LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(February 2026 Updates)

There are two (2) amendments for the February 2026 DRGD Updates as follows:

Appendix of DRGD Third Edition, 11th Revision January 2026

Appendix 18: List of Permitted, Prohibited and Restricted Substances

1. Addition of new information, Contents, Page 1
2. Addition of new information, 4. List of High-Risk Ingredients in Oral Liquid Dosage Forms That Require Diethylene Glycol (DEG) And Ethylene Glycol (EG) Testing, Page 15

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(February 2026 Updates)

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

1. **Addition of new information in Contents on page 1** by –

   (a) adding the following item:

   "4. List of High-Risk Ingredients in Oral Liquid Dosage Forms That Require Diethylene Glycol (DEG) And Ethylene Glycol (EG) Testing"

2. **Addition of new information after 3.2 List of Restricted Colouring Agents on page 15** by –

   (a) adding the following information:

"4. LIST OF HIGH-RISK INGREDIENTS IN ORAL LIQUID DOSAGE FORMS THAT REQUIRE DIETHYLENE GLYCOL (DEG) AND ETHYLENE GLYCOL (EG) TESTING

4.1	**List of High-Risk Ingredients**	**Requirement**
a)	Glycerin	Products in oral liquid dosage form that contain high-risk ingredients must be tested for Diethylene Glycol (DEG) and Ethylene Glycol (EG). Limit: Not more than 0.1% (1000 ppm).
b)	Propylene Glycol (PG)	
c)	Polyethylene Glycol (PEG)	
d)	Sorbitol and Sorbitol Solution	
e)	Maltitol and Maltitol Solution	
f)	Hydrogenated starch hydrolysate	

g)	Other sugar polyols synthesized via catalytic hydrogenation	The PRH/manufacturer may choose to conduct testing on either the ingredient or the finished product.

Note: The following lists above are by no means exhaustive.
For details on implementation, refer to **Directive No. 8, 2026**. *NPRA/600-1/9/13(2) Jld. 2 Direktif Keperluan Pengujian Kandungan Diethylene Glycol (DEG) dan Ethylene Glycol (EG) Dalam Bahan Aktif, Excipient dan / atau Produk Siap Berbentuk Dos Cecair Untuk Kegunaan Dalaman (Oral) Dengan Bahan Aktif / Excipient Berisiko* (10 February 2026)."

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(March 2026 Updates)

There are four (4) amendments for the March 2026 DRGD Updates as follows:

Appendix of DRGD Third Edition, 11th Revision January 2026

Appendix 4: Guideline on Registration of Biologics

1. Amendment of information, Page 2

Appendix 19: General Labelling Requirements

2. Amendment of information, Table 1, Page 2

Appendix 21: Special Conditions for Registration of A Particular Product or Group of Products

3. Addition of new information, No. 6. Oxycodone in oral dosage forms, Page 2
4. Addition of new information, No. 1. Ascorbic acid injection, Page 2

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(March 2026 Updates)

Amendment of Appendix 4: Guideline on Registration of Biologics

1. **Amendment information on page 2** by –

(a) replacing the following information:

"Animal derived materials/ products are commonly used in the manufacture of biologics/ biopharmaceuticals. A detailed information regarding the rationale for use of such material e.g., the source, etc. shall be provided, as per Checklist A and Checklist B; and also provide a confirmation on the presence/ absence of the animal materials in the final product through Deoxyribonucleic Acid (DNA) testing by Polymerase Chain Reaction (PCR) or any qualified and validated analytical method.

If the analytical results are positive or DNA test on the final product is not submitted, labels should contain the information of the animal origin (specifying the name of the animal(s)) accordingly.

Reference: *NPRA.600-1/9/12(20)*: Keperluan Ujian Deoxyribonucleic Acid (DNA) Ke Atas Produk Akhir Bagi Produk Biologik Yang Menggunakan Bahan Bersumberkan Haiwan Dalam Proses Pengilangan Produk (24 May 2023)"

with:

"Animal-derived materials or products are commonly used in the manufacture of biologics and biopharmaceuticals. Detailed information regarding the rationale for using such material (e.g., the specific source) must be provided in accordance with Checklist A and Checklist B. Additionally, applicants must provide a confirmation of the presence or absence of animal materials in the drug substance and/ or final product, accompanied by supporting scientific evidence where applicable.

