

APPENDIX 3

GUIDELINE ON REGISTRATION OF NEW DRUG PRODUCTS

IMPORTANT NOTES:

This document shall be read in conjunction with the relevant sections of the main guidance document: **Drug Registration Guidance Document (DRGD)**, which is in accordance to the legal requirements of the **Sale of Drugs Act 1952** and the **Control of Drugs and Cosmetics Regulations 1984**.

1. DEFINITION

New Drug Products (NDP) is defined as any pharmaceutical products that have not been previously registered in accordance with the provisions of the CDCR 1984.

An NDP may be classified according to the following categories:

1.1 New Chemical Entity (NCE) (single/ combination products with an active substance never registered by DCA)

Defined as an **active moiety**/ radiopharmaceutical substance that has not been registered in any pharmaceutical product.

An **active moiety** is defined as the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

A radiopharmaceutical substance is defined as a radionucleotide, ligand or the coupling mechanism to link the molecule and the radionucleotide that has not been registered in any pharmaceutical product.

1.2 Hybrid (single/ combination products with registered active moieties)

All other products registrable at New Drug Section which do not fall under **(1.1)**.

Examples of Hybrid (single/ combination) products:

- i. Registered chemical entity(s) in a new chemical form(s)
- ii. Registered chemical entity(s) in a new dosage form(s)
- iii. Registered chemical entity(s) in a new dosage strength(s) with a change in dosing/ posology
- iv. Registered chemical entity(s) for use by a new route of administration
- v. Registered chemical entity(s) for new indication(s), dosage recommendation(s) and/ or patient population(s)
- vi. Combination of registered chemical entity(s) in new chemical form(s) and registered chemical entity(s)
- vii. A product for which its innovator has never been registered by DCA
- viii. Second source product
- ix. Replacement product

For medicinal gases classified as new drug products, please refer to Directive No. 8, 2021 and [Guideline on Registration of Medicinal Gases](#).

Reference:

- Directive No. 8, 2021, [NPRA.600-1/9/13 \(18\)](#): *Direktif Berkenaan Pengukuhan Pelaksanaan Kawalan Regulatori Ke Atas Produk-Produk Gas Perubatan dan Penggunaan Guideline on Registration of Medicinal Gases* (11 February 2021)

2. REGISTRATION REQUIREMENT AND EVALUATION TIMELINE**Table 1:** Registration Requirement and Evaluation Timeline for NDP

ITEMS	REGISTRATION REQUIREMENTS	
	HYBRID	NCE
ACTD Module:		
1) Part I	Yes	Yes
2) Part II (S) ¹	Yes	Yes
3) Part II (P)	Yes	Yes
4) Part III	No ²	Yes ³
5) Part IV	BA/BE/pivotal study report(s), clinical overview and RMP	Full, including RMP
	HYBRID	NCE
Consultation with local clinical specialists⁴	No ⁵	Yes
Evaluation timeline	210 working days	245 working days

¹ Please refer to "GUIDANCE NOTES: ACTIVE PHARMACEUTICAL INGREDIENT (API) INFORMATION (PART II S) FOR QUEST3+ PRODUCT REGISTRATION APPLICATION",

which outlines the requirements when preparing submission of a new product application using the same source of an approved API of a registered product; API evaluation is manufacturer and PRH specific.

- ² Non-clinical overview only, if applicable.
- ³ [Good Laboratory Practice \(GLP\) Compliance Form](#) is to be submitted at E14 during initial evaluation (screening process).
- ⁴ Selected clinical publications/ study synopsis are sent to local clinical specialists to gather comments on product efficacy and safety.
- ⁵ Consultation with local clinical specialists is required for a product for which its innovator has never been registered by DCA and other hybrid application, when deemed necessary.

NOTE:

For a product in which the reference innovator product has never been registered in Malaysia, **specific requirements for Parts III and IV:**

- i. Nonclinical Overview, Nonclinical Summary & List of Key Literature References, by referring to studies by the innovator product
- ii. Clinical Overview, Clinical Summary & List of Key Literature References, by referring to studies by the innovator product
- iii. Bioequivalence study report(s)
- iv. Other pivotal study reports, if applicable
- v. Risk Management Plan (RMP)
- vi. Consultation with local clinical specialists