




**THE HON SUSSAN LEY MP
MINISTER FOR HEALTH AND AGED CARE
MINISTER FOR SPORT**

Ref No: MC16-029096

The Hon Greg Hunt MP
Minister for Industry, Innovation and Science
Member for Flinders
PO Box 274
HASTINGS VIC 3915

Dear Minister


Thank you for your representations of 14 September 2016 on behalf of
regarding the shortage of metformin extended release tablets.

My Department is aware of the limited availability of metformin in the extended release formulation. Certain suppliers have had limited or no stock which has led to an unexpected increase in demand on other suppliers that they have not been able to meet.

Temporary shortages of particular medicines can occur for number of reasons, including disruption of manufacturing processes, the unavailability of raw materials, manufacturing difficulties, changes to product formulation or manufacturer, commercial decisions and unexpected increases in demand due to disease outbreak or new clinical practice. There may also be fluctuations in demand in the international marketplace. The issue of temporary medicine shortages is not unique to Australia, and I am advised that the shortage of extended release metformin is an international shortage.

When a medicine is listed on the Pharmaceutical Benefits Scheme (PBS), a guarantee is sought from the supplying company that it will be able to continuously supply the product under section 99AEB of the *National Health Act 1953*. It is also in the company's commercial interest to do so. Prior to listing, drug sponsors and the Australian Government make an informed estimation of the level of subsidised use, but acknowledge that unforeseeable factors which cannot be measured at the time may affect usage levels.

Under the terms of the Sixth Community Pharmacy Agreement, which has been made between the Commonwealth of Australia and the Pharmacy Guild of Australia (the Guild), the Guild has agreed that approved pharmacists will keep adequate medicine stocks for the supply of medicines listed on the PBS to ensure reasonable and timely access to those medicines by consumers where the demand is, or should reasonably have been, anticipated by the relevant approved pharmacist.

All medicines listed on the PBS are expected to be available in all pharmacies if pharmacists order them, including medicines which have specific pharmacy chain names as part of their brand name.

However, in certain circumstances, disruptions to supply cannot be avoided. Pharmaceutical companies are private businesses. As such, they make their own decisions about how and where they will market their medicines, the price of their medicines and other production and inventory matters. In the context of more than 5,300 branded products listed on the PBS, interruptions to supply are relatively uncommon.

It is recognised that patients with chronic diseases such as type 2 diabetes require ongoing care and a consistent treatment regime. In the event of a medicine shortage, pharmacists are able to calculate and recommend changes in formulation, strength and dosage of available medicines to suit the patient's current treatment plan.

Following consultation with the prescriber, pharmacists can annotate and endorse prescriptions. If major changes to a prescription are needed, a new prescription is typically required. In emergency circumstances, a pharmacist may supply the medicine without a paper prescription following the confirmation of details from the relevant prescriber. The valid paper prescription is then sent to the pharmacist no later than seven days after the day on which the medicine was supplied.

The Therapeutic Goods Administration (TGA) has been in contact with the sponsors of extended release metformin products to clarify the reported shortage issue. The TGA has been advised that both 500mg and 1000mg of the extended release forms of metformin have had batch releases in the past few months. In some instances, it can take time for products to make their way through the supply chain.

Thank you for raising your constituent's concerns.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sussan Ley', is written over a large, faint watermark that reads 'THIS DOCUMENT HAS BEEN RELEASED UNDER THE FREEDOM OF INFORMATION ACT BY THE DEPARTMENT OF HEALTH'.

The Hon Sussan Ley MP

10 OCT 2016