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REMS Assessment Is As Challenging As Initial Design, Regulators Acknowledge

Regulators on both sides of the Atlantic are grappling with how to measure whether risk management programs imposed on pharmaceuticals are having the desired effect.

Assessing Risk Evaluation and Mitigation Strategies to determine if they are working “is on everyone’s mind” and a major challenge, Office of Surveillance and Epidemiology Director Gerald Dal Pan concluded during the Post-Approval Summit at Harvard Medical School, May 11.

Scientists from multiple disciplines need to be involved in the task, looking at adverse events, pharmacoepidemiology and outcomes, he said. In addition to determining whether the risk management efforts are having beneficial effects by avoiding risks, he noted, FDA and industry must assess whether REMS have had adverse consequences, such as whether people who should be getting the medicine are being denied treatment.

“We’re also going to have to figure out how this impacts the health care delivery system in a way that traditional product epidemiology doesn’t really look at,” he added.

Does Finding Adverse Events Show That The Program Is Working?

Stella Blackburn, the risk management development and scientific lead at the European Medicines Agency, stressed the need for better methodologies to evaluate the effectiveness of risk minimization plans.

A key issue, according to Blackburn, is selecting the true indicator of success. As an example, she cited the case of risk management for teratogenic drugs. If no children with congenital abnormalities are born to women taking such a drug, that may indicate success, she suggested. On the other hand, that finding may be due to pregnancy terminations and not the result of successful risk management. A better criterion might be if no women on the drug become pregnant, she suggested.

Discussing progressive multifocal leukoencephalopathy associated with Biogen Idec’s *Tysabri*, Blackburn pointed out that PML is caused by reactivation of the JC virus and it is difficult to differentiate clinically between a multiple sclerosis flare and JC infection.

If the risk minimization plan for the drug is aimed at detecting JC cases as early as possible and the number of reported cases increases, she said, plan evaluators must ponder whether more cases indicate failure, or whether they mean physicians are diagnosing more cases and the program therefore is successful.

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