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UPDATES ON VETERINARY PRODUCTS REGISTRATION

National Pharmaceutical Control Bureau, Ministry of Health (MOH)

Presentation Outline

- Introduction
- Legislation & Regulatory Control
- Registration Road Map
- Product Classification
- Registration Requirements
- Challenges
- Conclusion

INTRODUCTION

Introduction

Why Veterinary Registration is required?

To protect the health of the consumer of foodstuffs of animal origin as well as to ensure that foodstuffs obtained from animals treated with veterinary products must not contain residues of the drug or its metabolites which might constitute a health hazard for the consumer.

To ensure the quality, safety and efficacy of the product

LEGISLATION & REGULATORY CONTROL

LEGISLATION

- Legal requirement – Sale of Drug Act 1952
- Control of Drugs and Cosmetics Regulations 1984
- Guideline: Registration Guideline of Veterinary Products (REGOVP)

Definition

A "Product" means

a **drug** *in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or* **animals** *for a* **medicinal purpose**

Definition

"Medicinal Purpose" means any of the following purposes:

- alleviating, treating, curing or preventing a disease or a pathological condition, or symptoms of a disease;
- diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;
- contraception;
- inducing anaesthesia;
- maintaining, modifying, preventing, restoring or interfering with, the normal operation of a physiological function;
- controlling body weight;
- general maintenance or promotion of health or well-being

(CDCR 1984)

REGISTRATION ROAD MAP

Registration Road Map

Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Registration Aug 1985 (Prescription Drugs)	Registration 1988 (OTC)	Registration Jan 1992 (Traditional Medicine)	Registration Feb 2002 (Cosmetics)	Registration August 2007 (Veterinary)
Licensing May 1987	Licensing 1992	Licensing Jan 1999	Licensing Jan 2004	GMP requirement for local manufacturer Jan 2012 Licensing July 2015
Surveillance 1995	Surveillance 1995	Licensing Wholesalers July 2002 Surveillance 1999	Surveillance 2004	Surveillance ?

IMPLEMENTATION DATE

- Veterinary product registration: 1st August 2007
- The implementation of the regulations on veterinary products shall be on all **products** containing scheduled poisons and non –scheduled poisons, intended to be administered to the animals for **medicinal purpose**
- GMP requirement for local manufacturer:1st Jan 2012
- Licensing for manufacturers, importers & wholesalers: 1st July 2015

IMPLEMENTATION DATE(con..)

- Health/Dietary Supplements and Herbal/Natural Products are under the control of Department of Veterinary Services (DVS) in accordance to the Feed Act 2009 starting from 1st July 2014.
- Medicated Feed is under the control of DVS in accordance to the Feed Act 2009 starting from 1st January 2015.
- Premixes(antibiotics for prevention and growth promotion) is under the control of DVS in accordance to the Feed Act 2009 starting from 1st July 2015.

CHRONOLOGY

- **April 2013**: Preparation & Presentation of policy paper –Control of Feed Additive (Health Supplement products & Herbal products) in Malaysia
- **Jun 2013**: Early announcement regarding Control of Feed Additive (Health Supplement products & Herbal products) & Licensing for Veterinary products during dialogue with MAHNIA
- **October 2013**: Briefing & Discussion session with industries & announcement to the industries
- **October 2013**: Further discussion of policy paper with DVS
- **November 2013**: Presentation of policy paper to the Feed Board

CHRONOLOGY (con..)

- **February 2014:** Dialogue with MAHNIA & Industries & reminder announcement
- **February 2014:** Presentation of policy paper to the Drug Control Authority meeting
- **April 2014**: Circular to the association & industries
- **June 2014**: Directive of Licensing of Veterinary products (Manufacturers, Importers & Wholesalers)
- **June 2014:** Meeting with DVS
- **June 2014**: Circular to the association & industries- extension of licensing to 1st January 2015

CHRONOLOGY (con..)

- **September 2014:** Meeting with DVS (premixes & medicated feed products)
- **October 2014**: Dialogue with MAHNIA and industries
- **Disember 2014**: Meeting with VAM & DVS

  Medicated Feed is under the control of DVS in accordance to the Feed Act 2009 starting from 1st January 2015.

