Via Electronic Submission to: www.regulations.gov

January 4, 2021
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Risk Evaluation and Mitigation Strategy Assessment Summary for Web Posting; Establishment of a Public Docket; Request for Comments (Docket No. FDA-2020-N-1845)

Dear Sir or Madam:

The American Pharmacists Association (APhA) is pleased to submit these comments in response to the Food and Drug Administration's (FDA) proposal to publish a summary of FDA's review of Risk Evaluation and Mitigation Strategy (REMS) Assessments, published in the Federal Register on November 5, 2020 (85 FR 70639). Founded in 1852, APhA represents 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, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings and the uniformed services.

APhA appreciates FDA's efforts to improve the REMS program by publishing Summaries of FDA's review of REMS Assessments. APhA believes that making this information publicly available will serve both healthcare providers, including pharmacists, and patients alike by providing transparency and guidance for future REMS program improvement and assessments. APhA applauds FDA for its continual effort to increase patient safety through the REMS program, while simultaneously decreasing the burden of REMS on the healthcare system. While we generally support the initiative to publish FDA Summaries of REMS Assessments, APhA offers the following responses to FDA's requests, as well as additional comments for further consideration by FDA.

(1) Whether the information contained in the Summary of the REMS Assessment example would be beneficial to the public, and if so, why it would be beneficial:

> Yes, the information contained in the Summary of the REMS Assessment example would be beneficial to the public because it provides a complete picture of the REMS program with information on individual medications of which the public might not otherwise be aware. For example, a patient might know that the medication they are taking requires

them to use multiple types of contraception as part of the REMS. However, the patient might not understand why it is important for them to do so, or the goal behind that particular REMS mandate. In addition, the public will benefit from a greater understanding of FDA's role in helping them to use medications safely. Furthermore, this transparency will allow patients to understand what is expected of their healthcare providers and thus foster patient input into meeting the requirements for medications with REMS.

(2) Whether the Summary of the REMS Assessment would be useful to a wide range of stakeholders, including healthcare providers, patients, the pharmaceutical industry, and academics, and if so, why it would be beneficial:

APhA believes the Summary of the REMS Assessment would be useful to all stakeholders because these stakeholders' decisions, whether personal or business-related, are often based on findings in the REMS Assessments. Healthcare providers, including pharmacists, would use this information to gain a better understanding of REMS programs and how they contribute to drug safety. In addition to their first-hand experience, they will gain a more complete view of how the REMS is being carried out in provider settings distinct from their own. For example, if the healthcare provider is required under the REMS to counsel a patient on a particular warning, but does so only verbally beforehand, he/she would stand to benefit from learning that other healthcare providers in this REMS not only counsel the patient beforehand, but also provide a 24-hour courtesy call to confirm understanding of what was mentioned the day prior to ensure compliance with instructions.

Although patients may benefit from access to safety considerations related to their medications that require REMS, APhA is concerned that the example presented in the proposal may not be written at a literacy level appropriate for the lay public. APhA recommends that FDA test examples of the Summary of REMS Assessment with consumer focus groups to gain more insight into the most useful way to present this information at the appropriate literacy level. FDA may want to consider publishing the Summary of REMS Assessments in both a health care provider version and a patient version like is done for prescription drug information.

(3) Whether any additional information should be included in the Summary of the REMS Assessment:

APhA believes FDA can utilize the Summary of REMS Assessment to promote REMS quality improvement measures for continual process improvement. With this in mind, APhA believes that feedback from healthcare providers, including pharmacists, on the REMS program should be included in the Summary. As the FDA gains a better understanding of each REMS by asking providers about the realities of REMS implementation, publishing these "Providers' Perspectives" could lay the foundation for improvements to the specific REMS and reduction in administrative burdens for providers.

An example is shown below:

Provider Perspective: Providers commented to FDA on the time-consuming, burdensome process required to login to the REMS portal, as well as the difficulty navigating the site to complete required elements before prescribing. This provider perspective helps FDA and the manufacturer(s) to understand that the portal process is a barrier to patient care and prompts them to determine how to best minimize this barrier.

(4) Possible negative impacts of posting the Summary of the REMS Assessment:

APhA foresees revealing the inconsistency with which REMS programs are conducted as a possible negative impact of posting the Summary of REMS Assessment. For many years, APhA has urged FDA to standardize REMS program elements in order to enhance REMS programs and make them less burdensome. Currently, there are hundreds of REMS programs, each with its own unique administrative nuances and components. This variability can make compliance daunting for healthcare providers, including pharmacists, and patients.

Although flexibility in REMS program design is necessary and even desirable at times, introducing some level of consistency around the REMS elements would reduce compliance burdens without compromising program effectiveness. For example, using process and outcome metrics to evaluate the effectiveness of REMS elements may be more meaningful if results can be compared to other REMS programs. However, such comparisons will be more difficult if different metrics or sources of data are used. Comparing assessments that use standardized metrics could permit replication of effective REMS programs, elimination of ineffective ones, and refinement of others, among other benefits.

The lack of standardization in REMS programs is likely to become apparent and may lead to more questions as to why FDA determines some Assessments to warrant REMS program modification and others not. For example, in one Assessment objectives might be partially met and deemed acceptable, while for another Assessment objectives might also be partially met but deemed unacceptable. In these cases, it will be important for FDA to clearly delineate the rationale for decisions made so that the value REMS programs bring to public safety is not undermined.

Conclusion

In closing, APhA supports FDA's proposal to publish a summary of Risk Evaluation and Mitigation Strategy (REMS) Assessments and commends the agency for continually seeking to improve REMS to ensure patient safety. While APhA supports FDA's efforts to publicly promote the assessment of REMS programs, we encourage the agency to consider further standardizing REMS program requirements. We encourage a systematic, standardized process for REMS in order to minimize barriers to patient access and burdens to the health care system.

If you have any questions or require additional information, please contact Karin Bolte, Director, Health Policy, at kbolte@aphanet.org or by phone at (301) 648-0673.

Sincerely,

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Senior Vice President, Pharmacy Practice & Government Affairs