NATURAL HEALTH PRODUCT PROTECTION ASSOCIATION
nhppa.org

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Natural and Non-prescription Health Products Directorate
Health Products and Food Branch
Health Canada
2 Constellation Drive
Ottawa, Ontario
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Re: Submissions for the Consultation on the proposed NHP Compounding and Raw Materials Policy

The Natural and Non-prescription Health Products Directorate has called for submissions on Health Canada's NHP Compounding and Raw Material Policies.

Please accept this letter as the submissions of the Natural Health Product Protection Association (NHPPA) on these policies. The NHPPA is a federally incorporated not-for-profit corporation which provides the NHP industry and consumers with legal and policy expertise in the area of the regulation of NHPs.

Clarity on what the new Policies are accomplishing

The new Policies represent an illegal intrusion into the practice of medicine to such an extent as to be breathtaking.

The law is simple, so Health Canada's new Policies that deliberately violate the law must be intentional.

The clear effect of these Policies will be to interfere with the practice of medicine by restricting compounding. Because this is the obvious result of the illegal Policies, it is safe to assume that the underlying purpose of the new Policies is to get rid of compounding.

Health Canada is an enforcement agency. When an enforcement agency which demands that others follow the law, does not itself follow the law, respect for the law is lost.

There *are only two* legal requirements for the compounding exemption to apply

The only requirements for the compounding exemption are that:

1. the ingredient is itself a *natural health product* (see below), and
2. the NHP ingredient be used for compounding.

There are no other legal requirements. Issues such as whether there are other products available are illegal requirements created by Health Canada.

Requirement 1 - the ingredient must itself be a natural health product

Section 2 of the *Natural Health Product Regulations*, SOR/2003-196 (NHP Regulations) are clear that the NHP Regulations only apply to the importation of *natural health products*. Section 2 includes:

> 2 (1) These Regulations apply to....
>
> (b) the manufacture, packaging, labelling and importation for sale ***of natural health products***...

If a doctor is importing an ingredient **that is not** a *natural health product* ***the NHP Regulations do not apply and by consequence the compounding exemption does not apply***. In such a case, Health Canada has no authority to take any actions, such as recommending shipments be refused for non-compliance with the NHP Regulations (as the NHP Regulations do not apply if the ingredient being imported is not a NHP).

If a doctor is importing an ingredient that is a *natural health product*, the sole issue to determine whether the compounding exemption applies is, whether the ingredient is meant for compounding or not. There are no other legal requirements.

Requirement 2 - the ingredient is used for compounding

The compounding exemption is found in the definition of *manufacturer* in the NHP Regulations. This definition reads:

> *manufacturer* means a person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds ***a natural health product*** for the purpose of sale to that patient.

This definition is clear. Manufacturing does not include compounding a natural health product for a patient. There is no other legal requirement to be exempted from the manufacturing definition. All you have to do is compound.

There is no ambiguity in the NHP Regulations. The compounding exemption applies if:

1. the ingredient is itself a *natural health product*, and
2. the NHP ingredient be used for compounding.

The compounding exemption exists because Health Canada does not have jurisdiction over how medical practitioners practice

Medical practitioners are regulated by the provinces. That is why laws governing medical practitioners are provincial laws. The practice of compounding by a medical practitioner is solely within the jurisdiction of the provinces.

Health Canada regulates drugs (anything used to stay healthy or restore health) as an exercise of the Federal Government's criminal law power. This criminal law power cannot be used to regulate the practice of medicine, such as compounding.

It was a constitutional necessity to put the compounding exemption into the Natural Health Product Regulations, as the Federal Government acting through Health Canada does not have the jurisdiction to interfere with the practice of medicine (which includes compounding).

