ASEAN LABELING REQUIREMENTS :
ISSUES ON COUNTRY SPECIFIC REQUIREMENTS

COUNTRY REPORTS :

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1. LABELING REQUIREMENTS (COUNTRY SPECIFIC) - PHILIPPINES

● Regulations on labeling are country specific as pertains to existing laws and regulations (Republic Act 6675, Administrative Order 55, Administrative Order 85, Administrative Order 99, Memorandum Circular 6, Memorandum Circular 11) but for the proposed labeling requirements for ASEAN Harmonization, the following requirements will remain country-specific as to the Philippines :

Minimum Requirements

Item	Requirement	Reference / Current Regulation	Remarks
Product Name	In case of branded products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.	RA 6675 Sec 6 c	Difficult to change since this is a national law that requires legislative action (Congress and Senate)
	The generic name shall be enclosed in an outline box rendered in the same color as the generic name.	A.O. 55	To retain the requirement in the proposed AO to comply with the standard of prominence of generic name per RA 6675.
Pharmacologic Category		A.O. 55 and proposed A.O.	To retain the requirement as it is vital information to prescribers, dispensers and users.
Rx symbol and Caution Statement " Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription"		A.O. 55 and RA 3720 Ch. 8, sec. 20 (b.4)	To retain the requirement as it is vital information to prescribers, dispensers and users is required under RA 3720

Other Labeling-Related Issues :

Brand Name	Brand name clearance still required by BFAD even with trademark registration with the local IPO		
Manufacturing and Expiry Dates			Standard format as prescribed in the proposed labeling regulation; submit to ACCSQ PPWG

The minimum mandatory information that shall be included in the labeling materials are :

1) Name of the product (Generic name alone or with Brand name, as the case may be)
2) Dosage form and strength
3) Pharmacologic category
4) Rx symbol, in case of prescription drugs
5) Name and complete address of manufacturer and trader, when applicable
6) Net content
7) Formulation
8) Indication(s)
9) Contraindication(s), precaution(s), warning(s)
10) Mode of administration/directions for use
11) Batch and lot number
12) Expiry/expiration date and date of manufacture
13) Registration number
14) Storage conditions
15) (For Rx products) Foods, drugs and devices and Cosmetic Act prohibits dispensing without prescription

2. LABELING REQUIREMENTS (COUNTRY SPECIFIC) – INDONESIA

	Information should be included	Unit Carton	Inner Labels	Strips / Blisters	Catch Covers / Envelopes	Ampoules / Vials
1	**Product Name**	√	√	√	√	√
2	**Dosage Form**	√	√	-	√	√
3	**Package Size**	√	√	-	√	√
4	**a. Name and strength of active ingredient(s)**	√	√	√	√	√
	b. Generic name should appear under the brand name, minimal size is 80% of the brand name	√	√	√	√	√
5	**Local Production :** **- Name of Applicant** **- Address of Applicant**	√ √	√ √	√ -	√ √	√ √**
6	**Imported Drugs :** **- Name of Applicant and Manufacturer of imported drug** **- Address of Applicant and Manufacturer of imported drug**	√ √	√ √	√ -	√ √	√ √**
7	**Toll Manufacturing** **- Name of Applicant and Manufacturer** **- Address of Applicant and Manufacturer**	√ √	√ √	√ -	√ √	√ √**
8	**Local Production under Licence :** **- Name of Applicant and Licensee** **- Address of Applicant**	√ √	√ √	√ -	√ √	√ √**
9	**Registration Number**	√	√	√	√	√
10	**Batch Number**	√	√	√	√	√
11	**Date of Production**	√	-	-	√	-
12	**Expiration Date**	√	√	√	√	√

13	**Indications**	√*	*	-	√	-
14	**Posology**	√*	*	-	√	-
15	**Contraindications**	*	*	-	√	-
16	**Adverse Reactions**	*	*	-	√	-
17	**Drug Interactions**	*	*	-	√	-
18	**Warnings – Precautions**	*	*	-	√	-
19	**Special Warnings (if any)**	√	*	-	√	-
20	**Storage Condition**	√	√	-	√	√**
21	**-Specific information in accordance with valid provisions (if any) e.g.** *** Source of porcine** ***Alcohol contents** **-Specific information on ceiling price**	√ √	√ √	- -	√ √	√ √
22	**Warning for limited over the counter drug (OTC)**	√	√	-	√	-
23	**With physician prescription only in Indonesian language (for prescription drug)**	√	√	√	√	√
24	**Specific round mark of prescription drug / OTC / limited OTC**	√	√	-	√	-

