FDA Drug Safety Strategies

OVERVIEW

Risk Evaluation and Mitigation Strategy (REMS) programs are intended to enhance patient safety with respect to treatment and supportive medications with risky safety profiles. ASCO is concerned, however, that REMS programs do not take into consideration healthcare providers’ education, training and experience; varying patient health literacy, language and privacy concerns; as well as integrate, using sound education principles, technology and clinical practice knowledge. The administrative burden for some programs is unsustainable and may detract from instead of enhance patient safety. Additionally, some manufacturers appear to be using REMS elements for a medication even though other products with similar safety profiles are not required to have these programs (e.g. restricted distribution, patient registries, etc.). In addition, it may be difficult for generic medications to come to market if the innovator company restricts access to the branded product for testing and if generic companies cannot afford to implement the same large-scale, costly REMS program as for the branded product.

BACKGROUND

The REMS mechanism - formerly known as the unenforceable RiskMap - created in the 2007 Food and Drug Administration Amendments Act (FDAAA). These programs are developed by industry and reviewed/approved by FDA during the initial review of a new drug or as part of a safety review of a marketed product. Penalties for noncompliance are aimed at the manufacturer.

It is difficult to address REMS challenges because of their “behind closed doors” development and approval. ASCO has been working to address issues related to REMS programs, in partnership with other healthcare provider, patient and pharmaceutical organizations and the FDA through official comments, public meetings, published reports and collaborative relationships. Initially, many of the more onerous programs were related to oncology therapeutics or supportive care. The FDA Office of Oncology and Hematology Products (OHOP) has been working to improve programs since an ASCO workshop in July 2011.

RECOMMENDATIONS

1. Work with FDA to develop a “drug safety toolbox” intended to communicate and educate oncology healthcare providers and their patients when a serious and unexpected drug safety issue is identified.
2. Work with the FDA, industry, healthcare provider and patient organizations to develop specific recommendations regarding changes needed to REMS programs to reduce administrative burden, address patient privacy and health literacy concerns and implement “best education and communication practices.”
3. Monitor for REMS programs implemented by industry without requirement of the FDA that may create disparities in access for oncology patients and difficulty for generics to enter the market.

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