  Premixes (antibiotics for prevention and growth promotion) is under the control of DVS in accordance to the Feed Act 2009 starting from 1st July 2015.

CHRONOLOGY (con..)

- **December 2014:** Circular to the association & industries-extension of licensing to 1st July 2015
- **February 2015**: Meeting with DVS
- **Mac 2015**: Technical Working Group meeting(tentative: next meeting: Sept/Oct 2015)
- **Mei 2015**: Discussion and meeting with DVS & VAM


PRODUCT
CLASSIFICATION

REGISTRABLE PRODUCTS

- Scheduled Poisons
- Non-Poisons (OTC)

Registrable Products
Scheduled poisons

- All products containing scheduled poisons (substances listed in First Schedule of the Poison Act 1952)
- e.g. Antibiotics, Antiprotozoals, Antifungals
- Registration number ending with alphabet HA e.g MAL 10061234HA

Registrable Products
Non-poisons (OTC)

- All products which do not contain scheduled poison and products other than Dietary/Health Supplement & Herbal/Natural products
- e.g. Antiseptic, Dental products, Analgesic (e.g. Paracetamol)
- Registration number ending with alphabet HX e.g MAL 10061234HX

Registrable Products
Water Soluble Powder

- Scheduled Poison and OTC substance in soluble powder to be added to drinking water and/or animal feed which may contain one or more active ingredients with excipients intended for oral administration for medicinal purpose need to be registered.

Registrable Products
Premixes

Premixes:

- Mixtures of one or more active ingredients, usually in suitable bases, that are prepared to facilitate feeding the active ingredients to animals. They are used exclusively in the preparation of animal feed for medicinal purpose
- Premixes containing Scheduled Poison and Non-poison for medicinal purposes
- Premixes containing antibiotics:
  - For medicinal purposes i.e treatment

Registrable Products
Health/Dietary supplement products

- Health/Dietary supplement products with therapeutic claims/indication **are under the control of** DCA and registered as OTC products

Registrable Products
Herbal/natural products for external use

- Herbal/natural products for external use & making a therapeutic claim/indication are considered as Non-Poison (OTC) product and need to be registered.

PRODUCTS NOT–REGISTRABLE UNDER DCA

Not-Registrable Under DCA
Feed and Feed Additives

Feed:

- "Feed" means any single or multiple material whether processed, semi-processed or raw, which is intended to be fed to animals;

Feed Additives:

- "Feed additive" means any added ingredient including micro-organism and enzyme not normally consumed as feed by itself, whether or not it has nutritive value, which affects the characteristics of feed or animal products;

Not-Registrable Under DCA

Premixes

- Premixes: antibiotics for growth stimulation/growth promotion and prevention of diseases

