

## **Controlled Drugs and Substances, and Veterinary Biologics**

**Effective Date:** April 2007

**Up-dated:** September 2008

### **Applicable Legislation:**

*Controlled Drugs and Substances Act*

*Narcotic Control Regulations*

*Food and Drugs Act*

*Food and Drug Regulations*

*Natural Health Products Regulations*

*Health of Animals Act*

*Health of Animals Regulations*

*Canadian Environmental Protection Act*

*New Substances Notification Regulations*

**Intent:** to promote compliance with prescribed requirements for controlled drugs and substances, and to publicize University requirements for operational due diligence.

### **Definitions:**

- controlled drug* a drug set out in the Schedule to the *Food and Drug Regulations, Part G*. See <http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/125819.html>.
- controlled substance* a substance included in Schedule I, II, III, IV, or V of the *Controlled Drugs and Substances Act*; includes any substance that contains a controlled substance (natural or synthetic). See <http://laws.justice.gc.ca/en/C-38.8/index.html>
- DIN* drug identification number. An eight-digit numerical code assigned to each drug product marketed under or in accordance with the *Food and Drugs Act* and *Food and Drug Regulations*. Human and veterinary drugs must have a valid DIN to be sold in Canada.

<i>Departmental Appointee</i>	a faculty member appointed by a Department Chair to implement local procedures for drug control.
<i>drug</i>	any substance or mixture of substances manufactured, sold or presented for use in: <ul style="list-style-type: none"> <li>a. the diagnosis, treatment, mitigation or prevention of disease, disorder, or abnormal physical state, or its symptoms, in human beings or animals;</li> <li>b. restoring, correcting or modifying organic functions in human beings or animals;</li> <li>c. disinfection in premises where food is manufactured, prepared or kept.</li> </ul>
<i>experimental study</i>	a limited test of a new drug in animals carried out by an investigator.
<i>extra-label drug use</i>	the use of a drug product in a manner that is not consistent with what is indicated on the label or package insert of any drug product approved by Health Canada.
<i>hospital</i>	a facility that is licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness.
<i>Inspector</i>	a person designated as an Inspector pursuant to Section 30 of the <i>Controlled Drugs and Substances Act</i> (e.g., peace officer).
<i>lot number</i>	any combination of letters or figures by which a product may be traced in manufacture and identified in distribution.
<i>narcotic</i>	any substance set out in the Schedule to the <i>Narcotic Control Regulations</i> (Schedule I) or anything that contains any substance set out in the Schedule. See <a href="http://laws.justice.gc.ca/en/C-38.8/C.R.C.-c.1041/index.html">http://laws.justice.gc.ca/en/C-38.8/C.R.C.-c.1041/index.html</a>

<i>new drug</i>	a drug, or combination of drugs, for which the safety and effectiveness of use has not been established by Health Canada.
<i>pharmacist</i>	a person who is registered and entitled under the laws of a province to practise pharmacy and to operate a pharmacy or dispensary.
<i>Pharmacy Administrator</i>	a person who shall be licensed to practice pharmacy in the Province of Ontario and who shall oversee the operations of the Veterinary Teaching Hospital (VTH) Pharmacy. The Pharmacy Administrator shall report to the Vice-President Research concerning the use of controlled drugs and substances in University teaching and research programs, and in clinical applications.
<i>practitioner</i>	a person who is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry or veterinary medicine, and includes any other person or class of persons prescribed as a practitioner; pursuant to <i>Food and Drug Regulations</i> , Part G, Division 4, practitioners may administer controlled drugs to patients under their professional treatments.
<i>precursor</i>	a substance included in Schedule VI of the <i>Controlled Drugs and Substances Act</i> .
<i>prescription</i>	an authorization given by a practitioner that a stated amount of a specified controlled drug be dispensed for the person named therein.
<i>proper name</i>	the name internationally recognized for the narcotic or the name assigned to the narcotic in the latest edition of any generally recognized pharmacopoeia or compendium of drugs.
<i>provide</i>	to give, transfer or otherwise make available, directly or indirectly.

