ASHP Statement on Criteria for an Intermediate Category of Drug Products

Position

The American Society of Health-System Pharmacists (ASHP) supports the establishment of an intermediate category of drug products that would not require a prescription but would be available from a pharmacist after appropriate patient assessment and professional consultation.[1] These drug products would continue to be available by prescription from licensed health care professionals who are authorized to prescribe medications. Drug products appropriate for this intermediate category should have proven public health benefits and be identified by processes that include the input and advice of experts, such as pharmacists, physicians, and other licensed health care professionals. Identification of drug products for inclusion in the intermediate category should be based on the medical condition to be treated and potential adverse effects of the drug. Concerns that patients may not be able to fulfill a substantial self-care role associated with these drug products will be alleviated by taking into consideration the benefits of pharmacist oversight of these drug regimens. Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-reaction reports should be collected and analyzed to evaluate the ongoing safety and effectiveness of drug products placed in this category. This information would be used to determine whether the product would remain in the intermediate category, return to prescription-only status, or move to nonprescription status.

Background

Rationale for Establishing an Intermediate Drug Category. Reclassification of prescription drug products to nonprescription status (e.g., antifungal products used for the treatment of vaginitis, nonsedating antihistamines) has been associated with improvements in patient autonomy, health care knowledge, and self-care behavior.[2-4] However, proposals to reclassify some prescription drug products to nonprescription status have been denied because of concerns about safety and whether patients would be capable of determining if they were suitable candidates for treatment. In 2008, for example, the Food and Drug Administration (FDA) ruled a third time against making lovastatin, a hydroxymethylglutaryl-coenzyme A reductase inhibitor (or statin), available without a prescription,[5] although the predicted public health benefit of increasing the availability of statins was estimated to range between 23,000 and 33,000 coronary heart disease events prevented per 1 million treated for 10 years.[6] ASHP supports inclusion of statins in an intermediate category of drug products that provides the benefit of pharmacist oversight.[7] Other drug products that should be considered for the intermediate category include injectable epinephrine to treat anaphylaxis; inhaled corticosteroids, leukotriene modifiers, and inhaled ß-agonists used in the treatment of asthma; select therapies for osteoporosis and hypertension; and vaccines.

ASHP and other pharmacy organizations have long proposed the creation of an intermediate category of drug products that would bridge the large gap between prescription and nonprescription status.[1,8,9] An intermediate drug category could improve patient access to medications that offer substantial public health benefit but present challenges for safety or effectiveness if used under existing models for nonprescription drug dispensing. Two concerns regarding the use of existing models are that (1) a product's labeling information may be beyond most consumers' capacity to understand (or may be subject to misinterpretation) and (2) monitoring procedures are not readily accessible to patients. Pharmacists' expertise, licensure, and education, which includes instruction on physiology, pharmacology, disease management, and physical assessment, make pharmacists well qualified to help patients make appropriate therapeutic decisions about the use of these drug products.

The terms "behind-the-counter (BTC) drugs" and "pharmacist-only drugs" have also been used to describe the proposed intermediate category of drug products. While an FDA-established BTC category does not currently exist, the term BTC has been used to refer to drug products such as pseudoephedrine and levonorgestrel (marketed as Plan B) that are available for purchase only at the pharmacy counter.[10,11] Implementation of that restriction has largely been a policing action (e.g., to restrict the amount of drug a patient can obtain or to confirm the patient's age). In some instances, these functions are completed by pharmacy support staff under the supervision of a pharmacist. ASHP recommends the use of the terminology intermediate category of drugs to describe drug products appropriate for this category that would be used by patients in conjunction with clinical assessment and consultation provided by pharmacists. Distribution of the aforementioned nonprescription products via an intermediate category model of dispensing could improve appropriate use of those products.

The purpose of this statement is to describe the criteria that should be used to identify drug products for inclusion in an intermediate category. While the practice implications of an intermediate drug category are briefly described, that discussion is beyond the scope of this statement. Pharmacoeconomic analyses should be conducted to assess the overall impact and costs of an intermediate category of drug products on patients, health systems, and health insurers, and new models of reimbursement for pharmacists' services should be developed. It should be noted that a few studies have demonstrated that overall costs to the health system decrease when the cost of these medications is not transferred solely to the patient.[12,13] Alternative reimbursement models, such as insurance coverage for these products, would be necessary to optimize the use of the intermediate category of drug products.