Parliament made it clear when the NHP Regulations were passed, that the regulations were not meant to interfere with the practice of medial professions. The Regulatory Impact Statement included:

> Health care practitioners (for example, pharmacists, Traditional Chinese Medicine [TCM] practitioners, herbalists, naturopathic doctors) who compound products based on the needs of a patient are not included within the manufacturer definition. The regulations are not aimed at regulating the practice of complementary and alternative health care practitioners or the practice of traditional Aboriginal medicine.

Health Canada's proposed *Natural Health Product Compounding Policy: Policy statement*, is an attempt to create law and to add conditions that do not legally exist

As set out above:

1. the constitution prohibits Health Canada from interfering with compounding, which is the practice of medicine within the sole jurisdiction of the provinces;
2. the only actual legal requirements for the compounding exemption are that:
   (a) the ingredient is itself a *natural health product*, and
   (b) the NHP ingredient be used for compounding.

Health Canada's *Natural Health Product Compounding Policy: Policy statement* (the Compounding Policy) creates conditions that do not exist in the law. Health Canada does not have jurisdiction to add requirements that are not set out in the current law. Policy is not law, but should adhere to the law so that Health Canada inspectors in the field do not continue to illegally interfere with the practice of medicine. Health Canada inspectors are not qualified to interfere with medical decisions.

The Compounding Policy is based upon the following principles which are illegal and/or beyond Health Canada's jurisdiction:

1. "Compounding must be a legitimate part of the practice of the complementary and alternative health care practitioner and must not be used as a means to bypass the federal legislative/regulatory requirements (product and site licensing)."

   Comment - It is solely within provincial jurisdiction to determine whether compounding is a legitimate part of the practice of the medical practitioner. Health Canada inspectors have no jurisdiction. Health Canada inspectors are not qualified to decide whether compounding is a legitimate part of a practitioner's practice. Any Health Canada concerns about compounding should be referred to the provincial authorities. Health Canada has no jurisdiction to interfere with compounding on this ground.

2. "The compounded product must be customized by the practitioner to the patient's needs and sold in a different form/format or have a different composition than the original substance used for compounding. In other words, the original product must not be sold as is."

   Comment - This is not a legal requirement. It is a fabricated requirement created by Health Canada. There is no requirement in the law that a compounded product be "sold in a different form/format or have a different composition than the original substance". This is an illegal intrusion into provincial jurisdiction. This is a dangerous interference with the practice of medical practitioners that Health Canada inspectors are not qualified to make.

   This statement also creates an internal contradiction within the Compounding Policy. The Policy also sets out that if a practitioner wild crafts herbs, or cultivates a herb to compound, that this is permissible compounding. But it must be permissible only if the doctor does not decide that a single herb is the best treatment for the patient. Blending two herbs, which would create a "different composition" is compounding, but using a single herb is not (as a single herb will not be a "different composition"). This makes no sense. All this requirement will do is encourage practitioners to add an unneeded herb so as to be able to continue to practice for the benefit of their patients.

3. "A compounded product must only be made in the context of a practitioner-patient relationship. When requested, the practitioner must demonstrate that a patient-practitioner relationship exists, and the product needs to be customized to the patient's needs."

   Comment - Compounding is within a practitioner-patient relationship. Health Canada inspectors are not qualified to determine if this relationship exists or to question it. If Health Canada has a

concern they should refer it to provincial authorities. This is shameless overreach to needlessly intrude into the practice of medicine.

Health Canada inspectors, who are not medical practitioners, should not be allowed to breach doctor-patient confidentiality in order to enforce an illegal compounding requirement. Indeed, this is outrageous overreach.

4. "The compounded product treats the symptoms and needs of a particular patient, and if required, provides a product that is:

    - free of preservatives, dyes and chemical allergens and;
    - is in a palatable flavoured dosage form."

Comment - This is not a legal requirement. It is a fabricated requirement created by Health Canada. There is no requirement in the law that requires a pre or post assessment of efficacy. There are no requirements on purity and taste. The entire point of the compounding exemption is to free practitioners who compound from the interference of Health Canada to apply the NHP Regulations. This is an illegal attempt by Health Canada impose regulation requirements. Health Canada inspectors are not qualified to assess efficacy.

