PROGRAMME

0900 am - Registration

0920 am - Welcoming Remarks

by YBhg. Datin Dr. Faridah Aryani Md Yusof, Director of NPRA

0930 am – Part 1: New Amendment for Fee Schedule under CDCR 1984

by Cik Nurulfajar Mohd Jamid, Head Section of Policy and Strategic Planning, NPRA

1000 am - Q & A Session & Tea Break

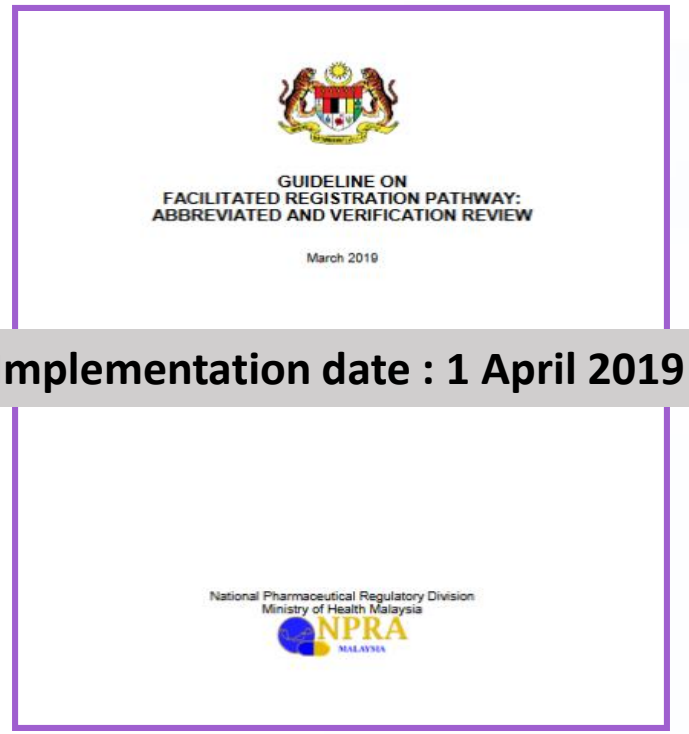
1030 am – Part 2: Regulatory Updates 2019-2020 & Strategic Plan 2021-2024

by YBhg. Datin Dr. Faridah Aryani Md Yusof, Director of NPRA

1130 pm - Q & A Session

PART 2: REGULATORY UPDATES 2019 - 2020

1. Guideline on Facilitated Registration Pathway: Verification and Abbreviated Review



Implementation date : 1 April 2019

Scope

Abbreviated Review

applies to a product that has been **evaluated** and **approved** by at least **one (1)** reference drug regulatory agency

Verification Review

applies to a product that has been **evaluated** and **approved** by at least **two (2)** reference drug regulatory agencies

Applies to New Chemical Entities (NCEs) and Biologics including Biosimilar

Reference Countries

- European Medicines Agency (EMA)
- United States Food and Administration (US FDA)

Normal Registration Pathway

- Full Dossier
- Approved by at least one regulatory agency
- Full evaluation: quality, non-clinical & clinical
- Timeline 245 w.d.

Facilitated Registration Pathway: ABBREVIATED REVIEW

- Full Dossier + Ref agency assessment report
- Approved by one reference agency
- Full evaluation: **quality** Abridged evaluation: **clinica**l
- Timeline 120 w.d.

Facilitated Registration Pathway: VERIFICATION

- Full Dossier + Ref agency assessment report
- Approved by two reference agencies
- Ref agency assessment report
- Timeline 90 w.d.

2. Limiting Colistin Use In Veterinary Product For Food-Producing Animal

BANNED

Veterinary products for food-producing animals in preparations mixed into animal feed and water (e.g., premix, water soluble powder dan solution)

