



Ruj. Kami : NPRA.600-1/9/13 (72) Jld.1

Tarikh : 15 Januari 2026

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 1 TAHUN 2026 DIREKTIF PELAKSANAAN MEKANISME *RELIANCE* DAN *PRIORITY REVIEW* BAGI PERMOHONAN TAMBAHAN INDIKASI PRODUK INOVATOR BERDAFTAR

Saya merujuk kepada perkara tersebut di atas.

2. Dikemukakan Arahan Pengarah Perkhidmatan Farmasi Bilangan 1 Tahun 2026, Direktif Pelaksanaan Mekanisme *Reliance* dan *Priority Review* Bagi Permohonan Tambahan Indikasi Produk Inovator Berdaftar untuk makluman dan perhatian tuan/puan. Tuan/Puan adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

"MALAYSIA MADANI"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(ROSLIZA BINTI LAJIS) RPh.3376

Timbalan Pengarah

b.p. Pengarah Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

sab/nlaj/pkpsr/npra

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**ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN
KAWALAN DADAH DAN KOSMETIK 1984**

BILANGAN 1 TAHUN 2026

**DIREKTIF PELAKSANAAN MEKANISME *RELIANCE* DAN *PRIORITY REVIEW*
BAGI PERMOHONAN TAMBAHAN INDIKASI PRODUK INOVATOR BERDAFTAR**

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-**416** pada **8 Januari 2026** telah bersetuju dengan pelaksanaan mekanisme *reliance* dan *Priority Review* bagi permohonan tambahan indikasi produk inovator berdaftar.
- 1.2** Sehubungan dengan itu, arahan ini dikeluarkan oleh Pengarah Perkhidmatan Farmasi di bawah peruntukan Peraturan 29, PKDK 1984 untuk memaklumkan Pemegang Pendaftaran Produk (PRH) berhubung perkara ini.

2. LATAR BELAKANG

- 2.1** Mekanisme *reliance* meningkatkan kecekapan regulatori dan mengoptimumkan sumber sedia ada dengan membolehkan NPRA memanfaatkan penilaian agensi regulatori rujukan, seterusnya mempercepatkan akses pesakit kepada ubat-ubatan dengan indikasi baharu yang telah diluluskan.

- 2.2 Bagi tujuan peluasan mekanisme *reliance* kepada permohonan tambahan indikasi, satu projek rintis telah dilaksanakan dari Ogos 2024 hingga Ogos 2025.
- 2.3 Selain itu, peluasan skop permohonan indikasi tambahan dengan penggunaan mekanisme *Priority Review* adalah penting bagi mempercepatkan kelulusan permohonan indikasi tambahan, khususnya bagi produk yang disokong oleh kajian klinikal yang dijalankan di Malaysia.

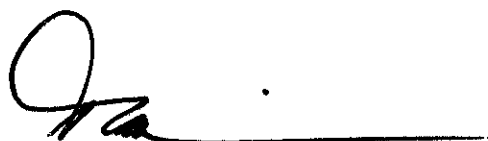
3. PELAKSANAAN DAN TARIKH KUAT KUASA

- 3.1 Pengemaskinian yang akan dilaksanakan ke atas *Drug Registration Guidance Document* (DRGD), khususnya pada Bahagian **20.4 *New/Additional Indication***, yang merangkumi maklumat lanjut berkaitan permohonan tambahan indikasi bagi produk inovator berdaftar melalui penggunaan mekanisme *reliance* dan *Priority Review*, adalah seperti yang dinyatakan dalam **Lampiran A**.
- 3.2 Pengemaskinian DRGD tersebut melibatkan perkara-perkara berikut, antaranya:
- 3.2.1 Pengenalan kategori *Reliance Full Evaluation* dan *Reliance Verification*
 - 3.2.2 *Reliance Eligibility Criteria*
 - 3.2.3 Dokumen sokongan untuk *Reliance*
 - 3.2.4 Pengenalan mekanisme *Priority Review*
 - 3.2.5 Tempoh masa penilaian
 - 3.2.6 Senarai semak yang berkaitan
- 3.3 Tarikh kuat kuasa Arahan ini adalah **SERTA-MERTA**.