Supporting scientific evidence is product-specific and will be evaluated by the NPRA based on the documentation provided. Acceptable evidence may include, but is not limited to, a DNA PCR test, or a detailed justification from the manufacturer describing the purification processes employed to remove such materials.

Regardless of the scientific evidence provided, where an animal-derived material is used as a component of the final product (e.g. active substances, excipient, gelatin), a clear declaration of the specific animal source on the product label is mandatory. Negative DNA or analytical test results at the drug product stage do not exempt a product from this requirement, as testing cannot be used to replace or waive mandatory labelling requirements.

However, if a manufacturer conducts DNA testing on the final product and the result is a negative detection of animal DNA, it is permissible to include a supplementary statement on the label, such as "[ANIMAL SOURCE] ORIGIN. DNA of [animal source] was not detected in the final product." For example, "PORCINE ORIGIN. No traces of porcine DNA found in the final product". This allows for full transparency, ensuring that consumers are aware of the DNA test results while maintaining mandatory regulatory disclosure of the material source.

Reference: *NPRA/600-1/9/12 (31): Pekeliling Berkenaan Pengemaskinian Keperluan Ujian Analitikal dan Keperluan Deklarasi Pada Label Bagi Semua Kategori Produk Yang Mengandungi Bahan Bersumberkan Haiwan* (16 March 2026)"

Amendment of Appendix 19: General Labelling Requirements

2. **Amendment of information in Table 1 on page 2** by –

(a) replacing the following information:

No.	Parameters	Outer Carton (Unit Carton)	Immediate Labels	Blister/ Strips
17.	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	✓	✓*	NA

	product.			

with:

No.	Parameters	Outer Carton (Unit Carton)	Immediate Labels	Blister/ Strips
17.	To declare source of all ingredients derived from animal origin, including active substances, excipients, and gelatin.	✓	✓*	NA

Amendment of Appendix 21: Special Conditions for Registration of A Particular Product or Group of Products

3. **Addition of new information,** No. 6. Oxycodone in oral dosage forms, **on page 2** by –

(a) adding the following information:

NO.	SPECIAL CONDITIONS/ REQUIREMENTS
6.	**OXYCODONE IN ORAL DOSAGE FORMS** The products shall only be sold or supplied to hospital, hospice, or specialists registered in the National Specialist Register (NSR).

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(March 2026 Updates)

4. **Addition of new information,** No. 1. Ascorbic acid injection, **on page 2** by –

(a) adding the following information:

NO.	SPECIAL CONDITIONS/ REQUIREMENTS
1.	**ASCORBIC ACID INJECTION** a) The product shall be sold or supplied for hospital use only. b) The label and package insert shall include the following boxed statement: For Hospital Use only

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(April 2026 Updates)

There are five (5) amendments for the April 2026 DRGD Updates as follows:

Main Body of DRGD Third Edition, 11th Revision January 2026

Section A: General Overview

1. Amendment of information, 5.1 Who Shall Apply for Product Registration, Page 21

Appendix of DRGD Third Edition, 11th Revision January 2026

Appendix 7: Guideline on Registration of Natural Products

2. Amendment of information, Table 8, Page 37

Appendix 9: Fees

3. Amendment of information, 2. Processing and Analysis Fees for Product Registration, Page 3

Appendix 20: Specific Labelling Requirements

4. Amendment of existing safety information, No. 122, Lamotrigine, Page 125
5. Addition of new ingredient and safety information, No. 224, Sunitinib, Page 229

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(April 2026 Updates)

Amendment of Section A: General Overview

1. Amendment of information in 5.1 Who Shall Apply for Product Registration on page 21 by –

(a) deleting the following information:

"(i) Name of a government agency

(ii) Name of an institute of higher education/ research"

from the statement, "b) The name of the PRH, including product manufacturer, shall not reflect the following:"

(b) adding the following information:

"e) Any government agencies and research or higher education institutions may establish subsidiary companies through their private wings to serve as Product Registration Holders (PRH) and/or manufacturers. Authorisation for these entities to act as a PRH and/or manufacturer without a subsidiary company is contingent upon strong justification and urgent patient needs, including matters of national interest or emergency and disaster situations.

f) Any private company (other than government agencies or research/higher education institutions) is prohibited from using company names or acronyms that resemble the names of government agencies or research/higher education institutions to avoid confusion among consumers."

