LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION

JANUARY 2025

(August 2024 Updates)

There is one (1) amendment for the August 2024 DRGD Updates as follows:

Appendix of DRGD Third Edition, Eighth Revision July 2024

Appendix 19: General Labelling Requirements

1. Amendment of information, Table 1, Page 2

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION
JANUARY 2025
(August 2024 Updates)

Amendment of Appendix 19: General Labelling Requirements

1. Amendment of information in Table 1 on Page 2 by –

   (a) substituting the parameter for item no. 17, “To declare source of ingredients derived from animal origin (active and excipient) including starting materials and gelatin.” with, “To declare source of ingredients derived from animal origin, unless a satisfactory confirmation can be provided verifying the absence of animal materials in the final product.”

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION
JANUARY 2025
(November 2024 Updates)

There are four (4) amendments for the November 2024 DRGD Updates as follows:

Appendix of DRGD Third Edition, Eighth Revision July 2024

Appendix 2: Medical Device - Drug - Cosmetic Interphase (MDDCI) and Combination Products

1. Amendment of information, Table I: MEDICAL DEVICE-DRUG-COSMETIC INTERPHASE (MDDCI) AND COMBINATION PRODUCTS CLASSIFICATION DECISION, Page 13

Appendix 18: List of Permitted, Prohibited and Restricted Substances

2. Deletion of information, Table 1.2 List of Restricted Active Ingredients and Combinations, Page 6
3. Deletion of information, Table 2.2 List of Restricted Excipients, Page 9
4. Addition of information, Table 2.2 List of Restricted Excipients, Page 9

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION

JANUARY 2025

(November 2024 Updates)

Amendment of Appendix 2: Medical Device - Drug - Cosmetic Interphase (MDDCI) and Combination Products

1. Amendment of information in Table I: MEDICAL DEVICE-DRUG-COSMETIC INTERPHASE (MDDCI) AND COMBINATION PRODUCTS CLASSIFICATION DECISION on Page 13 by –

   (a) substituting items no. 19 and no. 20 with the following:

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
19.	**i. Gas Cylinder** a. Gas Cylinder (empty) b. Gas Cylinder (empty) with valve c. Gas Cylinder (empty) (with integrated pressured regulator)	To store and transport compressed gases that are used for medical purposes.	**MEDICAL DEVICE**	**MDA**
	ii. Gas cylinder (with valve and/or with integrated pressure regulator) containing medicinal/medical gas	Gases or gas mixtures which mode of action is achieved primarily by physical in nature and not achieved primarily based on pharmacological, immunological or metabolic action in/on the body, such as: i. gases for insufflation of the abdominal cavity for laparoscopy and used as a cooling gas to assist a medical device in freezing and coagulation procedures (e.g. Carbon dioxide),	**MEDICAL DEVICE**	**MDA**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
		ii. gases for removal of warts (e.g. liquid nitrogen), iii. culture embryo and sperm in incubator (IVF) and power air driven medical equipment (e.g. compressed nitrogen).		
	iii. Gas cylinder (with valve and/or with integrated pressure regulator) containing following medicinal/medical gases: a. Oxygen, O_2 (not less than 99%v/v oxygen) b. Carbon dioxide, CO_2 (not less than 99%v/v carbon dioxide) c. Nitrous oxide, N_2O (not less than 98%v/v nitrous oxide) d. Nitric oxide, NO (not less than 99%v/v nitric oxide) e. Nitrous oxide/ oxygen mixture (50:50%) f. Medicinal air (oxygen/nitrogen mixture; 19.5-23.5%v/v oxygen)	Gases or gas mixtures which mode of action is achieved primarily based on pharmacological, immunological or metabolic action in/on the body, such as gases for hypoxia (oxygen gas)	**DRUG-DEVICE** **Combination** **product regulated** **as DRUG**	**NPRA**

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION

JANUARY 2025

(November 2024 Updates)