- Control by Department of Veterinary Services (DVS), Ministry of Agriculture

Not-Registrable Under DCA

Health/Dietary Supplement & Herbal/Natural products

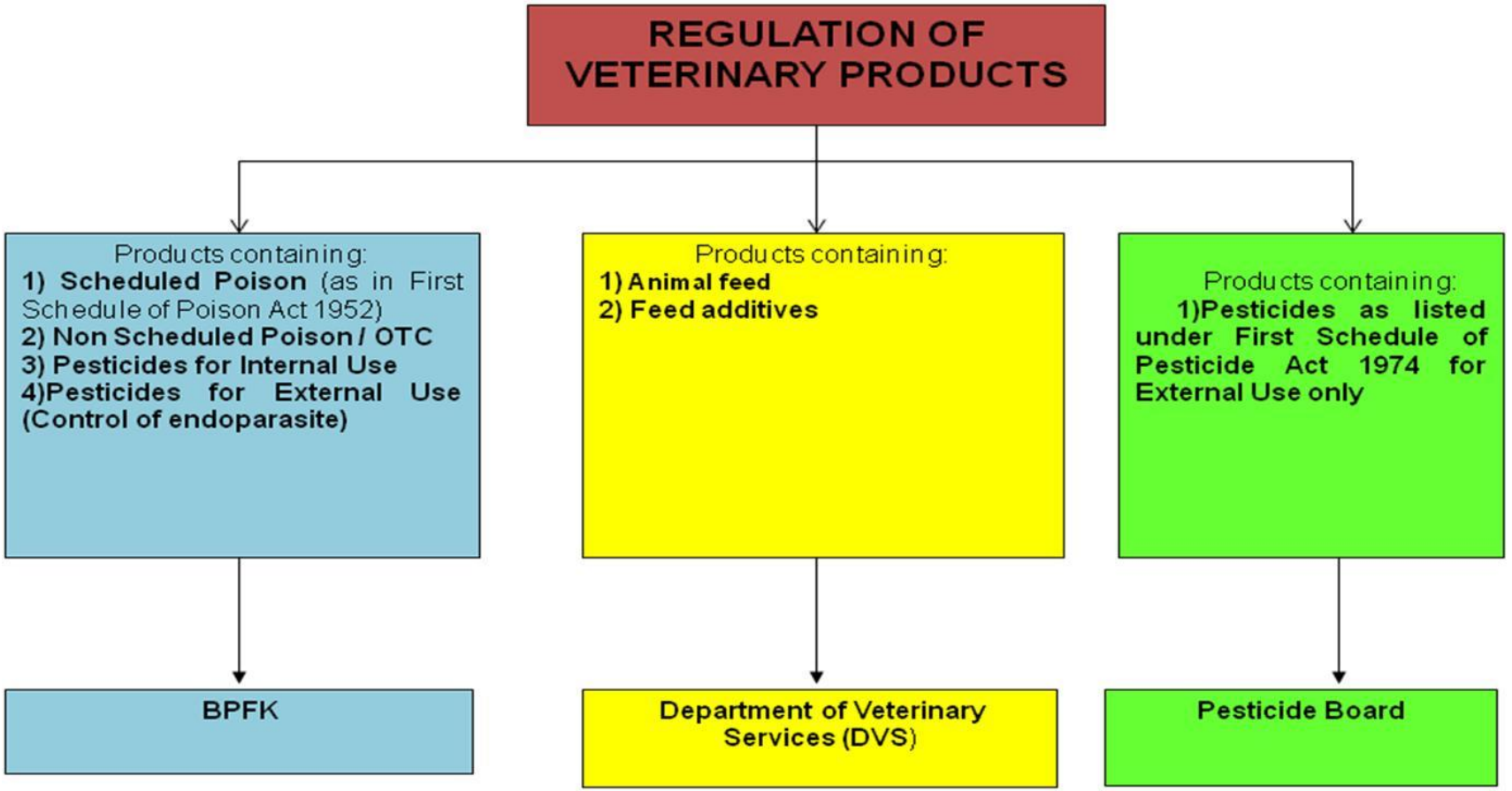
Dietary/ Health Supplements & Herbal/Natural products for oral use :

- Control by Department of Veterinary Services (DVS), Ministry of Agriculture

Not-Registrable Under DCA

Pesticides

- Pesticides as listed in the Pesticides Act 1974, used externally;
  "Pest" includes bacteria ,virus, fungi, weeds, insects, rodents, birds ,or any other plant or animal that adversely affects or attacks animals, plants, fruits or property
- Registrable under the Pesticide Board (Bahagian Kawalan Racun Perosak)
  Note: Oral preparations and injectables: DCA
- Products with combination of pesticides + scheduled poison are under the control of the DCA



- Products containing feed additives in combination with scheduled poisons will be regulated by the DCA.
- Products containing pesticide ingredients in combination with scheduled poisons will be regulated by the DCA.

NON-REGISTRABLE PRODUCTS

- Disinfectant
- Cosmetic
- Others

Non-Registrable Products
Disinfectant

Substance that is:

- recommended by its manufacturer for application to an inanimate object to kill a range of microorganisms
- not represented by the manufacturer to be suitable for internal use.