Health Canada inspectors that are not trained medical practitioners should not be able to violate the privacy of patients to impose compounding conditions that do not exist at law.

5. "Compounding should only be done if there is a therapeutic need or lack of authorized product availability and should not be done solely for commercial reasons for the health care practitioner."

Comment - This is not a legal requirement. It is a fabricated requirement created by Health Canada. There is no requirement in the law that requires (1) proof of a therapeutic need, (2) lack of a licensed NHP that could apply, or (3) to limit the business affairs of a practitioner.

Health Canada inspectors are not medical practitioners. They are not qualified to say that a compounded treatment by a qualified medical practitioner is the "wrong" treatment because there is a different licenced NHP which should be used. This is dangerous and reckless. This is the worst type of medical interference in the doctor-patient relationship.

This is the most dangerous type of interference and overreach. Health Canada inspectors are not medical practitioners. This requirement inserts Health Canada inspectors into the doctor-patient relationship where the doctor is overridden. Health Canada inspectors would get to say that compounded products cannot be similar to approved NHPs. There are many traditional compounded products that are traditional because they work. If a NHP manufacturer copies the traditional compounded product, this requirement removes the ability of practitioners to continue to use the traditional and proven compounded remedy. This is dangerous Health Canada overreach.

This illegal requirement assumes that any licenced NHP will be of the same quality and effectiveness as compounded remedies by practitioners. This assumption may be wrong.

This requirement places an unfair burden on medical practitioners to know all of the NHPs on the market and to compare them with a compounded remedy they may choose to use. This is not practical nor reasonable.

6. "The compounded product must not aim to replicate an authorized NHP that is available commercially for consumers."

   Comment - this is not a legal requirement. It is a fabricated requirement created by Health Canada. There is no requirement in the law that a compounded product cannot replicate an authorized NHP.

   This is the most dangerous type of interference and overreach. Health Canada inspectors are not medical practitioners. This requirement inserts Health Canada inspectors into the doctor-patient relationship where the doctor is overridden. Health Canada inspectors get to say that compounded products cannot be similar to approved NHPs. There are many traditional compounded products that are traditional because they work. If a NHP manufacturer copies the traditional compounded product, this requirement removes the ability of practitioners to continue to use the traditional and proven compounded remedy.

   This illegal requirement assumes that any licenced NHP will be of the same quality and effectiveness as compounded remedies by practitioners. This assumption may be wrong.

   This requirement places an unfair burden on medical practitioners to know all of the NHPs on the market and to compare them with a compounded remedy they may choose to use. This is not practical nor reasonable.

   Aside from being illegal, there is no public policy benefit to this requirement.

7. "Packaging and labelling compounded products are critical for safety and patient care. Packaging and labelling should reflect the compounded product. The label of the prepared product must be distinguishable from a commercial label (specific to the patient it was prepared for). Information on the product label must be accurate and clear, and the directions of use should be tailored to the patient's specific needs."

   Comment - this is not a legal requirement. It is a fabricated requirement created by Health Canada. There is no requirement in the law that requires specific labelling or that the label is distinguishable from a commercial label. There are no labelling requirements that apply at all.

   This is provincial jurisdiction. The provinces are not having concerns with the instructions given by licenced medical practitioners to their patients. There is not a problem to be solved. If there was a problem it is for the provinces to solve.

   This is another attempt to illegally apply NHP Regulation requirements that do not apply.

8. "All NHP manufacturing and compounding activities are to be regulated and fall under either federal, provincial or territorial jurisdiction."

   Comment - this is not a legal requirement. It is a fabricated requirement created by Health Canada. Health Canada does not have jurisdiction. Health Canada cannot make it a condition that the provinces or territories step in.

9. "In distinguishing between compounding and manufacturing, Health Canada may require additional information to verify the appropriate application of this policy and may take appropriate action to ensure compliance with the Food and Drugs Act (the Act) or the Natural Health Products Regulations (the Regulations)."

