Adherence of safety information on Over-The-Counter (OTC) product labels and leaflets to the regulatory guidelines

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Abstract

Aim: To evaluate the adherence of medication safety information provided on over the counter (OTC) product labels and patient information leaflets (PILs) to the Malaysian and international regulatory guidelines.

Methods: A total of 133 randomly sampled OTC medications (Gastrointestinal = 31, Pain = 36, Skin = 35, Cough & Cold = 31) from 17 community pharmacies located around Klang valley, Malaysia were evaluated. The adherence of relevant safety information provided on the OTC product labels and PILs by the manufacturing companies to the Malaysian and international regulatory guidelines was evaluated.

Results: Majority of the products (n=81) were locally manufactured, followed by 34 products from European region. About 31% (n=41) of the sampled OTC products were sold without PILs. Overall, 98% of the labels adhered to all the criteria, but none of the PILs adhered to all the parameters. Information on action to be taken in the case of missed dose (96%), advice on consulting doctor/pharmacist for further information (92%) and disposal instructions (98%) were generally missing. Surprisingly, none of the PILs included the compulsory statement which is essential for adverse drug reaction reporting. In addition, only 30% of the studied PILs provided information on the date of revision. Overall, imported products had slightly better adherence compared with locally-manufactured products.

Conclusions: The safety information stated on the OTC products marketed in Malaysia had room for improvement to ensure safe and effective use. A uniform format and collective effort is needed to ensure consumers receive adequate information about the OTC products.

Keywords: Drug safety, over-the-counter, patient information leaflet, product label

INTRODUCTION

Self-medication practice has been growing globally, involving both developed and developing countries. Likewise in Malaysia, self-medication practice has been proven to be prevalent.[1-3] According to World Health Organization, self-medication is the selection and use of medicines by individuals to treat self-recognized illnesses or symptoms.[4] The growing trend towards self-medication is mainly due to the drug reclassification policy from prescription status to non-prescription status,[5] which aimed to implement a patient-centred approach in the healthcare system, encouraging the public to take a greater role in managing their health.[6] Minor illnesses or symptoms that are generally self-limiting ranging from headache to Athlete's foot can be treated effectively with appropriate medications purchased over-the-counter. In Malaysia, over-the-counter (OTC) medication (not listed in Poison Act 1952),[7] can be purchased without any prescription, thus limiting a direct intervention from the healthcare professionals.

In the absence of (or limited) input from healthcare professionals, the medication safety information on the package labels and patient information leaflets (PILs) become the primary source of information for appropriate medication selection and use. In the process of self-care or self-medication, the safety information is considered essential in order to avoid overuse, underuse or inappropriate use of medication and thereby improve safety and optimise efficacy and compliance.[8] Patients should have access to sufficient high quality and comprehensible information to maintain safety. This also helps patients to participate fully in decision-making about medicines prescribed for or recommended to them by the healthcare professional.[9] Therefore, written information has an increased importance for safe use of the medicine.

Although OTC medications are of established safety and efficacy, their potentials of causing harm can never be underestimated. The unawareness of the public on the possible adverse effects and interactions could have severe implications, especially to the young and the elderly.[5,10] Studies have shown a general poor knowledge of the consumers on the potential side effects of their medications.[11,12] The overdose of OTC medications presented at the Accident & Emergency (A& E) Department due to the belief of "more might be better" has been reported.[13] Therefore, for the consumers to make informed decisions, the provision of information must be able to communicate

sufficient information about medication directions, risks and benefits of the particular medication.[14]

Various studies have been conducted in countries such as India, Germany and the United States of America and found an evidence of incomplete product information in their sampled products.[15-18] In Malaysia, National Pharmaceutical Regulatory Agency (NPRA) helps to ensure that therapeutic substances approved and marketed are safe, effective and of quality of use.[19] All the information printed on the labels and PILs must follow the labelling requirements of Drug Registration Guidance Document (DRGD) regulated by NPRA.[20] To the authors' best knowledge, there is no study done in Malaysia to analyse the safety information on the OTC product labels and PILs. Therefore, the study was undertaken to evaluate the adherence of medication safety information provided on OTC product labels and PILs to the Malaysian and foreign regulatory guidelines. The randomly sampled OTC products, commonly used in the management of gastrointestinal tract (GIT) related problems, cough and cold (CC), skin problems, and pain were evaluated in this study.

