

The approach to natural health products

The Natural Health Product Directorate was created to ensure that Canadians have ready access to natural health products (NHPs) that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

Natural Health Products are a class of health products which include: vitamin and mineral supplements, herbal preparations, traditional and homeopathic medicines, probiotics and enzymes.

NHPs are regulated under their own specific regulations, the *Natural Health Products Regulations*, which came into effect in 2004. These regulations take into account the unique nature and properties of these products.

To be legally sold in Canada, all natural health products must have a product licence, and the Canadian sites that manufacture, package, label and import these products must have site licences. Since 2004, Health Canada has authorized over 70,000 NHPs for sale and issued over 2,000 site licences.

For additional information on NHPD policies and guidance documents, please visit the Health Canada [website](#).

Background

When the *Natural Health Products Regulations* came into effect in 2004, the large number of products that were already on the market created an instant number of unprocessed applications. Since then, NHPD has been working with stakeholders to create a steady and predictable regulatory environment for NHPs. NHPD has heard from stakeholders, consumers and parliamentarians on the need for increased access to products, while maintaining consumer safety. This calls for a reduction of unnecessary administrative burden for companies trying to bring safe products to market.

In 2012, as part of NHPD's ongoing commitment to continuous improvement, the "New Approach to Natural Health Products" document was published. The document outlined a more efficient, flexible regulatory approach, protecting health and safety while enabling consumer access and industry innovation and growth. The current document provides an update on how NHPD is implementing this approach.

In February 2013, NHPD completed the review of all unprocessed applications. This achievement has enabled NHPD to create numerous tools aimed at building a more efficient and flexible regulatory environment.

What is the current regulatory approach to NHPs?

In November 2012, NHPD presented the “New Approach to Natural Health Products” during a series of sessions across Canada; feedback received was considered in the publication of three new guidance documents described below.

In December 2012, NHPD published the [Pathway for Licencing NHPs Making Modern Health Claims](#) and [Pathway for Licencing NHPs Making Traditional Health Claims](#). These guidance documents outline the approach to how NHPs are reviewed in Canada, including standards for health claims, the use of risk information and combination of NHPs.

Additionally, the NHPD published an updated [Quality of Natural Health Products Guide](#). It outlines the requirements for ensuring high quality NHPs, while allowing for flexibility in how these requirements are met.

Lastly, significant efforts have been made to increase the amount of monographs available for applicants. NHPD has published over 250 monographs representing hundreds of ingredients. Capitalizing on previous licensing decisions to create and update monographs will decrease unnecessary red-tape in the review of well characterized products.

Product licensing

Under the “New Approach to Natural Health Products”, application review times are based on how much is known to NHPD about a product's benefits and risks, relying on information amassed from over 70,000 authorized NHPs. This means that products with the greatest level of certainty are subject to the shortest review time.

A three-class system outlines the review targets, starting with Class I products attesting fully to a NHPD monograph, up to the more complex Class III products, which will require more review. Applicants are encouraged to use NHPD monographs to ensure the fastest review. As more monographs become available and as further process improvements are implemented, NHPD will continue redefining and expanding the three-class system criteria. As of today, the following rules have been established to allow for shorter review times, where possible.

Class I: High level of certainty → lowest level of pre-market review

Class I is comprised of products that can be indexed against an individual monograph. The level of certainty is higher, as the product has been licenced repeatedly due to its well established safety and efficacy profile. Applications submitted using the electronic Product Licence Application form (ePLA), and meeting all parameters of the monograph will have the opportunity to attest using the embedded form and receive a licence within 10 days. NHPD will continue to explore the expansion of this application stream.

