CalRecycle received: June 23, 2014

Plan for Supporting Safe Collection and Proper Disposal of Home Generated Sharps

Background:

The State of California recently enacted two laws to address home generated sharps disposal. The first law (SB 1305), makes it illegal for any person in the state of California to dispose of home generated sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in an approved sharps container. This law became effective September 1, 2008. In 2009, California enacted (SB 486) which requires any pharmaceutical manufacturer that sells or distributes medication that is self-injected at home through the use of hypodermic needles and other similar devices to submit to the board, or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of waste devices. This plan is due on July 1, 2010 and annually thereafter.

GSK Self – Injectable Products Subject to these Regulations

GSK currently markets, distributes, and/or sells two self-injectable products. The brand names of these products are Imitrex® (sumatriptan succinate) Injection and TANZEUM® (Albiglutide) Injection.

Imitrex® is indicated for the acute treatment of migraine attacks. There are 2 basic types of migraine-specific therapies — acute and preventative. Acute medications are designed to relieve a migraine after it starts, and preventative medications are designed to help eliminate or significantly reduce the frequency of a person's migraines. Imitrex® Injection is indicated for 1) the acute treatment of migraine attacks with or without aura in adults and 2) the acute treatment of cluster headache episodes in adults. Patients are instructed to administer via injection this medication in accordance with the instruction of a physician or other suitably qualified health care professional.

TANZEUM® - AlbiglutideTanzeum™ (albiglutide) for injection as a once-weekly treatment for type 2 diabetes. Tanzeum has been approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Albiglutide, a glucagon-like peptide-1 receptor agonist (GLP-1), is a biological product for the treatment of type 2 diabetes, administered once-weekly using an injector pen.

GSK Supports Safe Collection and Proper Disposal of Home Generated Sharps

GSK has demonstrated a strong commitment to the safe and proper use and disposal of its self-injectable medications. Patient safety and needle stick injury prevention were given serious consideration as the above-mentioned products were being developed.

IMITREX®

Imitrex® Injection is available in the easy-to-use Imitrex® STATdose System, which allows patients to conveniently administer Imitrex with just the push of a button.

The Imitrex® STATdose System includes two small, disposable cartridges pre-filled with a single dose of Imitrex®, and an easy to use autoinjector pen that allows patients to self-administer the medication about one-quarter inch under the skin. With the Imitrex® STATdose System, patients can treat migraines quickly and conveniently while avoiding direct contact with a needle or syringe. After injection, the used sharp is placed into the empty cartridge. The California Department of Health, Medical Waste Management Office has designated the empty cartridge as an approved sharps container that is suitable for transportation to an approved collection facility. Disposal instructions (including California specific requirements), are provided through an 800 number which connects to the GSK Customer Care Call Center.

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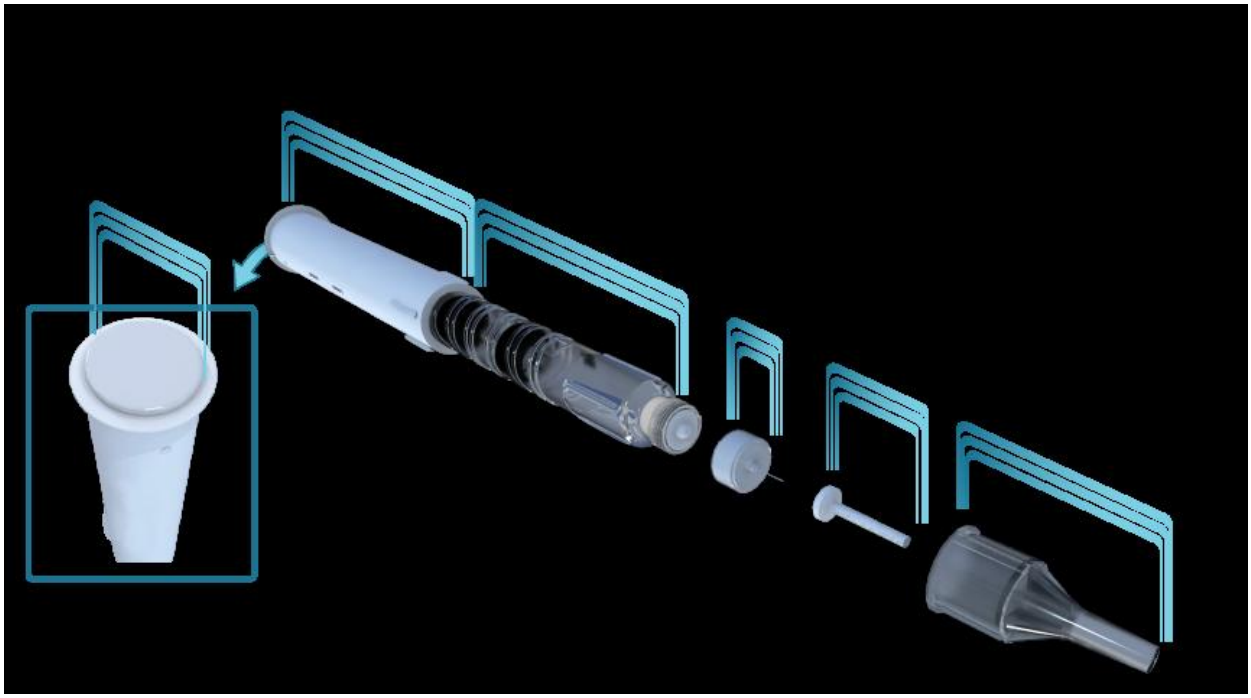
TANZEUM®