METHODS

Study design

This product-based descriptive study was conducted using randomly sampled OTC medications available in community pharmacies located around Klang valley, Malaysia. A total of 133 OTC products that are marketed in Malaysia, and used in common ailments, were randomly picked over a three-week period from 17 community pharmacies in Klang Valley. The study was conducted according to the principles expressed in the Declaration of Helsinki and the study was approved by the International Medical University Research and Ethics Committee (Project ID No: B01/10-Res (40) 2013).

Selection of OTC products

This study was completed in three phases. In phase one, the selected OTC products were observed for their sales in 17 different pharmacy outlets in Klang valley, Malaysia. The 133 randomly selected products (based on the products with greater sale) were then purchased by the researchers for their package labels and PILs from the pharmacy outlets. In the second and third phases, the package labels and PILs of

purchased products were evaluated against the Malaysian and International regulatory guidelines. The relevant safety information and checklist directed by the respective regulatory authorities were used to analyze the products for the completeness of information provided on the product labels and PILs by the manufacturing or marketing companies. The safety information checklist is categorized according to the type of OTC products.

A total of 31 gastrointestinal (GI) related OTC products with their labels and accompanied PILs were selected, covering four categories: antacids and anti-reflux agents (n=20), anti-diarrhoeal agents (n=2), laxatives (n=7) and anti-flatulent agents (n=2). Of 31 products, 14 products were manufactured locally, while 17 were imported from other countries. A total of 36 OTC products with their labels and accompanied leaflets, used for pain relief were selected. Of total, eight OTC products were imported from other countries. A total of 35 OTC skin products were selected. These include antifungal agents (n=13), anti-acne agents (n=5), keratolytic agents (n=4), antiseptic agents (n=6), and antipruritic agents (n=7). Out of 35 products, 21 products were manufactured locally and 14 were originated overseas. A total of 31 OTC medications used for cough and cold were selected. Of these, five products contained acetylcysteine and ambroxol, six products contained bromhexine, guaifenesin and carbocisteine, two of them contained cyclidrol and one of them contained methylcarbocisteine. Of 31 products, 15 were manufactured in countries other than Malaysia.

Evaluation

Adherence to Malaysian (NPRA) guidelines

The National Pharmaceutical Regulatory Agency (NPRA) checklist was used as a reference for comparison.[19,20] Both product labels and PILs were scrutinised for the presence of information on each criterion included in the NPRA checklist and international criteria. If the information was present, a score of one was given, if not a score of zero was given. By the summation of score from individual label and PIL, the total scores of each criterion were obtained, presented as absolute numbers and percentages. According to NPRA, if the product is intended to be sold without PILs, all the information needed to be included in PILs must be printed on the product label.[5]

Adherence to foreign regulatory requirements (international)

OTC medications manufactured from countries other than Malaysia were also evaluated. Only the additional labelling requirements from their respective guidelines were highlighted in this study. The aim was to find out the differences in the provision of medication safety information for OTC medications imported from other countries.

Product manufactured in United States (US) was evaluated against Food and Drug Administration (FDA) labeling guideline,[21] whereas products from Singapore were evaluated against Singapore labeling guideline regulated by Health Science Authority.[22] European Medicines Agency (EMEA) guidelines were used as a reference for products originated from the member states of EU.[23]

The data were analysed using the Microsoft Excel and Statistical Package for the Social Sciences (SPSS) ® version 22, with a significance level of ≤0.05. Descriptive statistics were used to calculate percentages, frequencies, means, and standard deviations. Authors checked whether there was full adherence (1 point), or no adherence (0 points) for each sub criterion. The maximum possible score was 23 for product leaflets and 14 for product labels. Each leaflet and label therefore was assigned an adherence score indicating the proportion of points accrued out of a total score, and a percentage was calculated. The ratings were performed by four researchers (one for each group of medications) on all criteria (local and international). The adherence scores are presented as mean percentages with ranges.

RESULTS

<u>OTC products for GI related problems</u>

Adherence to Malaysian guidelines

All GI related OTC products (n=31) were sold with their labels. Majority of the labels had information about dosage form (90.3%) and provided the warning statement “keep medicine out of reach of children” in both languages (Bahasa Malaysia and English) (87%); however two imported products provided the statement in English and two local products provided the statement in Bahasa Malaysia only. Overall, about 98% of the product labels achieved full adherence to all the criteria required by NPRA guidelines (**Table 1**).