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
20.	**Medicinal/Medical patch**	a. The primary mode of action (main mechanism of how a product exerts its therapeutic effect), must be scientifically plausible, via pharmacological, immunological and metabolic in/ on the body. E.g., patches for transdermal drug delivery	**DRUG**	**NPRA**
		b. A product with active substance which is responsible for the primary mode of action of the product or if it is achieved by pharmacological, immunological or metabolic means.	**DRUG**	**NPRA**
		c. Demonstrated by manufacturer that substance with plant origin achieves its primary mode of action by means other than pharmacological, immunological or metabolic.	**MEDICAL DEVICE**	**MDA**
		d. A product containing herbal substance(s) and/or herbal preparation(s) that have a demonstrated pharmacological action could be qualified as a medical device, if the action of the herbal constituent is ancillary and the primary mode of action of the product is achieved by physical or mechanical means. Physical means including mechanical action, physical barrier such as a film, lubrication, heat transfer, radiation, ultrasound, replacement of or support to organs or body functions.	**MEDICAL DEVICE**	**MDA**

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION
JANUARY 2025
(November 2024 Updates)

Amendment of Appendix 18: List of Permitted, Prohibited and Restricted Substances

2. Amendment of information in Table 1.2 List of Restricted Active Ingredients and Combinations on Page 6 by –

   (a) deleting 12. Chloroform.

3. Amendment of information in Table 2.2 List of Restricted Excipients on Page 9 by –

   (a) deleting a) Chloroform in 3. Preservatives.

4. Amendment of information in Table 2.2 List of Restricted Excipients on Page 9 by –

   (a) adding the following information on Chloroform in 4. Others:

2.2 List of Restricted Excipients	
Excipients	**Restrictions**
4. Others	
c) Chloroform	Not allowed to be used as preservative or other function(s) except solvent.

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION
JANUARY 2025
(December 2024 Updates)

There are eleven (11) amendments for the December 2024 DRGD Updates as follows:

Main Body of DRGD Third Edition, Eighth Revision July 2024

Section B: Product Registration Process

1. Amendment of information, Table in 11.2 Product Registration Number, Page 51

Section E: Post-Registration Process

2. Amendment of information, 21.1 Pharmacovigilance, Page 69
3. Amendment of information, 21.2.5 Product Quality Reporting, Page 72
4. Amendment of information, 21.2.7 Regulatory Action, Page 73
5. Amendment of information, 21.2.8 Adulteration, Page 76

Appendix of DRGD Third Edition, Eighth Revision July 2024

Appendix 3: Guideline on Registration of New Drug Products

6. Amendment of information, 2. Registration Requirement & Evaluation Timeline, Page 2

Appendix 4: Guideline on Registration of Biologics

7. Amendment of information, 2. Specific Requirements for Registration of Biologics, Page 20

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION
JANUARY 2025
(December 2024 Updates)

Appendix 5: Guideline on Registration of Generics

8. Amendment of information, 5. Requirements for Generic Application, Page 3

Appendix 11: Regulatory Control of Active Pharmaceutical Ingredients (APIs)

9. Amendment of information, 6.1 Stability Data, Page 12

Appendix 18: List of Permitted, Prohibited and Restricted Substances

10. Addition of new ingredient, 1.1 List of Prohibited Active Ingredients and Combinations, a) Prohibited Active Ingredients, Page 2

11. Addition of new Appendix 34: Guideline for Product Quality Reporting and Recall Procedures

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION
JANUARY 2025
(December 2024 Updates)

Amendment of Section B: Product Registration Process

1. Amendment of information in Table in 11.2 Product Registration Number on Page 51 by –

   (a) adding the following new information:

Alphabets/ symbols	Refers to:	
@ and ##	M	Natural Products With Modern Claim

Amendment of Section E: Post-Registration Process

2. Amendment of information in 21.1 Pharmacovigilance on Page 69 by –

   (a) deleting the statement, “For more details regarding product recalls linked to serious adverse drug reactions, please refer to 21.2.7 ii) Product Recall.” from ii. Product Recall due to Serious Adverse Drug Reactions.

