Environment Agency

Regulatory position statement

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 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 CDs on the premises.
- Pharmacists and medical practices denaturing CDs 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 CDs 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 CDs. In many cases the denaturing must be witnessed by an 'authorised person'. A number of organisations, including NHS Trusts, are required to have an '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 CDs 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.

Our approach

We will not pursue an application for an environmental permit for the activity where:

- 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 CDs, 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 CDs 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 management is carried out without endangering human health, without harming the environment and in particular:
  (i) without risk to water, air, soil, plants or animals;
  (ii) without causing a nuisance through noise or odours; and
  (iii) without adversely affecting the countryside or places of special interest.'

Enforcement

In not pursuing an application for a permit, 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 see our Enforcement and Sanctions statement. This can be found on the 'How we regulate you' page in the Business & Industry section of our web site.

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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 will be reviewed by June 2014.

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Appendix

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

Care Home Guidance

Primary Care Guidance

Secondary Care Guidance

Pharmacy Guidance (1), Pharmacy Guidance (2) .