Pharma Waste: Regulation & Impact on Pharmacy Practice

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October 1, 2009

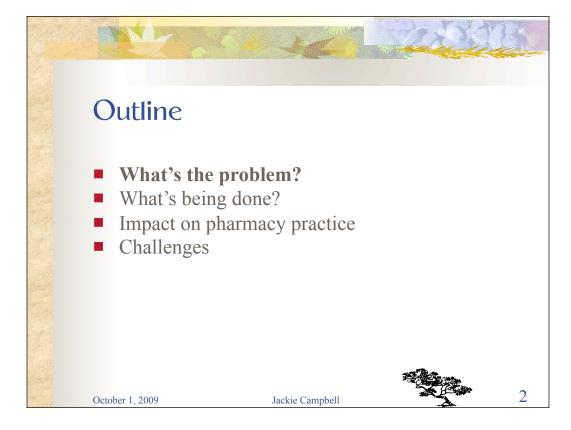
Jackie CampbellEnviropharm

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, poists 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?



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

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 October 1, 2009 Jackie Campbell

initiate Overnoe of drugs... Antimicrobials: resistance?... Antibiotics/antifringals/antivirals.... Allergies... Endocrine concerns... Effects of chronic, low-level exposure... B Little known re environmental or human health hazards from exposure to <u>drenic, subtherapeutic</u> levels of bloactive substances like drugs or their metabolites. Focus should be on <u>data effects</u> to detentional-by-technical approach—<u>Metabo affects</u>.

-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

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 cpds not seen at low levels currently detected in the environt, the poss of variations in sensitivity, che exposure and mixture effects such as <u>concentration addition and synergism</u> —What about <u>drug interactions</u>? Exposure is multidimensional – two biggest unknown domains in toxicology are (f) effect of chronic, multigenerational exposure to very low door chemicals and (b) simultaneous exposure to multiple detressers

WHAT CONC AS TRIGGER? In U.S. EA for approving new drug applications only required when conc of a drug predicted to enter the aquatic environment ic= IntegL(1 pph) - 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-targe

ermaceutical <u>soles</u> in Canada

Over 450 million Rx, 14/Cdn OTC - \$3.8 B - 2004 Natural Health Products ?

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

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$$\label{eq:continuous} \begin{split} & \underline{\text{Top S. classes}} \\ & CV - \text{and } HT \\ & \underline{\text{Psych}} - SSRI, tranquilizers, lithium} \\ & \underline{\text{Hormone}} - CC, \underline{\text{HIT, thyroid, corticosteroids, bone metabolism regulators}} \\ & \underline{\text{Anti-infectives}} - \text{antibotics, antipgals, antiTB, antivirals} \end{split}$$

Cholesterol - stating OTC - Nonprescription Drug Manufacturers Association of Canada (NDMAC). Effects on the environment

Categories - e.g., antibiotics, hormones

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% Le., over 24 million units (one bottle, tube, canister -- for wt of 659 tonnes

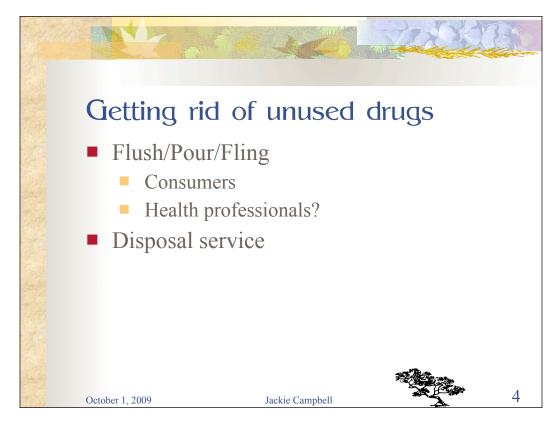
WDO Consolidated Prog Plan, July 30 2009)

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)

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 should target collection be?



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

<u>UK study</u> - 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
- -Llittle 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)



October 1, 2009

Jackie Campbell

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Pharmaceutical <u>sales</u> in Canada Over 450 million Rx, 14/Cdn OTC - \$3.8 B - 2004

Natural Health Products ?

How much is being wasted?