Non-Registrable Products
Cosmetics for Animals

A “cosmetic product” shall mean any substance or preparation intended to be placed in contact with the various external parts of the animal body or with the teeth and the mucous membrane of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition”

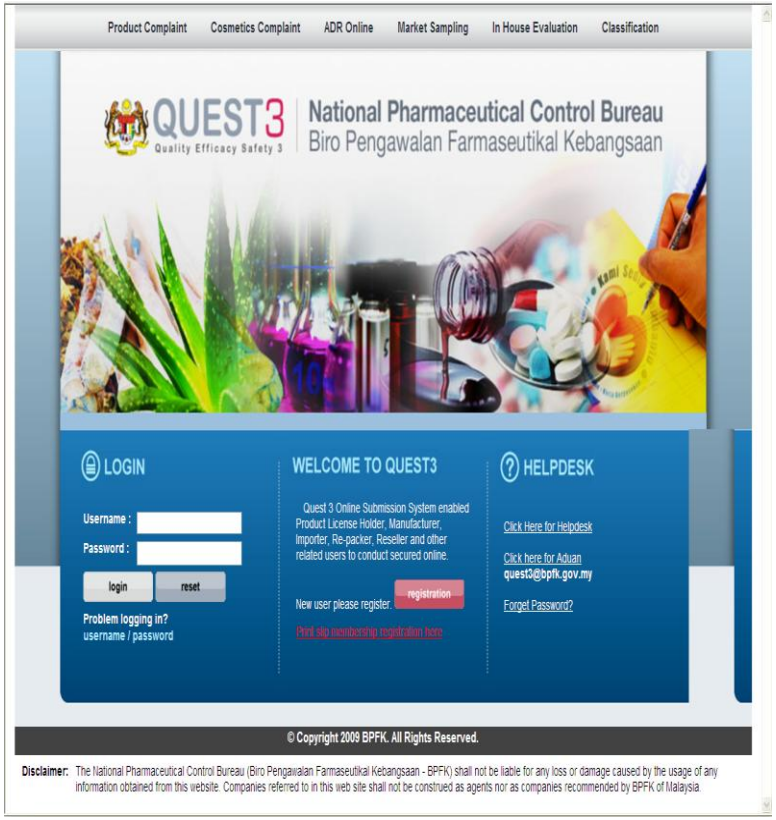
Non-Registrable Products
Others

- Diagnostic kits and reagents
- Non medicated medical and contraceptive devices
- Non-medicated bandages, surgical dressings, plaster, dental fillings
- Instruments, apparatus, syringes, needles, sutures, catheters.

