European Procedures

Strengthening Capacity in Africa for the Registration of New Drugs for Neglected Diseases

DNDi Workshop, Nairobi
24 June 2009
Matthias Dormeyer, Cologne

Drug Authorisation in the EU

- European Union (EU)
  - Not: Unites States of Europe
  - 27 countries
  - Similar to Africa?
  - Drugs: Free trade
- For major types of authorisations
  - National only (assessed by national authorities)
  - Mututal recognition procedure (MRP)
  - Decentralized Procedure (DCP)
  - Centralized Procedure (Article 58)

2

MRP/DCP

- Mutual Recognition Procedure
  - Authorisation already exists in one country (reference member state)
  - Recognition by other countries (concerned member states)
  - Defined timelines
- Decentralized Procedure
  - No authorisation exists
  - Several to all EU countries involved
  - Assessment by one county representative for all
  - Defined timelines
- National implementation phase

3

Centralized Procedure (I)

- Authorisation in the whole EU simultaneously
  - Can be mandatory, e.g. orphan drugs
- European Medicines Agency (EMEA)
- CHMP – Committee for Human Medicinal Products
  - Representatives from all EU member states
  - Responsible for assessment
- Rapporteur and Corapporteur are assigned
  - Initial review of the dossier on behalf of the CHMP
  - Followed by discussion and hearings in the committee
- CHMP adopts opinion!

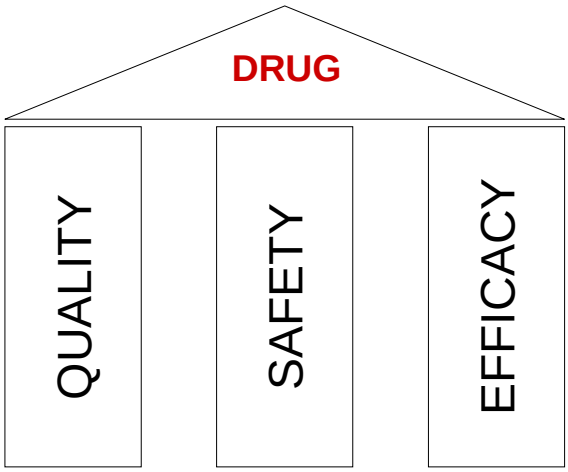
4

Centralized Procedure (II)

- Eligilibility request
- Assignment of Rapporteur/Corapporteur
- Submission of the dossier
  - CTD format (eCTD)
- Fixed Timelines: 210 days plus clock-stop
  - Day 80 – Draft assessment report
  - Day 120 – Assessment report and list of questions: Clock-stop
  - Day 121 – Submission of response: Restart clock
  - Day 210 – CHMP Opinion
- European Commission Procedure: Decision

5

"The Three Pillars of Drugs"



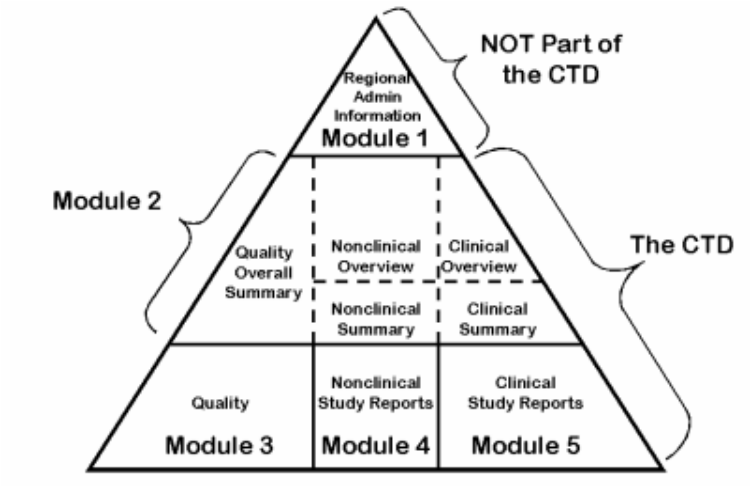
6

The Common Technical Document

- Structure for application dossiers
  - USA, EU and Japan
  - Accepted by other countries as well
- The CTD consists of five modules
  - Module 1 Regional and administrative
  - Module 2 Overview and Summaries
  - Module 3 Quality (pharmaceutical documentation)
  - Module 4 Non-clinical data (safety)
  - Module 5 Clinical data (efficacy)
- Today: eCTD

7

The CTD Structure



8

CPP Procedures

- Most Industrialized nations have strong regulatory authorities
  - E.g. Swiss, Canada, Japan, Australia, etc
  - Normally full application procedure
- Countries with less experienced authorities frequently rely on the assessment of "strong" authorities.
  - Certificate of Pharmaceutical Product
  - (WHO certification scheme)
  - Drug X is authorized for indication Y in COUNTRY
  - Legalisation required (e.g. public notary)
  - Authorisation on the basis of CPP
- No such procedure accepted by Western countries!

9

Article 58 (1)

- Drugs not intended for the use in the EU
- Orphan legislation
  - Intended to stimulate development for dugs against orphan diseases in the EU
  - Excluding procedures?
- Article 58 procedures follows the CP Principles
  - Eligibility request
  - Timelines
  - CTD structure
  - Assignment of Rapporteur/Corapporteur
  - Fees
  - Establishment in the EU (EEA) required
- Minor differences only
  - No brand name required, etc

10

Article 58 (2)

- Particular procedures apply
  - Accelerated review, exceptional circumstances etc
- Involvement of experts
  - Possibility for experts in the therapeutic field to be involved in the process
  - Identified and nominated by WHO
  - Non-voting in the CHMP
- CHMP opinion
  - Can be certified
- Post opinion procedures (variations etc)

11

Authorisation in Africa - Thoughts

- "Three pillars of a drug"
  - Quality – Uniform standards required
  - Non-clinical – Studies independent of the region
  - Clinical – Input from concerned countries required
- Favourable risk-benefit ratio
- Common procedures:
  - Language of dossier/information?
- CHMP/EMEA like apporach?
  - Committee representing various countries
  - External experts
  - Opinion can be nationally implemented

12