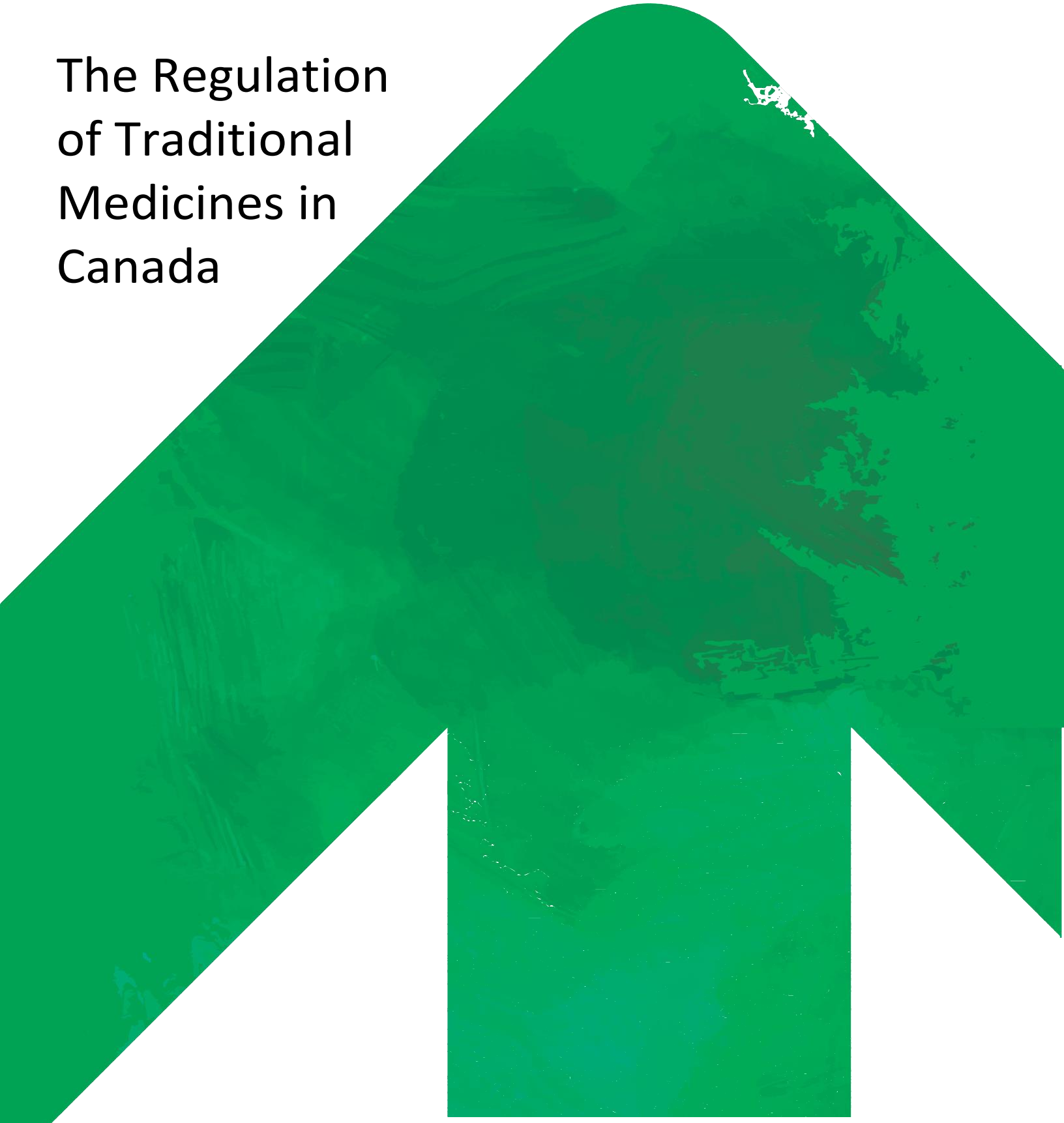
The Regulation of Traditional Medicines in Canada



l'Association Pharmaceutique Homéopathique du Canada

APHC CHPA

Canadian Homeopathic Pharmaceutical Association

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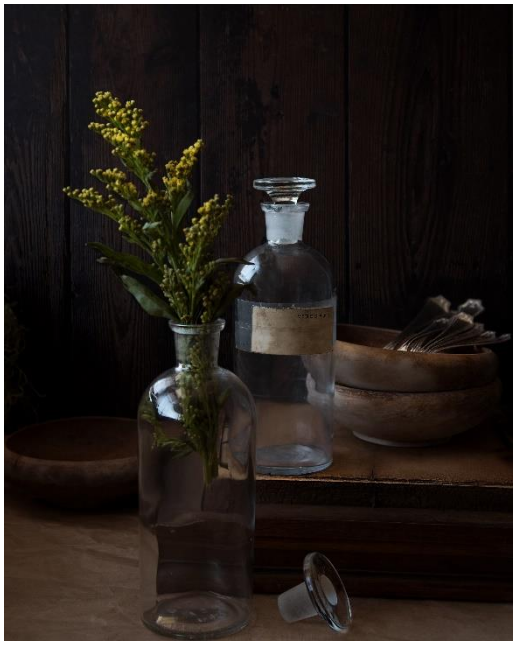
Why is this Important?



