PART V

EAC GUIDELINES ON FORMAT AND CONTENT OF LABELS FOR PHARMACEUTICAL PRODUCTS

1. GENERAL REQUIREMENTS

(a) The Label Text

Particulars in the label shall be easily legible, clearly comprehensible and indelible.

(b) Conformity with the Summary of Product Characteristics

The label text should be in conformity with the summary of products characteristics.

(c) Language

The labelling must be presented at least in English and any other language as may be required by the EAC Partner State(s) where the product is placed on the market. If more than one language is used, then all of the text must be in each language and the overall readability should not be adversely affected. The content of all language versions must be identical. It is recommended to group different text elements for each language, where appropriate.

(d) Products with different strengths

Container labels may look similar across multiple strengths of the same product or across multiple products within a company's product line.

Product labels for medicinal products with multiple pharmaceutical strengths, within a manufacturer's product line, should be designed such that the products are identifiable and can be significantly differentiated from one another. Colour differentiation on product labels should be an effective tool that can differentiate products within a manufacturer's product line.

When applying differentiating colour, the applicant should ensure that the text highlighted by the differentiating colour has adequate colour contrast against the background colour on the container label.

(e) Label layout and artwork

Images, pictograms and other graphics may be used to aid comprehension of the information on the labels of non-prescription medicines only and not on the container labels of prescription medicines.

Images, pictograms and other graphics should exclude any element of a promotional nature and should only be used to aid navigation, clarify or highlight certain aspects of the text and should not replace the actual text.

The overall layout should not be misleading or have any inappropriate connotations in a way that no doubt about the meaning of a particular pictogram will be perceived.

2. PARTICULARS TO BE INCLUDED ON THE LABEL

(a) Outer packaging or, where there is no outer packaging, on the immediate packaging

The label should include at least the following:

i. Proprietary Name where applicable
ii. International Non-Proprietary name(s) of the Active Pharmaceutical Ingredient(s)
iii. Amount of each Active Pharmaceutical Ingredient present in a dosage unit
iv. List of excipients known to be a safety concern for some patients, e.g. lactose, gluten, metabisulfites, parabens, ethanol, or tartrazine. For parenteral and topical preparations, all excipients should be listed.
v. Pharmaceutical form and contents of the container, e.g. number of dosage units, weight or volume.
vi. Method and route(s) of administration and the statement “Read the patient information leaflet before use.”
vii. Special warning that the medicinal product must be stored out of the reach and sight of children (“Keep out of the reach and sight of children”).
viii. Other special warnings and handling precautions, if necessary (e.g. in case of specific toxicity of the agents)
ix. The word “sterile” if the product is sterile
x. Batch number assigned by the manufacturer
xi. The manufacturing date
xii. The expiry date
xiii. Special storage conditions, if applicable
xiv. Special precautions for disposal of unused medicinal products or waste material derived from such medicinal products, if appropriate
xv. The name and address of the Marketing Authorization Holder in the EAC
xvi. Physical address of the site responsible for release of the finished product
xvii. Advice on general classification for distribution, e.g., Controlled Medicines, Prescription Only Medicines, Pharmacy Only Medicines, Over-the-Counter and General Sales List
xviii. Instruction on use
xix. The proprietary name, strength and expiry date in braille (Marburg Medium)
xx. A unique identifier (example a product specific barcode, unique code or registration number issued by NMRA).

(b) Guidance for Small Containers

For containers of less than or equal to 10 ml capacity that are marketed in an outer pack such as a carton, and the outer pack bears all the required information, the immediate container should contain at least these minimum information (added):-

i. Brand Name of the FPP, INN name, strength, pharmaceutical form, active substance(s) and route(s) of administration
ii. Method of administration
iii. Batch number assigned by the manufacturer
iv. Expiry date
v. Manufacturing date if space is enough
vi. Contents by weight, by volume or by unit
vii. The name and address of the manufacturing site— or a logo that unambiguously identifies the company.
viii. Directions for use, and any warnings or precautions that may be necessary

(c) Guidance for Blisters and Strips

Blisters and strips should include, as a minimum, the following information (printed directly):-

i. Name, strength and pharmaceutical form of the FPP.
ii. Name and physical address of the manufacturing site (the site responsible for release of the finished product)
iii. The batch number assigned by the manufacturer
iv. The expiry date [Note that for co-blistered products, the expiry date is that of the product which expires first.]
v. The manufacturing date, if space is enough
vi. The batch number assigned by the manufacturer
vii. Directions for use, and any warnings or precautions that may be necessary.

(d) Additional Labelling Information Required by Some Partner States

Partner State NMRAs may require the use of certain forms of labelling making it possible to indicate:

i. Price of the medicinal product;
ii. The reimbursement conditions of social security organisations;
iii. Identification and authenticity;
iv. A statement that the product is a property of government

The information specific to a Partner State NMRA should be accommodated on the label in a box, to appear on one side of the pack. Each box should only be presented in the official language or languages of the Partner State concerned and should state the name of that Partner State.

3. CONTROL OF THE CONFORMITY OF THE LABELLING

The labelling of the medicinal product forms part of the authorization and it must, therefore, be approved by the NMRA when the authorization is granted.

4. CHANGES TO THE LABELLING

Any changes to the labelling, which are not connected with the Summary of Product Characteristics, shall be notified to the NMRA where the authorization is granted. Therefore, if a Marketing Authorization Holder wishes either to introduce any label text additional to that in the decision or to change any aspect of the labelling, he must first notify this change to the relevant mentioned NMRA, who shall inform the Marketing Authorization Holder whether the proposed change is accepted or not.