Notes :

√ : Information must be included

√* : Information must be included for OTC and limited OTC (Prescription drug could refer to the brochure)

√** : Specifically for ampoule or vial more than 2 ml

* : Information could refer to the brochure

\- : Information not necessary to be included

3. LABELING REQUIREMENTS (COUNTRY SPECIFIC) – THAILAND

According to Drug Acts, these words have to **be written in Thai;**

Dangerous drug, Specially Controlled drug, For external use, Common Household remedy, Topical use, Expiry date.

According to Ministerial Notification;
There are **standard warning and precaution for specific drug** which are;
-Antibiotic drugs
-Antihistamine drugs
-Aspirin
-Dipyrone
-Phenylbutazone and Indometacin for internal use
-Tranquilizer for internal use
-Sedatives and Hypnotics
-Anorexigenics
-Antiepileptics
-Imipramine
-Mianserin
-Contraceptive drugs
-Diethyl Stilbestrol, Dienestrol, Hexestrol, Benzestrol,
-Corticosteroids for internal use
-Corticosteroids for eye treatment
-Antidiabetic drugs
-Antineoplastics drugs
-Arsenic compound
-Atropine,Hyoscine,Hyoscyamine,Stramonium
-Injection with Benzyl alcohol
-Boric acid
-Camphorated Opium Tincture
-Cinchophen, Neocinchophen
-Diamthazole for external use
-Ephedrine
-Hexylresorcinol, tetrachlorethylene
-Iodine, Iodide for internal use
-Laxative
-Loperamide
-Hair growth stimulant including Minoxidil
-Theophylline and derivative
-Combination of anabolic steroid and vitamins or anabolic steroid and cyproheptadine or anabolib steroid ,vitamins and cyproheptadine
-Combination with fat soluble vitamins
-Glafenine, Floctafenine
-Paracetamol
-Angiotensin-Converting Enzyme Inhibitors
-Solution with Ethyl alcohol
-Retinoid and derivative for external use
- Retinoid and derivative for internal use
-Cisapride
-Flutamide
-Sildenafil

-Ethambutol
-Anti HIV drugs (non-nucleoside reverse transcriptase inhibitor)
-Famotidine
-HMG-CoA reductase inhibitor
-Antituberculosis Drugs

According to Ministerial Notification; Some drugs are under limited-distribution.

Used only in hostpital ; anticancer drugs, HIV-treated drugs, Anti-acne of Retinoid group, Cisapride, Misoprostol, Dinoprostone, Sulprostone, Combination of L- tryptophan for medicated supplement and Chloramphenicol for human use.

Used in clinic and hospital; New drug approval with condition, Sildenafil, Caverject, Muse

4. LABELING REQUIREMENTS (COUNTRY SPECIFIC) – SINGAPORE

There are 2 levels of labeling requirements for medicinal products in Singapore :

(1) **Administrative labeling requirements** – These are not statutory requirements and are specified in the HSA's Guidance on Medicinal Product Registration in Singapore. Compliance with these labeling requirements are checked during the product registration process, prior to grant of marketing approval for the product.

(2) **Legal labeling requirements** – These are stipulated in the legislation related to medicinal products regulation in Singapore. Compliance with these labeling requirements are checked as part of HSA's surveillance programme.

For administrative labeling requirements linked to the product registration process, there are **no Singapore specific labeling requirements in addition to those specified in the ACTD**.