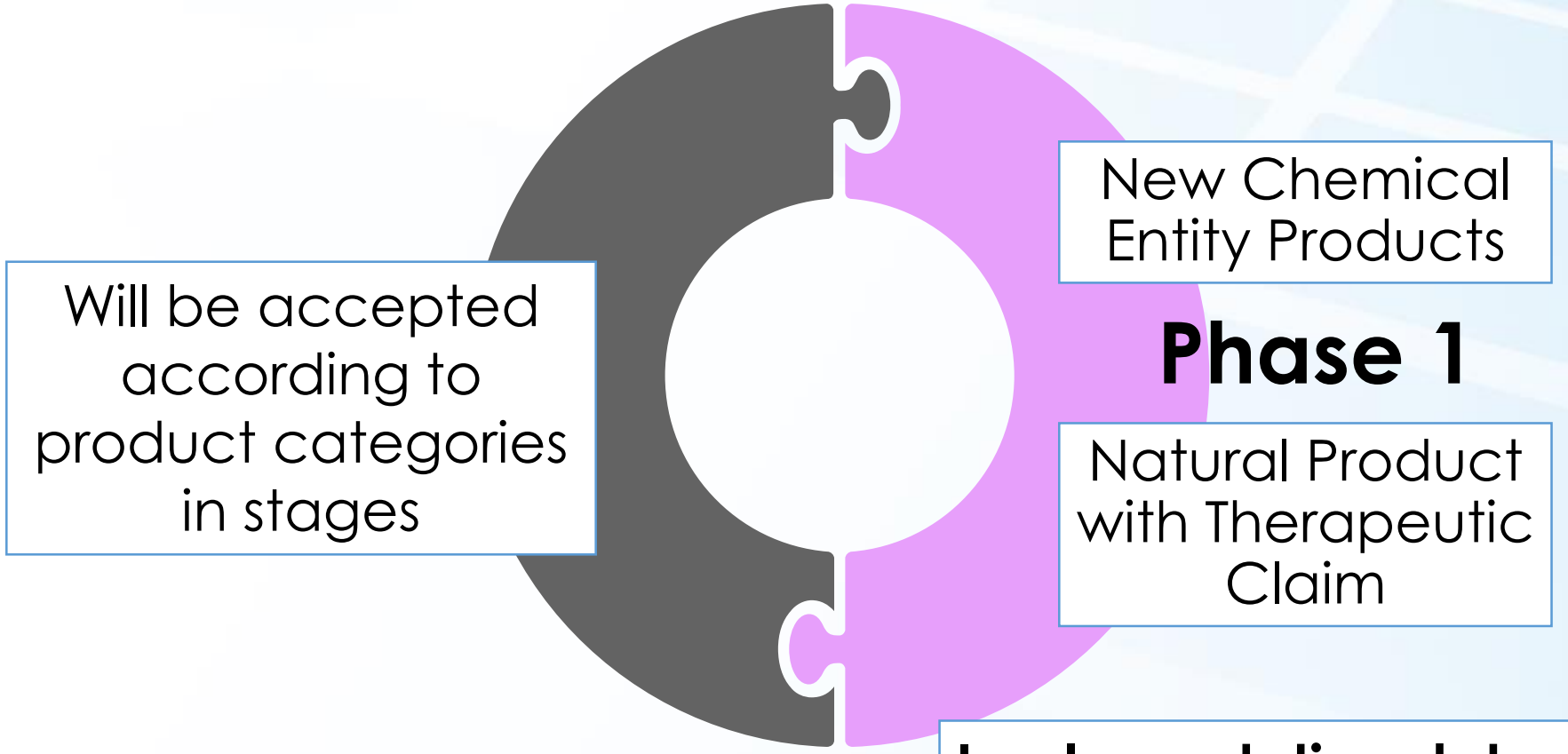
REJECTION

New registration and under review registration applications starting 1st May 2019

CANCELLATION

Registered product starting 1st January 2020

3. Application of Clinical Trial Import License (CTIL) and Clinical Trial Exemption (CTX) for First-In-Human (FIH) studies



Will be accepted according to product categories in stages

New Chemical Entity Products

Phase 1

Natural Product with Therapeutic Claim

Implementation date: 1 May 2019

4. New Security Label from Supplier Appointed by Ministry of Health Malaysia (MOH)

Implementation date : 1 September 2019

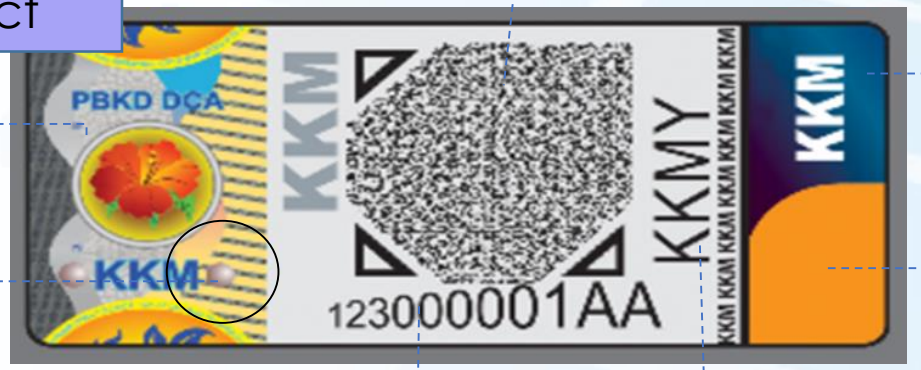
All pharmaceutical products for 3 years

Safety Features

Single Image Hologram with dynamic effect

Kod QR : T-QR (Uncopiable QR)