About 35% (n=11) of the products were sold without PILs. Safety information on pregnancy and lactation were only provided in half of the studied PILs (10/20). Information on action to be taken in the case of missed dose (2/20) were generally missing. Surprisingly, none of the leaflets had the disposal instructions as well as the compulsory statement which is essential for adverse drug reaction (ADR) reporting. Product appearance and product registration (MAL) number that are important in product identification was seen in only five and nine leaflets, respectively. Moreover, PILs of seven imported products did not disclose any Malaysian address though given on their outer cartons. Doubts on the recentness of the information could be raised as well due to the fact that only seven leaflets provided the date on which the information on leaflets was last updated (**Table 2**).

Adherence to International guidelines

All 17 products were originated from the member states of European Union (EU). The 17 leaflets and labels achieved an average adherence score of 67.3% and 94.1%, respectively. According to EMEA guidelines, instruction for use was required to be presented on the product label, which is not mandatory by the NPRA guidelines. It was revealed that imported products had slightly better adherence to the NPRA guidelines compared with locally-manufactured products (**Table 3**).

<u>OTC products for pain management</u>

Adherence to Malaysian guidelines

A total of 36 OTC products used for pain relief were evaluated. About 39% of the selected products were sold without the leaflets. Of 19 parameters required to be mentioned on product labels, only 14 parameters were mentioned on the labels. Four products did not provide the statement “keep medicines out of reach of children.” in both Bahasa Malaysia and English (**Table 1**).

Of 19 parameters required to be mentioned on PILs, only five parameters were fulfilled by the selected products (indications, dose, warning and precautions, name and address of manufacturer and product registration holder). Almost all selected products mentioned the product name, active ingredients and strength (21/22), storage conditions (21/22), side effects (17/22), and contraindications (18/22) (**Table 2**). None of the product mentioned the information on missed dose, compulsory statement and

disposal. One of the products containing camphor did not provide the specific information as required.

Adherence to International guidelines

The two products manufactured in the Philippines did not provide information on contraindications, precautions and warnings (average adherence score = 88.5%). One of the two products originated from Indonesia, excluded contraindications and side effects (average adherence score = 95%). The two products originated from Australia did provide safety information according to their country's specific guideline (average adherence score = 100%) (**Table 3**).

OTC medications used for skin

Adherence to Malaysian guidelines

About 86% (n=30) of the products were sold with outer carton; while 71% provided the PILs (n=25). Both manufacturing date and hologram were provided in 97% (n=34) of the products, while 91% (n=32) mentioned the statement "keep medicine out of reach of children" in both languages. Local products had slightly better adherence to guidelines as compared to the imported products (99.7% versus 98.2%).

Majority of the OTC products provided information on warnings/precautions (23/25) and duration of use (20/23). However, the method of medicine disposal was disclosed by only one product which was originated from Indonesia. Half of the imported products (n=7) included the information on the possible use during pregnancy and/or lactation, while this information was found in only five local products. Surprisingly, none of the product provided information for missed dose and the compulsory statement. There were six products containing benzyl alcohol (n=5) and camphor (n=1) that required specific labeling. However, only one product containing benzyl alcohol fulfilled the criteria as required by NPRA.

Adherence to International guidelines

The 14 imported products were originated from European Union, Singapore, Australia and Indonesia. The eight leaflets and labels for the products originated from European countries achieved average adherence scores of 74.4% and 98.2%, respectively. Again, the products originated from Australia achieved full adherence to the criteria.

The product originated from Singapore met one of the additional criteria, but the information regarding when consumer should consult the doctor was missing. None of the OTC products from Indonesia met the five additional requirements.

OTC product for cough and cold

Adherence to Malaysian guidelines

Of 31 OTC medications used for cough and cold selected, six of them did not contain PILs. A total of 21 parameters that are needed to be included in the leaflets, only 8 of the parameters were fulfilled by the products. Less than half of the leaflets provided information on time to take medicine (10/25) date of revision (10/25), MAL number (6/25), action taken when missed a dose (2/25) and way to dispose medicine (1/25). The OTC products containing acetylcysteine, carbocisteine and methylcarbocisteine require special labeling in the product label and PILs. All the products containing these three substances must include information on contraindication in children below two years old. Only one (out of 12) of the products did not include this information.

Adherence to International guidelines

As compared to Malaysian guideline, three additional parameters were found in FDA labeling requirement. The product manufactured in United States did include all the additional criteria (consult doctor before use, stop use and consult doctor and inactive ingredients).

