Therapeutic goods administration australia pdf

Therapeutic Goods Administration Agency overviewAustralia's Judicial Community Annual budget of $139 million (2015)HealthWebsitewww.tga.gov.au The Main Division of therapeutic Products Administration (TGA) is the regulatory body for therapeutic products (including drugs, medical devices, gene technology and blood products) in Australia. [1] It is a section of the Australian Department of Health established under the Therapeutic Products Act 1989 (Cth). [2] [3] The TGA is responsible for evaluation and monitoring activities to ensure that therapeutic products in Australia are of an acceptable standard and that access to therapeutic developments is timely. The TGA Expert Advisory Committees have nine different legal expert committees that the TGA can call for independent advice on scientific and technical issues, Included: Complementary Medicines Advisory Committee (ACCM) Medical Devices Advisory Committee (ACMD) Over-the-Back Medicines Advisory Committee (ACNM) Advisory Committee on Over-the-Back Medicines (ACPM) Advisory Committee on The Safety of Medical Devices (ACSMD) Advisory Committee on Drug Safety (ACSOM) Advisory Committee on the Safety of Vaccines (ACSOV) Therapeutic Products Committee (TGC) – Minister advises on standards for therapeutic products, including labelling and packaging, and principles that must be respected in the production of therapeutic products for use in humans. Trans-Tasman compliance The Australian and New Zealand governments were trying to establish a trans-Tasman partner agency to regulate drugs and therapeutic goods to replace the TGA and New Zealand's Medsafe. However, on July 16, 2007, New Zealand Minister of State Services Annette King announced that the Government had not continued at this stage with legislation that would allow the establishment of a joint agency with Australia to regulate therapeutic products. He also said the New Zealand Government does not currently have the numbers to put in parliament a sensible and acceptable compromise that would satisfy all parties. The Australian Government has been informed of the situation and says it accepts that suspending negotiations on the joint authority is a sensible action. More information is available on the Australian New Zealand Therapeutic Products Authority (ANZTPA) website. See also the Australian Competition and Consumer Commission australia New Zealand Therapeutic Products Authority International Conference on Compliance with Technical Requirements for Drug Registration for Human Use (ICH) Australian Commonwealth Government Assets List Australian Commonwealth Government Assets Uniform Timing Drug and Poisons References ^ About TGA. Department of Health Treatment Products ^ About Australian therapeutic products legislation. Department of Health Treatment Products Administration. ^ Therapeutic Products Act 1999 (Cth) External links TGA website Therapeutic Products Act 1989 New AU eCTD Guidance Australia Re-Releases M1 Guidance for CTD Articles Received from Australia's IT Scientist's TGA by TGA Read more - Therapeutic Goods Management website Read more from TGA Learn more about the TGA on the Medical Goods Administration website - Learn more about the Therapeutic Goods Administration website TGA - Learn more about the Therapeutic Goods Administration website TGA – Learn more about the Therapeutic Goods Administration website TGA – The Therapeutic Goods Administration website bee is aware of the risks of natural medicines and medical devices. Learn more about TGA - Therapeutic Goods Administration website Most Australians are not aware of low dose codeine (learn more about TGA - Therapeutic Goods Administration website Storage can be dangerous to expired and unwanted drugs at home, and unsafe disposal of unwanted drugs can lead to environmental damage. Learn more about TGA - Therapeutic Goods Administration website You can buy over-the-counter (OTC) drugs for self-treatment from pharmacies, selected products are also available in supermarkets, health food stores and other retailers. Read more TGA - Therapeutic Goods Administration website Home Security information Consumers Health professionals Industry About Industry TGA News room Home Safety information Consumers Health professionals TGA Newsroom About Industry If you have a question about a drug, medical device or other therapeutic goods, therapeutic goods administration (TGA) can help you. On this page: Frequently asked questions | We can't answer some questions | How to communicate with TGA e- Other contact points | Our customer service standards Frequently asked questions are answered on these pages: Importing a drug traveling with medicinal cannabis We can't answer some questions We can't answer questions that aren't related to therapeutic products. These questions should be directed to the relevant institution or organization. Here's a list of eligible people for specific topics. Keep in mind that we don't research or develop therapeutic products, give clinical advice to individuals, recommend products, or make decisions about subsidies. We can't answer questions about these things. For more information, see our pages organized by the TGA and what the TGA does not do. How to contact the TGA, if you have a question for the TGA, you can contact us through one of the methods listed below. Simple questions are usually a quick phone call can be answered. Complex questions questions take the time to address it properly. We ask you to send more complex questions by email, fax or mail. Contact information Phone 1800 020 653 (toll-free call in Australia) +61 2 6289 4124 (overseas call) 02 6289 4124 (1800 calls not allowed for mobile phones) Time: Monday-Friday, 09:00-17:00 (excluding AEST public holidays) Deaf, hearing impaired and/or speech impairment can call the TGA through the National Transition Service. TTY or modem users with computer phone 1800 555 677 then ask 1800 020 653. Speak and listen (speech-to-speech relay) users ask for phone 1800 555 727 then 1800 020 653. Those who do not speak English can use the Translation and Interpretation Service. You can contact 131 450 or outside Australia at +613 9268 8332. Fax info@tga.gov.au Fax 02 6203 1605 Postal Address TGA, PO Box 100, Woden ACT 2606, Australia Other contact points If your question is related to a specific function of the TGA, you can resolve this through one of these alternative communication points. Due to privacy considerations, the TGA does not publish contact information for individual personnel. Our customer service standards You can expect from our customer service representatives and see the TGA customer service standards page for details about what happens to the service you provide. Home » Industry » Regulation fundamentals The Therapeutic Goods Act, Regulations and Orders set out requirements for the inclusion of therapeutic goods in the Australian Therapeutic Goods Register, including advertising, labelling, product appearance and appeal guidelines. Certain provisions, such as the timing of items and the safe storage of therapeutic goods, are covered by the relevant State or Territory legislation. Australian legislation is available in full text from the Attorney-General's Federal Regulatory Register. If you want to rely on any legislation set out on this website, you must access copies of official versions. These tools are replaced from time to time and can be replaced from time to time or new tools can be made. On this page: About Legislation | Actions and regulations | Legislative tools | Other legal information about Legislation Acts & Regulations Other legislative tools Other legislative information Home Safety information Consumers Health professionals About Industry TGA Newsroom Main » TGA About Therapeutic Products Administration (TGA) is part of the Australian Government's Department of Health and is responsible for regulating therapeutic goods including prescription drugs, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. Almost every product that claims therapeutic claims must be entered into the Australian Therapeutic Products Register (ARTG) before being supplied in Australia. On this page: About TGA | TGA enterprise | TGA website TGA corporate information structureTGA Australian Government Department of Health TGA plans and reports TGA plans and reports, business plans, market research reports, key performance indicators, record lists TGA reformsTGA reforms Helps us stay able to comply with community and industry expectations Freedom of Information Act 1982 Australian Government TGA website is designed to give Australian community access to information held by the TGA website formstga publications The TGA website Disclaimer Information TGA website applies a number of security checks to protect their website about Home Security information Consumers Health professionals Industry TGA Newsroom room, abbreviation and dictionary list of abbreviations and dictionary terms likely to be found in the TGA Copyright Copyright Copyright TGA website Privacy Privacy and security information for users