



June 25, 2020

California Department of Resources, Recycling and Recovery (CalRecycle)
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RE: 2020 Sharps Management Plan for Merck & Co., Inc

To Whom It May Concern:

Merck Sharp & Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., (hereinafter "Merck" or "the Company") provides this letter in response to the requirements of California Article 3.3 of Chapter 1, Part 7 of the Public Resources Code (2009) (contained in Senate Bill 486). At Merck, our fundamental responsibility is discovering, developing and delivering innovative medicines and vaccines that can make a difference in people's lives and create a healthier future. We believe that fulfilling this responsibility in a sustainable manner demands high ethical standards and a culture that values honesty, integrity and transparency in all that we do.

Merck manufactures several medicines which a patient injects at home at the direction of his or her physician. These medicines are used in a variety of areas, including virology, oncology, and fertility. In addition, Merck Animal Health manufactures an injectable veterinary insulin to treat dog and cat diabetes. It is an important part of such therapeutic regimens for the patient to understand the appropriate methods by which to dispose of the resulting home generated sharps waste. Therefore, Merck supports the safe management of used sharps for its injectable medicines as described below.

Merck uses product enhancement programs to educate the healthcare provider, as well as the patient, on the methods for used sharps management. New patients are provided information on proper disposal and, where products utilize the safe sharps technology, detailed instructions on the use of these technologies for specific drug delivery injection devices. This information is

provided to the patient by the healthcare provider at the beginning of the therapy cycle. As part of the therapy support, the healthcare provider discusses the FDA approved administration of the Merck treatment, which includes discussion of the proper management of used sharps. Furthermore, for all Human Health products, appropriate disposal information and instruction are included on many of the package inserts and patient information sheets supplied to the patient. The following outlines the current therapeutic product area disposal assistance provided by Merck:

Oncology

Patients use either a standard syringe injector or a pen type injector, both are single use. The syringe injector utilizes the safe sharps technology and instruction on the proper use of the needle shield is included on the product package insert.* A new patient to this therapy receives a therapy bag. The bag contains items to help patients safely administer the medicine and dispose of used sharps. The patient information that accompanies the product packaging includes printed materials on the use and disposal of used sharps*. The patient's healthcare provider is encouraged to discuss used sharps disposal requirements as part of the initial therapy support. Merck advocates the use of approved sharps containers for the disposal of used sharps.

Women's Fertility and Virology

These treatments utilize pen injectors for multiple use or single use, pre-filled syringes and standard syringes for single-use products. Healthcare providers provide instructions on proper administration to patients and discuss proper procedures for the disposal of used needles and syringes. In addition to healthcare provider discussions, needle, syringe and cartridge disposal information is provided on the product inserts as well as the patient instructions for administering the injectable products. The Fertility pen injectable uses Outer Needle Shield technology to safely remove the needle from the pen so it can be disposed of appropriately. The syringe injector utilizes the safe sharps technology and instruction on the proper use of the needle shield is included on the product package insert. The patient information also instructs the patient not to dispose of the needle in their household trash.*

Animal Health

Animal therapies that utilize injectable delivery systems are strictly managed by veterinarians. The customer, while administering the medication at home, follows a specified treatment regimen including sharps management and follow-up visits. These visits allow the veterinarian

to collect used sharps, examine the patient and review the delivery system requirements for the next round of treatment.

In addition to the above-mentioned therapeutic support for our patients, Merck participates in the Pharmaceutical Product Stewardship Work Group sharps collection program for the counties that have promulgated sharps collection legislation. Merck provides support to our healthcare partners for the medicines we manufacture and distribute. Our relationship with our customers is of the utmost importance to the Company and we look forward to future efforts to assist them.

References

* <http://www.merck.com/product/prescription-products/home.html?WT.svl=mainnav>