Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Case studies

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These case studies provide practical examples that demonstrate our guidance, legislation and policy in action.

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Frank the importer

Frank saw a new kind of sling for limb sprains and breaks while he was overseas and he would like to import these slings into Australia.

Frank has no experience in importing therapeutic goods. When he returns to Australia, he visits the TGA website and discovers that the sling is a medical device (https://www.tga.gov.au/node/287636) and that he needs to become a sponsor and make an application for an ARTG entry under his name before importing it into Australia.

Frank investigates further and learns that to make his application he needs to obtain from the manufacturer the Global Medical Device Nomenclature (GMDN) (https://www.tga.gov.au/node/282893) code and the Australian classification. He also finds that it would be a good idea to obtain a Declaration of Conformity from the manufacturer; for low risk medical devices this can be a self-assessment by the manufacturer.

Frank begins discussions with the manufacturer to obtain the necessary information, to ensure they have the appropriate certificates and are able to properly monitor the device after marketing it (meet all ongoing legislative requirements). He develops an ongoing business relationship with the manufacturer to ensure that he will receive updates related to safety issues.

Becoming a sponsor

Frank fills out the organisation details form (https://www.tga.gov.au/node/288314) to obtain access to TGA Business Services (https://www.tga.gov.au/node/287189). He applies to enter the medical device in the ARTG and become its sponsor (https://www.tga.gov.au/node/287245).

Frank notes that there are both fees and charges (https://www.tga.gov.au/node/287173). He will need to pay an application fee to include a Class I medical device on the ARTG. Once he starts supplying the device, he will also need to pay an annual charge to the TGA.

TGA approves Frank's application. Frank is now the medical device sponsor and is able to legally import the sling into Australia for supply and sale. Frank reads all the relevant guidance on the TGA website to ensure that he understands his responsibilities as a sponsor and can meet them.

Claudia the herbalist

Claudia is a herbalist. She gave her mother the herb Claudius claudium while her mother was fighting cancer. Claudia is convinced that Claudius claudium helped her mother fight the cancer and is considering manufacturing and selling Claudius claudium tablets to help cancer sufferers.

Claudia wants to know more and has looked at the TGA website (https://www.tga.gov.au/node/287634) to find out whether the tablets would be considered a therapeutic good, and is pretty sure they would be. However, Claudia is reluctant to proceed with an application before she understands the law around supplying medicines. She checks the TGA website to find out more about what she will need to consider before she decides to proceed further.

Other products on the ARTG

Claudia decides it would be a good idea to check the Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/287251) on the TGA website to see if there are already listed or registered medicines containing Claudius claudium. Claudia searches the ARTG by the ingredient name and finds none.

Approved or new substance

Claudia wants to know whether Claudius claudium is an approved ingredient for listed medicines. Claudia searches the Therapeutic Goods (Permissible Ingredients) Determination (https://www.tga.gov.au/node/287264) and finds that Claudius claudium is not on the list. This means Claudia would need to make an application for a substance

evaluation before she could use Claudius claudium in a listed medicine. Claudia finds the data requirements for a substance evaluation described in the Australian regulatory guidelines for complementary medicines (ARGCM) (https://www.tga.gov.au/node/285058) on the TGA website.

Evidence for therapeutic claims

Next, Claudia looks at the Guidelines on the evidence required to support indications for listed medicines (https://www.tga.gov.au/node/285092). She learns that making a high-level claim like helping cancer patients must be supported by considerable evidence and Claudia does not have access to clinical trial data. Claudia also realises that the medicine would need to be registered, not listed, so the application process would be more expensive and require much more data than the listing process. Claudia decides not to proceed.

Andrew the researcher

Andrew has been conducting research on chemicals produced by coral for several years. He has identified three chemicals that have specificity for three separate human receptors. Andrew thinks that at least one of these compounds might be a useful medicine in the future. As he considers future research grants, collaborations and potential industry support, he decides to find out what studies would be required for an application to the TGA for a new prescription medicine.

Guidelines useful for designing studies

Andrew discovers that the TGA adopts international guidelines (https://www.tga.gov.au/node/282883) as a basis for the technical data requirements for applications to register prescription medicines in Australia. He learns that if he would like the findings of his studies to be useful in a registration application, it would be a good idea to comply with Good Laboratory Practice (https://www.nata.com.au/nata/accreditation-info/types-of-accreditation/30). He also learns that there are guidelines specific to quality studies (https://www.tga.gov.au/node/282883) and nonclinical studies (https://www.tga.gov.au/node/282883), as well as guidelines about clinical efficacy and safety (https://www.tga.gov.au/node/282883) on the TGA website.

Clinical trial information

Andrew is interested in eventually conducting clinical trials and finds helpful information on the TGA website under Clinical trials (https://www.tga.gov.au/node/287274) and the Australian clinical trial handbook (https://www.tga.gov.au/node/289564). He also looks up the NHMRC and finds the Australian Clinical Trials website (https://www.australianclinicaltrials.gov.au/researchers). He is happy to discover that this website also contains comprehensive information for researchers about clinical trials.

Topics:

Biological medicines (https://www.tga.gov.au/products/medicines/biological-medicines)

Therapeutic goods regulation (https://www.tga.gov.au/topics/therapeutic-goods-regulation)