

PHARMACEUTICAL LEGISLATION IN SLOVAK REPUBLIC

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Legislation background:

Medicines Act No 140/1998 - Medicinal Products and Medical Devices

Sub-laws:

- Registration of Medicinal Products
- Pharmaceutical and Toxicological-Pharmacological Testing
- Good manufacture and Wholesale Practice
- Good Pharmacy Practice
- Clinical Trials and GCP
- Good Laboratory practice
- Advertising Law No 220/1996 and amendmends
- Testing Law No 30/1968 and amendmends

DRUG LAW

Definitions

Manipulation with the Medicinal Products and Medical Devices

- general provisions
- licencing

Testing

- pharmaceutical and toxicological-pharmacological testing
- clinical trials

Marketing of the medicinal products and medical devices

- registration (MA)
- labeling/ information
- medical devices approval

DRUG LAW

M a n u f a c t u r i n g

Wholesale distribution

Pharmaceutical Care

S u p e r v i s i n g

Veterinary Medicines

Regulatory Authorities

MANIPULATION WITH DRUGS AND MEDICAL DEVICES

General Provisions

Natural Person - appropriate qualification

Legal Person - qualified person

Licensing

Application for the manufacture/wholesale to the MoH

Application for the pharmaceutical care to the regional authorities

Pre-requisites :

positive opinion of the SIDC

positive opinion of the professional associations

adequate premisses and equipments

Variations

Withdraw

TESTING

Approximation of the Directive 75/318/EEC with amendments

Pharmaceutical testing

- quality of the products, active ingredients, excipients
- testing laboratories authorisation
- SIDC opinion/binding

Toxicological - pharmacological testing

- potential toxicity of the product
- pharmacological properties
- testing laboratories authorisation
- SIDC opinion/binding

TESTING

Approximation of the Directive 75/318/EEC with amendments

Good Laboratory Practice - mandatory

Sub-law regulation :

- **Pharmaceutical and Toxicological-pharmacological Testing**
- **Approximation of the Annex Part 2 and 3 to Directive 75/318/EEC**

CLINICAL TRIALS

Approximation the Annex Part 420 Directive 75/318/EEC

General Requirements

Conduct of Trials

Investigator / Authorisation

Good Clinical Practice / mandatory

Definition - Phase I - IV

**Approval Process - SIDC
- documentation**

**Obligations : sponsor
investigator**

Sub - law regulation :

Clinical Trials and Good Clinical Practice

AMMENDMENT OF THE MEDICINAL ACT 2000

- **Definition of the Medical Devices - extended**
- **Notification procedure for IV phase of the clinical trials**
- **Definition and responsibility of the monitor**
- **Classification of the OTC products**
- **Novelisation of the application form**
- **Harmonisation of the requirements for the documentation**
- **Generic registration**
- **Data exclusivity**
- **Definition "essentially similar"**
- **Variations**

AMMENDMENT OF THE MEDICINAL ACT 2001

- More detailed definition of the MD
- State Institute for Drug Control is the licensing authority for MA
- Acceptance of the EU Assessment Report
- TSE requirements
- Data exclusivity - 10 years "high tech"
- Pre-condition MA
- Variations:
 - 90 days "type I"
 - 30 days "type II"
- Labelling exemptions
- MA exemptions
- Pharmacovigilance - new provisions

