

1. The pharmaceutical industry

The pharmaceutical industry aims to guarantee patient safety by producing a safe product which has been tested according to the highest standard of current scientific knowledge and which is approved by the authorities. Product safety refers to all components and aspects of a medicine:

- The active ingredient
- All auxiliary components
- Packaging
- Labelling
- Product information

In most cases, medicines require detailed additional information to ensure their safe use. Safe use depends among other important factors first on the ability of patient to read and understand the information on the packaging carefully and accurately as a prerequisite to acting accordingly. Therefore it is important to emphasise that medicine packaging and labelling must allow an unmistakable identification of the medicine and inform clearly about the conditions for its safe use.⁷⁻⁹

Further, it is increasingly important to be able to determine that the medicine is authentic, as the counterfeiting of medicines becomes an escalating problem. The need to determine authenticity has an impact on several steps of the manufacturing process of medicines, including packaging design, labelling, product naming, and packaging information development.

Packaging design

Recently, it has been stated that simple changes concerning format and style of design can make medicine packaging safer for patients.¹⁰ These changes which can be summarised as follows:

- INFORMATION: Certain items of information are vital for the safe use of the medicine and are mandatory per legislation and regulations.
- FORMAT: The information must be presented in a intelligible manner that is easily understood by all those involved in the supply and use of the medicine.
- STYLE: There is potential for confusion between both similarity in drug names and similarity in medicine packaging. The different user contexts, such as in homes and workplaces, pharmacies, hospital wards, and care homes, are of particular importance to how the packaging is styled. *Thea Swayne* points out that "design solutions that assist pharmacists to choose the correct pack from crowded shelves may not necessarily make it easy for a vision impaired older patient, for instance, to take the right medication at the right time. The challenge is to address multiple issues in a single design, and this is why user research is an essential component of patient-centred design, as emphasised in the MHRA guidance document."¹⁰

Another factor not yet addressed here, but important from a patient's point of view, is the way a medicines package can be opened for use, as many patients will have problems with tamper-safe bottles, blister packages, etc.

Labelling

The purpose of a label for a prescribed medicine is¹¹:

- To describe and identify the medicine
- 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

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

The working group encourages a regular and systematic review of product labelling and packaging by regulatory authorities and manufacturers with a specific aim of minimising medication errors.

The packaging and labelling of prescribed medicines should be designed with a view to minimizing errors in selection and use:

- Important information for the patient relating to the safe and effective use of the medicine should be prominent and in one section of the label.
- Patient information leaflets, produced either by the manufacturer or dispensing pharmacist, should be provided with all medicines when they are supplied to the patient.
- The largest print and type size on the label should be used for name and strength of the medicine
- When colour is used it should be designed to improve visual definition by way of contrast not to give priority to corporate design. Colour coding should not be used to indicate, for example, increasing strength.
- I.V. and other injectable products present more significant problems and require special attention in labelling. For example, all labels on containers for intravenous injections should indicate the total amount of active ingredient(s) in the container.
- Adequate space should be provided for the addition of a patient-specific label in the pharmacy.

In many countries, there is no legislation on product labelling and current conditions do not allow guidelines for labelling of prescribed medication to be achieved. Therefore, the working group considers it necessary to define an absolute minimum of information for labels of prescribed medicines which applies to medicines manufactured either by the pharmaceutical industry or the pharmacy:

- Generic name
- Strength of medicine
- Individual dosage Instructions
- Expiration
- Name of the patient (added when the medicine is dispensed in the pharmacy)

Naming (trade marks and generic names)

The working group encourages the following be considered in naming medicines:

- Names similar to those of other medicines on the market should be avoided. Regulatory authorities should consider this aspect of brand names when considering the granting of marketing authorisations.
- To aid practitioners in distinguishing between products which are already on the market, where the likelihood of confusion of names exists, innovative labelling should be used.
- If a medicine is a branded product, the generic name should appear prominently in close proximity to the brand name wherever it appears.

Machine-readable coding (e.g. bar coding) should be employed on labelling of all medicines. F.I.P. recognises the importance of standardisation of these codes for this use.

Package information leaflets

To make sure that patients understand the information given in a package information leaflet, readability testings with the target population groups should be performed. Such testings have been mandatory in the European Union since October 2005.¹²

The working group recommends that FIP encourage pharmaceutical companies to focus on the safety of medicines right from the stage of research and development. Their packaging designers should adopt best practices in graphic and information design. Furthermore, FIP should work for a better understanding among medicines regulators about the way good graphic design on medicinal product packaging can enhance patient safety, and how poorly designed packaging may compromise patient safety through medication errors and adverse drug reactions.¹¹

FIP should also encourage developing country regulators to insist on patient information leaflets for all medicines and should work with the pharmaceutical industry in ensuring that all medicines in all parts of the world are, as much as possible, in patient packs with understandable patient information leaflets bearing in mind language and cultural sensitivities.