THERAPEUTIC DECISION CASCADE FOR ANIMAL AND PUBLIC SAFETY

To support responsible use of medications[1], giving due consideration to both animal and public health, veterinarians should follow the Decision Cascade when prescribing medications for their patients.
Choose the first available level on the cascade below:

Approved Veterinary Drug - DIN
(Label Instructions)

Approved Veterinary Drug - DIN
(Extra Label Drug Use - ELDU)

Approved Human Drug - DIN
(ELDU)

Compounded Product*:
from Approved Veterinary Drug - DIN (ELDU)

Compounded Product*:
from Approved Human Drug - DIN (ELDU)

Compounded Product*:
from Active Pharmaceutical Ingredient - API (ELDU[2])

* Foreign approved veterinary drugs obtained through Health Canada's special authorization scheme may be an alternative option available to veterinarians when considering the use of a compounded drug.
1 ELDU does not apply to pesticides and biologicals (vaccines).
2 ELDU is not permissible in livestock feeds without a veterinary prescription. ELDU is not recommended by Health Canada with drugs/classes of Very High Importance in human medicine which are listed as Category I Antimicrobials.

Health Canada Santé Canada
Ordre des médecins vétérinaires du Québec
Saskatchewan Veterinary Medical Association
Newfoundland and Labrador College of Veterinarians
Prince Edward Island Veterinary Medical Association

THE APPROPRIATE USE OF COMPOUNDED PRODUCTS

Compounding is both **necessary and beneficial** for the treatment of veterinary patients. However, a **potential exists** for **causing harm** to **animals and to consumers** when compounded drugs are used. This includes the potential for **treatment failures, adverse reactions and death as well as for the risks associated with the development of antimicrobial resistance in bacteria of both animal and public health concern.** Compounded products are not subject to the same efficacy, safety, and quality assurance testing that licensed products are.

GENERAL GUIDANCE:

Compounding of products for the treatment of an **individual** patient/herd or flock should be used only for **therapeutic** purposes and only when there are **no other commercially available options** for that specific patient/herd or flock.

It is necessary to obtain **informed consent** from the client before prescribing a compounded product. The client must be aware of the **potential risks** and available alternative treatments.

Health Canada strongly recommends against extra-label use of Category I Antimicrobials in mass-medication situations.

Practitioners should reference the Canadian Veterinary Medical Association Guidelines for the Legitimate Use of Compounded Drugs in Veterinary Practice.

IMPORTANT POINTS TO CONSIDER:

Compounded drugs are **not generic drugs.** Generic drugs are second or subsequent entries to the Canadian market once a patent has expired on the initial drug marketed. Generic products undergo pre-market assessment by Health Canada to **ensure bioequivalence** and then are subject to all post licensing **quality assurance testing standards** as with all licensed pharmaceuticals.

Compounded drugs are a result of **the combining or mixing together** of **two or more ingredients** (of which at least one is a drug or pharmacologically active component) to create a **final product** in an **appropriate form for dosing.** It can involve the use of raw chemicals or the alteration of the form and strength of commercially available products. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug's labeling material.

Prescribing a compounded drug is considered ELDU. As such, the veterinarian is responsible for the safety and efficacy of the prescribed drug and, when used in food producing animals, for establishing adequate withdrawal times to avoid harmful residues. The Canadian global Food Animal Residue Avoidance Databank (CgFARAD) **is unable to provide withdrawal times for compounded drugs.**

In the absence of Health Canada regulatory controls, veterinarians must be aware that, when prescribing a compounded drug, they are solely **responsible** for **both its potency and purity**, as well as for **all outcomes, including adverse events (which may include lack of effect).**

Compounding is considered to be legitimate if the product is available but the appropriate method for dosing or dose concentration does not exist and a practical alternative does not exist. **Cost is not a defensible reason for prescribing a compounded drug.**