National Agency for Food & Drug Administration & Control (NAFDAC)

Drug Registration & Regulatory Affairs (DR & R) Directorate

LABEL GUIDANCE FOR PHARMACEUTICAL PRODUCTS

LABELS

1. OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

Labelling should include at least the following:

1. The name of the medicinal product (FPP), strength (amount of each API present in a dosage unit), list of API(s) (using INNs if applicable), pharmaceutical form.
2. List of excipients known to be a safety concern for some patients, e.g. lactose, gluten, metabisulfites, parabens, ethanol, or tartrazine.
   Consult European Commission (EC) guideline "Excipients in the Label and Package Leaflet of Medicinal Products for Human Use" for further guidance.

For parenteral and topical preparations, all excipients should be listed.

3. Pharmaceutical form and contents of the container, e.g. number of dosage units, weight or volume.
4. Route(s) of administration and statement "Read the patient information leaflet before use."
5. 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").
6. Other special warnings and handling precautions, if necessary (e.g. in case of specific toxicity of the agents)
7. The expiry date in an un-coded form. This should be in digital format (12/2016 or 2016 12), since other conventions where the month is indicated alphabetically
   Expiry Dates written in alphabetical format e.g. 2018 DEC is not acceptable as this is not internationally understandable.
8. Special storage conditions
9. Special precautions for disposal of unused medicinal products or waste material derived from such medicinal products, if appropriate
10. The name and address of the supplier manufacturer. The details of the applicant if different from the manufacturer can be stated.
11. The batch information (i.e. batch number, manufacturing and expiry dates) assigned by the manufacturer.
12. (Advice on) general classification for supply (e.g. "Medicinal product is subject to medical prescription." or "Medicinal product not subject to medical prescription."

For Over-The-Counter Products (OTC)

In addition to the requirements above, OTC Labels should include;

13. Directions for use of the medicinal product (How to Take the Medicine).

14. Indications for use of the medicinal product.

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 need only contain:

1. Name of the FPP (i.e. (Invented) name, strength, pharmaceutical form), active substance(s) and route(s) of administration.
2. Route of administration
3. Manufacturing Date
4. Expiry date
5. Batch number
6. Contents by weight, by volume or by unit
7. The name and address of the supplier (i.e. the manufacturer) if space permits otherwise the name of the manufacturer should be stated or a logo that unambiguously identifies the company.
8. Directions for use, and any warnings or precautions that may be necessary

2. FOR BLISTERS AND STRIPS

Blisters and strips should include, as a minimum, the following information:

1. Name, strength and pharmaceutical form of the FPP
2. Name of the supplier (i.e. the manufacturer)
3. Manufacturing date in un-coded form.
4. Expiry date in an un-coded form. [Note that for co-blistered products, the expiry date is that of the product which expires first.]
5. Batch number assigned by the manufacturer
6. Directions for use, and any warnings or precautions that may be necessary.