REGISTRATION - MARKETING AUTHORISATION

Approximation of the Directive 65/65/EEC with amendments and 92/26/EEC

No product may be placed on the market unless MA has been issued

Exemptions from the registration

Application

Format similar with Article 4 and 4a of the Directive 65/65/EEC

S a m p l e s

GMP, GLP, GCP compliance declaration

Assessment Reports

REGISTRATION - MARKETING AUTHORISATION

Approximation of the Directive 65/65/EEC with amendments and 92/26/EEC

SIDC

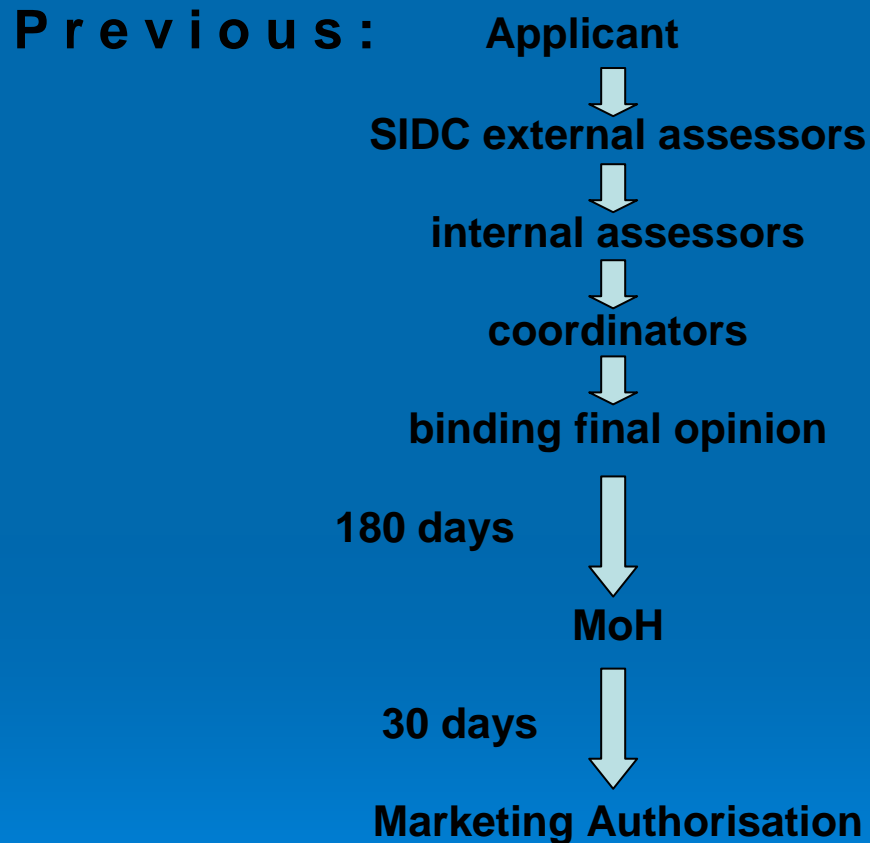
- evaluation process
- final opinion/binding
- time limit 180 days
 - 90 prolongation
 - 210 days issuing of the MA

Withdraw of MA

Sub-law regulation :

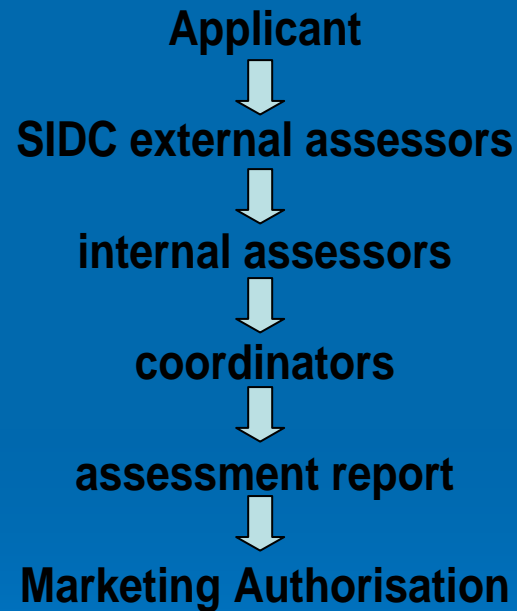
Registration of the medicinal products

REGISTRATION PROCEDURE



REGISTRATION PROCEDURE

Current situation:



210 days

APPLICATION FOR MARKETING AUTHORISATION

- Name (identification) of the applicant
- Manufacturing location
- Brand name
- Qualitative and Quantitative content of the product
- Manufacturing procedure
- Expire date
- Theapeutic indication
- Pharmaceutical Testing
- Pre-clinical and clinical Testing
- SPC
- Samples of the packaging

APPLICATION FOR MARKETING AUTHORISATION

- **PIL**
- **Manufacturing Authorisation**
- **Marketing Authorisation (if any)**
- **Samples**
- **GMP, GLP and GCP declaration**

