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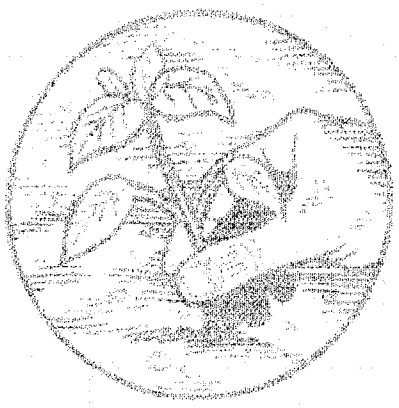
NATURAL HEALTH PRODUCTS:

A New Vision



Report of the Standing Committee on Health

Joseph Volpe, M.P.
Chair

November 1998

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PART II: REGULATION AND REGULATORY STRUCTURE

CHAPTER 4 - EXPERTISE AND REGULATORY STRUCTURE

Many witnesses asserted that the existing level of expertise and experience within Health Canada was insufficient to review NHPs for approval for sale on the Canadian market or to ensure appropriate post-market surveillance. They explained that, although employees of the department may have attempted to learn about NHPs, they do not fully understand either how these products work or the philosophical and cultural background behind them. A number of witnesses even suggested that some personnel at the department were openly hostile toward natural health and that they exercised their authority in an overtly partisan way.

Currently, there are no naturopaths, herbalists, homeopaths or traditional Chinese, North American and Ayurvedic representatives working within Health Canada or the Canadian Food Inspection Agency. Witnesses claimed that this situation has led to a regulatory environment fraught with confusion. Policies and regulations have been and continue to be developed by non-experts. Products are removed from the market or moved from food to drug status, often without a rational justification by anyone who has experience in NHPs. Field inspectors, including those working for Customs, the Canadian Food Inspection Agency as well as the Health Protection Branch, frequently do not have an adequate knowledge of NHPs and, as a result, do not uniformly enforce regulations across the country.

The Committee was also told that the HPB closed its sole natural products division Dr. Dennis Awang headed this division, which was within the chemistry division of the Bureau of Drug Research. The natural products division was involved in the investigation of particular hazards relating to NHPs. According to documents provided to the Committee, this NHP section was well established and internationally recognized. However, it was dismantled with the closing of the Bureau of Drug Research in 1991. Recently, a Natural Health Product Division was established within the Drug Assessment Bureau of the TPP. This new division, however, does not perform the

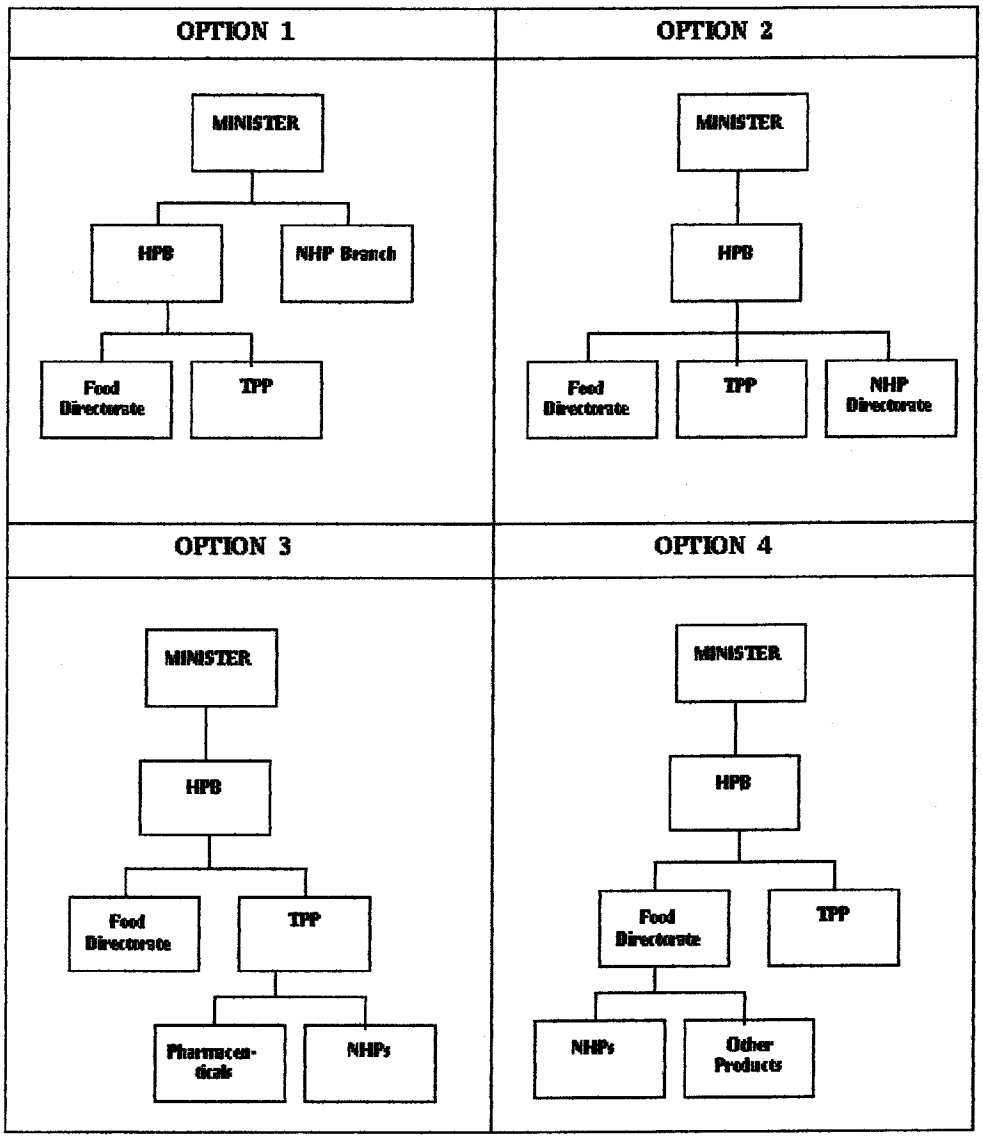
same functions as the former NHP division, nor does it have the capabilities to properly assess NHPs for the purpose of sale.

