

Natural Health Products (Unprocessed Product Licence Application) Regulations

May 4, 2010

Dear Stakeholders,

Health Canada has made significant progress in the processing of natural health product licence applications in backlog and I am pleased to advise you that the Natural Health Products Directorate has successfully met its internal target to address it by March 31, 2010¹. While we have achieved this milestone and are continuing to process these product licence applications in order to make final licensing decisions, we acknowledge that there are still challenges, and that we have not yet set performance standards for the review of product licence applications (PLAs). This letter outlines our intended approach to moving forward with the application and administration of the *Natural Health Products Regulations* (NHPR).

As you know, the Compliance Policy for Natural Health Products (NHPs) was adopted to provide a reasonable transition period to allow the NHP industry to apply for product licences and to bring their products into compliance with the NHPR. The Compliance Policy has been in place since the Regulations were first adopted and does not include a precise end date. This policy has presented challenges at the retail level as has been highlighted by the recent position statement released by the National Association of Pharmacy Regulatory Authorities (NAPRA), in which pharmacists are directed to sell only health products that have been authorized for sale by Health Canada².

Health Canada has developed a regulatory proposal that would address the current environment. This regulatory proposal would allow for certain natural health products to be issued exemption numbers by Health Canada. The regulatory proposal would mean that products for which an exemption number is issued by Health Canada will be exempted from the current prohibition against sale without a product licence (as set out in s.4 of the NHPR). In other words, these products could now be sold legally.

Health Canada's intent is to proceed with a public consultation period of 30 days following prepublication in the *Canada Gazette*, Part I, in the near future at the following address: <http://www.gazette.gc.ca/rp-pr/p1/index-eng.html>.

¹ "Addressed" means that the product licence application has: 1) received product authorization, 2) been refused or withdrawn, OR 3) received at least one request for information.

² issued a Drug Identification Number (DIN), Natural Product Number (NPN) or Drug Identification Number for Homeopathic Medicine (DIN-HM)

Formal adoption (publication in the *Canada Gazette*, Part II) of the regulatory proposal may follow, depending on the comments received and if there is general support, sometime in the summer of 2010.

Sincerely,



Michelle Boudreau
Director General
Natural Health Products Directorate