



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

ENSURING ON-GOING PATIENT SAFETY

THE ISSUE

Canada's generic pharmaceutical industry takes a global and pragmatic approach to pharmacovigilance – the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Health Canada is reviewing its post-market surveillance requirements, and the generic pharmaceutical industry has provided recommendations to address existing gaps in the Canadian system.

BACKGROUND

Monitoring the use and effect of medicines is an essential focus of a pharmaceutical company. Both brand-name and generic 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 may arise.

Generic drugs are identical or bioequivalent to the brand-name versions in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. By the time a generic version of a product 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 their post-market surveillance efforts and responsibilities very seriously.

Canada's generic pharmaceutical industry operates in a global environment. About 40% of our products are exported to the United States and more than 115 other countries – all of which have varying post-market surveillance require-

ments. As such, the industry is obligated to ensure our procedures for handling any adverse drug reactions and submitting expedited and periodic safety reports are robust and comply with the most stringent of pharmacovigilance regulations.

The ongoing surveillance of the safety profile of generic products involves comprehensive procedures for the collection, assessment, and reporting of adverse drug reactions in clinical trial and post-marketing experience. Literature reviews and ongoing monitoring are conducted on a global basis. Periodic and expedited safety reports are submitted to Health Canada. Some substances, such as Isotretinoin (acne) and Clozapine (schizophrenia), require ongoing risk management activities. These risk management processes are based on established practices in Europe and the United States.

Health Canada has been reviewing its guidelines for post-market surveillance of drugs and other products, and draft guidance was published for consultation in January 2008. Post-market surveillance will also be studied by the House of Commons Standing Committee on Health beginning in late January 2008.

The Canadian Generic Pharmaceutical Association and its member companies recommend the following changes to address existing gaps in the current system:

1. Upward international harmonization is strongly supported by the generic pharmaceutical industry. Canada should align itself with the more stringent 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 authorization 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.

CGPA POSITION

Ensuring ongoing patient safety is a priority for the Canadian Generic Pharmaceutical Association and its member companies. The industry remains committed to working collaboratively with domestic and international health authorities to minimize public risk and ensure the safe use of generic drugs. The measures outlined above would address existing gaps in the Canadian system, and have been shared with Health Canada.

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