Therefore, witnesses urged that the administration of the regulatory framework pertaining to NHPs be guided by the expertise of individuals skilled in the field of natural health and, accordingly, they recommended that a new regulatory authority or structure be established. There was confusion, however, as to the precise structure and organization for this new entity. The APNHP did not reach a unanimous consensus on this issue.

The Committee strongly agrees that decisions concerning NHPs must be made by people with expertise and understanding of the products. Committee members also acknowledge that decisions by the new regulatory structure must not be overturned by others without expertise. For these reasons, the Committee considered four major options which were drawn from the testimony. These options are illustrated in Table 1.

TABLE 1

OPTIONS FOR THE NEW REGULATORY AUTHORITY



Option 1 proposes that the new regulatory authority be within Health Canada but separate from the HPB. This option was recommended by those in favour of a separate category for NHPs (some witnesses even suggested that an NHP agency be created outside Health Canada). In Option 2, the regulatory authority responsible for NHPs would be separate from, and independent of, both the Food Directorate and the TPP, but would still fall under the HPB. This option was suggested by the advocates of a new process for these products, distinct from both foods and drugs, but with regulations administered by the HPB. Option 3 assumes that responsibility for NHPs would lie within the TPP but that NHP regulations would be different from that of pharmaceutical products. This option was favoured by those who suggested that, while NHPs are different from pharmaceutical products, the pre-market assessment and post-market surveillance for both categories of products share similar characteristics. Finally, Option 4 assumes that the Food Directorate would be in charge of administering NHP regulations. This option was mainly recommended by witnesses representing

consumers who contended that the current food regulations are adequate for NHPs. They stated that no new regulations were necessary and that what was needed was the effective enforcement of sections 4 and 5 of the *Food and Drugs Act*.

The Committee considered these 4 options very seriously. All four options are consistent with the guiding principles relating to decision-making and the nature of NHPs. However, both Options 3 and 4 are problematic for the Committee. As mentioned earlier, witnesses argued that the existing levels of expertise and experience within both the Food Directorate and the TPP are insufficient to address NHPs. Some linked this lack of experience and expertise to a negative organizational bias against NHPs. The Committee in rejecting Option 3 and Option 4 gave serious consideration to these views. However, its final assessment is based on its own belief that the assessment of NHPs would benefit from a fresh approach, one where NHPs are evaluated in a forum and through a process detached from either pharmaceuticals or foods.

