The Pharmacist Activist

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Editorial

Pfizer's Viagra Promotion

Puts Patients at Risk and is an Insult to Local Pharmacists

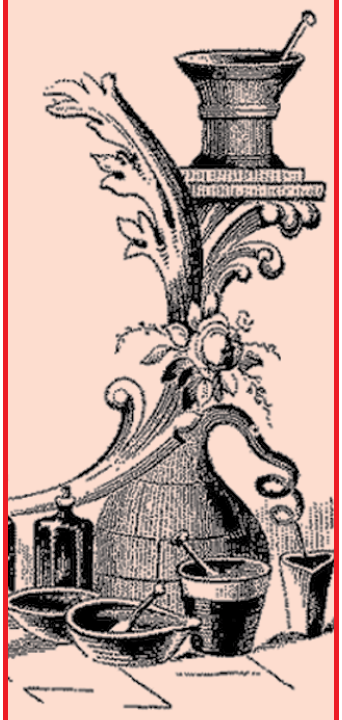
On May 6, Pfizer issued a news release that begins, "To meet the needs of customers who are increasingly going online to purchase prescription medications, Pfizer today launched Viagra home delivery, a new prescription-fulfillment website for Viagra (sildenafil citrate) tablets, Pfizer's most counterfeited medicine." Full-page advertisements appeared in major newspapers around the country, promoting "A new convenient way to fill your prescription online."

The theme of this program is the risk associated with the possibility of receiving counterfeit products from an online pharmacy. The Pfizer press release identifies "filthy and deplorable conditions" in which counterfeit medicines may be manufactured and identifies contaminants that its laboratories have detected in some of these products. The press release notes that "These findings motivate us to continue our aggressive global efforts to stop those who prey on unsuspecting patients."

The counterfeiting of medications is deplorable, and aggressive efforts are needed to identify those who are engaged in these activities and to prosecute them to the fullest extent. In one respect, Pfizer's attention to the problem of counterfeiting is commendable. However, the establishment and promotion of Viagra home delivery is not the answer and, indeed, places some patients at greater risk by encouraging them to obtain Viagra from a different pharmacy than the one from which they obtain their other prescription medications.

Pfizer conveniently ignores the most important reason for which Viagra is being counterfeited – the high price it charges that results in a cost to the patient of approximately $25 a tablet. The company's sales of Viagra totaled more than $2 billion in 2012 and, in the opinion of some, it is the potential for even greater revenue that has motivated Pfizer to promote its online program to obtain Viagra, rather than a concern that patients may be at risk. Pfizer also

Contents



ignores the fact that many individuals who obtain Viagra from an online "pharmacy" have not actually seen a physician but have simply responded to a few questions from the online pharmacy to go through the motions of attempting to legitimize the purchase of the drug.

In considering the extent to which counterfeit Viagra is suggested to be available, I am not aware of even a single report of a patient who has experienced harm from use of such a product. In Pfizer's communications, there is a conspicuous absence of any statistics or specific situations regarding complaints from patients to either the company or the FDA. Are such data available? While it is understandable that men with erectile dysfunction who have purchased from an online pharmacy what may be counterfeit Viagra are not likely to report their experience, it is also reasonable to conclude that if any serious problems did result, they would be recognized and publicized.

Pfizer and CVS

The Pfizer press release notes that the new Viagra website "is powered by CVS/pharmacy" and further notes that "CVS/pharmacy will handle all of the back-end functions (Editor's note: an unusual term for what presumably is the CVS dispensing process for this program), including the authentication of all prescriptions." It was, of course, CVS pharmacies that recently did such a terrible job of authenticating requests for purchases of pseudoephedrine-containing products that southern California was flooded with methamphetamine that was made from these products. The scope of this situation was so extensive that CVS agreed to pay $75 million (the largest ever civil penalty under the Controlled Substances Act) and to forfeit the $2.6 million in profits the company earned as a result of the illegal conduct. The number of packages of pseudoephedrine-containing products that were sold for the company to make $2.6 million in *profits* has to be huge.

For Pfizer to have selected CVS as its partner in promoting this Viagra program raises questions as to whether it is aware of previous CVS experiences in authenticating purchases of medications, or whether this was the "best deal" to increase its revenues from Viagra.

Risk for patients

Many individuals for whom Viagra is prescribed are also taking other prescription medications that they obtain at one or more pharmacies. As the number of different pharmacies that an individual uses increases, it becomes more difficult for any of the pharmacies to have a complete record of all of the medications a patient is using. This increases the risk of drug interactions and other drug-related problems. Although potential drug interactions and adverse events are identified in the information provided, the new Pfizer promotion to obtain prescriptions for Viagra online relies on the user's accurate interpretation of information in advertisements or on a website. By fragmenting the care and services provided by pharmacists, I would contend that the risk of drug-related problems with the new program is greater than the risk experienced by individuals who submit a legitimate prescription for Viagra to an online pharmacy and receive a counterfeit product. I further contend that this program is a marketing strategy and not a risk reduction initiative.

Pfizer ignores local pharmacies

The almost exclusive focus of the Pfizer news release is the online program it has established in collaboration with CVS. However, the following comment is also included: "Another way to buy safely is to look for other Verified Internet Pharmacy Practice Sites (VIPPS)." The VIPPS program was established by the National Association of Boards of Pharmacy (NABP) to evaluate and accredit online pharmacies that meet designated criteria.

