Archived Content

Post-Market Surveillance of Drug Products Derived From Biotechnology

Once new drugs are authorized for sale in Canada, including those made from biotechnology, it is important to monitor these drugs and their effects while they are in widespread use. To meet this need, Health Canada has in place a post-market surveillance and assessment program.

POST-MARKET SURVEILLANCE

- The Marketed Health Products Directorate (MHPD) assures the consistent coordination of safety surveillance, assessment and risk communication activities of all marketed health products. It does this by:

monitoring and collecting adverse reaction and medication incident data

reviewing and analysing marketed health product safety data

conducting risk/benefit assessments

communicating product-related risks to health care professionals and the public

coordinating regulatory advertising activities

providing policies to effectively regulate marketed health products

conducting active surveillance and effectiveness projects

WHAT ARE BIOLOGICALS AND BIOTECHNOLOGY PRODUCTS?

- Biologicals are derived from living organisms or their parts, such as blood and its components derivatives, and tissues.

- Biotechnology products can be therapeutic products such as monoclonal antibodies and interferons manufactured through biotechnological processes.

- Certain products are available as both; for example, recombinant human insulin is a product of biotechnology, whereas porcine and bovine insulin are biologicals. Likewise some blood clotting factors are available as products from human blood and as recombinant proteins.

- Some of the diseases currently treated with biologicals and biotechnology products include diabetes, haemophilia, rheumatoid arthritis, and multiple sclerosis.

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CHALLENGES WITH MARKETED BIOTECHNOLOGY PRODUCTS

Biotechnology products present unique challenges for effective post-market surveillance:

- Many of the adverse reactions may not be known based on the structure of the product.
- When compared to pharmaceutical products there are relatively few marketed biotechnology products and due to their very specific limited indications, few patients are treated with these products, making rare adverse reactions more challenging to identify.
- With many of the products the chemistry and manufacturing processes are complicated.
- These products are relatively new in the field of therapeutics, thus early detection of signals from adverse event data is important.

THE MARKETED BIOLOGICS AND BIOTECHNOLOGY PRODUCTS DIVISION

- The Marketed Biologics and Biotechnology Products Division (MBBPD) within MHPD performs safety surveillance, assessment and risk communication activities specifically for biologicals and biotechnology products.

COLLABORATIONS AND PARTNERSHIPS

- Working together with national and international groups gives MHPD greater access to Canadian and foreign adverse reaction information, thus strengthening surveillance capabilities.
- Such collaborations include the International Conference on Harmonization (ICH), an international body, working together to develop guidelines/recommendations for effective post-market surveillance of biotechnology products.
- Expert scientific advice and consumer input strengthens risk assessment and communication activities, as well as post-market policy development.

GETTING THE WORD OUT

- Risk information is made available to health professionals and the public through the Canadian Adverse Reaction Newsletter, health product Advisories, the Health_Prod_Info electronic mailing list, Health Canada's Web site, and other means.
- Voluntary reporting of adverse reactions for biotechnology products is important in the identification of adverse reactions.

All health professionals, as well as consumers are encouraged to report any suspected adverse reaction for biotechnology products to Health Canada.

HEALTH PROFESSIONALS AND CONSUMERS: HOW TO REPORT?

Complete the adverse reaction reporting form which can be obtained:

- at: *www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html*;
- by contacting your Regional Adverse Reaction Centre:
  Toll-free phone: 1-866-234-2345
  Toll-free fax: 1-866-678-6789
- in the CPS (Compendium of Pharmaceuticals and Specialties) publication.

Submit the report:

By toll-free fax: 1-866-678-6789
By toll-free phone: 1-866-234-2345

(calls are automatically directed to the National or a Regional Adverse Reaction Centre)

Reporting access for manufacturers will continue to be through the existing national ADR centre direct lines.

Telephone: (613) 957-0337
Fax: (613) 957-0335

FOR MORE INFORMATION VISIT THE BIOTECHNOLOGY THEME AT HEALTH CANADA'S WEB SITE:

http://www.healthcanada.ca/biotech

Or contact us at:

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