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

Top Rx classes: cardiovascular, psychotherapeutic, GI, cholesterol agents, hormones, anti-infectives, analgesics
Top non-Rx classes: analgesics, vitamins, cold, stomach, anti-smoking, natural health products

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Ontario info from p.19

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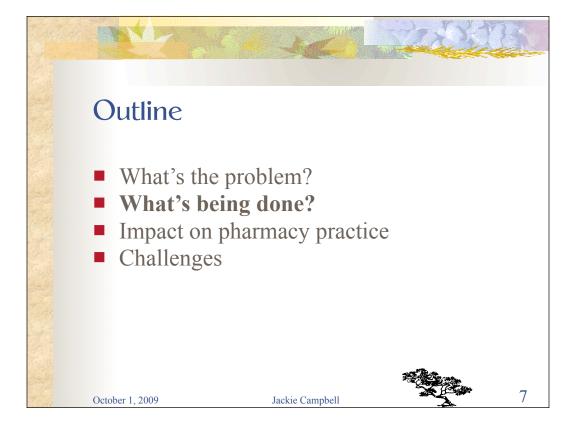
http://www.medicationsreturn.ca/ar2008.pdf

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What's "good" and "poor" wrt collection? What should target collection be?



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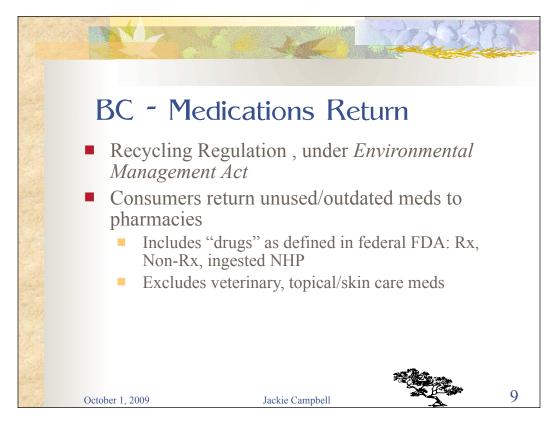
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 $OTC\ -\ Nonprescription\ Drug\ Manufacturers\ Association\ of\ Canada\ (NDMAC).$



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



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,(q) 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 mfgr) 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



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

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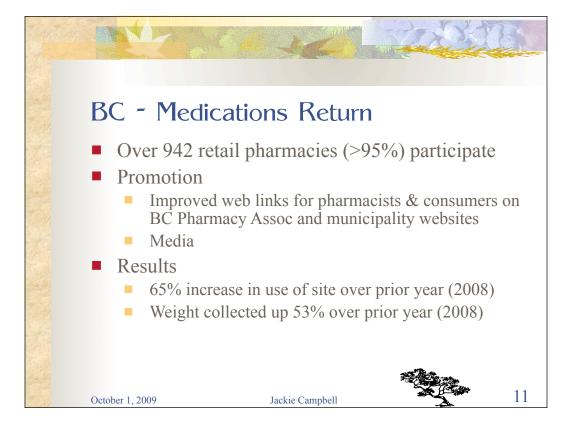
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Goals of program

Divert meds from landfills and sewerss 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 pharmas 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



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

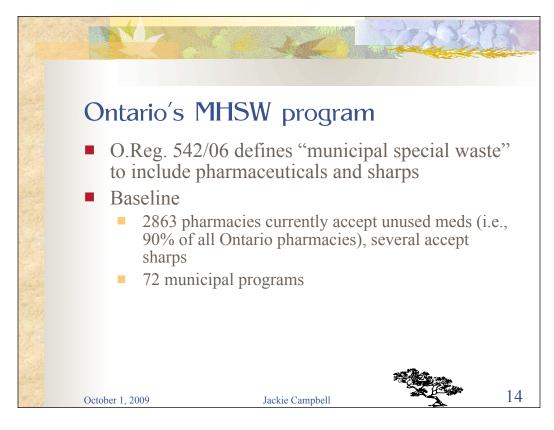
Protect environment from improper disposal practices



 $http://www.napra.ca/Content_Files/Files/Saskatchewan/PFM/Pharmaceutical_Waste_Disposal_Program_Aug 2008.pdf$

Health Cda slides Nov 08

- 90% of pcies participate



Oreg 542/06 to the Waste Diversion Act, 2002 - Munu 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 defin 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



Final consol prog plan - July 30 2009

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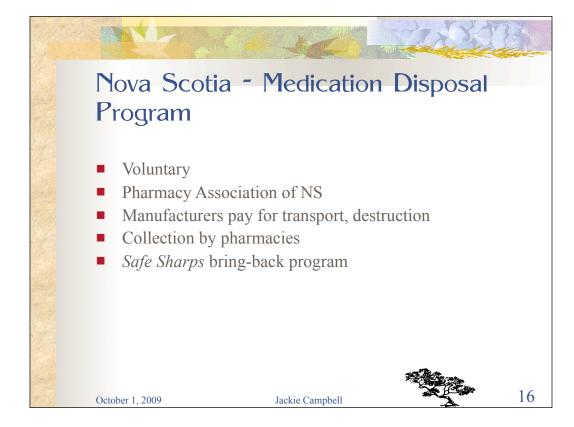
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P 40 - year 1 collection target - 312 tonnes pharma - 254 to pharmacies, 58 from depots, events, toxic taxi etc & 213 tonnes sharps - 38 tonnes "other" and 175 topharmacies