<i>Schedule</i>	a listing of controlled drugs and substances pursuant to specific federal legislation.
<i>veterinary biologics</i>	substances used for restoring, correcting or modifying organic functions in animals or for use in the diagnosis, treatment, mitigation or prevention of diseases, disorders, abnormal physical states, or the symptoms thereof, in animals. Veterinary biologics, which must be licensed by the Canadian Food Inspection Agency (CFIA) for use in Canada, include vaccines, bacterins, bacterin-toxoids, immunoglobulin products, diagnostic kits, and similar such substances derived through biotechnology.

## **Guidelines**

### **Controlled Drugs and Substances**

1. Only those persons authorized by the University pursuant to the *Controlled Drugs and Substances Act (CDSA)* shall have possession, care and custody of controlled drugs, controlled substances and narcotics, namely:
  - Veterinary Teaching Hospital (VTH) pharmacists;
  - practitioners who require controlled drugs for patient treatment;
  - employees of the VTH, designated by the Director of the Veterinary Teaching Hospital, who perform duties under the authority of a practitioner;
  - University Police constables acting in an enforcement capacity;
  - persons granted *CDSA* Section 56 Exemptions for Scientific Purposes and/or Experimental (Clinical) Studies based upon applications endorsed by the VTH Pharmacy Administrator (*e.g.*, veterinarians and/or investigators needing controlled substances for field or laboratory work; clinical trials of drugs and/or new drugs in animals).
2. No person shall possess a substance included in Schedule I, II or III of the *Controlled Drugs and Substances Act* unless authorized by regulations under *CDSA*.
3. Except as authorized under the *Controlled Drugs and Substances Act*, no person shall import in to Canada or export from Canada

a substance included in Schedule I, II, III, IV, V or VI. No person shall possess a substance included in these Schedules for the purpose of exporting it.

4. Except as authorized, no person shall produce a substance included in Schedule I, II, III, or IV of the *Controlled Drugs and Substances Act*.
5. The person in charge of a place entered by an Inspector or peace officer and every person there shall give the Inspector or peace officer all reasonable assistance in the power of that person and shall furnish the Inspector or peace officer with such information as may reasonably be required.
6. No person shall knowingly make any false or misleading statement verbally or in writing to an Inspector or peace officer. No person shall obstruct an Inspector or peace officer who is engaged in the performance of his/her prescribed duties.
7. No person shall knowingly make, or participate in, or assent to or acquiesce in the making of a false or misleading statement in any book, record, return or other prescribed document however recorded.
8. The Veterinary Teaching Hospital (VTH) Pharmacy Administrator shall, on behalf of the University and the OAC Colleges:
  - order, receive from licensed dealers, store, dispense to authorized persons, collect and dispose of all controlled drugs and substances, narcotics, and veterinary biologics used in University teaching and research programs and clinical activities;
  - maintain prescribed records concerning the receipt of controlled drugs and substances and veterinary biologics from all licensed dealers providing such substances to the University for sanctioned teaching, research and clinical purposes; VTH Pharmacy records shall be maintained for at least seven years from the date of the making of the record;
  - appropriately label and issue controlled drugs and substances and veterinary biologics to practitioners and principal investigators for sanctioned teaching, research and clinical purposes;

- stipulate requirements for responsible care and secure custody of controlled drugs and substances and veterinary biologics and shall require that all unused product be returned to the VTH Pharmacy for disposition.
- determine whether drug use Applications must be submitted to Health Canada and to liaise with federal authorities on behalf of University personnel; *e.g.*,  
**Application for an Exemption to Use a Controlled Substance for Scientific Purposes** submitted to the Office of Controlled Substances, Health Canada (see <http://www.hc-sc.gc.ca/dhp-mps/substancontrol/exemptions/applic-sci-eng.php>);  
**Application for an Experimental Studies Certificate for a Veterinary Drug** submitted to the Veterinary Drugs Directorate, Health Canada, (see [http://www.hc-sc.gc.ca/dhp-mps/vet/applic-demande/form/esc-cee\\_08-2002\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/vet/applic-demande/form/esc-cee_08-2002_tc-tm_e.html)).
- take reasonable precautions (*e.g.*, verifications of identification and signatures, requesting background checks by the Campus Community Police, confirming licensure with the College of Veterinarians of Ontario) to determine that persons are authorized under prescribed regulations to possess controlled drugs and substances, narcotics, and veterinary biologics;
- maintain prescribed records concerning controlled drugs and substances, narcotics, and veterinary biologics dispensed to authorized persons from the VTH Pharmacy;
- take all reasonable steps that are necessary to protect and secure all controlled drugs and substances, narcotics, veterinary biologics and discretionary veterinary health products under his/her care and custody against spill, loss or theft;
- report any loss or theft of controlled drugs and substances and veterinary biologics to the Office of Controlled Substances, Health Canada, as prescribed within 10 days of the discovery thereof;
- advise the Vice-President Research and the Director of Campus Community Police about any extra-ordinary drug-related situation concerning safety, security or regulatory non-compliance;

