Adams & Adams

Intellectual Property Specialists

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
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2009

Innovative Medicines South Africa

Training course partially sponsored by IMSA

CONTINUING EDUCATION
UNIVERSITY OF PRETORIA

Training course organised by CEat UP Trust

TRAINING COURSE

12-14 February 2009
Main Campus, University of Pretoria

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

Securing your INTELLECTUAL PROPERTY WITHIN Medicinal product registration PROCEDURES-technical issues

by
Salma Ismail

- IP is a pharmaceutical or biotech company's most valuable resource and its protection is key to that company's future success

CONTENTS:

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

PRODUCT DEVELOPMENT

Launch
Registration
Clinical Studies
Pharmaceutical Development
Pre-clinical Studies
Global Development Plan
Discovery

~ 7 Years (goal)
~ 10 years (current)
~ 12 Years (5 years ago)

Legislative requirements for registration of medicinal products with South Africa

5

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965
  - 15. Registration of medicines
  - 1. Every application for the registration of a medicine shall be submitted to the registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant medicine and by the prescribed registration fee.

MEDICINE REGISTRATION FORM 1

8

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

Part	Title	Contents
1A	Administrative Particulars	Particulars of Applicant, Pharmacist to communicate with MCC, manufacturer, packer, QC site, FPRR and basic med particualrs. Amendment history table.
1B	Table of content	Comprehensive TOC for all dossier Parts
1C a)	Package insert	Scientific Package Insert
1C b)	Patient Information Leaflet	PIL
1C c)	Label	e.g. Blister, vial, carton printing
1D	Foreign Registration	EU, Australia, UK, USA, Canada, Sweden, Japan details

MEDICINE REGISTRATION FORM 1 ctd

Part	Title	Contents
2A	Pharmaceutical and Biological Availability	In vivo and/or in vitro equivalence studies as proof of efficacy
2B	Summary Basis for Registration Application (SBRA)	Summary of clinical data
2C	Pharmaceutical Expert Report (PER)	Independent, objective and comprehensive discussion of the quality of the product
2D	Pre-clinical Expert Report (PCER)	Independent, objective and comprehensive discussion of the pre-clinical product development
2E	Clinical Expert Report (CER)	Independent, objective and comprehensive discussion of the clinical product development with reference to the clinical information in the PI
3A	Active ingredient(s)	Chemical details Source (name & address) Drug Master File

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

MEDICINE REGISTRATION FORM 1 ctd

Part	Title	Contents
3B	Formulation	Unit formula and purpose of ingredients
3C	Raw Materials	1. Specifications and limits 2. Control methods 3. Control Labs
3D	Container/packaging materials	1. Specifications and drawings of immediate container 2. Control procedures 3. Description of bulk container 4. Indication of supplier tests
3E	Manufacturing procedure	1. Manufacturer and packer 2. Manufacturing and packaging procedures 3. Validation protocol
3F	Finished product	1. Specifications and limits 2. Control methods 3. Validation 4. FPRC 5. FPRR 6. Certificate of Analysis

MEDICINE REGISTRATION FORM 1 ctd

Part	Title	Contents
3G	Stability data	1. Programme 2. Data 3. Shelf-life 4. Control procedures and validation if different to 3F
3H	Pharmaceutical development	Description of pharmaceutical development process
4	Pre-clinical studies	Toxicology, teratogenicity, carcinogenicity, animal pharmacokinetics and pharmacodynamics. PCER
5	Clinical studies	Efficacy, pharmacology, pharmacokinetics, safety. CER

Documents submitted to the Medicines Control Council

- PRACTICAL AREAS OF CONCERN:
- MRF1
- MRF2
- Additional Requirements
  - SAMPLES
  - SITE MASTER FILES? CONFIDENTIALITY
  - MANUFACTURING SITE INSPECTION REPORTS etc

MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

- **34. Preservation of secrecy**
  - ❖ No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer.

GENERAL INFORMATION
Version 4 Date for implementation of 3.1.3 a), b)1 August 2008

- 2.3 CONFIDENTIALITY/SECRECY
- The confidentiality of information submitted to the MCC is governed by Section 34 of the Act. The MCC, committee members or staff of the Medicines Regulatory Affairs (MRA), may NOT
- disclose to any person, any information acquired in the exercise of powers or performance of functions under the Act and relating to the business affairs of any person, except
- for the purpose of exercising his/her powers, or for the performance of his/her functions under the Act, or
- when required to do so by any competent court or under any law, or
- with the written authority of the Director-General, or
- use such information for self-gain or for the benefit of his employer.
- **The MCC may insist on written confirmation of the identity and affiliation of an individual inquiring telephonically, or in person, about a medicine. No information shall be disclosed telephonically unless the Medicines Control Officer knows the enquirer is entitled to receive the information.**

