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New Class of Diabetes Drugs Raises Safety Questions

Horsham, Pa—The newly-released QuarterWatch[™] annual report issue identifies sodium-glucose cotransporter-2 (SGLT2) inhibitor drugs for type 2 diabetes as ranking among the top safety concerns of the year. QuarterWatch, a drug safety publication of the Institute for Safe Medication Practices (ISMP), notes that these new drugs are spreading rapidly into clinical practice, with more than 2 million prescriptions by late 2015, but have unanswered questions about long term clinical benefits and emerging signals of additional safety concerns.

The latest issue of QuarterWatch examines adverse event and clinical trial data that provide growing evidence of adverse drug events associated with all three approved SGLT2 inhibitors --**INVOKANA** (canagliflozin), **FARXIGA** (dapagliflozin), and **JARDIANCE** (empagliflozin)--as well as combination products containing these medications.

Some of the safety problems identified include:

- Life-threatening ketoacidosis
- Electrolyte imbalances leading to severe dehydration and other problems
- Acute kidney injury
- Frequent genital infections, primarily fungal
- Increased risk of bone fracture

In the last year, the U.S. Food and Drug Administration (FDA) has issued five Drug Safety Communications about serious adverse events with SGLT2 medications. ISMP believes that the FDA should re-evaluate its decision to allow unrestricted long-term use of this class of drugs.

For a copy of the June 2016 QuarterWatch Annual Report issue, visit:

www.ismp.org/QuarterWatch/Default.aspx

About QuarterWatch: QuarterWatch analyzes all adverse drug events reported to the FDA. The project team includes experts who are co-author of more than 600 peer-reviewed scientific publications and 12 books, and have expertise in medicine, pharmacy, toxicology, clinical trials, and epidemiology. The non-profit Institute for Safe Medication Practices (ISMP) publishes *QuarterWatch* four times a year as a public service. For more information, visit: <u>www.ismp.org/QuarterWatch</u>/