REGISTRATION REQUIREMENTS

Online Application

- Via Quest2 and Quest3



Registration Requirements

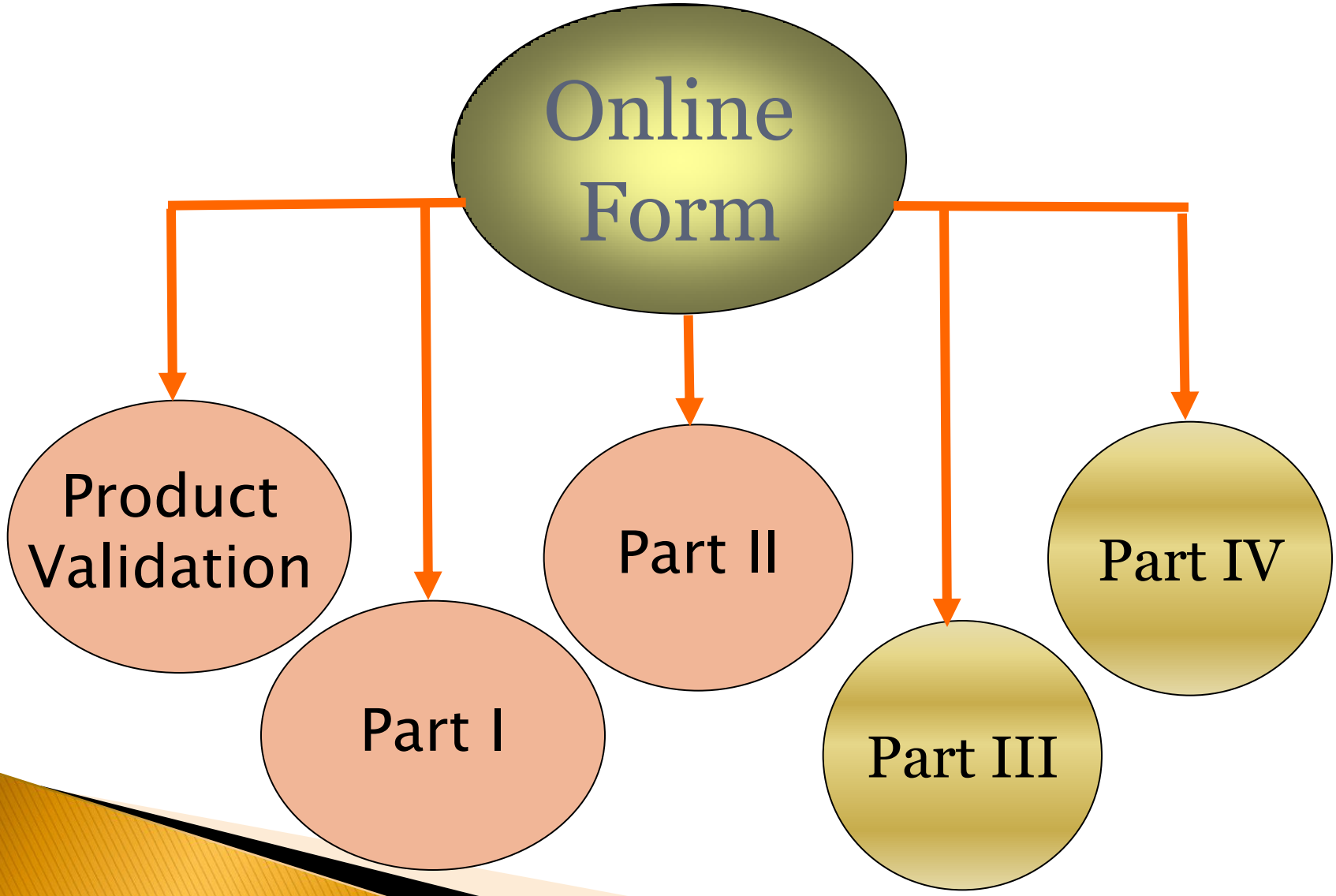
Data required to support an application is divided into :

a) Administrative documentation (Part I)
b) Quality documentation (Part II)
c) Safety and residues documentation (Part III)
d) Efficacy documentation (Part IV)

Data to be submitted will be based on each application type as follows :