For **legal labeling requirements**, the labeling requirements for compliance by dealers of medicinal products in Singapore include :

Name of active ingredient [Also a product registration requirement, in ACTD]

Quantitative particulars [Also a product registration requirement, in ACTD]

Product licence number [Also a product registration requirement, in ACTD]

Name and address of dealer [Also a product registration requirement, in ACTD]

The word "Poison" or other terms allowed under the 5th Schedule to the Poisons Rules (e.g. For sedating antihistamines to be labeled with "Caution. This may cause drowsiness. If affected do not drive or operated machinery.") [**Not in ACTD**]

Preparations containing tartrazine, benzoic acid or sodium benzoate – presence of substance. [**Not in ACTD**]

Preparations containing aspirin – "Caution : Not to be given to persons below the age of 16 years except under the direction of a doctor." [**Not in ACTD**]

	Parameters	Unit Carton	Inner Labels	Blister/Strips
1	**Product Name**	√	√	√
2	**Dosage Form**	√	√*	**NA**
3	**Name of Active Substance(s)**	√	√	√
4	**Strength of Active Substance(s)**	√	√	√

5	**Batch Number**	√	√	√
6	**Manufacturing Date*** **	√	√*	**NA**
7	**Expiration Date**	√	√	√
8	**Route of Administration**	√	√	**NA**
9	**Storage Condition**	√	√*	**NA**
10	**Country's Registration Number**	√	√*	**NA**
11	**Name & Address of Product Licence Holder*** **	√	√*	**Name/Logo of Manufacturer/product Owner**
12	**Name & Address of Manufacturer*** **	√	√*	**NA**
13	**Warnings (if applicable)**	√	√*	**NA**
14	**Pack Sizes (Unit/Volume)**	√	√	**NA**
15	**Special Labeling (if applicable)**	√	√*	**NA**

NA Not applicable
* Exempted for small label such as ampoule and vial
** The words "Batch release by" instead of "Manufactured by" should be used if the site named is responsible for product release. The name and address of either the manufacturer or the batch releaser should be present.
*** Proposed new ASEAN labeling requirements

If the product is supplied without an outer carton, the information that is required on the outer carton should be stated on the inner label.

5. LABELING REQUIREMENTS (COUNTRY SPECIFIC) - MALAYSIA

SECTION D - LABEL (MOCK-UP) FOR IMMEDIATE CONTAINER, OUTER CARTON & PROPOSED PACKAGE INSERT

Outer (Carton), Inner & Blister/Strips Labels
The following information should be present on the labeling of the product

	Parameters	Unit Carton	Inner Labels	Blister/Strips
1.	**Product Name**	✓	✓	✓
2.	**Dosage Form**	✓	✓*	**NA**
3.	**Name of Active Substance(s)**	✓	✓	✓**
4.	**Strength of Active Substance(s)**	✓	✓	✓**
5.	**Batch Number**	✓	✓	✓
6.	**Manufacturing Date**	✓	✓*	**NA**
7.	**Expiration Date**	✓	✓	✓
8.	**Route of Administration**	✓	✓	**NA**
9.	**Storage Condition**	✓	✓*	**NA**
10.	**Country's Registration Number**	✓	✓*	**NA**
11.	**Name & Address of Marketing Authorization (Product Licence) Holder/Product Owner**	✓	✓*	**Name/Logo of Manufacturer/ Product Owner**
12.	**Name & Address of Manufacturer**	✓	✓*	**NA**
13.	**Special Labeling (if applicable) e.g. Sterile, External Use, Cytotoxic, Alcohol Content, Animal Origin (Porcine, Bovine) - To declare source of ingredients derived from animal origin, including gelatin (active, excipient, and/or capsule shell)**	✓	✓	**NA**
14.	**Recommended daily allowance (RDA) for vitamins/multivitamins/ mineral preparations used as dietary supplements**	✓	✓	**NA**
15.	**Warnings (if applicable)**	✓	✓*	**NA**
16.	**Pack Sizes (unit / volume)**	✓	✓	**NA**
17.	**Security labeling - hologram**	✓	✓	**NA**

18	**Name & content of preservative(s) where present**	✓	✓	**NA**
19.	**Name & content of alcohol, where present**	✓	✓	**NA**
20.	**The words "Keep Medicine Out of Reach of Children" or words bearing similar meaning in both B.M. & English (For EPCs only, English optional)**	✓	✓	**NA**
21.	**Other country specific labeling requirements (if applicable)**	✓	✓*	**NA**

No. 17 – 21 of labeling requirements : Country specific for Malaysia

- NA Not applicable

* Exemptes for small labels such **as ≤ 5ml size** ampoules and vials

** Exempted for multi-ingredient product with more than 3 ingredients. For multi-vitamins and minerals preparations it is suggested to label as multi-vitamins and minerals.

