

# Pharma Waste: Regulation & Impact on Pharmacy Practice

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DIRC

Pharmacy Practice

How about

- what's the extent of the problem
  - # Rx,non Rx drugs etc - volume
  - lack of knowledge of harm - precaut principle
- What's being done
  - province/territory
  - uptake - successful?
  - regulation - in place? Needed?
  - municipalities v pharmacies or both?
- Costs - who pays? Stewards - who are they?
- Impact on pharmacy practice
  - If regular disposal sessions, pcists will know what pts are/are not using (e.g., Doc thinks pt using diuretic - makes him pee at nite, d/c after 3 days -- counselling opportunity
- Impact on home healthiness
  - Take meds that are in date
  - Fewer opportunities for med errors
- Gaps?
- What's working?
- What's not?

## Outline

- What's the problem?
- What's being done?
- Impact on pharmacy practice
- Challenges

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**IMS Health Cda's (IMS) CompuScript database & Cdn Drug Store and Hospital Purchase dbase: [imshealthcanada.com](http://www1.imshealth.com/web/channel/0,3147,77303623_63872702_77770072,00.html)**  
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### **Top 5 classes**

**CV – anti HT**

**Psych – SSRI, tranquilizers, lithium**

**Hormone – OC, HRT, thyroid, corticosteroids, bone metabolism regulators**

**Anti-infectives – antibiotics, antifungals, antiTB, antivirals**

**Cholesterol – statins**

**OTC - Nonprescription Drug Manufacturers Association of Canada (NDMAC).**

# What's the problem?

## Pharma waste

- Health risks?
- Effects on the environment
- Concentration?
- Inappropriate disposal



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### Pharma waste

Health: Overuse of drugs...Antimicrobials: resistance?...Antibiotics/antifungals/antivirals...Allergies...Endocrine concerns...Effects of chronic, low-level exposure...Biomagnification in food chain?

Little known re environmental or human health hazards from exposure to chronic, subtherapeutic levels of bioactive substances like drugs or their metabolites

Focus should be on class effects not chemical-by-chemical approach - McLean-Drum

Homecare - Many pts who used to be treated in hosp are receiving hosp-only drugs at home

No known adverse effect: too soon to tell - something NOT harmful to humans may be harmful to animals/plants/ecosystem

Most research has been on feminizing activity of endocrine disrupting compounds on fish or antibiotic resistance (from vet drug use) - lab tests generally show that the toxic effects of these cps not seen at low levels currently detected in the environ, the poss of variations in sensitivity, chr exposure and mixture effects such as concentration addition and synergism --What about drug interaction? Exposure is multidimensional - two biggest unknown domains in toxicology are (1) effect of chronic, multigenerational exposure to very low dose chemicals and

(2) simultaneous exposures to multiple stressors

WHAT CONC AS TRIGGERER IN US: EA for approving new drug applications only required when one of a drug predicted to enter the aquatic environment is > 1 mcg/L (1 ppb) - EMEA proposes trigger value of 0.01 mcg/L or 10 parts per trillion - how valid are these "triggers"? We don't know the effects of drugs on non-target species (Daughton)

### Pharmaceutical sales in Canada

Over 450 million Rx, 14.5 bn

OTC - \$1.8 B - 2004

Natural Health Products ?

How much is being wasted?

-NOTES

What is pharma waste?...Medi...Rx...Non-Rx...Natural health products?...Packaging

Top Rx classes: cardiovascular, psychotropic, GI, cholesterol agents, hormones, anti-infectives, analgesics

Top non-Rx classes: analgesics, vitamins, cold, stomach, anti-smoking, natural health products

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### Top 5 classes

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Effects on the environment

Individual vs classes

Categories - e.g., antibiotics, hormones

What concentration should be trigger for concern?

Ont MHSW Final Consolidation July 30 2009 at 121 - they go on to base collection targets on units of sale and convert to weight

-e.g., for 2007 - over 244 million units of Rx and OTC's supplied into market (6589 Tonnes).

-quantities avail for collection = 10% i.e., over 24 million units (one bottle, tube, canister -- for wt of 659 tonnes.

