

# PATIENT INFORMATION LEAFLETS

- A document providing additional information about the dosage forms or drug product.
- The purpose: inform patients about the administration, precautions and potential side effects of prescribed medication.
- gives the patient confidence in using the medication
- improves the overall experiences of the patient.
- Remind the patient the information told by the Health Care Provider.
- PIL's are especially important for chronic diseases and complex disorders

Ex: Hypertension, Asthma and Diabetes.

- heavy work load of HCP.
- Patient may not retain verbal information
- improves patient compliance.
- PIL's are essential for OTC drugs

## **Content**

- IDENTIFICATION OF THE MEDICINE
- THERAPEUTIC INDICATIONS
- INFORMATION NECESSARY BEFORE TAKING THE MEDICINE
- DOSAGE
- DESCRIPTION OF SIDE EFFECTS
- ADDITIONAL INFORMATION

## **IDENTIFICATION OF THE MEDICINE**

- The name,
- The active substance(s),
- The pharmaceutical form,
- Strength of the product

## **THERAPEUTIC INDICATIONS**

- The conditions for which the medicine is authorised must be listed.
- This section should include any benefit information considered appropriate

## **INFORMATION NECESSARY BEFORE TAKING THE MEDICINE**

- Situations where the medicine should not be used,
- any precautions,
- warnings,
- interactions with other medicines or foods,
- information for special groups of patients (pregnant or nursing mothers),
- effects of medicine on the patient's lifestyle.

## **DOSAGE**

- How to take or use the medicine
- route and method of administration,
- how often it should be given,
- how long the course of treatment will last,
- what to do if a dose is missed and if relevant
- what do in the event of an overdose
- risk of withdrawal effects.

## **DESCRIPTION OF SIDE EFFECTS**

- effects which may occur under normal use of the medicine
- what action the patient should take if any of these occur.
- These should be listed by seriousness and then by frequency.

## **ADDITIONAL INFORMATION**

- excipient details,
- a description of the product,
- registered pack sizes,
- storage conditions,
- name and address of manufacturer.

### ***Key Points***

- *Complex language and medical terminology cause difficulty in understanding*
- *Translate all the information into layman language*
- *Use short sentences and/or bullet points*
- *Side effects should be grouped by seriousness to enable patients to understand when to take action and what that action should be taken*

### **Design and Layout**

- Good readability, layout and design: important
- Flesch-Kicaid reading ease (FRE) score: used to assess readability of a written text.
- Baker Able leaflet design (BALD) criterion is used for good design characteristics of an information leaflet.

### ***Information Design***

- makes complex information easy to understand

### ***Information Architecture:***

- The way information is arranged
- Making the information easy to use is an important output from this.

### ***Typography:***

- designing with type in order to communicate a message.

### ***Clear Language:***

- This is already a legal requirement for PILs.

### ***Information for the healthcare professional***

- need to be presented in a separate tear-off portion of the leaflet
- address the issues which they need to be aware of whilst administering the medicine.

### **Key information for the patient:**

#### ***Helping patients navigate the information:***

- place headings and sub-headings

### **Other factors to consider**

- use of colour, symbols and pictograms
- For external use only:
- Not to be taken by (route):
- Potential interaction with food or drink:
- Potential interactions with medication:
- Special methods of Administration: (S/L)
- Caution in use:
- Pregnancy and lactation: