LABELLING VARIATIONS FOR PHARMACEUTICAL PRODUCTS IN ASEAN COUNTRIES

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ASEAN (Association of South East Asian nations) was established in 8th August, 1967 in Bangkok. Presently the association comprises of (Indonesia, Malaysia (Chair), Vietnam, Brunei Darussalam, Democratic republic of Laos, Cambodia, Singapore Philippines and Thailand (Co-Chair)). Labeling as being a very essential part of the Pharmaceutical product and giving an overview to the patient and healthcare professional with respect to the drug’s Administrative information, quality and some other important parameters such as its safety and efficacy. Although many countries in ASEAN region is accepting Harmonized ACTR for drug product registration product for human use, but still variation in the labeling is encountered during registration as per the country specific regulation on the labeling of pharmaceutical product for human use. This review article summarizes the requirement variation with respect to labeling and art-work of pharmaceutical product for human use in ASEAN Region and differences among the labeling provisions of different countries should be negotiate for further harmonization.

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INTRODUCTION:
The Association of Southeast Asian Nations (ASEAN) was created in 1967 with the signing of the ASEAN Declaration by Indonesia, Malaysia, Philippines, Singapore and Thailand. Brunei Darussalam then joined in 1984, Vietnam in 1995, Lao PDR and Cambodia in 1999, arriving at the current number of ten Member States. These ten countries with a total land area of 4.4 million sq. km. are home to 600 million. In 2003, ASEAN Heads of State agreed to establish an ASEAN Community by 2020, a community of nations that is outward looking, living in peace, stability and prosperity, bonded together in partnership in dynamic development and in a community of caring societies. The ASEAN Community has three pillars, namely, the ASEAN Political-Security Community, the ASEAN Economic Community and the ASEAN Socio-Cultural Community. In 1997 ASEAN began with harmonization of pharmaceutical standards when they felt the need to establish a PPWG (Pharmaceutical Product Working Group) during 13th meeting in 1997 and a proposal was given by the Malaysia and supported by relevant bodies.

Accordingly PPWG had its first meeting in September 1999 with Malaysia as chair and Thailand as co-chair. After the subsequent meetings PPWG had developed the ACTD, ACTR and its guideline [4-7], [12], [17].

Labeling is as important as the drug product which tells us about its attributes i.e. generic name of the drug, branded name, name of manufacturer, expiry date, manufacturing date, address of the manufacturer, batch number, indication, ingredients etc. all of these attributes help the user and health care professional to make proper use of it. Types of labels can be paper label, foil label, sleeve label, transfer label and it is varying from product to product. For the labeling different countries are having different labeling requirements, in case of drug whole world is divided into three types of markets regulated markets, semi regulated markets and non regulated markets. All of these markets are having different regulatory authority and all are having their different regulations for different parts of the product. Semi regulated markets themselves consist of many different areas and having different regulation and varying from zone to zone.

Definitions of labeling by different Regulatory Authorities:
The Federal Food, Drug and Cosmetic Act (FFDCA) are the law under which the FDA takes action against regulated products. Specifically [15], [16]

Section 201(k) defines 'label' as a:
- 'Display of written, printed, or graphic matter upon the immediate container of any article...'
The term 'immediate container' does not include package liners. Any word, statement, or other information appearing on the immediate container must also appear 'on the outside container or wrapper, if any there be, of the retain package of such article, or is easily legible through the outside container of wrapper.'

Section 201(m) defines 'labeling' as:
- 'All labels and other written, printed, or graphic matter
  (1) Upon any article or any of its containers or wrappers, or
  (2) Accompanying such article' at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.

The term ‘accompanying’ is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. 'Accompanying' also includes labeling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

Labeling defined in Decree of the national Agency of drug and food control of Indonesia:
Labeling is a complete information on drug, efficacy, safety, posology, and other information which are consider important to be put on the label, brochure, and carton of a drug packaging.

Definition of the label defined in Act 281 of Laws of Malaysia “label” includes any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, painted, embossed or impressed on, or attached to or included in, belonging to, or accompanying any food;

Labeling defined in the Philippines’s Republic Act No. 7394 "Label" means a display of written, printed or graphic matter on any consumer product its immediate container, tag, Literature, or other suitable material affixed thereto for the purpose of giving information as to identify, components, ingredients, attributes, direction of use, specifications and such other information as may be required by law or regulations.
### 2.1 Drug regulatory authorities of different country: [12]

