



The Hon. Greg Hunt MP
Minister for Health

MEDIA RELEASE

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New law to protect patients against medicine shortages

The supply of critical and life-saving medicine to Australian patients will now be protected with the Parliament passing the Morrison Government's landmark legislation last night.

Under the new law, medicine companies will now have to report shortages of important medicines as soon as they occur.

In addition, if a critical drug is being removed from the market, my Department must be notified by the manufacturer at least 12 months in advance, or as soon as possible.

This new law protects patients who rely on vital medicines. They also give the community, medicine company and patients the opportunity to take action to mitigate against a medicine shortage.

Mandatory reporting will apply to all prescription medicines as well as other medicines which are vital for public health, such as EpiPens and inhalers.

Tough penalties will apply to companies that do not comply with these new laws, including fines of up to \$210,000 for each infringement and the possibility of further court action.

I make no apologies for taking a hard-line approach to ensuring patients aren't kept in the dark about a potential medicine shortage.

A shortage that will severely impact on patients must be notified to the Therapeutic Goods Administration (TGA) as soon as possible, and no later than two working days after the medicine company knows or should know of the shortage.

Medicine shortages have become an increasing problem in recent years, as medicine companies (manufacturers or importers) have failed to comply with the current voluntary reporting scheme.

Earlier this year, Australia was one of several countries hit by a shortage of EpiPens, which provide lifesaving adrenalin for people who have had an acute allergic response.

In this and a number of other cases, the shortages were not reported in advance to the TGA within the Department of Health. As a result, patients and doctors were not alerted in time for them to make alternative arrangements.

Under the new law, a critical medicine is deemed to be in shortage if there is not enough, or likely will not be enough, for all patients in Australia who take it or may need to take it, at any time in the next six months.

If a medicine company decides to discontinue a critical medicine, the Department of Health must be notified at least 12 months in advance, or as soon as possible.

Shortages cannot always be avoided but, when they do occur, this mandatory reporting scheme will help Australian patients and health professionals to be more prepared.

Responses to a shortage could include re-directing the available supplies to patients who need them most, nominating alternative treatments and providing Pharmaceutical Benefits Scheme coverage for the alternatives.

Medicine companies must also notify my Department of shortages that will not have a severe impact on patients. They will have up to 10 working days to do so.

I want to thank the medical sector who have worked closely with my Department and the TGA on improving the process for reporting medicines shortages and their willingness to improve the system through legislative change.

In particular I want to thank Medicines Australia, the Australian Medical Association, the Society of Hospital Pharmacists of Australia, the Pharmacy Guild of Australia, the Australian Self Medication Industry, the National Pharmaceutical Services Association, the Pharmaceutical Society of Australia and the Generic and Biosimilar Medicines Association.

These groups have worked collaboratively together and with government to design a new approach that will support and protect Australian patients.

The new mandatory reporting scheme for medicines shortages is included in the Therapeutic Goods Amendment (2018 Measures No. 1) Bill 2018, passed by the Senate last night. The new law will come into effect on 1 January 2019.

(ENDS)

Authorised by Greg Hunt MP, Liberal Party of Australia, Somerville, Victoria.