   Comment - this is not a legal requirement. It is a fabricated requirement created by Health Canada. Health Canada does not have jurisdiction.

   Medical professionals regulated by provinces are not subject to the Food and Drugs Act, nor to the NHP Regulations if they are compounding. Health Canada has no authority to require information or to verify anything. Health Canada has no jurisdiction to ensure compliance of an activity for which they have no jurisdiction.

   Once Health Canada determines a shipment at the border is a NHP, they can ask a provincial regulatory body to confirm that the ingredients are for compounding. Health Canada does not have the jurisdiction, nor the expertise, to determine what is compounding within the scope of a medical professional's practice.

10. "Producing a product that requires only minor modification prior to direct administration when such modification amounts to mere directions of use (Example: addition of liquid to a powder) is not considered compounding."

    Comment - this is not a legal requirement. It is a fabricated requirement created by Health Canada. Health Canada does not have jurisdiction.

    This statement also creates an internal contradiction within the Compounding Policy. The Policy also sets out that if a practitioner wild crafts herbs, or cultivates a herb to compound, that this is permissible compounding. But under the Policy, it must be permissible only if the doctor does not decide that a single herb is the best treatment for the patient. A single herb for a tea would not be "compounding" under the policy as the instructions would be to add hot water (which is not allowed). Blending two herbs, which would create a "modification" would be compounding, even if the directions were then to add hot water. This makes no sense. All this requirement will do is encourage practitioners to add an unneeded herb so as to be able to continue to practice for the benefit of their patients.

11. "Producing a product identical to an approved NHP that is already commercially available in Canada. To be in line with compounding, this should only be done if there is a therapeutic need or lack of authorized product availability."

    Comment - this is not a legal requirement. It is a fabricated requirement created by Health Canada. There is no requirement in the law that a compounded product cannot replicate an authorized NHP. There is no requirement for the practitioner to demonstrate a therapeutic need.

    This is the most dangerous type of interference and overreach. Health Canada inspectors are not medical practitioners. This requirement inserts Health Canada inspectors into the doctor-patient relationship where the doctor is overridden. Health Canada inspectors get to say that compounded products cannot be similar to approved NHPs. There are many traditional compounded products that are traditional because they work. If a NHP manufacturer copies the traditional compounded product, this requirement removes the ability of practitioners to continue to use the traditional and proven compounded remedy.

    This illegal requirement assumes that any licenced NHP will be of the same quality and effectiveness as compounded remedies by practitioners. This assumption may be wrong.

    This requirement places an unfair burden on medical practitioners to know all of the NHPs on the market and to compare them with a compounded remedy they may choose to use. This is not practical nor reasonable.

    This requirement inserts untrained Health Canada inspectors into the realm of medical decisions. Health Canada inspectors will have to decide if there is a "medical need". Aside from being a reckless and dangerous interference with medical decisions, this is illegal. The provinces have not licenced Health Canada inspectors to be practicing medicine in this way.

    This is illegal Health Canada overreach at its worst.

Health Canada is the danger

Canada is blessed to have well trained and well regulated health care providers.

The Compounding Policy inserts Health Canada inspectors, who are not medically trained, into medical decisions made by qualified medical practitioners. This is dangerous and should be discouraged.

Health Canada is so intruding into the existing compounding exception that they are in effect regulating it away without regulations.

These policies represent the illegal practice of medicine by Health Canada inspectors.

Further Health Canada confusion in their Natural health Product Raw Material: Policy Statement

Health Canada adds confusion in its Natural Health Product Raw Material: Policy statement.

The Raw Materials Policy cites the following criteria to determine whether an ingredient is for compounding or not:

1. Nature of the substance and whether it is inherently therapeutic;
2. Form (e.g. in dosage form);
3. Packaging;
4. Labelling (including claims);
5. Accompanying information/advertising;
6. Sender;
7. Recipient (e.g. retail outlet);
8. To determine if a compounding ingredient is valid asks if the substance can be consumed as it is?

