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What Lies Beneath

A look at pharmaceutical waste issues

By Lisa James

Pharmaceuticals in the environment has been an emerging issue for some decades but this topic is currently gaining unprecedented attention from many groups including environmental advocates, the scientific community and government regulators. The primary reason is that pharmaceutical products can now be detected in the environment and recent studies have garnered media attention. Naturally where concern is that human health and aquatic life may be impacted as a result of exposure to pharmaceutical compounds.

In the past half century, there has been an enormous increase in the use of pharmaceuticals in humans; the application of drugs in veterinary medicine, farming practices, aquaculture has also grown. In Canada, 391 million prescriptions were filled in 2005, while sales of non prescription drugs totaled $3.8 billion in 2004. Consumers stockpiling in anticipation of a flu pandemic and government sponsored inoculations are just two recent examples of how “mainstream” drug use prevails in our culture.

The production of pharmaceuticals forms an ill-defined waste stream of end-of-life byproducts that include active ingredients, excipients sharps, and all forms of packaging. (Note: Although similar pharmaceutical waste is not to be confused with “biomedical” waste. Rather it is a sub-category of medical wastes.)

Historically, it’s been simpler and easier to define all pharmaceutical waste as hazardous. In broad terms there are two regulated forms of hazardous wastes. Listed Hazardous and Characteristic Hazardous (e.g. waste material that is not ignitable, corrosive, reactive, or leachate toxic).

According to Ontario’s regulation 347, acute hazardous wastes are those found in concentrations greater than 0.3 percent and listed as epinephrine, nicotine, nitroglycerine, physostigmine, and warfarin in Schedule 2A. The characteristic waste chemicals in Schedule 2B are wastes found in concentrations of less than 0.3 percent and are listed as chlorambucil, cyclophosphamide, hexachlorophene, nielphala, reserpine, and warfarin.

The aforementioned narrow definition actually excludes almost all prescription and non-prescription pharmaceuticals, not to mention naturopathic medicines, personal care products and cosmetics. Nonetheless, most pharmaceutical manufacturers and importers treat all unused and expired pharmaceutical products as “hazardous” and send them for incineration. This is primarily because of the tremendous liability risks associated with product that might find itself in the wrong hands. The few companies that have dabbled in trying to separate packaging waste from product have found it prohibitively expensive.

On the other end of the spectrum, consumers, pharmacists, physicians, dentists, veterinarians, and all manner of healthcare facilities have unused medications that need appropriate disposal. For example, a whopping 20 percent of overall waste from Toronto's Hospital for Sick Children, comes from the pharmacy department. Physician samples, generously and sometimes carelessly distributed to professionals are rarely even considered when pharmaceutical waste stream is studied. Very little is known about the extent of samples or "Clinical Evaluation Packages" (CEPs) as a contributing problem.

A January 2006 report issued by the Canadian Institute of Environmental Law and Policy (CIELP) says that while many contaminants enter the environment through the sink and shower drains, flushing old medications down the toilet is another significant contributor.

Municipalities have begun to recognize and classify pharmaceutical waste as a hazard. Some have lumped this waste into the household hazardous waste (HHW) stream to help consumers define and dispose of it properly. Medicine cabinet clean-up days are organized sporadically across the country and are primarily initiated by chain drug stores. This effort only addresses a fraction of "what lies beneath".

The Province of British Columbia is the only Canadian jurisdiction that manages a drug returns program through the force of regulations. The MRP (Medications Returns Program) is a product stewardship initiative funded by the pharmaceutical and self-care healthy products industries. It is overseen by a relatively new national organization called the PCPSA (Post-Consumer Pharmaceutical Stewardship Association).

However, with packaging stewardship programs in place in Ontario and soon emerging in Quebec and Manitoba, it is anticipated that one day the focus will extend from product packaging to the actual product as well.

Trying to apply the 3Rs hierarchy to pharmaceutical products is complicated, as many initiatives would be prohibited by Health Canada regulations. However, there is a tremendous room for improvement and innovative solutions that are environmentally sound. Many aspects of tertiary packaging can be made materials with high recycled content and (except for blister packaging) most primary packages are easily recyclable.

Opportunities for change

As outlined above, waste management in the pharmaceutical sector is particularly complex. Changes are needed for this sector to collaborate with government and come in line with environmentally responsible practices. The following are some suggested opportunities for change.

- Health Canada and Environment must begin working much more in tandern. For example, better characterization of this waste stream would assist regulators, manufacturers, importers, generators, haulers, and handlers with responsible practices.
- Less (or more innovative) packaging at source. Given some of the stringent packaging programs in Europe, one might think that pharmaceutical

manufacturers or importers whose “parent companies” are members of the EU would be more progressive in this area but they are not. In fact, generic companies lead the field in this regard because they typically use the least resources to gain the highest return. In addition they have more control over their packaging decisions because their manufacturing processes are here in Canada.

- Clearly, more studies are needed to assess the environmental risks of pharmaceutical products in the environment, particularly in water. Groups such as U.S based Pharmaceutical Research and Manufacturers of America (PhRMA) are using a science based approach to understand and address these concerns. They are working in conjunction with the member companies from the EU and Canada as well.
- Trent University’s Environmental and Resource Studies Program has been examining the environmental fate and toxic effects of pharmaceuticals in the aquatic environment. Professor Dr. Chris Metcalfe has been developing a scientific framework to assess the risks and to help influence policy decisions regarding the release of drugs into the environment. The January 2006 report issued by CIELP is another example of interesting research into this topic.
- Better treatment options are also needed. One promising waste treatment option called pyrolitic depolymerization uses the same technology used for recovery of hydrocarbons from paint and industry sludges. Estimates show that 25 percent of pharmaceutical waste is recoverable oil. Another promising treatment uses microwave technology. State of the art incineration is available in European countries but is unavailable in Canada.
- A collaborative approach between industry and their many stakeholders could provide a unified and affordable approach. Provincial stewardship programs are a step in the right direction but they must be harmonized and expanded to included the numerous professional association involved.

Ultimately, incentives always help to change behavior. Buying groups have an opportunity to take an environmental leadership role by rewarding companies that can demonstrate less environmental impact through innovative product stewardship programs.

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