Canadians have been increasingly seeking approaches to health and wellness that embrace other cultural forms of medicine. This is not only arising from the growing immigration from areas of the world where there are long-standing traditional medicine practices but also from people whose approach to health has not been otherwise satisfied. While some have labelled these medicines as “alternative”, they are most often used as complementary approaches to overall health, especially for those seeking a wholistic way to manage their health. Common traditional medicine types are traditional Chinese medicines (TCM), Ayurvedic medicine, Unani Tibb, homeopathy, Kampo and others.

Increasingly, Canadians want to have the freedom to choose from a wide array of products that are safe. The crucial feature of freedom of choice is to make efforts to ensure there is adequate regulations that allows an informed choice.

How did we get to the current regulations?

The evolution of regulation for these products has been driven by this consumer movement and the understanding that these medicines can have value for those who choose to use them. In the 1990’s, as the popularity of these historical products grew, it became clear that the regulatory system in place for the licensing of health products was rather inflexible and could not readily adapt to providing the conditions of licensure for these products. For many natural ingredients the regulatory system was so stringently confined that even vitamins generally could not make any claims other than “a factor in the maintenance of health”. This inflexibility triggered a call for updating the regulations and it began with an expert panel examining the rules for vitamins and minerals (Part D of the Food and Drug Regulations (FDR) at the time).

During the review, it became clear that there were other naturally occurring substances that could be of health value but were constrained by the basic structure of the FDR. At that time, it was just one part of the FDR that gave the authority for health product licensing (Part C) and the content was developed in the 1960s to provide for licensing of prescription drugs and nonprescription drugs following the thalidomide tragedy. Health Canada began their efforts to modernize these rules after recognizing the inflexibility and the need to be more adaptive to consumer need and new drug development.

As the modernization efforts progressed slowly, more interest in natural products fueled a movement to have a separate examination of how such products should be regulated. This led to the formation of an expert panel to examine the relevant parts of drug regulation to determine how natural health products (NHPs) could be accommodated.

The result was that the Minister of Health (Hon. Allan Rock) asked the Parliamentary Committee on Health to examine this and hear the views of Canadians. After deliberation, parliamentarians issued their report containing 53 recommendations for changes to the way the FDR needed to change. The principle conclusion was that applying the same standards for licensing across all types

of health products was inappropriate. The Committee recommended that for NHPs "The evidence not be limited to double blind clinical trials but also include other types of evidence such as generallyacceptedand traditionalreferences…".TheMinisterofHealthacceptedall53 recommendations and thus started the process towards replacing same narrow scope of evidence required by the drug regulations with the broader approach to evidence enabled through the passage of the Natural Health Product regulations (NHPR). These regulations removed NHPs from Part C and set them apart in a distinct, stand-alone statute administered separately from the FDR by the Natural Health Products Directorate (now known as the NNHPD) based on the 53 recommendations.

The Committee recommended that for NHPs "The evidence not be limited to double blind clinical trials but also include other types of evidence such as generallyacceptedand traditionalreferences…".

This is fundamentally why the strict evidence requirements for drugs is not the only type of information that can be used for licensing an NHPs.

What about Nonprescription Drugs Having Higher Evidence Requirements than NHPs?

Prescription drugs and nonprescription drugs have more in common with each other than they do with NHPs. This is evidenced by the fact that after a multi-year examination of this (since 2014) on how to regulate all self-care products, the government has concluded that they should keep nonprescription drugs in Part C with their prescription counterparts. Indeed, many of the modern nonprescription drugs have a prescription heritage. They previously were on the prescription drug list and subsequently switched for self-care purposes only after establishing a reasonable lower risk characterization for use without the intervention of a healthcare practitioner.

It is a fact that the nonprescription drug class has many fewer ingredients than the NHP category. This is because many of the older and well-established OTC medicines were made from NHP ingredients and these changed their regulatory status when the NHPR were passed. What is left in the nonprescription drug category has largely a historical evidence base from their prescription drug background and how they have been historically dealt with under Part C of the FDR. There may be some nonprescription drugs that lack full scientific agreement on their efficacy (most Cochrane reviews conclude that there is insufficient evidence supporting many medicines) but this is an artifact of how systematic reviews of evidence are conducted.