Ontario info from p.19

WDO Consolidated Prog Plan, July 30 2009)

Stericycle stated that this was quantity of pharma waste collected from pharmacies in 2008

Sharps and syringes - 28 tonnes (municipalities - 2007); 175 tonnes (2008 - stericycle)

BC

<http://www.medicationsreturn.ca/2008.pdf>

Health Canada Nov 08 presentation - states Alta - 37 T..... BC 23 T.....NS 10.6 T.....PEI 1.3T.....Sask 16.4 T (years not specified)

What's "good" and "poor" wrt collection?

What should target collection be?

## Getting rid of unused drugs

- Flush/Pour/Fling
  - Consumers
  - Health professionals?
- Disposal service

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**1996 study** --35% of Americans surveyed threw in sink/toilet FLUSH/POUR...54% discarded (FLUNG)...1.4% returned unused med to the pharm;  
Of these, 68% were disposed of in nonhazardous waste or via the drain

**UK study** - 392 people interviewed – 98% had some type of med at home ...11.5% FLUSH/POUR...63% discarded them in household waste...22% returned to pharmacist (Bound at 3 – UK 2005)

**Compas study** – Canada 2002

5% - toilet/sink...58% dispose of natural health products in regular garbage...

50% fling unused/expired non-prescription drugs; 19% use toilet/sink; “other”26%

39% .....prescription.....20% use toilets/sink; “other”37%

### **EXCRETE**

-No information re whether a drug’s properties correlate with its environmental toxicity – e.g., active/inactive metabolites in body may or may not be active in environment....-Focus should be on class effects not individ chem

-Little known re environmental or human health hazards from exposure to chronic, subtherapeutic levels of bioactive substances like drugs or their metabolites (Daughton I 2003)...Small concs – parts per tril = ng/L; ppb = mcg/L

# How much pharma waste?

- Nobody is certain
  - Ontario's MHSW Program Plan states approx 10% of pharmaceuticals not consumed
  - Estimate 659 tonnes avail for collection
- What's being collected?
  - BC
    - 35.7 tonnes (2008)
  - Ontario
    - 42 tonnes collected by municipalities (2007)
    - 250 tonnes via other channels - e.g., pharmacies (2008)

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Pharma waste

**Pharmaceutical sales in Canada**

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OTC - \$3.8 B - 2004  
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**How much is being wasted?**

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What is pharma waste?...Meds....Rx..Non-Rx..Natural health products ?...Packaging

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What's "good" and "poor" wrt collection?

What should target collection be?

## Who has pharma waste?

- Consumers
- Pharmacists
- Physicians
- Veterinarians
- Pharma companies

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**CONSUMERS believe that water pollution is from industry and agricultural sources, not consumerism and personal activities (Daughton 760)  
PHARMACISTS, PHYSICIANS, VETS**

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## What's being done?

- Some provinces regulate
  - BC
  - Ontario (2010)
- Voluntary programs
  - Most other provinces

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**Ontario's Phase 2 of the Municipal Hazardous or Special Waste program will come into effect July 1 2010**



## BC - Medications Return

- Recycling Regulation , under *Environmental Management Act*
- Consumers return unused/outdated meds to pharmacies
  - Includes “drugs” as defined in federal FDA: Rx, Non-Rx, ingested NHP
  - Excludes veterinary, topical/skin care meds

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**BC program started as industry initiative then got regulated by govt --Began in 1996 as BC EnviRx - initially voluntary .** With the enactment of the *Environmental Management Act* (EMA) on July 8, 2004, EMA incorporated the *Waste Management Act* to create a single statute governing environmental protection and management in British Columbia. The new act incorporated provisions allowing for the development of innovative and modern regulatory regimes. One such regime is the *Recycling Regulation*, enacted in 2004, which repealed the existing *Post-Consumer Residual Stewardship Program Regulation* and incorporated key provisions into a schedule of the *Recycling Regulation*.

