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Tarikh : 16 November 2023

SEMUA PEMEGANG PENDAFTARAN PRODUK

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan / Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984
ARAHAN PENGARAH PERKHIDMATAN FARMASI BILANGAN 13 TAHUN 2023
DIREKTIF BERKENAAN PENGEMASKINIAN DAN PELAKSANAAN *GUIDELINE FOR FACILITATED REGISTRATION PATHWAY (FRP), REVISION 1, 2023*

Dengan hormatnya saya merujuk kepada perkara di atas.

2. Dikemukakan Arahan Pengarah Perkhidmatan Farmasi Bilangan 13 Tahun 2023, Direktif Berkenaan Pengemaskinian dan Pelaksanaan *Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023* untuk makluman dan perhatian pihak tuan / puan.

3. Tuan / Puan adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

"MALAYSIA MADANI"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(ROSILAWATI BINTI AHMAD) RPh.1413
Pengarah
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ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

BILANGAN 13 TAHUN 2023

DIREKTIF BERKENAAN PENGEMASKINIAN DAN PELAKSANAAN *GUIDELINE FOR FACILITATED REGISTRATION PATHWAY (FRP), REVISION 1, 2023*

1. TUJUAN

1.1 Di bawah peruntukan Peraturan 8, Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984 (PKDK 1984), Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuarat kali ke-**390** pada **3 November 2023** telah bersetuju dengan pengemaskinian dan pelaksanaan *Guideline for Facilitated Registration Pathway* (*FRP), Revision 1, 2023.*

1.2 Sehubungan dengan itu, Arahan ini dikeluarkan oleh Pengarah Perkhidmatan Farmasi di bawah peruntukan Peraturan 29, PKDK 1984 untuk memaklumkan Pemegang Pendaftaran Produk berhubung perkara ini.

2. LATAR BELAKANG

2.1 Melalui Direktif Bilangan 7 Tahun 2019 bertarikh 27 Mac 2019, *Guideline on Facilitated Registration Pathway: Abbreviated and Verification Review* telah diperkenalkan dengan tujuan untuk meningkatkan kecekapan Bahagian Regulatori Farmasi Negara (NPRA) dalam mendaftarkan produk farmaseutikal.

Garis panduan ini berasaskan konsep *reliance* dan pendekatan *risk-based* di mana laporan penilaian produk agensi regulatori lain seperti *European Medicines Agency* (EMA) dan *United States Food and Drug Administration* (USFDA) dirujuk untuk melancarkan proses penilaian bagi produk yang sama. Pendekatan *reliance* ini adalah selaras dengan saranan *World Health Organisation* (WHO) untuk mengurangkan pertindihan kerja dalam kalangan badan regulatori dan meningkatkan kecekapan proses penilaian ubat baharu.

2.2 Malaysia melalui NPRA telah menyertai WHO *Collaborative Registration Procedure* (CRP) *for Products authorised by* WHO *Stringent Regulatory Authorities* (SRAs) dan WHO *prequalified* (PQ) *medicines and vaccines* masing-masing pada 2 Jun 2022 dan 9 Januari 2020. Selain itu, NPRA turut menyertai penilaian produk secara bersama ASEAN *Joint Assessment* (AJA) dan bertindak sebagai Pengerusi kepada AJA *Coordinating Group* (JACG).

Sehubungan itu, Garis panduan *Facilitated Registration Pathway* sedia ada perlu dikemaskini bagi mengambil kira juga produk yang telah diluluskan melalui WHO CRP atau yang dinilai melalui AJA tersebut.

2.3 Di samping itu, bagi meningkatkan bilangan produk yang layak dinilai melalui prosedur FRP dan dapat dinilai dalam tempoh masa yang lebih singkat, senarai agensi regulatori rujukan juga telah ditambah dan kini turut meliputi *Health Canada, Pharmaceuticals and Medical Devices Agency* (PMDA), *Japan, Swissmedic, Switzerland, Therapeutic Goods Administration* (TGA), *Australia,* dan *United Kingdom Medicines and Healthcare products Regulatory Agency* (UK MHRA). Skop jenis produk juga telah diperluas merangkumi produk generik.