Options 1 and 2 come closer to satisfying those who requested an administrative body separate from existing regulatory structures and modes of operating within the HPB. Both would ensure more independent decision-making with respect to NHPs. However, over the course of this study, the Committee has become aware of the level of information, equipment and personnel needed to support regulatory activities aimed at ensuring safety for Canadians. Still, the need for a new entity with a separate, small body of permanent staff is supportable. This can best be achieved without replication of existing bureaucracy and without significant cost if the new regulatory authority is placed within the HPB where it can have proximity and access to existing regulatory resources. Thus, the Committee sees Option 2 as more likely than Option 1 to result in low administrative costs. In addition, placing the NHP authority within the HPB as a directorate on equivalent terms with foods and pharmaceuticals reinforces the Committee's view that NHPs are different from, but complementary to, these other products for health.

The structure envisioned by the Committee reports directly to the Assistant Deputy Minister of the Health Protection Branch. With reference to lower administrative costs, the Committee members see it as consisting of a small number of permanent, full-time staff drawing external support as needed from the newly-created NHP Expert Advisory Committee and appropriate working groups. We feel that there can be a sharing of relevant resources already existing within HPB and a greater use of electronic linkages to facilitate information flow from outside resources and experts across Canada.

Committee members also want to stress that time is of the essence. The Committee agrees with the overwhelming view offered by witnesses that no one should tolerate a long wait for the system to be modified, which could happen if we have to wait for legislative changes. The Committee feels that appropriate regulatory and administrative changes can and should be affected, with the necessary legislative modifications to follow. The new regulatory authority can and should be established as soon as possible: a six-month period seems quite reasonable.

It may be difficult to establish a new structure with staff from all the various fields of NHPs. For this reason, the regulatory authority for NHPs, which would include only a limited number of administrators, should have the ability to establish working groups when necessary to examine specific products, specific claims, etc. These working groups would report their findings to the new regulatory authority. The Committee believes that in-house expertise, combined with relevant external consultation through electronic networking, will result in appropriate management of the NHP regulatory framework.

At this time, the Committee feels that it may not be necessary to hire new inspection staff. However,

all inspectors dealing with NHPs must be provided with training specific to NHPs.

Overall, the Committee recommends that:

The Government give consideration to the advisability of creating a new regulatory authority for NHPs that reports directly to the Assistant Deputy Minister of the Health Protection Branch;

The structure for this new regulatory authority be established within the next six months and be permanently staffed by individuals with expertise and experience in the field of NHPs;

The selection of personnel be agreeable to both government and NHP stakeholders;

When necessary, working groups reflecting the various segments that make up the NHP category be set up to advise the new regulatory authority;

All relevant inspection personnel be provided with training specific to NHPs;

The necessary process to amend the *Food and Drugs Act* not delay in any way the implementation of the regulatory and administrative changes that can proceed at this time.

The Committee agrees with many witnesses that, in creating the new regulatory environment, a new, external, independent Expert Advisory Committee must be established immediately. Its general tasks will include assistance to Health Canada in developing new regulations, revising legislation, and setting out appropriate policies. Some of the more specific work such as defining NHPs, developing safety protocols, etc. is indicated in other Committee recommendations. This Expert Advisory Committee should also examine the closure of the former NHP section headed by Dr. Awang with a view to proposing that it be re-established or that a different laboratory entity be created. Members of the Expert Advisory Committee should be required to provide full-time commitment until all their tasks are fulfilled. In addition, they should be reconvened at least once a year, or more frequently if necessary, to report on the progress of the new regulatory framework. The Expert Advisory Committee should report to the new regulatory authority and its findings should be made public. In line with the Committee's guiding principle, this would ensure the transparency of the overall regulatory system. Decisions regarding NHPs must be made in conjunction with those who have both the expertise and an understanding of the products and how they are used by consumers or recommended by practitioners.

Therefore, the Committee recommends that:

An Expert Advisory Committee be established immediately to assist Health Canada in the general and specific tasks necessary to design a new NHP regulatory environment;

This Expert Advisory Committee review the re-establishment options for an NHP section with research and laboratory capacities and report its findings to Health Canada;

The selection of members for the Expert Advisory Committee be agreeable to both NHP stakeholders and Health Canada.

A. Overview

1. Background

For Committee members, the subject of product assessment in relation to NHPs focused primarily on three areas: safety, quality and efficacy. Witnesses repeatedly raised questions in this regard. On safety, they asked: Will the product cause harm if taken as suggested? What are its side effects, if any? Are there any risks associated with its use? On quality, questions included: Is it what it says it is? What guarantees that the product is as described on the label? In relation to efficacy, the questions were: Will the product work as claimed? Will it improve health outcomes?

