



Victoria Government Gazette

No. S 309 Friday 18 June 2021
By Authority of Victorian Government Printer

Environment Protection Act 2017

DESIGNATION OF THE AUTHORITY UNDER REGULATION 86 OF THE ENVIRONMENT PROTECTION REGULATIONS 2021

Classification of Pharmaceutical Waste for the Purposes of the Return Unwanted Medicines (Rum) Project

1. Citation

This designation is 01 of 2021 and may be cited as: EPA Designation – classification of pharmaceutical waste for the purposes of the RUM project.

2. Summary

This designation is issued by the Environment Protection Authority (Authority) under Regulation 86 of the Environment Protection Regulations 2021 (Regulations) for the purposes of classifying unwanted or expired medicines (called ‘pharmaceutical waste’ in this designation) in relation to the Return Unwanted Medicines (RUM) project. The RUM project is a government collection scheme (within the meaning of Regulation 86(11) of the Regulations) that was established to provide a free and convenient way to return expired and unwanted medicines to a community pharmacy for temporary storage in a RUM bin and ultimate disposal following collection by a pharmaceutical wholesaler.

This designation classifies specified pharmaceutical waste, which would otherwise be classified as priority waste under the **Environment Protection Act 2017** (Act) and the Regulations, as not priority waste for the purposes of the RUM project.

The effect of this designation is that persons receiving, storing, transporting or consigning for transport the specified pharmaceutical waste, for the purposes of the RUM project and in accordance with the conditions set out in this designation, do not have to comply with the relevant priority waste obligations under the Act and Regulations and do not require a permission from the Authority to undertake those activities.

This designation ceases to apply to the pharmaceutical waste when it is consigned by the pharmaceutical wholesaler for transport to another premises for ultimate disposal. At that point, the classification of the pharmaceutical waste returns to being priority waste (and reportable priority waste) under the Act, as set out in Clause 4 of this designation, and any person receiving, storing, transporting or consigning for transport the waste must comply with the relevant obligations under the Act and Regulations, including applying for the relevant permissions.

3. Definitions

In this designation, words and phrases have the same meaning as in the Act and the Regulations unless otherwise specified, and –

community pharmacy has the same meaning as **pharmacy** under the **Pharmacy Regulation Act 2010**;

pharmaceutical waste means unwanted or expired medicines that are waste as set out in Clause 4(1);

pharmaceutical wholesaler means a person who collects pharmaceutical waste from one or more community pharmacies, temporarily stores the waste, then consigns the waste for transport to another premises for ultimate disposal, for the purposes of the RUM project;

RUM bin means a RUM project approved, secure container, provided to the community pharmacy for the collection of pharmaceutical waste for the purposes of the RUM project;

RUM project means the Return Unwanted Medicines project, managed by the National Return and Disposal of Unwanted Medicines Limited (a national not-for-profit company funded by the Commonwealth Department of Health).

SPECIAL

4. Application

- (1) This designation applies to pharmaceutical waste, accepted by a community pharmacy under the RUM project, which in the absence of this designation would be included within the following items set out in the Table in Schedule 5 to the Regulations –
 - (a) item 97 (Waste code R120, Waste from the use of pharmaceutical products, not otherwise specified in items 96, 98 or 99 in the Table in Schedule 5 to the Regulations);
 - (b) item 98 (Waste code R130, Cytotoxic substances).
- (2) This designation ceases to apply to pharmaceutical waste referred to in subclause (1) when the waste is consigned by a pharmaceutical wholesaler for transport to another premises for ultimate disposal (see Note 1).

5. Designation

For the purposes of Regulations 86(7)(e) and 86(11) of the Regulations the Authority determines that pharmaceutical waste is not priority waste, provided the conditions set out in Clause 6 are met.

6. Conditions

This designation is issued subject to the following conditions –

- (a) the pharmaceutical waste must be placed in a RUM bin at the community pharmacy;
- (b) the community pharmacy must not have more than five RUM bins containing pharmaceutical waste at its premises at any time;
- (c) the RUM bin containing pharmaceutical waste must be sealed, collected from the community pharmacy by a pharmaceutical wholesaler and transported to the premises of the wholesaler;
- (d) the pharmaceutical wholesaler must not store more than 5 m³ of pharmaceutical waste at any time;
- (e) the pharmaceutical waste must only be temporarily stored at the premises of the pharmaceutical wholesaler before being consigned by the wholesaler for transport for ultimate disposal.

7. Duration

This designation commences on 1 July 2021 and remains in effect until the revocation of the Regulations, unless earlier revoked by the Authority.

8. Notes

- (1) Persons transporting pharmaceutical waste from the premises of a pharmaceutical wholesaler for ultimate disposal must obtain the appropriate permissions from the Authority to undertake that activity.
 - (2) The Authority may amend or repeal this designation by way of written notice in the Government Gazette.
 - (3) This designation does not satisfy, alter or remove any requirement under the Act, except to the extent the designation expressly states otherwise.
 - (4) This designation and others can be found on the Authority's website: www.epa.vic.gov.au
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