KEMENTERIAN KESIHATAN MALAYSIA
(*Ministry of Health Malaysia*)
Bahagian Regulatori Farmasi Negara (NPRA)
Lot 36, Jalan Universiti
46200 Petaling Jaya
Selangor
MALAYSIA

No. Telefon : 03 - 7883 5400
No. Faksimili : 03 - 7956 2924
Portal Rasmi : http://www.npra.moh.gov.my
E-mel Rasmi : npra@npra.gov.my

Ruj. Kami : NPRA.600-1/9/12 (3)
Tarikh : 21 Julai 2020

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/Puan,

PEKELILING BERKENAAN PELAKSANAAN *GUIDELINES ON ABRIDGED REGISTRATION PATHWAY FOR VETERINARY PRODUCTS*

Adalah saya merujuk perkara di atas.

2. Dimaklumkan bahawa Bahagian Regulatori Farmasi Negara (NPRA) akan melaksanakan penggunaan *Guidelines on Abridged Registration Pathway for Veterinary Products.* Garis panduan dan prosedur kerja ini telah dibentangkan dan diambil maklum oleh Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuaratnya kali ke **346** pada **9 Julai 2020** .

3. Skop garis panduan ini adalah seperti berikut :

3.1 produk ubat veterinar yang telah diluluskan oleh agensi regulatori rujukan, ATAU

3.2 produk yang mempunyai *reference product*, di mana *reference product* tersebut telah diluluskan oleh agensi regulatori rujukan.

4. Produk veterinar yang memenuhi *eligibility criteria* yang diperincikan dalam garis panduan ini akan dinilai melalui *Abridged Registration Pathway* ini.

5. Tarikh pelaksanaan prosedur ini adalah **SERTA MERTA** mulai tarikh pekeliling ini.

6. Sekiranya tuan/ puan ingin mendapatkan maklumat lanjut, sila hubungi Seksyen Ubat Veterinar, Pusat Penilaian Produk dan Kosmetik, NPRA. Pihak pemegang pendaftaran dinasihatkan agar mengambil maklum mengenai perkara di atas.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR HASENAH BINTI ALI) (RPh 1517)
Pengarah
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia
SAB/NB/PKPSR/NPRA/10072020

✉ suhailah@npra.gov.my / nurhidayah@npra.gov.my
+603 - 7883 5463/5474

s.k. 1. Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

2. Pengarah
Bahagian Penguatkuasaan Farmasi
Kementerian Kesihatan Malaysia

3. Pengarah
Bahagian Amalan dan Perkembangan Farmasi
Kementerian Kesihatan Malaysia

4. Pengarah
Bahagian Dasar dan Perancangan Strategik Farmasi
Kementerian Kesihatan Malaysia

5. Semua Timbalan Pengarah
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

GUIDELINE ON ABRIDGED REGISTRATION PATHWAY FOR VETERINARY PRODUCTS

July 2020

National Pharmaceutical Regulatory Division
Ministry of Health Malaysia

NPRA
MALAYSIA

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GUIDELINE ON ABRIDGED REGISTRATION PATHWAY FOR VETERINARY PRODUCTS

1.0 INTRODUCTION

1.1 OBJECTIVE

The objective of this abridged registration concept is to ensure that veterinary medicines, especially those targeting a niche market of small animals, are accessible in a timely manner. It helps to reduce work duplication in approving products which have been evaluated and registered by the reference/trusted drug regulatory agencies. This is achieved by leveraging the assessment done by these agencies without compromising the quality, safety and efficacy of the veterinary products.

This guideline describes the scopes and requirements for submitting application to register a product via abridged pathway.

1.2 SCOPE

Abridged Registration Pathway applies to a veterinary medicinal which;

a) product with similar indication(s), dosing regimen, target species and/or direction(s) for use that have **been approved** by at least one (1) of the NPRA's reference drug regulatory agencies[1].

OR

b) Supported by a reference product registered by one of the NPRA's reference drug regulatory agencies[1].