From meetings with both Health Canada and the Canadian Food Inspection Agency, members heard that these issues were addressed through assessments at various stages of production for foods and drugs. According to representatives from both bodies, their assessments are based on measures aimed at identifying the appropriate balance between possible threats and/or potential benefits to human health if the product is consumed.

The task of reconciling divergent opinions about the appropriate risk/benefit ratio to apply to individual NHPs was a major one for Committee members. We became aware that, in assessing products for human consumption, the terms "risk" and "benefit" have particular meanings. Thus, risk is generally defined as the probability of the occurrence of an adverse event from exposure to a substance combined with the harm to human health if such an event occurs. Benefit is defined as the human health improvement attributable to the product. Risk analysis includes identifying the existence of a hazard and estimating the probability of its occurrence; benefit analysis involves recognizing the existence of a benefit and measuring the kind and degree of improvement. Traditionally, where risks have been related to safety, the benefits of a product have been linked to its efficacy or desired results under ideal or recommended conditions. Thus, while risk might be measured in terms of increases in morbidity and mortality, benefits could be measured by reductions in these.

The assessment of NHPs using this accepted risk/benefit model poses particular problems. Both the risks and the benefits associated with use of NHPs are perceived differently by the various involved groups. For example, regulators who see protection of consumers as a paramount responsibility focused on documented evidence of adverse effects while members of the public who are informed consumers practising self-care emphasized their experience of positive health benefits. This situation was further complicated by different assessments emanating from those who viewed NHPs as foods, those who identified them as drugs, and those who saw them as different from either of these. Emerging from the ongoing discussion was a strong sense that the current emphasis on level of risk misrepresents the majority of NHPs and that it would be more useful to approach the products from a perspective stressing margins of safety.

In order to understand how this type of analysis might apply to NHPs, the Committee members sought greater understanding of its current applications for foods and for drugs. We wanted more knowledge of the ongoing assessment process of products intended for human consumption. This process which begins before a product is marketed continues after it is available for sale. In the case of foods and of drugs, assessment can begin at a laboratory, or in the case of plants at a greenhouse and follow through to the post-consumption stage. Once production begins, good manufacturing

practices, whether mandated through regulation or voluntary through guidelines, are crucial to ensuring safety and quality, if not also efficacy.

2. Pre-market Product Assessment

Although the *Food and Drugs Act* prohibits the sale of any food or drug that has been adulterated or represented in a manner that is false, misleading or deceptive, the pre-market approval process for foods is very different from that for drugs.

NHPs sold as foods are generally not subject to pre-market evaluation and approval requirements. As with most other food products, it is the responsibility of manufacturers/sellers/importers to ensure that NHPs are safe. In this regard, Section 4 of the Act provides as follows:

> No person shall sell an article of food that (a) has in or on it any poisonous or harmful substance; (b) is unfit for human consumption; (c) consists in whole or in part of filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; (d) is adulterated; or (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

With safety in mind, Health Canada can prohibit products from being sold as foods due to their inherent harmfulness. At the beginning of the Committee's study, there was a list of sixteen NHPs deemed to be unacceptable as foods or components of foods. This list was drawn from Schedule 705 which proposed amendments to the Food and Drug Regulations pursuant to an earlier assessment of herbs and botanical preparations. The Committee was told that the assessment of potential risks from various hazards encountered in food production systems is usually based on toxicological and epidemiological data. Despite the absence of pre-market approval requirements, Health Canada's Food Directorate does use available data to provide potential sellers with opinions on the safety of various herbal preparations and components. In addition, pre-clearance of the safety of all "additives" is required, as is the establishment of maximum residue limits for pesticides in foods.

The Committee heard that, when NHPs are sold as foods, they constitute an exceedingly small proportion of the total Canadian food system and are also considered to represent a low health or safety risk relative to other staple foods. As such, both Health Canada's Food Directorate and the Canadian Food Inspection Agency (CFIA) assign a lower priority to assessments and scrutiny of this group of products. These government bodies conduct assessments of potential problems on a case-by-case, product-by-product basis. Thus, if it is determined that any NHP sold as a food poses a threat to consumer health, the Food Directorate of Health Canada will recommend to the CFIA that appropriate compliance action be taken.