3. Amendment of information in 21.2.5 Product Quality Reporting on Page 72 by –

   (a) adding the statement, “For further information, refer to: Appendix 34: Guideline for Product Quality Reporting and Recall Procedures.” after the first paragraph.

   (b) deleting the following information:

"Product quality reporting can be (non-exhaustive):

i) initiated by reports from healthcare facilities/professionals and public
ii) due to out-of-specification (OOS) during product life cycle. Once the incident is confirmed, it is recommended that reports are submitted to NPRA within 48 hours.

It is also the responsibility of the prescribers, pharmacists, as well as all other healthcare professionals to report any product quality defect or regulatory non-compliance by using the Quality Reporting of Registered Product (NPRA/435/2) form with complaint sample (if any).

All report on product quality-related issues received shall be investigated by NPRA as well as the PRH/ manufacturer. In the event of confirmed case of quality-related issues or regulatory non-compliance, NPRA may take necessary regulatory action on the product.

It is the responsibility of the PRH to determine the appropriate corrective and preventive action, as well as risk control measures such as (if appropriate/when necessary):

i) Issuance of "Dear Healthcare Professional Communication (DHPC)"
ii) A product recall
iii) Issuance of a press release
iv) Withdrawal of the product registration.

NPRA will review the information provided in the report submitted by the PRH and may request for further information required for assessment."

4. Amendment of information in 21.2.7 Regulatory Action on Page 73 by –

   (a) replacing the statement, “Product Recall means any action taken by its manufacturer, importer, and wholesaler to remove or withdraw a particular product from the market or to retrieve the product from any person to whom it has been supplied.” with, “Product Recall means any action taken by its PRH, licensed manufacturer, licensed importer and licensed wholesaler to remove or withdraw a particular product from the market or to retrieve the product from any person to whom it has been supplied.” in ii) Product Recall.

   (b) adding the statement, “For further information, refer to: Appendix 34: Guideline for Product Quality Reporting and Recall Procedures.” after “The PRH is responsible for conducting recalls of defective or unsafe products. No recall shall take place without first consulting/ informing the Authority.” in ii) Product Recall.

   (c) deleting the following information in ii) Product Recall.

   “The degree of recall is classified according to the severity of quality defects of the product.

	Degree I	**Degree II**	**Degree III**
Description	Products with major health risks that might cause serious injuries or death.	Products with minor health risks or are substandard.	Products with other reasons for recall that can cause health risks to users.

Notification to Authority **(for voluntary recall only)**	PRH to notify authority no later than 24 hours prior to the start of the intended voluntary recall.	PRH to notify authority no later than 48 hours prior to the start of the intended voluntary recall.	PRH to notify authority no later than 72 hours prior to the start of the intended voluntary recall.
Issuance of Communication /notification to purchaser	PRH is required to issue a Communication / notification to purchaser within 24 hours of recall commencement, notifying of the recall action and providing the required instructions to purchasers, including immediate cease in sale and supply of the product.	PRH is required to issue a Communication/ notification to purchaser within 48 hours of recall commencement, notifying of the recall action and providing the required instructions to purchasers, including immediate cease in sale and supply of the product.	PRH is required to issue a Communication/ notification to purchaser within 72 hours of recall commencement, notifying of the recall action and providing the required instructions to purchasers, including immediate cease in sale and supply of the product.

The PRH should notify their stakeholders about the recall as soon as possible. To ensure prompt notification, the PRH may consider disseminating the recall notice to their stakeholders via telephone and/or email first and follow-up with the letter/any method of communication to confirm this notification.

The level of recall depends on the nature of problem, extent of the product's distribution and degree of hazard involved.

Level A: To all consumers (end users)

a) Usually initiated when the risk to consumers is assessed to be unacceptable, and where the product is directly supplied to consumers.

b) All wholesale and retail supply of the affected product or batch(es) should be suspended.

c) Affected product or batch(es) are to be recalled from all wholesale and retail distributors as well as consumers who had been supplied with the affected batch(es).

d) Where necessary, the recall notification to consumers may need to be done via announcement on mass media such as press announcement, newspaper notification, television and/or radio.

e) The recalled product or batch(es) should be segregated in a secured area before the implementation of follow-up actions (e.g. destruction of the products).

