

**Presentation to the House of Commons
Standing Committee on Health**

Study on Post-Market Surveillance

GENERIC DRUGS.



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Canadian Generic Pharmaceutical Association

February 5, 2008

Check Against Delivery

Canadian Generic Pharmaceutical Association

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Introduction

My name is Dr. Colin D’Cunha and I am joined today by my colleague Jacqueline Conant. On behalf of the Canadian Generic Pharmaceutical Association and its member companies, I would like to thank you for this opportunity to participate in the Committee’s study on post-market surveillance.

The CGPA represents manufacturers and distributors of finished generic pharmaceutical products and active pharmaceutical chemicals. Generic drugs fill more than 47 percent of all prescriptions in Canada, even though they accounted for less than 20 per cent of the more than \$18 billion Canadians spent on prescription medicines last year.

Almost all of the generic drugs sold in Canada are made right here in this country. Canada’s generic pharmaceutical industry employs more than 10,500 Canadians in well-paid, highly skilled jobs, and reinvests 15 per cent of sales (or about \$450-million each year) in research and development.

Pharmacovigilance in Canada’s Generic Pharmaceutical Industry

Monitoring the use and effect of medicines is an essential focus for any pharmaceutical company.

Generic drugs are approved for sale by Health Canada, and are identical or bioequivalent to the brand-name version. By the time a generic version is licensed for sale in Canada, the active substances are very well documented and their safety profiles are well established. Unexpected adverse events for these well-known substances are rare. Even so, Canada’s generic pharmaceutical companies take our post-market surveillance efforts and responsibilities very seriously.

All pharmaceutical companies in Canada are required to monitor the use and effect of a given medication, and to detect, assess, understand and prevent any adverse reactions or any other medicine-related problems that arise. These activities and the science behind it are known as “pharmacovigilance” in the pharmaceutical industry.

Both Jacqueline and I are members of the CGPA’s Pharmacovigilance Working Group. This is a group of scientific experts from Canada’s generic pharmaceutical companies who share information about global best practices in pharmacovigilance, changes in international reporting requirements, and various scientific developments.

Our goals in pharmacovigilance are:

- To protect public health by monitoring for the safety and efficacy of our products.

- To limit risk, which we achieve by iterative risk management throughout the product's lifecycle, and by conducting signal detection and safety review of data.
- To undertake effective Risk Management activities, including Risk Communication, core safety information, registries and post-approval studies.
- To place a strong focus on any product with an identified safety concern.

Canada's generic pharmaceutical industry operates in a global environment, and about 40 per cent of the generic drugs manufactured in Canada are exported to the United States and more than 110 other countries worldwide. As you can imagine, these countries have a wide range of post-market surveillance requirements.

As such, Canada's generic pharmaceutical industry is obligated to ensure our procedures are as robust as possible and comply with the most stringent of international pharmacovigilance regulations.

Generic pharmaceutical companies in Canada have standard operating procedures for the collection, assessment, and reporting of adverse drug reactions in clinical and post-marketing experience. These procedures are compliant with national and international regulations and guidelines.

Our companies prepare safety reports to meet regulatory obligations – both the 7 and 15 day expedited reports for serious adverse drug reactions, and the annual and three year periodic safety reports. We conduct ongoing monitoring and literature reviews on a global basis to identify any adverse drug reaction case reports.

Our companies also develop customized ongoing safety evaluations for any products requiring post-approval Risk Management. Drugs in this category include isotretinoin (used for acne) and clozapine (used for schizophrenia). Our Risk Management process is based on established practices in Europe and the United States.

Recommendations

The generic pharmaceutical industry has identified some gaps in Canada's post-market surveillance system, and has made several recommendations to Health Canada. I know some of these points were included in the presentation by Health Canada officials last week. We are pleased to share our recommendations with you today.

1. Canada should align itself with the more stringent reporting requirements of the European Union and United States, moving towards the use of electronic reporting and the harmonization of birth dates for periodic reports.
2. Health Canada should work with other agencies – such as the European Medicines Agency and the FDA in the United States – to undertake a single source or one source literature review. This would allow for a concise and highly informative report, and avoid duplications in reporting.
3. Health Canada should provide safety information freely and without charge. Currently, Health Canada requires payment for this information. This may have the effect of compromising public health, and limiting the ability of manufacturers to perform risk benefit analysis and public communication.
4. Health Canada should take a leadership role in safety, working with all marketing authorization holders and conducting their own safety assessments. This is the current practice of the FDA.
5. Health Canada should also take a leadership role in coordinating the risk management activities of all relevant manufacturers and marketing authorisation holders of a multi-source drug product when a safety concern is identified. This would ensure the best communication and management of the risk to public health.
6. Post-marketing risk management activities should be identical for both brand-name and generic products. This is the current practice and it should continue. Generic products have the same risk management profiles as their brand-name equivalents, and should not be subject to additional requirements.

Conclusion

It is essential for all pharmaceutical stakeholders to play an active role in drug monitoring programs and ensuring that patients only receive safe and effective medicines.

Canada's generic pharmaceutical industry remains committed to good pharmacovigilance practice, and to working collaboratively with both domestic and international health authorities and other stakeholders to minimize public risk and ensure the safe use of generic drugs.

Jacqueline and I look forward to your questions this morning. Thank you.