Diabetes Australia

08/04/2015

Lloyd Sansom AO
Chair – Expert Review of Medicines and Medical Devices Regulation
MDP67
GPO Box 9848
CANBERRA ACT 2601

Submitted via email: medicines.review@health.gov.au

Dear Mr Sansom

Re: SUBMISSION TO THE REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION

Thank you for the opportunity to provide a submission to the Complementary Medicines part of the Expert Review of Medicines and Medical Devices Regulation (review).

Diabetes is a significant health burden
Diabetes is set to become the number one burden of disease in Australia in the next five years with approximately 280 Australians developing diabetes every day.

In the last 12 months, more than 100,000 Australians have developed diabetes. As the fastest growing chronic condition in Australia, diabetes affects 1.1 million Australians, and their families.

This includes 120,000 people with type 1 diabetes, and 956,000 people with type 2 diabetes. A further 23,600 women have diagnosed gestational diabetes. In addition, at least 2 million Australians have pre-diabetes.

High users of complementary medicines
As diabetes rates continue to grow, more Australians are accessing a range of medicines, including complementary medicines, to improve their quality of life. Studies indicate up to one in four people with diabetes use complementary medicines in addition to prescription

diabetesaustralia.com.au
Level 1, 101 Northbourne Avenue, TURNER ACT 2612, Australia
GPO Box 3156, CANBERRA ACT 2601, Australia
T: +61 2 6232 3800 F: +61 2 6230 1535. E: admin@diabetesaustralia.com.au
ABN 47 008 528 461

medicines[1]. Evidence suggests many people do not discuss the usage of these products with their health care teams, despite their potential interaction with other medicines[2] [3].

Changes to regulatory system

Australia has one of the safest and most stringent regulatory systems for medicines, including complementary medicine, in the world. Diabetes Australia believes the current standards should not be diminished, and nor should the safety of Australians using these products.

Australians living with diabetes rely on a health system which prioritises their safety, instils confidence, and provides clear and accessible information. Diabetes Australia supports a regulatory system that delivers these priorities. While simplification may be beneficial, it should be of secondary concern to exposing Australians living with diabetes to unnecessary risk. Any changes to the regulatory system must ensure consumer awareness and confidence is not downgraded in any way especially for those with low health literacy.

Theme 1: Duplication of regulatory processes

Using trusted overseas regulators

Diabetes Australia understands that currently, the TGA does not perform pre-market assessment of complementary medicines containing low-risk pre-approved ingredients. A small of number of medicines have unapproved ingredients or are deemed high risk, and are registered by the TGA, undergoing a greater level of assessment. Under the current system, Australia has a stand-alone assessment process for these higher risk ingredients regardless of previous assessments using standards within other jurisdictions. The review raises questions as to whether these processes are duplicative and whether 'trusted' overseas regulators can be used in lieu of Australian regulatory processes.

Australia currently has a robust regulatory system that instils consumer trust. Regardless of the origin of an ingredient, Australian consumers should have confidence in the Australian regulatory system and have no doubts about the safety of products sold in Australia.

There are challenges in comparing Australia's regulatory system to other countries.

For example, throughout Europe complementary medicines are integrated into the mainstream medical system. Many countries have either legislative or medical industry regulation of complementary medicine requiring health professionals to have formal training for the administration and prescription of the medicine. In these circumstances, the provision of complementary medicines in the market is well supported by trained health care professionals. We do not have this integrated system in Australia. As a result, the safety threshold for complementary medicines in Australia must be higher to accommodate the practice of Australians taking complementary medications in the absence of advice from health care professionals.

---

[1] Clifford, R.M., Batty, K.T., Davis, W. & Davis, T.M.E. (2003). Prevalence and predictors of complementary medicine usage in diabetes: Fremantle diabetes study. Journal of pharmacy practice and research, 33(4), 260-264.

[2] Dunning, T. (2003). Complementary therapies and diabetes. *Complementary Therapies in Nursing and Midwifery*. 9(2):74-78.

[3] Canaway R. Manderson L. (2013) Complementary therapy use among Australians with type 2 diabetes or cardiovascular disease *Alternative and Complementary Alternative Therapies*19(1), 18-27 doi:

The review highlights the considerable variability of regulatory systems across the world. Discarding Australia's regulatory processes in light of this inconsistency could pose considerable risks to Australian consumers.

While it is recognised the current system poses some burden on industry, consumer safety must be paramount in any considerations of decreasing regulation.