In order to facilitate the increased emphasis on the use and leveraging of product monographs, the licence format will be revised for class I applications. The updated licence will

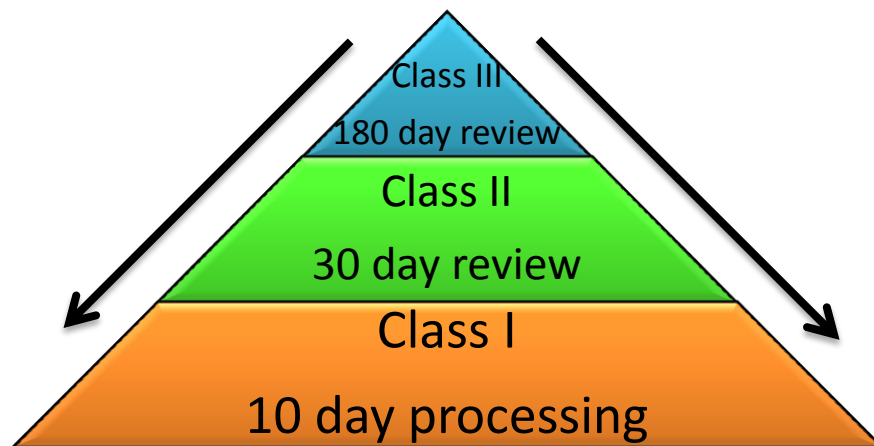
containsections with direct reference to the monograph. Additionally, key elements of the attestation will appear in the licence to remind licence holders of their responsibilities.

Class II: Medium level of certainty → medium level of pre-market review

Class II is comprised of applications with safety and efficacy profiles of medium certainty. This includes products supported by a combination of NHPD monographs. For applications in this class, applicants are required to submit an attestation confirming that their product meets the individual monograph parameters. These products are subject to an expedited risk-based review, with a target of 30 days. Combinations with lower certainty may be subject to a Class III review, or additional information may be requested if a risk to safety is identified. As more information becomes available on the combinations of monographs, NHPD will expand the Class I stream to include a wider variety of products. In addition, NHPD continues to explore the expansion of class II to include additional application categories, such as products with ingredients whose safety is well-established to NHPD.

Class III: Low level of certainty → higher level of pre-market review

Class III is comprised of applications with safety and efficacy profiles of higher uncertainty. Examples belonging to this class are: products with previously unlicensed claims for serious conditions, never before seen ingredients or combinations, and products with significant safety concerns. For the portions of these applications which are supported by NHPD monographs, applicants will be required to attest, in a standalone form, that the product meets the parameters from the relevant monographs. For the novel portions of these applications, applicants will be required to submit supporting evidence. NHPD aims to complete the review of these applications in up to 180 days. When possible, NHPD will capitalize on previous licensing decisions and complete reviews in less than 180 days.



As the certainty on the safety and efficacy profiles of novel natural health products increases, NHPD will develop and/or update monographs in order to facilitate movement from Class III to Class II and Class I. The performance rate of each class of review will be communicated in the NHPD Quarterly Snapshot.

For further details, please refer to the updated Application Management Policy available at [PLA management](#).

Attestation

Product licence application and post licensing changes based partially or completely on NHPD monograph(s) will be required to include an attestation to this effect. The attestation text can be found on the ePLA or as a standalone form available on the NHPD [website](#).

Post licensing quality control audit

To complement the attestation to NHPD monographs, NHPD will implement a post-licensing quality control audit. This will ensure that the parameters against which applicants have attested are accurately reflected in the product application, focusing on errors, inconsistencies, and deviations from the monograph(s).

The post-licensing quality control audit will be comprised of risk-based and random auditing streams.

NHPD reserves the right to communicate the results of any failed audits on the Health Canada website or through other avenues.

Site Licensing

During the fall of 2011, NHPD began consulting on a Risk-Based Approach to Site Licensing for NHPs. The majority of stakeholder feedback indicated support for a new approach supplementing the present paper-based self-assessment model. Since 2011, NHPD has continued to engage stakeholders regarding this approach and has revised several key areas of the proposal based on the feedback received.

