

GUIDELINES FOR THE LABELS OF PRESCRIBED MEDICINES

As envisaged in the FIP Guidelines for Good Pharmacy Practice (Tokyo 1993) with regard to the supply and use of medicines, all pharmacists should contribute to Good Labelling of Prescribed Medicines (GLPM). Member Associations should adapt these guidelines to their national circumstances.

The purpose of a label for a prescribed medicine is:

- To describe and identify it
- To contribute to optimal therapeutic outcome and to avoid medication errors
- To achieve appropriate handling and storage
- To allow the product to be traced if there are problems with either the manufacturing, prescribing or dispensing process

Prescribed medicines are those that are prescribed for a specific patient, irrespective of their legal status as prescription-only or non-prescription medicines.

Label information for prescribed medicines should be considered to supplement and reinforce oral communication between the patient and healthcare provider.

The guidelines and recommendations relate only to the labels of the inner and outer container of the prescribed medicine, as seen by the patient before taking the medicine. They do not cover medicines taken or administered under the direct control of health professionals, nor do they cover patient package leaflets.

Individualised Primary Patient Information

As a prescribed medicine is for a specific patient, recommendations from the FIP Working Group on Labelling describe individualised primary patient information in Appendix-1 to this document.

These recommendations are applicable, whether the dispensing process is from bulk packs or by using individual patient prepacks supplied by a manufacturer.

Good Labelling of Prescribed Medicines - GLPM

The FIP Working Group on Labelling evaluated the label elements for Good Labelling of Prescribed Medicines (GLPM). Their recommendations are shown in Appendix 2 to this document. The presentation of label elements is important for patient understanding.

Minimum Labelling - GSD

In many countries, there is no legislation on product labelling and current conditions do not allow GLPM to be achieved. Therefore, FIP considers it necessary to define an absolute minimum of information for labels of prescribed medicines as follows:

- Generic name
- Strength of medicine
- Individual Dosage Instructions

The route of administration should be stated if other than oral. This absolute minimum of information is termed GSD.

Design and Readability

On individual patient prepacks, the design of the manufacturer's label should allow the addition of the pharmacy label without covering important patient information.

Primary patient information elements should be adjacent to each other so that they can be read at a glance and should not be distributed amongst the remaining text. There should be a "patient side" reserved for primary patient information with a clear blank space for the pharmacy label.

Any information that is not primary information should appear on the other sides of the container.

- Pharmacy labels should be printed or typewritten. Print size should be a minimum 2 mm type size and in a clear font, such as Arial. The print should not fade when exposed to water or sunlight. Manufacturers' labels should fulfil established criteria for good readability.
- Abbreviations and unfamiliar expressions should not be used, especially for the indications for use and dosage instructions.
- Graphic symbols for patient instruction should not be used alone but should always be combined with written instructions.

FIP calls on Member Associations to incorporate the above guidelines in their national standards of Good Pharmacy Practice, having regard to the recommendations of the FIP Working Group on Labelling.

Appendix 1

Recommendations from the FIP Working Group on Labelling Individualised Primary Patient Information

Pharmacies/dispensing agencies should individualise the pack of the prescribed medicine by use of a pharmacy label.

Prescribed medicines are personal medicines. Many medicines can be used for a variety of illnesses and in a range of doses. The indication or intended use and dosage instructions are information generated for the specific patient by his/her prescriber.

Whenever practical, individualised information should be put on the inner packaging.

Primary patient information should be easy for the patient, especially the elderly patient, to read. It is the critical information to be read and understood before the patient starts taking the medicine. Therefore, it should not be broken up amongst any supplementary information that is less important to the therapeutic situation.

Primary patient information elements are:

General information:

- Name of medicine
- Strength
- Warnings and directions for use (if necessary)

Individualised information:

- Name of patient
- Dosage instructions
- Indication or intended use

A common format is recommended for primary patient information.

Appendix 2

Recommendations from the FIP Working Group on Labelling

Good Labelling of Prescribed Medicines- GLPM

The following label elements, in no particular order of priority, are considered optimal for Good Labelling of Prescribed Medicines (GLPM):

- Product name
This may be the generic name
- Generic name of active ingredient(s)

Preferably adjacent to the product name. The International Nonproprietary Name (INN) should be used, and the chemical form relevant to the strength.

- Strength

Expressed in numerals and units as part of the product name for each active ingredient.

- Dosage form

- Route of administration

- Total quantity in the package

(e.g. number of tablets, ml of liquid)

- Individual dosage instructions

As stated or agreed with the prescriber

- Individual indication or intended use

As stated or agreed with the prescriber

- Batch identification

This is applicable to both bulk dispensing or original packs

- Expiry date

Expressed as a "use before" date. If the medicine has a limited shelf life once the package is opened, this should also be on the label

- List of excipients

All excipients of medical relevance

- Any special instructions for use

For example "Do not chew", "Take with a meal"

- Any special storage instructions

For example "Store between 2-8 °C", "Keep out of sunlight"

- Any special warnings or precautions

For example "Do not drink alcohol", "This medicine may make you feel sleepy"

- Name of the prescriber

- Name of the patient

- Machine readable bar code

To reduce medication errors

- Name of marketing authorisation holder

- Name of the pharmacy/dispensing agency

- Date of dispensing