Policy on Extra-Label Drug Use (ELDU) in food producing animals

1.0 PURPOSE

This policy relates to ELDU in food producing animals in Canada. The objective of this policy is to promote the prudent use of drugs in food producing animals in order to minimize the risks of this practice to public health, animal safety and the environment by recommending a national approach.

2.0 BACKGROUND

Extra-label drug use (ELDU)\(^1\), also referred to as “off-label use” refers to the actual use or intended use of any drug, whether it is a prescription drug or over-the-counter (OTC) drug, in an animal in a manner that is not in accordance with the approved label or the package insert of the drug licensed by Health Canada\(^2\).

Currently, the practice of ELDU in Canada, by persons other than licensed veterinarians outside the context of a “valid”Veterinarian/Client/Patient Relationship (VCPR) presents certain potential human health risks of concern to Health Canada including the following:

- Presence of potentially harmful drug residues in foods derived from treated animals and in the environment; and
- Development and dissemination of antimicrobial resistance

ELDU is a complex concept involving aspects within federal and provincial jurisdiction. While the approval of drugs for sale in Canada is a matter falling within federal jurisdiction, the practice of veterinary medicine has traditionally fallen within provincial jurisdiction. Furthermore, legislation and regulations governing the practice of veterinary medicine vary from province to province.

The *Food and Drugs Act* and *Regulations* prescribe labelling and other requirements aimed at advising the public of potential human health risks due to drug residues contained in foods. The *Food and Drugs Regulations* prohibit the sale of meat for consumption as food if it contains certain drugs.

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\(^1\) ELDU Issue Identification Document (December 2001) Paragraph 1.

\(^2\) This includes the use of all unlicensed drugs, including unapproved bulk active pharmaceuticals ingredients (APIs) and compounded drugs.
3.0 Scope

This policy applies to ELDU in food producing animals in Canada.

4.0 Definitions

4.1 Veterinarian/Client/Patient Relationship (VCPR)

Health Canada considers a “valid VCPR” to exist when the following conditions apply:

- The client (owner or owner’s agent of the animal [s]) has given the responsibility of medical care to the veterinarian and has agreed to follow the instructions of the veterinarian, and;
- the veterinarian has assumed the responsibility from the client for making clinical judgment regarding the health of the animal(s), the need for medical treatment, and for ensuring the provision of ongoing medical care for the animal(s), and;
- the veterinarian has sufficient knowledge of the health status of the animal(s) and the care received or to be received. The knowledge has been obtained through a recent examination of the animal(s) and the premises where they are or through a history of medically appropriate and timely examinations and interventions, and;
- the veterinarian is readily available, or has made the necessary arrangements with another veterinarian, for ongoing medical care in case of adverse reactions or therapy failure.

4.2 Active Pharmaceutical Ingredient (APIs): Active Pharmaceutical Ingredient includes any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and the function of the body.

4.3 Compounding: 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

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3 Policy on Manufacturing and Compounding Drug Products in Canada POL-0051

4 Policy on Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use:
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/int/export-import/pol_18_te-tm_e.html

5 See Footnote 3.
performed in accordance with the directions for use on an approved drug’s labelling material.

5.0 Policy Statement:

Health Canada takes the following view:

1. ELDU is a recognized tool in the “practice of veterinary medicine” for animals within a “valid” Veterinarian-Client-Patient Relationship, since it facilitates access by veterinary practitioners to certain drugs for the treatment of animals.

2. ELDU in food producing animals by person other than licensed veterinarians is not recommended except when such use is conducted under the supervision of a veterinarian within the context of a valid Veterinarian-Client-Patient Relationship.

3. ELDU is not recommended with drugs of very high importance to human health which are listed as Category I Antimicrobials.

4. ELDU should only be undertaken in compliance with the Food and Drugs Act and its Regulations, which includes but is not limited to, banned substances (C.01.610.1), medicated feeds (C.08.012) and violative residues. (See 7.0 Appendix).

6.0 Associated Documents

• ELDU Issue Identification Document (October, 2004);

• Categorization of Antimicrobial Drugs Based on Importance in Human Medicine: Draft version - November 30, 2006

• Policy on Manufacturing and Compounding Drug Products in Canada POL-0051 (August 2006)

• Policy on Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use:
  http://www.hc-sc.gc.ca/dhp-mps/compli-conform/int/export-import/pol_18_tc-tm_e.html

7.0 Appendix

7.1 The Food and Drugs Act and Food and Drug Regulations:

Food and Drug Regulations C.01.610.1:

No person shall sell a drug for administration to animals that produce food or that are intended for consumption as food if that drug contains:

(a) chloramphenicol or its salts or derivatives;
(b) a 5-nitrofuran compound;

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6 “High importance” is defined in the categorization document.
(c) clenbuterol or its salts or derivatives;
(d) a 5-nitroimidazole compound; or
(e) diethylstilbestrol or other stilbene compounds.

Food and Drug Regulations C.08.012:

(1) Notwithstanding anything in this Division, a person may sell, pursuant to a written prescription of a veterinary practitioner, a medicated feed if

(a) as regards to the drug or drugs used as the medicating ingredient of the medicated feed.
   (i) the Director has assigned a drug identification number (DIN) pursuant to section C.01.014.2 or
   (ii) the sale is permitted by section C.08.005 (Investigational New Drug), C.08.011 (Emergency Drug Release) or C.08.013 (Experimental Study Certificate);

(b) the medicated feed is for the treatment of animals under the direct care of the veterinary practitioner who signed the prescription;

(c) the medicated feed is for therapeutic purposes only; and

(d) the written prescription contains the following information:
   (i) the name and address of the person named on the prescription as the person for whom the medicated feed is to be mixed.
   (ii) the species, production type and age or weight of the animals to be treated with the medicated feed,
   (iii) the type and amount of medicated feed to be mixed,
   (iv) the proper name, or the common name if there is no proper name, of the drug or each of the drugs as the case may be, to be used as medicating ingredients in the preparation of the medicated feed, and the dosage levels of those medicating ingredients,
   (v) any special mixing instructions, and
   (vi) labelling instructions including
      (A) feeding instructions,
      (B) a warning statement respecting the withdrawal period to be observed following the use of the medicated feed, and
      (C) where applicable, cautions with respect to animal health or to the handling or storage of the medicated feed.

(2) For the purpose of this section, “medicated feed” has the same meaning as in the Feeds Regulations.

Food and Drugs Act, Article 4:

No person shall sell an article of food that

(a) has in or on it any poisonous or harmful substance;
(b) is unfit for human consumption;
(c) consists in whole or in part any filthy, putrid, disgusting rotten, decomposed or diseased animal or vegetable substance;
(d) is adulterated; or
(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.