Level B: To all points of sales a) Usually initiated when the risk to consumers is assessed to be moderate to high, but recall at consumer level is not deemed necessary. b) All wholesale and retail supply of the affected product or batch(es) should be suspended. c) Affected product or batch(es) are to be recalled from all wholesale and retail distributors including: wholesale distributors; government/private hospitals and clinics; retail pharmacies; other healthcare practitioners' establishments; nursing homes and other related institutions; and other retail outlets, e.g. health food stores, supermarkets, departmental stores.
Level C: To all distributors, wholesalers and manufacturer a) Usually initiated when the risk to consumers is assessed to be low or where other measures can be taken to mitigate the risk. b) All wholesale supply of the affected product or batch(es) should be suspended. Affected product or batch(es) are to be recalled from all affected: wholesalers; distributors; third-party logistics providers holding the product for distribution to retailers, etc. c) The recalled product or batch(es) should be segregated in a secured area before the implementation of follow-up actions, e.g. destruction of the products.

For further information, refer to: Chapter 7, Guidelines on Good Distribution Practice, Third Edition, 1 January 2018."

5. Amendment of information in 21.2.8 Adulteration on Page 76 by –

(a) replacing, “involved in adulteration” with “of adulterated products” in statement iii).

Amendment of Appendix 3: Guideline on Registration of New Drug Products

6. Amendment of information in 2. Registration Requirement & Evaluation Timeline on Page 2 by –

(a) adding the heading, “2.1 Requirements for Registration of NDP” before Table 1: Registration Requirement and Evaluation Timeline for NDP.

(b) adding the following information:

“**2.2 Stability Data Requirements**

2.2.1 Stability Data of Drug Substance

The submitted stability data should be from batches manufactured at the drug substance manufacturing site proposed for registration in Malaysia. At the time of submission of the new product application, the stability data requirements are as follows:

Study condition	Minimum time period covered by data during submission	Number of batches required

Long term	12 months	A minimum of 3 primary batches of the drug substance. The batches should be at least pilot scale, manufactured by the same manufacturing process and packaged in the same container closure system as that proposed for registration.
Accelerated	6 months	

Primary batch *refers to a batch used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a re-test period or shelf-life, respectively. A primary batch of a drug substance should be at least a pilot scale batch - ICH Q1A(R2)*

Where multiple drug substance manufacturers are proposed for registration, drug substance stability data of at least 6 months for 3 batches from each of the other sites are required, unless otherwise justified. Full real time data covering the proposed drug substance retest period from one of the drug substance manufacturing site intended to be registered in Malaysia should be available. Where full real time data is not available from each drug substance manufacturing site to support the proposed drug substance retest period, it may be acceptable to extrapolate the stability data from other sites if comparability can be demonstrated.

Drug substance is considered representative when the following criteria are fulfilled:

- The quality to the drug substance used in the stability batches are comparable (e.g., physical characteristics/attributes, established process validation)
- Manufactured using the same synthetic route and process. Scientific justification should be provided to demonstrate equivalence between the sites if differences exist
- Controlled by the same set of specifications
- Packaged in the same type of container closure system

If any of the above criteria are not met, complete site-specific stability data are required to support the application.

2.2.2. Stability Data of Drug Product

The submitted stability data should be from batches manufactured at the drug product manufacturing site proposed for registration in Malaysia. At the time of submission of the new product application, the stability data requirements are as follows:

Study storage	Minimum time period covered by data at submission	Number of batches
Long term	12 months	A minimum of 3 primary batches of the drug product. The batches should be at least pilot scale, manufactured by the same manufacturing process and packaged in the same container closure system as that proposed for registration.
Accelerated	6 months	

Primary batch *refers to a batch used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a shelf-life. A primary batch of a for a drug product, two of the three batches should be at least pilot scale batch, and the third batch can be smaller if it is representative with regard to the critical manufacturing steps. However, a primary batch may be a production batch. - ICH Q1A(R2)*

<u>Drug product stability in the case of multiple drug substance manufacturers.</u>

Where possible, batches of the drug product should be manufactured using different batches of drug substance including different drug substance manufacturers intended to be registered. If multiple drug substance manufacturers are proposed for the drug product, a

commitment to conduct drug product stability studies for 1 production batch using the drug substance from each drug substance manufacturer that is not represented in the drug product stability batches is required.