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(April 2026 Updates)

Amendment of Appendix 7: Guideline on Registration of Natural Products

2. Amendment of information in Table 8 on page 37 by –

(a) amending the following information:

No.	Items	Immediate Label	Outer Label	Package Insert	Blister Pack
2.	Dosage Form	√	√	√	
11.	Registration number (MAL)	√	√		
12.	Name and address of product registration holder (Example: Product Registration Holder: XXXXX)	√	√	√	**Name/ Logo of Manufacturer/ Product Owner**

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION
JULY 2026
(April 2026 Updates)

Amendment of Appendix 9: Fees

3. Amendment of information in 2. Processing and Analysis Fees for Product Registration on page 3 by –

(a) deleting "c) Health Supplement" from "2. Pharmaceutical".

(b) adding the following new information:

No.	Category of Product	*Processing Fees (RM)	Analysis Fees (RM)	Total Fees (RM)
3.	a) Health Supplement products with general claim	1,000.00	Single active ingredient: 1,200.00	2,200.00
	b) Health Supplement products with functional claim	1,000.00	Two or more active ingredients: 2,000.00	3,000.00
	c) Health Supplement products with disease risk reduction claim	1,000.00	Single active ingredient: 3,000.00	4,000.00
			Two or more active ingredients: 4,000.00	5,000.00

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(April 2026 Updates)

Amendment of Appendix 20: Specific Labelling Requirements

4. **Amendment of existing safety information, No. 122, LAMOTRIGINE on page 125** as follows in accordance with Directive No. 12, 2026: *Direktif untuk semua produk yang mengandungi lamotrigine: Pengemaskinian sisip bungkusan dan RiMUP bagi memperkukuhkan maklumat keselamatan berkaitan risiko fotosensitiviti (photosensitivity)* as decided in DCA Meeting No. 419, which takes effect on 14 April 2026 –

"LAMOTRIGINE

The following statements shall be included in the package insert and Consumer Medication Information Leaflet (RiMUP) for products containing lamotrigine;

Package Insert

a) Adverse Effects/ Undesirable Effects:

Skin and subcutaneous tissue disorders
Frequency 'uncommon': Photosensitivity reaction

Consumer Medication Information Leaflet (RiMUP)

a) Side effects:

Increased sensitivity of the skin to sunlight (photosensitivity reaction)

Reference: Directive No. 12, 2026. *NPRA.600-1/9/13 (6)Jld.2* *Direktif untuk semua produk yang mengandungi lamotrigine: Pengemaskinian sisip bungkusan dan RiMUP bagi memperkukuhkan maklumat keselamatan berkaitan risiko fotosensitiviti (photosensitivity)"*

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(April 2026 Updates)

5. **Addition of new ingredient No. 224, SUNITINIB on page 229** as follows in accordance with Directive No. 11, 2026: *Direktif untuk semua produk yang mengandungi sunitinib: Pengemaskinian sisip bungkusan dan RiMUP dengan maklumat keselamatan berkaitan risiko hyperammonaemic encephalopathy* as decided in DCA Meeting No. 419, which takes effect on 14 April 2026 –

"SUNITINIB

The following statements shall be <u>included in the package insert and Consumer Medication Information Leaflet (RiMUP)</u> for products containing sunitinib;

<u>Package Insert</u>

a) Warnings & Precautions:

Hyperammonaemic encephalopathy

Hyperammonaemic encephalopathy has been observed with sunitinib (see Section Undesirable effects). In patients who develop unexplained lethargy or changes in mental status, ammonia level should be measured and appropriate clinical management should be initiated.

b) Adverse Effects/ Undesirable Effects:

System Organ Class (SOC): <u>Nervous system disorders</u>

Frequency 'Not known': Hyperammonaemic encephalopathy

<u>Consumer Medication Information Leaflet (RiMUP)</u>

a) While you are using [product name]:

If you have symptoms such as lack of energy, confusion, sleepiness, unconsciousness/coma, your doctor will measure your ammonia level and determine appropriate treatment because these may be signs of brain toxicity caused by high blood levels of ammonia (hyperammonaemic encephalopathy).