- prepare a report annually for the Vice-President Research concerning the use of controlled drugs and substances and veterinary biologics at the University, which summarizes noteworthy compliance issues and enforcement actions.
9. A practitioner and/or principal investigator shall:
- complete a **Request for Issue of Drugs for Use in Academic and Research Programs**, have it co-signed by his/her Departmental Appointee, and submit it to the VTH Pharmacy Administrator. (This form, necessary for billing and audit purposes, is available as hard copy from the VTH Pharmacy or is found on-line at [www.uoguelph.ca/research/forms](http://www.uoguelph.ca/research/forms).)
  - consult with the VTH Pharmacy Administrator and complete as necessary the following forms for Health Canada:
    - Application Form for an Exemption to Use a Controlled Substance for Scientific Purposes** (see <http://www.hc-sc.gc.ca/dhp-mps/substancontrol/exemptions/applic-sci-eng.php>);
    - Application for an Experimental Studies Certificate for a Veterinary Drug** (see [http://www.hc-sc.gc.ca/dhp-mps/vet/applic-demande/form/esc-cee\\_08-2002\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/vet/applic-demande/form/esc-cee_08-2002_tc-tm_e.html)). (Additional information herein provides guidance about prescribed requirements for these Applications.)
  - maintain records of controlled drugs, substances and veterinary biologics as prescribed by regulations and explained by the Pharmacy Administrator (*e.g.*, the date received, the name and quantity of controlled substance, the name and address of the person from whom the drug was received, the particulars of use, the running balance, and the return of any quantity to the VTH Pharmacy) in logbooks; such records shall be in a place, form, and manner that will permit an Inspector or peace officer to readily examine them and to obtain information, and shall be retained for at least seven years from the date of the making of the record;
  - take adequate steps to contain, protect and secure all controlled drugs and substances, narcotics, veterinary biologics and discretionary veterinary health products, against spill, loss or theft in accordance with instructions from the VTH Pharmacy Administrator (*e.g.*, store in a locked safe, drawer, cabinet or lockable refrigerator set between 2 and 8 degrees Celsius);

- seek permission from the Pharmacy Administrator to relocate the secure storage of controlled drugs and substances, narcotics, and veterinary biologics from any location previously identified and approved;
  - notify the Pharmacy Administrator of his/her extended absence from the University and to make alternate arrangements for possession and safekeeping of his/her controlled substances;
  - report any spill, loss or theft of a controlled drug or substance to the Departmental Appointee and to the Pharmacy Administrator immediately after the discovery of the spill, loss or theft;
  - submit annually an inventory of controlled drugs and substances, narcotics, and veterinary biologics under his/her care and custody (*e.g.*, names of controlled substances, balances, secure locations) to the Pharmacy Administrator;
  - permit the Pharmacy Administrator (or designate), Departmental Appointee, Inspector or peace officer to audit all records and stocks of controlled drugs and substances, narcotics, and veterinary biologics under the practitioner's or principal investigator's care and custody;
  - consult with the Pharmacy Administrator, University Staff Veterinarian and the Director of Research Risk Management about proposed work with *novel* veterinary biologics, new substances to be used in investigational veterinary drugs or new human drugs, and about new substance notifications and permit applications to federal agencies;
  - upon completion of a teaching or research program, immediately return all unused controlled drugs and substances, narcotics, and veterinary biologics to the VTH Pharmacy for authorized disposition or destruction.
10. If requested, an *ad hoc* peer review committee shall be convened by the Vice-President Research to advise about extraordinary issues related to the management and use of controlled drugs and substances.
11. Authority to enforce compliance with University and prescribed requirements ultimately resides with the Vice-President Research.