Multiple primary packaging sites

If more than one primary packaging (PP) site is proposed for registration, stability data from three drug product (DP) batches using PP from at least one of these sites must be provided.

For additional PP sites (using the same manufacturing process and container closure system), a commitment is required to conduct stability studies on two (conventional dosage form) or three (critical dosage form) DP batches.

NON-SITE SPECIFIC STABILITY DATA FOR DRUG PRODUCT

In the case of technology transfer where site-specific stability data for drug product is not available from the manufacturing site proposed for registration, it may be acceptable to extrapolate the stability data from another site to the site proposed for registration if it can be demonstrated that the submitted data is representative of the proposed drug product manufacturing site (the data must be from primary batches manufactured using drug substance intended to be registered in Malaysia).

Drug product is considered representative when the following criteria are fulfilled:

- The quality of the drug product used in the stability batches is comparable (e.g., dissolution profile and established process validation)
- Manufactured using the same formulation
- Manufactured using the same manufacturing process, including equipment type, process parameters and in-process tests. Scientific justification should be provided to demonstrate equivalence between the sites if differences exist.
- Controlled by the same set of specifications
- Packaged in the same type of container closure system

In addition, a commitment to conduct stability studies for drug product for at least one production batch of drug substance is required for each site that is not represented in the submitted stability studies.

If any of the above criteria are not met, site-specific stability data are required to support the application."

Amendment of Appendix 4: Guideline on Registration of Biologics

7. Amendment of information in 2. Specific Requirements for Registration of Biologics on Page 20 by –

(a) adding the following information:

"**2.3 STABILITY DATA REQUIREMENTS**

2.3.1 Stability Data of Drug Substance

The submitted stability data should be from batches manufactured at the drug substance manufacturing site proposed for registration in Malaysia. At the time of submission of the new product application, the stability data requirements are as follows:

Study condition	**Minimum time period covered by data during submission**	**Number of batches required**
Long term	12 months	At least 3 commercial scale batches or representative* of the manufacturing scale of production.
Accelerated	6 months	

** Representative data: Representative of the quality of batches used in pre-clinical and clinical studies; Representative manufacturing process and storage conditions; Representative containers - ICH Q5C*

Where multiple drug substance manufacturers are proposed for registration, drug substance stability data of at least 6 months for 3 batches from each of the other sites are required, unless otherwise justified. Full real time data covering the proposed drug substance shelf life from one of the drug substance manufacturing site intended to be registered in Malaysia should be available. Where full real time data is not available from each drug substance manufacturing site to support the proposed drug substance shelf life, it may be acceptable to extrapolate the stability data from other sites if comparability can be demonstrated (Refer ICH Q5E).

2.3.2 Stability Data of Drug Product

The submitted stability data should be from batches manufactured at the drug product manufacturing site proposed for registration in Malaysia. At the time of submission of the new product application, the stability data requirements are as follows:

Study condition	**Minimum time period covered by data during submission**	**Number of batches required**
Long term	12 months	At least 3 commercial scale batches or representative* of the manufacturing scale of production.
Accelerated	6 months	

** Representative data: Representative of the quality of batches used in pre-clinical and clinical studies; Representative manufacturing process and storage conditions; Representative containers - ICH Q5C*

Where multiple drug product manufacturers are proposed for registration, drug product stability data of at least 6 months for 3 batches from each of the other sites are required, unless otherwise justified. Full real time data covering the proposed drug product shelf life from one of the drug product manufacturing site intended to be registered in Malaysia should be available. Where full real time data is not available from each drug product manufacturing site to support the proposed drug product shelf life, it may be acceptable to extrapolate the stability data from other sites if comparability can be demonstrated (Refer ICH Q5E).

