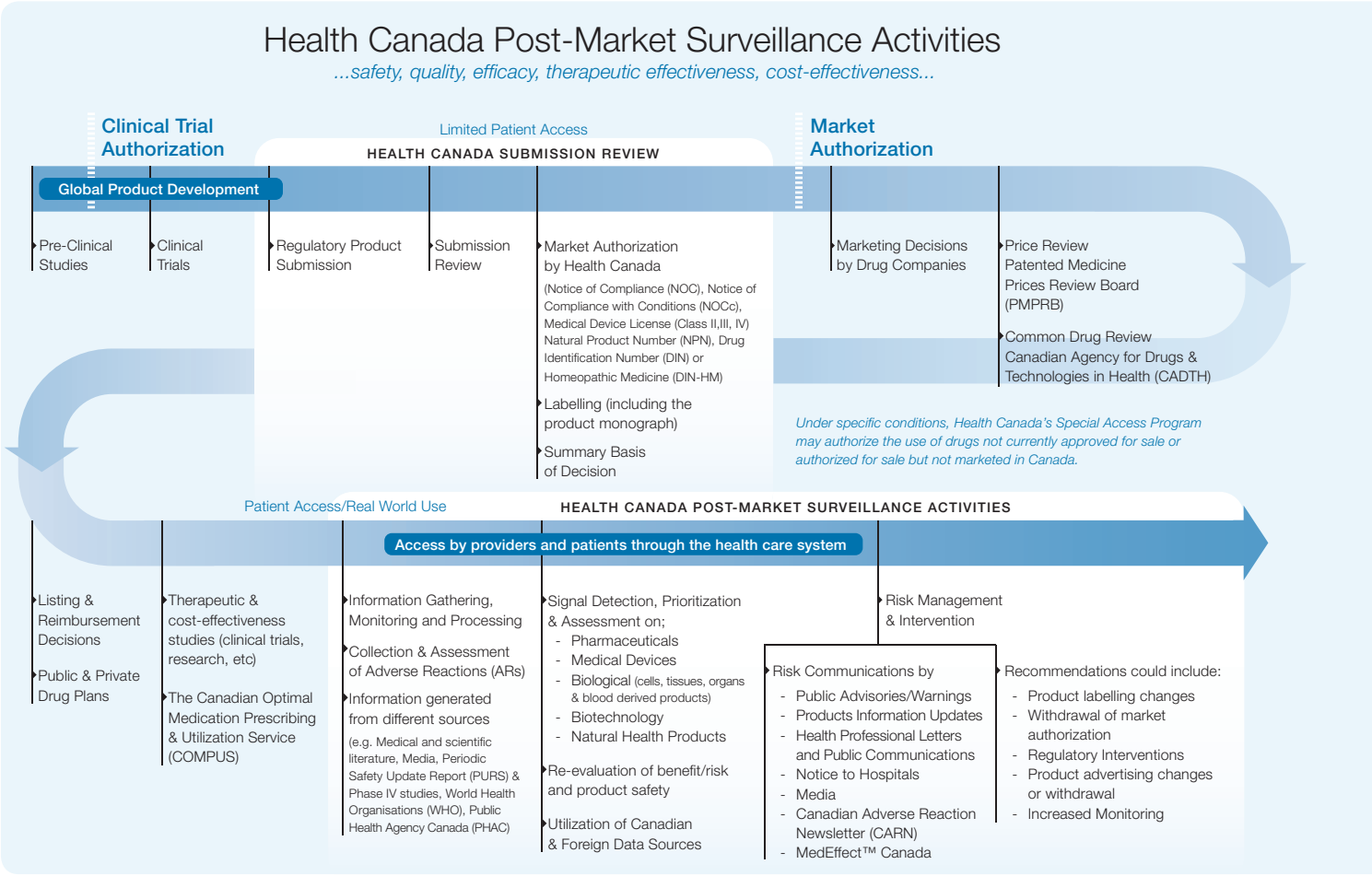
Health Product Review: An Ongoing Process

Health Canada's regulatory environment spans thousands of human and veterinary drugs, vaccines, medical devices, natural health products and other therapeutic products available to Canadians, including the safety and quality of the foods they eat. The regulatory responsibility for these products is distributed among the various directorates within the Health Products and Food Branch. For health products sold in Canada, the primary functions of the directorates are pre-market review, post-market surveillance, and regulatory compliance and enforcement.

Pre-Market Review

Once pre-clinical studies are completed and the data shows promise of being beneficial for human use, a manufacturer



Print: HC Pub: 4768 Cat#: H164-82/2008 ISBN#: 978-0-662-05735-2 | PDF: Cat#: H164-82/2008E-PDF ISBN#: 978-0-662-48758-6

can apply for authorization to conduct a clinical trial.

If the product is effective under the specified conditions of clinical trials, the manufacturer then seeks authorization to sell the product in Canada by filing a submission. HPFB scientists review the submitted information and evaluate the safety, efficacy, and quality of the product.

If the benefits outweigh the risks, therapeutic products are issued a Notice of Compliance and/or a Drug Identification Number under the Food and Drugs Act and Regulations, or receive a class II, III, or IV medical device licence under the Medical Devices Regulations. Whereas, natural health products are issued a product licence and NPN under the Natural Health Products Regulations.

After products are authorized for sale, with the exception of radiopharmaceuticals, blood and blood products, and medical devices, they are assigned one of the following types of numbers:

- Drug Identification Number (DIN),
- Natural Product Number (NPN), or
- Homeopathic Medicine Number (DIN-HM).

These numbers make it easier to identify, follow, recall, inspect, and monitor therapeutic products marketed in Canada.

Class I medical devices do not require a medical device licence since they are monitored by the Health Products and Food Branch Inspectorate through Establishment Licensing.

Post-Market Surveillance

Post-market surveillance is the continuation of the health product review process and contributes to new and up-to-date information that can only be obtained after a product is widely used under real life conditions.

Using rigorous scientific processes, MHPD evaluates reports of suspected adverse reactions (ARs)—undesirable effects due to health products—and determines whether a cause-and-effect relationship exists between the health product and the suspected AR. The MHPD conducts risk assessments and recommends appropriate measures that range from informing the public and health care professionals of product safety information, to recommending labelling changes, to removing a product from the market.

MHPD develops guidelines and implements the regulations that govern the advertising of marketed health products (except medical devices) in Canada. It also works closely with advertising pre-clearance agencies such as the Pharmaceutical Advertising Advisory Board, Advertising Standards Canada and the Broadcast Clearance Advisory to clarify standards regarding what information—including health claims and product safety information—may be included in advertising health products.

Compliance and Enforcement

The Health Products and Food Branch Inspectorate leads branch-wide compliance and enforcement activities. The Inspectorate's core functions are compliance monitoring, verification and investigation, establishment licensing, and laboratory analysis.

HPFB Mandate

The mandate of Health Products and Food Branch (HPFB) is to take an integrated approach to the management of the risks and benefits to health related products and food by:

- Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,
- Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

Did you know?

As of 2007, more than 22,000 human drug products, 81,605 medical devices, and 50,000 natural health products are available on the Canadian market. Millions of people trust that the products have passed Health Canada's rigorous standards for safety, effectiveness, and quality.

Canada's Food and Drugs Act authorizes Health Canada to regulate the safety, efficacy, and quality of therapeutic products.