

FDA CENTER FOR DRUG EVALUATION AND RESEARCH
Office of Medication Error Prevention and Risk Management
M E M O R A N D U M

DATE: November 15, 2011

FROM: Claudia Karwoski, PharmD, Director
Division of Risk Management
Office of Surveillance and Epidemiology, CDER, FDA

TO: Chair, Members and Invited Guests
Drug Safety and Risk Management Advisory Committee (DSaRM)
Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)

RE: Addendum to FDA Background Package
December 1, 2011, Advisory Committee Meeting
Isotretinoin REMS

Description of Drug Utilization Databases:

IMS, Vector One®: National (VONA)

The IMS, Vector One®: National (VONA) database measures retail dispensing of prescriptions or the frequency with which drugs move out of retail pharmacies into the hands of consumers via formal prescriptions. Information on the physician specialty, the patient's age and gender, and estimates for the numbers of patients that are continuing or new to therapy are available.

The Vector One® database integrates prescription activity from a sample received from payers, switches, and other software systems that may arbitrage prescriptions at various points in the sales cycle. Vector One® receives over 1.4 billion prescription claims per year, representing over 120 million unique patients. Since 2002 Vector One® has captured information on over 8 billion prescriptions representing over 200 million unique patients.

Prescriptions are captured from a sample from the universe of approximately 59,000 pharmacies throughout the U.S. The pharmacies in the database account for most retail pharmacies and represent nearly half of retail prescriptions dispensed nationwide. IMS receives all prescriptions from approximately one-third of stores and a significant sample of prescriptions from many of the remaining stores.

Wolters Kluwer SOURCE Lx®

The Wolters Kluwer Source® Lx database is a longitudinal patient data source, which captures adjudicated claims across the United States from a mix of prescription claims from commercial plans, Medicare Part D plans, Cash and Medicaid claims. The database contains approximately 4.8 billion paid, non-reversed prescriptions claims linked to over 172 million unique prescription patients of which approximately 70 million patients have 2 or more years of prescription drug history. Claims from hospital and physician practices include over 190 million patients with CPT/HCPCS medical procedure history as well as ICD-9 diagnosis history of which nearly 91 million prescription drug patients are linked to a diagnosis. The overall sample represents 27,000 pharmacies, 1,000 hospitals, 800 clinics/outpatient facilities, and 80,000 physician practices.