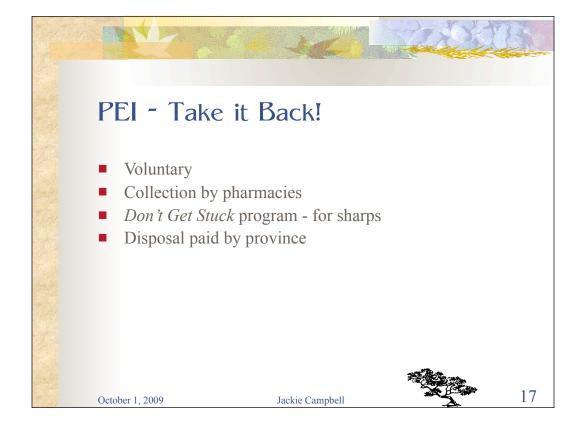
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Since 1990's

-collection up $18\,\%$ from 2005/06 - per Health Canada slideshow Nov 08

-- 100% of pharmacies participate



Since 2004 Health Canada Nov 08 slides



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

And 2005 report

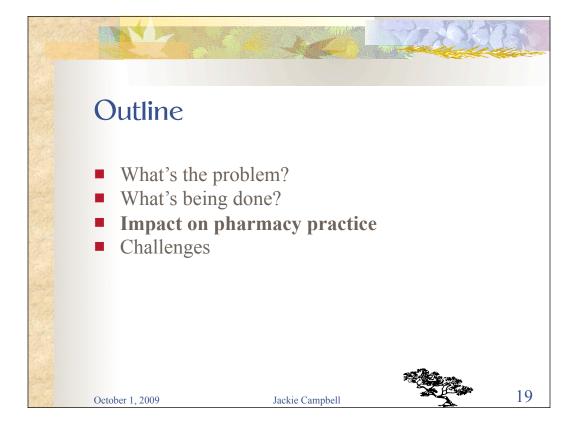
http://www.greenmanitoba.ca/cim/dbf/HHW_DiscPaper.pdf?im_id=31&si_id=1001

See PCPSA Feb 07 newsletter

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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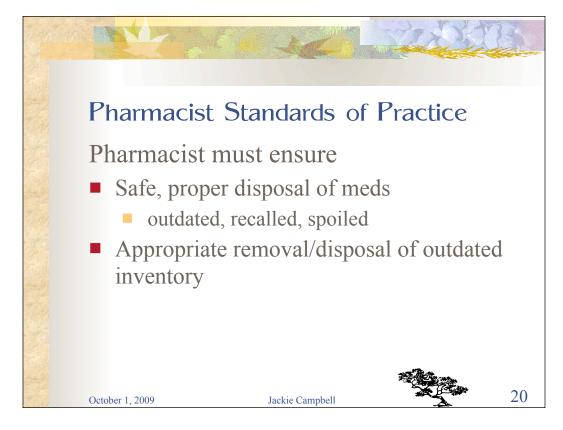
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PHARMACISTS ARE REGULATED HEALTH PROFESSION -- Ontario

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: ...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

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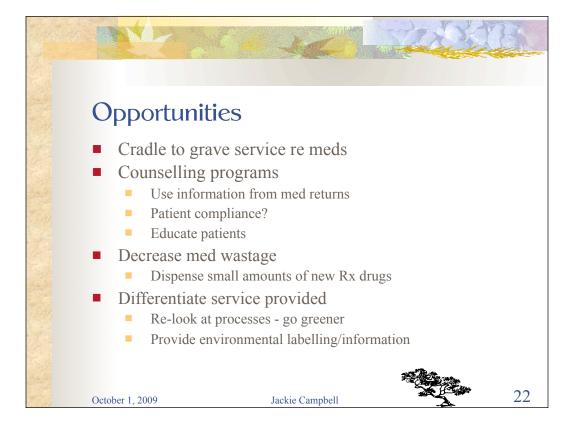
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Cradle to grave service wrt pharmaceuticals

Contextualize Counselling programs

Use information from med returns - e.g., advise patients to tell poist 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.

