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MEDICAL AID SOCIETY

THERAPEUTIC EQUIVALENTS

Similar drugs, same benefits?

In the ever-evolving landscape of pharmaceuticals, understanding the distinctions between originator medicines and their varying pharmaceutical equivalents (i.e., generics and biosimilars) can be very confusing. These equivalents have become essential in improving access to affordable medicines, by offering cost-effective alternatives to brand-name originator drugs, without compromising quality of care.

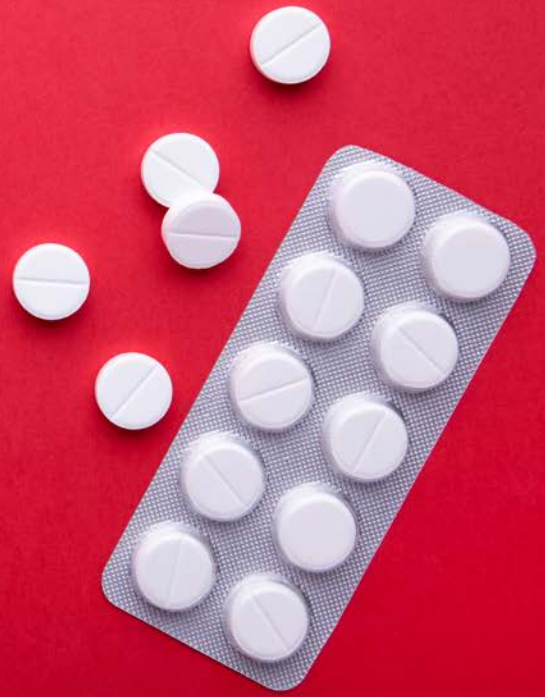
Generics and biosimilars are both considered therapeutic equivalents to the brand-name originator products. However, they differ significantly in terms of their medicinal categorisation, their origins, manufacturing processes and their interchangeability.

This booklet aims to demystify the differences and highlight the unique benefits and regulatory pathways of each, to help you make informed decisions about medicine options.

GENERIC MEDICINES:

Generic medicines are chemically produced molecules and considered to be identical to their brand-name counterparts in terms of active pharmaceutical ingredients (API), dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. For regulatory bodies to approve a generic for the market, the generic company needs to demonstrate therapeutic equivalence (i.e., same clinical effect and safety profile) to the originator product.

Intensive testing for generic manufacturing is primarily aimed at demonstrating bioequivalence. This focus on bioequivalence allows generic companies to bypass the extensive initial research and development studies required for novel (originator) medicines. As a result, significant cost savings are achieved, enabling generics to enter the market at much lower prices compared to their branded counterparts. Originator manufacturers protect their investments and recover research and development costs by holding product patents that prohibit the launch of generics for a limited period.



THERE ARE 3 TYPES OF GENERICS:

Clones

These drugs are identical in all apects to the originator drug, except for the tradename and packaging. Clones are often manufactured by the same company as the originator product.

Licensed generic

These drugs have the same formulation as the originator but are made by a different manufacturer.

True generic

A true generic has the same active ingredient as the originator, but has different inactive ingredients (sugar, flavour, preservatives etc.).

WHAT ARE BIOLOGICAL MEDICINES?

Biological products encompass a variety of complex substances produced from living organisms or containing components of living organisms. These substances can come from humans, animals, or microorganisms and are used in the prevention, diagnosis, and treatment of many diseases. Biological products work by mimicking or enhancing the body's natural processes. These highly specialised molecules are designed to target very specific cells, to change or enhance the immune system to treat various diseases.

EXAMPLES OF BIOLOGICALS:

- **Blood and blood components:** Used for blood transfusions and to replace elements of the blood that are missing or at low levels due to injury / illness.
- **Monoclonal antibodies:** Used for treating autoimmune diseases like rheumatoid arthritis and inflammatory bowel disease, and some cancers.
- **Immunomodulators:** Such as beta-interferon, which is used in the treatment of multiple sclerosis.
- **Recombinant proteins:** Used in various conditions like certain cancers, type 2 diabetes, and in some rare conditions.
- **Vaccines:** Administered to both children and adults to prevent numerous diseases.

Biological products play a crucial role in modern medicine, offering targeted treatments that enhance the body's natural defences and improve patient outcomes. However, these complex molecules come with a higher price tag, often limiting access.

Due to the complex biological nature of these molecules, generic substitution does not apply. Instead, therapeutically similar biosimilars have entered the market. These biosimilars are highly similar to their reference originator product but cannot be classified as identical. The launch of biosimilars following the expiry of product patents has ushered in an era of cost-saving alternatives, with the potential of improving access to treatments.

WHEN ARE PHARMACISTS ALLOWED TO SUBSTITUTE MEDICINE?

Pharmacists are allowed to substitute the originator product with a generic equivalent and an updated prescription from the treating doctor is not required. According to the South African Pharmacy Council (SAPC), pharmacists are obliged to offer and encourage the substitution to less costly generic medicines, unless specifically declined by the patient.

Biosimilars are subject to different regulations in terms of substitution as these are deemed to be highly similar and not identical to the originator. Pharmacists are therefore not allowed to substitute the originator for a biosimilar at dispensing level without consultation with the treating provider.

Understanding the differences between originator molecules, generics and biosimilars is crucial for making informed healthcare decisions. There is often a misconception that the originator is superior in terms of efficacy and safety; however, generics and biosimilars offer a safe, cost-effective alternative for patients and healthcare providers. Speak to your healthcare provider about your options and remember that your pharmacist may need to engage your healthcare provider about making a substitution.

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