### S. 5 of BC Reg 449/2004

5 The pharmaceutical product category consists of all unused or expired drugs, as defined in the *Food and Drugs Act* (Canada) except without reference to animals or paragraph (c) of that definition, except(a) unused or expired drugs from a hospital, as defined in section 1 of the *Hospital Act*, or the office of a medical practitioner,(b) contact lens disinfectants,(c) antidandruff shampoo or products,(d) antiperspirants,(e) antiseptic or medicated skin care products,(f) sunburn protectants,(g) mouthwashes, and(h) fluoridated toothpastes.

### Mandatory

In BC, Pharmaceutical producers are currently regulated under the *Recycling Regulation* and their program allows consumers to return (at no charge) their residual medications to most pharmacies in the province. As of 2004, over 90 per cent of pharmacies in the province participate in the return program.

This new regulation continues to ensure that consumers are provided with a safe and convenient method to manage household hazardous waste and reduce improper disposal. Key provisions for producers of solvents/flammable liquids, domestic pesticides, gasoline and pharmaceuticals to take responsibility for the management of their leftovers or wastes are incorporated in Schedule 2 of the *Recycling Regulation*.

-- Pharmaceutical products category (Sched 2) includes “all unused or expired drugs” as defined in the *Food & Drugs Act*; EXCEPT those from a doc’s office or hospital, contact lens solns, anti-dandruff shampoos,antiseptics/medicated skin care products, sunburn protectants, mouthwashes, fluoridated toothpastes

- No drugs from farms, no cosmetics, no sharps

-- producer (eg mfr) must have a stewardship plan that provides for collection of residuals and containers; free access to the service and promotion to the public

**OF CONCERN: 2004 MEDICATIONS RETURN PROGRAM REPORT** - Post Consumer Pharmaceutical Stewardship Association participates in the *Recycling Council of BC(RCBC)* hotline that provides toll-free information regarding the disposal of expired and unused medications. A total of 155 calls were made to the recycling hot line representing less than .2% of their total calls. This is a 40% increase over 2003 calls. Program cost \$195,600 Jan-Dec 04 (management, communications, collections, disposal) – for collecting 15.5 tonnes (15,500 kg) – by my calculation nearly \$13/kg

<http://www.ec.gc.ca/epr/default.asp?lang=En&n=0B57BF17-1>

The *RecyclingRegulation* requires producers (brand-owners) of the designated products to submit a stewardship plan for approval by the BC Ministry of Environment. All producers are required to have an approved plan and comply with the approved plan in order to sell, offer for sale or distribute the product in BC

## BC - Medications Return

- Administered by Residuals Management Group Ltd w funding by PCPSA
- Stewardship plan required
  - Free collection service
  - Promotion to public
- Jan 08 - Metro Vancouver banned unused meds from curbside garbage/recycling bins

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<http://www.metrovancouver.org/about/media/Media%20Releases/2009-03-20-MediaRelease.pdf>

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## BC - Medications Return

- Over 942 retail pharmacies (>95%) participate
- Promotion
  - Improved web links for pharmacists & consumers on BC Pharmacy Assoc and municipality websites
  - Media
- Results
  - 65% increase in use of site over prior year (2008)
  - Weight collected up 53% over prior year (2008)

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Goals of program

Goals

- Divert meds from landfills and sewers
- Ensure safe, effective collection & disposal

<http://www.medicationsreturn.ca/ar2008.pdf>

**Funding by PCPSA - post consumer pharmaceutical stewardship association**

**BC 2008 report - Wt up 54% over prior yr in part to media coverage and ban of pharma from regular waste stream in Metro Vancouver** - <http://www.medicationsreturn.ca/ar2008.pdf>

**Recycling hotline receives 120 pharma-related calls/year ie 1% of their total calls NOT MANY CALLS**

The residual medications are stored in 23 litre plastic containers provided by the program administrator, Residual Management Group Ltd. Once the container is full, the pharmacy contacts the Administrator who arranges for pick up within 7 days. The Administrator also consolidates and then sends the collected residual medications to a licensed incinerator for destruction.

regulated under the *Environmental Management Act* (EMA), specifically, the *Recycling Regulation*, 2004. The pharmaceutical product category is defined under the Residual Product Categories in Schedule 2 of the *Recycling Regulation*. This regulation is administered by the British Columbia (BC) Ministry of Environment.