It should be noted that currently 98 per cent of complementary medicines are listed medicines containing pre-approved ingredients and subsequently do not incur a rigorous review. Only two per cent contain new ingredients and are subject to the TGA's safety and quality review. These regulatory requirements do not seem excessive. It is understood there are currently significant delays in approval processes. Options to better resource the regulator should be considered before cuts to regulation.

Interface between advertising and listing evidence requirements
Diabetes Australia understands that when complementary medicines are listed, sponsors must certify they have evidence to support claims. The review suggests this process is duplicated when seeking advertising pre-approval. Diabetes Australia does not agree that medical sponsors applying for pre-publication approval should be allowed to bypass the TGA requirement to hold evidence supporting their claims and indications. The TGA should remain the central authority dealing with all matters relating to the safety and quality of all medications including complementary medicines.

Theme 2: Regulatory requirements not commensurate with risk

Interface between complementary medicines and pharmaceuticals
Complementary medicines are medicines. They pose the same range of risks as pharmaceuticals. Downgrading regulation brings increased consumer risks around self-prescription, and insufficient information around interactions or excessive use.

Greater informality may reinforce community perceptions that complementary medicines are not harmful, even if used incorrectly. As stated previously, people with diabetes are high users of complementary medicines. People often do not disclose usage to their health care professional and are at risk of potential interactions or complications with other medicines.

The Fremantle Diabetes Study (2003) found that 23 per cent of people with diabetes had consumed at least one complementary medication in the last year. Of the medications used, approximately 42% could be considered inappropriate for people with diabetes.

While some complementary therapies have been shown to be beneficial to people with diabetes, their use can also lead to adverse events with people self-treating at the expense of seeking appropriate, timely management advice from a health professional. (Dunning, 2003).

Monash University's CAMelot (2012) study found that a significant number of people with diabetes use complimentary medicines, in addition to conventional pharmaceutical

therapies, to improve general health and wellbeing. But only 36 per cent of their respondents always reported complementary medicine use to their doctors.

Some complementary medicines can be harmful if used with other medications or conditions. Some products have the potential to diminish efficacy of prescribed medicines or to contraindicate their use. Even readily available and widespread supplements and vitamins, including glucosamine and niacin, can be harmful for people with diabetes.

Diabetes Australia supports strengthening the level of information available to consumers about complementary medicine interactions. Manufacturers are currently not obliged to provide information or warnings regarding interactions. Diabetes Australia encourages further investigation into this issue and into the appropriate level of literacy required to ensure the greatest access to this information.

Threshold for therapeutic goods

Diabetes Australia does not support regulating low risk complementary medicines as general consumer goods, or regulating certain dietary supplements as foods. Complementary medicines, including products deemed low-risk, are therapeutic and fit well within the medicines framework to ensure consumer safety issues are appropriately considered. Unlike general consumer goods, complementary medicines can pose harm to the Australian public through drug interactions and prolonged use.

While some complementary medicines may be based on, or contain, products generally regarded as food, when they are taken as complementary medicines it is generally in a higher dosage, frequency and with a different intent. Complementary medicines containing foodstuffs should be regulated according to their consumption and the intended therapeutic effects, not according to what they contain.

Diabetes Australia believes regulating some complementary medicines as food would cause consumer confusion. It would also fail to meet consumer expectations around health and safety and therapeutic benefits.

Theme 3: Complex regulatory framework

Diabetes Australia agrees there is currently poor consumer understanding of the role of the TGA and level of scrutiny applied to complementary medicines, particularly with regards to the limited scrutiny afforded listed products. Diabetes Australia supports the need for greater transparency around the assessment process to determine the quality and safety of complementary products.

Listed products are not rigorously evaluated by the TGA. To improve consumer awareness, it may be beneficial to consider product disclaimers (like in the United States) citing that the product's health claims are not endorsed by the TGA. This may encourage people with diabetes to better engage with their health care professional.

Theme 4: Inadequate deterrents

Diabetes Australia believes post market compliance needs to be strengthened. It is concerning that in 2010, 90 per cent of listed products were found to be non-compliant with regulatory requirements. Post market surveillance on its own is not enough 'when the horse has bolted'. Awareness campaigns and education to support access to reliable and trustworthy consumer information, must and should be provided.

In summary, Diabetes Australia supports the simplification of the regulatory system if there is no increased risk to Australians. While there are faults with the current regulatory system, it offers a higher degree of consumer protection than the alternatives outlined in the review. Reforms that are made to the current system should promote better consumer awareness, more clarity in what constitutes complementary medicine, and better gradation of regulation according to the risks to consumers. It is essential that consumer safety is the foremost consideration in any changes that are to be made.

Yours sincerely,

Greg Johnson
Chief Executive Officer