Criteria for an Intermediate Category of Drug Products

Appropriate identification of drug products for inclusion in the intermediate category should address the concerns associated with a substantial self-care role for patients by

providing the benefits of pharmacist oversight of these drug therapy regimens (e.g., assessing for appropriate indications, contraindications, precautions, adverse drug events, drug interactions, and therapeutic response). ASHP believes drug products proposed for inclusion in the intermediate category should

- Meet many of the criteria currently used to reclassify prescription drugs to nonprescription status (e.g., the drug product has a well-established benefit:risk ratio and a wide safety margin).
- Have been marketed as a prescription product for a length of time and been used by a number of patients deemed sufficient by FDA to detect serious adverse effects. Likewise, a product could be marketed as a nonprescription product but would benefit from pharmacist oversight because safety and effectiveness concerns have arisen with its nonprescription use.
- Have evidence of effectiveness and safety for the dosage and regimen recommended for the formulation intended for intermediate classification.
- Be used to prevent or treat a disease, symptom, or condition that can be readily detected by the patient or identified by the pharmacist or other health care provider.

Further, if the drug is used for a condition that requires laboratory or other medical monitoring, the pharmacy should be able to offer testing or have access to the results of that monitoring. Signs and symptoms of deterioration in health and the need for medical attention should be identifiable by the pharmacist or patient, as should signs demonstrating the effectiveness of the drug therapy. If the drug has the potential to rarely cause serious toxicity that can result in death or serious harm, there should be reliable early warning signs that can be readily detected and interpreted by the pharmacist or patient.

Antiinfective agents (systemic or other formulations) for which the emergence of resistance is a concern would not be appropriate for the intermediate category.

In applying these criteria, an independent decision should be made about each individual chemical entity, dosage form, and drug product because differences among various members of a drug class and dosage forms prevent using therapeutic class as a basis for classifying groups of related drug products.

Because drug information is continually evolving, drug products in the intermediate category may be reclassified as prescription or nonprescription medications as new effectiveness and safety information becomes available. Similarly, products could be permanently classified in the intermediate category if ongoing evidence documents the necessity of pharmacist intervention to ensure safe and effective use. The postmarketing surveillance of these medications through the collaboration of FDA and product manufacturers should be supported, in part, by information reported by pharmacists and patients to an established surveillance system, such as MedWatch, or similar reporting mechanisms.

Practice Implications

Implementation of the intermediate drug category would require that an ongoing relationship be established and maintained between the pharmacist and the patient and that documentation of the care provided be available to the patient's other health care providers, upon approval of the patient to provide such information. The exact nature and duration of the patient–pharmacist relationship would depend on the condition being treated and the drug therapy selected. A practice model that includes collaboration among the patient, the pharmacist, and the patient's physician (or other primary care provider) would enhance the use of these drug products and result in improved patient outcomes.

Increased pharmacist time for patient assessment, counseling, and documentation of services provided with these drug products would require reimbursement for these cognitive services. In addition, other conditions and procedures would be necessary to ensure the safety and effectiveness of these therapies, including the following:

- If the drug is to be used in conjunction with other therapies, such as diet and exercise, information about those adjunct therapies should be readily available to the patient from the pharmacist or through recommendation of the pharmacist or other health care provider.
- Patient care services provided by the pharmacist should be documented in the pharmacy record and available for sharing with other health care providers.
- Pharmacists and patients should provide information on actual or suspected adverse effects or drug interactions to programs such as MedWatch for the purposes of drug safety surveillance.
- Pharmacies should adopt standardized processes for the use of medications in the intermediate category that would guide patient triage, treatment, and referral to a physician when necessary. The expertise offered by clinical practice guidelines and professional associations should serve as the basis for these protocols, with appropriate modifications based on the unique characteristics of the patient population at the practice site.
- Pharmacies should adhere to quality measures that would be developed to assess the care provided (similar to those offered by the Pharmacy Quality Alliance) and engage in ongoing quality-improvement activities to assess and improve the quality of services provided.

A detailed discussion of these topics is addressed by other ASHP position and guidance documents, including the ASHP Statement on the Pharmacist's Role in Primary Care[14]; the ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling[15]; the ASHP Guidelines on the Pharmacist's Role in the Development, Implementation, and Assessment of Critical Pathways[16]; the ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records[17]; and the ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting.[18]

Conclusion

An intermediate category of drug products would increase patient access to and benefit from drug products that would otherwise be available only by prescription. The use of appropriate criteria for classifying drug products in an inter-

mediate drug category—in conjunction with pharmacist oversight of patient assessment, counseling, and monitoring—would improve public health without compromising patient safety.

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This statement was reviewed in 2017 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

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