By contrast, all products sold as drugs, including NHPs, must be assessed and pre-approved before they can be marketed. Generally speaking, there are different ways of evaluating new products, known products for new uses, prescription products and non-prescription products. The pre-market evaluation is based on an analysis of benefits and risks associated with each drug product: the higher the risk, the greater the level of evidence and data required. When an evaluation shows a positive benefit-risk ratio, a market authorisation is issued by means of a Drug Identification Number (DIN) or a General Public Number (GP). This number indicates that a product has successfully passed through a review of its formulation and labelling.

The TPP has developed and implemented particular processes for each of the three categories of NHPs included in our Committee's mandate - herbal products, homeopathic preparations, and

vitamin and mineral supplements.

For traditional herbal medicines, submissions to obtain DINs must comply with the related guidelines and policy. Firstly, traditional herbal medicines must present no safety concerns. Secondly, each submission must include traditional herbal references, a monograph, reputed pharmacological actions, dosage and other information. Lastly, the indications for use must be consistent with the principles of self-medication: consumers must be able to understand clearly the purpose of products. Approval of traditional herbal medicines is based mainly on traditional herbal references, provided that the herbal medicines are not known to be unsafe in treating minor ailments. Those herbal products not satisfying traditional herbal medicine criteria are assessed through a different process. Manufacturers wishing to market herbal medicines for the treatment of more serious ailments must provide supporting scientific and clinical data; at present, there are few herbal medicines with such data.

Homeopathic preparations and indications for their use must also be approved. Firstly, indications for use must be suitable for self-diagnosis and self-treatment and correspond to self-limiting conditions. Secondly, indications for use are permitted on the labels of multi-ingredient low-dilution homeopathic preparations, but not single-ingredient or multi-ingredient intermediate- or high-dilution homeopathic preparations. Lastly, a Health Canada Labelling Standard applies if a manufacturer does not wish to include indications for use on a label. In this case, the medicinal ingredients and their concentrations are restricted to those specified in the Labelling Standard. Having recognised that sections C.01.036, C.01.038 and C.01.040 of the current Regulations block legal access to many commonly used, high-dilution, low-risk homeopathic preparations manufactured from certain potentially toxic prohibited substances, the TPP has made recommendations to revoke these sections. This change would give Health Canada the flexibility to evaluate homeopathic preparations manufactured from prohibited substances on the basis of their benefits and risks. According to Health Canada, this change would provide legal access to these products, without compromising consumer safety where higher-risk products are concerned.

Vitamins and mineral supplements are generally classified as products that present minimal risks. Extensive prior knowledge and experience regarding the safety, efficacy and quality of their active ingredients are widely available. Health claims and daily limits for vitamins and minerals are regulated under Divisions 4 and 5 of Part D of the Regulations. Some observers consider these Regulations restrictive: Health Canada requires manufacturers wishing to include health or therapeutic claims beyond the scope of claims contained in the Regulations to provide objective scientific evidence in support of these expanded claims. The department is considering the possibility of amending the Regulations in order to expand allowable health claims for vitamin and mineral supplements.

3. Post-market Product Assessment

Post-market surveillance continues the monitoring of risks and benefits. The level of monitoring after marketing is based on the degree of risk attributed to the product. The monitoring can take place during production and after consumption.

For drugs, this monitoring is required through regulations that outline procedures for reporting side-effects and for GMP licence renewals. Thus, regulations require the collection and analysis of post-approval adverse drug reaction data. When authorized to market, the drug must be produced in adherence with GMP standards that seek to ensure that quality and safety are ensured.

For foods, equivalent monitoring activities are not regulated. The collection of data on adverse reaction to herbs and botanicals sold as foods is not required and no system is currently in place. Production practices and facility standards are not regulated; instead voluntary compliance with recommended guidelines aimed at safety and quality and developed through consensus by government and industry is encouraged.

4. Relevant Proposals for Drugs and Foods

Ongoing consultations by the federal government have yielded suggestions for changes to the way both drugs and foods and "in-between products" might be assessed.

The ongoing work to develop an appropriate regulatory framework for products being called nutraceuticals and functional foods has relevance for NHPs. As noted earlier, the working definitions developed for both categories of products have applicability to various products brought to the attention of the Committee. Thus, current ways of distinguishing between foods and drugs must be re-evaluated to include products seen as having important nutritional elements with the potential to prevent disease or to modify physiological functions.

More specifically, related to drugs, the gradual implementation of the Product Licensing Framework (PLF) aimed at streamlining the review and approval process for therapeutic products is seen as suitable for many NHPs. Products with potentially high risks will require the most comprehensive pre-market data submission and scrutiny as well as a higher level and frequency of post-market surveillance. Products of low risk will have minimal pre-market requirements and post-market assessments will be based on adverse event reporting. The Committee has borrowed from this PLF framework to develop one that is appropriate for NHPs.