In a risk-based system, the graduated levels of evidence are indeed consistent among all self-care products. The fact that NHPs have a long history of use and are generally well characterized means that more of them do not have the prescription heritage described above. However, some NHPs have been switched from prescription status and these products have followed exactly the same evidence requirements that nonprescription drugs abide.

For those NHPs seeking novel claims or new dosages they must follow the same requirements for safety and efficacy that nonprescription drug follow.

Overall, in the risk-based system applied under the Food and Drugs Act, nonprescription drugs and NHPs have similar evidence standards. The fact is, more nonprescription drugs have switched from prescription status than have NHPs, so the availability of clinical trial data is actually an artifact of the switch data requirements.

What About Reports that There Isn't Scientific Proof of Efficacy?

To understand the frame of reference for this, it is important to understand the hierarchy of evidence use to make reasonable decisions on the licensing of health products. Figure 1 shows that there is a wide variety of information that regulators can use to make their decisions.

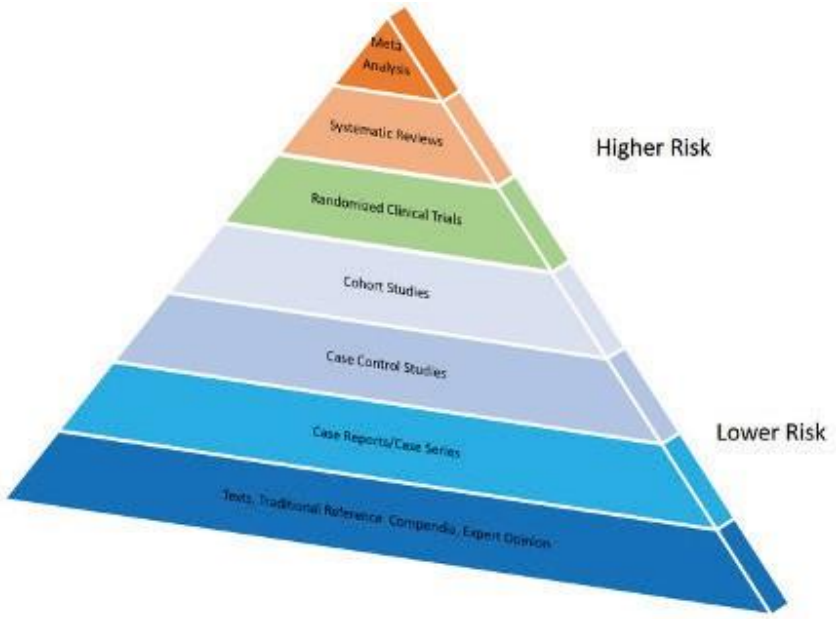


Figure 1. Hierarchy of evidence for claims

Some would suggest that only "scientific" evidence should be acceptable for supporting the intended use of a product. But this would narrowly construe what science would be defined as if the standard used is the so-called "gold standard" which sits at the apex of the pyramid. While this approach lacks any sense of pragmatism, it would certainly assuage those who hold such a narrow view of evidence. But that is not what competent regulatory authorities around the world use to administer their health product regulations. Many take a broader view of science.

Science is commonly defined as "the intellectual and practical activity encompassing the systematic study of the structure and behaviour of the physical and natural world through observation and experiment". While clinical trials are indeed science, science isn't just clinical trials. Take, for example, traditional references used for TCM, homeopathy and other cultural medicines. These are the cumulative recorded experiences of traditional medicine practices and their outcomes. While the mechanisms of action underlying these traditional medicines may not be seen as valid in a modern pharmacology frame, the outcomes are presented as a result of experimentation and observation that have led to results which have been repeated sufficiently to become a part of the traditional reference. Broadly speaking that type of evidence is indeed within the scope of science as well.

Some would argue that only clinical trial evidence should be used to grant a product license. Such a view is rooted in the community that examines the vast amount of research undertaken for new chemical entities (new drugs). These are substances and therapies that lack the requisite clinical history to allow the approval of a product based on recorded clinical outcomes described above. Therefore, the relative certainty that exists for both safety and efficacy of these substances cannot be generally determined by any other means than well-controlled clinical trials.

For some Rx ingredients, a track record can be established through a history of use that would

permit them to be sold without the intervention of a practitioner. This type of experiential information is what can lead to the switch of a product from prescription to self-care status (Rx heritage switch). However, traditional medicines, having a long history of documented use for self-care, would have a level of certainty about its merits and safety which alleviates the need to apply a single standard of clinical trial evidence as a mandatory condition of authorization. In fact, the strict application of clinical trial criteria to determine if a product produces a clinical outcome can be misleading.

