

Bristol-Myers Squibb Company (BMS)

Sharps Management Plan

Introduction

California Senate Bill (SB) 486, Simitian. Medical Waste: Sharps Waste was approved by the governor of California on October 11, 2009. SB486 requires, on or before July 1, 2010, and annually thereafter, a pharmaceutical manufacturer that sells or distributes medication that is self-administered at home through the use of hypodermic needles and other similar devices to submit to the California Integrated Waste Management Board (Board), or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of these waste sharps. The bill requires the manufacturer and the Board, or its successor or agency, to post and maintain the plans on their respective Internet web sites.

Currently, Bristol-Myers Squibb is conducting several clinical trials in California which involve subcutaneous injection of our pharmaceuticals. These clinical trials are administered at investigative sites located throughout California by third parties. In each of these trials, the patients are provided with sharps to self-administer the medication in a home environment and puncture resistant containers for the safe collection of the used syringes. As an element of the clinical trial, patients are provided with instructions on the proper administration of the medicine and requested to return the used sharps materials to these investigative sites using the puncture resistant containers. At this time, BMS has no home generated sharps-related products which are sold commercially in California.

Elements of the BMS Plan

Safe collection and proper disposal of the waste devices

As stated above, BMS does not currently have commercial subcutaneous home administered pharmaceuticals on the market; however, clinical study home administered waste sharps are generated in California at this time. As an element of the clinical study, patients are requested to return their used sharps to the investigative site using the provided puncture resistant containers. The investigative site ultimately disposes of these sharps and containers in accordance with all applicable regulatory requirements. BMS home-generated sharps materials are not expected to enter into the California municipal trash cycle.

Educate consumers about safe management and collection opportunities

The patients involved in each of the clinical trials are provided with a puncture-resistant sharps container marked with the biohazard label for the safe collection of the used syringes. The patients are provided with written instructions on the proper use and disposal of the sharps container (please refer to Appendix A).

Support efforts of groups with interest in protecting public health and safety through the safe collection and proper disposal of waste devices

BMS continues to evaluate employing “safe needle technologies” (i.e. retractable needles; use of a blunting media) for our future products which will be entering commercial application. Such technologies/approaches aim to reduce the potential for inadvertent “sticks”.

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Appendix A Sharps Container User Requirements



MEDICAL
ACTION
INDUSTRIES, INC.

INSTRUCTIONS FOR USE
AND DISPOSAL



SHARPS-tainer™ (BOTTLES)

**** NOTE POST THESE INSTRUCTIONS NEAR THE POINT OF USE**

CAUTIONS:

1. Before use, make certain the clear trap is located in the throat of the bottle.
2. Locate container out of traffic areas so as to minimize the possibility of the container being knocked over.
3. Never place hands inside the container.
4. Always grasp or carry the container by the handle or from an area above the fill line.
5. Do not compact the contents of the container or force sharps into the container. When the contents have reached the recommended fill line (approximately 3/4 full), the container must be changed.
6. Follow *Closing Instructions*. **DO NOT PRESS ON THE MIDDLE OF THE TOP WHEN CLOSING.**

CLOSING INSTRUCTIONS:

1. When the contents of container reaches the fill line, it is time to close the lid.
2. Place the lid (tethered to the bottle) over the opening of the container.
3. Place your thumbs and/or fingers on the edge of the white cap and, while gently pushing on the edge of the cap, move your fingers around the edge.
4. As your fingers move around the edge of the cap, the cap will snap into place.

DISPOSAL INSTRUCTIONS:

1. Disposal of contaminated sharps containers must be done in compliance with national, state and local regulations and in accordance with institutional policy.
2. Inspect container prior to moving it to ensure there are no sharps protruding from the container.