Reference: Directive No. 11, 2026. ***NPRA.600-1/9/13 (5)Jld.2*** *Direktif untuk semua produk yang mengandungi sunitinib: Pengemaskinian sisip bungkusan dan RiMUP dengan maklumat keselamatan berkaitan risiko hyperammonaemic encephalopathy"*

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(May 2026 Updates)

There are three (3) amendments for the May 2026 DRGD Updates as follows:

Main Body of DRGD Third Edition, 11th Revision January 2026

Section B: Product Registration Process

1. Addition of new information, 7.10 Proposed Package Insert, Page 43
2. Addition of new information, 7.11 Consumer Medication Information Leaflet (RiMUP), Page 44

Appendix of DRGD Third Edition, 11th Revision January 2026

Appendix 19: General Labelling Requirements

3. Addition of new information, 1. LABEL FOR IMMEDIATE CONTAINER AND OUTER CARTON, Page 6

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(May 2026 Updates)

Amendment of Section B: Product Registration Process

1. **Addition of new information in 7.10 Proposed Package Insert on page 43** by –

   (a) adding the following information, "(iv) *Pekeliling Berkenaan Pemberhentian Pengeluaran Dear Healthcare Provider (DHCP) Letter Bercetak Berserta Salinan Bercetak Package Insert (PI) dan / atau Risalah Maklumat Ubat untuk Pengguna (RiMUP) bagi Pelaksanaan Electronic Labelling (e-Labelling) ke atas Produk Farmaseutikal* NPRA/600-1/9/12 (3) Jld.1" to, "For information regarding e-labelling, refer to:"

2. **Addition of new information in 7.11 Consumer Medication Information Leaflet (RiMUP) on page 44** by –

   (a) adding the following information, "(iv) *Pekeliling Berkenaan Pemberhentian Pengeluaran Dear Healthcare Provider (DHCP) Letter Bercetak Berserta Salinan Bercetak Package Insert (PI) dan / atau Risalah Maklumat Ubat untuk Pengguna (RiMUP) bagi Pelaksanaan Electronic Labelling (e-Labelling) ke atas Produk Farmaseutikal* NPRA/600-1/9/12 (3) Jld.1" to, "g) For information regarding e-labelling, refer to:"

Amendment of Appendix 19: General Labelling Requirements

3. **Addition of new information in Additional Requirements in 1. LABEL FOR IMMEDIATE CONTAINER AND OUTER CARTON on page 6** by –

   (a) adding the following information, "(iv) *Pekeliling Berkenaan Pemberhentian Pengeluaran Dear Healthcare Provider (DHCP) Letter Bercetak Berserta Salinan Bercetak Package Insert (PI) dan / atau Risalah Maklumat Ubat untuk Pengguna (RiMUP) bagi Pelaksanaan Electronic Labelling (e-Labelling) ke atas Produk Farmaseutikal* NPRA/600-1/9/12 (3) Jld.1" to, "m) For information regarding e-labelling, refer to:"

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(June 2026 Updates)

There are nine (9) amendments for the June 2026 DRGD Updates as follows:

Main Body of DRGD Third Edition, 11th Revision January 2026

Section E: Post-Registration Process

1. Amendment of information, 20.4 New/ Additional Indication, Page 73
2. Deletion of information, Appendix1, 20.4 New/ Additional Indication, Page 75

Appendix of DRGD Third Edition, 11th Revision January 2026

Appendix 3: Guideline on Registration of New Drug Products

3. Amendment of information, 1.1 New Chemical Entity (NCE) (single/ combination products with an active substance never registered by DCA), Page 1

Appendix 18: List of Permitted, Prohibited and Restricted Substances

4. Amendment of information, 1.2 List of Restricted Active Ingredients and Combinations, Page 6

Appendix 20: Specific Labelling Requirements

5. Addition of new ingredient and safety information, No. 118. Itraconazole, Page 120
6. Addition of new ingredient and safety information, No. 239. Vancomycin, Page 245
7. Addition of new ingredient and safety information, No. 38. Caffeine Citrate, Page 42
8. Addition of new ingredient and safety information, No. 241. Vitamin B6, Page 246

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(June 2026 Updates)

Appendix 21: Special Conditions for Registration of A Particular Product or Group of Products

9. Amendment of information, No. 6 Paracetamol in combination with caffeine, Page 3

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(June 2026 Updates)

Amendment of Section E: Post-Registration Process

1. **Amendment of information in Additional documents - for Reliance Full Evaluation and Reliance Verification, 20.4 New/ Additional Indication on page 73** by –

   (a) adding the following information, "(NCE), (Bio)" and its respective URL: https://www.npra.gov.my/index.php/en/nce-application-forms.html and https://www.npra.gov.my/index.php/en/component/content/article/159-english/application-form-biologics/1527063-application-forms-biologics.html?Itemid=1391 to the statement, "c) Checklist for AI (Reliance) - refer Appendix I."

