

# position statement

## Export of Waste Medicines

### Background

Organisations, for example charities, in the UK may seek to export waste medicines for use overseas. This statement sets out our position on this in the context of current national and international guidance from healthcare professionals.

Waste medicines can be broadly considered in two groups;

- certain waste medicines from the manufacturer, medical practice or pharmacy and
- other waste medicines including all those issued to patients and returned to the medical practice or pharmacy.

### Certain waste medicines from a manufacturer, medical practice or pharmacy

Medicines from a medical practice or pharmacy, that have not been issued to patients and are not at the end of their useful life, or similar medicines donated by pharmaceutical companies, can be segregated from other waste medicines for donation.

If the segregation occurs at the medical practice, pharmacy or manufacturers premises then the medicines would not enter the waste chain. For example, the Royal Pharmaceutical Society of Great Britain (RPSGB) has [published criteria](#) for pharmacists that medicines should meet to be suitable for donation. Where these criteria are met the medicines would not normally be considered a waste, and would not be subject to waste controls, if transported, collected and exported for use.

However if waste medicines are collected from the manufacturer's premises, medical practice or pharmacy and taken to another place for sorting, then the material must be managed as a waste until it has been sorted. This means that:

- hazardous waste medicines must be moved from the producer premises in compliance with the [Hazardous Waste](#) Regulations, with particular note of the requirements for premises notification, consignment, registers and consignee returns;
- non-hazardous waste medicines must be moved in accordance with the [Duty of Care](#);
- the relevant requirements of the Carriage of Dangerous Goods Act must be complied with;
- the waste must be transported by a registered waste carrier;
- the place to which the waste is taken for sorting must hold a suitable authorisation (such as an environmental permit) for that activity.

Once the medicines have been sorted, and the criteria for donation have been met, the onward movement would not be subject to waste controls. However they would still be subject to medicines legislation control.

### **Other waste medicines including all those issued to patients and returned to the medical practice or pharmacy**

Medicines that do not meet the criteria set out by the RPSGB will remain unsuitable for donation, and therefore a waste. They are subject to waste controls and cannot be exported for use.

We have considered the guidance from the [RPSGB](#) and [WHO Guidelines on Charitable Donations](#) and confirmed with the Department of Health that patient returned medicines cannot be re-used, and will therefore remain a waste.

Although there is potential to sort patient returned medicines that are not at the end of their useful life from other waste medicines there remain significant quality, safety and security concerns. For that reason the export of patient returned medicines is not supported by the World Health Organisation, Department of Health, or Royal Pharmaceutical Society of Great Britain.

### **Our position**

It is illegal to send waste medicines to a country outside of the European Union.

Where medicines that are suitable for donation have been separated from other waste medicines, they can be exported for that purpose without being subject to any waste controls.

We expect any organisations engaging in drug donation to follow guidelines from the the Royal Pharmaceutical Society of Great Britain (RPSGB) and the World Health Organisation. Site operational procedures for permitted facilities engaged in sorting of waste medicine should be consistent with these guidance documents.

We support the views of the RPSGB, WHO and Department of Health in that patient returned waste medicines should not be exported for re-use overseas as the recycling of such medicines is regarded as unsafe.

We will consult the Department of Health and RPSGB on applications for environmental permits for waste operations or installations for the sorting of waste medicines for re-use other than in accordance with the relevant guidance.

### **When will this position be reviewed?**

We will review this position if the national advice issued by the RPSGB or Department of Health on the export of medicines is revised.

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