In examining the Cochrane Library, reviews are conducted under very tightly defined criteria to decide which studies should be included and which should be excluded. From an academic perspective this may have value, especially where a serious disease is being treated. When using inclusion criteria, it is not uncommon to find that reviewers can start with hundreds of studies and after applying their screening tools, they arrive at a very small number of studies that they choose to include in their assessment. Frequently, the conclusion reached about many medicines is that there is insufficient high quality evidence supporting the use of product X for condition Y. Not coincidentally, this type of conclusion is more frequent for products with a long history of general use and historical origins while newer products that have a prescription drug heritage (described above) are more likely to have studies that fulfill the inclusion criteria.

An example can be drawn from a well-known Australian review of homeopathy. The Australian National Health and Medical Research Council (NHMRC) commissioned a systematic review of homeopathy that they received in 2012. The researchers who delivered the report noted that "*There is encouraging evidence for the effectiveness of homeopathy*" in five medical conditions among those that were examined. Even though this conclusion was not a definitive statement of clear efficacy, it acknowledged that some evidence exists. This conclusion was rejected by the ANHMRC and it commissioned another review where the inclusion criteria were changed. As noted above, increasingly more restrictive inclusion criteria result in less evidence being reviewed in depth. Therefore, it was unsurprising that the 2015 report could not conclude that there was robust evidence supporting the efficacy referred to in the original report. The conclusion that there are "no good quality studies with sufficient participants for a meaningful result" is a factual statement made on the basis of how the review was conducted but it was mistakenly reported by media that there is no evidence that homeopathy works. From this example it is apparent that narrowing the focus of what constitutes acceptable evidence can bias conclusions. In fact, the NHMRC Chief Executive Prof Anne Kelso said that "Contrary to some claims, the (2015) review did not conclude that homeopathy was ineffective".

This example highlights why regulators apply a full range of evidence to reach their decisions about market authorization. The general thought is that decisions should be informed by more types of evidence rather than less.

In developing the NHP regulations and its policies, this question was examined thoroughly. It was felt that there needed to be a decision on what types of traditional references could be used to support the decision-making for product licenses. It was through that exercise that the mono-graphs for several traditional types of medicine were established.

What types of evidence do NHPs require?

It is important to note that the NHPR state that those seeking an authorization to sell an NHP must submit "information that demonstrates the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use" (NHPR Part 5(g)). This information is not restricted to the provision of randomized clinical controlled trials (RCTs) or systematic reviews and meta-analyses.

For example, homeopathic medicines (HMs) must provide evidence for safety, quality and the recommended use (claim) but they may use a variety of information for this purpose. The HM Guidance policy notes that "different levels of evidence, ranging from traditional use to randomized, placebo-controlled, double-blind clinical trials" are considered and reviewed before a license is issued. The policy sets out the acceptable references for supporting claims (Appendix 3 of the Guidance "Evidence for Homeopathic Medicines"). However, the use of these references does not preclude any sponsor from conducting their own RCTs in support of their claim. Indeed, the NHPR sets out specific regulations for how NHP trials should be constructed.

With respect to all traditional medicines intended to be used by consumers for self-care and be sold alongside of other licensed products, the government requires that these products not have claims for any schedule A diseases and contain either a single or multiple ingredients (the same as for all NHPs and nonprescription drugs). For claims, some HM formulations may be supported by the relevant monograph/references and/or other types of evidence (including RCTs) while others may not make claims unless supported by additional information. Applying a range of informational standards in consideration of the for safety, quality and the recommended use of a product is well founded in the risk-based approach for all self-care products.

What is the Risk-Based Approach to Regulating NHPS?

Risk-based regulatory systems are in use in all major countries so that information derived from various source materials can facilitate administrative decision making on health products. Competent regulatory authorities all share a similar set of considerations and tools for decision making and evidence parameters are applied broadly and in accordance with the relative risk of various health products seeking market authorization. This means that evidentiary standards applied across all health products are proportional where the relative risk is equivalent and where the risk profiles differ between products, different levels of evidence are suitable for decision making. This is exemplified by the differing evidence requirements under the same legislative authority of the Food and Dugs Act in Canada (e.g. foods vs devices vs prescription drugs vs NHP products).

One notion is that all products with similar claims should have the same levels of evidence applied to their evaluation for granting a product licence. However, such an idea ignores relative risk and the corresponding need for standards of evidence that align with the assessed risk. In a risk-based system the practical policy perspective is to align similar evidence to products of similar claims and similar risks.

The basic definition of science is instrumental in understanding how it is used in regulatory decisions. In this respect, science involves the recognition and formulation of a problem, the collection of information through observation and experiment, recording of those observations and the use of those records to replicate the outcomes. As described earlier, there are many forms of scientific evidence that can be used to make regulatory decisions about product claims and safety.

