



**Royal
Pharmaceutical
Society**
of Great Britain

**THE HAZARDOUS WASTE (ENGLAND AND WALES)
REGULATIONS 2005**

**Interim Guidance for Community Pharmacists for
England and Wales and Information for Scotland**

This guidance was prepared on behalf of the Practice and Quality Improvement Directorate of the Royal Pharmaceutical Society of Great Britain.

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Interim Practice Guidance for Community Pharmacists on “The Hazardous Waste Regulations 2005”

This guidance applies to England and Wales and provides information for those working in Scotland.

The Essential Services within the new pharmacy contract for England and Wales include the disposal of unwanted medicines.

The storage, carriage, processing and supply of waste are subject to stringent controls designed to minimise the negative effects of waste on the environment and promote public safety.

Due to forthcoming changes to the waste legislation, which will come into operation on 16 July 2005, this summary has been compiled to clarify some of the issues regarding waste.

Duty of Care

Under the **Environmental Protection Act 1990**, every producer of waste is under a duty to ensure safe handling and disposal of the waste. This duty of care continues throughout the chain and includes all intermediaries from producer until final disposal. If any part of the disposal chain fails, the initial waste producer can be considered to have failed in their duty of care.

Waste Classification

The definition of ‘household waste’ under **The Controlled Waste Regulations 1992** includes waste medicines from a patient’s own home and waste medicines from a residential home.

Medicines and clinical waste from a nursing home or other commercial establishment are classed as ‘industrial waste’.

Storage of waste

The storage of waste on the premises of production by the producer does not require a waste management licence. This means that a pharmacy does not require a licence to store its own unwanted date expired stock, pending disposal.

The holding of waste from other sources requires a licence or registered exemption under the **Waste Management Licensing (WML) Regulations 1994**. There is an exemption for the secure storage at a pharmacy of waste medicines (including those which are hazardous waste) which have been returned from households or by individuals. The total quantity of such returned waste medicines must not exceed 5 cubic metres at any time and must not be stored for longer than six months.

Community pharmacies will need to register exemption for each premise from the WML with the local Environment Agency office. They will then be able to store returned medicines from patients/ customers living in their own home or a care home which was classified as a residential home.

Care Homes/ Nursing Homes

As the exemption from holding a WML does not extend to storage of industrial waste, an exempt pharmacy cannot store returned medicines from a care home that would have classified as a nursing home i.e. provides nursing care. The situation for controlled drugs is not clear. The Misuse of Drugs regulations 2001 permit any person who has lawfully received a controlled drug to return it to the person who supplied it. However under the new waste regulations, pharmacies cannot accept waste medicines (including controlled drugs) from nursing homes. The Society and PSNC are trying to seek clarification on this.

Any queries from nursing homes relating to the disposal of waste can be referred to the local Environmental Agency.

If a “nursing home” disposes of its waste via a pharmacy then both have committed an offence and could be prosecuted.

Carriage of Waste

If you transport waste medicines as part of your business you must register with the Environment Agency as a waste carrier, unless you are carrying only your own waste medicines. In the course of visits to patients’ homes or to residential homes, pharmacists and their staff may be handed unwanted medicines for return to the pharmacy for safe disposal and this can be classed as carriage of waste. It is questionable whether carrying unwanted medicines back to the pharmacy when returning from delivering medicines constitutes part of a business and the Environmental Agency office will be able to offer guidance.

It should be noted that the collection of unwanted medicines during the course of visits to patients’ homes or to residential homes is outside the requirements of Essential service.

The cost of a licence in June 2005 was £136 and this may be obtained from the Environment Agency (EA) and will cover the whole business of any pharmacy contractor i.e. several pharmacies if owned by the same contractor. It will be valid for three years and renewal costs £91.

Destruction of controlled drugs

Controlled drugs can be placed into waste containers only after the controlled drug has been rendered irretrievable (i.e. by denaturing).

