



APhA

2215 Constitution Avenue, NW • Washington, DC 20037-2985

July 31, 2018

RE: Development of a Shared System Risk Evaluation and Mitigation Strategy; Draft Guidance for Industry; Availability (FDA-2018-D-1041)

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) welcomes the opportunity to respond to the Food and Drug Administration’s (FDA’s) draft guidance, “Development of a Shared System Risk Evaluation and Mitigation Strategy” (hereinafter, “Draft Guidance”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA appreciates FDA’s efforts to improve the Risk Evaluation and Mitigation Strategy (REMS) program to help generic drug makers get their products through the development and approval processes efficiently while maintaining the safety controls sought by the REMS program. Like FDA, APhA believes a shared system REMS makes it easier for pharmacists to complete administrative requirements and distribute REMS materials and information to patients. We offer the following recommendations related to the Draft Guidance.

I. Levels or tiers of REMS

In the Draft Guidance, FDA clarifies it may request applicants for a class of products with a similar risk profile to develop a shared system REMS. In addition, FDA will set forth expectations of the shared system REMS application for the development of a shared system REMS. APhA believes the shared system REMS process can be improved by creating different levels or tiers of REMS based on the required intensity needed to mitigate the risks for which the REMS program is designed.¹ These different levels or tiers could be an early indicator of FDA’s expectations for shared REMS programs and help minimize significant changes to REMS program requirements when a shared system is developed.

II. REMS Assessments

Although the draft guidance addresses shared system REMS assessments, it does not address evaluation of program components. Currently, REMS assessments tend to focus on negative outcomes of a REMS while each element’s effectiveness in mitigating risk or improving care is generally not disclosed unless changes to the program are warranted. To improve REMS assessments, APhA encourages FDA broaden its assessment measures, such as unintended consequences of REMS (e.g., limiting patient access to because prescriber/pharmacist lacks participation in a REMS program, shifting prescribing patterns to non-REMS medications that may be less therapeutically appropriate) and capture reasons why a REMS was or was not successful.

¹ See American Pharmacists Association, (2009). White paper on designing a risk evaluation and mitigation strategies (REMS) system to optimize the balance of patient access, medication safety, and impact on the health care system, *Journal of the American Pharmacists Association*, 49:729-743.



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III. Front-line provider input and pilot programs

The Draft Guidance states an applicant may form an industry working group (IWG) to help facilitate negotiation and agreements among applicants for a shared system REMS on issues such as confidentiality, governance, voting structure, cost-sharing, any potential changes to the drug distribution model, and any other issues that may come up during the collaboration. APhA has long advocated for the input of front-line providers and pilot programs in REMS program development. APhA recommends FDA encourage IWGs to obtain input from front-line providers and run pilot programs when considering any potential changes to the drug distribution model and other aspects of the REMS program that may impact patient care, including provider-directed education.

APhA supports FDA's efforts to improve the REMS program and encourages a systematic, standardized process for REMS programs to minimize the impact on patient access and the health care system. Should you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPHarm, JD, Senior Vice President, Pharmacy Practice and Government Affairs