Much has been discussed about the types of evidence that could be used to establish a reasonable degree of certainty about claims being made for a product or ingredient. It is clear that the government does not require absolute certainty when it makes decisions about health products. In fact, it is government's stated policy that lack of certainty does not preclude deciding to permit an

action. This historically has meant that there is a significant consideration about the types of evidence and risks when considering a product approval.

Safety is Primary

The primary focus for evaluating safety is the likelihood of harm of a product or ingredient. Harm, being the basic level of toxicity inherent in a substance, must also be viewed through a lens of risk which is the likelihood of harm. When a substance is toxic or produces adverse effects only in large amounts (e.g. nutmeg), then the likelihood of harm increases with the amount consumed but governments must also include in their analysis the likelihood that such an acute or chronic exposure will occur. While relatively safe substances can produce toxic effects when used irrationally or unusually, the harm from such exposures would be expressed as a low likelihood even if consumed reasonably beyond the normal conditions of use.

Similarly, harm may result from slight variations from the normal conditions of use if a substance has a narrow therapeutic index (where the difference between a therapeutic dose and a toxic dose is small) For these harms, the risk is certainly higher than a substance or product that has a wide therapeutic index.

Risk being the product of harm and the likelihood of such harm occurring means that absolute risk is measured using both numerator data (incidences of harm) and denominator data (exposures). Relative risk compares an ingredient or product with other substances or products.

Thus, relative risk is the key to establishing the level of information that would satisfy decision making for regulatory purposes. What this means is that products with similar risk should attract similar evidentiary standards.

Risk Identification

Take, for example, two products intended to ease a dry cough due to cold. One is a honey-based cough lozenge and the other is a low-dose codeine syrup. Even before examining what evidence is available for efficacy, a risk assessment needs to be performed. Clearly, one is a common food substance that has a well characterized and generally recognized safety profile while the other is a known narcotic. The number of possible harms from each treatment when delineated, and their probability of occurrence examined, would result in a conclusion that the codeine product has a greater risk unrelated to the benefit. Since the risk of product failure would be the same (the patient coughs during part of the limited duration of the cold), the codeine product would be of higher risk than the honey lozenge. Given the higher inherent risk of the codeine product it should be expected that the evidence required to support its safe use needs to be more robust. As a corollary to this, the honey lozenge should not have to rise to the same robustness of evidence. In this example, even if the codeine product was more likely to relieve a cough, it would not make sense to have the same level of data requirements for both.

Beyond the inherent toxicity of an ingredient, there is a risk of unintended consequences to a product's use. These risk factors must also be brought into the decision-making process. Several common concerns exist across all products claiming health benefits. Two of the main considerations are the potential for masking a more serious disease with the use of a product and the risk of disease progression should a product fail to achieve the intended outcome.

Masking Risk

This is one of the key factors in the regulatory difference between a prescription drug and a product intended for self-care. If a product is an NHP or a nonprescription drug, then it has been determined that there is a low

likelihood that the product's use would mask a serious disease. This potential harm is highly unlikely to occur when used as labelled and thus the relative risk of this harm is lower for self-care products than for prescription drugs.

Masking is most often thought of in terms of how a product may delay the diagnosis of an underlying serious disease. If one considers pain relievers (since pain is associated with many severe as well as minor illnesses) in this context, it is reasonable to apply higher evidentiary standards to assess the likelihood of harm (i.e. risk) from the potential for masking and the impact on clinically significant progression of a disease. When there is a demonstrated risk then products may be labelled for short-term duration only.

It is noteworthy that the greater the product's efficacy, the higher the likelihood of its masking risk and this is also a consideration.

Thus, there needs to be higher evidentiary standards for those products most likely to have a higher relative risk of masking. It is one reason why this prescription drug factor would tend to place such products into the prescription framework where clinical trial evidence is a standard tool for such evaluation. Where there is a lower risk of masking, other forms of evidence may provide useful answers for decision making.

Risk of Failure

Another risk element that must be considered relates to the harms that may occur if a product fails to achieve the claimed outcome for some individuals. At the outset, it is important to note that there are few, if any, products that will provide the claimed benefit for every person who uses the product. Therefore, it must be assumed that every product will have a risk of failure, but the key question is whether the harms resulting from that failure are clinically significant.

It is generally accepted by regulatory health authorities that where an illness being treated will resolve on its own without medication over a reasonable period of time, the failure to provide the intended benefit is unlikely to result in clinically significant harm. For example, a cold will normally last about 7 days. The underlying illness will be unchanged by symptomatic treatment and will resolve on its own, so the risk of failure is less relevant than for a more serious disease like diabetes.

