Health Canada Santé Canada

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Emergency drug release (EDR) request form
Veterinary drugs directorate (VDD)

This form is for veterinary practitioners to request authorization for emergency access to an unapproved drug for veterinary use:

- for first time and repeat requests for a known patient
- for an anticipated future emergency, or when the patient is unknown (often referred to as a future use request)

Note that patient means an animal or group of animals.

Complete this form and submit your request by either: Email: edr-dmu@hc-sc.gc.ca or Fax: 613-946-1125

We will contact you if we require any additional information or clarity regarding your form.

We make every effort to respond to applications within 2 working days. If your request is urgent or if you have not received a response within 2 working days after submitting an inquiry or application, contact the EDR program.

Section A: Veterinary practitioner information		
Veterinary practitioner's name: (First Last)		
Hospital or clinic name:		
Hospital or clinic address:		
City:	Province:	Postal code:
Telephone #:	Fax #:	
Email:		
Select 1 preference for communication regarding your application (i.e. request(s) for clarification and/or EDR Letter of Authorization): ○ Fax ○ Email		
Shipping information		
Shipping address for the drug is the same address as above ☐ If alternate shipping address, complete section below:		
C/O name and address:		
City:	Province:	Postal code:

Canada

Section B: Drug and manufacturer information

Drug brand name:	
Strength:	
Active ingredient(s):	
Format (package size):	
Manufacturer (name and location):	
Name of contact person at the manufacturer (if applicable): (First Last)	
Telephone #:	Fax #:
Email:	
Quantity requested:	

Notes:

- Specify the total quantity of drug requested (the sum of the quantities requested for all patients listed in this application)
- Ensure the packaging of the drug is taken into account
- A quantity equivalent up to 1 year of treatment can be requested, in the case of patients requiring chronic therapy, or one course of treatment depending on the condition being treated

Section C: Patient and treatment information

New or repeat EDR request for this drug: ○ New ○ Repeat

If this is a repeat request, state the previous EDR number:

Has a follow-up form been submitted for the previous EDR? ○ Yes ○ No

Note: The submission of a completed and signed follow-up form is mandatory after the drug released has been completely used. This follow-up form must also be received by the EDR program in order for further authorization of the same drug to be given.

Future use request (in-clinic or in-hospital use): ○ Yes ○ No

Future use requests are made in anticipation of treating patients, for species, indications and dosages described below, when the identity for some or all of the patients is unknown. Complete the patient information, as applicable, and be informed that the outstanding patient information (i.e. list of patients treated, diagnosis, treatment information etc.) must be submitted with the follow-up form.

Patient information:

Provide patient information for new or repeat EDR requests, as per selection below. If applying for **multiple patients**, include indication, and dosage by species on a separate sheet annexed to this application if extra space is needed.

- ☐ Pets and horses: Animal's name, owner's name
- ☐ Farms and/or breeding units: Producer's name, address
- ☐ Aquaculture: Site/facility name, company/owner name, address
- ☐ Free-ranging wildlife: Location(s) (i.e. parks)
- ☐ Laboratory (research) animals: laboratory name, address
- ☐ Zoo: name, address
- ☐ Other: specify

Patient information (as per your selection above):

Number of animals:	Age:	Weight:	Sex:

Species:

Indication for use (veterinary situation, disease, justification):

Dosage, route of administration and duration (e.g. #mg BID x # days):

Treatment date(s): Indicate planned date(s) for use of drug and treatment of animal(s)

Indicate if treated animals may be directed toward human food consumption:

- ○ Food (including wildlife, which could be hunted for food)
- ○ Non-food

For animals traditionally considered food animals (e.g. fish, hunted wildlife), justify if you have selected them to be non-food animals:

For treated animals, which are directed towards human food consumption, VDD conducts human food safety assessments including the determination of appropriate withdrawal periods for drugs authorized by the EDR program. You may be required to provide relevant data to assess food safety.

Section D: Attestation and signature

By signing and checking the boxes below, I attest that:

- ☐ All information above is true and correct to the best of my knowledge
- ☐ I have read and understood my roles and responsibilities outlined in the Food and Drug Regulations
- ☐ I understand that for EDR drugs that are medically important antimicrobials for veterinary use on List A **and** that were not present in Canada at the time of sale (this means I am the person importing the drug), I must report annually to the Veterinary Antimicrobial Sales Reporting (VASR) system of Health Canada on:
  - the total quantity sold or distributed
  - the approximate quantity sold or distributed for each intended animal species

  Email vasr-vavr@hc-sc.gc.ca to be added to the VASR system.

Note that if the EDR drug that is on List A was present in Canada at the time of its sale, the manufacturer will undertake the sales reporting (not the veterinary practitioner).

Veterinary practitioner's signature:	Date:

Veterinary drugs directorate (VDD)

Tel.: 613-240-3916 Fax: 613-946-1125

Email: edr-dmu@hc-sc.gc.ca

Website: Emergency Drug Release

Note: All drugs made available through the EDR program have not been comprehensively reviewed by VDD, Health Canada. Therefore, veterinary practitioners should be vigilant in following the patient's response to treatment, including monitoring for potential adverse events or lack of product efficacy.