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Sharps Disposal Plan for Janssen Biotech, Inc. (Janssen)

Janssen Biotech, Inc. is a Johnson & Johnson (J&J) company. J&J is committed to the health and wellbeing of families everywhere. Our commitment is evident in the various sustainability goals, initiatives and programs that we undertake across a broad spectrum of environmental, social, economic development and corporate governance areas. More information about J&J's sustainability progress and programs can be found at: http://www.jnj.com/responsibility/esg.

This plan describes the processes to ensure the safe use, collection and disposal of the used injection devices for the following Janssen Biotech, Inc. self-injected drugs:

A) SIMPONI® (golimumab) - the drug is provided in a pre-filled syringe or a SmartJect® autoinjector for both 50 mg and 100 mg doses (50 mg packaging & devices are shown below).



B) STELARA® (ustekinumab) - the drug is provided in a pre-filled syringe for 45 mg and 90 mg doses.



Both SIMPONI® and STELARA® are approved for use in the United States by Janssen Biotech, Inc. The sharps disposal programs described in this Plan are available to patients nationwide at no cost to the patient.

I. Description of sharps disposal program:

Janssen Biotech, Inc. provides patients of SIMPONI® (golimumab) and STELARA® (ustekinumab) with the following programs for the safe collection and disposal of their used injection devices:

A) SIMPONI® - When healthcare professionals prescribe SIMPONI®, they provide the patients with educational materials. Information about the used sharps return service, called SimponiOne® Safe Returns®, is presented in these patient education materials. Patients who are currently treating with SIMPONI® can also get information on SimponiOne® Safe Returns® by calling 1-877-MY SIMPONI (1- 877-697-4676), or by going to the website: www.Simponi.com/SafeReturns, and then navigating to the "Get Support" section.

Patients sign up for the program by either calling the toll-free number, by completing a business reply card in the Patient Guide for SIMPONI®, or by visiting the website (above). Following enrollment, they will receive a Safe Returns® Starter Pack in the mail. Included in this pack are the Safe Returns® instruction guide and a one-gallon white plastic disposal container. Once the disposal container is full (about 1 year later), patients call the toll-free number or visit http://www.Simponi.com to request either a Replacement Pack, for continuing patients or a Mail-Back Pack to return their filled container.

The Replacement pack includes a new one-gallon Safe Returns® disposal container, the Safe Returns® instruction guide, and a postage-paid mail-back box with everything needed to return a filled container (waste generator form, tape, plastic bag and tie).

The Mail-Back pack includes the Safe Returns® instruction guide and a postage-paid mail-back box with everything needed to return a filled container (waste generator form, tape, plastic bag and tie).

By following the Safe Returns® instructions and giving the box to the mail carrier, dropping it at a U.S. post office, or anywhere the U.S. Postal Service arranges pickup, the used SmartJect® autoinjectors or used syringes will be shipped to Stericycle, a licensed medical waste facility for disposal.

When the mail-back box is received by the disposal facility, the patient will be mailed a copy of the waste generator document, confirming that the mail-back box has been destroyed.

The SimponiOne® Safe Returns Instruction Guide, is available to the public on this website: www.Simponi.com/SafeReturns, and then selecting the "Get Guide" button.

B) STELARA® (ustekinumab) - The Safe Returns® program for STELARA® patients who are self-injecting is available to the public and to patients on this website: http://www.safereturnsinfo.com under the "Syringe Disposal" tab.

When a patient who self-injects STELARA® enrolls in the Safe Returns® program, he or she will be sent a starter pack that includes a plastic container for holding a year's worth of used syringes. There are instructions included on contacting StelaraSupport™ after the container is full. After notifying StelaraSupport™ that the container is full, a postage-paid mail-back box and a new plastic syringe container will be sent to the patient.

II. Patient Education about sharps disposal:

Information about proper disposal of used SmartJect® autoinjectors and used syringes are provided to patients through patient education brochures, websites, and toll-free numbers for SIMPONI® (golimumab) and STELARA® as described above. SimponiOne® Safe Returns® and the Safe Returns® program for STELARA® are covered in the patient education materials and on the product websites.

III. Coordination with regional and state sharps management efforts:

The sharps disposal programs are available free to SIMPONI® and STELARA® patients nationwide. We believe that the programs meet the intent and requirements of local, regional, and state level sharps management efforts, including but not limited to California SB 486 and Minnesota Statutes 2008, section 116.835. We will consider other opportunities to engage with the state and regional authorities on sharps management patient education.

IV. Consumer Involvement:

The SimponiOne® Safe Returns® program was developed using market research and feedback from patients and healthcare professionals. Feedback from patient support centers is tracked and assessed. We also involved stakeholders such as representatives from the medical waste disposal partner and the U.S. Post Office in the program's development. Since the program was launched in late 2009, Janssen Biotech, Inc. has continued to monitor the patient enrollment and participation to look for opportunities for improvement. Patients, caregivers, and healthcare professionals may inquire about the program, have questions answered, and concerns addressed by calling 1-877-MY SIMPONI (1-877-697-4676).

STELARA® in a pre-filled syringe, was approved for patients to self-inject in May 2013. Shortly following FDA approval, STELARA® launched their own sharps disposal program modeled after the SimponiOne® Safe Returns® program and incorporates dosing schedule and patient insights into the frequency and collection of kits.

Please read the Full Prescribing Information, including Boxed Warnings and Medication Guide for SIMPONI® and discuss with your doctor.

Please read the Full Prescribing Information, Medication Guide for STELARA® and discuss with your doctor.