Only 11% of the products from EU countries provided the information on additional criterion about excipients. The nine leaflets and labels from EU countries achieved adherence scores of 87.3% and 81.5%, respectively.Two products manufactured in Singapore fulfilled all the labeling requirements, which were similar to NPRA labeling requirement. However, one additional parameter for the leaflets that is “when to consult doctor” was not mentioned in the two products imported from Singapore.

DISCUSSION

The randomly sampled OTC products showed good adherence to the regulatory requirements on product labels and PILs. This first comparison of patient information leaflets and labels routinely supplied to patients in Malaysia shows wide variation in the quality of leaflets and labels in terms of both clinical and non-clinical content. The leaflets and labels of products originated from Australia were generally superior

compared with Malaysian products as well as products originated from Europe and the U.S. This supports the findings of a previous study by Raynor et al (2007), where Australian leaflets received a mean adherence score of 90%, the U.K. leaflets 81%, and the U.S. leaflets 68%.[24]

The result showed that the statement “keep medicines out of reach of children” in both Bahasa Malaysia and English was the most missing parameter from the studied products. Ideally, all package labels should carry the statement “keep medicine out of reach of children” in both languages (Bahasa Malaysia and English), failure to do so can lead to accidental child poisoning. According to Center for Disease Control and Prevention (CDC), more than 60,000 children are treated in emergency departments due to accidental unsupervised ingestion every year.[25] In Australia, as high as 20% unintentional ingestion of OTC medications in children resulted in hospital admissions, probably due to unsafe medication storage.[26] Moreover, accidental ingestion of products containing camphor and eucalyptus oil could be harmful and even life threatening to the children.[27]

Majority of the studied leaflets were lacking information on adverse drug reaction (ADR) reporting, duration of use, pregnancy and lactation, hologram, possible side effects, and date of revision. The involvement of consumers in ADR reporting has been shown to contribute to a better pharmacovigilance system.[28-30] Therefore, without the consumers being made aware of the ADR reporting system, they are less likely to be involved in the ADR reporting. Duration of use is crucial to be included for OTC products like laxatives as misuse or abuse of laxatives may result in serious complications such as dehydration, electrolyte disturbances and renal failure.[31,32] The studied PILs and labels also lacking information on drug use during pregnancy and lactation. McDonald and colleagues elaborated the importance for the pregnant and lactating women to be informed of the risks and benefits of any medication as this will significantly influence an individual’s decision making.[33] The absence of hologram should not be neglected as it may indicate that the product was not protected from duplication, which can cause a potential threat to the consumers’ health.[34] Furthermore, a disclosure of common and possible adverse effects would help the patient to recognize the undesired effects.[24,35,36] Surprisingly, only 30% of the studied PILs provided information on the date of revision. Similar findings were also reported

in studies conducted in India and Germany, where authors found out-of date information in PILs.[37,38] Date of revision is the date on which the information in the PILs was last updated and this information is needed to ensure the consumer receives the most recent and updated information.[37] Absence or out-of date information could negatively influence the consumers' trust in the product.[22]

There are variations in regulatory requirements on the product labels and PILs globally, due to different drug policies and regulations. Most of the country-specific guidelines provide additional criteria that are not needed in the local guideline. Some consumers may find additional requirements helpful for them to make decision for self-medication. The labelling requirements for both local and non-local guidelines were generally similar though the FDA and EMEA labelling requirements covered a wider and more complete perspective. A statement "to consult doctor" was found in US FDA, EMEA and Singapore labeling guideline. Studies has shown that parents who did not consult doctor before the use of OTC cough and cold remedies has resulted in the death of their infants.[39,40] Information on excipients is one of the additional criteria found in both USA and EMEA labeling guidelines. Some excipients such as tartazine (a coloring agent present in OTC medication used for cough and cold), has shown to aggregate eosinophilia and hyperkinesia in hyperactive patients. Besides that, taking lactose-containing medications can lead to flatulence, diarrhea and bronchospasm in lactose-sensitive individuals.[41,42] Therefore, it is important to list out the excipients for the safety of patients with certain types of diseases or allergies.

