N.B. This document was developed by Legislative Renewal staff as a working document for internal purposes, with a focus on content rather than presentation. However, it is being made available to the public to provide background information.

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EXECUTIVE SUMMARY

The sampling of any drug is prohibited in Canada, except to certain health professionals under prescribed conditions. Manufacturers of low-risk drug products (anti-dandruff shampoo, anti-perspirant, etc.) would like to be able to distribute their products and are constantly trying to find ways to circumvent the sampling prohibition.

There are multiple reasons for prohibiting the distribution of drug sampling. First, drugs are inherently risky. They have side effects and contraindications, and there is the potential for poisoning. Further, the free distribution of samples convey the message that to medicate is the way to alleviate a minor ailment without considering the cause or other non-drug options. In addition, the uncontrolled sampling of drugs to practitioners

can result in diversion, abuse and deterioration of the quality of the samples due to inadequate storage.

One of the options being considered recommends that the sampling prohibition on drugs be maintained, but that the sampling of certain specific types of non-prescription drugs generally recognized to contribute positively to public health (e.g. sun screen lotion with a Sun Protection Factor higher than 15) be allowed. The distribution of samples of cosmetics with a structure function claim as defined in the proposed legislation, could also be allowed.

1. ISSUE

The purpose of this Issue Paper is to discuss whether there should be a sampling prohibition for health products in the proposed legislation.

2. BACKGROUND AND ISSUE ANALYSIS

2.1 Current Situation

The *Food and Drugs Act* currently prohibits the sampling of any drug. Sampling to certain health professionals is allowed in the Regulations under prescribed conditions. Section 14.(1) of the *Food and Drugs Act* stipulates:

> *14.(1) No person shall distribute or cause to be distributed any drug as a sample.*
>
> *(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.*

The "prescribed conditions" are further described in the Regulations:

> *C.01.048. (1) Where a physician, dentist, veterinary surgeon or pharmacist registered and entitled to practice his profession in a province of Canada has signed an order specifying the name and quantity of a drug other than*
> *(a) a narcotic as defined in the Narcotic Control Act,*
> *(b) a controlled drug, or*
> *(c) a new drug in respect of which a notice of compliance has not been issued under section C.08.004*
> *the person who receives the order may distribute the drug to the physician, dentist, veterinary surgeon or pharmacist as a sample if the drug is labelled in accordance with these Regulations.*
>
> *(2) An order referred to in subsection (1) may provide that the order be repeated at specified intervals during any period not exceeding six*

months.

C.01.049 A person who under section C.01.048, distributes a drug as a sample shall

(a) maintain records showing
(I) the name, address and description of each person to whom the drug is distributed,
(ii) the name, quantity and form of the drug distributed,
(iii) the date upon which each such distribution was made; and

(b) keep those records and all orders received for drugs in accordance with section C.01.048 for a period of not less than two years from the date upon which the distribution referred to in the records was made.

There appears to be no common and accepted understanding as to what sampling constitutes.

To add to the existing confusion, manufacturers of low-risk drug products have started to distribute samples of their products to consumers through different schemes, such as distributing free samples in magazines (or attached outside the magazine), offering coupons that are exchangeable for drug samples, offering checks with a nominal value of $0.01 that are exchangeable for a drug sample, etc., all practices designed to circumvent the intent of section 14 of the Act.

2.2 History of Sampling

In April of 1953, when the *Food, Drugs, Cosmetics and Therapeutic Devices Act* was enacted, section 14 read as follows:

Section 14. (1) No person shall distribute or cause to be distributed any drug as a sample.
(2) Subsection (1) does not apply to the distribution of samples of drugs by mail or otherwise to physicians, dentists or veterinary surgeons or to the distribution of drugs, other than those mentioned in Schedule F, to registered pharmacists for individual redistribution to adults only or to a distributor in compliance with individual requests. [1]

Samples of all drugs could therefore be sent to physicians, dentists and veterinary surgeons, while samples of over-the-counter drugs only could be sent to pharmacists. The four groups of professionals could redistribute these drugs to adults.

In October 1962, Information Letter 211 indicated that the Act had been amended to

[1] R.E. Curran, Canada's Food and Drug Laws, Food Law Institute, 1953, p. 1077.

add a section authorizing the Governor-in-Council to promulgate regulations respecting the distribution or the conditions of distribution of samples of any drug.

