

Introduction

EPRUMA promotes the responsible use of medicines in animals (www.epruma.eu) and shares information on responsible use of medicines by promoting best practices to prevent, control and treat animal diseases, supporting animal health and welfare, contributing to food safety and One Health.

This fact sheet outlines approaches for veterinary medicines waste reduction and correct disposal at the prescriber and user level, with the aim of raising awareness on the need to minimise environmental impacts through the appropriate disposal of pharmaceutical waste resulting from animal health management.

Why is waste reduction and disposal important?

Proper management of pharmaceutical waste, from households, veterinary practices or at farm level, is an integral part of the responsible use of medicines and contributes to human, animal and environmental health and sustainability. Best practices that may be implemented by all operators of the animal health management chain to reduce pharmaceutical waste and minimise the impact of their disposal on the environment are therefore important.

There is a growing concern that the release in the environment of veterinary and human medicines may have an impact on ecosystems, animal, and human health, *e.g.*, contributing to an increase of antimicrobial resistance in the environmental microbiome.

- In the framework of the circular economy policy, reduction of waste is a major objective.
- Improper disposal of pharmaceutical waste can contribute to this environmental release.

Existing national rules/best practice guidelines take precedence over the recommendations contained in this paper. Veterinarians, animal keepers and owners, pharmacists, retailers and operators should therefore verify the compliance of these recommendations with their national approaches. A non-exhaustive list of those national rules is provided in the annex to this document under "National Recommendations".

The present document integrates the new concepts supporting good practice for the use of veterinary medicinal products laid down in Regulations (EU) 2019/4 on Medicated Feed and 2019/6 Veterinary Medicinal Products, applicable from 28 January 2022.

What is pharmaceutical waste?

This fact sheet covers measures to reduce pharmaceutical waste resulting from animal health care in particular, as well as the correct disposal methods for veterinary medicinal products and their immediate packaging. Other packaging systems such as secondary packaging which is not in direct contact with the medicinal product are not included in the scope and can be disposed of or recycled according to the regular nationally established procedures. All veterinary medicinal products, all routes of administration for those products, as well as any devices for their administration are considered as pharmaceutical waste in this fact sheet.

Waste may be found at the veterinarian, pharmacist, or medicated feed manufacturer's level, as well as at animal keepers' level including farms, breeders, kennels and pets and other animal owners.

For the purposes of this fact sheet the following definitions are used:



- Pharmaceutical waste means used, unused or expired veterinary medicines or medicated feed containing medicinal products, including their immediate packaging.
- Medical Devices refers solely to non-reusable equipment that is in direct contact with the veterinary medicines (e.g., syringes) that is used to administer the medicine.

Other definitions are as those outline in the Veterinary Medicine Regulation $2019/6^1$ and the Medicated Feed Regulation $2019/4^2$.

How and where does pharmaceutical waste occur?

Pharmaceutical waste can arise for many different reasons, for example:

- Immediate packaging and the remains of medicines within after use.
- Veterinary medicines, pre-loaded medical devices or medicated feed that have passed their expiry date.
- Veterinary medicines, pre-loaded medical devices or medicated feed that have not been stored in accordance with the instructions (e.g., not refrigerated) and therefore the stability of the product may have been compromised.
- Prescription of a quantity of medicine, medicated feed or pre-loaded medical device exceeding the required quantity.
- Purchasing of a quantity of non-prescription veterinary medicines (e.g., certain worming treatments for pets) exceeding the requirements.
- Uncompleted course of treatment due to either administration difficulties, adverse reactions, change in treatment (e.g., switch to a different antibiotic due to resistance), surplus of medicated feed not used at the expiration of the duration of the treatment specified in the prescription, e.g., due to overestimation of animals' requirements (e.g., animals eating less than expected)³, or because animals died during treatment.

Who is responsible for correct disposal?

Everybody (prescribers and users) is responsible for minimising pharmaceutical waste and ensuring the correct disposal of that waste.

Education on the approaches to minimise pharmaceutical waste should be an integral part of the training of all professional parties (veterinarians, pharmacists, farmers, animal health industry, medicated feed manufacturers, wholesalers, and distributors).

Additionally, the veterinarian, pharmacist, medicated feed manufacturer etc. plays an important role in instructing clients on the need for proper storage of the medicine and correct disposal of any pharmaceutical waste. Furthermore, this should go along with the creation of wider communication campaigns by the national competent authorities on the correct measures for the disposal of pharmaceutical waste in their territory.

¹ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

² Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC

³ In accordance with article 17 of Regulation 2019/4 on medicated feed, surpluses of medicated feed may not be used for a treatment under another prescription.



How to reduce pharmaceutical waste?

Good stock management practices should be put in place by veterinarians and pharmacists to ensure that whilst sufficient stock is available for the immediate needs, there is not a large surplus that may lead to stocks expiring before use. This should include measures to ensure stocks are used appropriately (e.g., first in-first out). Similarly, where medicated feed is manufactured in advance care should be taken that the quantities produced can be used before expiry.

