DISPOSAL OF USED FENTANYL TRANSDERMAL PATCHES

I. INTRODUCTION

Fentanyl is a synthetic narcotic subject to international control, included in List I of the Narcotics Convention of 1971. Used as an analgesic and anesthetic, it is about 100 times more potent than morphine, and is considered in medical use as the “second step” in the treatment of intense chronic pain. Excessive overdose can prevent a patient’s breathing and cause coma and death. In some countries fentanyl is used as a recreational drug.

Transdermal fentanyl is a pharmaceutical applied in skin patches that release a continuous dose for the established duration and is indicated for management of moderate to severe chronic pain.

The International Narcotics Control Board, in its 2010 annual report, urged governments to prevent the improper use of fentanyl patches, and recommended that they take specific measures for the secure disposal of used fentanyl patches.

Local public and national authorities are responsible for waste management policies and for ensuring the control and monitoring of the waste elimination system.

It is necessary to control the drugs until their final disposal, and establish guidelines for the proper disposal of fentanyl transdermal patches used by patients. This guide is intended as a tool for reducing the risk of use or unintentional overdose and illegal use of fentanyl transdermal patches, and for improving management of the waste in the Latin American countries.
II. DEFINITIONS

**Dispensing:**
Professional action of the pharmacist to inform and guide the patient or user regarding the proper use of the medicine (adverse reactions, medical interactions, storage and disposal of the product).

**Encapsulation:**
This waste treatment method consists of immobilizing the products in a solid block in a steel or plastic drum. The drums must be cleaned before use and cannot have contained explosives or hazardous materials.

**Pharmaceutical establishment:**
An establishment dedicated to the storage, distribution, pharmaceutical care, preparation, or dispensing of pharmaceutical products, etc., which is licensed to operate by health authorities.

**Generator:**
A person or corporation that by virtue of their activities generates waste as a producer, importer, distributor, seller, or user.

**Waste management:**
Any technical or administrative activity involving planning, coordination, arrangement, design, application, or evaluation of policies, strategies, plans, and action programs for appropriate waste management at the national, regional, and local levels.

**Incineration:**
Method of waste treatment that consists of chemical oxidation for the complete combustion of waste in appropriate installations in order to reduce and control risks to health and the environment.

**Inertization:**
A variation of encapsulation that includes the separation of the products’ packaging material (paper, cardboard, plastic, or other).
Waste disposal:
Any technical operation on waste that involves the manipulation, conditioning, separation, transport, storage, transfer, treatment, final disposal, or any other technical operation used from the generation of the waste to its final disposal.

Transdermal patch:
A pharmaceutical product that consists of a multi-layer system with the following parts: an impermeable covering sheet, a reservoir with the active ingredient, and a plastic cover. Its purpose is to gradually release the active ingredient when applied to the skin.

Waste in the local government area:
Waste in the local area is the responsibility of the local government from the moment the generator delivers it or disposes of it in the place established by the local government for its collection.

Hazardous waste:
Refuse or waste that by its characteristics and handling poses significant danger to health or the environment.

III. SPECIFIC CONSIDERATIONS
Fentanyl patches must be purchased by prescription in pharmaceutical establishments and dispensed by the pharmacist, who gives instructions for their proper disposal. If the package seal is broken, or the patch is cut, damaged, or altered in any way it is recommended that it not be used and be disposed of immediately.
1. GUIDELINES FOR THE DISPOSAL OF FENTANYL PATCH WASTE AT HOME:

1. Remove the patch from the skin, holding the edges between the thumb and index finger, being careful not to touch the adhesive.

2. After removing the patch, fold it in half so that the adhesive side attaches to itself.

3. Place the folded patch in its original package or, if you don’t have it, in a sealed bag, to prevent contact with the fentanyl.

4. After handling the patch, hands should be washed with lots of water.

5. Store the patch in a bag labeled “Hazardous waste” in a safe place out of reach of children and pets.
6. Leave the labeled bag at the establishment authorized by the appropriate health authority.

