National Clinical Programme for Gastroenterology & Hepatology

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

BIOSIMILARS

PATIENT INFORMATION

ISCC Irish Society for Colitis & Crohn's Disease

BIOSIMILARS

A biosimilar medicine is a highly similar but not identical copy of an originator biological 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 biological counterpart because of the complex production process needed for these medicines. Like 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 difference 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 has to show that it is 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.

Biosimilar infliximab was introduced in Ireland for IBD in 2014 and has been in widespread use in hospitals since then. Now, there is increasing availability of new biosimilars for patients with IBD in Ireland, including self-administered sub-cutaneous adalimumab. Biosimilar versions of other biologic drugs in IBD are likely to become available in the future.

ARE BIOSIMILAR MEDICINES THE SAME AS GENERIC MEDICINES?

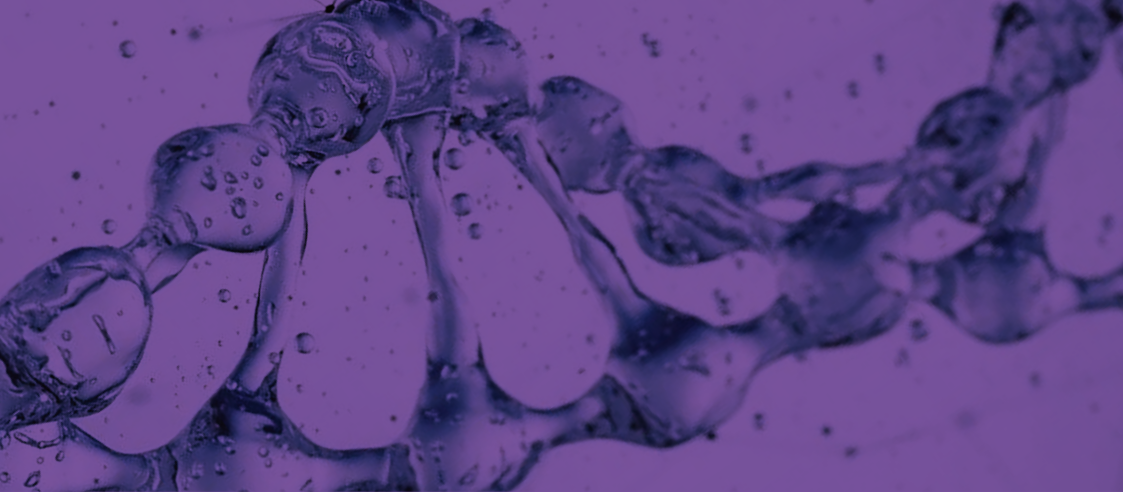
No. Generics are small-molecule drugs made from synthesised chemicals that can be easily replicated, whereas biosimilars of biological medicine are much larger, complex molecules derived from living cells.

BIOSIMILARS IN IRELAND

Since 2016 the HSE Medicines Management Programme (MMP) has supported the appropriate introduction of subcutaneous biosimilars into clinical use in Ireland to enable safe and effective prescribing, while also promoting cost-effective initiatives.

In 2018, the MMP started a process to evaluate therapeutic areas where there is potential for biosimilar medicines to be introduced to allow for their safe, effective and cost-effective use. In deciding on the best-value biological (BVB) medicine, the MMP invited submissions from all relevant stakeholders including clinicians, professional bodies and the pharmaceutical industry to the process.

What this means is that when clinicians look to prescribe treatments for patients with IBD, these will be considered to be the best-value treatments. Overall by carrying out the BVB process and its implementation by clinicans, this will lead to significant savings for the health service.



NEW PATIENTS

From 1st February 2020, it is HSE policy that adult patients who are commencing treatment with adalimumab will be prescribed a BVB medicine.

A new patient is an adult, who has never been prescribed treatments before, or has not received these medicines within the last six months.

EXISTING PATIENTS

There is currently no change for existing patients. They will continue to receive their medicines under the high tech arrangement from their pharmacy.

However, according to HSE policy, when existing patients present for a repeat prescription for adalimumab, the patient should be considered for switching to a BVB medicine. The decision to switch a patient to a biosimilar rests with the clinician; where it is clinically appropriate and in consultation with individual patients. Those that switch to a biosimilar are expected to have the same response as if they had stayed on the originator biological medicine.

HOW ARE BIOSIMILARS ADMINISTERED?

Generally biosimilars need to be given by infusion (intravenous or IV) in a hospital which may take several hours, or self-injected, using a needle and syringe or pen. This means, they are administered in the same way as originator biological medicines.

This leaflet has been prepared with the assistance of the IBD Working Group of the National Clinical Programme for Gastroenterology and Hepatology (NCPG&H).

The National Clinical Programme for Gastroenterology & Hepatology (NCPG&H)

National Clinical & Integrated Care Programmes
Person-centred, co-ordinated care

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

The NCPG&H was established in October 2019 as a collaboration between the HSE and the Royal College of Physicians of Ireland. Working in partnership with patients, nursing, health and social care professionals and relevant stakeholders, the programme sets out to develop and design a patient-centred model of care, clinical pathways and guidelines for gastroenterology and hepatology services. The NCPG&H reports to the National Clinical Advisor and Group Lead for Acute Operations, HSE. Multi-disciplinary working groups deliver the work of the programme. This work is overseen by a Clinical Advisory Group set up by the Royal College of Physicians of Ireland.

ISCC Irish Society for Colitis & Crohn's Disease

The Irish Society for Colitis and Crohn's Disease (ISCC) is a support organisation in Ireland for people who are living with, or impacted by, Crohn's disease or ulcerative colitis (collectively known as Inflammatory Bowel Disease or IBD). We are here to support people who are living with IBD, along with their parents, partners, family and friends. We work to improve the quality of life and well-being of the IBD community through sensitive support services, including advocacy, provision of information, training and events. We aim to encourage and educate healthcare professionals in the importance and value of peer support as an adjunct to their management of IBD.

Our mission: To improve the quality of life and well-being of those living with and impacted by IBD, through sensitive support services, including advocacy, the provision of information, training and events.
Our vision: We aim to be a patient-centred and trusted hub of the IBD community in Ireland.

The Irish Society for Colitis and Crohn's Disease
Carmichael Centre
North Brunswick Street
Dublin
D07 RHA8

Support line: (01) 531 2983

To find out more or to become a member check out our website **www.iscc.ie**

info@iscc.ie
ISCCIRL
Irish Society for Colitis and Crohns Disease - ISCC
@iscc_colitis_crohnsdisease

Print by Conmore Press **056 7767692**