Information Letter 214, issued in February 1963, explained that the Regulations had been amended by the addition of sections C.01.048 and C.01.049, which prescribed the conditions under which samples could be distributed to certain health professionals. To get samples, the health professionals specified in the regulations had to fill a written order. The reason for that amendment was to limit the number of samples distributed to health professionals by manufacturers which, at the time, was considered to be excessive.

Information Letter 219 issued in April 1963 informed that subsection (2) of section 14 of the *Food and Drugs Act* had been amended to exempt the sampling to certain professionals from the application of section 14 "under prescribed conditions" (as it currently reads):

14.(1) No person shall distribute or cause to be distributed any drug as a sample.

(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.

Information Letter 229 issued in September 1963 clarified the intent of the revised section 14 by providing guidance. The guidance indicated that physicians, dentists and veterinary surgeons could use the samples in their practice according to their professional judgement, but that if they distributed these samples outside their practice, they had to keep records (which is not in line with the current interpretation). With respect to pharmacists, the Information Letter indicated that the Act did not allow them to further distribute samples to the public (which is also not in line with the current interpretation).

Information Letter 382, issued in March 1973, recommended that over-the counter drugs also be subject to a written order from the recipient. Information Letter # 407, issued in December 1973, indicated that these regulatory changes had been effected.

In 1976, an HPB guideline entitled Distribution of Drug Samples I.L. 382 was published to clarify the implications of the conditions specified in the Regulations, sections C.01.048 and C.01.049. The guideline explained that it is deemed essential that a consumer makes a knowledgeable effort to acquire a drug product, and that the payment of any amount of money indicates such an effort. The exact same guideline was re-issued in 1981, this time referring to the Information Letter 407. This guideline is still in use today and refered to as the Therapeutic Products Directorate policy on sampling.

The Canadian Cosmetic Toiletry and Fragrance Association proposed to the Health Protection Branch a schedule of Cosmetic Drugs (drugs of minimal criticality of dosage and suitable for routine use without professional guidance) in November 1973, April 1979 and again in November 1980. In 1982, an Health Protection Branch Committee was created to look at this issue.

Information Letter 632, issued in August 1982, proposed that the Regulations be modified to authorize the provision of samples of drugs to members of the general public for the purpose of Consumer Acceptance Research. This would have allowed manufacturers to test the acceptability of new products, prior to their entry on the market, rather than as a way of promoting products available on the market. No regulatory changes resulted from this exercise.

2.3 Issues to Consider

2.3.1 Definition of a "Sample"

A definition of "sample" is absent from both the Act and Regulations. In the "Guide for Drug Advertisers", issued by the then Food and Drug Directorate, a sample was defined as: "a trial package of a product distributed without cost to a potential customer" (1963, C.A. Morrell, Director of the Food and Drug Directorate). This administrative definition is still used today with the guideline which deems essential that a consumer makes a knowledgeable effort to acquire a drug product, and that the payment of any amount of money indicates such an effort.

But what is the effort that has to be made? Is an insignificant cash payment enough of an effort? What is the validity of a payment which is either insignificant or not related to the production cost of the drug "sampled"? Also, since a sample might not always be in a trial size, a regular package size could be sampled. In view of all this, it is felt that the definition of sample should be modified to include products distributed without cost or at a marginal cost (cost not related to the production cost of the product or its usual market value). In addition, no effort on the part of the promoter to provide the payment to the consumer should be accepted (e.g. coupons, checks, etc.) as a way to circumvent the sampling prohibition. A sample should be defined in the Regulations and promotional activities like trial size for a low price (but not insignificant) and low priced sales should not be considered sampling.

2.3.1.1 Clinical Evaluation Packages

The Canadian Pharmacists Association, the Conference of Registrars of Pharmacy of Canada and the "Rx & D" or "Canada's Research Based Pharmaceutical Companies" (formerly known as Pharmaceutical Manufacturers Association of Canada(PMAC)) refer to samples as "clinical evaluation packages" as they most likely allude to samples provided by health professionals. In the Code of Marketing Practices, Rx&D defines a clinical evaluation package as a package containing a limited quantity of a

pharmaceutical product sufficient to evaluate clinical response, distributed to authorized healthcare professionals. Based on this definition, drugs that can take months before being clinically effective (e.g. anti-depressives, vitamins and minerals, some oral antifungals, ...) would not be suitable candidates for sampling. In any case, the definition proposed above would also apply to the clinical evaluation packages.