   (b) adding the following information, "d) In the event that the chosen reference drug regulatory agency does not bear the most stringent indication(s), dosing regimen(s), patient group(s) and/or direction(s) of use among those approved by the reference drug regulatory agencies, clinical justifications are to be provided upon submission."

2. **Amendment of information in 20.4 New/ Additional Indication on page 75** by –

   (a) deleting Appendix 1.

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

3. **Amendment of information in 1.1 New Chemical Entity (NCE) (single/ combination products with an active substance never registered by DCA) on page** 1 by –

   (a) replacing "radionucleotide" with "radionuclide" in "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."

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(June 2026 Updates)

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

4. **Amendment of information in 1.2 List of Restricted Active Ingredients and Combinations on page 6** by –

(a) replacing the statement, "All Preparations Except for an Oral Preparation in Combination with Paracetamol/ Acetaminophen or Combination with Ergotamine" with the following for 10. Caffeine:

"All preparations except:

i) Oral Preparation in Combination with Paracetamol/ Acetaminophen or Combination with Ergotamine; and

ii) Caffeine citrate preparations (solution for infusion and oral solution) indicated for the treatment of primary apnoea of premature newborns under the supervision of a physician experienced in neonatal intensive care."

Amendment of Appendix 20: Specific Labelling Requirements

5. **Addition of new ingredient, No. 118. Itraconazole on page 120** as follows in accordance with Directive No. 17, 2026: *Direktif untuk semua produk yang mengandungi itraconazole: Pengemaskinian sisip bungkusan dan RiMUP bagi memperkukuhkan maklumat keselamatan berkaitan risiko pseudoaldosteronism* as decided in DCA Meeting No. 421, which takes effect on 16 June 2026 –

"ITRACONAZOLE

The following statements shall be included in the package insert and Consumer Medication Information Leaflet (RiMUP) for products containing itraconazole;

Package Insert

a) Adverse Effects/ Undesirable Effects:

Endocrine disorders
Frequency 'very rare': Pseudoaldosteronism

LIST OF UPDATES FOR
DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION
JULY 2026
(June 2026 Updates)

Consumer Medication Information Leaflet (RiMUP)

a) Side effects:

Increased blood pressure, muscle weakness, swelling of legs, lethargy, lack of appetite, nausea, vomiting, headache, confusion, tingling, numbness.

Reference: Directive No. 17, 2026. ***NPRA.600-1/9/13 (11)Jld.2*** *Direktif untuk semua produk yang mengandungi itraconazole: Pengemaskinian sisip bungkusan dan RiMUP bagi memperkukuhkan maklumat keselamatan berkaitan risiko pseudoaldosteronism*"

6. **Addition of new ingredient, No. 239. Vancomycin on page 245** as follows in accordance with Directive No. 16, 2026: *Direktif untuk semua produk yang mengandungi vancomycin: Pengemaskinian sisip bungkusan dengan maklumat keselamatan berkaitan risiko toxic epidermal necrolysis (TEN) serta penyeragaman maklumat keselamatan produk berkaitan severe cutaneous adverse reactions (SCARs)* as decided in DCA Meeting No. 421, which takes effect on 16 June 2026 –

"VANCOMYCIN

The following statements shall be included in the package insert for products containing vancomycin;

Package Insert

a) Warnings & Precautions:

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with vancomycin treatment. Most of these reactions occurred within a few days and up to eight weeks after commencing treatment with vancomycin. At the time of prescription, patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, vancomycin should be withdrawn

immediately and an alternative treatment considered. If the patient has developed a SCAR with the use of vancomycin, treatment with vancomycin must not be restarted at any time.

b) Adverse Effects/ Undesirable Effects:

Skin and subcutaneous tissue disorders

Very rare: Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN)

