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Media release

Drug company scaremongering, says Pharmac

People can be confident a generic version of a widely-used gastrointestinal drug will work just as well as the medicine it is replacing, says PHARMAC.

PHARMAC's Medical Director Dr Peter Moodie labels claims by pharmaceutical company AstraZeneca as scaremongering, motivated by the company losing the market for its product. AstraZeneca is putting out incorrect information, including overstating the number of patients taking its product, and citing an unrelated medicine change from several years ago.

The patent for Losec (omeprazole), one of the proton pump inhibitor (PPI) drugs used to treat indigestion, reflux and stomach ulcers, has expired and PHARMAC has run a competitive process to continue funding omeprazole. Following that process, PHARMAC has awarded sole supply to the Dr Reddy's Omeprazole brand from 1 May next year.

Omeprazole is taken by about 370,000 New Zealanders.

"We ask companies to compete and AstraZeneca failed to match the offer of its competitors," says Dr Moodie. "Quite simply they have priced themselves out of the market."

"Medsafe, the regulatory body for medicines in New Zealand, has thoroughly assessed and reviewed all the different brands of omeprazole, including Dr Reddy's Omeprazole, and consider them to be bioequivalent. This means they work the same way, contain the same amount of active ingredient, and are absorbed into the body the same way. So people can be confident that the new brand will work for them just as well as Losec."

Moving to a generic once the patent had expired is standard practice, not just in New Zealand but around the world, says Dr Moodie.

"Paying less for the same medicine – in this case a \$29 million saving over five years – means we have more funds available for other new medicines. This is a classic example of where commercial interest does not equate with the public interest."

It is also unfortunate that AstraZeneca is making an issue that the new drug is made in India.

"No matter where a drug comes from, it needs to demonstrate it's of good quality, effective and safe. From both PHARMAC's, and Medsafe's, point of view, Dr Reddy's Omeprazole meets these standards, so the country of origin isn't an issue."

"Many funded drugs are already sourced from India, and are trusted by New Zealanders. AstraZeneca itself sources pharmaceutical materials from India, as do other large pharmaceutical companies."

Dr Moodie points out that AstraZeneca will continue to promote Losec, and is attempting to preserve a market for its product.

"You don't have to look very hard to see their self-interest," he says.

"If they want to keep selling their product, that's fine. But it's not acceptable for them to shake people's confidence in a medicine they can have confidence in."

PHARMAC carefully considers what medicines it chooses to tender for sole supply, including taking expert clinical advice and consulting with interested parties on what products are tendered.

ENDS

Further information

What is a 'generic' medicine?

Generally the first version of a type of medicine that is sold in the world is called the 'innovator' and it is often referred to by its brand name. The original branded name medicine often enjoys a period of "market exclusivity" or monopoly where it is the only medicine of that kind that can be sold in a country; and this monopoly lasts for the period of any patent on the medicine.

A generic medicine is a copy of the original brand name medicine. A generic must contain the same active ingredient(s) as the original medicine. Because a generic medicine acts in the same way in the human body, it should be interchangeable with the original product. Generic medicines are generally launched when the original product's patent has expired.

Many of the medicines introduced by generic manufacturers have already been sold in New Zealand for a decade or more, and may already be well-known to patients and health service providers (although often under their branded name).

Generic medicines are increasingly used by general practitioners, specialists and hospitals as equally effective alternatives to higher-priced originator branded name medicines.

Is there a difference between generic medicines and originator medicines?

Generic medicines must contain the same active ingredients as the original brand name medicine and they must act in the same way on patients. Equivalent generic medicines may contain different non-active ingredients (such as starches, colourings, sugars, etc) and they may differ in size, colour or shape, but none of these differences should have any impact on the way they work in your body.

In some cases, there may be differences in the salts and esters (chemical compounds) of the active ingredients used in generics as compared with the originators. Again, these differences must not affect the therapeutic equivalence between the generic medicine and the original brand name medicine, that is, the generic medicine should work in the same way.

Who checks the quality, safety and efficacy of generic medicines?

