MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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Michelle Sullivan
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Dear Michelle

Re: PHARMAC brand switch to generic octreotide

Thank you for your letter informing Medsafe of your concerns about the brand change for octreotide. I appreciate that medicine brand changes can be a significant source of uncertainty for patients, especially for vulnerable people like those with neuroendocrine cancers.

As you are aware, Medsafe is not involved in funding decisions for medicines. However, I would like to comment on Medsafe approval of generic products such as Octreotide Depot Teva, and Medsafe monitoring of the safety profile of medicines.

As you have alluded to in your letter, Medsafe requires bioequivalence studies as evidence that there is no significant difference in bioavailability between generic medicines and corresponding innovator medicines. These studies are performed in healthy volunteers to measure the rate and extent of absorption of the active ingredient in plasma and to compare the plasma concentration time curves.

If the products have equivalent bioavailability, it is generally considered they will have the same clinical effects when starting the medicine for the first time. However, bioequivalence alone cannot demonstrate that a patient can be freely switched between brands. If there is evidence that a medicine should not be switched between brands, for example due to characteristics of the active ingredient, this must be stated in the medicine data sheet that is published on the Medsafe website.

Prior to approval, Medsafe also assesses the pharmaceutical chemistry aspects of new generic medicines and compares them to that of the relevant innovator. This includes quality parameters that may be critical for in vivo performance such as solubility/hydrophobicity and I can confirm that a thorough assessment has been conducted of these aspects for this particular medicine.

Variation between individuals means that it is possible that a very small proportion of patients could experience differences in bioavailability. Most of the time, these differences are not clinically significant.

Medsafe encourages healthcare professionals and patients to report any suspected adverse reactions after the brand change to the Centre for Adverse Reactions Monitoring (CARM). Safety issues relating to administration can also be reported. These reports are valued by Medsafe as they are essential for investigation of any potential safety issues arising from the change.

If a person has a known intolerance to a certain excipient, they can check the Consumer Medicines Information (CMI) for the product on the Medsafe website to see the list of excipients contained in the product.

Thank you again for getting in touch.

Yours sincerely

Chris James
Group Manager
Medsafe