CTD/eCTD guidelines PIASA'S comments

Abeda Williams

PIASA general comments

- The guidelines appears to be adequate
- Reserve the right to comment once CTD / eCTD is implemented and operational
- Major concern is Roadmap and planned implementation
- Based on TGA guideline – older version

CTD guideline

- Based on TGA version of September 2007 – latest November 2008
- Impact on General Information guideline
- Introduction
  - Need to limit it to Human medicines
    - Not used for Vet or complimentary
- Documentation
  - Paper & electronic copies:
    - Need clarity on MCC policy on paper & electronic copies. Also see 1.1.3 (c) Part I (c) (b)
  - Module 1: Letter of application
    - Confidentiality of submissions – need to make re-emphasis compliance to Section 34 of Act.

General requirements guidelines

2.6 WHEN A PRODUCT SHOULD BE REGISTERED

- **(i) listed in Schedules to the Act;**
  - **Only schedule 0 requires registration. No list of S0**
  - **Schedules is intended to control of medicines i.e. 22A**
- **(iii) Under pharmacological classifications (Reg. 25).**
  - **Is not a criteria for registration**
- **iv) Intended use of a product and the text/words**
  - Vague therefore could be challenged as invalid

Act 101 – refer to section 14 as criteria for registration

General requirements guideline

- Same formulation with different proprietary names / same applicant = same application
- Cancellations or withdrawals:
  - Section 16 makes provision for Council to decide to cancel / withdraw medicine
  - When HCR makes decision it should be a notification
  - Need guidance on what is required for this notification
- Confusion between 2.10.5 (a) separate (same strength volume different) and 3.1.1. (e) separate (different strength)
- (m) (iii): CoPP – if available as per CTD requirements
- 3.1.3 (c) – heading not aligned to PIL guideline
  - If you are taking medicines ~~(bold and boxed)~~

General requirements guideline

- 3.1.3 (d) – Part 1 C c: Label
  - Section 36 labelling exemption – considered for both registered and pre-registration products
  - Similar comment in P&A CTD guideline (3.2.P.5.4) on Imported products
- 4. Preparation: CTD acceptable for **conversions**
- Each **cover** page of application
- 4.2. Have a header **or footer**
- 4.9. ~~Compliance to Trade and Metrology Act –~~ this not within the scope of Act 101
- 11. Samples: need to explain the process
- 13.9 – New codes
  - conversions (notification)
  - Pre-registration withdrawals
  - Pre-registration naming
  - General notification which is product specific

P&A CTD / e CTD

- 3.2.P.4.1 Specifications (name, dosage form)
- Additional specifications e.g. isomers, chirality, etc
  - not applicable to inactive? Copied from API
- 3.2.R.3: Information and data: API sources from multiple manufacturers.
  - Refer to P&A guideline section 3.1.7 as CTD used for amendments
- 3.2.R.3.3 ~~Confirmation of compliance with guidelines~~
  - Exemptions to the guideline needs to be considered on a case by case basis as guidelines are **"Guideline"** and could be outdated or not apply to a specific product

CTD / eCTD Roadmap

- Applications for registration of Medicines → ZA-CTD
- TGA "Guidance for Industry on Providing Regulatory submission for Prescription Medicines in Electronic Format (eCTD) in Australia ver 1.5 01/", for eCTD submission
- eCTD is limited to **prescription** medicines until the process is well defined and functional.
- Implementation phase in over a longer period of time
- **Conversion is a notfication** - format change with existing data