U.S. FOOD & DRUG ADMINISTRATION

Proposed Rule Snapshot for Patients

Medication Guide: Patient Medication Information (PMI), Proposed Rule

Why is this proposed rule important for patients?

The primary goal of the Medication Guide: Patient Medication Information (PMI) proposed rule is to improve public health. The rule would provide patients with clear, concise, accessible, and useful written information about their prescription drug products and blood and blood components dispensed or transfused on an outpatient basis. The information would be delivered in a consistent and easy-to-read format and is intended to help patients use their prescription drug products safely and effectively.

What does the proposed rule require?

The proposed rule requires applicants[1] to prepare a new type of FDA-approved Medication Guide for prescription drug products[2] used, dispensed, or administered in an outpatient setting. The proposed rule also requires the creation and distribution of a Medication Guide for blood and blood components transfused on an outpatient basis.

What content would the PMI have?

The proposed PMI must be made available in a printed copy and, if the patient prefers, can be made available in a digital format. PMI would be a one-page document with the following headings:

- Drug Name
- Important Safety Information
- Common Side Effects
- Directions for Use

See page 3 for an example of a proposed PMI.

FDA refers to the new Medication Guide as PMI. PMI would be stored in an online database managed by FDA and would be freely accessible to the public. PMI would replace two types of FDA-approved patient information: Patient Package Inserts (PPIs) and current Medication Guides. PMI would not replace the Prescribing Information, Instructions for Use, or patient counseling.

[1] As defined in part 314.3 in Title 21 of the Code of Federal Regulations (CFR), an applicant is any person who submits a New Drug Application (NDA), Biologics License Application (BLA), or an Abbreviated New Drug Application (ANDA) to FDA for approval of a new drug. An applicant is also any person who owns an approved NDA or ANDA.

[2] A prescription drug product also includes a biological product licensed under the Public Health Service Act.

A Proposed Rule Snapshot is a communication tool and is not a substitute for the proposed rule. To learn more about Patient Medication Information (PMI), read the proposed rule. To read other Snapshots, visit the Guidance Snapshot Pilot page.

When would a patient receive PMI?

Patients would receive PMI from an authorized dispenser on an outpatient basis. Outpatient settings include retail pharmacies, hospital ambulatory care pharmacies, and places where prescription drugs are dispensed by a health care provider who administers it to the patient. Outpatient settings for blood or blood products include dialysis centers.

An authorized dispenser is an individual(s) or entity who is licensed, registered, or otherwise permitted to provide prescription drug products in the course of professional practice. Authorized dispensers may be pharmacists, physicians, nurses, or other licensed health care providers legally permitted under state law to provide prescription drug products to patients.

What are the benefits of the proposed PMI for patients?

Once finalized, the proposed rule PMI would offer the following benefits:

- ☑ Improve public health by providing patients with clear, concise, accessible, and useful patient information.
- ☑ Highlight key information in a patient-friendly manner to help patients use their prescription drugs safely and effectively.
- ☑ Provide information on a single sided printed document with key information clearly outlined. On the page, the headings used would be the same across all drugs to make it easier for patients to find the information they are looking for.
- ☑ In addition to the paper format, offer patients an option to receive PMI in an electronic format.

What is a proposed rule?

Rules, also referred to as regulations, are made by federal agencies such as FDA. A regulation is a general statement issued by an agency, board, or commission that has the force and effect of law. Federal regulations are created through a process known as "rulemaking." The rulemaking process is governed by U.S. laws, and these laws grant FDA the authority to issue a rule.

U.S. law requires the publication of a new regulation in the *Federal Register* so that people or organizations interested in or affected by the rule—including the public—can comment on the proposed rule. After this public comment period ends, FDA reviews the comments received. FDA may continue with the rulemaking process and issue a final rule. The final rule explains the regulatory requirements, or the codified portion of the final rule, and is published in the Code of Federal Regulations. In lieu of a final rule, FDA may issue a new or modified proposal or withdraw the proposal.