- 3.4 Sekiranya tuan/puan ingin mendapatkan maklumat lanjut, sila hubungi Seksyen Ubat Baru atau Seksyen Biologik, Pusat Penilaian Produk dan Kosmetik, Bahagian Regulatori Farmasi Negara (NPRA). Pihak tuan/puan dikehendaki mengambil maklum dan mematuhi perkara-perkara yang dinyatakan di atas.

"MALAYSIA MADANI"

"BERKHIDMAT UNTUK NEGARA"



(DR. AZUANA BINTI RAMLI) RPh.1889

Pengarah Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

saib/riaj/bkper/npra

- s.k.
1. Pengarah Bahagian Regulatori Farmasi Negara, KKM
 2. Pengarah Bahagian Amalan dan Perkembangan Farmasi, KKM
 3. Pengarah Bahagian Penguatkuasaan Farmasi, KKM
 4. Pengarah Bahagian Dasar dan Perancangan Strategik Farmasi, KKM

LAMPIRAN A**NEW/ ADDITIONAL INDICATION****1. Definition and scope**

New/ additional indication (AI) is defined as an indication not initially approved for a registered innovator product. This may include, but not limited to, the following:

- i) new therapeutic indication
- ii) new route(s) of administration (parenteral)
- iii) indication for new age group, such as usage in children
- iv) new dosing regimen (different cumulative dose over the dosing interval)
- v) additional bacterial strains to expand the indications for antimicrobial products
- vi) additional viral serotypes or genotypes to expand the indications for antiviral products, etc.

This application does not include changing/ rephrasing of sentences.

2. AI Category

There are two (2) categories of AI applications: AI Full Evaluation and AI Verification.

a) AI Full Evaluation**Main criteria**

This category applies to a new indication that has been approved in any one (1) of the DCA's reference agencies (EMA, UK MHRA, Swedish Medical Products Agency, ANSM France, US FDA, TGA Australia, Health Canada, PMDA Japan and Swissmedic).

This application may require comments from relevant specialists

Notes:

- EMA centralised approval is considered as ONE approval

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- An application to add a new indication without prior approval by a DCA's reference agency may be considered for evaluation by NPRA for the following conditions:
 - i) new indication deemed not feasible for submission to DCA's reference agencies
 - ii) new indication for a product that has not been registered with any DCA reference agency

AI Full Evaluation is divided into two (2) types:

i) **Standard Full Evaluation**

Standard Full Evaluation applies to applications for a new indication where NPRA is unable to rely fully on a reference agency's assessment (e.g. when assessment reports are not available) or when no reference agency approval available. In such cases, NPRA will conduct an independent assessment of the indication's suitability under local conditions and regulatory requirements to support its decision.

ii) **Reliance Full Evaluation**

Reliance Full Evaluation applies to a new indication where NPRA relies on prior assessments conducted by one of DCA's reference agencies to inform its local decision, leveraging regulatory tools such as the agency's assessment report. NPRA may conduct (where necessary) a targeted review to address any gaps, adapt the assessment to local regulatory requirements, and ensure the indication's suitability in the Malaysian context.

The eligibility criteria for a new indication via Reliance Full Evaluation are as follows:

- The new indication has been approved within **three years** from the date of approval by the chosen primary reference agency
- The new indication, dosing regimen(s), patient population(s), and/or directions for use must be similar as those approved by the chosen reference agency. However, NPRA reserves the right to propose revisions where necessary to ensure alignment with local clinical practice and to provide clearer indication for safe and effective use in Malaysia.

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- The new indication may require an assessment by NPRA to review the benefit-risk profile due to local disease epidemiology, medical practice, and/or public health considerations. Examples of products that may require more stringent assessment due to differences in local disease patterns and/or medical practices include some anti-infectives and vaccines for endemic pathogens.
- The new indication has not been rejected, withdrawn or approved via appeal process or pending deferral by a national regulatory agency for safety or efficacy reasons.

b) AI Verification

Main criteria

This applies to a new indication that has been registered **in at least two (2)** DCA's reference agencies (EMA, UK MHRA, Swedish Medical Products Agency, ANSM France, US FDA, TGA Australia, Health Canada, PMDA Japan and Swissmedic).

