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Generic medicines - The cost-effective copycat

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A hundred-million prescriptions are filled for generic medicines in South Africa per annum. This equates to 78% of the generics market opting for a far more cost-effective drug where the pharmacological effects are exactly the same as those of their brand-name counterparts.

The WHO definition of generics

Gerhard van Emmenis, Principal Officer of Bonitas Medical Fund, says, "The World Health Organisation (WHO) defines generics to mean a pharmaceutical product which: is usually intended to be interchangeable with an innovator product, manufactured without a licence from the innovator company, and is marketed after the expiry date of the patent or other exclusive rights."

The costs

The road to the development of new pharmaceuticals is long and complex. Not to mention exorbitant. It generally takes 15-20 years to develop new chemical entities and capital outlay varies between US$800 million to US$2 billion. This equates to several billions in South African rands.

Why so long?

New chemical entities need to go through stringent tests before approval, including research and development. During pre-clinical and clinical studies of any 10,000 new chemical entities investigated to potentially treat a disease, only 510 will qualify for testing on humans and only one or two will make it to the market. Taking on the development of new drug is not for the faint-hearted or companies short of capital reserves.

The cost for biological drugs is even bigger and takes much longer. These large complicated molecules are manufactured from living organisms, often using genetics. Biological drugs are used to produce the latest cancer therapies, vaccines and blood treatments. For this reason biosimilars are not equivalent to the innovator biologic because their chemical characteristics cannot be precisely duplicated during the manufacturing process as they are made from living things which causes natural variability. There can even be variability between different batches of the same biologic medicine.

Protecting return on investment

It makes sense then that the originator companies need to protect their investments in the form of patent protection. This means that the developing pharmaceutical company has exclusive rights and owns the intellectual property of the drug for a pre-determined number of years. These are patent-protected - ostensibly to allow for recovering of costs.

A patent grant generally protects a medicine for around 12 years, from copycat versions (generics) to be registered. In practical terms, this could mean that a product only has five to eight years on the market with patent protection, because it takes so long to register.

In order to exend patents, pharmaceuticals do employ a process called "evergreening". By making minor adjustments to the active pharmaceutical ingredient (API) to obtain secondary patents. This includes developing slow release versions of the same API or a different way of administering it for example subcutaneous vs intravenous administration.

The cost-effective copycat

After the patent has expired other drug companies can make the generic equivalent without the initial clinical research costs. These generics are copies of the brand-name drugs and have exactly the same dosage, intended use, effects, side effects, route of administration, risks, safety and strength as the original drug. "In other words," says Van Emmenis, "their pharmacological effects are exactly the same as those of their brand-name counterparts."

But considering that another pharmaceutical company has done the spadework, it makes sense that generics are marketed at a fraction of the price of the originator. Often the pharmaceutical company that made the original drug also manufacture a generic, or clone, in their own factory, selling it under a different brand name. In this way they capture the original medicine market and the generic.

What guarantee is there that generics are true replicas?

The SA Health Products Regulatory Authority (SAHPRA) which took over from the Medical Control Council (MCC) in 2018, carries the responsibility of making sure that generic drugs are safe and effective. Generic manufacturers have to prove their medicine is bioequivalent to the innovator brand before a product is allowed into the local market.

Why do some patients believe that generics don't work?

"Even though generic drugs have been around for more than half a century, many patients are unreasonably suspicious of what is, in essence, a 'carbon copy' of the original brand of drug or medicine," explains Van Emmenis. "We believe it may be because consumers believe that if they are cheaper they must be inferior. This lack of understanding costs consumers and medical aids millions of rands each year."

The Pharmacy Act of 1997 and the Medicines Control Amendment Act, among others, have made it mandatory for dispensers of medicine, be they doctors or pharmacists, to offer the patient a generic substitute if one is available.

"The patient is under no obligation to accept the generic," says Van Emmenis, "but most do as financial implications, regardless of whether you are on medical aid or not, are significant."

Pharmacy Direct, a courier pharmacy for chronic medicine that is a designated service provider for Bonitas, offers patients generic equivalents when available. This is explained and patients are assured that they can change to the originator if they are dissatisfied with the generic. However, as there are often many different generics available, no pharmacy can possibly stock all generic brands.

Using generic medicines has a knock-on effect for both consumers and the healthcare industry in general. Generic use can help to lower the costs of healthcare, especially in the case of chronic medicines. From a consumer perspective, using generic medicine for acute illnesses and over-the-counter medicine can help stretch your money and medical aid benefits even further. "The recent VAT increase has led to an increase in prices for most goods and commodities including healthcare services, using generics will give consumers more value for money," Van Emmenis says.

"Generics are a way of saving millions on healthcare costs in South Africa and more specifically making your medical aid go so much further and work better for you," says Van Emmenis. "Ultimately, using generics means generous savings for consumers and is consistent with government's overarching goal of health reform."

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