



Thomas Polton, Sr. Director Product Stewardship

July 1, 2010

CalRecycle
Attn: Mr. Burke Lucy, Integrated Waste Management Specialist
801 K Street, MS 19-01
Sacramento, CA 95814

Re: Pfizer, Inc. SB 486 Safe Sharps Disposal Plan

Dear Mr. Lucy:

In accordance with Senate Bill 486, codified within Public Resources Code, Chapter 1 of Part 7 of Division 30, Sections 47115-47116, Pfizer is pleased to submit this report, which describes the Company's current sharps disposal support provided to patients who self-inject Pfizer medicines at home, and our plans for next year. As required, this report has been posted to Pfizer's public website, [here](#).

As background for public readers of this report, the California Legislature passed and the governor signed SB 486 in October 2009. The bill requires, on or before July 1, 2010, and annually thereafter, a pharmaceutical manufacturer that sells or distributes medication that is self-injected at home through the use of hypodermic needles and other similar devices (i.e., sharps) to submit to CalRecycle a plan that describes how the manufacturer supports the safe collection and proper disposal of the used sharps.

Highlights

- Pfizer provides information to patients for one on one instruction for all its self-injecting patients for all its self-injected products, nationwide.
- Pfizer provides information to patients to help them understand how to safely dispose of their injection devices, and the state and local requirements for sharps disposal, nationwide.
- Patients have multiple options to get sharps disposal questions answered, and get assistance in finding a local disposal option nationwide.

- Pfizer is innovating, by offering safer injection devices or reducing the number of sharps needed to administer its medicines.
- Pfizer supports the Coalition for Community Safe Needle Disposal, and its efforts to ensure patients can find the latest information on local, regional, and state sharps disposal programs.

Pfizer's Position

Pfizer is committed to helping assure the safe disposal of the used sharps and injection devices associated with its self-injected medicines. Each medicine and the patients who use it are unique and the sharps disposal support is customized to fit the medicine and patients' needs. Pfizer's highest priority is to its patients, to ensure they understand how to safely use and dispose of the injection device to protect the patient, family members, friends and the community from improper use of an injection device or the medicine in it, or an accidental needlestick.

Pfizer believes patient education and expansion of community programs serve patients' disposal needs best. Patient education is important because many patients simply do not know what disposal options are available to them. Pfizer is in an ideal position to educate new self-injecting patients through written materials we provide to our patients with our medicine, through the doctors who prescribe the medicines, and through the nurses and home healthcare providers who may assist the new patients. Pfizer believes that voluntary community based collection programs and expansion of them to include physician offices, pharmacies, hospitals, and medical waste facilities is one of the safest, easiest and least costly methods for disposal of used sharps for patients.

Keeping the cost of our medicines affordable is imperative for Pfizer; our patients and, third party payers insist on it. This is particularly the case for our older medicines that have or will soon lose patent protection. Pfizer must carefully weigh the costs and added benefits to patients of all enhancements to our product programs, including sharps disposal support.

Therefore, it is Pfizer's goal to educate its patients to safely dispose of used sharps and provide sharps disposal support to assist patients in finding a sharps disposal option that is as convenient as practical for the patient, and which meets all state and local requirements.

Overview

Pfizer has nine products that are self-injected by patients in the home. Six of the products are biopharmaceuticals (BeneFix, Enbrel, Genotropin, Rebif, Somavert, and Xyntha) that are provided to patients through specialty pharmacies, which are specially equipped to store and ship the medicines to patients properly (often they are refrigerated or frozen). Biopharmaceuticals are large molecules, often proteins, that are produced through

biotechnology. The remaining three products are older products that are or will soon face generic competition (Caverject and Neumega), and a Pfizer-generic product (Epinephrine Injection, USP). These products are attractive to patients and “buyers” of medicines as low cost options.

It is Pfizer’s policy to customize our support uniquely to the characteristics of each product and its patients’ needs; therefore, the sharps disposal support will likely differ product by product. Pfizer’s first priority is to ensure that its patients are properly trained and supported to ensure that they use their injection device correctly, and dispose of it safely so the patient, family members, friends, and community are protected from improper use of an injection device or the medicine in it, and from a possible accidental needlestick. All new patients who self inject at home receive training from their doctor, and if the doctor requires, a nurse trainer. The product inserts (written patient instructions that are provided with the medicine) all provide proper disposal instructions. Patients can find additional disposal information and support on Pfizer’s product stewardship [website](#), or by calling product specific 1-800 patient support numbers.

Pfizer recommends that patients do not throw sharps in the household trash without first checking the local requirements. Patients are encouraged to talk with their doctors, nurse trainers, pharmacists, or Pfizer about the local requirements and disposal options. Patients, in states such as California, are instructed that sharps cannot be thrown in the trash by law. Doctors, nurse trainers, call center staff and patients have access to www.safeneedledisposal.org via Pfizer’s product stewardship website. This site has an up-to-date summary of state sharps disposal requirements, with links to state programs. It also has an easy-to-use search tool that allows a patient to find local disposal options by county and state. Pfizer is a supporter of the Coalition for Community Safe Needle Disposal, the sponsor of www.safeneedledisposal.org, and our support is focused on keeping the state requirements, and disposal option information up-to-date.

Pfizer is innovating by offering safer injection devices for several of our medicines. Enbrel is offered in a single-use, autoinjector that can be considered a safe needle device because the needle retracts into the device after use. Approximately 40 percent of patients using the medicine are using this device and we expect the usage to increase. Two of our medicines (Xyntha and BeneFix) are now offered exclusively in a kit that includes a pre-filled diluent syringe that is needleless. This system reduces the number of waste sharps generated by the patients using these medicines by 50 percent, when compared to the old system of administration, which required a syringe and butterfly needle.

Pfizer carefully evaluates feedback received by patients, pharmacists and healthcare providers on its medicines, and feedback on its injection devices and sharps disposal is no exception. Pfizer is committed to continuously improve its patient support based on this feedback.

Sharps Disposal Support Plans for 2010-2011

The majority of Pfizer medicines that are self-injected at home reach patients through specialty pharmacies, which are specially equipped to store and ship the biopharmaceutical medicines properly to patients. Pfizer has reached out to several pharmacy trade associations in the hope of finding a means of reaching, on a national basis, this subset of patient pharmacies. In 2010, we would like to explore if a sharps management program could be arranged through them that would be convenient to patients and be cost effective, and develop the scope of a pilot program to be implemented in 2011, if a program indeed is deemed practical.

The product inserts associated with Pfizer's self-injected products currently provide correct and detailed sharps disposal instructions. However, the language is not consistent between all products and devices. Pfizer is planning to revise the sharps disposal language in all product inserts to assure consistent messaging, but as those product inserts require modification for other reasons, Pfizer expects this process to take a few years.

If CalRecycle has any questions regarding this report, feel free to contact me at tom.polton@pfizer.com or 212-573-7356.

Thomas Polton, Sr. Director Product Stewardship

cc: Donna Kaylor – Pfizer Government Relations and Public Affairs