

A NEW MANDATORY REPORTING SCHEME TO REDUCE THE IMPACT OF MEDICINE SHORTAGES

JANUARY 16, 2019 | HEALTH SECTOR

In response to the increasing threat of medicine shortages the Australian parliament has passed the *Therapeutic Goods Amendment (2018 Measures No. 1) Act 2018* (Cth) (the Act).

The Act amends the *Therapeutic Goods Act 1989* (Cth) to introduce mandatory reporting of medicine shortages and discontinuation of supply of medicines. These changes will better allow the Therapeutic Goods Administration (TGA) to prepare Australian patients and health practitioners for an impending medicine shortage and provide advice about alternative medicines available.

BACKGROUND

Earlier this year EpiPen auto-injectors sold out across the country, with some pharmacies being out of stock for up to four months. With no alternative products approved by the TGA available, families that relied on the life-saving medicine received advice to keep their expired EpiPens in case of emergencies or future shortages.

The EpiPen is just one example. In recent years medicine shortages have increased around the world, in many cases placing patients' lives at risk.

Since 2014, medicine sponsors (sponsors) have been able to report medicine shortages on a voluntary basis. However, this system has been criticised as ineffective and has resulted in instances where critical medicine shortages went unreported.

NEW REPORTING OBLIGATIONS

The Act received Royal assent on 21 September 2018, with the new reporting scheme to commence from 1 January 2019.

Under the new amendments, sponsors who identify a shortage of certain medicines, or intend

on discontinuing certain medicines must report to the Department of Health within specified timeframes. Medicines which are required to be reported are those which include one of more substances under Schedule 4 or 8 of the current Standard for the Uniform Scheduling of Medicines and Poisons October 2018 (the Poisons Standard).

Schedules 4 and 8 contain thousands of ingredients found in medicines in Australia. To assist sponsors, a “Medicines Watch List” (the Watch List) will be established as a legislative instrument in order to identify those medicines which, if in shortage, would have a critical impact on patients.

From 1 January 2019, sponsors will have 10 working days from the date they become aware (or ought to become aware) of a shortage of a reportable medicine in which to notify the Department of Health, or 2 working days if the shortage is likely to have a “critical impact”. A critical impact will occur where:

1. The medicine subject to the shortage is included on the Medicines Watch List;
2. There are no registered alternatives to the medicine;
3. There is a shortage of suitable alternative medicines; or
4. The shortage is likely to have life-threatening impacts or serious impacts on the health of those who rely on the medicine.

Sponsors who intend on discontinuing medicines on the Watch List or other medicines likely to be of critical impact must report its decision to do so at least 12 months before the discontinuance is to be likely. In cases involving other reportable medicines, a report must be made at least 6 months before the discontinuation.

Practical Implications

The amendments include new civil penalties for sponsors who breach the reporting requirements. The penalties carry maximums of 100 penalty units for an individual and 1,000 penalty units for a body corporate. Non-compliant sponsors and their affected products will also be published on the TGA’s website.

Sponsors should familiarise themselves with the details of the amendments in order to identify products which constitute a reportable medicine and to ensure compliance with reporting requirements. Failure to do so will not only threaten the wellbeing of patients who rely upon such medicines, but will now also carry a significant financial penalty.

A copy of the *Therapeutic Goods Amendment (2018 Measures No.1) Act 2018* (Cth) can be found here: <https://www.legislation.gov.au/Details/C2018A00104>

AUTHORS



MITCHELL HAUSER
SENIOR ASSOCIATE

+61 7 3231 6344

mitchell.hauser@bnlaw.com.au