

Management of Waste Medicines

The Environment Agency for England and Wales and the Scottish Environment Protection Agency are the enforcement bodies for waste arrangements in England, Scotland, and Wales.

Normally handling waste requires a licence, however under the Non-Waste Framework Directive (for England and Wales) and The Waste Management Licensing Regulations 2011 (for Scotland) registered pharmacies are permitted to accept returned medicines from patients or individuals and care services.

- Waste medicines must be kept in secure waste containers in a designated area preferably away from medicines that are fit for use.
- If sharps (syringes / needles) are accepted, they should be disposed in a sharps container.
- Blister strips can be removed from their inert outer packaging but tablets should not be de-blistered, unless they are controlled drug tablets and capsules, which require denaturing.
- The whole bottle (including empty bottles that may contain residue) should be placed into a pharmaceutical waste container because the mixing of different medicines could be hazardous (except when denaturing controlled drugs).
- All patient identifiable information must be destroyed or totally obscured before disposal.
- Patients should be encouraged to return unused and/or unwanted medicines to a pharmacy for safe disposal.

Controlled drugs waste management:

Pharmacies are required to denature controlled drugs prior to disposal. Usually, this process requires an appropriate licence but pharmacies are exempt from needing one (yet they must register their exemption). In England and Wales, an exemption is issued by the Environment Agency and is known as the “T28 exemption”.

In Scotland, the exemption is issued by the Scottish Environment Protection Agency (SEPA).

- The Home Office has advised that **all** controlled drugs in schedules 2, 3 and 4 (part 1) should be denatured and, therefore, rendered irretrievable before disposal.
- The destruction of **pharmacy stock** (e.g. expired stock) of schedule 2 controlled drugs needs to be witnessed.
- For schedule 3 medicines it would be good practice to have another member of staff witness the denaturing but is not a legal requirement.
- The destruction of patient returned controlled drugs does not require witnessing (although it is good practice to have another member of staff who is familiar with controlled drugs be a witness anyway).

For pharmacy stock that has been destroyed, an entry should be made in the controlled drug register for the denaturing of schedule 2 controlled drugs and the controlled drug balance updated accordingly. For patient-returned controlled drugs a separate record should be kept at the pharmacy that includes entries of patient-returned controlled drugs received by the pharmacy and when they are denatured.

Note: If a pharmacy is engaged in manufacturing, compounding, importing or exporting schedule 3 or 4 controlled drugs then record keeping arrangements apply, which means that destruction of these items requires an authorised witness.

In prisons use of schedule 3 controlled drugs (e.g. buprenorphine) should be recorded in the controlled drugs register therefore, any destruction should also be recorded.

Various individuals and classes of person (e.g. police constables) are authorised to witness the destruction of controlled drugs. This authority is derived from the Home Secretary. It can also be derived from the Secretary of State for Health or from an accountable officer.

Following the Shipman Inquiry, accountable officers were introduced with responsibility for supervising and managing the use of controlled drugs in their organisation or setting.

One of the many roles of accountable officers is to appoint authorised witnesses for the destruction of controlled drugs.

Note: An accountable officer has the power to authorise other persons to witness the destruction of controlled drugs. However the 2001 Regulations prevent an accountable officer from being an authorised person directly. Persons authorised by the accountable officer are usually senior members of staff who are not involved in the day-to-day management or use of controlled drugs.

Home Office guidance:

- All controlled drugs in schedule 2, 3 and 4 (part 1) should be destroyed by being denatured and rendered irretrievable before being placed into pharmaceutical waste containers and sent for incineration.
- For all forms of denaturing, and particularly if grinding or crushing tablets or breaking containers is involved, individuals should work in a well-ventilated area and wear suitable protective gloves, a face-mask and goggles as appropriate; following good Health and Safety practice.
- Whilst this guidance acknowledges the use of CD denaturing kits, it is the responsibility of the manufacturer or supplier of the kit to ensure that the kit and the instructions for use are fit-for-purpose. Pharmacists are responsible for using a kit that has been obtained from a reputable source and to use those kits in accordance with the manufacturers' instructions.

Method of destruction:

- Grind or crush solid dose formulations before adding to the CD denaturing kit / pour liquid dosage forms into CD denaturing kit / open ampoules and pour liquid contents into CD denaturing kit or add water to dissolve powder before emptying into denaturing kit / for patches remove the backing and fold the patch over on itself, then place into a waste disposal bin or a CD denaturing kit / for aerosol expel into water and pour the resulting liquid into CD denaturing kit or expel into an absorbent material and dispose as pharmaceutical waste.
- Alternative method: place crushed and dissolved solid dose forms or pour liquids onto an appropriate amount of cat litter (or similar product) and add to an appropriate waste disposal bin supplied by the waste contractor.
- Methadone stock bottles: when bottles have been emptied as much as possible during dispensing, bottles should be rinsed and liquid disposed into a pharmaceutical waste bin
- For patient returned liquid Controlled Drug containers- must denature excess liquid and container should be rinsed and the rinsing liquid added to the denaturing kit
- Remember that all containers (glass ampoules, aerosols, bottles) should also be disposed of safely in the appropriate waste disposal bins.

Further information on management of waste medicines can be found at:

- The Environment Agency website
<https://www.gov.uk/government/organisations/environment-agency>
- The Pharmaceutical Services Negotiating Committee:
<http://psnc.org.uk/services-commissioning/essential-services/disposal-of-unwanted-medicines/>