The relative risk under this measure can be illustrated by the example of a sunscreen and a cold/allergy product. If the sunscreen fails to deliver its claimed benefit, then there is a potential that the individual will be exposed to sufficient UV radiation to cause severe skin damage. This would range from minor sunburn to second degree burns and potentially a risk of future skin cancer. On the other hand, if an allergy or cold product fails to relieve itchy eyes, sneezing or congestion, the person is most likely to simply have to suffer through the progression of the illness (usually 7 days for colds and possibly longer for seasonal allergies). This example illustrates that the risk of failure concern needs to be aligned with the clinical consequences and where there is a higher relative risk then the standards of evidence for regulatory decision making should be higher.

Evidence for Claims

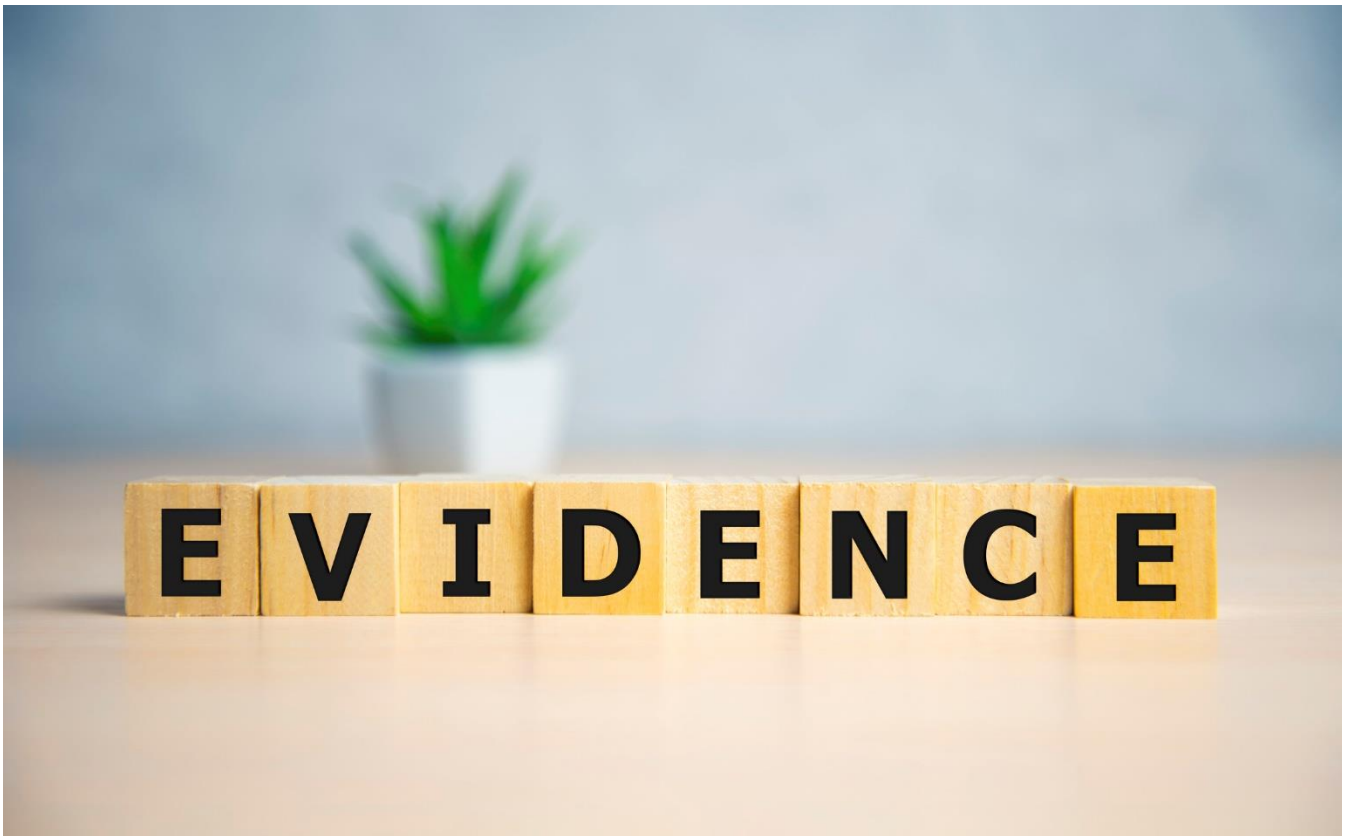


Figure 1 lays out the generally accepted hierarchy of evidentiary tools for decision making. All have utility in making assessments on claims. In fact, regulatory authorities often base their post-market decisions on the use of the case reports and observational data.