## Additional Information and References

The Health Products and Food Branch (HPFB) Inspectorate of Health Canada ([http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/index\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/index_e.html)) is responsible for compliance and enforcement activities pursuant to the *Controlled Drugs and Substances Act* (CDSA) and the *Food and Drugs Act* (see <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-droques/index-eng.php>). The possession, import, export, production, distribution and sale of narcotics, controlled drugs, targeted substances and precursor chemicals are all subject to legislated controls for public health and safety.

Canada's Drug Strategy and Controlled Substances Program falls within the Healthy Environments and Consumer Safety Branch (HECSB) of Health Canada (see [http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsec/dscsp-psasc/index\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsec/dscsp-psasc/index_e.html)).

The Office of Controlled Substances (OCS) oversees the national compliance and enforcement program for all products under the HPFB mandate (excluding food products regulated by the Canadian Food Inspection Agency, CFIA). It is also responsible for administering the exemption process that allows possession of controlled drugs and substances for scientific and medical research.

The Veterinary Drugs Directorate (VDD) in HFPB (see <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/vdd-dmv/index-eng.php>) ensures that veterinary drugs are safe and that food-source and companion animals treated with veterinary drugs are not endangered by use of the product.

Health Canada's Drug Product Database (DPD) contains specific information on all drugs approved for use in Canada. The DPD includes human pharmaceutical and biological drugs, veterinary drugs and disinfectant products (see <http://www.hc-sc.gc.ca/dhp-mps/index-eng.php> and <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php>.)

Canadian web-based resources on drug related information are accessed via portals such as:  
<http://pharmacy.dal.ca/druginfo/canadianresources.html>.

The Canadian Council on Animal Care (CCAC) *Guide to the Care and Use of Experimental Animals*, chapters X, XI and XII, addresses the subjects of pain control in animals, anesthesia and euthanasia (see [http://www.ccac.ca/en/CCAC\\_Programs/Guidelines\\_Policies/GUIDES/ENGLISH/toc\\_v1.htm](http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/GUIDES/ENGLISH/toc_v1.htm)).

## **Exemptions under Section 56 of CDSA**

Researchers (*e.g.*, physicians, veterinarians and university principal investigators) who require controlled drugs and substances for medical or scientific research purposes (*i.e.*, for non-treatment purposes in laboratory or wild animals, for *in vitro* utilization, for human or animal clinical trials) must obtain an exemption under Section 56 of the *Controlled Drugs and Substances Act*. Exemptions to certain provisions of CDSA, which must be applied for and are subject to prescribed terms and conditions, allow researchers to legally possess specified quantities of controlled substances for specified research purposes. Exemptions, if issued, are valid for no longer than one year.

The Evaluation and Authorization Division of the Office of Controlled Substances (OCS) manages the exemption process. The Application Form for an Exemption to Use a Controlled Substance for Scientific Purposes is available at <http://www.hc-sc.gc.ca/dhp-mpps/substancontrol/exemptions/applic-sci-eng.php>.

Principal investigators must consult with the VTH Pharmacy Administrator about their Applications to OCS. The VTH Pharmacy should be identified on the Form as the Intended Supplier, and a copy of the completed Form must be forwarded to the Pharmacy Administrator.

## **Investigational New Drugs – Experimental Studies Certificates**

The Veterinary Drugs Directorate issues Experimental Studies Certificates to researchers who undertake clinical evaluations of new drugs. Principal investigators must apply to the VDD; see [http://www.hc-sc.gc.ca/dhp-mpps/vet/applic-demande/form/esc-see\\_08-2002\\_cp-pc\\_e.html](http://www.hc-sc.gc.ca/dhp-mpps/vet/applic-demande/form/esc-see_08-2002_cp-pc_e.html). The VTH Pharmacy Administrator must be consulted about any Application to VDD for an Experimental Studies Certificate for a Veterinary Drug; a copy of the Application must also be forwarded to the Pharmacist.

## **Extra-Label Drug Use**

Numerous risk issues are associated with extra-label drug use (ELDU) in animals. These issues are explored at [http://www.hc-sc.gc.ca/dhp-mps/pubs/vet/eldu-umdde\\_issue-enjeux\\_intro\\_let\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/pubs/vet/eldu-umdde_issue-enjeux_intro_let_e.html)

## **Reporting Adverse Reactions**

Health Canada's guidelines concerning adverse reaction reporting are described at <http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/reaction-eng.php>.