<table>
<thead>
<tr>
<th>Country</th>
<th>Drug Regulatory Authority</th>
<th>Languages Used in labelling of drug Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singapore</td>
<td>Ministry of health</td>
<td>English</td>
</tr>
<tr>
<td>Malaysia:</td>
<td>National Pharmaceutical Health Bureau (Ministry of Health) and Drug Control Authority</td>
<td>Bahasa Malaysia or English</td>
</tr>
<tr>
<td>Philippines:</td>
<td>Department of Health</td>
<td>English or Filipino or any major dialect or a combination thereof</td>
</tr>
<tr>
<td>Lao’s</td>
<td>Ministry of Health</td>
<td>Lao language or English</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Ministry of Health</td>
<td>English or Khmer</td>
</tr>
<tr>
<td>Brunei Darussalam:</td>
<td>Ministry of Health</td>
<td>English or/and Malay</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Ministry of Health</td>
<td>Indonesian Language (Bahasa Indonesian)</td>
</tr>
<tr>
<td>Thailand</td>
<td>Food and Drug Administration</td>
<td>Thai</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Drug Administration of Vietnam</td>
<td>Vietnamese</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Union of Myanmar (Ministry Of Health and Department Of Health)</td>
<td>Burmese</td>
</tr>
</tbody>
</table>

**Medicinal product labeling in ASEAN region:**

**Drug labeling requirement in Philippines:**

Drug labeling requirement is different in different country. As per Section 6(c) of republic Act No. 6675 of Philippines. Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name 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. [1], [10], [11]

As given in the Section 7 of republic Act No. 6675.

Provision of Quality, Manufacturer’s Identity and Responsibility. — In order to assure responsibility for drug quality in all instances, the label of all drugs and medicines shall have the following: name and country of manufacture, dates of manufacture and expiration. The quality of such generically labeled drugs and medicines shall be duly certified by the Department of Health. PNF Form No. 6 (Evaluation Form for Inclusion of New Dosage Strength, Net Content and Immediate Packaging of Medicines – Minor Inclusions) which is hereto appended as Annex F for all medicines with new dosage strength, net content and packaging and chronologically numbered as it is accomplished and logged in an official logbook. It shall contain the same data elements as PNF Form No. 1

A. Annex B – PNF Form No. 2 (Letter of Request and Proposal Form for New Dosage Strength, Net Content and Immediate Packaging – Minor Submissions).
B. PNF form no. 6:

<table>
<thead>
<tr>
<th>Medicines</th>
<th>Particulars</th>
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<tr>
<td></td>
<td>Generic Name/INN</td>
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<td></td>
<td>Brand Name</td>
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<td>Dosage Form and Strength</td>
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<td>Route of Administration</td>
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<td>Therapeutic Classification</td>
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<td>Manufacturer</td>
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<td>Importer/Trader</td>
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<td></td>
<td>Distributor</td>
</tr>
</tbody>
</table>

Proponent

Fec initiated

Name

Designation

Doh unit/health facility

Representative

Designation

Unit/Health Facility Name

Pharmaceutical Company

Company name

Representative

Designation

Unit/Department/Health facility name

Others

Name/s

Designation

Company/Organization/Office Name

APPLICATION FOR: (Please check)

- Inclusion of new dosage strength of medicine listed in PNF
- Inclusion of new net content of medicine listed in PNF
- Inclusion of new immediate packaging

Drugs exempt from the section 89

Article 30. Exemption in Case of Drugs and Devices. –

a) The Department is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processes or packed, on conditions that such drugs and devices are not adulterated or mislabeled under the provisions of this Act upon removal from such processing, labeling or repacking establishment.
b) 1) Drugs intended for use by man which:
   (i) Are habit-forming;
   (ii) Because of their toxicity or other potentiality for harmful effect, or method of their use is not safe for use except under the supervision of practitioner licensed by law to administer such drug;
   (iii) Are new drugs whose applications are limited to investigational use; shall be dispensed only (a) upon written prescription of a practitioner licensed by law to administer such drug, or (b) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (c) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being mislabeled while held for sale.

2) Any drug dispensed by filling or refilling a written prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Article 89, except paragraphs (a), (h), (2) and (3), and the packaging requirements of paragraphs (f) and (g), if the drug bears a label containing the name and address of the dispenser, the serial number and the date of the prescription or its filling, the name of the prescriber and, if stated in the prescription the name of the patient and the directions for use and cautionary statements, if any, container in such prescription.

3) The Department may, by regulation, remove drugs subject to Article 89 (d) and Article 31 from the requirements of sub-article (b) (1) of this Article, when such requirements are not necessary for the protection of the public health.