None of these have anything to do with the real legal issue: is the ingredient for compounding? These criteria confuse Health Canada Inspectors by having them consider criteria that have nothing to do with the legal issue of whether the ingredient is to be used for compounding.

1. Nature of the substance and whether it is inherently therapeutic

As set out above, the NHP Regulations only apply to *natural health products*. If the substance is not inherently therapeutic the NHP Regulations do not apply. The presence of this criterion shows the legal confusion in the policy.

If this criterion is met, it indicates that the ingredient is for compounding. Doctors import therapeutic ingredients for compounding. The purpose of compounding for a patient is to get a therapeutic purpose.

Heath Canada inspectors are not qualified to assess whether a product is therapeutic or not. So aside from being a requirement that exceeds the law, it is misguided.

2. Form (e.g. in dosage form) 3. Packaging; 4. Labelling (including claims); 5. Accompanying information/advertising;

These criterion have nothing to do with the sole legal issue of whether the ingredient is for compounding.

The packaging/labelling/accompanying information/dosage form of NHP ingredients used by doctors has no bearing on the compounding done by those doctors.

If a doctor imported NHP ingredients that were packaged for consumers, that has no bearing on compounding. Doctors should be permitted to import based on factors such as quality and price. Their medical decisions should not be influenced by packaging that has nothing to do with the end use by the doctor.

A dosage form that would make the ingredient impractical for compounding is a relevant factor to indicate the purpose is not compounding.

6. Sender

This criterion has nothing to do with the sole legal issue of whether the ingredient is for compounding.

Doctors should be free to source their ingredients based on factors such as quality and price. These medical decisions should not be influenced by the vendor which has nothing to do with the end use by the doctor.

7. Recipient (e.g. retail outlet)

This could be a factor but would need further investigation. If a retail store without any compounding practitioners was importing *natural health products* the concern would be that the intention is for sale to the consumer. Investigation would have to be done to see if the intention is for re-sale to compounding practitioners.

8. To determine if a compounding ingredient is valid, one factor asks if the substance can be consumed as it is?

This is not a legal requirement and leads to confusion. A single dried herb can be used in that form as a NHP and as a compounding ingredient. Similarly, an extract of a herb, either liquid, or in granules, can be both a NHP and a compounding ingredient.

Summary - the Compounding Policy is gross overreach and should be abandoned

Health Canada inspectors needed guidance on determining whether or not to allow shipments to medical practitioners as compounding ingredients. On May 19, 2017, an internal Health Canada letter was written to give guidance to Health Canada inspectors. The May 19, 2017 letter was legally flawed. It became policy and has now gained acceptance within Health Canada as the way it should be.

The new Compounding Policy and the new Raw Materials Policy are largely a restatement, with multiple additions, of the May 19, 2017 policy letter. The “additions” are clear illegal policy creep.

The new policies, like the old policy in the May 19, 2017 letter, ignores the law, as set out above, that:

1. the constitution prohibits Health Canada from interfering with compounding which is the practice of medicine within the sole jurisdiction of the provinces;

2. the only requirements for the compounding exemption are that:

   (a) the ingredient is itself a *natural health product*, and

   (b) the NHP ingredient be used for compounding.

These new policies will lead to increased interference with the ability of medical practitioners to properly manage their patients. It will make it more difficult for compounding doctors to access the best ingredients they can for compounding.

Health Canada has not done a risk assessment to assess the risk of interfering with the ability of doctors to properly manage their patients.

Recommendation

The new policies should be abandoned in their entirety. Health Canada should stop interfering in the practice of medicine by imposing illegal conditions on doctors.

Health Canada is an enforcement agency. Health Canada demands that others follow the law. Public respect for the law and for Health Canada is lost when Health Canada blatantly violates the law with illegal policy.

Respectfully submitted,

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