Medsafe, part of the Ministry of Health, is responsible for giving consent to the sale of medicines in New Zealand and thus for checking the quality, safety and efficacy of those medicines.

To become registered for use in New Zealand, the generic manufacturer must satisfy Medsafe that a generic medicine is 'bioequivalent' to the original product— it must prove that the generic works in essentially the same way as the original brand name medicine in the patient's body. Generic medicines are subject to the same checks as originator medicines and are carefully scrutinised by Medsafe.

Medsafe makes medicine safety data sheets freely available online which anyone can view. A medicine safety data sheet is a document that is created in relation to each medicine registered for use in New Zealand, which describes the specific generic or original brand name medicine, its uses, dosage, warnings and precautions, adverse effects, the name and address of the supplier, along with other useful information.

Medsafe's website is: www.medsafe.govt.nz.

Are generic medicines really as good as the original branded medicines?

Generic medicines must comply with exactly the same standards of quality, safety and efficacy as other medicinal products. They are produced in factories that must be accredited by Medsafe and those factories must produce the medicines in accordance with what is known as "GMP" or "Good Manufacturing Practice". And, as with original products, once a generic medicine is sold in New Zealand, it is subject to the same monitoring processes as all other medicines in New Zealand

What about generics from developing countries like India?

India is a significant source of active pharmaceutical ingredients for many original and generic pharmaceutical companies. These active ingredients are ultimately used to manufacture the final dose form (i.e. a tablet, injection, ointment or inhaler) of a medicine (either in India or in other countries).

It's not just generics that are manufactured in India. For some time a number of medicines sold in New Zealand, whether generic or an original brand name, have been manufactured in India.

Factories where medicines are manufactured and supplied to developed countries are regularly audited by regulatory teams, either from New Zealand or other developed countries.

Are generic medicines less expensive?

Yes, and the savings can be significant. Generic medicines can cost up to 90% less than the first price of their original brand-name equivalents. This is because generic manufacturers do not incur the cost of research to discover new medicines and do not need to conduct the full range of clinical trials as the originator. In addition to the difference in pricing between a generic medicine and the original brand-name medicine, competition from rival generic medicines can sometimes force originators to reduce their own medicine prices after — or sometimes before — patent expiry.

How do generic medicines benefit patients and our national healthcare system?

When we use generic medicines, our national healthcare system saves considerable sums of money — many millions of dollars. This frees up money to pay for other medicines, or other treatments and services that patients' may need, such as operations. Generic competition also acts as an important stimulus for originator companies to focus on new research to create new medicines.

How many years does a patent last on an original brand pharmaceutical product?

As in other industries the standard patent duration is 20 years from the date of filing of the patent. Many medicines are not ready for marketing or sale for a number of years after the patent was first filed.

How does PHARMAC choose a generic medicine?

Every year, we run tenders for off-patent medicines; – those medicines where there are several generic alternatives available – inviting all suppliers (including generic and original brand name manufacturers) to submit bids for the sole subsidised supply of a generic medicine within New Zealand.

The decision to tender a medicine is not made lightly and is reviewed by PHARMAC's clinical committees and also widely consulted upon.

When the tender closes, our specialist clinical advisory group, the Tender Medical Committee, carefully assesses tender responses and advise on whether bids should be accepted. The Tender Medical Committee's recommendations are then considered by our main clinical advisory committee (PTAC – the Pharmacology & Therapeutics Advisory Committee), which makes its recommendation to PHARMAC. Final decisions are made by the PHARMAC Board. This way, many clinical and medical specialists give their views on the appropriateness of subsidising certain generic medicines before a decision is made.

Why does PHARMAC use sole supply tendering for medicine?

One of the key mechanisms by which PHARMAC is able to achieve significant savings is by tendering for sole subsidised supply of a medicine. By definition, this means that the successful tender bidder will be the only subsidised supplier of the tendered medicine for up to a three year period. Without that incentive, PHARMAC is not able to negotiate savings to the magnitude that the tender achieves, in order to then reinvest those savings in additional medicines.