As outlined in the *Recycling Regulation*, the program focuses on leftover and/or unused consumer medications as defined by the Drugs Directorate of Health Canada. The program excludes veterinary products, and medications from a hospital.

Running x 7-8 yr

Only includes solid tabs

Can leave liquids in bottles

Consumer awareness level

31%

<http://www.ec.gc.ca/epr/default.asp?lang=En&n=0B57BF17-1>

## Alberta - EnviRx

- Voluntary
  - Run by RxA
  - Consumers return meds to pharmacies;
  - No sharps
  - Approx 800 community pharmacies participate
  - Funded by industry groups and government grants
- Goals
  - ↓ health care costs
  - Remove meds from municipal waste stream
  - Protect environment

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### Voluntary program

**Alta program run by Pharmacists Assocn of Alta (RxA) - started in 1988 by Alta Pharmaceutical Association; expanded to needles/syringes in 1995 and in 2001 mgt moved from Alta College of Pcists to Pcists Assoc of Alta.**

### Sharps removed from program in 2003 - funding, safety issues

There are no product-specific fees for this program. ENVIRx is administered by the Alberta Pharmacists Association in partnership with Alberta pharmacists, and funded by Canada's Research Based Pharmaceutical Companies (Rx & D), NDMAC- Advancing Self-care, Canadian Generic Pharmaceutical Association (CGPA) with small grants from the Alberta Government.

Info on program efficiency not available ; annual report not publicly avail

From 1988 to 2005, the program collected and disposed of 520 tonnes of unused/expired medications. In 2004, the program collected 32 metric tonnes of waste medication and in 2005, 37 metric tonnes were collected.

<http://www.ec.gc.ca/epr/default.asp?lang=En&n=CDA75A7C-1>

### Goals

- ↓ health care costs
- Remove meds from municipal waste stream
- Protect environment from improper disposal practices

## Saskatchewan - Pharmaceutical Waste Disposal Program

- Voluntary
- Collection by pharmacies
  - Sharps accepted
- Pharmacies pay for pickup of wastes

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[http://www.npra.ca/Content\\_Files/Files/Saskatchewan/PFM/Pharmaceutical\\_Waste\\_Disposal\\_Program\\_Aug2008.pdf](http://www.npra.ca/Content_Files/Files/Saskatchewan/PFM/Pharmaceutical_Waste_Disposal_Program_Aug2008.pdf)

Health Cda slides Nov 08

- 90% of pcies participate

## Ontario's MHSW program

- O.Reg. 542/06 defines “municipal special waste” to include pharmaceuticals and sharps
- Baseline
  - 2863 pharmacies currently accept unused meds (i.e., 90% of all Ontario pharmacies), several accept sharps
  - 72 municipal programs

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### **Oreg 542/06 to the Waste Diversion Act, 2002 - Muni Hazardous or Special Waste**

#### **Final consol prog plan - July 30 2009**

**At 14 (says 2863), 24 (2860 pharmacies - 90% of all Ontario pharmacies), 33 -- destroyed via incineration/landfill**

#### **At 24 - re muni programs**

**At 24 - 32 municipal programs, return to retail pharmacy programs also (no number provided) -- destroyed via autoclave, landfill, incineration**

At 33 - pharma and sharps returns - return to retail - year 5

At 36 -Current self-managed programs - “The PCPSA’s Medications Return program, that manages product stewardship initiatives for pharmaceutical and self-care health products on behalf of its members across Canada”

At 37 - possible pilot program re Hg thermoms to pharmacies

Stakeholder sessions - WDO report

P 40 - year 1 collection target

Asked by SO to review defn of “Pharmaceutical Drugs”; noted that this definition is taken directly from the Food and Drug Act Regulations, but this term is not found in these regulations or in current federal legislation. Do not “Drug”. Many of the products wrongly captured are safe products that the general public does not think of as drugs. Moving forward: 1) Request that SO correct the definition to reflect pharmaceuticals, not drugs. 2) Request that sales data only be gathered for pharmaceutical products, not drug products.