No known frequency: Drug reaction with eosinophilia and systemic symptoms (DRESS), Acute generalised exanthematous pustulosis (AGEP)

#Note: For products using the term Lyell's syndrome, please replace the term with toxic epidermal necrolysis (TEN)

Reference: Directive No. 16, 2026. *NPRA.600-1/9/13 (10)Jld.2* *Direktif untuk semua produk yang mengandungi vancomycin: Pengemaskinian sisip bungkusan dengan maklumat keselamatan berkaitan risiko toxic epidermal necrolysis (TEN) serta penyeragaman maklumat keselamatan produk berkaitan severe cutaneous adverse reactions (SCARs)*"

7. **Addition of new ingredient, No. 38. Caffeine Citrate on page 42** as follows in accordance with Directive No. 14, 2026: *Direktif Berkenaan Pengemaskinian Had Penggunaan dan Maklumat Keselamatan Bagi Caffeine dalam Produk Farmaseutikal* as decided in DCA Meeting No. 421, which takes effect on 16 June 2026 –

"**CAFFEINE CITRATE**

The following statement shall be included on the labels and in the package inserts and RiMUP of products containing Caffeine Citrate:

Package Insert:

Posology and method of administration:

"Treatment with caffeine citrate should be initiated under the supervision of a physician experienced in neonatal intensive care. Treatment should be administered only in a neonatal intensive care unit in which adequate facilities are available for patient surveillance and monitoring."

Consumer Medication Information Leaflet (RiMUP):

How to use (product name):

"(Product name) should only be used in a neonatal intensive care unit in which adequate facilities are available for patient surveillance and monitoring. Treatment should be initiated under supervision of a physician experienced in neonatal intensive care."

Reference: Directive No. 14, 2026. *NPRA.600-1/9/13 (8)Jld.2* *Direktif Berkenaan Pengemaskinian Had Penggunaan dan Maklumat Keselamatan Bagi Caffeine dalam Produk Farmaseutikal*"

8. **Addition of new ingredient, No. 241. Vitamin B6 on page 246** as follows in accordance with Directive No. 15, 2026: *Direktif Berkenaan Penambahan Pernyataan Amaran bagi Produk Suplemen Kesihatan (HS) dan Produk Bukan Racun Berjadual (OTC) yang Mengandungi Vitamin B6 Berkaitan Risiko Peripheral Neuropathy* as decided in DCA Meeting No. 421, which takes effect on 16 June 2026 –

"**VITAMIN B6**

The following statement shall be included in the label, package insert and Consumer Medication Information Leaflet (RiMUP) for Health Supplement and OTC products containing Vitamin B6 above 10mg;

Warning:

This product contains Vitamin B6. Stop taking this product if you experience tingling, burning or numbness and see your doctor as soon as possible.

Reference: Directive No. 15, 2026. *NPRA.600-1/9/13 (9)Jld.2* *Direktif Berkenaan Penambahan Pernyataan Amaran bagi Produk Suplemen Kesihatan (HS) dan Produk Bukan Racun Berjadual (OTC) yang Mengandungi Vitamin B6 Berkaitan Risiko Peripheral Neuropathy*"

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(June 2026 Updates)

Amendment of Appendix 21: Special Conditions for Registration of A Particular Product or Group of Products

9. **Amendment of information, No. 6 Paracetamol in combination with caffeine on page 3** by –

(a) Replacing ”b) Products containing caffeine for pediatric patients are not allowed.” with “b) Products containing paracetamol in combination with caffeine for pediatric patients are not allowed.”

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(July 2026 Updates)

There is one (1) amendment for the July 2026 DRGD Updates as follows:

Appendix of DRGD Third Edition, 11th Revision January 2026

Appendix 6: Guideline on Registration of Health Supplements

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

LIST OF UPDATES FOR

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD) THIRD EDITION, 12TH REVISION

JULY 2026

(July 2026 Updates)

Amendment of Appendix 6: Guideline on Registration of Health Supplements

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

   (a) adding new functional claim, “Act as antioxidants” to L-Carnitine.

   (b) adding new functional claims, “Act as an antioxidant to protect the body from oxidative damage, Maintain skin health, Maintain eye health” to Vitamin B2 (Riboflavin).

   (c) adding new functional claim, “Support cognitive function” to Zinc.