APPENDIX 14

EVALUATION ROUTES

There are four (4) types of methods of evaluation for product registration.

1) **Full Evaluation (Standard Pathway)**

2) **Full Evaluation (Conditional Registration)**
   - This applies to new registration applications for New Drug Products and Biologics.
   - At the point of submission, the product must be registered in at least one (1) Drug Control Authority (DCA) reference agency.
   - A conditional registration does not apply to additional indications submitted post-registration. However, the approval of additional indication with less than comprehensive clinical data may be considered on a case-to-case basis.
   - A conditional registration is valid for two (2) years. Thereafter, the conditional registration may be renewed two (2) times (with the possibility of two (2) extensions of two (2) years each).
   - For further details, refer to *Guidelines on Conditional Registration for New Chemical Entities and Biologics*.
   - For medicinal products or vaccines to be used during disaster, the guideline must be read in conjunction with *Guidance and Requirements on Conditional Registration of Pharmaceutical Products During Disaster*. The validity of conditional registration is one year. Thereafter, the conditional registration may be renewed two (2) times (with the possibility of two (2) extensions of one (1) year each).

   References:
   i. Directive No. 15, 2018, *BPFK/PPP/07/25 (15) Jld.2*: *Direktif Untuk Melaksanakan* Guidelines on Conditional Registration for New Chemical Entities and Biologics (30 May 2018)
   ii. Directive No. 18, 2020, *NPRA.600-1/9/13(9)*: *Direktif Berkenaan Pelaksanaan Pendaftaran* Fast-Track *Bersyarat Untuk Produk Farmaseutikal Semasa Bencana* (14 December 2020)
   iii. Directive No. 15, 2021, *NPRA.600-1/9/13(25)*: *Direktif Berkenaan Pelaksanaan Pendaftaran Bersyarat Produk Farmaseutikal Semasa Bencana Secara Recognition* (12 July 2021)

3) **Full Evaluation via Abbreviated and Verification Review**
   - This applies to New Drug Products and Biologics, including biosimilars.
   - Abbreviated Review applies to a product that has been evaluated and approved by one (1) DCA reference agency.
   - Verification Review applies to a product that has been evaluated and approved by two (2) DCA reference agencies.
   - Refer to *Guidelines on Facilitated Registration Pathway: Abbreviated and Verification Review*. (Effective 1 April 2019)

     Reference: Directive No. 7, 2019, *BPFK/PPP/07/25 (7) Jld.3*: *Direktif Untuk Melaksanakan* Guidelines on Facilitated Registration Pathway: Abbreviated and Verification Review (27 March 2019)

4) **Abridged Evaluation**

Methods of Evaluation According to Product Category:

No.	Product Category	Method of Evaluation	
		Full Evaluation	**Abridged Evaluation**
1.	New Drug Products	√	Not Applicable
2.	Biologics	√	Not Applicable
3.	Generics (Scheduled Poison)	√	Not Applicable
4.	Generics (Non-Scheduled Poison) [or known as OTC]	* All products from this category, unless stated in Abridged Evaluation	Includes, but not limited to the following: • Antiseptics/ skin disinfectants; • Locally acting lozenges/ pastilles; • Topical analgesic/ counter-irritants; • Topical nasal decongestants; • Emollient/ demulcent/skin protectants; • Keratolytics; • Anti-dandruff; • Oral care; • Anti-acne; • Medicated plasters/patch/pad; and • Topical antibacterial.
5.	Health Supplements a) General or Nutritional Claims	Not Applicable	√
	b) Functional Claims (Medium)	Not Applicable	√
	c) Disease Risk Reduction Claims (High)	√	Not Applicable
6.	Natural Products	Not Applicable	√
7.	Natural Products with Therapeutic Claim	√	Not Applicable