



WASTE MANAGEMENT OF PHARMACEUTICALS IN EUROPE

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In 1991 the Hazardous Waste Disposal Directive 91/689/EEC, which covers pharmaceuticals, was published by the EU Commission for incorporation into the law of Member States.

Those responsible for disposal must have a close understanding of the product. Pharmacists have a responsibility for the products they handle and distribute.

Medicines are complex products that are liable to contaminate the environment. The packaging is also sophisticated and cumbersome. Both aspects require careful waste management. It would be an easy decision to categorise all medicines as hazardous and dispose of by incinera-

tion, but this would not be environmentally friendly. To dispose of unused Sodium Chloride 0.9% by such an energy-consuming method is wasteful and burdensome to disposal systems.

So a second level of decision making is required to distinguish hazardous products from medicinal products and to assist other healthcare professionals in identifying these products efficiently. Pharmacists must take a lead in these discussions. Once it has been agreed within Member States which products fall into each category then there is a need for a partnership between industry and the pharmacist. Industry can help by identifying the method of disposal by some means through the label. As a sug-

gestion a symbol or coloured dot on a label will go a long way to helping healthcare professionals identify hazardous products. Without such an indicator energy and resources will be wasted, as most will opt for the easy path and dispose of all medicines as though they were hazardous.

A reasonable compromise must be found and the hospital pharmacist is a pivotal person in the decision-making process. In this article we bring you reports from across Europe to give an indication of the involvement of the hospital pharmacist in this process.

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Sweden

Sweden has incorporated the EU Directive on Waste into its national legislation.

Drugs that only contain solutions of salt and nutrients may be discarded into the waste water stream. All other drugs that are classified as non-hazardous waste and that come from households and from most other bodies, such as most healthcare centres and hospitals, are collected by Apoteket AB. In some parts of the country other operators collect the hospital medical waste.

Householders should sort out drugs that are classified as hazardous waste, e.g. cytotoxic and cytostatic drugs, and take them to the communal systems for collecting hazardous waste from the public. From the hospitals the cytostatic waste should be transported by competent operators for hazardous waste. Apoteket AB takes no part in the handling of hazardous waste.

In a regulation from the Swedish Work Environment Authority, AFS 2005:5, we find the text that is closest to the US NIOSHs definition:

- A) Pharmaceuticals that the Medical Products Agency has listed as belonging to ATC group L01, Cytostatic/cytotoxic products
- B) Trimetrexate and other drugs with cytotoxic effect
- C) Drugs that have received a preliminary classification by the Medical Products Agency as belonging to group L01

This is not a very clear definition. Point B obviously gives some latitude in the assessment. I would however guess that, in reality, all drugs, that when discarded are treated as cytostatic/cytotoxic waste, either belong to L01 or contain trimetrexate.

Narcotics are subject to controlled handling when discarded. When these drugs are discarded at hospitals and in pharmacies, that handle their own narcotics, they should be de-identified, for example by putting pills or sheets of pills in bottles or boxes for other drugs. This is monitored so that two members of staff together sign in a logbook, that this amount of narcotics is being destroyed. When drugs are de-identified they are considered as transformed into ordinary pharmaceutical waste. Therefore, no special license is needed to incinerate controlled drugs.

There is no legislation that demands incineration of drug waste. However, all drug waste that has been assembled in these ways in Sweden is incinerated. Incineration of waste is subject to rigorous legislation and the incineration plants used have permission to incinerate pharmaceuticals.

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Germany

The EU Directive on Waste has been incorporated into our national legislation. The two main waste disposal organisations are: DSD (Duale System Deutschland) and VfW (Verband für Wertstoffrecycling). The DSD is mainly active in the consumer area, the VfW also in the professional area, e.g. hospitals.

In the private and consumer area medicines take the way of the regular household rubbish. Retail pharmacies offer a disposal service. Bigger amounts are collected separately. Most cities have a "Mobile poisons service"; you can give in household toxic substances such as paint, batteries, rat poisons and medicines free of charge. In the professional area medical non-toxic waste is handled like regular waste. Most hospitals have a list for distinguishing toxic and non-toxic waste. There are special permanently-sealed containers for high-temperature incineration.

Germany uses the term "CMR" for cytotoxic + mutagenic + reproduction-toxic compounds. All substances of this type are handled identically in hospitals. Antineoplastics are only a part of the problem.

The German equivalent of the American NIOSH list is a "Dangerous Substances List" "Gefahrstoffliste". This list includes substances like tar/nicotine, hormones ...similar to the US definitions. At the moment a discussion is being held regarding fine dusts.

Large amounts of dangerous substances are denatured by for example alkaline hydrolysis. There are specialised companies for handling problem waste. They need a license and are supervised by the authorities.

Smaller amounts of mixed waste are sealed permanently in special containers and incinerated at high temperature at licensed facilities with highly-effective filtering of the combustion dust. The hospital gets a receipt of acknowledgement and a confirmation that the waste has been incinerated. So Germany has a similar

approach to the "consignment" system of the UK.

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Ireland

Ireland incorporated the EC waste management directive into its national legislation in 1996. There is also secondary legislation - a number of regulations for particular aspects, e.g. SI 147 of 1998 regarding the movement of hazardous waste, SI 163 of 1998 regarding hazardous waste generally. However Ireland already had guidelines in place and these have continued to develop in the absence of detailed legislation. Waste collection on a commercial basis is subject to regional permits.