It would be most reasonable to align the seriousness of the claim with the types of evidence required to support such a claim. For example, prescription drugs generally are marketed for serious illnesses or where the substance requires oversight by a practitioner practicing within the scope of their provincial licensure. The threshold for deciding on a claim for a serious illness or disorder might best be related to the higher evidentiary legal standards where evidence must support the claim "beyond a reasonable doubt". In determining the veracity of the claim, reviewers must consider all the facts and evidence submitted by the applicant and ascertain whether the evidence demonstrates that the claim likely to be true. For this threshold to be met it is more likely that evidence must be sourced from the upper half of the pyramid in Figure 1.

For most self-care health products, claims relate to minor ailments that will mostly resolve over time without intervention and are mainly symptomatic in nature. These types of claims can be considered to align with the standards of evidence where decisions are based on the provision of documentation that would lead a reviewer to determine that on the balance of probabilities the proposed claims may be acceptable.

While the RCT is often cited as the “gold standard” it is important to note that such a toll isn’t necessary to make every decision. RCTs have value but also have limits. Current thinking about the use of RCT has shifted to focus more on real world evidence of utility in the patient population.

Burke observed in his paper, published in the journal Annals of Neurology, what researchers call an "efficacy paradox." Compare two hypothetical treatments. One has a small placebo effect (e.g. only 10% of the patients received benefit from placebo), and a moderate result for the "real" treatment (e.g. 20% of treatment patients had a benefit). The second has a large placebo effect (e.g. 20%) but a small result for the actual treatment (e.g. 25%). The first study fits what many would describe as the gold standard while those same people would not accept the second. From a strict application of clinical evidence by a regulator to approve a medicine, treatment A, Burke says, would likely be approved; the second rejected. "This conclusion would be a mistake", especially if the active treatment causes more side effects. Also, the second treatment helped more patients.

As previously noted, there are few health products that work for 100% of the population. This is evidenced by the examination of RCT results that clearly show not just how many people a product worked for, but how many did not obtain the intended outcome.

In fact, some prescription drugs are approved where the difference between treatment and placebo are small, meaning that the product will not work for most patients. However, the benefit (claim) may be so significant for serious disease that even a high level of failure is acceptable. In any case, RCTs have reducing returns as a decision-making tool when the diseases are minor, or a product is for symptomatic relief because the costs of the data acquisition is immense compared to the utility of this tool in decision making.

As noted above, where safety is less certain and the risks more serious, the RCT may have a role to play. This does not mean that RCT is mandatory across all product submissions but should be used judiciously as a requirement for market authorization (nothing prevents any sponsor from providing RCT data if they so choose).

Turning to other forms of evidence for claims, it is important to note that regulatory agencies worldwide are faced with and use the same breadth of tools for their decisions on benefits. In general, there is more reliance on narrower types of evidence for a higher risk product (upper part of the pyramid) and the use of broader tools for products with lower risk (base p art of the pyramid). It is important to note again that while there may be enough information in the broader evidence types to make a fair decision, the system would allow any type of evidence above the *de minimus* level based on relative risk.

Regarding the information that would allow regulatory decisions for products of lower risk, there are several tools that can be utilized. For those of the lowest relative risk, simple standards such as those monographs or standards in use by other regulatory authorities could suffice. If a product of lower risk has a slightly higher risk relative to others, greater certainty can be gained by including multiple sources from a level of evidence or from adjacent levels.

This gradation of evidence is best illustrated by looking at decongestion as a claim. There are medical devices (nasal strips, netipots), NHPs (menthol, camphor, eucalyptus or pseudoephedrine), nonprescription drugs (xylometazoline or fluticasone propionate) in addition to prescription drugs that could provide nasal relief. As the relative risk is lowest for those products with a wider therapeutic index, lowest toxicity (inherent safety), lower incidence or severity of side effects, then those products would only require broader evidence levels to support the decongestion indication. Higher relative risk for the same claim would likely require higher or multiple levels of evidence.

Other regulatory authorities have adopted similar approaches to risk-based evidence and the United States, for example, has a three-tiered system for establishing what may be sold as a self-care product. Category 1 ingredients are those where there has been sufficient evidence gathered to support its safe and effective use without the intervention of a practitioner (these are

set out in monographs similar to Canada's monograph system). Category 2 products are those that have not been recognized as generally safe or effective for self-care (these products are not to be sold to the general public). And category 3 products are those whose ingredients are not supported by the same level of evidence as category 1 but are not deemed unsafe or ineffective. Both Category 1 and 3 products may be sold as consumer health products unless the FDA determines that there is new data that would necessitate a change to Category 2. This was ratified as recently as the spring of 2020 with the passage of the CARES Act.

What about Real-World Evidence

While this may seem novel to some, it is historically the way claims for products found their support. Some examples of real-world evidence include professional practice experience, consumer therapeutic value experience and other crowd-sourced outcomes information.

