# ⟨1265⟩ WRITTEN PRESCRIPTION DRUG INFORMATION—GUIDELINES

The purpose of these guidelines—comprising format, content, and accessibility of prescription drug leaflets—is to help ensure that leaflets are useful. In this context, "useful" means that recipients receive, understand, and are motivated to apply written information about their medicines to achieve maximum benefit and minimize harm. Dispensers, prescribers, health care providers who counsel patients about their medicines, and the patients themselves are intended to be the primary beneficiaries for these guidelines.

## CRITERIA (FROM THE KEYSTONE ACTION PLAN[1] )

Written prescription medicine information should be based on the following criteria:

1. Scientifically accurate,
2. Unbiased in content and tone,
3. Sufficiently specific and comprehensive,
4. Presented in an understandable and legible format that is readily comprehensible to consumers,
5. Timely and up-to-date, and
6. Useful.

## FORMAT GUIDELINES

1. Group all information from the same category, using brief, clear titles and bullets or subheadings as needed. Avoid symbols and subheadings not directly connected to the information they mark.
2. Be consistent in the placement and labeling of categories of information in all leaflets.
3. Provide information at the sixth-grade reading level or below, if possible (never above eighth-grade level). Do not exclude information to achieve a lower reading level.
4. Use simple, common, accurate terms (for example, use "noise in the ears", not "tinnitus").
5. Use direct language that avoids words with opposite meanings (for example, use "decrease blood pressure", not "increase low blood pressure effect").
6. Provide reasons for instructions (for example, "take with food to avoid upset stomach").
7. Emphasize the most important information. Clearly distinguish warnings from instructions or from other text that may be misinterpreted as warnings.
8. Accompany each pictogram, if used, with corresponding text placed close to the pictogram. Use the simplest pictograms possible. For pictograms intended to prompt patients to ask questions or inform health care providers, add text such as "Tell Doctor" or "Ask Pharmacist".
9. Make text readable by using 12-point or larger type, both uppercase and lowercase letters, an easy-to-read font (for example, a serif font), and adequate space between lines and paragraphs. To call attention to important information, use a larger, boldface type.
10. Evaluate format by performing tests of readability, comprehension, memory, problem solving, and behavioral efficacy and intention, using representative samples of the target population.

## CONTENT GUIDELINES

1. Provide enough detail to facilitate correct use, achieve maximum benefit, and minimize harm, including a statement that identifies activities (such as driving or sunbathing) that the patient should avoid.
2. Write text that is unbiased in content and tone and scientifically accurate. The uses described should be consistent with FDA-approved labeling or otherwise permitted by FDA, or should appear in federally recognized drug compendia. Distinguish unlabeled from labeled use.
3. For drugs sold under a brand name, provide both brand and generic names, and include a pronunciation guide for each.
4. Describe the drug and its dosage form. Include indications and contraindications, specific directions for use, what to do if a dose is missed, and what to do in the event of an overdose or poisoning.
5. Do not use abbreviations.
6. Indicate the intended type of benefit (for example, "cure", "prevention", "to help relieve symptoms"). Indicate how—and how soon—the patient should recognize the benefit and what to do if none is observed.
7. Give a balanced evaluation of risks and benefits.
8. List side effects, in order of severity, such as "serious", "most common", and other similar type groupings. It may not be appropriate to provide sufficient detail for the patient to be able to monitor serious or common side effects. Provide guidance to consult the doctor or pharmacist, and indicate that not all the side effects are listed.

[1] In December 1996, the "Action Plan for the Provision of Useful Prescription Medicine Information" was presented to the Secretary of Health and Human Services. The plan, commonly known as the "Keystone Plan," described certain criteria for written prescription medicine information. These criteria are described in detail in the action plan, which can be found at www.fda.gov/cder/offices/ods/keystone.pdf.

9. List sufficiently specific and comprehensive information that includes the provision of all important risk information. Patients should be advised to be sure to inform the provider about all the medicines they are taking.
10. Indicate the potential for therapeutic duplication if the drug is available under multiple names or over-the-counter, or if the active ingredient is contained in other products.
11. If known, include a statement concerning the safety of use in the presence of other conditions and during pregnancy or breast-feeding. Direct affected patients to discuss their condition with health care providers. If the safety of use during pregnancy or breast-feeding has not been established, say so.
12. State whether safety and efficacy have been established in pediatric, geriatric, and other special populations. Patients should be encouraged to discuss with their health care provider any recommendations for dosage adjustment.
13. Illustrate information with diagrams when appropriate. Label the diagram components (for example, device parts) if they are not obvious. The words on the label should be prominently placed thereon with such conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
14. Include the following:
    A. A statement that the product is to be used only by the person for whom it was prescribed,
    B. Storage information,
    C. A completeness disclaimer advising the patient to discuss this issue with the health care provider,
    D. The publisher of the leaflet and the date the leaflet was developed or revised,
    E. Sources of in-depth information and answers to questions, and
    F. Other relevant general statements.
15. The patient should be advised about risks of developing dependence on, or tolerance to, the medication.

## ACCESSIBILITY GUIDELINES

1. Write text that is relevant to the intended use of the drug.
2. Design the leaflets to be easy to recognize, consistent in format, and easy to store and retrieve.
3. Supplement the leaflets with oral counseling of patients, including children, the elderly, and caregivers.
4. Include a statement asking the patient to reread the leaflet.
5. Distribute the leaflets with all prescription medicines to consumers (namely, persons independently responsible for any aspect of medicine use or for giving medicines to others).
6. Produce leaflets in Spanish, English, or other languages; and establish criteria for producing them in other languages and for special populations (for example, children, visually handicapped) [NOTE—Ideally, prescription drug information leaflets would be customized for the patient's condition and for other relevant information (for example, gender, age, or physical limitations), and would be available in the patient's primary language. Currently, such customization is neither feasible nor practical, but it remains a goal.]