The news release completely ignores local pharmacies as the locations from which most prescriptions for Viagra are obtained. Not only does Pfizer insult these pharmacies by not even mentioning them, but it also misses an opportunity to encourage patients to

(Continued on Page 4)

New Drug Review

Canagliflozin (Invokana – Janssen)

Antidiabetic Agent

New Drug Comparison Rating (NDCR) = 4

(significant advantage[s]) in a scale of 1 to 5 with 5 being the highest rating

Indication:

Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Comparable drugs:

Glimepiride, sitagliptin (Januvia).

Advantages:

- Has a unique mechanism of action (inhibits sodium-glucose co-transporter 2 [SGLT2] and increases urinary glucose excretion);
- Less likely to cause hypoglycemia (compared with glimepiride);
- Use is often associated with weight loss;
- May reduce hemoglobin A1C to a greater extent (compared with sitagliptin).

Disadvantages:

- More likely to cause renal adverse events;
- More likely to cause hypotension, hyperkalemia, and genital mycotic infections;
- Not available in combination formulations with other antidiabetic agents.

Most important risks/adverse events:

Renal function impairment (contraindicated in patients with severe renal impairment; renal function should be monitored in patients at risk); hypersensitivity reactions (contraindicated in patients with a history of a serious hypersensitivity reaction); hypotension (risk is increased in patients with impaired renal function, the elderly, and in patients treated with diuretics, angiotensin-converting enzyme inhibitors [ACEIs], and angiotensin receptor blockers [ARBs]); hyperkalemia (risk is increased in patients with renal impairment and in patients treated with potassium-sparing diuretics, ACEIs, or ARBs); hypoglycemia (when used concomitantly with insulin and/or an insulin secretagogue [e.g., sulfonylureas]); metabolized via glucuronidation and action is decreased by concurrent use of uridine diphosphate glucuronosyl transferase (UGT)1A9 and UGT2B4 inducers (e.g., rifampin); may increase the action of digoxin.

Most common adverse events:

Female genital mycotic infections (11%; e.g., vulvovaginal candidiasis), urinary tract infections (6%), increased urination (5%), male genital mycotic infections (4%; e.g., balanitis).

Usual dosage:

Initially, 100 mg once a day taken before the first meal of the day; in patients tolerating treatment who have adequate renal function and require additional glycemic control, dosage may be increased to 300 mg once a day; increase in dosage to 300 mg once a day should be considered in patients taking an UGT inducer concurrently; treatment should not be initiated in patients with an estimated glomerular filtration rate (eGFR) less than 45 ml/minute/1.73 m2, and treatment should be discontinued if the eGFR is persistently below this value.

Products:

Film-coated tablets – 100 mg, 300 mg.

(Continued on Page 4)

personally speak with a pharmacist with the anticipated benefit of assuring the safest use of their medications with the least risk.

The Pfizer insult to local pharmacies (other than CVS whose online program is being used) extends further. Many local pharmacies, including large chains, view CVS as an unfair competitor, in part because its Caremark division administers prescription benefit programs that provide incentives for patients to use CVS pharmacies, thereby stealing patients from local pharmacies.

Local pharmacists anticipate that once CVS obtains the email and mailing addresses for individuals submitting prescriptions online for Viagra, it will recruit (steal) these patients with promotions, discounts, etc. as incentives to use CVS mail-order and local pharmacies for their other prescriptions.

Some local pharmacists are so incensed by Pfizer's Viagra program using CVS that they are actively exploring ways in which they can promote the use of nonprescription and prescription medications made by other pharmaceutical companies rather than the corresponding Pfizer products to which they are similar in effectiveness and safety.

Recommendation

Pfizer should immediately abandon its program. One of the themes in the promotion of its program on its website is, "Buy Real Viagra." Pfizer should change this theme to "Buy Real Viagra at a Real (Local) Pharmacy," rather than promoting availability from an online/mail-order pharmacy from invisible pharmacists.

Daniel A. Hussar

New Drug Review (cont.)

Comments:

Sodium-glucose co-transporter 2 (SGLT2) is expressed in the proximal renal tubules and is responsible for the reabsorption of the majority of glucose filtered by the kidney. Canagliflozin is the first SGLT2 inhibitor and reduces reabsorption of filtered glucose, thereby increasing urinary glucose excretion and lowering blood glucose concentrations. Its effectiveness has been demonstrated in studies in which it was used as monotherapy, in combination with metformin, a sulfonylurea, metformin and a sulfonylurea, metformin and pioglitazone, and with insulin. The use of canagliflozin resulted in reductions in hemoglobin A1C concentrations and fasting plasma glucose concentrations, and, in many patients, weight reduction. In a study in which canagliflozin or sitagliptin was added to treatment with metformin and a sulfonylurea, canagliflozin (in a dosage of 300 mg once a day) reduced HbA1C to less than 7% in 48% of patients, whereas sitagliptin attained this endpoint in 35% of patients. Canagliflozin provided a 2.5% reduction in body weight from baseline, compared with a 0.3% increase in patients treated with sitagliptin. Canagliflozin was also compared with glimepiride and provided similar reductions in HbA1C.

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