#### **Final Consolidated MHSW Program Plan**

**Says** 2863 pharmacies currently accept unused meds (i.e., 90% of all Ontario pharmacies), several accept sharps

There are 72 municipal programs

## Ontario's MHSW program

- Goals
  - Year 1 - pharmaceuticals: 254 tonnes via pharmacies, 58 tonnes via depots, events etc
  - Sharps/syringes: 175 tonnes via pharmacies
  - By year 5, all 3181 pharmacies targetted to accept pharma and sharps returns
- Pilot programs?
  - e.g., for return of mercury thermometers to pharmacies

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### **Final consol prog plan - July 30 2009**

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Stakeholder sessions - WDO report

P 40 - year 1 collection target - 312 tonnes pharma - 254 to pharmacies, 58 from depots, events, toxic taxi etc & 213 tonnes sharps - 38 tonnes "other" and 175 to pharmacies

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## Nova Scotia - Medication Disposal Program

- Voluntary
- Pharmacy Association of NS
- Manufacturers pay for transport, destruction
- Collection by pharmacies
- *Safe Sharps* bring-back program

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**Since 1990's**

**-collection up 18% from 2005/06 - per Health Canada slideshow Nov 08**

**-- 100% of pharmacies participate**



## PEI - Take it Back!

- Voluntary
- Collection by pharmacies
- *Don't Get Stuck* program - for sharps
- Disposal paid by province

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Since 2004

Health Canada Nov 08 slides

## Other provinces

- Manitoba
  - Green Manitoba working on developing formal provincially regulated stewardship program that will include pharmaceuticals
- Québec
  - No formal province-wide program
  - Recy-Québec advises consumers to return medications to pharmacy or to an Eco-centre or permanent depot
- New Brunswick
  - No formal province-wide program
- Newfoundland & Labrador
  - Plan to establish framework for waste pharmaceuticals/sharps diversion program

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<http://www.gov.mb.ca/conservation/pollutionprevention/waste/hhw.html>

And 2005 report

[http://www.greenmanitoba.ca/cim/dbf/HHW\\_DiscPaper.pdf?im\\_id=31&si\\_id=1001](http://www.greenmanitoba.ca/cim/dbf/HHW_DiscPaper.pdf?im_id=31&si_id=1001)

**See PCPSA Feb 07 newsletter**

[http://www.medicationsreturn.ca/bulletins/2007\\_feb\\_en.pdf](http://www.medicationsreturn.ca/bulletins/2007_feb_en.pdf)

<http://www.recyc-quebec.gouv.qc.ca/client/fr/gerer/maison/detail.asp?id=156>

Newf program - Atlantic Stewardship Oct 08 PPT

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## Pharmacist Standards of Practice

Pharmacist must ensure

- Safe, proper disposal of meds
  - outdated, recalled, spoiled
- Appropriate removal/disposal of outdated inventory

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### **PHARMACISTS ARE REGULATED HEALTH PROFESSION -- Ontario**

**Standard of practice: pharmacist accepts returns & must ensure “the safe and appropriate storage and disposal of those drugs according to environmental regulations under written policies and procedures.”**

**What does this mean? OCP goes on: ...pharmacists should ensure all drugs disposed of according to “principles of preferred management” – and state the MOE’s preferred options are –**

**-(1) management outside sewer system (no flushing, not down drain),**

**-(2) off-site management by commercial waste management company**

**-(3) management outside of non-hazardous landfills – ie not in regular municipal garbage**

**NAPRA Standards of Practice – National Association of pharmacy regulatory authorities: “--safe and proper disposal of drugs and non-prescription medications...-- ensures the appropriate removal and disposal of out of date inventory”**

[http://www.napra.org/pages/Practice\\_Resources/resources\\_for\\_pharmacy\\_operators.aspx?id=2128](http://www.napra.org/pages/Practice_Resources/resources_for_pharmacy_operators.aspx?id=2128)

## Responsible enviro practice

- Benefits of “responsible environmental practice”
  - ↓ drug abuse opportunity
  - ↓ accidental poisonings
  - ↓ inadvertent use of expired drugs
  - ↓ harm to environment
  - Better monitoring of patient medication therapy - will ultimately ↓ waste, so more cost-effective system