[1]*NPRA's reference drug regulatory agencies are as follows:*

- *European Medicines Agency (EMA)*
- *Veterinary Medicines Directorate, UK (VMD)*
- *US Food and Drug Administration (FDA)*
- *Health Canada (HC)*
- *Australian Pesticides and Veterinary Medicines Authority (APVMA)*
- *National Veterinary Assay Laboratory (Japan)*
- *The French Agency for Veterinary Medicinal Products (France)*
- *Swedish Medical Products Agency (Sweden)*
- *Swiss Agency for Therapeutic Products (Switzerland)*
- *Spanish Agency of Medicines and Health Products (Spain)*
- *Federal Agency for Medicines and Health Products (Belgium)*
- *Federal Office of Consumer Protection and Food Safety (Germany)*
- *Animal and Plant Quarantine Agency (South Korea)*

Approval by these reference drug regulatory agencies does not oblige the Drug Control Authority (DCA) to approve the application.

2.0 ELIGIBILITY CRITERIA

a) All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site(s), release and shelf life specifications and primary packaging, are identical to **that currently approved** by the chosen reference drug regulatory agency at the time of submission.

   OR

   Must be supported by a reference product registered by one of the NPRA's reference drug regulatory agencies.

b) The product/ reference product and its intended use (indications, dosage information, and target species) have not been rejected, withdrawn, suspended, approved via appeal process, or pending deferral by any reference drug regulatory agency for quality, safety and/or efficacy reasons.

c) For products under 1.2 (a), the proposed Package Insert (PI)/ Patient Information Leaflet (PIL) information should be identical to that approved by the reference drug regulatory agency (with the exception of country-specific information).

3.0 DOCUMENTS REQUIRED

Abridged Registration pathway

Administrative	- Product Validation part - All Part I, Section A - For products for food- producing animals: MRL and withdrawal period - BMF Attachment - Particulars of packing - Labels and Package inserts** - Application letter undersigned by an authorized person (PRH) to request for Abridged Registration Pathway. - Declaration letter from PRH/ owner that the submission is identical to that **currently approved by** the reference agency at the time of submission (if applicable) - All supplementary documentation: - Product owner - Letter of authorization from product

	owner - Letter of appointment/ acceptance of contract manufacturer/ repacker - CPP - CFS - GMP - Manufacturer/ other manufacturer - Importer - Store address - SPC of the product and/ or reference product - Other supporting document - Worldwide Registration Status - Post- approval commitments ** Labels still need to follow current requirement: Jauhi kanak-kanak, MAL No., Controlled medicine
Quality	• Section S: - Manufacturer name - Specification of drug substance - CoA of drug substance - Stability of drug substance (NCE only) - If DMF is submitted: Declaration letter from PRH/ owner to state that the DMF submitted to NPRA is identical to that submitted to the reference drug regulatory agency. • Section P: - Pharmaceutical Development of Finished product and container closure system - Manufacturing process and process control - Manufacturing flowchart - Specification excipient - Excipients of Animal/ Human origin - Finished product specification - Analytical protocol - CoA of finished product - Container closure system - Stability data
Non-Clinical (for NCE only)	- For Non food- producing: • Non-clinical Overview - For food- producing animals • Non-clinical Overview • Residue documentation (Residue studies)

Clinical (for NCE only)	- Published papers and synopses of all pivotal studies relevant to the claimed indication, dosing, target species - Clinical safety and efficacy overview

NOTE

i. NPRA reserves the right to request additional supporting documents where it is deemed appropriate.
ii. NPRA may also re-categorise the applications if deemed appropriate.

4.0 TIMELINE FOR REGISTRATION PROCESS

Innovator/ New Chemical Entity (NCE)	225 working days
Generics	190 working days

5.0 DRUG CONTROL AUTHORITY RIGHTS

Notwithstanding the requirements stipulated in this guideline, DCA reserves the rights to use its own discretion whichever it deems fit.

6.0 REFERENCES

Adapted from the:

1. Guideline on Facilitated Registration Pathway: Abbreviated and Verification Review, March 2019