4) A drug which is subject to sub-article (b) (1) of this Article shall be deemed to be mislabeled if any time prior to dispensing, its label fails to bear the statement “Caution: Should not be dispensed without prescription.” A drug to which sub-article (b) (1) of this Article does not apply shall be deemed to be mislabeled it at any time prior to dispensing; its label bears the caution statement quoted in the preceding sentence.

**Article 77. Minimum Labeling Requirements for drug Products.**

All consumer products domestically sold whether manufactured locally or imported shall indicate the following in their respective labels of packaging:

a) Its correct and registered trade name or brand name;

b) Its duly registered trademark;

c) Its duly registered business name;

d) The address of the manufacturer, importer, repacked of the consumer product in the Philippines;

e) Its general make or active ingredients;

f) The net quality of contents, in terms of weight, measure or numerical count rounded off to at least the nearest tenths in the metric system;

g) Country of manufacture, if imported; and

h) If a consumer product is manufactured, refilled or repacked under license from a principal, the label shall so state the fact.

The following may be required by the concerned department in accordance with the rules and regulations they will promulgate under authority of this Act:

a) Whether it is flammable or inflammable;

b) Directions for use, if necessary;

c) Warning of toxicity;

d) Wattage, voltage or amperes; or

e) Process of manufacture used if necessary.

Any word, statement or other information required by or under authority of the preceding paragraph shall appear on the label or labeling with such conspicuousness as compared with other words, statements, designs or devices therein, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase or use.

The above requirements shall form an integral part of the label without danger of being erased or detached under ordinary handling of the product.

**Drug labeling requirement Thailand:**

Drug labeling regulation in Thailand as give in Thai Law Drug Act, B.E. 2510 (1967)

Section 25[7]

Persons licensed to produce modern drugs shall:

(3) Provide labels corresponding to the formula registered affixed to containers and packing for drugs produced shall always be fully labeled to show:

a) The name of the drug;

b) Numbers or codes of the drug contained;

c) The quantity of the drug contained;

d) The name and quantity or strength of the important active ingredients of the drug;

e) Numbers or letters indicating the lot and analysis;

f) The name of the producer and the province where the place of production is located;

g) Date of production;
h) The words “dangerous drug” “specially controlled drug” “external drug” “specific place drug” as the case may be in clearly visible red letters where the drug is a dangerous or specially controlled or external or specific place drug;

i) The words “common household drug” if the drug is a common household use;

j) The expiry date if the drug has been notified by the Minister under Section 76(7) or (8)

Section 76 (7) defined as “Drugs whose expiry date must be given on the label”

Section 76 (8) defined as “Duration of usage of some drugs”

Pursuant to the provisions of R.A. 3720, otherwise known as the “Food, Drug and Cosmetic Act”

Drug labeling requirement in Brunei Darussalam:

All medicinal products in Brunei Darussalam are controlled under the Medicines Order 2007 & Poisons Act 1956. As a preliminary step, the Department of Pharmaceutical Services (DPS) issues provisional registration of all medicinal products for human use prior to their use in Brunei Darussalam. All local manufacturers, wholesalers and importers of medicinal products must be licensed before they can conduct their businesses. [7], [15]

Product details:

3.1 Proprietary Name
3.2 Dosage Form
3.4 Product Formula
3.11 Packaging, Shelf-life and Storage Conditions

1) Product Name
2) Dosage Form
3) Name of Active Ingredient(s)
4) Strength of Active Ingredients(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 Marketing Authorization Holder
12) Name and Address of Manufacturer
13) Special labeling (if applicable) e.g. Sterile, External Use, Cytotoxic, Alcohol Content, Animal Origin (Bovine, porcine)
14) Recommended Daily Allowance (For Vitamins and Minerals)
15) Warning (if applicable)
16) Pack sizes (Unit/Volume)

A special type of labeling is generally used called as HALAL logo and it is decided as per Hakum Syara.

Drug labeling requirement in Singapore regulations:

Labeling refers to any printed or graphic information on the immediate container, outer packaging and any other form of printed material supplied together with the product.

