

Novartis Pharmaceuticals Corporation

Plan for Supporting Safe Collection and Proper Disposal of Waste Sharps from Self-Injected Home Medications

Background

Novartis Pharmaceuticals Corporation ("Novartis") supports appropriate and safe disposal of home-generated waste sharps. During the development of innovative home injectable medicines, Novartis employs safe needle technologies in order to protect patients and individuals assisting in the disposal of waste sharps. Patients who self-inject Novartis products at home receive instructions from their physicians on how to use injection devices properly. Novartis provides physicians with Prescribing Information (PI) instructions for each Novartis product. The Novartis PI's recommend proper disposal of unused product or waste.

Extended Producer Responsibility (EPR) initiatives have been expanding broadly, with several focused on the pharmaceutical manufacturing industry. In several states and local jurisdictions, laws have been passed that mandate that pharmaceutical manufacturing companies establish take-back programs for the collection and disposal of unwanted medicines and sharps from households.

Novartis participates with <u>PPSWG</u> (Pharmaceutical Product Stewardship Work Group) to meet these obligations. PPSWG's mission is to provide infrastructure, guidance, and subject matter expertise to support member compliance and improve awareness of other existing pharmaceutical and sharps disposal options, which are extensive. The <u>MyOldMeds</u> website is provided by PPSWG as an easy way for patients to find a kiosk location near them to dispose of unwanted, unused, or expired medicines from households. As a member of PPSWG, we are proud to assist in the funding of this valuable service to our customers.

Regulations

California: Beginning on September 1, 2008, State law (Section 118286 of the California Health and Safety Code) makes it illegal 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 a sharps containers or other containers approved by the enforcement agency."

<u>Section 117671</u> of the California Health and Safety Code defines "home-generated sharps waste" as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household.

Senate Bill 486 requires pharmaceutical manufacturers that sell or distribute a medication in California that is usually intended to be self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device, to submit a plan to CalRecycle on or before July 1, 2010, and annually thereafter, that describes how the manufacturer supports the safe collection and proper disposal of the waste devices. The latest pharmaceutical manufacturers' sharps collection and disposal plans are available.

Minnesota: The State of Minnesota enacted Senate Bill 1323 which requires that a manufacturer that sells or distributes sharps usually intended for home use post on its website, prior to July 1, 2011, a plan that describes how the manufacturer supports the safe collection and proper disposal of sharps.

Novartis Pharmaceuticals Corporation has developed this Plan for Supporting Safe Collection and Proper Disposal of Waste Sharps from Self-Injected Home Medications (the "Plan") to meet the requirements of California's SB 486 and Minnesota's SB 1323.

Education and Outreach

Novartis will include a copy of this Plan on the following internet site https://www.pharma.us.novartis.com/corporate-responsibility/business-conduct/state-laws in order to educate patients and the public regarding the proper disposal of waste sharps.

Collection

Proper collection of waste sharps includes:

- Place waste sharps in a sharps container such as a red biohazard container, hard plastic containers such as a detergent bottle or metal containers such as an empty coffee can. Do not use glass or clear plastic containers.
- Seal the container using heavy duty tape and properly dispose of it;
 - Do not re-cap waste sharps
 - o Do not recycle waste sharps collection containers
 - o Do not put waste sharps containers in the trash or recycling bins
 - Keep these containers out of the reach of children and pets.

We are a member of the Pharmaceutical Product Stewardship Work Group (PPSWG), which coordinates pharmaceutical manufacturer efforts to respond to state and local household medicine and sharps take-back laws. We are a participating company in MED-Project USA and MED-Project LLC ("MED-Project"), owned by PPSWG, which serve as the stewardship organization designated by PPSWG members to implement and operate mandated household unwanted medicine and sharps take-back programs. The MyOldMeds.com website is provided by PPSWG as an easy way for patients to find a site near them to dispose of unwanted, unused, or expired medicines from households.

Novartis participates in the MED-Project, an organization which operates community level pharmaceutical product stewardship take-back programs in compliance with and as mandated by legislation. Residents in the following California areas can visit https://med-project.org/locations/ for sharps disposal locations: Alameda, Capitola, Santa Cruz, Scotts Valley, Watsonville, Costa County, Marin, San Francisco, San Luis Obispo, San Mateo, Santa Barbara, Santa Clara, Santa Cruz.

Disposal - General

Patients and consumers have several options available to them to safely dispose sharps waste.

Patients in California may visit California's CalRecycle web site at https://calrecycle.ca.gov/homehazwaste/sharps/to become familiar with all disposal options available and select the option that is most convenient. Below is a summary of the disposal options detailed on the California CalRecycle website:

Patients may access the following link for a <u>list of home-generated sharps consolidation</u> <u>point located throughout California</u> to identify the locations of over 550 sites where sharps containers can be properly disposed.

Patients may contact their health care provider or pharmacist for information on where to bring waste sharps.

Patients may contact their local household hazardous waste agency and ask if they collect sharps at their collection facilities or on household hazardous waste days.

Patients in Minnesota may visit the Minnesota Pollution Control Agency's (MPCA) website for information and guidance pertaining to safe disposal options for needles and syringes. Patients can access this information by clicking on this <u>Link.</u>

Disposal for Cosentyx

Patients prescribed Cosentyx have the option to enroll in Novartis Patient Support Services, which includes a sharps mail-back system available for no charge. Each mail-back system includes a 1.2-gallon FDA - cleared sharps collection container, Instructions for Use and a pre-paid mail-back box with all components required by the United States Postal Service for authorized mail-back of medical waste (UN 3291) to a regulated facility for environmentally responsible treatment and disposal. With Novartis's emphasis on environmentally sustainable solutions, the sharps mail-back program for Cosentyx provides our patients a responsible process that avoids disposal in landfills while protecting the patient and their community.

The sharps mail-back container is available by calling Cosentyx patient support at **1-844-267-3689** or via **Cosentyx.com**.

Other Resources

The United States Food and Drug Administration also provides information to patients and caregivers on the safe disposal of needles and other sharps on a website that is accessible by clicking this <u>Link</u>.

Company Contact Information

If you have any questions about how to dispose of your Novartis injection device, please call Novartis at 1-888-NOW-NOVA (1-888-669-6682).

Future Updates

Novartis Pharmaceuticals Corporation remains committed to help facilitate the safe disposal of its products and will continue to evaluate feedback and make modifications to our Plan as needed. This Plan will be updated annually and submitted to CalRecycle on July $\mathbf{1}^{\text{st}}$ in accordance with the requirements of California's SB 486. In addition, updates to the Plan will be posted on the Novartis website in accordance with Minnesota's SB 1323