RxLegal

Expanding the Definition of Nonprescription Drugs: Potential Impact on Pharmacists

*Michael Gabay, PharmD, JD, BCPS**

In March 2012, the US Food and Drug Administration (FDA) held a public hearing regarding a proposed “new paradigm” where the FDA would move toward approving certain medications that normally require a prescription to nonprescription status under conditions of safe use.¹ These conditions of safe use, which could involve pharmacy-based kiosks or other aids that lead the patient through an evidence-based algorithm for a particular drug product, performance of simple diagnostic tests by pharmacists, or some other type of pharmacist intervention, may significantly expand the current role of pharmacists in retail and clinic pharmacy settings. Over 240 million individuals self-treat with nonprescription medications annually and approximately 60 million of these would not otherwise seek treatment; therefore, the potential impact of expanding the definition of nonprescription drugs is enormous.²

Currently, medications are approved by the FDA either as prescription or nonprescription.¹ The FDA requires a medication to be dispensed under a valid prescription if, “because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.” The agency has wide latitude to decide whether or not data submitted as part of a new drug application are sufficient to ensure that a drug is safe for use under its proposed labeling and if the new medication should be prescription-only.

The FDA has begun to consider expanding the definition of nonprescription medications for a variety of reasons, not the least of which is the sometimes burdensome process of obtaining a prescription. Oftentimes, patients must see a prescriber in person to obtain an initial prescription and, in some cases, for additional refills. The time and cost associated with

prescriber visits can discourage patients from receiving needed medications.³ In addition, undertreatment of a variety of common disorders (eg, hypertension, dyslipidemia, asthma) is a well-recognized problem in the United States.¹ By making certain prescription medications widely available without a prescription, but with standardized conditions for safe use, the FDA hopes to address this public health issue.

The FDA is considering multiple potential approaches to the expanded definition of nonprescription drugs, including the following¹:

- requiring an in-person visit to a prescriber for an initial prescription, but then allowing a specific number of refills to be authorized under conditions of safe use without a return visit (most beneficial for rescue medications such as asthma inhalers or epinephrine injection for allergic reactions),
- allowing some medications to be available simultaneously as both prescription and nonprescription medications under conditions of safe use (allowing for greater flexibility in obtaining needed medications),
- approving medications that generally have required a prescription as nonprescription products in conjunction with some sort of pharmacist intervention.

The FDA believes that reducing or eliminating the number of “required” prescriber visits through some of the above mechanisms may not only allow prescribers to focus care on the more seriously ill, but may also decrease overall health care costs.

All of these approaches, if adopted, would have an impact on the role of the pharmacist, particularly in the retail setting where pharmacists are the most accessible to patients. Some diseases or conditions might require confirmation of a diagnosis or routine monitoring using a diagnostic test that could be available in a pharmacy.¹ Pharmacists may then use the results

*Director, Drug Information Group and Prior Authorization Services, Clinical Associate Professor, Department of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy, Chicago, Illinois

to determine whether use of a certain drug product is appropriate for a specific patient. Other potential roles for the pharmacist include assessing whether the patient has any conditions or risk factors that would indicate that the drug should not be used or assisting patients in choosing between various drug products.

There are potential challenges to carrying out this initiative, including changing nonprescription regulations, concerns from prescribers regarding separating patients from appropriate medical care, liability issues, and the impact on health care costs.³ Already, the American Medical Association (AMA) has adopted a policy that opposes federal and state legislation that allows pharmacists to prescribe medications without a valid order by a physician and also opposes letting pharmacists dispense medications beyond the expiration of the original prescription.⁴ These moves by the AMA stem directly from the March public hearing. In addition, some individuals have questioned whether moving prescription products to nonprescription status would actually increase patient use, because most insurers do not cover nonprescription medications.

FDA officials have acknowledged these concerns but state that the agency is looking toward the future,

when all health care providers will be better connected through the use of electronic health records and patient portals. In addition, greater pharmacist involvement has the potential to increase patient participation in their health care needs and improve medication adherence. The agency is gathering public input on this issue until May 7, 2013.

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