POSITION STATEMENT

USE OF "BIOSIMILAR" INSULINS FOR DIABETES

Background

This Position Statement represents the collective views of the Australian Diabetes Society, the Australian Diabetes Educators Association and Diabetes Australia.

The Therapeutic Goods Administration (TGA) has approved "biosimilar" insulin products for use in Australia, including Basaglar and Semglee.

A "biosimilar" is a copy of a biological molecule that has already been approved for use and has a demonstrated similarity in physiological characteristics, efficacy and safety.

The Pharmaceutical Benefits Advisory Committee (PBAC) is considering the PBS listing and use of biosimilar insulins and the option to allow pharmacy level substitution whereby a pharmacist could substitute the biosimilar insulin for an originator or vice versa.

Summary of Position Statement

Diabetes Australia, the Australian Diabetes Society and the Australian Diabetes Educators Association are strongly opposed to biosimilar insulin substitution at the pharmacy level due to insufficient evidence of safety.

We support substitution of insulins only under appropriate medical supervision and with the involvement of the diabetes healthcare team including diabetes educators and practice nurses.

Over 370,000 Australians with diabetes are currently using insulin therapy, and pharmacy level substitution has the potential to seriously disrupt diabetes management for large numbers of people with diabetes. We have particular concerns about the increased risk of hypoglycaemia which may be associated with switching insulins.

We support government objectives to expand affordable access to diabetes medicines and treatments, where it is safe and effective to do so.

However there has been insufficient consultation with diabetes consumers, consumer organisations and diabetes health professional experts in Australia about this issue.

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Evaluation of Biosimilar Insulins

Amendments to the National Health Act contained in the *National Health Amendment (Pharmaceutical Benefits) Bill 2015* will allow substitution of biosimilar drugs at the pharmacy level.

Under this legislation, the pharmacist would be able to substitute the biosimilar insulin for an originator insulin without consultation with the person's doctor or health professional team.

Biosimilars are complex mixtures of isoforms that are by nature complex. Unlike generics, they are different in composition from their originator, and cannot be identical to the originator drug.

There is currently insufficient evidence with respect to clinical equivalence of the biosimilar insulin and the originator, and pharmacodynamic and pharmacokinetic similarity is not necessarily enough to assume clinical equivalence.

The case of changing from porcine to human insulin in the 1980's illustrates the concerns. Theoretically, there was not expected to be any issue with direct substitution of porcine with human insulin based on pharmacodynamic and pharmacokinetic similarity. However, there were many patient reports of people experiencing hypoglycaemia unawareness with human insulin leading to increased hospitalisation and accidents. This was supported by peer-reviewed publications and extensive evidence.

This experience led to caution with the subsequent change from human to analogue insulins. We should be equally cautious in considering biosimilar insulin substitution.

There is not yet any evaluation of the impact on a person's management of their diabetes if they alternate between originator and biosimilar insulin over the long term. Switching to biosimilar insulin could have a negative impact given the long-term nature of insulin therapy and this has not yet been examined sufficiently to inform a decision on substitutions.

There have been reports that the PBAC could allow biosimilars unless companies can provide evidence demonstrating that pharmacy-level substitution should not occur. This shift in the 'burden of proof' is concerning. Medicines should not be subject to considerations that rely on the 'absence of data' to prove their safety.

Other Clinical Issues

There are important considerations which are crucial to the wellbeing of people with diabetes who need insulin therapy.

For example, the main delivery source of insulin in Australia is through high-precision, pen-delivery devices designed to deliver exact doses of insulin. Exact dosing is critical to the wellbeing of the person with diabetes. A change from insulin to a biosimilar insulin may require a change in dosage which may, in turn, require the use of a new insulin delivery device.

Devices differ between manufacturers. People with diabetes require training from healthcare professionals about their specific device when they commence insulin therapy. If a person's insulin is switched to a biosimilar insulin at the pharmacy level and without the knowledge of their diabetes healthcare team, then they may not be provided with the training necessary to operate the device safely. Pharmacy staff are often not familiar with, nor trained in the use of, these devices.

Changes in dosage amounts between the original and the biosimilar could also cause confusion and inappropriate dosage.

Not all insulins are the same. A person's diabetes healthcare team is best placed to consider potential reactions to biosimilar insulins, based on the person's past reactions to different kinds of insulin. The pharmacist dispensing the biosimilar insulin may not be aware of the previous reactions the patient has had with alternate insulin sources.

Role of Biosimilar Insulins

We recognise there are scenarios where it is appropriate to consider the use of biosimilar insulin as follows.

- when insulin therapy is being commenced for the first time
- when other insulins have been tried, and the biosimilar is deemed a suitable alternative by the patient's doctor.

However, any pharmacy level substitution of biosimilar insulins should not be considered until there is sufficient clinical experience and evidence developed in Australia about switching conducted under medical supervision.

We look forward to working with the PBAC to ensure that as biosimilar drugs are considered, efficacy and safety issues remain paramount and appropriate measures are in place to safeguard the health of Australians with diabetes.

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