PHARMACEUTICALS AND INTELLECTUAL PROPERTY TRAINING SEMINAR

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Medicines: from discovery to patient

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Medicines: from discovery to patient

1. Innovation: the discovery and development process
2. The application for marketing authorisation
3. Data submission
4. Concession to generic manufacturers

Innovation: the discovery and development process

- Understand the disease and underlying cause
- Choose a target molecule
- Find ‘lead compounds’
- Perform early safety tests – ADME/Tox
- Lead optimisation
- Pre-clinical testing
- Clinical trials
- Pharmaceutical development

Innovation: the discovery and development process

Outcome: a body of evidence of safety and efficacy for the new medicine and its delivery mechanism, formulation and large-scale manufacture

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Organise, analyse, summarise ……. data

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Dossier: Application to a Health Authority for Marketing Authorisation of the new medicine

Innovation: the discovery and development process

The intellectual property (discoveries and inventions) resulting from this process include:

- The process to manufacture the active pharmaceutical ingredient
- The process to manufacture the medicine
- The medicine itself
- The first indication for use

Innovation: the discovery and development process

The discovery and development of new medicines is a very lengthy, complicated and costly process

- **Time investment**

About 9 – 13 years to develop 1 new medicine from the time it's discovered to the compilation of a marketing authorisation application

+

Time taken for registration by a Health Authority (timelines vary between countries)

innovative medicines South Africa

COMPARISON OF REGULATORY APPROVAL TIMES OF SEVEN PRODUCTS IN SOUTH AFRICA, CANADA AND EUROPE

SA TAKING >3X AS LONG

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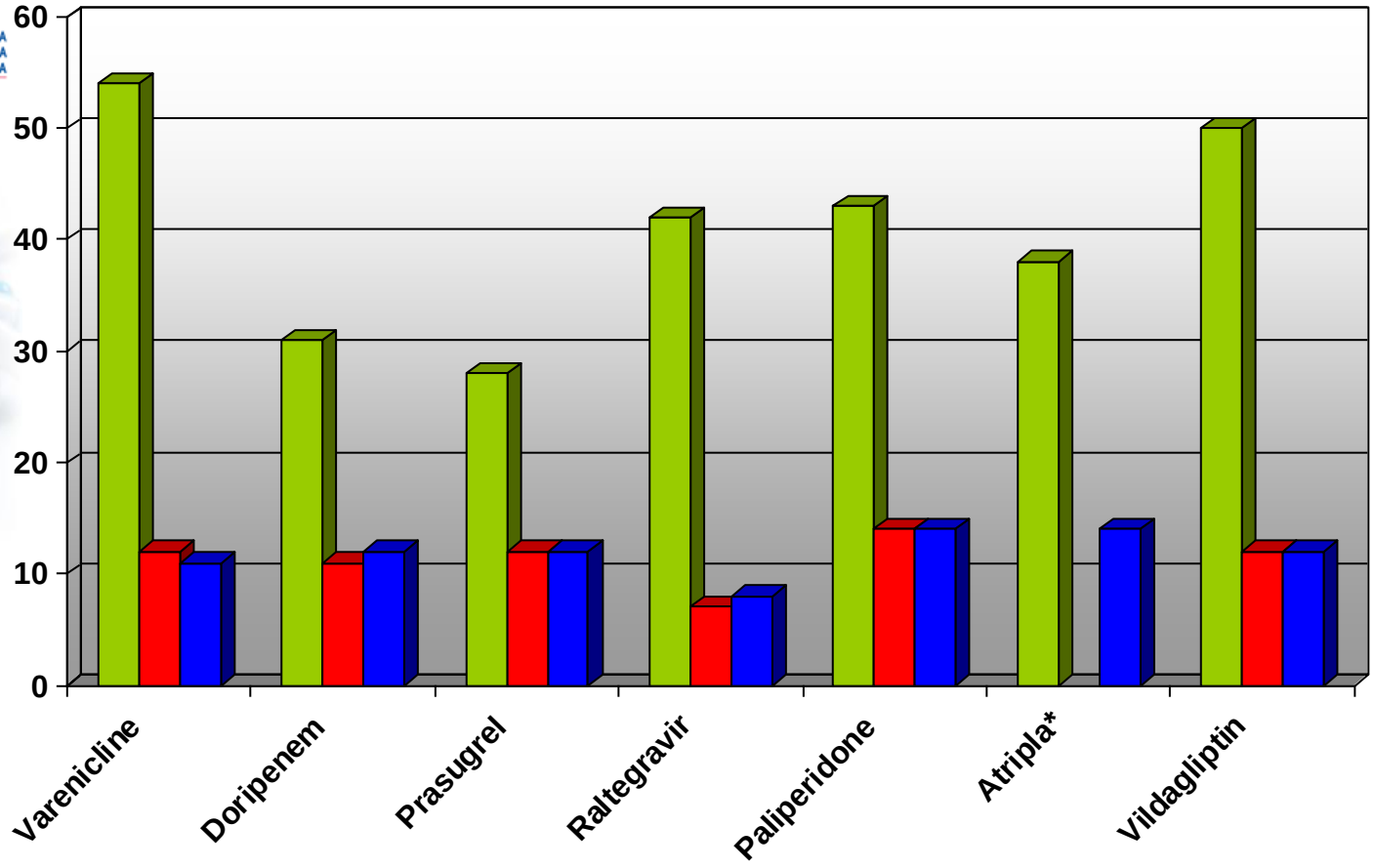