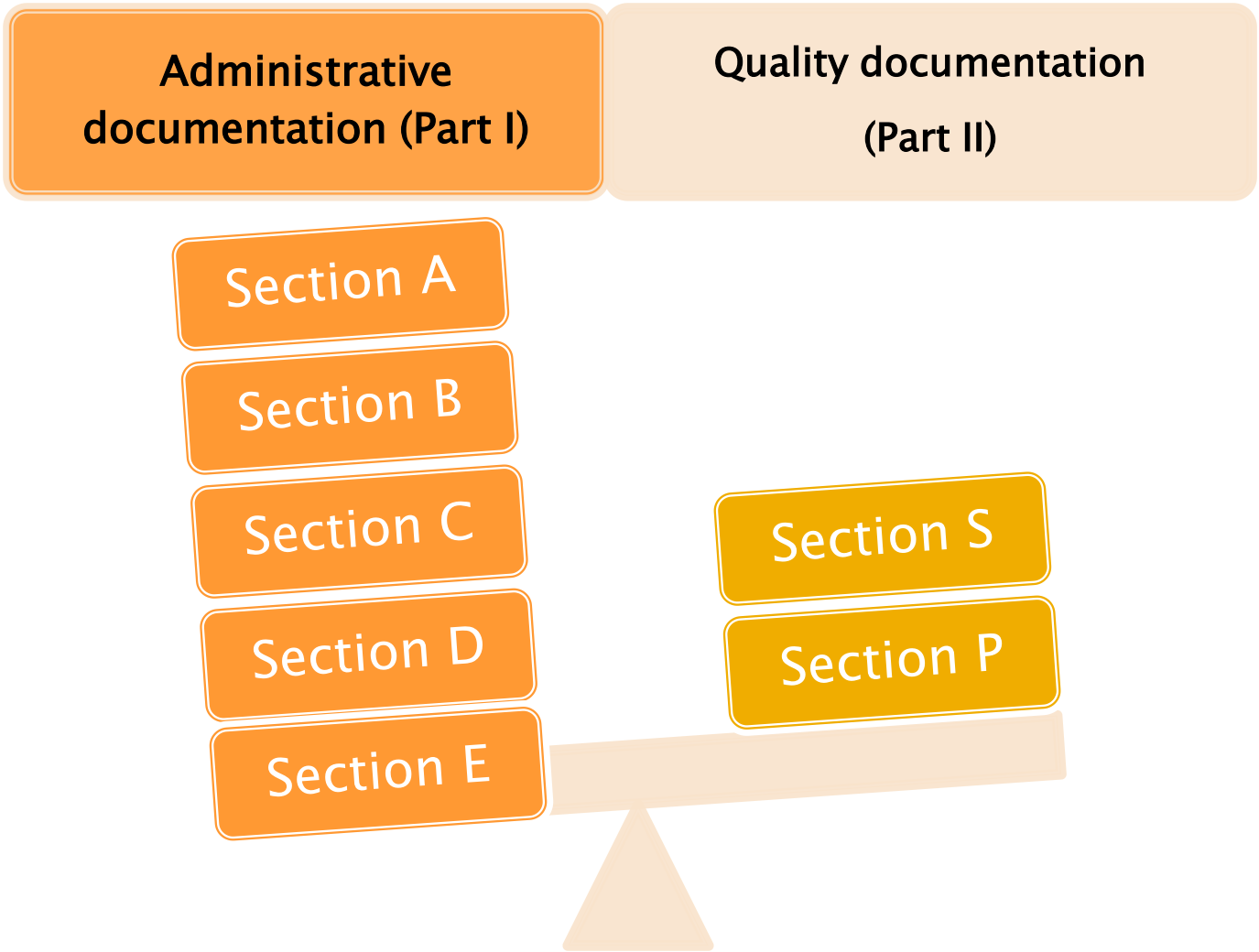
- Innovator Product : Parts I to IV
- Generic Product : Parts I & II

Application Form



Product Validation

- 1. PRODUCT NAME
  - Product name + strength + dosage form
- 2. DOSAGE FORM
- 3. ACTIVE SUBSTANCE
- 4. EXCIPIENT
- 5. ANY ANIMAL PARTS/MATERIALS
- 6. MANUFACTURER
- 7. PRODUCT CLASSIFICATION


Administrative documentation (Part I)
Quality documentation (Part II)
Section A
Section B
Section C
Section D
Section E
Section S
Section P

Administrative Documentation (Part I)
Section A: Product Particulars

- Product Description
- Pharmacodynamics
- Pharmacokinetics
- Indication(s)
- Target species
- Recommended dose
- Route of administration
- Contraindication

Section A: Product Particulars

- Warning & Precaution
- Drug interactions
- Pregnancy & Lactation
- Undesirable/Side effects/Adverse reactions
- Signs and symptoms of overdose and Treatment
- Storage Conditions
- Shelf Life – stability data
- Therapeutic code

Section A: Product Particulars

- **If the product is for food producing animals**
  - **Withdrawal period(s)**
  - Different withdrawal period for – meat and offal, milk, eggs
  - **Maximum Residual Limit (MRL)**
  - According to target species
  - Appendix 9 (REGOVP) – Allowable MRL

Section A: Product Particulars

- Maximum Residual Limit

  A Maximum Residual Limit (MRL) is defined as the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or g/kg on a fresh weight basis) which may be accepted to be legally permitted or recognised as acceptable in or on a food.

- Withdrawal Period

  The withdrawal period is defined as the period between the last administration of the veterinary product to animals under normal conditions of use and the production of foodstuffs from such animals.

