

6th Pharmacovigilance Congress

September 28-30, 2016 Toronto, Canada

Pharmacovigilance and compliance of drugs labeling information with the 2015 FDA Lactation Guidelines

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This study was conducted to evaluate published and manufacturer labeling information (PI) for commonly prescribed drugs in the USA, and to examine compliance with the new 2015 FDA labeling guidelines. Data were also compared to the authors' previously published information on the development of the first clinical classification of drugs used during lactation (FG-LA). Of the top 200 drugs prescribed in 2015, 85% included a lactation section but information was limited and not in compliance with all elements of FDA guidelines. Only 5% included risk versus benefits section, 54.5% were excreted into breast milk or included data on milk-plasma ratio. Utilizing FG-LA clinical classification, 53.5% were clinically compatible with lactation but 19.5% caused mild to moderate adverse effects on infants, and 1.5% caused mild to moderate adverse effects on the mothers. A total of 23.5% were classified as incompatible with lactation, secretion of 11.5% was unknown, 6.5% caused mild to moderate adverse effects on infants and 1.5% caused mild to moderate adverse effects on the mothers. A total of 23% were classified as unknown with compatibility and no data on adverse effects were reported on infants or mothers. A total of 25.5% caused adverse effects on infants and 3% had adverse effects on the lactating mothers. Several conflicts existed between data in the PI and the literature addressing secretion or concentrations in breast milk. A firmer deadline is recommended by the FDA to drug manufacturers to update PI data in order to enhance patient safety and therapeutic outcomes.

Biography

Faten Sabbagh is a PharmD Candidate at South College School of Pharmacy in Knoxville, Tennessee, USA. Her undergraduate study included Biological Sciences at the University of Michigan-Dearborn and Henry Ford College. He has been in the practice of pharmacy since 2010 with certifications in Medication Therapy Management, AHS-BLS, Immunization Delivery, Smoking Cessation, and Diabetes. Her areas of interest are Pharmacokinetics, Pharmacovigilance and Patient Safety.

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