Companies and Intellectual Property Commission
a member of the dti group

Average approval time in months: MCC 41 vs Health Canada 11 vs EMEA 12

Adams & Adams

* Brand Name (Combination product of Efavirenz, Emtricitabine, Tenof[illegible])

Innovation: the discovery and development process

- **Cost investment**

$ 800 million - $ 1 billion

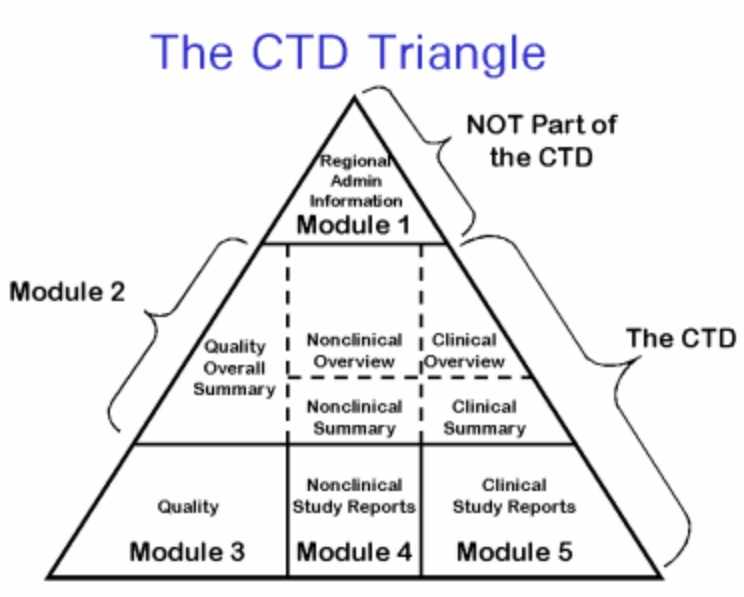
This includes the costs of thousands of failures:

- 5 000 – 10 000 molecules enter the R & D pipeline
- Only 1 receives HA approval

The application for marketing authorisation

- Section 15 of Act 101/1965: Registration by MCC a pre-requisite to sale of a medicine
- Prescribed form and particulars:
  - ZA Common Technical Document
  - Form, regulations and guidelines give details
  - 5 Modules

The application for marketing authorisation



The application for marketing authorisation

- **Module 1:** Letter of application and other regional-specific information
- **Module 2:** Quality overall summary, and non-clinical and clinical overviews and summaries
- **Module 3:** Quality – API, PP, facilities, equipment ….
- **Module 4:** Non-clinical study reports
- **Module 5:** Clinical study reports

Data submission

- ZA CTD MAA contains comprehensive data to facilitate evaluation by the HA of the safety, quality and efficacy of the medicine
- The application is a full disclosure of all collected data or grants access by the HA to such data if not provided (e.g. raw data)
- The ZA HA has a statutory obligation to preserve the secrecy of this information

Data submission

- Section 34 of Act 101/1965

- Obligation to preserve secrecy of data by MCC, MRA and their agents, except when performing *bona fide* functions and ……..
- All processes and procedures of MCC, MRA and their agents must give effect to this section

Concession to generic manufacturers

- **Bioavailability** refers to the rate and extent to which the API or active moiety is absorbed and becomes available at the site of action to exert its therapeutic effect
- Innovator medicines – bioavailability is determined in clinical trials
- Generic medicines - bioavailability is determined/assumed:
  - *In vivo* study:
    - e.g. narrow safety/efficacy margin
    - bioequivalence study (comparative bioavailability study using innovator comparator)
  - *In vitro* study - biowavers (e.g. comparative dissolution)
  - Assumed – dependant on formulation and dosage form e.g. IV solutions

Concession to generic manufacturers

- The Bolar Provision of the Patents Act allows:
  - these experiments to be conducted
  - using the patented medicine as the comparator
  - during the lifetime of the patent
  - to enable generic manufacturers to demonstrate bioequivalence of their medicines
  - prior to patent expiry of the innovator medicine
- the Bolar Provision facilitates the registration of generic medicines
  - Reduced development time
  - Reduced development costs
  - Reduced registration time