Generics Application

Data Exclusivity

Essencial Similarity

New Composition

New Indication

- **Patent Protection evidence**

LABELIG / INFORMATION

Approximation of the Directive 92/27/EEC

Outer packaging - Article 2

Immediate packaging - Article 3

Additional information - Article 5

U s e r P a c k a g e L e a f l e t

according the Article 7

local language/mandatory

multilingual - essentially similar

S u m m a r y o f P r o d u c t C h a r a c t e r i s t i c s

Article 4a of the Directive 65/65/EEC

local language / mandatory

GENERIC REGISTRATION

Approximation of the Directive 65/65/EEC Article 4

A b r i d g e d p r o c e d u r e

Results of the pharmacological-toxicological tests and results of clinical trials shall not be required if can be demonstrated

- product is essentially similar/registered in SR consent by holder
- well established” product
- product is essentially similar/6 years marketed

D i f f e r e n t t h e r a p e u t i c a l u s e - full dossier

New combination - pharmacological - toxicological and clinical data for combination

VARIATION / RENEWAL

V a r i a t i o n s

Obligation of the MA holder

- ❖ ensure, that the properties of the medicinal product registered are in accordance with the documentation submitted with the application for the registration

Holder has to apply for any intended variation concerning the registered product

O f f i c i a l f o r m

Definition of the variations which has to be approved

R e n e w a l

MA is valid 5 years

three months before expire date

declaration that no changes date on pharmacovigilance

MANUFACTURING OF MEDICINAL PRODUCTS

Approximation Directive 91/356/EEC

Requirements:

- premises and equipments with GMP compliance
- testing laboratories
- qualified persons for :
 - manufacturing
 - registration
 - quality assurance

GMP definition / GMP mandatory

Obligations

WHOLESALE DISTRIBUTION

Approximation of the Directive 92/25/EEC

R e q u i r e m e n t s :

- **premises and equipments with GWP compliance**
- **qualified person**

Limitation for licence

Good wholesale distribution practice

O b l i g a t i o n s

Sub-law regulations :

Good Manufacturing Practice and Good wholesale Practice

PHARMACEUTICAL CARE

Definition

Community Pharmacies/outlets

Hospital Pharmacies

Outlets for Medical Devices

Licencing for pharmaceutical care in the community pharmacy

- only natural person
- pharmacist with qualification
- one pharmacy/outlet

Good Pharmacy Practice - mandatory

Obligations

Licencing for hospital pharmacies M o H

Pre-requisites

- binding opinion of SIDC

Sub-law regulation :

Good Pharmacy Practice

REGULATORY AUTHORITIES / SUPERVISING

Ministry of Health

- licencing the manufacturers
wholesalers
hospital pharmacies
- appeal process
- supervision

Regional Authorities

- supervision
- licencing the community pharmacies and outlets of Medical Devices

REGULATORY AUTHORITIES / SUPERVISING

State Institute for Drug Control

- Marketing Authorisation
- Supervision : manufacture
wholesale
pharmacies
- Opinion: licencing
- Medical Devices - Competent Authority
- Clinical Trials Approval
- Laboratory Control
- ADR monitoring
- Control of Advertising
- Inspection : GMP
GLP
GCP
- Authorisation

ADVERTISING OF MEDICAL PRODUCTS

Approximation of the Directive 92/28EEC Amendment the Advertising Law

Definition

Rx and OTC in reimbursement list not allowed

Only Holder of the MA

Content of the advertising

Shall not be misleading

SPC compliance

Shall not contain material which

- suggests that the medicinal product is foodstuff or cosmetics
- refers to recommendation by scientists.....
- suggests that the safety or efficacy is due to the fact that it is natural e.t.c.

ADVERTISING OF MEDICAL PRODUCTS

Monitoring of advertising

SIDC

- monitoring
- withdraw
- punishment

no pre-approval procedure

HEALTH CARE BIOTECHNOLOGY

Health Care Biotechnological Products

- defined as the Medicinal Products
- registration and granting of the MA according the Medicinal Act
- GMP is strictly required
- patent protection according the Law 527/1990
- SPC
- GLP requirements
- generics