The proposed approach includes the following:

Independent on-site audit: NHP manufacturers, packagers, labellers and importers may elect to undergo an independent on-site audit to demonstrate compliance with Good Manufacturing Practice (GMP) standards. Alternatively, the NHPD may request that a site licence applicant undergo an audit by a Health Canada recognized third party, when critical quality issues are identified, or when activities involving higher risk product types are being conducted.

Enhancements to the current assessment process: The current self-assessment process will continue to be an option for site licence applicants. The NHPD is proposing to streamline and enhance the current process by aligning evidence requirements to the risk profile of a site. Sites

conducting lower risk activities or handling lower risk products would need to submit less evidence than sites dealing with high risk activities or high risk products.

The primary objective of this approach is to develop a strengthened site licensing framework, which will provide greater assurance that NHPs sold in Canada meet appropriate standards of quality. A system for ensuring product quality, based on appropriate GMP standards, creates confidence in the capability and capacity of an organization's processes and the quality of their products.

NHPD plans to publish a proposal document on the Revised Approach to NHP Site Licensing in late 2013/early 2014 and aims to conduct a pilot in the spring of 2014. To support the new approach, revisions to the Site Licensing and the GMP guidance documents will be released for consultation during the pilot phase.

Compliance and enforcement

The Inspectorate is modernising its compliance and enforcement approach for NHPs. The modernised approach is being developed in consultation with stakeholder associations and will lead to a rebalancing of the Inspectorate's activities. The modernised approach will lead to investments in proactive areas such as compliance monitoring and activities aimed at generating compliance throughout the supply chain. The Inspectorate will continue to apply a risk based approach to non-compliance and respond to consumer and trade complaints.

The Regulated parties marketing NHPs will maintain the primary responsibility for the safety and quality of any product they sell, manufacture, import or distribute to the Canadian public. The Inspectorate will continue to focus compliance and enforcement efforts at higher points in supply chain

Until the new approach is finalised, stakeholder can refer to the NHP Compliance and Enforcement Policy (POL-0044) for more detail on the current compliance and enforcement approach and the NHP Transition Period. [Policy](#)

What impact do these approaches have on product safety?

Shortened review time does not change the current tools in place to assess health product safety. The level of evidence required to demonstrate safety remains the same, and health products will continue to be labelled with required cautionary statements, e.g. reported adverse reactions and potential interactions with other health products; duration of use; warnings for certain populations like pregnant women etc.

Health Canada will also continue to focus its post-market activities for NHPs on situations that pose risks to the health and safety of Canadians, e.g., serious adverse reactions, poor

manufacturing, adulteration (e.g. addition of prescription and non-prescription drugs to NHPs), or products making claims not substantiated by evidence. These safety issues may occur in products independent of product class. In addition, post-market activities may be heightened for those products having less certainty (e.g., class III products).

The regulatory requirement for a company to submit reports of serious adverse reactions will not change; companies are required to prepare and maintain summary reports of adverse reaction data, on an annual basis, for each of their licenced products. Health Canada continues to collect, track, and analyze adverse reaction data for NHPs through the [Canada Vigilance Program](#), and other sources such as published literature, foreign regulatory agencies, the World Health Organization (WHO) adverse reaction database, and data submitted by industry. When analysis of adverse reaction information shows that there is a need to take action to protect the health and safety of Canadians, Health Canada can take a range of steps. These include changes to product labelling, product recalls, public communications which include distribution of information to consumers and health professionals, and, in more serious cases, removal of a product from the market.

Next steps

NHPD will continue capitalizing on previous decisions to create and update monographs, in order to expand classes I and II. This will expedite the review of products with high certainty, while allowing for resources to be reallocated to the review of products with lower certainty profiles. As a result, NHPD will reduce unnecessary administrative burden for companies trying to bring safe products to market, and simultaneously ensure Canadians have access to innovative products. The directorate will also continue to improve the electronic tools available for applicants and continue to engage stakeholders on current and future initiatives.