Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical devices and IVDs: Cancellations of certain devices within an entry

Guidance

Cancellations from the ARTG under section 41GK, 41GL, 41GM or 41GN of the Therapeutic Goods Act 1989.

Last updated: 5 July 2021

Following a review by the TGA, medical device entries (including IVDs) can be cancelled from the Australian Register of Therapeutic Goods (ARTG) by the Secretary of the Department of Health under section 41GK, 41GL, 41GM or 41GN of the *Therapeutic Goods Act 1989* (the Act).

The Act requires the TGA to publish information about any such cancellation.

With the exception of Class III and Active Implantable Medical Devices (AIMDs), an entry in the ARTG is for a kind of medical device, meaning more than one device can be authorised for marketing by that entry.

Under section 41GO of the Act, a cancellation can be limited by the Secretary if satisfied that the grounds for cancellation apply to only one device, or only some of the devices, covered by the entry. In such a case, rather than the entry being cancelled, it is varied by the Secretary under that section to make it clear that marketing authorisation does not extend to the cancelled device.

The records below include information on the types of cancellation decisions described above and any subsequent decisions to revoke such cancellations. To find out whether a product is currently authorised for supply in Australia, check the ARTG entry. For cancellations at the request of the sponsor that result in only one or more medical devices being cancelled and not the entry being removed from the ARTG, see Medical devices and IVDs: Cancellations requested by the sponsor of certain devices within an entry.

Where other actions are taken in relation to safety, the TGA will generally publish additional information about the issue on its alerts page.

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Medical device cancellation - certain devices within an entry

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Topics: In Vitro Diagnostic medical devices (IVDs)