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### **PHARMACISTS ARE REGULATED HEALTH PROFESSION -- Ontario**

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**What does this mean? OCP goes on: ...pcists should ensure all drugs disposed of according to “principles of preferred management” – and state the MOE’s preferred options are –**

**-(1) management outside sewer system (no flushing, not down drain),**

**-(2) off-site management by commercial waste management company**

**-(3) management outside of non-hazardous landfills – ie not in regular municipal garbage**

**NAPRA Standards of Practice – National Association of pharmacy regulatory authorities: “--safe and proper disposal of drugs and non-prescription medications...-- ensures the appropriate removal and disposal of out of date inventory”**

[http://www.napra.org/pages/Practice\\_Resources/resources\\_for\\_pharmacy\\_operators.aspx?id=2128](http://www.napra.org/pages/Practice_Resources/resources_for_pharmacy_operators.aspx?id=2128)

# Opportunities

- Cradle to grave service re meds
- Counselling programs
  - Use information from med returns
  - Patient compliance?
  - Educate patients
- Decrease med wastage
  - Dispense small amounts of new Rx drugs
- Differentiate service provided
  - Re-look at processes - go greener
  - Provide environmental labelling/information

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Cradle to grave service wrt pharmaceuticals

## **Contextualize** Counselling programs

Use information from med returns - e.g., advise patients to tell pcist if d/c med

Educate pts that returning meds helps protect enviro

## Differentiate service provided

Label meds or provide handouts that include how to dispose of meds (and link this to "protect enviro")

**Processes** - when we were implementing all of our green initiatives, it wasn't so much that we needed to reinvent the wheel on our assembly line dispensary and those kinds of things it was thinking about the whole process and there were small things we could do without impacting the quality of the care that we delivered. ...For example we generate now extra bag stuffers, our delivery tags, we give out pads of paper because there's a bottom corner of our labels that isn't even used. And we stack them up and give them out to customers, and it's got our name and our number on the bottom. So they become almost advertising. And that alone, just the labels, has cut down on 30 or 40 per cent of our waste.

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"Meds should not be disposed of via wastewater or household waste...ask your pcist how to dispose of meds no longer required.

These measures will help to protect the enviro"

## Outline

- What's the problem?
- What's being done?
- Impact on pharmacy practice
- **Challenges**

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**IMS Health Cda's (IMS) CompuScript database & Cdn Drug Store and Hospital Purchase dbase: [imshealthcanada.com](http://www1.imshealth.com/web/channel/0,3147,77303623_63872702_77770072,00.html)**  
[http://www1.imshealth.com/web/channel/0,3147,77303623\\_63872702\\_77770072,00.html](http://www1.imshealth.com/web/channel/0,3147,77303623_63872702_77770072,00.html)

### Top 5 classes

**CV – anti HT**

**Psych – SSRI, tranquilizers, lithium**

**Hormone – OC, HRT, thyroid, corticosteroids, bone metabolism regulators**

**Anti-infectives – antibiotics, antifungals, antiTB, antivirals**

**Cholesterol – statins**

**OTC - Nonprescription Drug Manufacturers Association of Canada (NDMAC).**

## Challenges

- Laws - Gaps
  - Definition of “pharmaceuticals”
- Need to expand targets
  - Long term care facilities
  - Veterinary drugs
  - Doctors’ offices
- What’s next - Packaging? Personal care products?

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Same molecule/med may be used in Rx, Non-Rx, veterinary med -- we don't want any of it to end up in landfill

Drugstores, hospitals - targeted

**Why not MANDATE appropriate**

**--disposal**

**--Labelling – packaging should include Rx information & clear info re how to dispose**

**EXAMINE THE VARIOUS LAWS IN CDA AND HOW THEY COULD BE USED TO MINIMIZE PHARMA WASTE**

**FEDERAL - Cdn Env Protection Act, Food & Drugs Act**

**PROVINCIAL ENVIRO laws**

**MUNICIPALITIES - by-laws**

**WHAT'S WORKING**

**KNOWLEDGE GAP**



## Definitions

- What are “pharmaceuticals”?
  - All products with DIN/NPN?
  - “pharmaceutical” interchangeable with “drug”?
- Ontario - List of exclusions - confusing?
  - Non-orally ingested NonRx drugs, NHP incl topical creams (excepting NonRx topical antibiotic, antifungal creams)
  - Orally ingested Non-Rx, NHP drops, lozenges, chewing gum
- Suggest - consistency across Canada
  - Minimize confusion

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What are “pharmaceuticals”?