Section B: Product Formula

- Batch size : kg , L
- Genetically Modified Organism (GMO)- if yes, please declare.
- Actual **Batch Manufacturing Master Formula**

Doc.No: XXXXXXXXX	**BPKK Sdn. Bhd** **Batch Manufacturing** **Formulation/Record**	Batch No
Effective Date:		Mfg Date
Batch Size:	**Name of Product: XXXXXXXXXX**	Exp Date
Prepared by:	Reviewed by:	Date Started
	Approved by:	Date Completed

Issued by: QA manager Date:

FORMULATION						
Batch No.	**Ingredients**	**Material code**	**Strength**	**Batch Quantity**	**Weighed by**	**Checked by**
		TOTAL	**100%W/W**	**1000KG**		

Section C: Particular of Packing

- **Pack size**
  - Weight , volume , quantity
- **Container type**
  - Type of packaging
  - Bottle , sachet , bag
  - HDPE , PP , aluminium

Section D: Label (Mock Up) for Immediate Container, Outer Carton & Proposed Package Insert

- Label – Immediate container
- Label – Outer Carton
- Proposed Package Insert

Section E: Supplementary Documentation/Other Information

- Product Owner
- Letter of Authorization from the Product Owner
- Letter of Appointment of Contract Manufacturer from the Product Owner
- Letter of Acceptance from Contract Manufacturer to the Product Owner
- Is the Active Substance(s) patented in Malaysia

Section E: Supplementary Documentation/Other Information

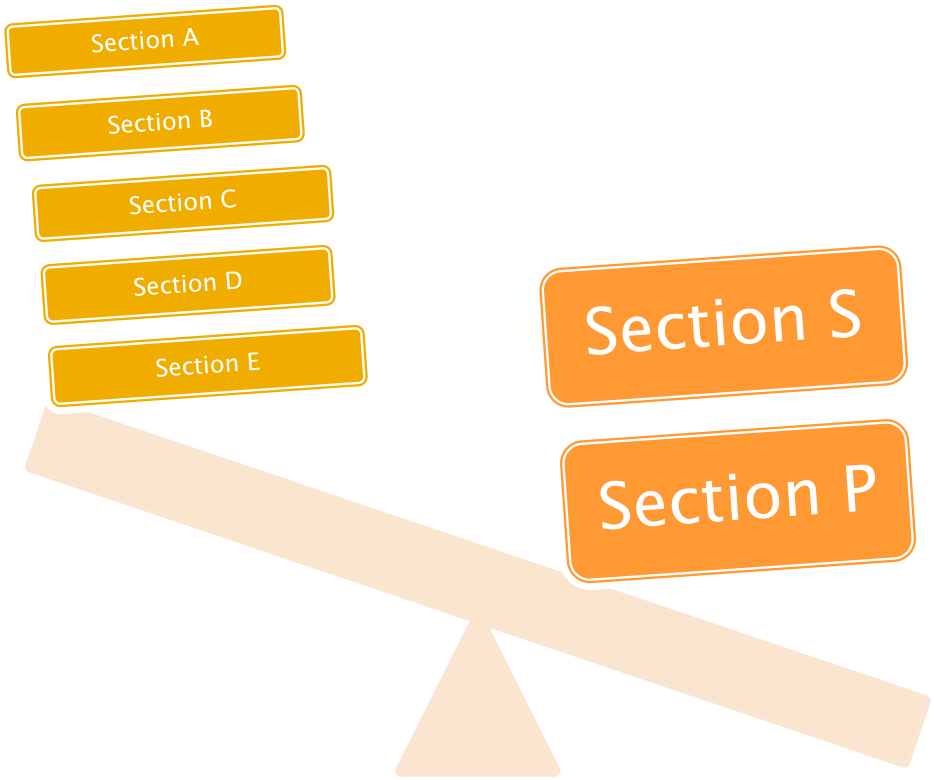
- **Certificate of Pharmaceutical Product (CPP)**
  - From the **competent authority** in the country of origin
- **Certificate of Free Sale (CFS)/Second Certificate of Pharmaceutical Product (CPP)**
  - From the **competent authority** in the country of origin
- **Good Manufacturing Practice Certificate(GMP)**
  - From the **competent authority** in the country of origin
- **Protocol of Analysis**

Section E: Supplementary Documentation/Other Information

- Attachment of Certificate of Analysis (COA)
- Other Supporting Document
- Worldwide Registration Status

