

Increasing Access to Nonprescription Drugs

Hybrid Meeting | National Press Club, Washington, D.C.

April 23, 2026

12:30 – 5:00 pm ET

Discussion Guide

This hybrid public meeting, convened by the Duke-Margolis Institute for Health Policy under a cooperative agreement with the U.S. Food and Drug Administration, will convene drug developers, health care providers, patient and consumer representatives, and other relevant stakeholders to discuss opportunities to increase access to nonprescription drugs. The meeting will focus on the new drug application process for nonprescription drugs, which includes direct-to-nonprescription applications, prescription-to-nonprescription “switch” applications, and applications with Additional Conditions for Nonprescription Use. Participants will also discuss practical considerations related to access, innovative strategies to increase access, and how increased access may affect individual and public health outcomes.

Opportunities to Improve Public Health with Nonprescription Treatments

A presentation will analyze the potential impacts of increased nonprescription drug access on health outcomes, consumer access, and health care system costs. Panelists will discuss drug classes that are unavailable without a prescription that may be appropriate candidates for nonprescription status. Discussion will also cover the existing nonprescription and switch landscape and the potential impact of expanded use of these treatments in nonprescription settings.

Discussion Questions:

1. Considering historical switches or modeling of potential future switches, how do Rx-to-OTC switches generally affect outcomes, cost, and access for patients and consumers? What factors are key contributors to improved health outcomes or reduced costs?
2. How do Rx-to-OTC switches affect public health outcomes and health system costs?
3. What characteristics of a product class or therapeutic area indicate potential for improved health outcomes from an Rx-to-OTC switch?
4. What potential downsides may exist in expanding nonprescription access? How can these downsides be mitigated?
5. What research or evidence exists to support Rx-to-OTC switches for product classes that are currently available as prescription-only? How can stakeholders in this space support further evidence generation?

Evidence Generation to Demonstrate Safety and Efficacy in the Nonprescription Setting

Panelists will discuss how clinically significant risks and benefits can be most effectively characterized to support regulatory submissions for nonprescription drugs, including consumer studies and potential, supportive use of real-world data from the U.S. or other jurisdictions. Panelists will also consider methods for ensuring safe and appropriate use in the nonprescription setting. Topics for discussion may include additional conditions for nonprescription use and how sponsors might adequately demonstrate the efficacy of these methods in regulatory submissions.

Discussion Questions:

1. When a drug product's benefit-risk profile is assessed for the nonprescription setting, outcomes of interest may include how well consumers understand product labeling, whether consumers can accurately determine whether a drug product is right for them, and whether consumers can use the drug correctly – all without the supervision of a healthcare provider.
 - a. What may be appropriate thresholds for consumer comprehension and/or demonstration of correct self-selection and usage in nonprescription drug programs? How can appropriate thresholds be evaluated or determined?
 - b. What might constitute an effective demonstration of correct consumer comprehension, self-selection, and use in a nonprescription drug program?
 - c. Are there examples where higher or lower thresholds for success may be appropriate?
2. What role does evidence of a drug's safety profile have in predicting its safety in a nonprescription setting (without the supervision of a health care provider)?
3. What approaches to evidence generation could decrease the time required to demonstrate that a drug can be used safely and effectively in a nonprescription setting without the supervision of a health care provider?
4. How could real-world data from the U.S. or from other jurisdictions be used to characterize the benefit-risk profile of a drug in the nonprescription setting to support regulatory submissions for Rx-to-OTC switches?
 - a. What barriers exist regarding collection or use of these data?
5. How can nonprescription drug labeling be improved to ensure consumers understand the most clinically significant information about appropriate use and potential risks?
 - a. What barriers exist to the use of innovative labeling strategies that enhance consumer comprehension and support appropriate self-selection and use?
6. What evidence might be needed to demonstrate that an additional condition for nonprescription use sufficiently ensures appropriate self-selection and actual use in the real world?

Innovation to Enable Increased Access to Nonprescription Drugs

Panelists will discuss how additional conditions for nonprescription use could be implemented most effectively and consistently for different therapeutic areas with different risks. Discussion will also focus on access points across various pharmacy, retail, and online settings where consumers may purchase nonprescription drugs. Panelists will identify innovative approaches that maximize feasibility of implementation and expanded, appropriate consumer access to nonprescription drugs.

Discussion Questions:

1. What innovative approaches or tools are under development or could be developed to support submissions, including but not limited to those that could be proposed as an ACNU?
2. What are some key considerations for implementing innovative approaches or tools in different settings through which consumers obtain nonprescription drugs, including:
 - a. Pharmacies or drug stores
 - b. Non-pharmacy retail locations
 - c. Online retail
3. How could innovative approaches or tools address important conditions for appropriate self-selection, such as:
 - a. Lab testing for initial diagnosis
 - b. Synthesis of multiple pieces of personal health information (e.g., diagnostic calculation)
 - c. Screening for serious and/or complex drug-drug interactions
4. How could innovative approaches or tools address important conditions for appropriate use, such as:
 - a. Follow-up testing or monitoring to ensure ongoing appropriateness
 - b. Counseling on lifestyle or risk factor modification, particularly for chronic conditions
 - c. Adverse events that could warrant discontinuation of use and/or consultation with a healthcare provider

This event is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award U01FD008451 totaling \$1,399,999 with 100 percent funded by FDA/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.