Drug product stability in the case of multiple drug substance manufacturers

Where possible, batches of the drug product should be manufactured using different batches of drug substance including different drug substance manufacturers intended to be registered. If multiple drug substance manufacturers are proposed for the drug product, a commitment to conduct drug product stability studies for 1 production batch using the drug substance from each drug substance manufacturer that is not represented in the drug product stability batches is required."

Amendment of Appendix 5: Guideline on Registration of Generics

8. Amendment of information in 5. Requirements for Generic Application on Page 3 by –

(a) adding 5.1 to, "Please refer to the following Appendices supplemented together with the DRGD for further information, where applicable:"

(b) adding the following information:

"5.2 STABILITY DATA REQUIREMENTS

Stability data of Active Pharmaceutical Ingredients (APIs)

For requirements of stability data of APIs, kindly refer to Appendix 11- Regulatory Control of Active Pharmaceutical Ingredients (APIs).

Stability data of finished product

The submitted finished product stability data should be from batches manufactured at the finished product manufacturing site proposed for registration in Malaysia. At the time of submission of the new product application, the stability data requirements are summarized as follows:

Study conditions	**Minimum data at the time of submission**	**Number of batches**
Long term	6 months	Minimum 2 (at least pilot scale) for conventional dosage form and stable API
	12 months	Minimum 3 (primary batch) for critical dosage form or unstable API
Accelerated	6 months	Minimum 2 (at least pilot scale) for conventional dosage form and stable API
		Minimum 3 (primary batch) for critical dosage form or unstable API

Primary batch *refers to a batch used in a stability study, from which stability data are submitted in a registration application for the purpose of establishing a shelf-life. A primary batch of a for a finished product, two of the three batches should be at least pilot scale batch, and the third batch can be smaller if it is representative with regard to the critical manufacturing steps. However, a primary batch may be a production batch. - ICH Q1A(R2)*

Where possible, batches of the finished product should be manufactured using different batches of Active Pharmaceutical Ingredients (API). If multiple API manufacturers are proposed for the finished product, a commitment to conduct finished product stability studies for 1 production batch using the API from each API manufacturer that is not represented in the finished product stability batches is required.

Multiple primary packaging sites

If more than one primary packaging (PP) site is proposed for registration, stability data from three finished product batches using PP from at least one of these sites must be provided.

For additional PP sites (using the same manufacturing process and container closure system), a commitment is required to conduct stability studies on two (conventional dosage form) or three (critical dosage form) finished product batches.

NON-SITE SPECIFIC STABILITY DATA FOR FINISHED PRODUCT

In the case of technology transfer where site-specific stability data for finished product is not available from the manufacturing site proposed for registration, it may be acceptable to extrapolate the stability data from another site to the site proposed for registration if it can be demonstrated that the submitted data is representative of the proposed finished product manufacturing site (the data must be from primary batches manufactured API intended to be registered in Malaysia).

Finished product is considered representative when the following criteria are fulfilled:

- The quality of the finished product used in the stability batches is comparable (e.g., dissolution profile and established process validation)
- Manufactured using the same formulation

- Manufactured using the same manufacturing process, including equipment type, process parameters and in-process tests. Scientific justification should be provided to demonstrate equivalence between the sites if differences exist.
- Controlled by the same set of specifications
- Packaged in the same type of container closure system

In addition, a commitment to conduct stability studies for finished product for at least one production batch of API is required for each site that is not represented in the submitted stability studies.

If any of the above criteria are not met, site-specific stability data are required to support the application."

Amendment of Appendix 11: Regulatory Control of Active Pharmaceutical Ingredients (APIs)

9. Amendment of information in 6.1 Stability Data on Page 12 by –

   (a) deleting the statement, "6.13 Where the API is sourced from multiple sites or from different route of synthesis, stability data from each source shall be provided."

