Draft Discussion Paper on the Natural Health Products (Unprocessed Product Licence Applications) Regulations

Prepared by Shawn Buckley, president of the Natural Health Products Protection Association on May 12, 2010.

Summary of Proposed Regulations:

(1) negative if you do not sell to pharmacies;

(2) positive if you do sell to pharmacies;

(3) positive for Health Canada Inspectors wanting to remove unlicenced products (negative if it is your unlicenced products - negative if you are a consumer who relies on the products - negative for Health Food Stores);

(4) No change on the current regulatory path which will result in the majority of NHPs available prior to 2004 being removed from the market.

Discussion Paper Only

This is a discussion paper only and does not reflect the position of the NHPPA or of the NHPPA Advisory Board. The thoughts and comments are those of the author, Mr. Shawn Buckley and are intended to encourage Canadians to read the proposed Regulations and to foster discussion.

This is an initial discussion paper only. The author expects that as feedback is received and further study of the proposed Regulations is undertaken, that the opinion of the author will broaden.

The NHPPA is inviting comments on this discussion paper. Feedback and comments can be forwarded to the NHPPA at **info@nhppa.org**.

Background

On May 8, 2010, the Government published the *Natural Health Products (Unprocessed Product Licence Applications) Regulations* in the Canada Gazette Part I. After a discussion period the Government has the option of publishing them in the Canada Gazette Part II which would make them law.

Analysis Framework

When analyzing proposed regulations it is helpful to:

(1) first understand the current law;

(2) identify how the current law will be changed, and

(3) examine how the change will affect those being regulated.

Step 1 – Understanding the Current Law

A. The Conviction Issue

The purpose of the proposed regulations is to "legalize" products that are waiting for licences. If certain conditions are met, products for which licence applications have been submitted can be deemed to be licenced until the licencing process is completed.

This is being touted as a major breakthrough as it will "legalize" products in the licencing backlog. By deeming these products to have a licence, persons cannot be charged for selling them without a licence.

Under the current NHP Regulations, it is an offence to sell a NHP unless it has a product licence (see section 4). The current Regulations also require Health Canada to process some licence applications within sixty days (section 6). Health Canada has, however, been unable to process licence applications in a timely manner. Many applications have been pending for years. This has created a situation where the Regulations require a licence but licences are not granted because Health Canada has not been able to get through the backlog.

It does not necessarily follow that persons selling unlicenced products for which licence applications have been submitted are in danger of convictions for selling unlicenced products. There are two major reason for this. First, the optics would be terrible for Health Canada. It would appear, appropriately, grossly unfair to charge a person for selling without a licence when an application has been submitted and it is Health Canada that if failing to comply with the Regulations. Second, a Court would be highly unlikely to convict because the defense of due diligence would apply. The defense of due diligence prevents convictions for regulatory offences such as selling a NHP without a licence when the person selling did everything that a reasonable seller would have done to comply with the law. As the law currently stands, all a reasonable seller would do to comply with the licencing law is to submit a licence application.

As the law currently stands, persons who have submitted licence applications are not in danger of convictions for selling without a licence. There is no need to exempt them or deem licences to avoid convictions. It would simply be incorrect to think that the proposed Regulations are needed to mitigate any danger of convictions. On the conviction issue, the Regulations are not necessary. Rather the driving force appears to be to ensure pharmacies will sell products with pending licencing applications.

B. The Pharmacy Issue

In January the National Association of Pharmacy Regulatory Authorities (the "NAPRA") issued a position statement which recommended that pharmacists should not sell unlicenced products. This has led to some pharmacies cancelling orders.

For persons whose business depends on sales to pharmacies, the potential impact of this policy is significant. The proposed Regulations should serve to ensure that pharmacies will continue to purchase products with pending licencing applications, provided they fit within the conditions outlined below.

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Suprisingly, the NAPRA policy did not consider that:

(1) the same class of products are readily sold by U.S. pharmacies without licences (as in the U.S. NHPs are deemed to be legal and do not require licences), and

(2) the entire NHP industry has a significantly lower risk profile than over-the-counter pain medications and cold medications which contain acetaminophen (just to pick one example) which pharmacies readily sell without concern of legal liability.

C. The Enforcement Issue

There are three classes of products currently being sold:

(1) licenced products;

(2) unlicenced products with submitted licence applications, and

(3) unlicenced products with no pending licence applications.

The Health Canada Inspectorate (the Health Canada police arm) does not want unlicenced products with no pending licencing applications left on the market. They are clearly "illegal". However, as things currently stand, it is not feasible for the Inspectors to walk into health food stores and seize all the unlicenced products which have no pending licencing applications. This is because while they are in the store they cannot currently determine which unlicenced products have submitted licence applications and which products do not. Even the cumbersome process of making a list and checking with the NHPD is complicated, as several products with submitted licence applications are being sold under different names than are listed on the licence applications. The persons who submitted the applications are not obligated to inform Health Canada of the name change until after a potential licence is granted.

We have cautioned that the NHPD clearing the back-log would enable Inspectors to clear the market of unlicenced products. Once the back-log is cleared, Inspectors can walk into health food stores and seize every product which does not have a licence number on the label. One only has to speculate that if the Inspectorate did this across the country for a week or two, many stores would be scared into submission and limit their stock to licenced products. Prior to these proposed Regulations, it was clear that any such enforcement initiative would have to wait until the licencing back-log is cleared.

If passed, the proposed Regulations would enable the Inspectorate to remove all unlicenced products which:

(1) do not have submitted licence applications, or

(2) do not meet the conditions for a deemed licence.

The proposed Regulations require all products with deemed licences to have the exemption number on the label within a reasonable time. Once this is done, Inspectors will be able to walk into stores and remove all products that do not have either licence numbers or

exemption numbers on the labels.

