INVIVA LIFESCIENCES AUSTRALIA

# Your Trusted Regulatory Advisors in Australia

The Therapeutic Goods Administration (TGA) requires all Therapeutic Goods, including Pharmaceuticals, Nutraceuticals, and Medical Devices, be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in, or exported out of Australia. We understand medical product registration with the TGA can be a challenging process. That is why our team of experts at Inviva LifeSciences are here to help. We can assist your company with regulatory support, ensure your Therapeutic Goods comply with all TGA requirements, and are ready for market commercialisation. Our company can help with registration of Therapeutic Goods ranging from Prescription, OTC, and Complementary Medicines, to Medical Devices and Biologicals.

## Register your product with the TGA prior to commercialization

We provide assistance with TGA registration, regulatory compliance, and commercialisation of your Therapeutic Product. This includes ensuring your technical file is made available for inspection by the TGA, maintaining confidentiality of all documentation, and preparing a scientific report. A project coordinator from our team will be assigned to manage and coordinate between you and the TGA.

## Represent your company for all liaisons with the TGA

Our offices act as your primary point of contact for the TGA and address all TGA regulatory compliance needs. Additionally, we provide in-house customer care and can field all Australian and international inquiries related to your medical product. Our team can also aid with vigilance including reporting recalls/adverse events in collaboration with the TGA, local distributors, and you.

## Provide in-house regulatory and technical expertise

Our experienced team can assist in preparing and submitting all required technical documentation for TGA approval. Our process involves auditing documents for errors, updates, and compliance with TGA guidelines and preparing a report on gaps for non-compliant documents. Additionally, we can advise on compliance of product promotional material including label claims, scientific literature, and packaging.

## Be your Australian contact for all TGA related queries

With our offices in Australia, we provide authorisation for use of our office address for all commercialisation purposes including product labels, packaging, and instructions for use. We can also advise you on importing and exporting Therapeutic Products in to and out of Australia.

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## Our 3- year package:

As your sponsor, we will manage all required communications for TGA registration and approval for 3 years. This includes ensuring all required registration documents are in line with TGA requirements, communicating with the TGA during the registration and approval process, and handling all communications related to the product post-market.

After your therapeutic product is included in the ARTG, we will provide post-market maintenance for 3-years including:

### TGA Communication Management:

- Updates on all required legislative changes
- TGA recall notices, product corrections, and product defect notices
- Hazard alerts and other safety notices
- Biovigilance: Adverse event reporting and TGA follow-up
- Manufacturing: Regulatory actions overseas, significant changes to the manufacturing site, quality management system, or product GMP compliance

### Throughout the 3- years, we will keep you informed on:

- Advisory statements that affect your therapeutic good
- Best practices as defined by the TGA
- Complaints and alerts related to your therapeutic product
- Compliance and reinforcement information
- Regulatory changes and outcomes
- Regulatory reforms including changes to ingredient names and warning labels
- Updates on any labeling including changes to ingredient names
- Updates on any packaging changes

With our in-house expertise and constant monitoring of your product on the ARTG, we can assure that you are in good hands.

Please contact us for further information.