Specifically, TANZEUM® uses a 5mm 29-gauge needle and an automatic needle protection system that retracts once the medication is dispensed. Patient instructions are provided for self-administration to guide patients on how to properly inject and dispose of the pen. Additionally within the Patient Information Leaflet patients are guided to follow the instructions of their nurse or doctor about the right way to dispose of used syringes. The leaflet also notes that there may be state laws about the right way to dispose of used syringes.

Injection button / Pen Body / Clear cartridge / Needle / Inner needle cap / Outer needle cap



Disposing of Your Used Pens and Needles

- **Do not** recap the needle or remove needle from the pen.
- Put your used needles and pens in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and pens in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,

  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and pens. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website: http://www.fda.gov/safesharpsdisposal.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

General Instructions to Patients on the Safe Storage and Disposal of Home Generated Sharps (The GSK call center provides additional instructions for consumers located in California)

Collection and Storage

- Place used needles, syringes, lancets and other sharps devices in a container approved for the storage of sharps.
- When your sharps disposal container is about three-quarters (3/4) full, follow your community guidelines for proper disposal methods. Do not throw sharps in the trash in the State of California.
- Keep sharps storage containers away from children and pets
- Do not place loose needles or other sharps in the household or public trash cans or recycling
- Do not flush loose needles and other sharps down the toilet
- Do not attempt to remove the needle without a proper needle destruction device
- Additionally, patients or Healthcare professionals may call the GSK Customer Care Call Center to receive disposal instructions (including California specific requirements), through a number provided in the prescribing information.

Sharps Disposal Options

Current best practices have been recommended by the EPA1, FDA2, and state and local municipalities throughout the United States. Current disposal options generally accepted for home generated sharps waste include the following:

- **Drop-Off Collection Sites** - Where available, home generators take filled sharps containers or other appropriate rigid storage container, to appropriate collection sites. These may include doctors' offices, hospitals, health clinics, pharmacies, police and fire stations, and medical waste facilities.

- **Household Hazardous Waste Collection Sites** – Where available, home generators take filled sharps containers or other appropriate rigid storage container to municipal household hazardous waste/recyclable waste collection sites for proper disposal.

- **Needle Exchange Programs –** Used sharps are exchanged for clean unused devices and the used sharps are properly managed and disposed of by the clinic or exchange venue. These programs are intended for illicit drug users and are not typically used by a prescription patient to obtain an injection device. However, the exchange venue can serve as a disposal location for a prescription patient.

In summary, GlaxoSmithKline supports the safe collection and proper disposal of home generated sharps by providing at no cost to the patient, educational materials on proper sharps disposal. Patients may contact our Toll Free Customer Call Center Hotline to obtain California specific disposal information including the locations of sharps collection facilities near their homes where they can dispose of their sharps free of charge.

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1 EPA Website http://www.epa.gov/wastes/nonhaz/industrial/medical/disposal.htm

2. FDA Website:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=sharps disposal&utm_content=1