The proposed Regulations will enable the Inspectorate to remove far more products from the market prior to the licencing back-log being cleared.

Step 2 – How the Law Will be Changed

The proposed regulations will create a temporary exemption from the licencing requirement. An exemption in the form of a deemed licence will be granted if a person has:

(1) submitted a licence application;

(2) consented to the posting of their name, exemption number and brand name of their product on the Health Canada website;

(3) made a statement confirming the product is not;

(i) a sterile product for ophthalmic use;

(ii) a drug:

(a) referred to in Regulations C.01.036 (phenacetin in combination with any salt or derivative of salicylic acid; a drug for human use containing oxyphenisatin, oxyphenisatin acetate or phenisatin; a drug for human use containing mercury or a mercury salt or derivative as a preservative [unless described in Schedule C or D to the Act, used in the area of the eye, for nasal or otic administration, or used for parenteral administration packaged in a multi-dose container, and for which there is evidence demonstrating that the only satisfactory way to maintain the sterility or stability of the drug is to use mercury]); C.01.36.1 (nitrous oxide); C.01.040 (chloroform; arsenic or any of its salts or derivatives); C.01040.1 (methyl salicylate as a medicinal ingredient in a drug for internal human use);

(b) containing: Strychnine or any of its salts; extracts or tinctures of *Strychnos nux vomica*, *Strychnos Ignatii*, or a *Strychnos* species containing strychnine; Methapyrilene or any of its salts; Echimidine or any of its salts; or any of the following plant species or extracts or tinctures thereof: *Symphytum asperum*; *Symphytum x uplandicum*, or any other plant species containing echimidine.

(iii) recommended for a condition listed on Schedule A of the *Food and Drugs Act*;

(iv) recommended for use in children under 12, and

(v) recommended for use in pregnant or breast-feeding women;

(4) made a statement that to the best of their knowledge the product does not contain an ingredient that is likely to result in injury and whose presence in any drug has led to a recall or a stop sale under section 17 of the NHP Regulations;

(5) made the confirmation in number (3) and the statement in number (4) in a form set out by the Minister.

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The deemed licence will end when the licence application is withdrawn or processed. The Minister can suspend a deemed licence if he/she believes the person holding the licence has violated the regulations or does not fit within the requirements for a deemed licence under the proposed regulations.

Once a deemed licence is granted by being posted on the Health Canada website, the assigned exemption number must be put on the product label within a reasonable time.

Step 3 – Impact of Regulations

A. If you do not sell to pharmacies

For persons who have submitted pending licence applications, the proposed Regulations create more work in that the confirmations outlined above will have to be done to prevent the products from being subject to enforcement action. Currently, the products can remain on the market without these additional hoops.

As outlined above, there is really no net gain from the perspective of avoiding a conviction.

The proposed Regulations will add some additional costs of compliance with no benefit to persons with pending licence applications which do not sell to pharmacies.

Health food stores set to benefit from pharmacies no longer competing with unlicenced products will lose the sales that would have resulted from this loss of competition.

B. If you do sell to pharmacies

The proposed Regulations are designed to protect sales to pharmacies. Any additional compliance costs should be off-set by continued sales to pharmacies.

The proposed Regulations "should" solve the pharmacy issue created by the NAPRA policy.

C. Enforcement Implications

The proposed Regulations will enable the Inspectorate to remove all unlicenced products which:

(1) do not have submitted licence applications, or

(2) do not meet the conditions for a deemed licence.

The proposed Regulations require all products with deemed licences to have the exemption number on the label within a reasonable time. Once this is done, Inspectors will be able to walk into stores and remove all products that do not have either licence numbers or exemption numbers on the labels.

Consumers who depend on these products for health conditions risk losing access to them.

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Safety Issues

The proposed Regulations are curious in that they presume that any potential safety issues posed by the estimated 10,000 NHPs in the licensing back-log can be adequately addressed by the simple information confirmations outlined above. If this is true, it begs the question as to why such simple attestations are not adequate for licencing.

The NHP safety issue is one that the industry must address to arrive at a fair and reasonable regulatory environment. The current regulations which deem NHPs to be dangerous and illegal, unless barriers to enter the market are overcome, can only serve to restrict consumer access to NHPs. There are serious problems with this starting assumption on safety, including but not limited to:

(1) the same products are deemed to be safe in the U.S.;

(2) Health Canada has not produced a single risk analysis on NHPs to justify the imposition of chemical drug-style regulations including the presumption the products are not safe;

(3) Health Canada has not done a single risk analysis to show **that it is safe to remove NHPs Canadians rely on from the market**. The current NHP Regulations can only have the effect of removing NHPs from the market. The presumptions must be that the NHPs that are removed are not necessary, and are not helping the persons who rely on them. These are starting presumptions that will not assist the natural health community to obtain fair and balanced regulations.

No Change in Direction

The NHPPA is predicting that the current regulatory path will result in:

(1) the majority of NHPs that Canadians were free to access prior to 2004, being removed from the market;

(2) innovation into multi-ingredient products continuing to be reduced;

(3) the expansion of the monograph system which will serve to limit dosage amounts;

(4) increased costs for the natural health community as the barriers to entry change, including the introduction of licencing and licence renewal fees;

(5) the continued criminalization of the natural health community;

(6) more efficient enforcement enabling Inspectors to remove far more products from the market than has been previously possible.

For this trajectory to be altered to create a fair and balanced regulatory environment more in line with the 53 Recommendations, the underlying assumptions underpinning the current regulatory environment will need to be changed. "Increased" access to NHPs cannot be accomplished under regulations that deem NHPs to be illegal and which only allows products which can overcome various barriers to be sold.

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