This came up at WDO stakeholder meetings

What are “pharmaceuticals”?

All products with DIN/NPN?

What about toothpastes, sunscreens - have DIN

“pharmaceutical” not interchangeable with “drug”

Ontario - List of exclusions - confusing?

Non-orally ingested NonRx drugs, NHP incl topical creams (excepting NonRx topical antibiotic, antifungal creams)

Orally ingested Non-Rx, NHP drops, lozenges, chewing gum (does this include nicotine?)

Part of the confusion in what we can and cannot recycle comes from the inconsistencies across communities. I think that is a major problem in that in one community five minutes from my house they cannot recycle things that I can. So you don't have a standard playing field.

I DON'T KNOW ABOUT YOU, BUT THE CURRENT GARBAGE SYSTEM IN TO CONFUSES THE HECK OUT OF ME

-WHAT GOES IN THE SMALL COMPOST BUCKET VS THE RECYCLING STUFF- USED TO BE THAT I HAD TO SORT

-NEWSPS -- THEN THERE'S THE GARBAGE. MAKE SURE THE SYSTEM THAT IS IMPLEMENTED IS EASY TO UNDERSTAND

-AND NOT FRUSTRATING FOR PCISTS OR CONSUMERS

-- vol 1 July 30 WDO consolidated prog at 141

O.Reg. 542/06 defines “municipal special waste” to include pharmaceuticals and sharps

Asked by SO to review definition

of “Pharmaceutical Drugs”; noted that this definition is taken directly from the Food and Drug Act Regulations, but this term is not found in these regulations or in current federal legislation. Do not “Drug”. Many of the products wrongly captured are safe products that the general public does not think of as drugs. Moving forward: 1) Request that SO correct the definition to reflect pharmaceuticals, not drugs. 2) Request that sales data only be gathered for pharmaceutical products, not drug products.

## Barriers

- Public awareness
  - Of service
  - Of need
- Awareness by health professionals
- Convenience
- Cost

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**AWARENESS - Rx, non-Rx, sample meds can come to Pcy**

**COMPAS STUDY – Canada 2002– barriers to safe disposal of household products were**

- (1) lack of info/education – 27%;**
- (2) inconvenience – 25%;**
- (3) effort involved – 13%;**
- (4) location/accessibility – 10%;**
- (5) laziness – 10%**

**COST is another concern, many of the costs for these programs are borne by pharmacists.**

## Tips from other jurisdictions

- Sweden
  - Environmental labelling classification system
  - Includes enviro impact of medication
- European Medicines Agency (EMA)
  - Recommends that package inserts include “Medicines no longer required should not be disposed of via wastewater or the municipal sewage system”

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[http://www.epa.gov/nerlesd1/bios/daughton/Chap1\\_Petrovic&Barcelo.pdf](http://www.epa.gov/nerlesd1/bios/daughton/Chap1_Petrovic&Barcelo.pdf)

As an example, an "environmental labeling" classification system is being developed in Sweden in a collaborative project between Sweden's Department of the Environment and the Stockholm County Council Pharmaceutical Unit (Wennmalm and Gunnarsson 2005; Wennmalm and Martini 2005). Another example is from the European Medicines Agency (EMA 2005): "Appropriate disposal of unused pharmaceuticals, e.g. when shelf life is expired, is considered important to reduce the exposure of the environment. In order to enhance environmental protection, it is therefore recommended that – even for medicinal products that do not require special disposal measures - package leaflets (patient information leaflets) should include the following general statement: ' Medicines no longer required should not be disposed of via wastewater or the municipal sewage system!.' " But note that Europe has the option of returning medications to pharmacies

[http://ec.europa.eu/enterprise/pharmaceuticals/patients/respons\\_publ\\_consult\\_200805/healthcare\\_professionals/stockholmcountycouncil.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/patients/respons_publ_consult_200805/healthcare_professionals/stockholmcountycouncil.pdf)

Stockholm City Council and Apoteket AB (AAB) sole owner of all pharmacy shops in Sweden - propose that info to pts be provided that sets out benefits and risks of medications. As well, they want to include info on the enviro impact of the medicinal product.

