U.S. healthcare stakeholders uncertain on benefits of risk evaluation strategy

Tufts CSDD survey is first assessment of REMS program since launch in 2008

- Most respondents said it is virtually impossible to measure the benefits of a Risk Evaluation & Mitigation Strategy (REMS), compared to its costs, for a newly approved drug.
- 58% said two years are required to effectively measure the benefits of a REMS for an already marketed drug.
- 86% felt that under current guidelines, risk and benefit information was not well-balanced in REMS communications.
- A strong majority said the REMS program needs a major overhaul and felt that a REMS is a poor substitute for other improvements needed system-wide in drug education, communication, use monitoring, patient access, and delivery of care.
- Only 22% of respondents thought the REMS program has been an improvement over the existing risk management system.

Since March 2008, drug developers are required to submit a proposed Risk Evaluation & Mitigation Strategy (REMS) to the U.S. Food and Drug Administration (FDA) as part of a new product approval application (or even for a prior approved product) when the FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks. A REMS must have a timetable for submission of assessments and may include the following: medication guide; patient package insert; communication plan to health care providers; and/or Elements to Assure Safe Use. To assess the impact of the REMS program on a diverse set of stakeholders groups, Tufts CSDD interviewed and later surveyed payers, pharmacists, health care providers, patients, and biopharmaceutical companies to determine their concerns about program implementation and its impacts on the delivery of healthcare.

Interviewees were selected based on knowledge, experience, and interest, especially with REMS programs having certain characteristics, such as those requiring more than just a Medication Guide, and/or those with a REMS assessment due or due soon. Survey questions were based on issues and problems reported in interviews. Of the original 47 interviewees, a total of 32 accessed the survey and 28 provided responses, giving a final response rate of 60%. This Tufts CSDD Impact Report summarizes results of the survey.