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Natural Health Products: Proposed Canadian Regulations to Provide Certainty About Unprocessed Applications

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In 2004, when the Canadian *Natural Health Products Regulations* (the Regulations) came into force, an estimated 40,000 unlicensed Natural Health Products (NHPs) were on the Canadian market. The Regulations prohibit the sale of unlicensed NHPs; however, instead of requiring the market withdrawal of all unlicensed NHPs, Health Canada implemented a compliance policy under which enforcement was focused on NHPs that posed an unacceptable health risk and on NHPs in respect of which an application for approval had not been submitted by the manufacturer. The issue with this approach is that a compliance policy is not law and can be revoked anytime, leaving manufacturers open to prosecution for selling unlicensed NHPs.

The current backlog of applications has resulted in an estimated 10,000 unlicensed NHPs on the market in Canada that are awaiting regulatory approval. Earlier this year, the National Association of Pharmacy Regulatory Authorities (NAPRA), citing safety concerns, issued a directive urging pharmacists to stop selling unlicensed NHPs. This directive was adopted by the colleges of pharmacists in some provinces, thereby hindering market access for manufacturers of unlicensed NHPs.

On May 8, 2010, in order to address concerns regarding safety of unlicensed NHPs and the legality of selling unlicensed NHPs, the government published the *Natural Health Products (Unprocessed Product License Applications) Regulations* (the Proposed Regulations). The Proposed Regulations provide a temporary solution intended to provide Canadians with lawful access to NHPs awaiting regulatory approval, while ensuring performance of interim safety and monitoring checks. The proposed Regulations would make the sale of these unlicensed NHPs legal.

Under the Proposed Regulations, the Minister of Health must exempt manufacturers from the prohibition against selling an unlicensed NHP, provided that two conditions are satisfied: first, the proposed regulations would apply only to NHPs for which an application has been filed with Health Canada, has not been withdrawn and has been pending for more than 180 days, and Health Canada has made no decision to issue or refuse a license;[1] second, the NHP must meet certain safety requirements, discussed in greater detail below.

For eligible NHPs, the Minister of Health must notify the applicant that an exemption number has been assigned. The applicant then has 30 days to provide its consent to

[1] In respect of applications filed before the Proposed Regulations come into force, an exemption will be issued within 15 days of the proposed Regulations coming into force or 180 days from the date the application was submitted, whichever is later.

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the posting of the exemption number, the brand name and the manufacturer's name on Health Canada's website.

Within 30 days of receiving the written notification of the exemption number, applicants must also confirm that the NHP

- is not a sterile product for ophthalmic use;
- does not contain any ingredient prohibited by the *Food and Drugs Regulations*;
- does not contain an ingredient that is likely to result in injury to the health of a consumer/purchaser (to the best knowledge of the manufacturer);
- is not recommended to treat, prevent or cure a serious disease (as listed in Schedule A of the *Food and Drugs Act*); and
- is not intended for use in children under 12 years of age or for pregnant or breastfeeding women.

Once the applicant provides its consent and the foregoing statement, the exemption number will be posted on Health Canada's website. The applicant will then be deemed to hold a product license, which will allow the NHP to be lawfully sold in Canada. If the applicant does not consent or provide the required safety statement, the applicant will not be deemed to hold a product license for the NHP.

Under the deemed license regime, manufacturers would be required to comply with most of the safety requirements imposed by the Regulations, but would not be entitled to certain rights accorded to manufacturers whose products are licensed and hold NHP numbers (NPNs). Specifically, holders of deemed licenses would be required to file safety information, maintain records, report adverse reactions, meet site licensing requirements and maintain good manufacturing practices. Labelling requirements would be substantially similar to those applicable to licensed NHPs, although the manufacturer will be required to display the exemption number instead of the NPN on the product label. Manufacturers will be given a reasonable time to bring their labelling into compliance with this requirement. Manufacturers under a deemed license will not be entitled to make certain post-market changes to the NHP, as is permitted for products with NPNs.[2] The Minister of Health would have the authority to issue a stop sale direction and/or suspend or revoke a deemed license upon identifying a safety issue.

Once the underlying NHP application is processed (or withdrawn by the applicant), the deemed license exemption ceases to apply. Furthermore, because the Proposed Regulations are a temporary solution, they are set to be repealed 30 months after coming into force, at which time any existing deemed license would no longer be deemed valid.

The government is accepting comments on the Proposed Regulations until June 7, 2010.

[2] Holders of NPNs can make certain post-marketing changes by filing a license amendment or providing notification to the Minister of Health.