13

PHARMACEUTICAL AND ANALYTICAL
Date of implementation2 July 2007

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- **3.1 PART 3A ACTIVE PHARMACEUTICAL INGREDIENT (API)**
- ……3.1.4 The name and physical address of each manufacturer of the API being applied for should be stated. No API from any source, other than the approved source(s), may be used.
- 3.1.5 The **Active Pharmaceutical Ingredient File (APIF), or the open part of the DMF, should be submitted in the dossier and should include the following information: (Neither the complete nor the open part of the DMF should be sent directly to the MCC.)**
- The name and physical address of the manufacturer (including any intermediate manufacturer).
- The approved/INN name of the relevant API.
- The chemical name and chemical structure of the API……

14

PACKAGE INSERTS FOR HUMAN MEDICINES
Version 2 Date of Implementation1 August 2008

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- **For a multisource medicine (MSM) the most recent approved innovator package insert and/or MCC approved standardised package insert (SPI) template, if available, should be used as reference for the compilation of MSM package inserts. The indications and the safety profile for a MSM should at least be in line with that of the innovator package insert. Any additional information as required by the applicant should be submitted with relevant clinical data.**
- **Standardised package inserts (MCC approved) contain only the minimum information required. It is the applicant's responsibility to add new safety information to a package insert which is based on an SPI as soon as such information becomes available and make any other necessary amendments, with supporting references (as it is for applicants of innovator products). The information is subject to approval by MCC.**
- **Reference to the following standard references are generally acceptable if SPIs are not available:**
  - **Pharmacological actions: Goodman & Gilman. The Pharmacological Basis of Therapeutics.**
  - **Safety matters: Martindale, The Complete Drug Reference**
  - **General: USP DI**

15

GUIDELINE ON PROPRIETARY NAMES FOR MEDICINAL PRODUCTS

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- The issue of whether a particular proprietary name may constitute an infringement of another entity's intellectual property rights cannot be one of the Medicines Control Council's concerns and is, therefore, not taken into account during consideration of the acceptability of a proposed proprietary name.

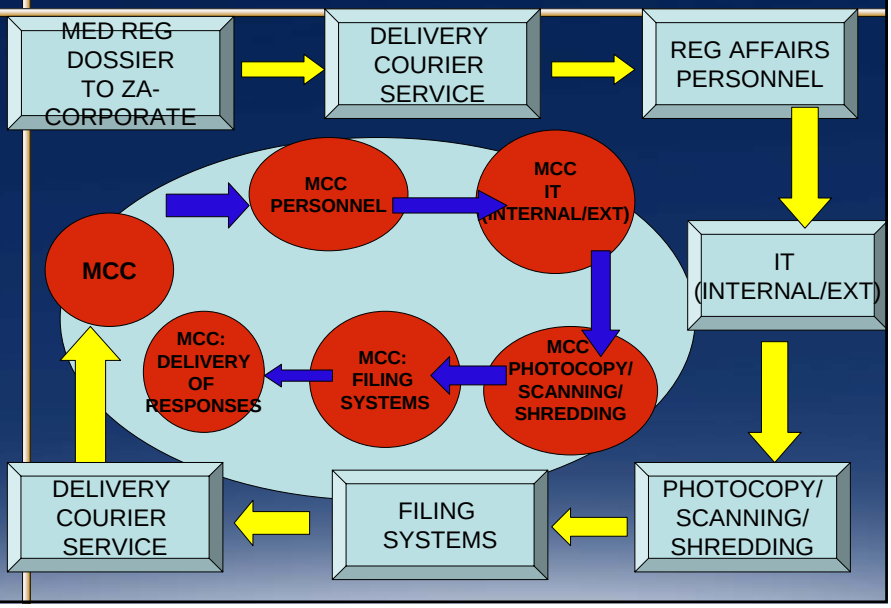
16

Handling regulatory submissions in South Africa- practical points to consider.

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- TECHNICAL ASPECTS

PROCESS: REGULATORY AFFAIRS AND HANDLING OF IP



DELIVERY/COURIER SERVICE

- MAINTANING CONFIDENTIALITY
  - CORRECT DELIVERY ADDRESS
- COURIER BEEN INTERCEPTED-
  - MALICIOUS INDUSTRIAL ESPIONAGE

19

REGULATORY AFFAIRS PERSONNEL

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- IN-HOUSE/CONSULTANTS:
- Training on handling information:
  - Intellectual property/confidentiality
- TEMP STAFF-copying etc
- Dealing with "outside world" –telephonically or other
- Potential resignation: consider info accessible to person

20

I.T-(IN-HOUSE/EXTERNAL)

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- ACCESS: INTER-DEPARTMENTAL IT limitations
- Back-up systems

21

PHOTOCOPYING/SCANNING/ SHREDDING

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- Outsourced copiers- internal hard drive—??
- ACCESS TO COPING DOSSIERS
- FOOL PROOF SHREDDING SYSTEM

22

FILING SYSTEMS/OFF-SITE STORE

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- ACCESS
- AUDIT

AUDITORS & OTHER

- IN-HOUSE/EXTERNAL
- ACCESS TO INFORMATION
- MARKETING/PROMOTIONAL INDIVIDUALS

IN CONCLUSION:

- PHARMACEUTICAL REGULATORY AFFAIRS PERSONNEL HAVE THE RESPONSIBILITY TO SECURE INTELLECTUAL PROPERTY!!