The leaflets and labels with appropriate standard and format should be used to increase the usability of leaflets and labels because too much information might deter patients from reading it.[43] This is supported by a study conducted in Germany where participants indicated their preference for more concrete action-directed information.[44] In overall, both local and imported products (label and leaflet) were not fully compliant to the NPRA guidelines. For the safety of the consumers, both pharmaceutical companies and drug authorities are responsible to ensure that the information provided to the end users are accurate and sufficient for safe and effective use. Self-regulation by pharmaceutical companies could be part of the solution by fully compliant to the NPRA guidelines and by working together with the Malaysian drug authorities, to further review and refine the written information for both local and imported products. Lastly, in acknowledging the presence of variations in drug policies and

regulations among countries, there is still a need to update our relevant guidelines, for the benefits of the consumers.

There are number of limitations that could affect the generalizability of the findings. First of all, not all OTC products marketed in Malaysia were included in the analysis. Secondly, we had difficulty in accessing guidelines from certain countries and also the difficulty in finding a gold standard to compare the accuracy of the information presented. Thirdly, this study did not take into account the information received by the end users in the case of the separation of the medications from their outer carton and leaflets. Because some community pharmacies had the practice of selling OTC products separately due to a large packing size of certain products, thus the information received by the ends users could be incomplete.

This study indicates that the safety information stated on the OTC products marketed in Malaysia had room for improvement to ensure safe and effective use. The omission of the important information on the majority of the studied products have particular implications for the safe and effective used of the marketed OTC medications. A uniform format should be implemented to ensure consumers receive adequate information about the OTC products. Also, pharmaceutical regulators and companies should meet the responsibility of providing more complete, sufficient and up-to-date product safety information for the benefits of consumers. Greater efforts are needed from both pharmaceutical companies and the local drug authorities. Further study can be done to analyse the readability and comprehensibility of the information, also to include a larger sample covering variety of brand names.

CONFLICT OF INTEREST

None to declare

ETHICS STATEMENT

The study was approved by the International Medical University Research and Ethics Committee (Project ID No: B01/10-Res (40) 2013).

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Table 1: Percentage of product labels that fulfilled the labeling requirements by NPRA criteria

No.	Parameter	GI (n=31) N (%)	Pain (n=36) N (%)	Skin (n=35) N (%)	CC (n=31) N (%)
1	Brand or Product Name	31 (100)	36 (100)	35 (100)	31 (100)
2	Dosage Form	28 (90.3)	35 (97.2)	35 (100)	31 (100)
3	Name of Active Substance(s)	31 (100)	36 (100)	35 (100)	31 (100)
4	Strength of Active Substance(s)	31 (100)	36 (100)	35 (100)	31 (100)
5	Batch Number	31 (100)	36 (100)	35 (100)	31 (100)
6	Manufacturing Date	31 (100)	34 (94.4)	34 (97.1)	31 (100)
7	Expiry Date	31 (100)	36 (100)	35 (100)	31 (100)
8	Route of Administration	31 (100)	36 (100)	35 (100)	31 (100)
9	Country's Registration Number	31 (100)	36 (100)	35 (100)	31 (100)
10	Name and Address of Manufacturer	31 (100)	36 (100)	35 (100)	31 (100)
11	Warnings and/or Specific Labeling	31 (100)	36 (100)	35 (100)	31 (100)
12	Pack Size (Unit/Volume)	31 (100)	36 (100)	35 (100)	31 (100)
13	Name and Content of Preservative(s), where present	30 (96.8)	36 (100)	35 (100)	31 (100)
14	Name and Content of Alcohol, where present	31 (100)	36 (100)	35 (100)	31 (100)
15	To declare source of ingredients derived from animal origin, including gelatin (active excipient, and/or capsule shell)	31 (100)	36 (100)	35 (100)	31 (100)
16	The words "Keep medicine out of reach of children" or words bearing similar meaning in both Bahasa Malaysia and English.	27 (87.1)	32 (88.9)	32 (91.4)	31 (100)
17	Security Label (Hologram)	31 (100)	35 (97.2)	34 (97.1)	31 (100)
18	Storage Condition	31 (100)	34 (94.4)	35 (100)	30 (96.8)
19	Name and Address of Product Registration Holder (PRH)	31 (100)	36 (100)	35 (100)	30 (96.8)

CC = Cold and Cough; GI = Gastrointestinal; PL = Product Labelling; PIL = Product Information Leaflet

Table 2: Percentage of PILs that fulfilled the labeling requirements by NPRA criteria