Note:

EMA centralised approval is considered as ONE approval

This application will not require comments from relevant specialists.

AI Verification is divided into two (2) types:

i) Standard Verification

Standard Verification applies to applications for a new indication where NPRA is unable to rely fully on the reference agency's assessment (e.g. in cases where assessment reports are not available). In such situations, NPRA will conduct a limited independent assessment to support its local decision.

ii) Reliance Verification

Reliance Verification applies to a new indication where NPRA relies on prior assessments conducted by the DCA's reference agencies to inform its local decision, leveraging regulatory tools such as the agencies' assessment report.

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The eligibility criteria for a new indication via Reliance Verification are as follows:

- a) The new indication has been approved within **three years** from the date of approval by the chosen primary reference agency
- b) The new indication, dosing regimen(s), patient population(s), and/or directions for use must be similar to those approved by the chosen reference agency.
- c) The new indication does not require an assessment by NPRA to review the benefit-risk profile due to local disease epidemiology, medical practice, and/or public health considerations (e.g. some anti-infectives, vaccines for endemic pathogens, etc.).
- d) The new indication has not been rejected, withdrawn or approved via appeal process or pending deferral by a national regulatory agency for safety or efficacy reasons.

ADDITIONAL NOTES FOR ALL NEW/ADDITIONAL INDICATION SUBMISSION

- All application submissions other than those listed above will be considered on a case-by-case basis. The applicant is advised to consult the respective section prior to submission.
- NPRA reserves the right to reclassify an application from the reliance pathway to the standard pathway, if additional review is deemed necessary during the evaluation process.
- Concurrent manual submissions may be considered based on unmet medical needs.
- For reliance submissions, multiple indications can be submitted if they are all approved by the chosen reference agencies and covered within one assessment report.

3. Priority Review for Additional Indications

Priority Review may be requested and granted for Additional Indications which fulfils the following conditions:

- Additional indication supported by a Phase III global, multicentre pivotal clinical trial conducted locally in Malaysia specifically for an oncology indication. A minimum of 5% of the total randomised subjects are subjects in the clinical trial conducted at study sites in Malaysia.

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Applicants seeking Priority Review for an additional indication shall submit a formal request, in the form of a cover letter, through the QUEST3+ system concurrently with the application. This request must be accompanied by a justification and clinical evidence demonstrating compliance with the specified eligibility requirement. Following submission, the NPRA will assess the request and determine its qualification for Priority Review. After the screening stage, applicants will be notified of the outcome via remarks in the system; applications that do not meet the criteria will be evaluated under the standard review pathway.

4. Supporting documents for all AI categories

The supporting documents include, but are not limited to the following:

- a. Approval of AI(s) in country of origin (if applicable);
- b. Approval status in the reference countries, together with the corresponding approval letter and approved package insert;
- c. Approval indication status in ASEAN Member States, and the corresponding approved package insert (if applicable)
- d. Revised Package Insert (annotated and clean);
- e. World Wide Approval status
- f. Consumer Medication Information Leaflet (RiMUP), if applicable;
- g. Clinical Overview, Summary of clinical efficacy and Summary of clinical safety;
- h. Synopsis of Individual Studies;
- i. Clinical Studies Report/ In-House Clinical Trials;
- j. Published Clinical Papers (if applicable);
- k. Latest available Periodic Benefit-Risk Evaluation Report (PBRER)

NOTES

- The relevant updates (e.g new adverse event(s), warnings and precaution(s), drug interaction(s), contraindication, pharmacodynamics, pharmacokinetics identified in clinical trials supporting the new indication) must be included in the Package Insert.
- Editorial changes including rewording of sentences (without changing the content) is allowed.
- Any other changes to the Package Insert that are not related to the new indication shall not be included and must be filed as a separate variation application.