In Sweden, a national system for enviro info on human meds has been developed - gives info to pts and doctors -- avail at [www.fass.se](http://www.fass.se)

## What's working - Europe

e.g., EVRA Patch - Contains ethinyl estradiol(EE)

- EMEA: Ecotoxicity/Environmental Risk Assessment
  - 0.1 ng/L EE has had negative effects on fish
  - 5 ng/L – lethal
  - Based on sales volume (629 kg EE) and volume of wastewater produced – PEC of 2.28 ng/L estimated for surface water

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**Contains ethinyl estradiol(EE)+ norelgestromin..European Medicines Agency for the Evaluation of Medicinal Products –developing risk assesst guidance to predict enviro impact caused by new pharmaceuticals and line extensions.**

EMEA: Ecotoxicity/Environmental Risk Assessment

0.1 ng/L EE has had negative effects on fish

5 ng/L – lethal

Based on sales volume (629 kg EE) and volume of wastewater produced – PEC of 2.28 ng/L estimated for surface water

Avoid water exposure via special *disposal container*

**Evra: Env Risk Assesst: Patch still contains substantial quantities of EE. Negative effects of even low levels (0.1 ng/l) of EE shown both in the lab & from estrogenic effects on fish near sewage trt works in several countries. Effects incl production of egg-yolk proteins in male fish, and the development of fish with both male and female reprod tissues, with changes in gender ratio and reduced reproduction....At higher concs (5 ng/l), EE leads to arrest in the development of eggs, i.e. a lethal effect. EE found in both surface water and tap water suggest that EE transported long distances over time and resists degradation. ...Based on the 2001 sales of EE in Europe (628.7 kg) and the avge vol of wastewater per capita per day (0.20 m3, ...), the predicted environmental concentration surface water (PEC) is 2.28 ng/l. Although these PEC values are below the limit of 10 ng/l for the crude PEC, measures taken to ensure avoid any increase of enviroental concs of EE due to market introduction of EVRA. Therefore recommendations on patch disposal were included in the relevant sections of the SPC. Mfgr agreed to include in the package a disposal container for used patches. In February 2003, the addition of a disposal system (for used patches) to the outside of the container of EVRA was authorised for used patches-- can then be discarded with solid waste. SPC (summaries of prod characteristics) & label amended to incl how to dispose of the used patch.... In Canada – product monograph states – “carefully fold in half so the adhesive side sticks to itself and dispose of in the garbage...remaining active hormonal ingredients may have harmful events if reach aquatic environt”**

## Last words

- **Health professionals**
  - Wiser prescribing practices
  - Marketing re disposal
- **Engage consumers**
  - Not to expect Rx from MD
  - Responsible med disposal
  - Demand NO excessive packaging
- **Drug design/dosage/delivery**
- **Government funding mechanisms**
  - Formulary analysis should include enviro impact

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**Enviro surprise is where ultimate hazards differ from those that were anticipated (Daughton I at 762)**

**Improve wastewater treatment technologies, detection of drugs in waste – also need to minimise from consumer end**

**Health professionals - talk to patients/caregivers – include info on how to dispose of meds**

**Provide patient handouts that include how to dispose of meds (demand from mfr)**

**Consumers – DEMAND disposal mechanism – at pharmacy**

**Drug Design –**

**-Enantiomerically pure drugs – reduce environmental loadings**

**--- citalopram (Celexa) vs escitalopram (Lexapro)**

**--- omeprazole (Losec) vs esomeprazole (Nexium)**

**-Low dose OC, HRT**

**-Targeted drugs – ie go right to site of action**

**Pharmacoeconomic analysis - Include cost of disposal**

**Precautionary principle (reverse onus) – in the face of uncertainty, science must be integrated with policy/political judgment to decide course of action**

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