No.	Parameter	GI (n=31) N (%)	Pain (n=36) N (%)	Skin (n=35) N (%)	CC (n=31) N (%)
	No product information leaflet	11 (35.5)	14 (38.9)	10 (28.6)	6 (19.4)
1	Product name, active ingredient(s) and strength	20 (100)	21 (95.5)	25 (100)	25 (100)
2	Indication (s)	20 (100)	22 (100)	25 (100)	25 (100)
3	Mechanism of action	11 (55.0)	6 (27.3)	14 (56.0)	25 (100)
4	Dose	20 (100)	22 (100)	16 (64.0)	25 (100)
5	Duration of use	8 (40.0)	2 (9.1)	20 (80.0)	25 (100)
6	Possible side effects	12 (60.0)	17 (77.3)	16 (64.0)	25 (100)
7	Storage condition	20 (100)	21 (95.5)	24 (96.0)	25 (100)
8	Name and address of manufacturer	20 (100)	22 (100)	24 (96.0)	25 (100)
9	Contraindication (s)	17 (85.0)	18 (81.8)	19 (76.0)	24 (96.0)
10	Warnings and precautions	20 (100)	22 (100)	23 (92.0)	24 (96.0)
11	Pregnancy and/ or lactation	10 (50.0)	2 (9.1)	9 (36.0)	23 (92.0)
12	Name and address of product authorization holder	15 (75.0)	22 (100)	0 (0.0)	18 (72.0)
13	Drug interaction (s)	10 (50.0)	15 (68.2)	7 (28.0)	17 (68.0)
14	Product appearance	5 (25.0)	9 (40.9)	9 (36.0)	16 (64.0)
15	Overdose treatment	11 (55.0)	13 (59.1)	7 (28.0)	15 (60.0)
16	Time to take (before/after meal)	20 (100)	2 (9.1)	17 (68.0)	10 (40.0)
17	Date of revision	7 (35.0)	3 (13.6)	8 (32.0)	10 (40.0)
18	MAL number	9 (45.0)	9 (40.9)	8 (32.0)	6 (24.0)
19	Action for missed dose	2 (10.0)	0 (0.0)	0 (0.0)	2 (8.0)
20	Disposal of medicine	0 (0.0)	0 (0.0)	1 (4.0)	1 (4.0)
21	Compulsory statement in both Bahasa Malaysia and English	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
22	Listing of active & inactive ingredients	20 (100)	0 (0.0)	0 (0.0)	0 (0.0)
23	Advice on consulting doctor/pharmacist for further information	7 (35.0)	0 (0.0)	0 (0.0)	0 (0.0)

CC = Cold and Cough; GI = Gastrointestinal; PL = Product Labelling; PIL = Product Information Leaflet

Table 3: Adherence scores (mean % and range) of leaflets and labels by country

Country of origin	OTC GI products			OTC Pain products			OTC Skin products			OTC CC products		
	N	PIL Mean % (Range)	PL Mean % (Range)	N	PIL Mean % (Range)	PL Mean % (Range)	N	PIL Mean % (Range)	PL Mean % (Range)	N	PIL Mean % (Range)	PL Mean % (Range)
Local (Malaysia)	14	52.2 (0.0-100)	98.1 (78.6-100)	29	54.1 (0.0-100)	98.5 (88.9-100	21	55.7 (0.0-100)	99.7 (95.2-100)	17	70 (0.0-100)	96 (92-100)
European	17	67.3 (0.0-100)	94.1 (88.2-100)	-	-	-	8	74.4 (0.0-100)	98.2 (75-100)	9	87.3 (0.0-100)	81.5 (11.1-100)
United States	-	-	-	-	-	-	-	-	-	1	100 (-)	100 (-)
Singapore	-	-	-	-	-	-	1	85.7 (-)	100 (-)	2	80 (0-100)	100 (100-100)
Taiwan	-	-	-	-	-	-	-	-	-	1	NA	NA
Thailand	-	-	-	-	-	-	-	-	-	2	NA	NA
Australia	-	-	-	2	100 (100-100)	100 (100-100)	2	100 (100-100)	100 (100-100)	-	-	-
Indonesia	-	-	-	2	95.0 (50-100)	95.0 (50-100)	3	NA	85.4 (0.0-100)	-	-	-
Philippines	-	-	-	2	88.5 (0.0-100)	88.5 (0.0-100)	-	-	-	-	-	-
Japan	-	-	-	1	NA	NA	-	-	-	-	-	-

Note: CC = Cold and Cough; GI = Gastrointestinal; PL = Product Labelling; PIL = Product Information Leaflet; NA = Not Accessible/Available. NPRA for Malaysian products; EMEA for European products; FDA for US products; HAS for Singaporean products;