LAMPIRAN A**Additional documents - for Reliance Full Evaluation and Reliance Verification only**

The following additional documents will need to be submitted for AI Reliance:

- a) **Full assessment report** - Unredacted and unedited assessment reports and supporting documents from the chosen primary reference agency only [complete clinical assessment reports, including assessment on the question and answer (Q & A) documents between the applicant and agency]

Notes: NPRA may also consider accepting a Public Assessment Report from the **EMA and US FDA** to be submitted with a Q & A document. However, the acceptance of Public Assessment Report from other DCA reference agencies may be considered on a case-to-case basis. Please consult the respective section prior to the submission.

NPRA may also consider unredacted and unedited assessment reports without the necessity of accompanying Q&A documents, where PMDA is selected as the reference agency.

- b) Declaration statement to indicate that the assessment report, list of Q & A and all other relevant documents provided are authentic.
- c) Checklist for AI (Reliance) - refer **Appendix I**

5. Timelines

AI category	Screening timeline (working days)	Evaluation timeline (working days)	Evaluation timeline - Priority Review (working days)
AI Standard Full Evaluation	30	180	120
AI Standard Verification		150	100
AI Reliance Full Evaluation		90	Not applicable
AI Reliance Verification			

Note: Evaluation timeline stated excludes screening and stop clock.

LAMPIRAN A**Appendix I****CHECKLIST FOR NEW/ADDITIONAL INDICATION (AI Reliance - to be filled by the applicant)**

PRODUCT NAME :

REGISTRATION NO. (MAL) :

PRODUCT REGISTRATION HOLDER (PRH) :

CHOSEN REFERENCE AGENCY :

ADDITIONAL INDICATION	MALAYSIA	CHOSEN REFERENCE AGENCY	COMMENTS
Proposed Indication			
Proposed Posology			
APPROVAL BY OTHER REFERENCE AGENCIES			
Reference agency	Date of AI approval	Approved Indication / Posology (specific to new indication only)	Comment
EMA			
US FDA			
UK MHRA			
TGA Australia			
PMDA Japan			
Health Canada			
ANSM France			
Swedish Medical Products Agency			
Swissmedic			

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DOCUMENTS SUBMITTED		Yes/ No	COMMENT
- complete clinical assessment reports (unredacted/unedited)			
- question and answer documents between the applicant and agency and all annexes			
- declaration statement to indicate that the assessment report, list of Q & A and all other relevant documents provided are authentic			
- Other supporting document/clinical guidelines (to support the new indication) – <i>if any</i>			
CLINICAL STUDIES SUBMITTED			
Clinical study (s)	Malaysia	Chosen reference agency	Comments
Clinical Study 1	- Study name		
	- Study design - Primary objective - Primary endpoints		
	Results (brief)		
	Clinical efficacy & safety conclusion		
Clinical Study 2 <i>(if any)</i>	- Study name		
	- Study design - Primary Objective - Primary endpoints		
	Results (brief)		
	Clinical efficacy/ safety conclusion		
PACKAGE INSERT (SUMMARY OF CHANGES)			
<i>summary of other changes must be those consequential to the Additional Indication (e.g., Summary of other changes resulting from the new indication and posology)</i>			
Section	Malaysia	Chosen reference agency	Comments

SENARAI EDARAN:

1. Presiden
Pharmaceutical Association of Malaysia (PhAMA)
C-18-2, Block C 3 Two Square (Dataran 3 2),
No. 2, Jalan 19/1,
46300 Petaling Jaya, Selangor.
2. Presiden
Persatuan Industri Farmaseutikal Malaysia (MOPI)
Global Business & Convention Centre
Mezzanine Floor, Block A,
No. 8, Jalan 19/1, Section 19,
46300 Petaling Jaya, Selangor.
3. Presiden
Malaysian Association of Pharmaceutical Suppliers (MAPS)
c/o Medispec (M) Sdn Bhd,
B-1-7, Block B,
Jalan SS 25/22, Mayang Avenue,
Taman Mayang,
47201 Petaling Jaya, Selangor.