



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Communicating with the Regulator

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Group Coordinator

Market Authorisation Group





Market Authorisation Group

- Responsible for evaluation and authorisation of therapeutic goods
- Ensures they meet appropriate standards of quality, safety and efficacy
- Includes medicines, medical devices, blood and tissues





Market Authorisation Group

- Office of Medicines Authorisation
- Office of Complementary Medicines
- Office of Devices Authorisation
- Office of Scientific Evaluation
- Group Support Unit





Communicating with the Regulator

- Practicalities
 - Guidance documents
 - Meetings
 - Email, telephone
- Challenges
- New processes





Guidance documents

- ARGPM – Prescription Medicines
- ARGOM – OTC medicines
- ARGCM – Complementary Medicines
- ARGMD – Medical Devices
- European Guidelines adopted by TGA





Pre-submission Meetings

- Conduct of meetings described in ARGPM Appendix 5
- Need to advise TGA which areas:
 - Clinical, non-clinical and chemistry
 - Risk Management Plans
- Give TGA adequate notice – a month
- Not for sales pitch about sponsor or company



Format of Submission

- The Therapeutic Goods Administration (TGA) requirements for prescription medicines data are based on the European Union requirements
- TGA accepts data packages in the EU version of the international Common Technical Document





Contact the TGA

- Go to the TGA website –
phone numbers and email addresses for enquiries
Eg: for device enquiries 1800 141 144
cab.medical.device.information@tga.gov.au
- Directly with evaluator or delegate
phone or email





- electronic CTD (eCTD) format
- Draft Guidance For Industry On Providing Regulatory Submissions For Prescription Medicines In Electronic Format in Australia (Jan 2009)





Application Entry

- assessment on an administrative level to make sure there is compliance with basic guidelines.
- at the end of this phase, a decision is made to either accept the application for evaluation or to reject it.





- Submission content
 - Indication, presentations
 - For the Australian market
- Submission contents
 - Study reports, legibility, English,





S31 Questions

- Questions to clarify issues during the evaluation process are asked under Section 31 of the Act.
- Response must be received in timeframe.
- The company is allowed to provide corrections or comments on the views expressed within the evaluation report.





New business processes – what we are trying to achieve

- More timely and efficient processing of applications
- Consistent and transparent regulatory framework stratified by risk
- Reliable performance measures which are reported to key stakeholders





New business process - questions

- One round of formal questions
 - Informal questions at any time
- Sponsor to nominate time frame for response
- Decision made on responses to questions





AUSPAR

- An AusPAR provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application.
- The TGA provides the sponsor with an opportunity to review the AusPAR (14 days).





Reality Check –

Submissions being received by the TGA

Module 1 contains the details of the number of volumes in each module so it must be opened first.

Common causes of delays:

- box containing Module 1 in middle/at bottom of palette
- box containing Module 1 not clearly identified.





Reality Check cont'd

- submission is unpacked from the boxes. Modules are laid out in order – Module, Volume, Copy. This allows staff to determine that all volumes have been received and to label or volumes.

Common causes of delays:

- packaging dossier incorrectly
- not paletting boxes sequentially
- not packing volumes sequentially
- volumes not labelled sequentially
- omitting volumes (whether intentional or not).





Preparation Tips

- ✓ Do select binders with durable covers, not paper files or flimsy cardboard covers.
- ✗ Don't bundle several modules into one volume, no matter how small they are.
- ✗ Don't overload the volumes. They should be no more than $\frac{3}{4}$ full.
- ✓ Do label each volume with the Module, volume and copy numbers.
- ✓ Do ensure that volume numbers within each Module are sequential and without gaps.
- ✗ Don't number volumes as 1A, 1B etc.



Packaging Tips

- ✗ Don't pack folders with spine at the top of the box.
- ✓ Do pack folders flat or standing upright with spine to the side of the box.
- ✗ Don't bubble wrap folders individually.
- ✗ Don't use polystyrene beads or peanuts to pack folders.
- ✓ Do use bubble wrap to fill voids between the folders and the box.





Boxing Tips

- ✓ Do number each box sequentially.
- ✓ Do put Module 1, along with any electronic copies, in box 1.
- ✓ Do put box 1 at the top of the palette, on the outside, clearly identified.
- ✓ Where there are more than 10 boxes, do put the boxes on a palette.
- ✗ Don't put more than one submission in the set of boxes on the one consignment note.





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Thank you
Questions?