The Department of Health and Children published the third edition of Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste in April 2004 [1]. This document brings together good practice principles and the various regulatory requirements relating to waste generation and management. It does not offer a legal interpretation of such regulations. The guidelines apply a practical definition to waste categorisation.

There is no definitive list as all medicines are defined as Healthcare Risk Waste, i.e. chemical, toxic or pharmaceutical including cytotoxics. Waste medicines are part of the 5% of healthcare risk waste that must be separately classified and carried in UN approved containers bearing the appropriate UN number, hazard label and specified information about the contents. As there are no statutory definitions in place, there may be local interpretation about the disposal of the products that are non-toxic, e.g. water for injection or sodium chloride infusion but most medicines are disposed of by incineration.

There are no statutory definitions of the terms 'cytotoxic and cytostatic'. However, these terms are generally understood and to adopt another term in the absence of a legal definition would not be helpful. Controlled drugs are disposed of by destruction, in the presence of an authorised witness, as governed by legislation. These medicines are made unusable (e.g. tablets are dissolved in water, ampoules are opened, etc.) and the waste then put into the appropriate UN container for incineration.

The Waste Management Regulations 1998 are intended to enable local authorities to keep track of the movement of hazardous wastes at all stages from production to disposal. All healthcare waste containers are required to be appropriately tagged with a specific tag that can identify the origin of the waste. Medicines are specifically tagged and exported from Ireland to countries with suitable incineration facilities.

1. www.dohc.ie/

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Poland

In the year 2001 the Waste Act was passed by Poland, implementing the EU Directive on Hazardous Waste. In 2005 the first decrees were published.

Under Polish law all medicines are considered as medical waste and are treated as hazardous. Five methods are allowed for medical waste disposal. However cytotoxic and cytostatic drugs are in a special category of hazardous waste but are not defined as hazardous substances. Polish law categorises hazardous waste as Toxic (H6), Carcinogenic (H7), Toxic for Reproduction (H10) and Mutagenic (H11).

Only one method is permitted incineration at a minimal temperature of 1100°C.

Hazardous substances do not include cytostatic or cytotoxic drugs. There is no formal legal definition of “cytotoxic” and “cytostatic”. When dealing with cytotoxic and cytostatic drugs, European and Polish guidelines drawn up by the pharmacy associations are more helpful than legal regulations, which at the moment are unfortunately not complete.

Italy

In Italy, EC Directive 91/689/EEC has been promulgated into two laws (DL 22/97 and DL 254/2003) on waste management. Waste from human healthcare or related research is divided into two classes: hazardous waste - subject and not subject to special requirements in order to prevent infection; and non-hazardous waste - disposed of in the same way as urban waste.

Cytotoxic and cytostatic drugs are classed as non-infective hazardous waste. Both the expired anticancer drugs and the residues from preparation are put in hermetically closed plastic boxes and a company with a special licence for treating toxic waste, collects them once a day and disposes of them by incineration (all the products are documented and traced to disposal).

The terms cytotoxic and cytostatic are used overall for the anticancer drugs while the *A special thank you to Dr Ilaria Uomo for her English revision of the article.*

We understand “cytostatic” to be a synonym for “antineoplastic” in the meaning of the ATC list and “cytotoxic” as ones that possess at least one attribute in accordance with NIOSH Publication No. 2004-165. In our opinion the NIOSH list is soundly based. A European list of antineoplastic and cytotoxic drugs would clarify the situation.

Polish law determines particular conditions of use and disposal for Controlled Drugs. A waste treatment license is necessary. This area of action in the healthcare system is supervised by government agencies.

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term anti-neoplastic is not used yet. At the moment, we in Italy do not have a specific list like the American NIOSH list, with hormone preparations, antibiotics, oral contraceptives and all the other hazardous drugs.

Hazardous waste such as expired pharmaceuticals including addictive drugs or solutions for infusion (e.g. water for injection or Sodium Chloride infusions) are disposed by incineration. Hazardous waste is denatured and sterilised in authorised plants in accordance with the law 22/97. To implement this, the Italian Regions have created a monitoring system to guarantee a quality process for collecting, storing and treating waste medicines.

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Hungary

EC Directive 91/689/EEC has been incorporated into Hungarian law to govern hazardous waste in hospitals. An order of the Hungarian Health Ministry (20/2005 (VI.10.)) has been published, which designates all personal medical waste as hazardous waste.

Each manufacturer of pharmaceuticals has their own SOPs in accordance with their own GMP and they follow these regulations to dispose of their own products. In retail pharmacies it is possible to collect the personal Prescription Only Medication waste in special disposal boxes. This method is non-selective, as is disposal itself, which takes place in a refuse centre.

In medicine we differentiate between cytotoxic drugs, which are directly toxic to cells and cytostatic drugs, which suppress cell growth and multiplication. However, there is no difference between cytotoxic and cytostatic properties for handling and disposal. This type of waste has to be collected in special yellow bags with hazardous waste signs on them, separately from other medicinal waste and be disposed of according to the law.

Hospital medicinal waste has to be collected and stored in hospital pharmacies, categorised into POM medicines, Controlled Drugs and Cytotoxic/Cytostatic Drugs. All medicinal waste has to be transferred by special medicine carriers to the refuse centres, where all POM drugs can be disposed of. A Waste Treatment Licence is needed for the disposal of Controlled Drugs and cytotoxic/cytostatic drugs.

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