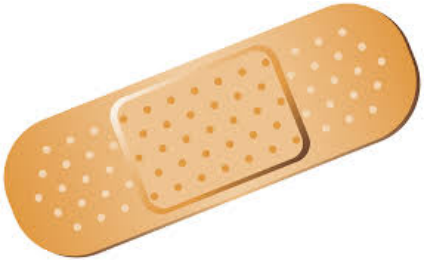
Consumer Guide to Reforms

Australian Government
Department of Health
Therapeutic Goods Administration

What is the TGA?

TGA Stands for **Therapeutic Goods Administration** and is part of the Australian Government Department of Health. TGA is responsible for ensuring therapeutic goods in Australian are safe for consumers and medical devices performed as the intended.



What is a Medical Device?

Medical devices can range from low risk such as a simple bandage that you would use for a scratch through to high risk products such as pacemakers that are implanted in your body.

Medical Devices Regulation Reform:

- One of the recommendations was to align with the European Union Framework, wherever possible.
- In response to concerns raised by consumers about the limited or absence of information provided about a medical device implanted during surgery, TGA will implement this recommendation.
- ***Patient information leaflets*** will supply consumers with important information prior to providing consent, empowering consumers to make more informed decisions.
- ***Patient implant cards*** will provide consumers with after surgery care.

TGA to implement across Australia in a staged approach over three years.

	Patient Information Leaflet	Patient Implant Card
Urogynaecological mesh		
New devices	1 Dec 2018	1 Dec 2018
Existing devices	1 Dec 2019	1 Dec 2019
Surgical mesh		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021
Implantable devices (other than those exempted)		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021

For more information visit www.tga.gov.au or email info@tga.gov.au

CHF
Consumers Health Forum OF Australia