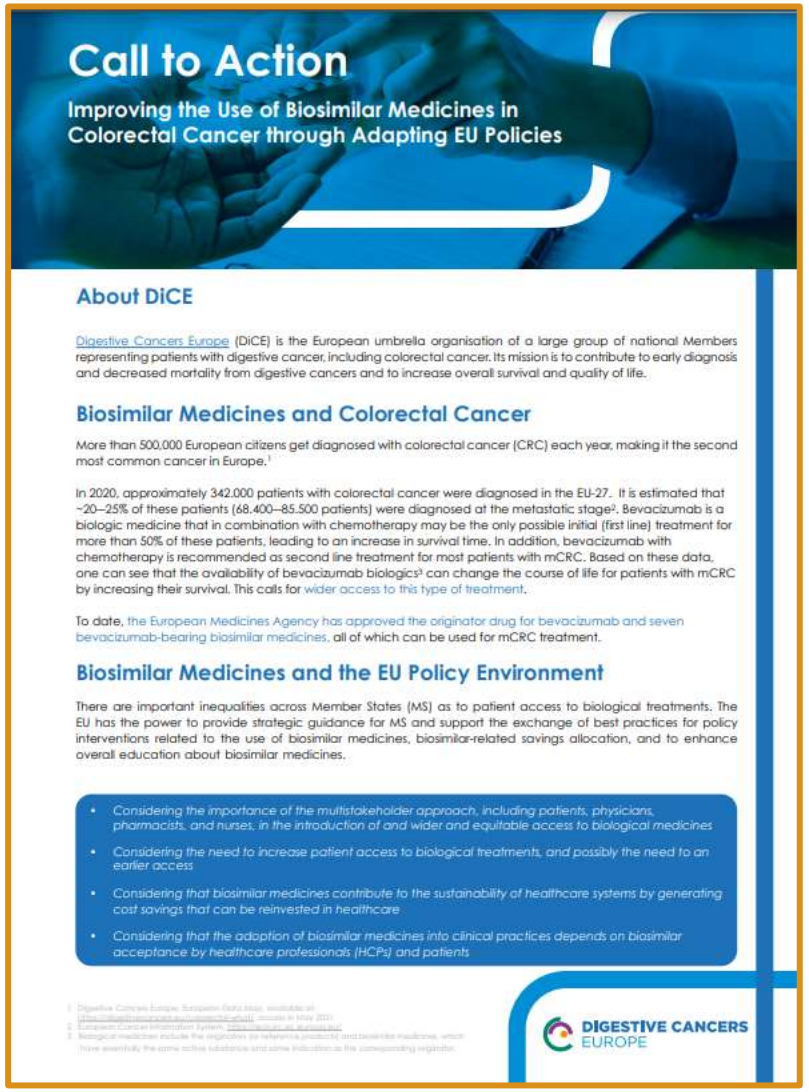
A lunch time presentation for clinicians and nurses on Biosimilar Medicines – Definitions, Development and Regulation in the EU.

Biosimilar Medicines - Lunch Time Presentation Part II

A lunch time presentation for clinicians and nurses on Biosimilar Medicines – The European Experience, Switching, Added Value, and Communication Around Biosimilars.

Policy activities

- On 28 September 2021 , we organised a **workshop** on the importance of biosimilars for patients with colorectal cancer in Europe.
- Experts from the biosimilar group presented on biosimilar on the use and its current difficulties with respect to implementation across EU Member States.
- **MEP Dolors Montserrat**, who was the rapporteur of the European Parliament's report on the Pharmaceutical Strategy, participated to share the view of the Parliament on this important topic.



Call to Action

Improving the Use of Biosimilar Medicines in Colorectal Cancer through Adapting EU Policies

About DiCE

Digestive Cancers Europe (DiCE) is the European umbrella organisation of a large group of national Members representing patients with digestive cancer, including colorectal cancer. Its mission is to contribute to early diagnosis and decreased mortality from digestive cancers and to increase overall survival and quality of life.

Biosimilar Medicines and Colorectal Cancer

More than 500,000 European citizens get diagnosed with colorectal cancer (CRC) each year, making it the second most common cancer in Europe.[1]

In 2020, approximately 342.000 patients with colorectal cancer were diagnosed in the EU-27. It is estimated that ~20–25% of these patients (68.400–85.500 patients) were diagnosed at the metastatic stage[2]. Bevacizumab is a biologic medicine that in combination with chemotherapy may be the only possible initial (first line) treatment for more than 50% of these patients, leading to an increase in survival time. In addition, bevacizumab with chemotherapy is recommended as second line treatment for most patients with mCRC. Based on these data, one can see that the availability of bevacizumab biologics[3] can change the course of life for patients with mCRC by increasing their survival. This calls for wider access to this type of treatment.

To date, the European Medicines Agency has approved the originator drug for bevacizumab and seven bevacizumab-bearing biosimilar medicines, all of which can be used for mCRC treatment.

Biosimilar Medicines and the EU Policy Environment

There are important inequalities across Member States (MS) as to patient access to biological treatments. The EU has the power to provide strategic guidance for MS and support the exchange of best practices for policy interventions related to the use of biosimilar medicines, biosimilar-related savings allocation, and to enhance overall education about biosimilar medicines.

- *Considering the importance of the multistakeholder approach, including patients, physicians, pharmacists, and nurses, in the introduction of and wider and equitable access to biological medicines*
- *Considering the need to increase patient access to biological treatments, and possibly the need to an earlier access*
- *Considering that biosimilar medicines contribute to the sustainability of healthcare systems by generating cost savings that can be reinvested in healthcare*
- *Considering that the adoption of biosimilar medicines into clinical practices depends on biosimilar acceptance by healthcare professionals (HCPs) and patients*

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Thank you for your attention

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