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*

1 Digestive Cancers Europe, European Data Map, available at: https://digestivecancers.eu/colorectal-what/, access in May 2021.
2 European Cancer Information System, https://ecis.jrc.ec.europa.eu/
3 Biological medicines include the originators (or reference products) and biosimilar medicines, which have essentially the same active substance and same indication as the corresponding originator.

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Call on the **European Commission** to

- Support transparent and tangible benefit-sharing practices across Europe.

To maximise the potential of biosimilar medicines (biosimilars), transparency practices must be promoted about the savings derived from biosimilar use and how they are allocated.

The Commission should support the tangible and transparent application of biosimilar-related saving projects, which will allow any savings arising from biosimilar prescriptions to be reinvested in the national healthcare systems. Considerable cost savings may contribute to improving patients' quality of life (QoL) and care and widening patient access to biological treatment.

- Build a dedicated Europe-wide online resource centre to support the exchange of best practices on biosimilar savings reinvestment.

In collaboration with the MS, the Commission should identify countries and hospitals where biosimilar savings are best re-allocated to address patients' needs. The centre would serve as a go-to point for other countries or individual hospitals when deciding on which are the most efficient measures to incentive biosimilars use and how to allocate saved finances, to improve patient care in a dedicated facility.

- Set up a dedicated Europe-wide online resource centre for HCPs and patients.

The adoption of biosimilars into clinical practice largely depends on the biosimilar acceptance of HCPs and patients. Since the full understanding of the value of biosimilars is crucial to gain trust in this type of medicine, HCPs and patients need to be offered continuous education, for example through an online resource centre.

When developing the centre, the Commission should use materials already developed by EU institutions (such as the EC European Medicines Agency material for patients and HCPs), EU organisations: patient organisations[4] and medical societies.

Call on the Member States to:

- Adjust national policies to ensure that biosimilar-related savings are reinvested locally in a tangible and transparent way.

As biosimilars are less expensive to develop than the originators, they can generate cost savings that can be further reinvested in the healthcare systems. Often physicians and other HCPs may not be aware of the long-term positive impact biosimilars can have on patients' QoL and care.

Savings can be invested in many ways to improve hospital services and patient care: hiring additional hospital staff, enhancing HCPs' education about the treatment, organising patient support programmes, investing in new treatments, or updating hospital equipment to administer the treatment.

To fully capitalise on the savings that arise from biosimilar use, MS should regulate national policies to ensure that these savings are re-invested in transparent and easy-to-access procedures.

4 - Informative brochure for patients with colorectal cancer on biosimilars
- A checklist with questions patients with metastatic colorectal cancer may have around biosimilars

- Introduce incentives to encourage hospitals and healthcare professionals to consider biosimilars in all purchasing processes.

Every MS should introduce or tailor the system of national-wide incentives to support the introduction or wider use of biosimilars. Incentives should focus on ensuring that savings from biosimilar competition are re-allocated back to hospitals and/or care services.

Supporting the implementation of incentives directly to a particular entity would support HCPs' understanding of the benefits of biosimilars (for instance through gain-sharing agreements). Similarly, direct reinvestment can be used to improve patient care in each healthcare setting, which would present tangible benefits for cancer patients.

- Invest in educational and communication activities for healthcare professionals and support patient organisation initiatives.

The trust in biosimilars and the full understanding of their societal benefits represent one of many barriers to biosimilar uptake. In collaboration with medical societies, the Member States should organise events dedicated to scientific evidence on biologics, including biosimilars, as well as establish guidelines on how to clearly communicate to patients the often-complicated language on this form of treatment.

In collaboration with patient organisations, the governments should support hospitals in creating patient-targeted educational programmes – both for patients and their families.

- Invest in the creation of national patient data bases.

Biosimilars entrance into the marketplace may impact on the treatment paradigm of cancer and other diseases. Indeed, having an earlier access to treatment, treating other forms of the disease, etc. may uncover further benefits of a specific drug. Hence creating a large database that collect patient information will revert into more efficacious and efficient treatments.

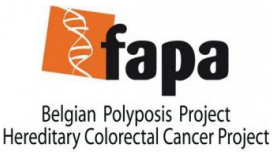
Call on all **other stakeholders to**

- Support patient organisations in raising overall awareness about biosimilars.

Patients have a right to receive clear information, if they wish, about biosimilars, and how they help their treatment. This will help patients to consider a personalised approach to their treatment and enable an active and informed role in the decision-making about their treatment.

We urge all stakeholders, involved in the topic of biosimilars, to actively call on the MS to organise communication campaigns to reinforce patients' knowledge, acceptance and trust in biosimilar medicines.

The recommendations received the endorsement of the following stakeholder groups, including DiCE Patient Organisations:



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