The Environmental Agency is the regulatory authority for the waste legislation and has confirmed that the sorting of waste medicines and denaturing of controlled drugs returned to a pharmacy, from households and by individuals is a “low risk” activity. The Agency does not believe it is in the public interest to expect pharmacies to obtain a waste management license for these activities. The Environment Agency emphasises, however, that it may amend or revoke its position at any time and will continue to consider enforcement in all circumstances where an activity has or is likely to cause pollution or harm to health.

In general pharmacists are advised to use CD denaturing kits wherever possible in order to denature CDs. Pharmacists should ensure that where alternative methods are used to denature CDs, these should protect the environment and workers who might be affected by this activity.

CDs returned by patients from their own homes and residential homes can be sorted, de-blistered and denatured using a CD denaturing kit. Fentanyl patches should have the backing removed and the patch folded over on itself and placed in the waste disposal bin. Ampoules should be opened, the liquid poured into the resin kit and the ampoule itself placed in a sharps bin. An ampoule that contains powder can have water added to it to dissolve the powder and the resulting mixture can be poured into the CD denaturing kit.

Pharmacists are reminded that they can destroy patient returned CDs without an authorised witness, and these should be destroyed as soon as possible. Denaturing of expired CD stock can also take place without a waste management licence, in the presence of an authorised witness. Authorised witnesses include inspectors of the Royal Pharmaceutical Society, police chemist inspection officers, Home Office inspectors and authorised personnel within primary care trusts. The method of destruction should give the same consideration to environmental impact and risk to health, as for controlled drugs returned from patients.

Note: Pharmacies cannot accept CDs from care homes previously registered as nursing homes and stock CDs from prescribers e.g. doctors, dentists etc. Further guidance on CD waste destruction is being produced and will be available on the website.

'De-Blistering'

The removal of individual tablets or capsules from a blister strip or the decanting of liquids from bottles should be avoided as this falls within the definition of waste treatment, which is a licensable activity. The Environment Agency has confirmed that the removal of a blister strip from other inert packaging, so that the blister strip can be placed in the waste container and the outer packaging can be recycled, would not be regulated as a licensable waste treatment.

De-blistering is allowed only in the case of controlled drugs where it is necessary to remove the solid dosage form from the blister strip or tablet bottle in order to denature the drug and render it irretrievable.

Segregation of medicines into solids, liquids and aerosols

The NHS (Pharmaceutical Services) Regulations 2005 require segregation of waste medicines into solids, liquids and aerosols only if the waste contractor or PCT demands this. If the PCT requires segregation, it must therefore make arrangements for separate containers to be provided to pharmacy contractors.

With regard to the new legislative controls on the segregation of medicines please refer to the hazardous waste section.

Sharps

The recommended method of disposal of sharps by patients is through the local authority, which has a duty to arrange safe disposal of sharps. Under the exemption from WML, a pharmacy is able to accept waste medicines from households. This exemption does not extend to other clinical wastes, for example needles and syringes, as they are not 'medicines'. This has caused difficulties in practice.

The Environment Agency has confirmed that certain activities undertaken in pharmacy are "low risk". Having considered the risks posed by the secure storage of waste sharps at a pharmacy returned from households and by individuals, the Agency has decided that it does not believe it is in the public interest to expect pharmacies to obtain a waste management licence for this activity. The Environment Agency emphasises, however, that it may amend or revoke its position at any time and will continue to consider enforcement in all circumstances where an activity has or is likely to cause pollution or harm to health. Therefore pharmacists should ensure that consideration is given to the need to protect the environment and pharmacy staff when accepting sharps, storing and arranging for their disposal. The preferred method of disposal is with the local authority and before accepting sharps pharmacists should ensure that there are suitable arrangements for their disposal.

Clinical wastes, including sharps produced within the pharmacy for example as part of diagnostic testing arrangements can be stored in the pharmacy, pending safe disposal through a licensed waste disposal contractor. Needle exchange services can continue.