PHARMACISTS ARE REGULATED HEALTH PROFESSION -- Ontario

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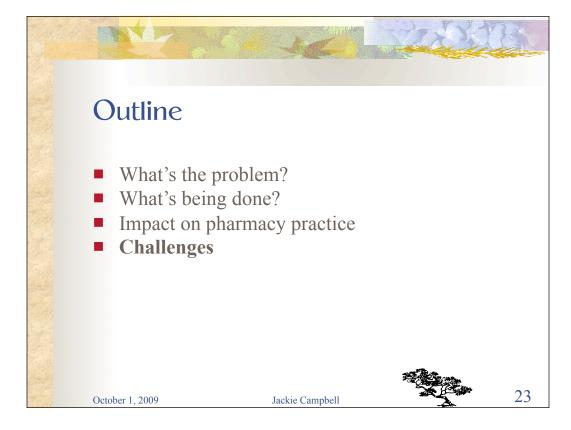
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"Meds should not be disposed of via wastewater or household waste...ask your poist how to dispose of meds no longer required.

These measures will help to protect the enviro"



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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 - targetted

Why not MANDATE appropriate

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

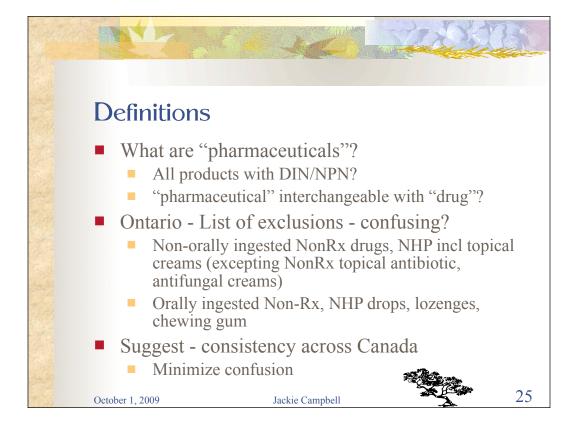
EXAMINE THE VARIOUS LAWS IN CDA AND HOW THEY COULD BE USED TO MINIMIZE PHARMA WASTE

FEDERAL - Cdn Env Protection Act, Food & Drugs Act

PROVINCIAL ENVIRO laws

MUNICIPALITIES - by-laws

WHAT"S WORKING KNOWLEDGE GAP



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.

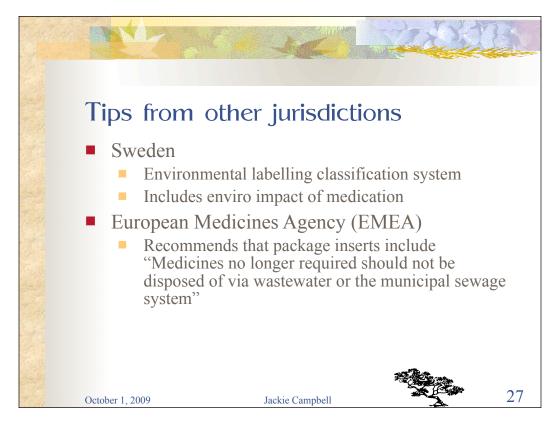


AWARENESS - Rx, non-Rx, sample meds can come to Pcy

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.

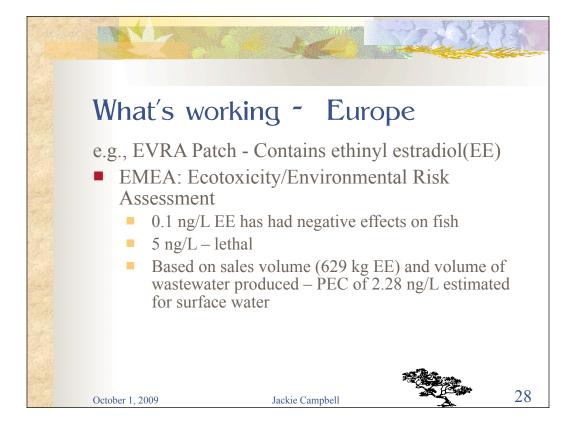


http://www.epa.gov/nerlesd1/bios/daughton/Chap1_Petrovic&Barcelo.pdf

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 (EMEA 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
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 devleoped - gives info to pts and docturs -- avail at www.fass.se



Contains ethinyl estradiol(EE)+ norelgestromin. <u>European Medicines Agency for the Evaluation of Medicinal Products</u> –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 environtal 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"



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

<u>Health professionals</u> - talk to patients/caregivers - include info on how to dispose of meds

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

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

<u>Drug Design</u> –

- -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

