

PHARMACEUTICALS

Pharmaceutical & Personal Care Products (PPCPs):

Modern society uses products that contain various chemicals for a wide variety of personal health and hygiene uses, including preventing and combating disease, alleviating symptoms from illness and injury, personal comfort, grooming and cosmetic purposes. Pharmaceutical and Personal Care Products (PPCPs) include medicines, insect repellents, sunscreens, perfumes, soaps, fragrances, and lotions. These products, which can be found in any drug store, have the potential to enter the environment through domestic sewage and other sources. Some are endocrine disrupting compounds (or EDCs) and could possibly affect the system of glands that produces hormones that help control the body's metabolic activity and development. The following are some examples of PPCPs:

Over the Counter (OTC) Pharmaceuticals

- Aspirin
- Acetaminophen (Tylenol)
- Antihistamines (Benadryl, etc.)
- Ibuprofen

Prescription Pharmaceuticals

- Pain medications (Codeine, Vicodin, Percodan)
- Blood Pressure medications
- Heart medications
- Antibiotics

Personal Care Products

- Lotions and creams
- Fragrances (perfumes)
- Sunscreens
- Cosmetics
- Insect repellants (DEET)

<http://www.mass.gov/dep/toxics/stypes/ppcpedc.htm>

HOW PHARMACEUTICALS SHOULD BE STORED AND TRANSPORTED

Storage conditions for pharmaceutical products and materials should be in compliance with the labeling, which is based on the results of stability testing

Recorded temperature monitoring data should be available for review. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored material or product plus 1 year, or as required by national legislation. Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

Written instructions and records should be available which document all activities in the storage areas including the handling of expired stock. These should adequately describe the storage procedures and define the route of materials and pharmaceutical products and information through the organization in the event of a product recall being required.

Permanent information, written or electronic, should exist for each stored material or product indicating recommended storage conditions, any precautions to be observed and retest dates. Pharmacopoeial requirements and current national regulations concerning labels and containers should be respected at all times

Records should be kept for each delivery. They should include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt, assigned batch number and the expiry date. Where national regulations prescribe that records must be retained for a certain period, this must be observed. (Otherwise such records should be retained for a period equal to the shelf-life of the incoming materials and products, where applicable, plus 1 year).

Transported

Materials and pharmaceutical products should be transported in such a way that their integrity is not impaired and that storage conditions are maintained

Special care should be exercised when using dry ice in cold chains.

In addition observing to safety precautions, it must be ensured that the materials or product does not come in into contact with dry ice, as this may adversely affect the product quality, e.g. by freezing

Where appropriate, the use of devices to monitor conditions such as temperature during transportation is recommended. Monitoring records should be available for review.

The outside container should offer adequate protection from all external influences and should be indelibly and clearly labeled

http://apps.who.int/prequal/info_general/documents/TRS908/WHO_TRS_908-Annex9.pdf

Key requirements generally include ensuring that goods are appropriately classified, packaged and labelled. It is also important that everyone involved understands how to minimise risks. Special training may be required.

DISPOSAL METHODS

Decision

The hospital, district or regional pharmacist or organizations with pharmaceutical programmes decide when action needs to be initiated, because of an accumulation of unwanted pharmaceuticals which are unfit for human consumption and for veterinary treatment.

Approval

Approval and sanctioning of disposal of pharmaceuticals must be sought from the appropriate authority. This authority will differ from country to country and may be the department responsible for pharmaceutical management within the ministry of health, the drug regulatory authority, or the regional or local health authority (pharmaceutical officer). In some countries the ministry of the environment should be involved. The guidelines are particularly useful in emergency situations or for countries in transition where official regulations have not yet been developed. In non-emergency situations when significant quantities of donated pharmaceuticals are disposed of, for whatever reason, it may be necessary and judicious to inform the donor.

Planning

Planning, in terms of funding, necessary expertise, human resources, professional time, space, equipment, material and available disposal options will be required. This is essential before practical steps can be taken to start disposal. To obtain a rough estimate of the volume of materials to be sorted, it is recommended that measurements are made using a tape measure, and conversion from volume of material to weight is made using a density figure of 0.2 metric tons/cubic metre.

Forming work teams

Work should be conducted by teams consisting of supervising pharmacists and general medical workers, who are preferably pharmaceutical technicians or experienced pharmaceutical warehouse personnel. The size of each team, and the ratio of experts to workers, will be determined by the volume and composition of the stockpiles, and working conditions at the sites.

Health and safety of work teams

All workers should wear appropriate protective equipment including overalls and boots at all times, and gloves, masks and caps when appropriate. Masks should be worn when tablets or capsules are being crushed as part of the disposal technique (for example, inertization, and see Section 2.4) and when there is a risk of powders being liberated. Particular care is required when handling antineoplastics.

Sorting

The objective of sorting is to separate the pharmaceuticals into separate categories for which different disposal methods are required. The separation should be made into those that can be safely used and returned to the pharmaceutical supply system and those that require disposal by different methods. For example, controlled drugs (e.g. narcotics), antineoplastic drugs and antibiotics all require special methods of disposal. Substantial investment in human resources may be required for identifying and separating pharmaceuticals.

Disposal

Disposal options vary considerably between situations, and the ideal solution may not be feasible. The aim of these guidelines is to propose the simplest, safest and most practical alternatives.

Security

Controlled substances (e.g. narcotics and psychotropics) require tight security and control. In some countries, scavenging of material from landfills is a frequent problem, and, disposed drugs may be recovered and sold by the scavengers. Measures are therefore necessary to prevent diversion during sorting, and pilfering of drugs from landfills. Immobilization (see Sections 2.3 and 2.4) is the best method of preventing pilfering from a store or landfill. If, as a last resort, pharmaceuticals must be discarded direct to a landfill then they must be covered immediately with a large quantity of municipal waste.

http://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf

ENVIRONMENTAL RISKS

- Sewage treatment plant (STP) effluents,
- Surface waters,
- Seawater, groundwater and even drinking water.

<http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=672612>

See also: <http://phys.org/news/2010-10-environmental-pharmaceuticals-inadequate.html>

<http://www.mass.gov/dep/toxics/stypes/ppcpedc.htm>

http://environmentalhealthcollaborative.org/images/Buxton_Health_Summit_final.pdf