Hazardous Waste

From 16 July 2005 the **Special Waste Regulations 1996** will be replaced by the **Hazardous Waste Regulations 2005**. At this time, the majority of prescription only medicines will no longer be classed and consigned as hazardous. The only medicinal products that are automatically deemed to be hazardous are cytotoxic and cytostatic medicines.

Cytotoxic and cytostatic medicines are defined as any medicinal product that has one or more of the following hazardous properties: toxic, carcinogenic, mutagenic or toxic for reproduction.

(Note toxic for reproduction should not be confused with contraindicated for use in pregnancy, the former is based on specific chemical risk phrases).

No definitive list of such products has been prepared. The National Institute for Occupational Safety and Health (NIOSH) in the United States produced a list of human medicines known to have these properties, and this can be used as a starting point in identifying medicines that are 'hazardous'. See "List of Hazardous Medicines".

It is proposed to produce an agreed list in the near future for the UK.

Notification of Premises

If a pharmacy produces or stores in excess of 200kg of hazardous waste in any one premise in a year then they must notify the Environment Agency

The Environment Agency has confirmed that a pharmacy, which dispenses NHS and private prescriptions, and accepts unwanted dispensed medicines from individuals, households and residential homes may be exempt. To be exempt they must produce and store less than 200kg of hazardous waste in any period of 12 months in that premise.

It is, therefore important to minimise the amount of waste consigned as hazardous waste, as the pharmacy would need to notify its premises to the Environment Agency if the limit is exceeded. It is important to note that hazardous waste does not just refer to medicines but also includes items such as computers, fridge's, single use cameras and fluorescent light tubes.

Consignment

Cytotoxic and cytostatic medicines must be consigned with a new form of consignment note. The consignment note requires the wastes to be listed, together with the six digit 'List of Wastes' code. The description should also include an estimate of the quantity in kilograms, the chemical/ biological components of the waste (e.g. cytotoxic medicines), the physical form (e.g. solid, liquid, aerosol, mixed), and the hazard codes. It is also necessary to list each hazardous medicine, which may require a continuation sheet to accompany the consignment note. The container type and size is also specified.

Segregation

The **Hazardous Waste Regulations 2005** prohibit the mixing of different types of hazardous waste, and the mixing of hazardous waste with non hazardous waste. This means that pharmacies will require at least two containers, one for cytotoxic and cytostatic medicines, and the other for all other medicines, which are considered to be not hazardous.

The effect of the **Hazardous Waste Regulations 2005** means that pharmacists will be under a duty to try to determine whether unwanted medicines returned from patients contain hazardous or non hazardous waste. There is a requirement for separation of cytotoxic and cytostatic medicines from non hazardous waste, where these are already mixed, if technically and economically feasible. However, if cytotoxic and cytostatic medicines are not separated from a collection of returned medicines, then the whole assortment must be consigned as hazardous waste. This could mean that a pharmacy would exceed the 200kg limit for the exemption from notification.

Pharmacists should make reasonable efforts to identify such products returned to the pharmacy, unless it is likely to put their staff at risk

Note:

An in-depth version of the waste guidance is available at the PSNC website and this includes the six digit 'List of Wastes' code.