To learn more about the regulatory process, visit Regulations.gov or watch *The Rulemaking Process: A Primer by FDA*.

What are Medication Guides?

Medication Guides are written information about prescription drug products. They are required for certain types of drug products to allow patients to use their drugs safely and effectively.

The proposed PMI would be a new type of Medication Guide. In time, the proposed PMI would replace PPIs and existing Medication Guides that exist for certain prescription drugs.

Example of a Proposed PMI

PMI would need to comply with the content and format requirements set forth in the regulation. There are different approaches that may meet the requirements. The PMI example shown here is for a fictitious drug and is one possible approach that would meet the requirements set forth in the proposed rule. If FDA were to issue the final rule, the requirements for PMI may remain the same as in the proposed rule (shown here) or may differ. Therefore, if FDA were to issue the final rule, applicants would need to comply with the requirements in the PMI final rule.

PATIENT MEDICATION INFORMATION
RHEUTOPIA (roo-toh-pee-ah) (arixalate injection, for subcutaneous use)

RHEUTOPIA Is:
- Used to treat rheumatoid arthritis in adults. RHEUTOPIA reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Used to treat polyarticular juvenile idiopathic arthritis in children at least 4 years old who did not have good results from other medicines. RHEUTOPIA reduces pain, improves mobility, and decreases the number of painful joints.
- Used to treat ankylosing spondylitis. RHEUTOPIA reduces back pain, swelling, and improves mobility.
- Used to treat plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). RHEUTOPIA improves or clears up areas of skin with psoriasis.

Important Safety Information

Warnings:
- RHEUTOPIA can cause serious infections. Do not use RHEUTOPIA if you have an active infection.
- Do not use RHEUTOPIA if you are allergic to arixalate or any of the ingredients in RHEUTOPIA.

Serious side effects:
RHEUTOPIA can affect the immune system and lower your ability to fight infection. People taking RHEUTOPIA have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Stop using RHEUTOPIA and call your health care provider right away if you develop:
- Fever, cough, flu-like symptoms, or a skin infection (red, warm, painful skin or open sores).
- Numbness, tingling, weakness, vision problems, or dizziness
- Chills, swollen lymph nodes, night sweats, fever, or weight loss
- Bruising, bleeding, and pale skin
- Shortness of breath, swelling of ankles or feet, or sudden weight gain
- Chest discomfort or pain, shortness of breath, joint pain, or a rash on your cheeks or arms

Tell your health care provider before taking:
- If you have an infection, are being treated for an infection, or think you have an infection (such as cold, flu, or skin infection)
- If you have TB or have been near someone who has TB
- If you have any nervous system or heart problems
- If you have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot)
- If you have lived in or traveled to other countries
- If you are taking the medicine Kineret (anakinra)

Common Side Effects
The most common side effects in adults and children include:
- Headache
- Runny nose
- Redness, rash, swelling, itching, or bruising where the injection (shot) was given

These are not all of the possible side effects of RHEUTOPIA. Call your health care provider if you have side effects that worsen or do not go away. You may also report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use
- Use RHEUTOPIA exactly as prescribed. Your health care provider will tell you how often to use RHEUTOPIA.
- RHEUTOPIA is injected directly under the skin (subcutaneous). Do not use RHEUTOPIA until your health care provider has shown you how to give a shot.
- Store RHEUTOPIA in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.

Manufactured by: Drug Company Name, City, State Zip Code

The content of this Patient Medication Information has been approved by the U.S. Food and Drug Administration Revised: Month/Year

PMI in Brief

- ☑ PMI would be approved by FDA.
- ☑ PMI would highlight the essential information that patients need to know about their prescription drug product.
- ☑ Authorized dispensers would provide FDA-approved PMI to patients with prescription drug products used, dispensed, or administered on an outpatient basis.
- ☑ Patients would have a choice to receive PMI in paper or electronic format. Paper is the default method.

Proposed Rule Recap Podcast

Hear highlights straight from FDA staff

Speaker: Christopher Diamant, Regulatory Counsel, Office of Medical Policy, Center for Drug Evaluation and Research

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