In a 2019 research study conducted by Hill & Knowlton, it was found that approximately 5 million Canadians used homeopathy during the year. In examining the satisfaction levels related to achieving the desired health outcomes, the data showed that 77% of people reported that they were satisfied with how well the medicine worked for them. This satisfaction rate was also reflected in the intent to re-purchase with 76% of patients saying that they plan to use this type of medicine again in the future.

While real-world evidence has limitations, there is some high-level insights into therapeutic experience and consumer preferences that can be gleaned from these types of studies. Furthermore, Well-designed prospective research using social media and other platforms can provide data about actual use experience and outcomes.

Freedom of Informed Choice

The need for reform of consumer health product regulation was identified in the 1990s and while it took quite some time to move towards actual changes, it began with the Minister of Health appointing an Advisory Panel on NHPs to develop recommendations for regulation. Following the report of the APNHP in 1998, Parliamentary representatives put the same issue in front of the Standing Committee on Health with a desire to make the examination of the issues open, transparent and public.

When the Parliamentary Committee on Health conducted their review of NHPs, they developed a list of guiding principles that evolved from testimony and the Committee's evaluation of how these products had been regulated under Part C of the Food and Drug regulations. Historically, Part C was the section of regulations that contained the requirements for all drugs from prescription to OTC and NHPs). Three of these principles standout as relevant to how traditional medicines are regulated.

The committee established a clear direction that "NHP regulations must not unduly restrict access by consumers". When examining the other principles, it is clear that reasons for restricting access are focused on safety as a "primary concern" as well as quality.

When combined with two other principles, namely that "NHP consumers must be provided with pertinent information about the products they purchase" and that the "NHP regulations must respect diverse cultural traditions", it is abundantly apparent that the freedom of informed choice for products deemed to be safe for unsupervised use is a driving imperative for NHP regulations. With respect to how evidence should be dealt with for efficacy, the Committee heard arguments for and against using clinical trials as the primary means to demonstrate a claim. Their

recommendations after weighing the evidence and arguments were that:

- The Evidence not be limited to double blind clinical trials but also include other types of evidence such as generally accepted and traditional references, professional consensus, other types of clinical trials and other clinical or scientific evidence.

- The evidence required vary depending on the type of claim being made, with different evidence being required for structure-function claims and risk-reduction claims for minor self-limiting conditions than for therapeutic or treatment claims

The Report of the Standing Committee included discussions concerning evidence for efficacy. In that narrative the committee said "Thus, unlike pharmaceuticals, the evidence that is required for certain NHP claims should be more flexible. They should include generally accepted and traditional references…" To illustrate the how different types of claims would attract different levels of evidentiary requirements they set out the following table:

EXAMPLES OF HEALTH CLAIMS	
STRUCTURE FUNCTION CLAIMS	"Calcium builds strong bones."
RISK REDUCTION CLAIMS	"Garlic decreases the risk of cardiovascular diseases."
THERAPEUTIC OR TREATMENT CLAIMS	"St. John's Wort is useful in the treatment of mild to moderate depression"

The lack of conclusive evidence generally shouldn't prohibit consumers from accessing a safe therapy or diagnosis. For example, the Ontario government, among others, have decided that using a PSA test to screen for prostate cancer does not have conclusive evidence supporting its routine use. Accordingly, the government will not pay for these tests. However, this does not mean that a person who would like to use the test can't have access to it. As long as a person pays for the test themselves, they can have it done. To achieve a sense of informed use, doctors are asked to explain how the data show that only 3 in 100 patients tested will have prostate cancer.
While this information is data-driven, the notion that a patient may just be one of those 3 cases gives them the right to choose to have the test performed in spite of the evidence.

Recommendation 23 in the report of the Standing Committee states that the label indicate the type of evidence used to support the claim. For traditional medicines that rely solely on traditional references, they must state on their label that these products are "traditionally used for…" For homeopathic products, the label also carries a statement to ensure consumers are made aware when a product is supported only by a traditional reference. Traditional medicines (including homeopathic products) that use other forms of evidence in addition to, or instead of, traditional references do not need to place such a statement on their labels. This policy fulfils against the requirements for informed choice.

Definitions

Modern Health Claims: Claims based on evidence from a range of sources, including (but not limited to) clinical studies, animal and in vitro studies, pharmacopoeias, textbooks, peer-reviewed published articles, and regulatory authority reports.

Traditional Health Claims: Claims based on the sum total of knowledge, skills, and practices based on theories, beliefs, and experiences indigenous to a specific culture, used in the maintenance of health, as well as prevention, diagnosis, improvement, or treatment of physical and mental illness. For a claim to be categorized as "traditional use," it should be founded upon the theories, experiences and beliefs embodying the respective ancient practice of medicine.