One potential problem for NHPs lies in Health Canada's emphasis on particular types of scientific data in defining risk. When grouping products into the four broad categories (Category I to IV), risk is defined by the amount of knowledge/experience related to quality, efficacy and safety or known risk available on the product. On the highest risk level, Category IV products with little or no prior knowledge require comprehensive data and scrutiny while on the lowest risk level, Category I products with extensive knowledge require sponsor compliance with a pre-established monograph. Witnesses asserted that many NHPs, because of the current lack of knowledge or experience within Health Canada, would be grouped into the potentially high-risk category along with products for which there are identified safety issues.

Many witnesses readily acknowledged and supported the role of the federal regulatory system in evaluating products in terms of their benefits and risks. They also agreed that this evaluation must be based on adequate and accurate information. They did, however, have reservations about the appropriateness of using the current drug risk assessment model for NHPs. More specifically, they felt that assessments based on considerations of safety, quality, dosage, type of claim, seriousness of the disease and evidence of efficacy must be adapted for NHPs. They particularly argued that the model over-emphasized the risks of NHPs as a group and wanted more attention to the higher margin of safety associated with most products. In addition, they asserted that the requirements were slanted too strongly toward clinical trials and western science to the detriment of traditional knowledge and other culturally-based methods of assessment. They argued for a new approach that would, among other things, involve some changes to terminology, to conceptual underpinnings, and to evaluation processes.

For assessments of NHPs, the Committee favours a revised risk/benefit system that is more stringent than the one currently in place for foods but less stringent that the one applied to drugs. It agrees that the majority of NHPs are inherently safe and that regulatory efforts should be directed toward those that are less safe. In this regard, it notes that any product may be unsafe for reasons unrelated to its nature such as the way it is produced, stored or used. The following sections on safety, quality, efficacy and product licensing provide a more detailed discussion of how product evaluations might proceed for NHPs.

B. Safety

The vast majority of witnesses argued that most NHPs are safe and that assessments must be conducted with this view in the forefront. They emphasized that their uses are well known and pose minimal or no risk of harm. Witnesses noted that both mortality and morbidity rates associated with NHP use were negligible in comparison with pharmaceuticals. In fact, witnesses said that the majority of NHPs are safe if used correctly, that is when used for the appropriate indications and in correct doses. Some witnesses stated that, in the absence of scientific data to the contrary, a long history of human usage is generally sufficient evidence of a product's safety. They emphasized that it is not practical, necessary or economically feasible to conduct in vivo and clinical toxicological studies to establish the safety of most NHPs.

The Committee heard repeatedly that there were no reported deaths due to the consumption of vitamins, minerals, homeopathic preparations or traditional herbal remedies.

The discussions did point to the multiple elements that relate to safety and, in many instances, referred to factors that point in the opposite direction - toward danger. Thus, questions arose about the harm, toxicity, side effects, or risks associated with the use of a product. Witnesses acknowledged that assessing NHP safety meant testing for such things as acute and chronic toxicity of various dosage forms; evaluating finished products for contamination (bacteria, heavy metal, insect parts, artificial chemicals or pharmaceutical drugs); using epidemiological and toxicological data to identify short and long-term sensitivities and health outcomes. Others linked safety for consumers to standardization of potency, labelling, information, and professional practices.

The Committee heard from several international regulators about their method of assessing products with respect to safety. For example, Germany has a pharmacovigilance system for all medicinal products and has relied on this to ban certain products. In the United Kingdom (U.K.), the general trend is to upgrade control on products with demonstrated risk, for example, making them prescription only rather than banning them. For unlicensed herbal medicines, legislation lists products where there must be greater control over sale and supply. In Australia, restricted herbs must undergo a more extensive registration process than listed products.

Of particular concern was the fact that NHPs, like all forms of self-treatment, can present a potential risk to human health for several reasons. First, as some witnesses explained, the self-administration of any treatment may delay a patient from seeking qualified advice or cause a patient to abandon treatment without first seeking a professional opinion. They argued that people who do not receive appropriate treatment from the onset would eventually cost more to the system. Second, it was indicated that the scarcity of documented information on the interaction of NHPs with conventional medicines poses some problems with negative interactions. There is a need to identify herbal ingredients that may potentially interfere with specific categories of conventional drugs based on