- If the product is supplied without an outer carton, the inner label should bear all the information that is required

Examples for item 15 or 21 : Warning / Other country specific labeling requirements

HYDROQUINONE
Some users of this product may experience skin irritations. Should this occur, stop use and consult a doctor.

BENZYL ALCOHOL
As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

PARACETAMOL
This preparation contains PARACETAMOL.
Do not take any other paracetamol containing medicines at the same time.

ST. JOHN'S WORT (Hypericum perforatum)
(Please consult your physician/pharmacist before using this product if you are on any prescription medicines as there is possibility that interactions may occur with certain drugs).

6. LABELING REQUIREMENTS (COUNTRY SPECIFIC) – VIETNAM

The Labeling requirements of Vietnam are legal ones in compliance with the government Decree on goods labeling and Circular No. 14/2001/TT-BYT dated 26 June, 2001 of the Ministry of Health instructing to label medicines and cosmetics directly affecting human's health.

Parameters		Requirement	Special Labeling		Package Insert
			Vials, ampoules	Blister/Strips	
1	**Product name**	√	√	√	√
2	**Name of Active Substance(s)**	√	√ **(1)**	√ **(1)**	√
3	**Strength of Active Substance(s)**	√	√	√	√
4	**Expiry date**	√	√	√	√ **(7)**
5	**Name & Address of manufacture**	√	**Name of Manufacturer**	**Name of Manufacturer**	√
6	**Batch number**	√	√	√	
7	**Indications**	√	√		√
8	**Remarkable note**	√ **(5)**	√ **(6)**		√ **(5)**
9	**Dosage form**	√			√
10	**Contra-indications**	√			√
11	**Dosage/Route of Administration**	√			√
12	**Adverse Reactions**				√ **(2)**
13	**Drug Interactions**				√
14	**Manufacturing date**	√			
15	**Storage condition**	√			√
16	**Registration number**	√			√
17	**Name & Address of importer**	√			√
18	**Pack Sizes (Unit/Volume)**	√			√
19	**Warnings (If applicable)**				√
20	**Name & content of excipient**				√
21	**With physician prescription only (for prescription drug)**	√ **(3)**			√ **(4)**
22	**Quality specification**	√			√

√ (1) : Applied to drugs with single content

√ (2) : Must be written : "Inform doctors about unexpected reactions after using drugs"

√ (3) : The drugs that belongs to prescription list must be written : "Drug sold by prescription",
and marked Rx on the left top corner; the eye drop must be written : "Eye drop"; the nose drop must be written : "Nose drop"

√ (4) Package inserts must be written : "This drug is administered according to doctors' prescription"

√ (5) Remarkable note : "Keep out of reach of children"; "Read carefully the package insert before use"

√ (6) For injectable drugs, route of administration must be stated intramuscular injection, subcutaneous injection or intravenous injection; the orally administered drug bottle must be written "No injection"

√ (7) Shelf-life of drugs must be stated

Other requirements :

- **Vials, ampoules and blister / strips must be contained in labeled box according to regulations.**
- **For Parameter No. 5, 6 and 7, if the box is too small to mention those parameters, the sentence "Please read the package insert" must be written.**
- **Imported drugs must state name of the manufacturing country.**
- **Expiry date must be written by 2 numbers of a month and 2 numbers of a year (For example, 20/03/06).**
- **Package insert must be written in Vietnamese.**

7. LABELING REQUIREMENTS (COUNTRY SPECIFIC) – LAOS

	Parameters	Unit Carton	Inner Label	Blister/Strips
1	**Product Name (generic and brand name)**	√	√	√
2	**Dosage form**	√	√*	
3	**Name of Active Ingredient(s)**	√	√	√#
4	**Strength of Active Ingredient(s)**	√	√	√#
5	**Batch Number**	√	√	√
6	**Manufacture Date**	√	√*	
7	**Expiration Date**	√	√	√
8	**Route of Administration**		√	
9	**Storage Condition**	√	√*	
10	**Country's Registration Number**	√	√*	√
11	**Name and address of manufacturer**	√	√*	Name/Logo of Manufacturer/Product Owner
12	**Special Labeling (if applicable) e.g. if dangerous drug, add the word 'Dangerous' in red letter and in a red box**	√	√*	
13	**Warnings (if applicable)**	√	√*	
14	**Lao language and/or English, French is required**	√		
15	**Recommended Daily Allowance (for vitamins and minerals)**		√*	