The pharmacovigilance program is explained at:  
[http://www.hc-sc.gc.ca/dhp-mps/vet/advers-react-neg/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/vet/advers-react-neg/index_e.html).

Suspected adverse reactions to veterinary drugs should be reported to the VDD. For further background information, please see:  
[http://www.hc-sc.gc.ca/dhp-mps/vet/faq/dar-rim\\_program\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/vet/faq/dar-rim_program_e.html).

The VDD drug adverse reaction notification form is available at:  
[http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/vet/dar-rim\\_form\\_e.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/vet/dar-rim_form_e.pdf).

For adverse effects reporting related to veterinary pesticides, see:  
<http://www.pmr-arla.gc.ca/english/legis/aer-e.html#4>.

## **Veterinary Biologics**

Veterinary biologics, which include vaccines, immunoglobulin products and diagnostic test kits for the diagnosis, prevention or treatment of animal diseases, are regulated by the Veterinary Biologics Section (VBS) of Canadian Food Inspection Agency (CFIA). See  
<http://www.inspection.gc.ca/english/anima/vetbio/vbpbve.shtml>.

Veterinary biologics approved for sale in Canada are listed at  
[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/list/index\\_e.html#2005](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/list/index_e.html#2005). Suspected adverse reactions to veterinary biologics must be reported to VBS in accordance with  
<http://www.inspection.gc.ca/english/anima/vetbio/info/vb315e.shtml>. The CFIA adverse event report form is available at  
<http://www.inspection.gc.ca/english/for/pdf/c2205e.pdf>.

All veterinary biologics produced by biotechnology are regulated under the *Health of Animals Regulations*. CFIA guidelines are available at <http://www.inspection.gc.ca/english/anima/vetbio/info/vb302e.shtml>.

Proposed research with **novel** veterinary biologics should be discussed with the Director of Research Risk Management (ext. 52048), the Pharmacy Administrator (ext. 54439), and the University Staff Veterinarian (ext. 58856). Assistance will be provided concerning compliance with the aforementioned CFIA guidelines, laboratory and/or agricultural animal containment, operational biosecurity and environmental protection protocols, prescribed research stage notifications to the VBS, and with animal care and welfare issues.

### **Natural Health Products**

Natural health products are regulated by the *Natural Health Products Regulations* pursuant to the *Food and Drugs Act*. The regulations apply only to human products; they include substances or medicinal ingredient substances set out in Schedule 1 of the Regulations (see <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>), but not substances set out in Schedule 2. Natural health products are identified with a natural products number (NPN) or a DIN-HM number which designates the product as a Homeopathic Medicine approved by Health Canada. The University's Research Ethics Board must approve research involving natural health products and human subjects.

### **Disposal of Controlled Drugs and Substances**

Unwanted controlled drugs and substances (as liquid, powder, tablet or injectable preparations) must be returned to the VTH Pharmacy for proper disposal. Logbook inventory records shall be annotated.

Unwanted biologics must be disposed of as hazardous waste through services provided by Environmental Health and Safety. Empty bottles, vials, syringes and sharps must be collected in University standard (red or yellow) sharps collectors which are also disposed via the EHS service.

## Departmental Appointees

Departmental Appointees have been identified in those departments where controlled drugs and substances are used in Academic and Research Programs. The Appointees provide assistance to implement the University's drug control procedures by:

- co-signing **Request to Issue** forms;
- verifying that the Principal Investigator's proposed storage for controlled drugs and substances is safe and secure;
- liaising with the VTH Pharmacy Administrator on drug control matters;
- performing internal audits and accommodating external audits.

The Departmental Appointees (as of November 2005) are:

<b>Department</b>	<b>Appointee</b>
Animal and Poultry Science	John Walton
Animal Health Laboratory	Grant Maxie
Biomedical Sciences	Peter Conlon/Brad Hanna
Clinical Studies	VTH Pharmacist
Environmental Biology	Chris Hall
Food Science	Ramon Mira de Orduna
Human Health and Nutrition	Kelly Meckling
Integrative Biology	Gordon McDonald
Land Resource Science	Stewart Hilts
Molecular and Cellular Biology	David Josephy
Pathobiology	Andrew Peregrine
Plant Agriculture	Praveen Saxena
Population Medicine	Cate Dewey
Psychology	Harvey Marmurek