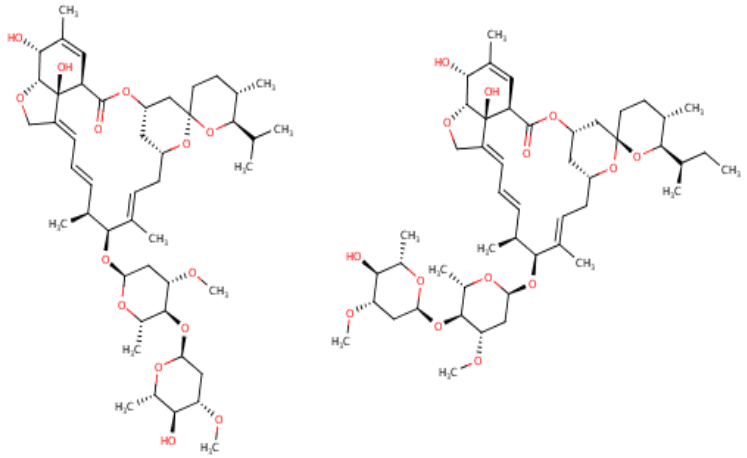
Administrative documentation (Part I)

Quality documentation (Part II)



Administrative Documentation (Part II) Section S: Drug Substance

- Nomenclature
- Structure
- General Properties
- Manufacturer Name
- Specification
- Batch Analysis
- Stability



Section P: Drug Product

- Description and Composition
- Formula development summary
- Container Closure System
- Microbiological Attributes
- Manufacturing Process , Process Control, Flowchart
- Controls of Critical Steps and Intermediates

Section P: Drug Product

- **Excipient of Human or Animal Origin**
- **Specification**
  - List of tests and specifications, limits or criteria of acceptance
  - Reference used
- **Analytical Procedures**
- **Batch Analysis**
- **Stability**
  - Appendix 7 (REGOVP) – Guideline for Stability Data

Safety requirements (Part III)

- Pharmacology
- Toxicology
- Studies of other effects
- User safety
- Environmental Risk assessment
- Residue documentation

Efficacy requirements (Part IV)

- Pre Clinical and Clinical Documentation

Other requirements

- Post registration activities such as pharmacovigilance & market surveillance will also be implemented to ensure that the products being manufactured and sold comply to specified criteria /requirements

- Registration status of a product shall be valid for five (5) years or such period as specified unless the registration is suspended or cancelled by the Authority.

Other requirements (cont..)

- Renewal of product registration can be done six (6) months prior to the expiry of the validity period of product registration.
- After the expiry date, status of product registration shall change to status of expired, and application for renewal of the product registration can no longer be submitted.
- Responsibility of Product Registration Holder to submit the renewal application.

CHALLENGES

Challenges

- The emergence of resistance to antibacterial drugs mainly antibiotics used in food producing animals has been a rising concern in both public and animal health.
- This will pose a new challenge for both the food producing industry as well as NPCB in the near future.
- The development of antibiotic list is the first step taken to establish the national guidelines for antimicrobials drugs in food producing animals.
- Promoting the proper use of antimicrobials drugs, and restricting or limiting the use of antimicrobials drugs are considered necessary for assuring animal health.

CONCLUSION

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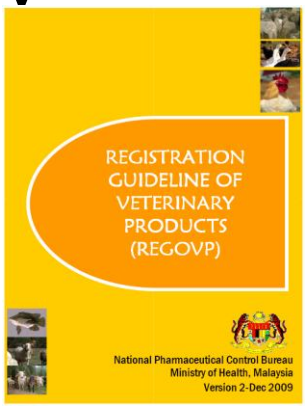
The current Guideline (REGOVP) will be reviewed from time to time, as and when the need arises.

Log on to www.bpfk.gov.my

Industry → Registration and Notification →Veterinary→ Regulation of Veterinary Products



CONCLUSION

- Download Registration Guideline of Veterinary Products (**REGOVP)** – Version 3 (latest updates July 2015)
- **FAQ**
- **CIRCULARS**


THANK YOU
FOR
YOUR KIND
ATTENTION