   (b) adding the following information:

"6.13 The submitted API stability data should be from batches manufactured at the API manufacturing site proposed for product registration in Malaysia. At the time of submission of the new product application, the API stability data requirements are summarized as follows:

Study	Minimum time period covered by data at submission	Number of batches required

Long term	12 months	A minimum of 3 primary batches of the API. The batches should be at least pilot scale, manufactured by the same manufacturing process and packaged in the same container closure system as declared in S6 Container Closure System.
Accelerated	6 months	

6.1.4 If API is sourced from multiple sites or from different route of synthesis (ROS) are proposed in product registration, stability data of 3 batches from each API site or from each ROS are required.

6.1.5 Where full long time data is not available from each API manufacturing site to support the proposed retest period, it (e.g., on-going 6 months long-time data) may be acceptable to extrapolate the full long time stability data from other site if it can be demonstrated that the submitted data is representative of the proposed site by fulfilled the following criteria:

- The quality to the API used in the stability batches are comparable (e.g., physical characteristics/attributes, established process validation, impurities profile, etc)
- Manufactured using the same route of synthetic and same manufacturing process. Scientific justification should be provided to demonstrate equivalence between the sites if differences exist
- Controlled by the same set of specifications
- Packaged in the same container closure system

If any of the above criteria are not met, full long time API site-specific stability data are required to support the application.

In addition, a commitment to provide full long stability data for the related on-going API stability studies once full data available. A process validation protocol and report from all related API manufacturers are required to support this scenario."

Amendment of Appendix 18: List of Permitted, Prohibited and Restricted Substances

10. Amendment of 1.1 List of Prohibited Active Ingredients and Combinations, a) Prohibited Active Ingredients on Page 2 by –

    (a) adding a new prohibited active ingredient, 17-Hydroxyprogesterone Caproate (17-OHPC).

11. Addition of new Appendix 34: Guideline for Product Quality Reporting and Recall Procedures

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION
JANUARY 2025
(January 2025 Updates)

There are three (3) amendments for the January 2025 DRGD Updates as follows:

Appendix of DRGD Third Edition, Eighth Revision July 2024

Appendix 6: Guideline on Registration of Health Supplements

1. Amendment of information, 5.26 Product label, Page 27
2. Amendment of information, Table 17: Allowable claims for specific active ingredients in HS products, Page 56

Appendix 7: Guideline on Registration of Natural Products

3. Amendment of information, 2.6 Labelling Requirements, Page 39

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION

JANUARY 2025

(January 2025 Updates)

Amendment of Appendix 6: Guideline on Registration of Health Supplements

1. Amendment of information in 5.26 Product label on Page 27 by –

   (a) adding a new statement, "For small label, the labelling requirements may follow that of blister packaging subject to satisfactory justification. * *Definition of small label: Small label refers to the label on a small primary (immediate) container, where the container is not large enough to accommodate an immediate label that includes all the information and formatting typically required.*" to Additional Requirements for Labelling.

2. Amendment of information in Table 17: Allowable claims for specific active ingredients in HS products on Page 56 by –

   (a) adding new functional claims, "Helps oxygen transport to body tissues" and "Support energy production" to Iron.

   (b) adding the following new ingredient and claims:

Ingredients	**Claims**		
	General	**Functional**	**Reduced Risk Reduction Claim**
L-Arginine	- Helps in maintenance of good health	- A non-essential amino acid that is involved in protein synthesis	

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, NINTH REVISION
JANUARY 2025
(January 2025 Updates)

Amendment of Appendix 7: Guideline on Registration of Natural Products

3. Amendment of information in 2.6 Labelling Requirements on Page 39 by –

   (a) adding a new statement, “g) For small label, the labelling requirements may follow that of blister packaging subject to satisfactory justification. * *Definition of small label: Small label refers to the label on a small primary (immediate) container, where the container is not large enough to accommodate an immediate label that includes all the information and formatting typically required.*”