Note : * (exempted for small ampoule and vial)
Note : # (exempted for multi-ingredients product with more than 3 ingredients. For example multivitamins and multiminerals it is suggested to label as multivitamins and multiminerals)

8. LABELING REQUIREMENTS (COUNTRY SPECIFIC) – CAMBODIA

	Parameters	Unit Carton	Inner Label	Blister/Strips
1	**Product Name (bigger than Generic Name)**	√	√	√
2	**Dosage form**	√	√*	
3	**Name of Active Ingredient(s)**	√	√	√#
4	**Strength of Active Ingredient(s)**	√	√	√#
5	**Batch Number**	√	√	√
6	**Manufacturing Date**	√	√*	
7	**Expiration Date**	√	√	√
8	**Route of Administration**	√	√**	
9	**Storage Condition**	√	√*	
10	**Country's Registration Number**	√	√*	√
11	**Name and address of the Marketing Authorization Holder (Full Address)**	√	√*	**Name/Logo of Manufacturer/Product Owner**
12	**Name and Address of Manufacturer (Manufacturer Name, Area and/or City, Country)**	√	√*	
13	**Special Labeling (if applicable) e.g. Sterile, External Use, Cytotoxic, Alcohol Content, Animal Origin (Bovine, Porcine)**	√	√*	
14	**Warnings (if applicable) : e.g product containing Yellow Tartrazine which caused allergic reactions to patients whose are hypersensible to this coloring agent**	√	√*	
15	**Pack Size**	√	√	

	(Unit/Volume)			
16	**Recommended Daily Allowance (for vitamins and minerals)**	√	√*****	

* Exempted for small ampoule and vial

** For Inner Label : Route of Administration : constituted powder for injection co packed with solvent should be mentioned the route of administration whether for IM/IV. The composition of the solvent can determine the route of administration. Sterile water can be solvent if only use for IV but not for IM which make patients very painful.

Note : # (exempted for multi-ingredients products with more than 3 ingredients. For example multivitamins and minerals it is suggested to label as multivitamins and minerals).

9. LABELING REQUIREMENTS (COUNTRY SPECIFIC) – BRUNEI DARUSSALAM

PART 1 – SECTION 4 : PRODUCT LABELING

- Applicant should provide samples or proposed drafts of product labeling for the application of registration of medicinal products.
- Language used for labeling shall be English and/or Malay.
- Samples or proposed drafts of the product labeling are for unit carton, inner label and blister/strips.

	Parameters	Unit Carton	Inner Label	Blister / Strips
1	**Product Name**	√	√	√
2	**Dosage form**	√	√*	
3	**Name of Active Ingredient(s)**	√	√	√#
4	**Strength of Active Ingredient(s)**	√	√	√#
5	**Batch Number**	√	√	√
6	**Manufacturing Date**	√	√*	
7	**Expiration Date**	√	√	√
8	**Route of Administration**	√	√	
9	**Storage Condition**	√	√*	
10	**Country's Registration Number**	√	√*	√ **(optional)**
11	**Name and Address of the Marketing Authorization Holder**	√		
12	**Name and Address of Manufacturer**	√	√*	**Name/Logo of Manufacturer/Product Owner (optional)**
13	**Special Labeling (if applicable) e.g. Sterile, External Use, Cytotoxic, Alcohol Content (to declare strength), Animal Origin (Bovine, Porcine, to declare origin)**	√	√*	
14	**Warnings (if applicable)**	√	√*	
15	**Pack Sizes (Unit/Volume)**	√	√	
16	**Recommended Daily Allowance (for vitamins and minerals)**	√	√*	

Note : * (exempted for small ampoule and vial)

Note : # (exempted for multi-ingredients products with more than 3 ingredients. For example multivitamins and multiminerals it is suggested to label as multivitamins and multiminerals).

If there is no outer carton available for the product, all the information required to be stated on the unit carton must be available on the inner label.

With reference to item no. 14 on warnings, there are a few standard warnings and cautionary statements that would be required to be stated on the unit carton and inner label such as 'POISON' or 'May cause drowsiness', etc. A list on the warnings and cautionary statements is available when requested.