The product labels, PI and/or PIL must be in English. If non-English text is included in the labeling, applicants must provide an official statement to declare that the non-English text is complete, accurate and unbiased information and is consistent with the English text. Information provided in the labels should be consistent with the information submitted in the application dossier. Any deviation should be highlighted and brought to HSA’s attention. [4], [16], [19]

Drug labeling requirement in Cambodian regulation

In 2000, the Law on the Management of Quality and Safety of Products and Services was adopted. Manufacturers and service providers are required to have product labels in Khmer language detailing ingredients, composition, users’ guidelines, manufacturing date and expiration date along with other requirements which guarantee the safety and health of consumers prior to their commercialization. Also, foodstuff labeling must indicate clearly name of goods, producer name and address, source, quantity, batch number, production and expiration dates, ingredients and directions for use if necessary. The Ministry of Commerce is responsible for inspecting the implementation of these regulations and repressing frauds and violations. [6], [14]

Drug labelling requirement in Vietnam

Circular No. 04/2008/TT-BYT of may12, 2008 guiding the labeling of medicine published by the ministry of health and Republic of Vietnam which describe the follows:

Medicine label means handwritten, printed or drawn letters, drawings, images and signs printed in inlay or relief directly on commercial packages of medicines or sheets bearing such letters, drawings, images and signs securely stuck, pinned or attached thereto in order to display essential information on medicines, helping consumers choose and use proper medicines and serving as a oasis for functional agencies to conduct inspection, supervision and management.

Medicine labeling means the presentation of basic and necessary information on a medicine on its label. [13]
Original label of a medicine means the first label printed or securely stuck, pinned on or attached to the commercial package of the medicine after the packaging step in the manufacturing chain is completed. Auxiliary label means a label bearing mandatory contents in Vietnamese, which are translated from those appearing on an original label in a foreign language and added with other mandatory contents in Vietnamese which are absent from the original label as required by law.

Method of labeling medicines:
1. Names of medicines
2. Active ingredients, their contents or concentrations
3. Packaging specifications
4. Indications, administration and contraindications (if any) of medicines
5. Preparation form, registration number, import permit number and manufacture batch number, manufacturing date, expiry date and storage conditions
6. Remarkable signs
7. Names and addresses of organizations or individuals responsible for medicines
8. Origin of medicines
9. Use instructions of medicines
10. Auxiliary labels of medicines

Drug labeling requirement in Lao People’s Democratic republic.
Drug label: Drug labels are documents which give details of the respective drug and are affixed to the containers thereof; i.e. glass bottles, vials ampoules etc. and contain the following details:
- Name of Drug (Trade name and Generic name) dosage form and strength; [5][9]
- Drug formula and quantity of the active ingredients;
- Package unit;
- Manufactured date and expiry date;
- Lot Number (Lot No), control number and registration number;
- Indication/instructions of the use;
- Precautions and contra indication;
- In case of dangerous drug or drug using in special areas there shall be the wording “Dangerous Drug”, “For hospital use only” in red letter and also in a red bracket;
- Keeping condition;
- Name and full address of the manufacturing;
- The Contents of the label must be written in Lao and/or English, French.

Code number for drug registration:
Registered drug shall be allotted the following number:
- Modern drug produced within the country shall have the following: XX (Month) LXX XX (Number)/year A.D
- Traditional drug produced within the country shall have the following: XX (Month) LTXXXX (Number)/year A.D
For drug allotted with registration numbers, the respective product owners (i.e. manufacturers, importers or exporters) shall print the registration number on the labels, boxes, containers, blisters, vials.

CONCLUSION:
ASEAN consist of ten member countries and now a day’s ASEAN countries follows harmonized regulation, registration process and following ASEAN guidelines to fulfill the local regulatory requirement for the registration of the medicinal product. ASEAN have harmonized the ACTD requirement but there are some other requirements which used to vary from country to country. Labeling is one of the important parts of a dossier and a drug product packaging. Appropriate drug labeling is a norm which provides comprehensive concise statement of a drug’s safety, quality and efficacy. Effective medicinal products is directly proportional to the health gains in health around a country and labeling is an important asset which helps to give the information to the user about the drug’s quality, safety and efficacy. As there is no harmonized medicinal product guideline for the ASEAN region, so each country having its own specific labeling requirement. In this paper we have gave an overview on drug labeling requirement of blister/strip and unit carton of medicinal products which used to varying among the ASEAN countries".
3.1 Variation in drug labeling requirement of 9 ASEAN countries in Unit carton:

<table>
<thead>
<tr>
<th>Unit carton</th>
<th>Philippines</th>
<th>Indonesia</th>
<th>Thailand</th>
<th>Singapore</th>
<th>Malaysia</th>
<th>Vietnam</th>
<th>Laos</th>
<th>Cambodia</th>
<th>Brunei</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product name</strong></td>
<td>Generic name has to appear above the generic name</td>
<td>Generic name should be under the brand name, Minimal size of the generic name is 80% of the brand name.</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>Bigger generic name</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Dosage form</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td><strong>Package size</strong></td>
<td>-</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td><strong>Name of ingredients:</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td><strong>Local production</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
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<td>YES</td>
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<td>YES</td>
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<tr>
<td><strong>Imported Drug</strong></td>
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<td><strong>Toll Manufacturing Name</strong></td>
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<tr>
<td><strong>Local Production Under license</strong></td>
<td>YES</td>
<td>YES</td>
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<td><strong>Registration Number</strong></td>
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<tr>
<td><strong>Batch Number</strong></td>
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<td>YES</td>
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<td><strong>Date of production</strong></td>
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<td>YES</td>
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<td>YES</td>
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<tr>
<td><strong>Expiration Date</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
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<td><strong>Expiration Date</strong></td>
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<td><strong>Indication</strong></td>
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<td></td>
<td>Posology</td>
<td>Contraindication</td>
<td>Adverse Drug reaction</td>
<td>Drug Interaction</td>
<td>Warning and precaution</td>
<td>Special Warning</td>
<td>Storage condition</td>
<td>Specific Information:</td>
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<td></td>
<td>YES</td>
<td></td>
<td></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>

**Special Warning**

“Ya Antarai”

For dangerous drug

**Storage condition**

YES

**Specific Information:**

Source of porcine

Alcohol Content

**Warning for limited OTC(Over the counter Drug)**

YES

**With physician prescription only Specific round mark of prescription drug**

YES

**Route of administration**

YES

**Name and address of MAH**

YES

**Recomendation**

YES
3.2 Variation in drug labeling requirement in 9 ASEAN countries in strips and blisters:

<table>
<thead>
<tr>
<th>Blister/Strips</th>
<th>Philippines</th>
<th>Indonesia</th>
<th>Thailand</th>
<th>Singapore</th>
<th>Malaysia</th>
<th>Vietnam</th>
<th>Laos</th>
<th>Cambodia</th>
<th>Brunei</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product name</strong></td>
<td>Generic name has to appear above the generic name</td>
<td>Generic Name should appear under the brand name, 80% of the brand name</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>Bigger generic name</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Manufacturing Name and Address</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>Logo of the manufacturer</td>
<td>Name of the manufacturer</td>
<td>Name/Logo of manufacturer</td>
<td>YES</td>
<td>Name/Logo of Manufacturer/Product Owner</td>
</tr>
<tr>
<td><strong>Registration Number</strong></td>
<td>YES</td>
<td>YES</td>
<td>-</td>
<td>NA</td>
<td>-</td>
<td>-</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Batch Number</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>-</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Expiration Date</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Name of active Ingredient</strong></td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
</tr>
<tr>
<td><strong>Storage condition</strong></td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Exempted for small ampoule and vial.

CONCLUSION:
ASEAN consists of ten member countries and now a day’s ASEAN countries follow harmonized regulations, registration process and following ASEAN guidelines to fulfill the local regulatory requirement for the registration of the medicinal product. ASEAN have harmonized the ACTD requirement but there are some other requirements which used to vary from country to country. Labeling is one of the important parts of a dossier and a drug product packaging. Appropriate drug labeling is a norm which provides comprehensive concise statement of a drug’s safety, quality and efficacy. Effective medicinal products is directly proportional to the health gains in health around a country and labeling is an important asset which helps to give the information to the user about the drug’s quality, safety and efficacy. As there is no harmonized medicinal product guideline for labeling in the ASEAN region, so each country having its own specific labeling requirement.

In this paper we are trying to give an overview on drug labeling requirement of blister/strip and unit carton of medicinal products which used to varying among the ASEAN countries*.

When any applicant is going to submit an ACTD format to any country among the ASEAN region he/she can refer this paper in order fulfill labeling requirement for BLISTER/STRIP and UNIT CARTON.
Reference:
2. Drug product labeling in ASEAN countries.
   http://www.ipophil.gov.ph/images%5Cenforcement%5CRA3720Foods_Drugs_Devices_and_Cosmetic_Act.pdf, 12th Nov, 13
4. Labeling requirement of medicinal product in Singapore
5. Drug labeling requirement in Medicinal product registration in Singapore
7. Drug labeling requirement in ASEAN countries
   https://www.google.co.in/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CCsQFjAA&url=http%3A%2F%2Fportal.bpfk.gov.my%2Fview_file.cfm%3Ffileid%3D126&ei=GF97UoXFMISJrQfIpoGICw&usg=AFQjCNEI6mDsdfbPzBw9YRCOnQyOeW8gwg&bvm=bv.56146854,d.bmk 18th November, 13
8. Requirements for labeling materials of categories of pharmaceutical products containing four or more active ingredients outside the coverage of a.o. 85 s. 1990.

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