7. It is important not to discard the original package of the product after opening it, so that the user can put the fentanyl patch back in the original package after use.

IN CARE CENTERS:

Disposal of fentanyl patch waste in care centers should be done in accordance with the guidelines for home disposal of fentanyl patch waste presented above in numbers 1 to 7.

The methodology to be followed is:

1. Wrapping the waste:

   The containers need to be of a size, weight, color, form, and material to ensure proper identification, facilitate transport and cleaning operations, and be sealed to prevent exposure.

2. Collection and internal transport:

   Consists of transferring the waste safely and rapidly from the source of generation to the place selected for its temporary storage. The personnel collecting it must use minimum protective equipment.
3. Temporary storage:

Will be done in an appropriate place to centralize the collection of waste until it is transported to the place of treatment or final disposal. It must meet the following technical criteria:

a. Exclusivity: the place must be used only for hazardous medical waste and have signs indicating its danger, and can never be used to store other materials. Containers shall be a single color, labeled for identification.

b. Security: The place must have a physical structure to prevent damage from the climate or accidents, or easy access by unauthorized persons. Access to the area should only be permitted for personnel responsible for these activities. The place should preferably be located far from the areas for patients, visitors, kitchen, dining room, bathrooms, meeting rooms, recreation areas, offices, workshops, and laundry, and near the service doors of the facility in order to facilitate external transport operations.

4. Collection and external transport: this will be done with waste that complies with the wrapping, sealing, and labeling described above.

5. Treatment and final disposal: the special waste, depending on its characteristics, must be given specific treatment or packed for disposal in secure or confined landfills.

2. OPERATING PROCEDURE FOR DISPOSAL

The health authority will prepare a plan for the disposal of medicine, raw material, and waste according to the classification categories, methods, and procedures described in this guide.

As needed, it will coordinate with authorities of local governments, police, and others.
• CONDITIONING

a) General storage conditions: the health authority must designate the establishments authorized to collect waste fentanyl patches.

b) These establishments must have duly identified secure containers that cannot be opened except by competent authority, labeled “COLLECTION OF HAZARDOUS WASTE,” in a dry, secure, and preferably isolated space until they are collected for their final disposal.

c) The container will be collected as often as necessary, depending on the use of these medicines in the country. A replacement container should be left in the authorized center.

Transfer of the container must be done according to the security measures established by the corresponding health authority.

A record of container delivery must be maintained. This register should include the name of the establishment, date of delivery, etc.

• TREATMENT PRIOR TO FINAL DISPOSAL

GRINDING

The fentanyl patches must be ground before their final disposal.

• FINAL DISPOSAL TREATMENT

Three types of treatment are used for hazardous wastes, depending on the technology used for the purpose:

a) Incineration.

b) Inertization.

c) Encapsulation
a) **Treatment by incineration:**

Incineration is done in a boiler that complies with environmental safety measures to prevent contamination.

b) **Treatment by inertization:**

This is done by mixing water, cement, and limestone to form a homogeneous paste, transformed into a semi-liquid state, which is deposited in the bottom of a sanitary landfill where it hardens to form a solid mass dispersed among the other waste.

c) **Treatment by encapsulation**

The solid waste is deposited in a plastic or steel container that is sealed and buried at the bottom of the sanitary landfill.

The containers must be cleaned before use and not have contained explosive or hazardous materials.
APPENDIX

SCHEME OF THE FINAL DISPOSAL PLAN

1. **Justification:**
   The International Narcotics Control Board, in its 2010 annual report, urged governments to take specific measures for the secure disposal of used fentanyl patches and prevent their improper use.

2. **General objective:**
   To achieve the proper disposal of fentanyl transdermal patches.

3. **Date and place:**

4. **Responsible parties:**
   Local and national public authorities are responsible for formulating waste management policies and ensuring the control and monitoring of the waste disposal system.

5. **Budget:**

6. **Financing:**