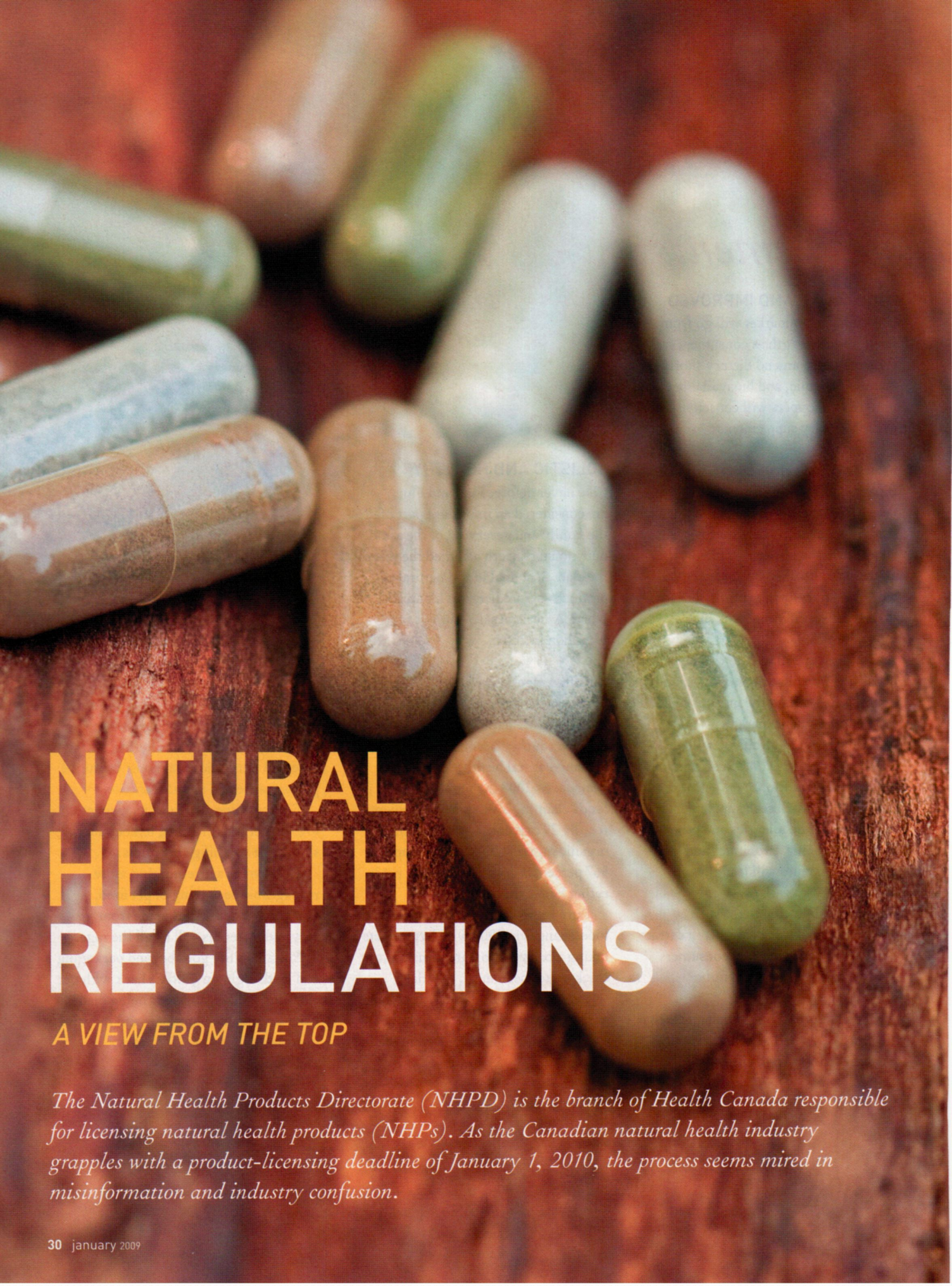

NATURAL HEALTH REGULATIONS

A VIEW FROM THE TOP

The Natural Health Products Directorate (NHPD) is the branch of Health Canada responsible for licensing natural health products (NHPs). As the Canadian natural health industry grapples with a product-licensing deadline of January 1, 2010, the process seems mired in misinformation and industry confusion.

To help paint a clearer picture of the licensing issue and its effect on the natural health consumer, *alive* published *Regulating natural health* (December 2008) by Brian Wagner of NHP Consulting. The article highlighted his concerns with respect to product licensing and government deadlines. This month *alive* asks Michelle Boudreau, Director General of the NHPD to respond. Here's what she had to say:

Q | WHAT IS THE OBJECTIVE OF THE NHPD?

A | Our mission is to help ensure that all Canadians have ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

The NHP regulations aim to protect the health interests of consumers, but are also intended to be flexible enough for the NHP industry to develop useful, reasonably priced products. Health Canada continues to work with industry in the implementation of the regulations to ensure they are not overly burdensome and do not result in inappropriate expenses for manufacturers or consumers.

Q | WHY ARE NHP REGULATIONS BEING IMPLEMENTED?

A | The NHP regulations are a direct response to Canadian consumers' expressed desire for a regulatory system that provides assurance that natural health products are indeed safe, effective, manufactured according to standards that ensure their quality and integrity, and labelled accordingly to enable Canadians to make safe and informed choices.

The NHP regulations were implemented on January 1, 2004, following extensive, multi-year consultations with Canadian stakeholder groups and consumers from across Canada.