Optical Changeable Ink (OCI) – Blue Lilac



Mirror Effect Hologram Effect

Serial number

Randomized number

Fluorescence Orange Ink Anti Copy

5. Registration of “Drug-Medical Device” and “Medical Device-Drug” Combination Products

Guidance

Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combination Products

Implementation Date : 1 July 2019

Classification

Combination products regulated as **drug** -> **Drug Control Authority**

Combination products regulated as **medical device** -> **Medical Device Authority**

Combination products regulated as **drug** -> **Drug Control Authority**

Requirement for Acknowledgement Receipt/Endorsement Letter

New Product

Product will be given a 5-year conditional registration after submitting Acknowledge-ment Receipt (**temporary**) and fulfilling registration requirement

Full registration status will be given after submitting Endorsement Letter from Medical Device Authority (MDA)

Renewal

Endorsement Letter from the MDA should be submitted before renewal application

Implementation date :

11 October 2019

FUTURE PLANS

1. Pre-submission Meeting (PSM) Services in NPRA

01 Provides regulatory advice to applicants prior to submission of product registration application

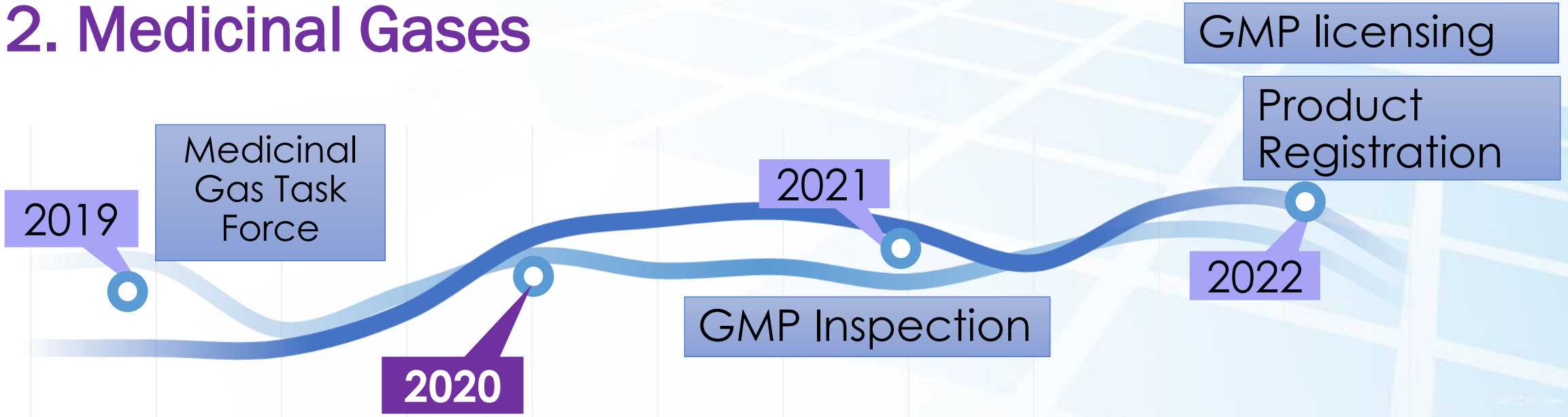
02 To ensure quality dossier submitted to NPRA

03 To improve the evaluation process of product registration application

04
- New chemical entities
- Biologics (including biosimilars)
- Natural product with therapeutic claims
- Health supplement product with disease-risk reduction claims

05 **Implementation date:** March 2020

2. Medicinal Gases



Drafting guideline

Unified Public Engagement

Training for industry

To regulate by phases

NO | N_2O | O_2 | CO_2

Entonox | Medical Air

Starting with medicinal gas in cylinder

3. Pre-Registration Testing for Natural Products

Pre-registration testing of natural products shall be done by **local panel laboratories** or in **local manufacturer's** own laboratories

Fees and timeline :
No changes

- Abolishment of sample for laboratory testing requirement by NPRA
- PRH shall submit COA upon submission of new product registration

4. Safe & Secure Initiative for Natural Product

- To ensure Natural Products are safe and of quality by strengthening quality control requirement

- Manufacturers are responsible to make sure their **raw materials** used are **identified** or **authenticated** before release their finish product to market.

5. Natural Products with Therapeutic Claims

1 Registration according to *Guidance Document For Natural Product with Therapeutic Claims*

2 Registration requirement is based on ASEAN Common Technical Dossier (ACTD) and Drug Registration Guidance Documents (DRGD) 2.1.1 General Requirements For Full Evaluation

3 PIC/S Guide to Good Manufacturing Practice for Medicinal Products

4 OECD Good Laboratory Practice (GLP)

5 COA for raw material and standardized extract need to comply with raw material specifications as stated in the monograph/ pharmacopeia of that related species

6 Clinical and pre-clinical data is needed to ensure the quality, safety and efficacy of the therapeutic claims

7 Single Active Ingredient: RM4000.00

Two or More Active Ingredients: RM5000.00

8 Timeline : 245 working days

6. Desktop Assessment on Traditional Medicines and Health Supplement (TMHS) Foreign Manufacturer for the Purpose of GMP Confirmation

- For GMP evidence evaluated by NPRA found to be **not equivalent** to Malaysian GMP TMHS.

