NATURAL HEALTH PRODUCTS: PRODUCT LICENSING REQUIREMENTS IN CANADA

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Natural Health Products ("**NHPs**") are substances that include homeopathic medicines, traditional medicines, and other naturally-occurring substances including minerals, certain vitamins, essential fatty acids, amino acids, probiotics, plants and extracts thereof.[1] Such substances are regulated under the *Natural Health Products Regulations*[2] (the "**Regulations**") which fall under the Food and Drugs Act.[3] The Regulations also set out the requirements that are applicable to NHP manufacturers, distributors, importers, packagers and labelers.

In Canada, no person shall sell an NHP unless a product licence (an "**NHP Licence**") has been issued in respect of such NHP.[4] Under the Regulations, an applicant initiates the process of acquiring an NHP Licence by submitting an application to the Minister of Health (the "**Minister**").[5] Such application (a "**PLA**") must include the information set out in Section 5 of the Regulations including, as set out in Subsection 5(g), "information that demonstrates the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use". If all of the conditions set forth in Section 7 of the Regulations are met, the Minister shall issue an NHP License to the applicant for the relevant NHP. Such conditions include:

i. as set out in Subsection 7(a), a determination of whether the application is submitted to the Minister in accordance with Section 5 of the Regulations; and
ii. as set out in Subsection 7(d), a determination of whether the issuance of the NHP Licence is not likely to result in injury to the health of a purchaser or consumer.

Despite the seemingly straightforward nature of Sections 5 and 7 of the Regulations, applicants submitting PLAs to the Minister may nevertheless wonder what information is actually required to satisfy the requirements of such Sections. The recent Federal Court of Appeal decision of *Canada RNA Biochemical Inc. v. Canada (Health)*[6] (the "**C-RNA Decision**") provides guidance on this question.

In the C-RNA Decision, Canada RNA Biochemical Inc. ("**C-RNA**") sought to set aside the Federal Court's decision to uphold the Minister's decision to refuse to grant an NHP Licence to C-RNA under the Regulations.[7] The Minister had concluded that the information submitted by C-RNA as a part of its PLA was insufficient to

support the safety of the NHP in question. At the Federal Court level, C-RNA argued that Subsections 5(g) and 7(a) of the Regulations do not create a substantive standard but only an administrative requirement to file information of safety and efficacy. C-RNA also argued that the substantive requirement for safety is found in Subsection 7(d), which requires that approval of the NHP is "not likely to result in injury to the health of a purchaser or consumer."[8] The Federal Court disagreed.

On appeal, the Federal Court of Appeal affirmed the Federal Court's finding on this point, noting that Subsection 7(a) (with reference to Section 5 and in particular Subsection 5(g)) and Subsection 7(d) of the Regulations create two separate requirements for the issuance of an NHP Licence:

> [24] … As the Federal Court observed, safety and efficacy considerations are joined in subsection 5(g) as part of the risk-benefit analysis, whereas subsection 7(d) confirms that even if this risk-benefit analysis favours licensing, a product license will not be granted if it is likely to cause injury. In sum, an applicant must not only show that their product is not likely to cause injury to health (subsection 7(d)), but also that it is safe when used under the recommended conditions of use (subsections 5(g) and 7(a)).

The C-RNA Decision also provides the following take-aways that are important for all applicants of NHP Licenses to bear in mind during the PLA process:

1. the onus is on the applicant to demonstrate to the satisfaction of the Minister that the product for which an NHP License is sought is both safe and efficacious, and that such product would be so in the circumstances or conditions under which it would be used or made available;[9]
2. the applicant must provide evidence which demonstrates, to the satisfaction of the Minister, that the product is safe and efficacious.[10] That is, the Minister must be satisfied that the applicant has not just filed information on safety and efficacy, but that the evidence supports that the product is safe and effective when used in accordance with its recommended conditions of use;[11]
3. in addition to satisfying the risk-benefit analysis contemplated in Subsection 5(g) of the Regulations, the applicant must also show that the product is not likely to result in injury to the health of a purchaser or consumer – regardless of the efficacy of the product;[12] and
4. there is no burden on the Minister to prove that a product for which an NHP License is sought is not safe or efficacious.[13] However, any reason for refusal must be rationally supported by scientific analysis, regulatory criteria, and relevant policies.[14]

Through such regulatory framework, Canadian consumers can continue to take comfort that the NHPs to which they have access are safe and effective and regulated in a manner commensurate with the level of risk

that such NHPs may pose to such consumers.

[1] *Natural Health Products Regulations*, SOR/2003-196, s. 1(1) and Schedule 1.
[2] SOR/2003-196 [Regulations].
[3] RSC 1985, c F-27 [Act].
[4] Regulations, *supra*, s. 4(1).
[5] Regulations, *supra*, s 4.
[6] 2021 FCA 213.
[7] *Canada RNA Biochemical Inc. v. Canada (Health)*, 2020 FC 668.
[8] *Ibid*, ¶28.
[9] *Supra* note 6, ¶14-15.
[10] *Supra* note 6, ¶15.
[11] *Supra* note 6, ¶21.
[12] *Supra* note 6, ¶24.
[13] *Supra* note 6, ¶14.
[14] *Supra* note 6, ¶15.

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A Cautionary Note

The foregoing provides only an overview and does not constitute legal advice. Readers are cautioned against making any decisions based on this material alone. Rather, specific legal advice should be obtained.