Denaturing of controlled drugs at a place other than the premises of production

If you comply with the requirements below, we will allow the denaturing of controlled drugs (CDs) at a place other than the premises of production.

Background

Denaturing of controlled drugs (CDs) typically involves physically mixing the medicines with a binding matrix to make the material physically irretrievable in the waste chain. The resultant material is classified, described and disposed of as a waste medicine.

Denaturing can be undertaken by many different people and in many different settings for example:

- Pharmacists in registered pharmacies or hospitals and medical practices denaturing their own expired stocks of CD's on the premises.
- Pharmacists and medical practices denaturing CD's returned from patients' homes and community care.
- Healthcare workers denaturing controlled drugs in patients' homes before leaving the premises for security reasons.
- Medical practices or pharmacies bringing CD's together at a central point for denaturing witnessed by an authorised person.
- Police or other regulatory bodies.

There is a substantial amount of legislation regulating the supply, storage, transport and use of CD's. In many cases the denaturing must be witnessed by an 'authorised person'. A number of organisations, including NHS Trusts, are required to have a 'accountable officer' who has overall responsibility for the management of controlled drugs. Further information on this can be found in the appendix.

The Environmental Permitting (England and Wales) Regulations 2010 provide an exemption (T28) for the denaturing of controlled drugs at the premises of production. However no exemption is provided for the denaturing of controlled drugs at a place other than a place of production. This means that there is no exemption for the denaturing of waste CD's returned by patients or healthcare workers or for drugs brought together at a collection point or denaturing sessions.

We believe there is an over-riding public health requirement to ensure such drugs are made safe as soon as possible. And that the activity poses a low environmental risk as long as the requirements below are complied with.

The Environment Agency's position
We will not pursue an application for an environmental permit for the activity provided:

- the method of denaturing used is consistent with the guidance provided by the RPSGB

- the activity is witnessed by an 'authorised person' where required.

- the storage of the controlled drugs prior to denaturing meets the conditions of the non-waste framework exemption for temporary storage of waste at a place controlled by the producer or for temporary storage at a collection point. Storage of waste in a secure place, to which the public are unable to gain access and from which the waste cannot escape, is required in both cases..

- the sorting and unpacking of CD's, for example to recycle cardboard packaging, is considered to be an ancillary treatment under these storage exemptions.

- the denaturing, storage, transfer and transport of the waste CD's complies with the requirements of relevant legislation[1] and the Hazardous Waste Regulations[2] and the requirements of the Duty of Care.

- you meet the relevant objectives of the Waste Framework Directive;

'… ensuring that waste is recovered or disposed of without endangering human health and without using processes or methods which could harm the environment and in particular without –

(i) risk to water, air, soil, plants or animals; or
(ii) causing nuisance through noise or odours; or
(iii) adversely affecting the countryside or places of special interest.'

Enforcement
In not pursuing an application for a permit, this means we will not normally take enforcement action unless the activity has caused, or is likely to cause, pollution or harm to health. For a more detailed explanation of this enforcement position, please refer to the Public Interest Factors in the **Guidance to the Enforcement and Prosecution Policy**. This can be found on the 'How and Why we Regulate Your Business' page in the Business & Industry section of our web site.

[1] the Misuse of Drugs Act 1971 and its associated regulations and the Additional Statutory measures laid down in the Health Act 2006 and its associated regulations

[2] With particular note of the requirements for premises registration, consignment notes, registers, and consignee returns.

This regulatory position statement will be reviewed by June 2012.

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Appendix

Further information on legislation regulating the supply, storage, transport and use of CD's can be found below:

- Care Home Guidance
- Primary Care Guidance
- Secondary Care Guidance
- Pharmacy Guidance (1), Pharmacy Guidance (2) .

T28 – Sorting and denaturing of controlled drugs for disposal

What is the purpose of this exemption?

This exemption enables pharmacies and other similar places to comply with the requirements of the Misuse of Drugs Regulations 2001 by denaturing controlled drugs.

What types of activities can I do?

Example activities include:

- A pharmacy or veterinary surgery is required to denature controlled drugs prior to their disposal.

Where can I carry out this activity?

This can be done at the place of production only.

What can't I do?

You can't:

- treat any waste drugs that are hazardous waste.
- treat controlled drugs at any place other than the place of production.

What are the key limits?

You can store or treat **up to 1 cubic metre of waste** at any one time.

You can store waste for **up to six months.**

What are the key conditions?

Under this exemption you can only sort or denature controlled drugs prior to their disposal.

What else do I need to know?

"Controlled drug" means a controlled drug specified in Schedules 1 to 5 of the Misuse of Drugs Regulations 2001.

The collection of other drugs and medicines may be allowed under a Non-Waste Framework Directive exemption which does not need to be registered.

What waste can be used under this exemption?

The waste codes below are those listed in the List of Wastes (LoW) Regulations. You should read the guidance on the LoW to ensure that the waste type you want to treat fits within the waste code.

You need to make sure your waste falls within the LoW code and the written description in the table.

Further guidance on this can be found at http://www.environment-agency.gov.uk/business/topics/waste/32140.aspx

Codes	Waste types
180109	Medicines from natal care, diagnosis, treatment or prevention of disease in humans
180208	Medicines from research, diagnosis, treatment or prevention of disease involving animals
200132	Medicines separately collected as municipal waste

The full text of the legislation can be found at:
http://www.opsi.gov.uk/si/si2010/draft/ukdsi_9780111491423_en_1

Registration of this exemption

You cannot register this exemption until **6 April 2010.** A link to the registration process is available on the following web page:

http://www.environment-agency.gov.uk/business/topics/permitting/116406.aspx

Definitions

"controlled drug" means a controlled drug specified in Schedules 1 to 5 of the Misuse of Drugs Regulations 2001.

"hazardous waste"**,** except in Section 5.1 of Part 2 of Schedule 1:

> (a) in relation to England, has the meaning given in regulation 6 of the Hazardous Waste (England and Wales) Regulations 2005,
>
> (b) in relation to Wales, has the meaning given in regulation 6 of the Hazardous Waste (Wales) Regulations 2005.

Guidance on what is hazardous waste can be found at:

http://www.environment-agency.gov.uk/business/topics/waste/32200.aspx

"place of production" means in relation to any waste, the place where the waste was originally produced.

The full **'Glossary of terms'** can be viewed here.