- The equivalency issues raised may be due to different classification of product or GMP guide of the foreign country.

6. Desktop Assessment on Traditional Medicines and Health Supplement (TMHS) Foreign Manufacturer for the Purpose of GMP Confirmation

- Objective:
  - Minimize barriers on registration or re-registration of TMHS product in Malaysia
  - gap analysis and documentary evidence to ensure that they able to meet Malaysian GMP requirements.

- Implementation date: January 2020

7. Foreign GMP Inspection & GMP Desktop Assessment (GDA)

- GMP Desktop Assessment (GDA):
  - Based on documentary evidence from GMP inspection conducted by NPRA
- Applicable to:
  - Foreign manufacturer that have been inspected by NPRA
  - Non-sterile product
  - Application by at least 1 year before expiry of GMP status
  - Passes screening from GDA Selection Tool (GDAST)

- Outcome of GDA: Extension of GMP status

7. Foreign GMP Inspection & GMP Desktop Assessment (GDA)

- Purpose:
  - Renewal of product registration
  - New product registration (if applicable)

- Implementation date:
  - Expected July 2020
  - To be implemented together with latest guidance document (Prior to implementation, there will be another public engagement where initial public engagement was conducted in August 2019).

8. ASEAN Mutual Recognition Arrangement (MRA) for Bioequivalence (BE) Study Reports of Generic Medicinal Products

Implementation of the MRA = Year 2022.

Inspection fee for ASEAN Panel of Experts (PoE) = USD 500/man day/inspector

Payment will be made directly to the government account

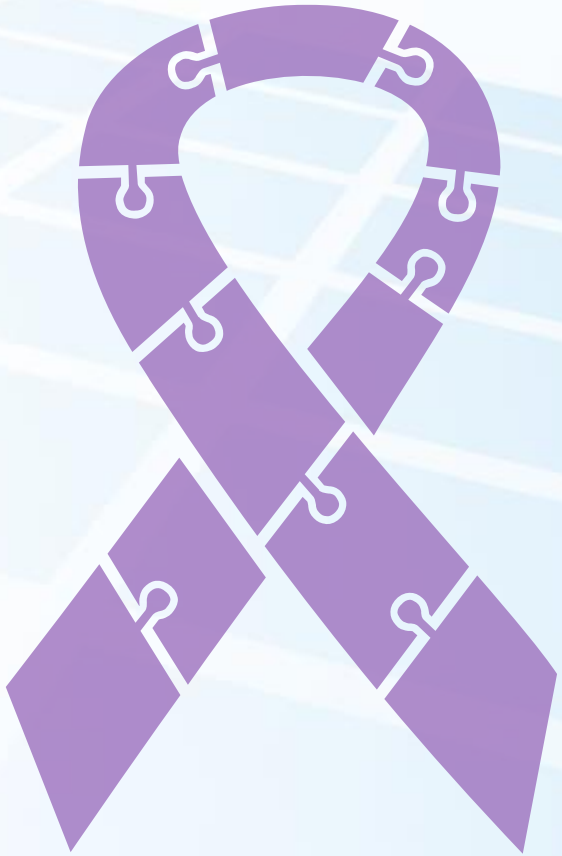
Cost of inspection = depending on the origin of PoE and location of inspection

Procedure according to the respective state

9. Confirmation of Cold Chain Product Handling Facilities for Importers and Wholesalers of Registered Products

- To enforce 'Syarat Lesen' (License Condition) imposed by NPRA.
- For stakeholder who handle/intended to handle 'time & temperature sensitive products, TTSPs), Good Distribution Practice (GDP) inspection had to be conducted to verify that the premises has appropriate facilities to receive, store & distribute TTSPs.

1. Becoming WHO listed agency maturity level 4 (ML4)
2. Strengthening Pharmacovigilance Inspection (PVI)
3. Strengthening of cosmetic post market surveillance
4. Drafting of the new act for regulatory control of clinical trials in Malaysia
5. Regulatory control of medicinal gases in phases



NPRA STRATEGIC PLAN 2021 -2025

ANNOUNCEMENT

Part 2: REGULATORY UPDATES 2019 – 2020 & STRATEGIC PLAN 2021-2024

will be uploaded in the NPRA official website

(www.npra.gov.my)

THANK YOU

Q & A Session