3. RUMUSAN PENGEMASKINIAN

3.1 Pengemaskinian ke atas *Guideline for Facilitated Registration Pathway: Abbreviated and Verification Review, 2019* kepada *Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023* adalah seperti berikut:

Aspect	***Initial version***	***Guideline FRP Version 1, 2023***
Expansion of the scope of products	*New drug products and biologics including biosimilars.*	*New drug products, generic medicines and biologics including cell and gene therapy products (CGTPs).*
Addition of more reference agencies/ procedures	*EMA and US FDA.* *WHO CRP (PQ) which is covered by the alternative listing procedure and evaluated by US FDA and EMA.*	*EMA, US FDA, Health Canada, PMDA, Swissmedic, TGA, and UK MHRA.* *WHO CRP (SRA and PQ) and ASEAN Joint Assessment.*
Types of review pathways	*Abbreviated Review:* *Applies to a product that has been approved by 1 reference agency.* *Verification Review:* *Applies to a product that has been evaluated and approved by 2 reference agencies.*	*Abbreviated Review:* *WHO CRP & products approved by the reference agencies.* *Verification Review:* *ASEAN Joint Assessment.*
Re-definition of abbreviated review and verification review	*Abbreviated Review:* *A limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements, while relying on prior assessment and inspection outcomes from a reference authority or trusted institution to inform the local decision.* *Verification Review:* *Applies to a product that has been evaluated and approved by 2 reference agencies. NPRA only validates the submission and ensures that it*	*Abbreviated Review:* *A limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements, while relying on prior assessment and inspection outcomes from a reference authority or trusted institution to inform the local decision.* *Verification Review:* *Review of the sameness of the product dossier to ensure that the medical product is the same as the one that has been assessed*

Aspect	***Initial version***	***Guideline FRP Version 1, 2023***
	conforms to the registration conditions as approved by the reference agencies.	*by ASEAN Joint Assessment.*
Submission of application to NPRA from the date of approval by the chosen reference drug regulatory agency	*Within 2 years.*	*Within 3 years.*
Revision of the timeline [working days (w.d.)]	*Abbreviated review: 120 w.d.* *Verification review: 90 w.d.*	*Abbreviated review: 90 w.d.* *Verification review: 30 w.d.*
Addition of a template for the declaration statement by the applicant	*There is no template provided.*	*Annex 1: Declaration statement by the applicant.*
Addition of dossier checklist	*There is no dossier checklist provided.* *Annex: Checklist for Protocol Analysis and Analytical Method Validation.*	*Annex 2a: Dossier checklist (for Generic/ Hybrid).* *Annex 2b: Dossier checklist (for New Chemical Entity/ Biologic).* *Removal of Checklist for Protocol Analysis and Analytical Method Validation.*
Addition of flow chart	*There is no flow chart provided.*	*Annex 3a and 3b: Process Flowchart for WHO CRP (SRA and PQ).* *Annex 3c: Process Flowchart for Products approved by the EMA and/or Health Canada and/or PMDA, Japan and/or Swissmedic, Switzerland and/or TGA, Australia and/or UK MHRA, and/or the US FDA.* *Annex 3d: Process Flowchart for ASEAN Joint Assessment.*

4. TARIKH KUAT KUASA

4.1 Tarikh pelaksanaan *Guideline for Facilitated Registration Pathway, Revision 1, 2023* (rujuk **Lampiran A)** adalah mulai **1 Januari 2024**.

"BERKHIDMAT UNTUK NEGARA"

(NORHALIZA BINTI A. HALIM) RPh. 1750
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2. Pengarah
Bahagian Penguatkuasaan Farmasi
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3. Pengarah
Bahagian Amalan dan Perkembangan Farmasi
Kementerian Kesihatan Malaysia

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