

The final list of the harmonised labelling requirements for TMHS :

- a) Product name
- b) Dosage form
- c) Active ingredient(s) and Strength of active ingredient(s)
- d) Batch or Lot number
- e) Manufacturing and expiry date or Expiry date only
- f) Route of administration (include directions of use)
- g) Uses and Indication of use
- h) Storage condition
- i) Country's registration/Listing/Notification number (if applicable)
- j) Manufacturer's name and address
- k) Name and address of Marketing Authorisation Holder
- l) Warning (if any)
- m) Package size
- n) Special statements:
 - alcohol content
 - for external use (for TM)
- o) National and/or English language and Latin names for the active ingredients (plants or animals)

The list of country-specific labeling parameters

Figure 1. Country - Specific parameters on TM labeling regulations

Item (✓ = Required)	BR	CB	IN	LS	ML	MM	PH	SP	TH	VT	Notes/Justifications
1 "Traditional medicines" or alike	-	✓	✓	✓	✓	-	-	-	✓	-	IN: Optional, depend on the category of Traditional Medicines, whether it is Jamu, Standardized Herbal Medicines or Phytopharmaca (For Local product). TH: A term "Traditional medicine" needs to be displayed in Thai language.
2 Drug classification statement	-	-	-	✓	-	-	✓	-	✓	✓	BR: Brunei Darussalam has no classification on traditional medicines. All are considered as OTCs. PH: Rx, OTC or Household remedy. TH: If Traditional medicine is classified as "Household remedy", A term "Household remedy" needs to be displayed in Thai language.
3 Hologram	-	-	-	-	✓	-	-	-	-	-	-
4 Sources if derived from animal origin	-	-	✓	-	✓	-	-	-	-	-	IN: if porcine. This parameter is justified by Act & Decrees. ML: if porcine
5 The clause "Allowed for sale as a Chinese Proprietary Medicine based on information submitted to the Authority, Consumer discretion is advised"	-	-	-	-	-	-	-	✓	-	-	SP: Legal requirement for Chinese Proprietary Medicines only. Must be stated in both English and Chinese on the outer label.
6 Statement on additive added (Preservative, colorant, flavour, sweetener)	-	-	-	-	✓	-	✓	✓	-	-	ML: Only Preservative [Name & strength / concentration of preservative] SP: Legal requirement for all traditional medicines. (Labeling of tartrazine, sodium benzoate and/or benzoic acid if these substances present in product).
7 Logo (According to the TM classification)	-	-	✓	-	-	-	-	-	-	-	IN: Logo (According to the classification).

8 Font size	-	-	✓	-	-	-	✓	✓	-	-	<p>IN: The size of the letter of traditional medicines name must be bigger than the size of the other letters.</p> <p>PH: For prescription product, the Rx symbol should be printed in a type size no less than 1/5 of the height of the principal display panel.</p> <p>SP: For Chinese Proprietary Medicines label and Package Insert, font size for English words must legally not be less than 1.5mm in height, and the Chinese characters not less than 2mm in height.</p>
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Figure 2. Country - Specific parameters on HS labeling regulations

Item (✓ = Required)	BR	CB	IN	LS	ML	MM	PH	SP	TH	VT	Notes/Justifications
1. "Health supplements" / "Food supplements" / "Dietary supplements"	-	✓	✓	-	-	-	✓	-	✓	✓	TH: Notification No.293 (B.E.2548 Re: Dietary Supplement.
2.Statement on additive added (Preservative, colorant, flavour, sweetener)	-	-	✓	-	✓	-	✓	-	✓	✓	<p>IN: -Act of the Consumer Protection, No.8 of 1999. -Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.23.3644 of 2004, on Principle of Food Supplement Control. -Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.41.1381 of 2005, on Registration Guidelines of Food Supplement. -Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.52.4321 of 2004, on Guidelines of Food Labeling.</p> <p>ML: Only Preservative [Name & strength / concentration of preservative]</p> <p>TH: Notification No.293 (B.E.2548) Re: Dietary Supplement.</p>
3."Vegetarian"-Consume plants & dairy products or "Vegan"-Consume plants	-	-	-	-	-	-	-	-	-	-	
4. "Should take as a rational proportion of 5 groups food of sorts" or similarly meaning statements	-	-	-	-	-	-	-	-	✓	-	TH: Notification No.309 (B.E.2550) Re: Dietary Supplement (No.2).
5 Hologram	-	-	-	-	✓	-	-	-	-	-	

6. Source of ingredient derived from animal origin inc. gelatin	-	-	✓	-	✓	-	-	-	-	-	<p>IN: -Act of the Consumer Protection, No.8 of 1999. -Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.23.3644 of 2004, on Principle of Food Supplement Control. -Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.41.1381 of 2005, on Registration Guidelines of Food Supplement. -Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.52.4321 of 2004, on Guidelines of Food Labeling.</p>
7. Recommended daily allowance (RDA) for vitamins/minerals used as health supplements	-	-	✓	-	✓	-	✓	-	-	-	<p>IN: Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.52.6291 of 2007, on Nutrition Reference Values PH: Revised standard termed as Recommended Energy and Nutrients Intake (RENI) 2002 (adopted as per Bureau Circular No.16 s.2005)</p>