diabetes australia

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Submission on the *National Health Amendment (Pharmaceutical Benefits) Bill 2015*

Diabetes Australia is the peak body representing 1.7 million Australians living with all types of diabetes. Diabetes is the world's fastest growing chronic disease and Australia is no different. Every day, 280 Australians are diagnosed with the condition.

Diabetes Australia, together with its state-based member organisations, are the nation's leading diabetes organisations with extensive expertise in diabetes education and care. We are the trusted source of support for millions of Australians seeking help in managing their diabetes.

The *National Health Amendment (Pharmaceutical Benefits) Bill 2015* raises several issues of concern for Diabetes Australia and the diabetes sector. Both the changes to the National Diabetes Services Scheme (NDSS) and the decision to allow substitution of biosimilar medicines at the pharmacy level potentially have adverse consequences for people with diabetes.

1. The National Diabetes Services Scheme caught up in changes and at risk.

The recently signed 6th Community Pharmacy Agreement (6th CPA) included a provision that the "product supply and delivery under the Commonwealth funded NDSS will be redirected through the established wholesale distribution network to approved pharmacists."

Diabetes Australia was surprised and deeply concerned that despite 27 years of successful operation of the NDSS by Diabetes Australia, there was no consultation about changes to the NDSS to help inform the assumptions made in the 6th CPA.

In addition, the 2015-16 Federal Budget papers revealed that there was no funding for the NDSS beyond 30 June 2016. This has created serious concern amongst Australia's diabetes community including the 1.2 million Australians with diabetes who currently benefit from diabetes-specific information, education, and services provided by Diabetes Australia through the NDSS. Diabetes Australia has successfully delivered the NDSS for 27 years and enjoys a 96% satisfaction rating within the diabetes community.

Diabetes Australia remains concerned that full consideration has not been given to the complexities of transferring the product delivery component of the NDSS to the pharmacy sector. These include concerns around access to products that pharmacies may be unwilling to stock and provide.

Currently between 25% and 40% of all NDSS product orders are <u>not</u> provided through pharmacy due to access through other health services, remoteness, special needs or desire to access by phone or web with these access channels well provided already. These people should not be disadvantaged by the change.

We are also concerned calculations for the 6th CPA assumptions may include a reduction in funding and may be less than what is required to maintain the existing level of NDSS services.

We have had reassuring comments from the Federal Government that there is no intention to disrupt or reduce the critical, front line information, education and self care support services provided cost effectively and very efficiently under the current NDSS model, nor to disrupt the registration process and database management by Diabetes Australia for the 1.2 million people with diabetes registered to the NDSS. Understandably, people with diabetes and their carers and the many other stakeholders would appreciate formal confirmation that the changes to the NDSS beyond 30 June 2016 will not reduce services to people

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with diabetes and not affect the integrity of core services provided by Diabetes Australia through the NDSS.

This scheme is a vital, national asset for people with diabetes, providing affordable access to the vital, evidence-based information, advice and education. There is no cure for diabetes and it requires a lifetime of treatment and care. The services provided by Diabetes Australia enable people to self manage their diabetes, preventing unnecessary complications and the high cost of managing the co-morbidities to which people with diabetes are susceptible to including blindness and limb amputation.

2. Biosimilar substitution

Diabetes Australia is concerned that proposed amendments to the National Health Act contained in the *National Health Amendment (Pharmaceutical Benefits) Bill 2015* to allow biosimilar substitution could cause harm to people with diabetes.

The lack of consultation about the proposed changes, combined with the potential to reduce the quality of evidence-based determinations from the Pharmaceutical Benefits Advisory Committee (PBAC), mean the proposed changes create risks for the very people they are supposed to assist.

The immediate and direct implications for people with diabetes relate to biosimilar insulin products. This has the potential to impact over 365,000 Australians currently using insulin to manage their diabetes. We have three main areas of concern.

Diminishing the role of Therapeutic Goods Administration and shift in 'burden of proof'
Under the proposed changes, biosimilar substitution decisions could be made by the PBAC not the Therapeutic Goods Administration (TGA), and the PBAC could allow the substitution of biosimilars unless companies can provide evidence demonstrating they should not. 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 or efficacy.

The TGA plays an important role in the safeguarding the health of Australians. We believe the TGA should continue to regulate and determine the safety and efficacy of any new treatment, including biosimilars. The TGA should answer the questions – "how similar is this product in terms of efficacy and safety and side effects" and ensure there is the same level of evidence of safety and efficacy as would apply for any new drug. This role should not be diluted or confused by involving the PBAC.

Evaluation of diabetes biosimilars
Diabetes Australia is strongly opposed to PBAC recommending "a flagging" of pharmacy level substitution of any biosimilar insulin product.

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

Biosimilars are complex mixtures of isoforms that are, by nature, complex. Unlike generics, they are different in composition from their originator. When dealing with products such as insulin which is, in the majority of cases, used multiple times per day, every day of a person's life, there are important considerations.

For example, the main delivery source of insulin in Australia is through high-precision, pen-delivery devices designed to deliver exact does of insulin. This is critical to patient wellbeing. Subtle differences

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between insulin and biosimilar insulin may not be clinically significant but it can render a delivery device less effective or ineffective. This could have major consequences for a person's health.

Each manufacturers' devices are different and patients are provided specific training from healthcare professionals about their specific device when they commence insulin therapy. Pharmacy staff are often not familiar with, nor trained in the use of, these devices.

The proposed changes mean a patient could have their insulin switched at the pharmacy level, without the knowledge of their diabetes healthcare team. That means, in addition to an alternate insulin, patients could be supplied with different devices which they are not trained to use.

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

Similarly, there is not yet any evaluation of the impact on a person's management of their diabetes if they alternate between originator and substituted medication over the long term. Switching to biosimilars could have a negative impact given the long-term nature of insulin, and this has not yet been examined to a sufficient extent to inform a decision on substitutions.

Lack of consultation with diabetes experts
There has been no consultation with diabetes consumers or diabetes health professional experts in Australia on the matter of biosimilars to date.

The 365,000 Australians currently using insulin therapy, the diabetes health professional community and experts, and the community in general need to have confidence in the rigorous process to approve the use of safe and effective diabetes treatments. Without consultation, this is impossible.

No "a flagging" or pharmacy level substitution of biosimilar insulins should be considered until after there has been broad ranging consultation with the diabetes sector including consumers, diabetes health professionals and experts in fields such as pediatric endocrinology, diabetes in pregnancy and other.

DIABETES AUSTRALIA CONTACTS

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