Q | HOW MANY NHPS ARE CURRENTLY AVAILABLE IN CANADA?

A | Health Canada estimates that the Canadian NHP market consists of approximately 40,000 products. This includes: vitamin and mineral supplements, herbal and plant-based remedies, traditional medicines (such as traditional Chinese medicines), homeopathic medicines, omega and essential fatty acids, probiotics, as well as many everyday consumer products such as toothpastes, antiperspirants, shampoos, facial products, and mouthwashes.

Q | TO DATE, HOW MANY NHPS HAVE BEEN GIVEN A NATURAL PRODUCT NUMBER (NPN) OR A HOMEOPATHIC MEDICINES NUMBER (DIN-HM)?

A | Thus far, Health Canada has received over 31,600 product licence applications and has completed the assessment of 19,600 applications. To date, Health Canada has licensed 9,751 products.

Q | MANY COMPANIES SEEM TO BE STRUGGLING TO MEET LICENSING REQUIREMENTS. THEY CLAIM THAT THE LICENSING PROCESS IS TOO STRINGENT; WHAT DOES THE NHPD SAY TO THAT?

A | Health Canada continually monitors the implementation of the NHP regulations to ensure that they are appropriate for the Canadian NHP market and continue to meet the needs of Canadian consumers.

In May 2007 the NHPD launched the Natural Health Products Regulatory Review Initiative as part of a commitment to review the regulatory system for NHPs. Health Canada heard from stakeholders that the regulation of NHPs should be "proportional to their risk."

Taking into consideration the feedback received during the

"The NHP regulations are a direct response to Canadian consumers' expressed desire for a regulatory system."

consultation, the NHPD is moving forward with the implementation of a new risk-based approach for the assessment of natural health products.

The new risk-based approach proposes to categorize natural health products into one of two classes based on what is known about their safety and efficacy. Where safety and efficacy are well established through domestic and international standards, assessment on our part would be more administrative in nature, ensuring quick and easy access to products known to be safe and effective. Where safety and efficacy are less certain, consistent with our current practice, products would undergo a full and thorough assessment.

Q | DOES THE NHPD ASSUME A NATURAL HEALTH PRODUCT IS DANGEROUS OR INEFFECTIVE UNLESS IT IS ACCOMPANIED BY PROOF TO SAY OTHERWISE?

A | Health Canada is of the view that the safety and [effectiveness] of health claims associated with NHPs must be supported by appropriate evidence so that consumers and Health Canada can have assurance that products are indeed safe and effective.

Generally speaking, most natural health products are of relatively low risk. However, just because something is "natural" doesn't necessarily mean it's safe or effective. While Health Canada does not assume that all NHPs are dangerous and ineffective unless proven otherwise, our role as a regulator is to question and validate the claims made about natural health products so that consumers can have confidence and assurance that what they are taking is indeed safe and effective. ➢

Q | **WHAT LEVEL OF PROOF DO YOU REQUIRE FOR AN NHP LICENCE?**

A | Health Canada accepts varying types of evidence to support the safety and efficacy of NHPs, ranging from references, published studies, journals, pharmacopoeias, and traditional resources to clinical trial data.

There is no single standard or level of proof to which all NHPs must comply. The type and amount of supporting evidence required is dependent on the proposed health claim of the product, its ingredients, and its overall risk(s).

The amount and type of evidence required to support the safety and efficacy of a single-ingredient herbal product for the relief of headaches is different than the evidence needed to support a multi-ingredient product for the prevention of a serious disease.

Q | **WHAT ABOUT THE BACKLOG OF NEARLY 10,000 PRODUCTS WAITING FOR LICENCES; WILL THE NHPD EXTEND THE LICENSING DEADLINE BEYOND DECEMBER 31, 2009?**

A | Health Canada is committed to addressing the current product licence application backlog by March 2010.

Q | **WHAT HAPPENS TO PRODUCTS THAT HAVE NOT RECEIVED A LICENCE BY DECEMBER 31, 2009; WILL THEY BE REMOVED FROM RETAILER SHELVES AND BE UNAVAILABLE TO CONSUMERS?**

A | The Compliance Policy for Natural Health Products, which is what Health Canada uses to determine when compliance action will target non-compliant products, will remain in place until such a time as Health Canada has addressed the current backlog and is meeting firm, yet realistic, performance targets.

"Health Canada is of the view that health claims associated with NHPs must be supported by appropriate evidence."

In accordance with this policy, compliance action will only target those products that present an unacceptable risk to health and/or do not have a product licence application under review with Health Canada.

If a product has a licence application under review with Health Canada and does not present an unacceptable risk to health, even though it may not be licensed for sale in Canada, the product will not necessarily be removed from store shelves.

Q | **WHAT DOES THE NHPD SAY TO CANADIAN CONSUMERS WHO ARE FEARFUL OF LOSING THEIR FAVOURITE NATURAL HEALTH PRODUCTS IF LICENCES AREN'T APPROVED BY THE DEADLINE?**

A | The NHP regulations have been in place since January 1, 2004. Under this regime, consumers have access to a wide range of natural health products. This will not change after January 1, 2010. Consumers will not see a mass removal of products from store shelves. We have licensed for sale nearly 10,000 products and the number continues to grow.

As is current practice, compliance action will target those products that present an unacceptable risk to health and/or do not have a product licence application under review with Health Canada. Products that do have an application in queue and do not present an unacceptable risk to health will not be targeted for compliance action (that is, will not be removed from store shelves). **a**