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A PROPOSAL FOR NEW EASY-TO-READ MEDICATION GUIDE FOR PATIENTS & IT'S PATIENT MEDICATION INFORMATION

JYOTHI N[1], SHUBHASHAYA K H[2] AND ABHISHEK B V[3]

1: M Pharm, Department of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy, B G Nagara, Karnataka, India

2: M Pharm, Department of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy, B G Nagara, Karnataka, India

3: Assistant Professor, Department of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy, B G Nagara, Karnataka, India

***Corresponding Author: Ms. Jyothi N: E Mail: njyothibharathi@mail.com**

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ABSTRACT

The US Food and Drug Administration (FDA) is developing a new framework to provide patients with quality, up-to-date prescription product information that will promote the safe use of prescribed medication. The primary goal is to provide patient-oriented information for each prescription product. The efforts of FDA is to ensure that patients receive essential prescription medication information, the concept of creating easy-to-read medication guides has gained prominence, To tackle this issue, FDA proposing to require a new type of Medication Guide called Patient Medication Information for prescription drugs and certain biological products (both brand name and generic) used, dispensed, or administered on an patient, A Medication Guide is a type of patient labeling found in **the 21 CFR 208** prescription drug labeling that has been approved by the FDA. The FDA provides informational materials in the form of paper leaflets known as **Patient Package Inserts (PPI), Medication Guides (MG), and Instructions for Use (IFU)** that

are packaged with many prescription drugs. Creating effective easy-to-read medication guides requires collaboration between healthcare professionals, pharmacists and patient.

Keywords: FDA, Patient Medication Information, Medication Guidance, 21 CFR 208

INTRODUCTION

Prescribing Information: FDA-approved Prescribing Information (PI), often referred to as United States Prescribing Information (USPI), provides FDA's conclusion regarding the safety and efficacy of the human prescription medicine when used in accordance with the parameters specified on the label **[1]**. The PI is written for healthcare professionals and must:

1. Provide an overview of the key scientific knowledge required for the safe and effective use of the human prescription drug;
2. Be accurate and informative; and
3. Be updated whenever new information becomes available that could lead to labeling that is no longer accurate, true, or misleading.

Formats for the prescribing information.

There are two formats for the prescribing information (PI):

- The previous (non-PLR) format and
- Physician Labelling Rule (PLR) format

Advantages of PLR

1. It represents a more practical and up-to-date method of disseminating accurate and current information on the safe and effective use of medications;
2. It decreases the number of adverse reactions resulting from medication errors caused by incorrectly understood or applied drug information; and
3. It increases the accessibility of PI for use with electronic prescribing tools and other electronic information resources **[2]**.

Objective: To access essential medication information for patients in US.

DISCUSSION

Table 1: Regulations

S. No.	Regulation	Description of regulation
1	21 CFR 201.56	General requirements on the content and format of PLR format labeling and "old" format (non-PLR) labeling
2	21 CFR 201.57	Specific requirements on content and format of PLR format labeling for human prescription drugs
3	21 CFR 201.80	Specific requirements on content and format of "old" format (non-PLR) labeling for human prescription drugs
4	PHYSICIAN LABELING RULE	Final rule revised the content and format of Prescribing Information (PI) for human prescription drugs

Table 2: Guidance Documents

S. No.	Guidance Documents	Issued date
1	Best Practices in Developing Proprietary Names for Human Prescription Drug Products	December 2020
2	Cross labeling oncology drug in combination regimens	November 2022
3	Labeling of human prescription drug and biological products – implementing the PLR content and format requirements	February 2013
4	Medical product communication that are consistent with the FDA-required labeling – questions and answers	June 2018

Patient Medication Use:

The FDA-approved prescription medicine labeling for a biologics license application (BLA), a new drug application (NDA), or an abbreviated new drug application (ANDA) includes the Instructions for Use (IFU). The IFU is created by applicants for users of prescription medications who need to follow sophisticated or in-depth patient instructions.

For the patient, the IFU offers comprehensive, action-oriented, step-by-step written and visual instructions on how to use the medication, including guidance on administration, handling, storage, and disposal. The FDA reviews and approves the IFU before it is created by the applicant and distributed to patients (or their caretakers) at the time the medicine is dispensed. The FDA has not given its approval to all IFUs **[3]**.

Example:

INSTRUCTIONS FOR USE
MYDRUG [mye-drug]
(drugoxide injection)
for intramuscular use

This Instructions for Use contains information on how to take MYDRUG.

Important Information You Need to Know Before Taking MYDRUG
…
Preparing to Take MYDRUG
…
Taking MYDRUG
…
Storing MYDRUG
…
Disposing of MYDRUG
…

Drug Company X, City, State, zip code

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Approved: MM/YYYY

Figure 1: Template for patient medication use

Medication Guides:

When the FDA determines that patient labeling could help prevent major adverse reactions, a Medication Guide is included in the FDA-approved prescription drug labeling for those specific prescription medications **[4]**.

- Patients should be made aware of any significant risks associated with the drug since they may influence their decision to use, continue using, or tolerate the medication.
- The success of the medication depends on patient adherence to the recommended dosage.

MEDICATION GUIDE
DRUG-X [drug X]
(drugimab-cznm)
injection, for intramuscular use

What is the most important information I should know about DRUG-X? …
What is DRUG-X? …
Who should not take DRUG-X? …
Before taking DRUG-X, tell your healthcare provider about all of your medical conditions, including if you: …
How should I take DRUG-X? …
What should I avoid while taking DRUG-X? …
What are the possible side effects of DRUG-X? … Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
How should I store DRUG-X? …
General information about the safe and effective use of DRUG-X. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DRUG-X for a condition for which it was not prescribed. Do not give DRUG-X to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DRUG-X that is written for health professionals.
What are the ingredients in DRUG-X? Active ingredients: Inactive ingredients:
Manufactured for: Manufactured by:

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: MM/YYYY

Figure 2: Template for medication guides

MG resources include:

- MG regulations available at: 21 CFR 208
- Medication Guides - Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS) **[5]**.

SUMMARY AND CONCLUSION

In response to the growing need for clear and accessible prescription medication information, the US Food and Drug Administration (FDA) has taken steps to develop a comprehensive framework. This framework aims to provide patients with high-quality and up-to-date information about their prescribed medications, with the ultimate goal of promoting the safe and effective use of these products.

Central to this effort is the creation of patient-oriented information for each prescription product. Recognizing the importance of ensuring patients receive essential information about their prescription medications, the FDA has highlighted the significance of creating user-friendly medication guides. These guides are intended to provide patients with clear instructions and essential information to help them use their medications safely and effectively.

The FDA is proposing the introduction of a new category of Medication Guide, known as the Patient Medication Information. This guide will encompass prescription drugs and certain biological products, both brand name and generic, that are used, dispensed, or administered to patients. Medication Guides are a type of patient labeling that has received FDA approval, and they are specified in the 21 CFR 208 prescription drug labeling.

The FDA has also developed various informational materials, including Patient Package Inserts (PPI), Medication Guides (MG), and Instructions for Use (IFU). These materials are provided in the form of paper leaflets that are packaged with many prescription drugs. The focus is on making these materials easy to understand for patients, and achieving this goal necessitates collaborative efforts involving healthcare professionals, pharmacists, and patients themselves.

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CONFLICT OF INTREST

The authors declared that there is no conflict of interest.

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