



Generics changes

Generics are an established part of the New Zealand medicines landscape and have been in use for many years. Generic (off-patent) medicines become available when the patent on a branded medicine expires. This means other manufacturers can make the same chemical (generic medicine) in competition.

In New Zealand more than 50% of all medicines dispensed are generics. This is a similar pattern to other countries. For example, in the United States 56% of medicines are dispensed as generics.

Despite their prevalence, some people continue to be suspicious about generics, in New Zealand and internationally. An article published in the Journal of the American Medical Association in December 2008 (Kesselheim, Misono, Lee et al), looked at studies comparing generic and brand name medicines used to treat cardiovascular disease. The study authors found that branded and generic drugs were clinically equivalent – including those with a narrow therapeutic index. However, the study noted that many editorials continued to advise against changing from branded to generic. The authors commented: “Evidence does not support the notion that brand-name drugs used in cardiovascular disease are superior to generic drugs”.



In Australia, its consumer watchdog organisation Choice has advised people that generics hold no cause for alarm. Choice assures that the generic drugs contain the same active ingredients, and must meet the same standards for safety and efficacy as branded drugs.

The same applies in New Zealand. The Government's medicines regulator Medsafe decides if a medicine is safe and effective for use in New Zealand. To make this decision, Medsafe examines data to ensure the medicine contains the same level of active ingredient, and that it is used in the body the same way as the branded product (the technical term is 'bioequivalence').

PHARMAC also thinks carefully about which generic medicines to fund, and takes advice from a committee that includes doctors and pharmacists. When it does decide to change a medicine brand, PHARMAC can provide support for health professionals and information for patients to help them adjust.

There is also an established medicines surveillance programme to keep track of any adverse reactions people might experience. This programme, managed by Medsafe using the Centre for Adverse Reactions Monitoring, can identify areas of concern so that action can be taken if required.

Wholesaler Uplift Fee

A number of very widely used medicines are currently undergoing brand changes, to generic versions. Some of these have been subject to rebate payments, which means the price published in the Pharmaceutical Schedule is higher than the actual price. However, because pharmacists and pharmacy wholesalers' mark-ups are based on the Schedule price, the price reduction of the generics means there will be a loss of income in the pharmacy supply chain, which may be passed on to patients.

To address this in the immediate term, PHARMAC has worked with the Pharmacy Guild and District Health Boards to develop a mechanism to reinvest the reductions in mark-ups incurred throughout 2009 back into community pharmacy. The payments will be made until August 2009. From September onwards payment will continue by cheque or through a 'Wholesaler Uplift Fee' which is an additional subsidy on certain products.

The payments are not from the pharmaceutical budget. The payments are being made by DHBs from the funding they use for distribution fees. PHARMAC is assisting DHBs to make payments.

Information for consumers

Before Christmas we published two documents that provide better information for people about PHARMAC.

Information Sheets – these summarise various aspects of PHARMAC's business and are designed to be user-friendly guides to PHARMAC for a wide audience. Topics covered include how the pharmaceutical budget is set and managed, how PHARMAC decides which medicines to fund, how PHARMAC helps ensure continued supply of medicines, and a guide to the Pharmaceutical Schedule.

Getting involved in PHARMAC decisions – this document outlines how people can engage with PHARMAC around its funding decisions, from making funding applications to making consultation submissions.

Both these publications are available on the PHARMAC website www.pharmac.govt.nz; and the Information Sheets are available both as a booklet, or individually by subject.

Setting the Pharmaceutical Budget

We have begun working with District Health Boards to set the pharmaceutical budget for 2009-10 and beyond. The new Government has signaled a desire to inject \$40 million of new spending into pharmaceuticals, and this will form part of the budget-setting process.

The first step is for us to discuss our forecasts of expenditure growth with DHBs, who hold the funds, so they can balance these forecasts with other competing demands. Once decided, PHARMAC and DHBs take a recommendation to the Minister, who sets the budget.

Demand for pharmaceuticals continues to rise, and this drives up the cost of funded medicines each year, even before we can consider new investments. This eats into budget increases and reduces the amount available for new investments. To help counter this, PHARMAC also runs savings programmes like the annual tender.





**ONE HEART
MANY LIVES**

Improving heart health

PHARMAC's campaign to improve men's heart health continues to expand. It is currently running in conjunction with District Health Boards in Hawke's Bay, Northland and Lakes DHB regions. In Northland, it has produced an award-winning programme called the Bro Files, developed by the Kaitiāia-based Te Hauora O Te Hiku O Te Ika Trust.

In early February PHARMAC teamed with the Heart Foundation, Quitline, Te Hotu Manawa Maori and others at the Te Ra o te Raukura festival in Lower Hutt. The One Heart Many Lives programme offered free heart checks to men, and advice on how to manage heart risk. The stand was extremely popular with queues throughout the day for the 90-minute heart check process.

Isotretinoin access widening

People with severe acne will be able to get the drug isotretinoin subsidised through their GP from 1 March.

The decision to widen access has been made with full awareness of patient safety issues. Isotretinoin is potentially dangerous, with a range of side effects including risks for pregnant women, and there is ongoing debate around the evidence of increased risk of suicidal ideation.

Up until now, isotretinoin has only been available subsidised through a dermatologist. This had created equity of access issues, because not all potential patients could afford, or had access to, a specialist dermatologist. This was particularly the case for people in lower socio-economic areas.

To support the access change, doctors will have information provided through the Best Practice Advocacy Centre (bpacnz), and through PHARMAC's Seminar Series. We have also worked with the College of General Practitioners to provide information and training to GPs, including as part of their continuing medical education.

PHARMAC expects the decision will probably lead to a 5-10% increase in the use of isotretinoin, possibly translating to an increase in spending of \$55,000 to \$100,000 per year.

PHARMAC
Pharmaceutical Management Agency

PHARMAC is the Government agency responsible for deciding which medicines are subsidised for New Zealanders. It manages spending on pharmaceuticals for the District Health Boards, and ensures that a comprehensive list of medicines (the Pharmaceutical Schedule) is subsidised for New Zealanders, and that the list of medicines continues to grow to meet the needs of patients.

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