Care should be taken to minimise the risk of over-prescription considering:

- Use of diagnosis to ensure the application of the most appropriate treatment and dosage.
- Choosing the most appropriate route of administration, consistent with effective treatment, to minimise the risk of medicines' surplus:
 - Type of animal (cattle, fish, pigs, poultry, cat, etc.).
 - Equipment (e.g., for a drinking water treatment).
 - Ability of the farmer/animal owner to administer the treatment.
- Use of appropriate pack sizes to meet the prescription.
- Where permitted under national law, the veterinarian/pharmacist should split packs and dispense only the amount required for a full treatment course where necessary to minimise the waste.
- For medicated feed, guidance on incorporation rates from the manufacturer and feed consumption of the animals should be followed by the veterinarian when calculating the amount required for the treatment, taking into account cases where animals may not be eating as normal (e.g., digestive problems, high fever).

If the product remains under the direct personal control of the veterinarian (e.g., veterinary medicines pack, used partially on a farm) this may be used for another prescription at the same location (provided compliance with storage conditions, in-use shelf-life and absence of adulteration can be shown) or at another location (in which case attention must be paid to biosecurity and the risk of contamination of the veterinary medicine). Medicated feed shall not be used for a further prescription or transferred to another facility.

Best practices for disposal

Disposal of pharmaceutical waste via waterways (e.g., sinks, toilets) should be excluded: municipal wastewater treatment plants are not designed to remove and dispose of pharmaceutical residues in wastewater.

Prior to the correct disposal, any pharmaceutical waste should be stored in a dedicated container, bin, or facility to ensure adequate protection to animal health, human health, feed, food and the environment. This must be separated from any stocks of veterinary medicines to ensure that the waste cannot be inadvertently used.

Waste must be disposed of in accordance with the Summary of Product Characteristics (SPC) and the waste legislation and national systems developed in consultation with all parties for the collection, transport, and disposal of the waste.

Member States shall ensure that appropriate collection or discard systems are in place for waste veterinary medicinal products (including medicated feed). Member States shall take measures to ensure that the location of collection or discard points as well as other relevant information is made available to farmers, animal keepers, veterinarians, and other relevant persons.



More information

- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/ECR2019/6 on VMP.
- Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.
- Communication from The Commission to The European Parliament, The Council and The European Economic and Social Committee: <u>European Union Strategic Approach to</u> Pharmaceuticals in the Environment COM (2019)128.

Annex

Some examples of national recommendations on veterinary medicines waste disposal in force in 2021.

Estonia: In Estonia pharmacies should take back all the medications (human and veterinary drugs) or they should be placed/thrown in special container, claiming "extra dangerous items".

Finland: 387/2014 states the veterinarian is responsible of correct disposal of medicines according to current legislation and official guidelines -MMMa 17/14: veterinarian is responsible of correct disposal of medicines according to 646/2011 and 19.4.2012/179: medicines are hazardous waste (does not differentiate human and veterinary medicines). There are several regulations concerning transport, handling etc. of hazardous waste, that have a basis in EU legislation. Concerning the veterinary practice, the essential responsibilities would be not mixing liquid medicines and finding an appropriate company to dispose of the medicine waste produced and taking care of proper accounting of medicines (special legislation for controlled drugs such as opiates) and being aware of any particular (safety) regulations concerning certain drugs such as ones used for chemotherapy.

Germany: The disposal is subject to the local communities. In general, the municipal waste disposal system can be used as in most communities this is subject to incineration.

https://www.bfarm.de/DE/Buerger/Arzneimittel/Arzneimittelentsorgung/ node.html

https://www.bundesgesundheitsministerium.de/arzneimittelentsorgung-und-aufbewahrung.html

https://arzneimittelentsorgung.de/home/

https://www.bmu.de/richtigentsorgenwirkt/

Ireland: Veterinarians dispose of unused/expired medicines via the purple waste stream for specialist incineration.

Slovenia: Regulation on the management of waste medicinal products (http://www.pisrs.si/Pis.web/pregledPredpisa?id=URED4793#)

which was issued by Slovene Government in 2008 to pursue the implementation of Articles 36 and 104 of the Environmental Protection Act

(http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO1545#), issued in 2004, regulates the disposal of veterinary medicine.

Sweden: The Swedish body regulating this is the Swedish Medical Products Agency (Läkemedelsverket). More information can be found on their website, including an English version www.lakemedelsverket.se.

Left over medicines from clinics and animal hospitals must be sent for destruction, the same rules apply as for human doctors. Owners are encouraged to return non-used medicines to the pharmacy.



The pharmacy must ensure returned medicines are sent for destruction. Contact info for Läkemedelsverket: registrator@lakemedelsverket.se

UK: There are two types of Veterinary Medicinal Waste: Hazardous (Scotland call it Special) and Non-Hazardous (Non-Special in Scotland). The regulation of waste is devolved so there are variants in England, Wales, Scotland, and Northern Ireland.

For the disposal of whole pharmaceuticals (i.e., returned, out of date or damaged medicines) the disposal must be incineration for Non-Hazardous and High temperature specialist incineration for Hazardous. Note the differing types of incinerator.

Hazardous disposal is much more complex, requires additional paperwork and is additionally taxed by the government. Disposal must be from point of production and there cannot be movement between branch surgeries.