PSNC website – www.psnco.co.uk

Environmental Agency telephone number – 08708 506 506

Practice points

- Register the licensing exemption for storage of waste for each pharmacy premises with the local Environment Agency office
- Inform any nursing home that the pharmacy provides a dispensing service for, that no waste can be accepted by the pharmacy. Refer the home to the Environment Agency.
- Obtain one or more of the special controlled drug destruction kits, of a size, which will meet the needs of the pharmacy. The kits can be obtained from the NPA.
- Ensure members of staff who handle unwanted medicines know that blister strips can be removed from outer cartons, but that individual tablets and capsules cannot be removed from blisters before being put in waste containers. Note: deblistering is allowed for the purpose of denaturing controlled drugs.
- Those pharmacies providing re –usable Monitored Dosage System trays to nursing homes should discuss with the nursing home the procedures for removal of unused medicines so that the re –usable equipment can be returned to the pharmacy
- Establish whether the waste contractor or PCT requires segregation into solids, liquids and aerosols, and if so ensure there are arrangements in place to provide different containers for each category of waste.
- Establish the contact details for the local authority sharps collection service, so you may provide this information to patients requesting disposal of sharps.
- Assess likely quantities of hazardous waste that will be handled on the premises in any 12 month period. If this is likely to exceed 200kg, notify the Environment Agency.
- Revise Standard Operating Procedures for handling waste to include the additional steps of identifying cytotoxic and cytostatic products
- Ensure that the PCT has arranged for separate waste containers to be provided, one for hazardous waste and one for non hazardous waste.
- Look at the PSNC and RPSGB website for any updates on the management of waste.

Practice: Dec 2005

List of 'Hazardous' medicines

(Caution- this is a list from an American paper, so the names used may not be familiar)

Aldesleukin	Exemestane
Alemtuzumab	Finasteride
Alitretinoin	Floxuridine
Altretamine	Fludarabine
Amsacrine	Fluorouracil
Anastrozole	Fluoxymesterone
Arsenic trioxide	Flutamide
Asparaginase	Fulvestrant
Azacitidine	Ganciclovir
Azathioprine	Ganirelix acetate
Bacillus Calmette-Guerin Vaccine	Gemcitabine
Bexarotene	Gemtuzumab ozogamicin
Bicalutamide	Choriogonadotropin alfa
Bleomycin	Goserelin
Busulfan	Hydroxycarbamide
Capecitabine	Ibritumomab tiuxetan
Carboplatin	Idarubicin
Carmustine	Ifosfamide
Cetrorelix acetate	Imatinib mesilate
Chlorambucil	Interferon alfa-2a
Chloramphenicol	Interferon alfa-2b
Choriogonadotropin alfa	Interferon alfa-n1
Cidofovir	Interferon alfa-n3
Cisplatin	Irinotecan HCl
Cladribine	Leflunomide
Colchicine	Letrozole
Cyclophosphamide	Leuprorelin acetate
Cytarabine	Lomustine
Ciclosporin	Chlormethine hydrochloride
Dacarbazine	Megestrol
Dactinomycin	Melphalan
Daunorubicin HCl	Menotropins
Denileukin	Mercaptopurine
Dienestrol	Methotrexate
Diethylstilbestrol	Methyltestosterone
Dinoprostone	Mifepristone
Docetaxel	Mitomycin
Doxorubicin	Mitotane
Dutasteride	Mitoxantrone HCl
Epirubicin	Mycophenolate mofetil
Ergometrine/methylergometrine	Nafarelin
Estradiol	Nilutamide
Estramustine phosphate sodium	Oxaliplatin
Estrogen-progestin combinations	Oxytocin
Estrogens, conjugated	Paclitaxel
Estrogens, esterified	Pegaspargase
Estrone	Pentamidine isethionate
Etoposide	Pentostatin
	Perphosphamide

Pipobroman	Thalidomide
Piritrexim isethionate	Tioguanine
Plicamycin	Thiotepa
Podofilox	Topotecan
Podophyllum resin	Toremifene citrate
Prednimustine	Tositumomab
Procarbazine	Tretinoin
Progesterone	Trifluridine
Progestins	Trimetrexate glucuronate
Raloxifene	Triptorelin
Raltitrexed	Uramustine
Ribavirin	Valganciclovir
Streptozocin	Valrubicin
Tacrolimus	Vidarabine
Tamoxifen	Vinblastine sulfate
Temozolomide	Vincristine sulfate
Teniposide	Vindesine
Testolactone	Vinorelbine tartrate
Testosterone	Zidovudine