2.3.2 Purpose of Sampling

There are really three types of sampling: the distribution of samples of drugs (prescription or nonprescription) by manufacturers to health professionals, by health professionals to patients, and the distribution of over-the-counter drugs by the manufacturer directly to the consumer. There are problems with the first two, and technically, the second type of sampling is prohibited by section 14 of the *Food and Drugs Act*.

It is felt that sampling serves one major purpose, which is to promote the sale of products by manufacturers. In the case of the sampling of drugs (prescription and over-the-counter) by health professionals, manufacturers and professional associations claim they are beneficial for the following reasons:

- To help the health professional establish the physical identity of the drugs referred to in the medical/promotional information;
- To determine clinical response to drug therapy before a full course of therapy is prescribed;
- to provide free medication to people in need (though the argument has been made that most people in need are covered by provincial plans, so there is no real need to provide drug samples free of charge);
- To initiate immediate therapy if necessary.

It should be noted that since samples of prescription drugs are usually for new products, it is unlikely that optimal therapy could be instituted in all cases, as new drugs or drugs the physician happens to have in his drawer are not always the first choice treatment for that particular patient.

2.3.3 What are the Reasons to Prohibit Sampling?

Drugs are not just another commodity. They should not be distributed like other consumer products. For the most part, drugs are inherently risky. They are often one of many courses of treatment for a given ailment. They have side effects and contraindications. A cough and cold preparation could have serious side effects in individuals with hypertension, diabetes, chronic respiratory disease, glaucoma, heart diseases, etc. Many over the counter drugs with Drug Identification Numbers (DIN) can only be sold in pharmacies[2] because it is considered necessary that they be sold in an

[2] Provinces decide what can be sold where, may vary from one province to another.

environment where there is a pharmacist in case counseling is needed.

When drugs are distributed freely to the general public, the message that is communicated is that it is normal, usual and customary to take drugs to relieve minor ailments. It also conveys a message that the real cause of the problem does not have to be examined because there is a free treatment which is "delivered to your door". It does not encourage the consumer to consider other types of treatment. It reinforces the thinking that there is a pill for every ailment, and that taking drugs is a proper way to manage common minor ailments. The acquisition of a drug should not be a passive exercise, but an active and informed one. There should be no inference that drugs are to be used routinely.

It should be recognized that one of the disadvantages of sampling is that it is likely to be used to push products that are not essential for the promotion or maintenance of health (antiperspirants, mouthwashes), rather than improving consumer access through price reduction on products that consumers should use, e.g. high Sun Protection Factor (SPF) sun screens. Therefore, the "public good" argument is rather weak. The sampling of drugs is primarily an advantage for the industry: it is a powerful promotional tool.

The original intent of the prohibition was to prevent companies from pushing products on people at malls or leaving them in mailboxes or doorsteps and potentially have people take products they do not need and/or should not use. Also, the intent included having people make a decision as to whether or not they want to obtain a drug product, not to place restrictions on the price charged for the product. It is for this reason that two for one, or bonus amounts, or a reduced price or savings coupon for a product, are not considered to be sampling as the consumer still needs to make a conscious decision to obtain the product.

Many believe that the cosmetic-like drugs which are used for daily hygiene (anti-perspirant, anti-dandruff shampoo, fluoride toothpaste, etc.) are more suitable for general public distribution. They are usually low-risk, and not used to treat ailments. On the other hand, it needs to be recognized that there are risks associated even with some low risk cosmetic-like drugs. For example, although fluoride toothpastes are generally seen as beneficial, we are now seeing adverse effects of ubiquitous use of fluoride and are being pressed by the Canadian Dental Association to recommend reduced use of fluorides. Some antibacterial mouthwashes often have high concentrations (15 to 30%) of alcohol to enhance the solubility of other ingredients: a single container can supply an alcohol dose lethal to a small child.

Other health products that many would like to be able to distribute as samples are the sun screens (currently classified as drugs), which are beneficial to public health when they have a sufficient Sun Protection Factor (SPF). However, if a firm distributes as a sample a sun screen with a low SPF, for example SPF 2, (less costly to the company

as sun screen agents are very expensive and the higher the SPF, the higher the cost to the company), while an SPF 15 should be used, insufficient protection will be provided, and potential injury may occur.

2.3.4 Methods of Distribution

Different marketing schemes have been used to circumvent the sampling prohibition: distribution of checks that could be exchanged for a sample of a drug, pouches of sun screens or make-up with a Sun Protection Factor (SPF) attached to or in a magazine, etc., all of which have been and should continue to be considered to meet the definition of sampling.

The proposed Act would enable the government to adopt regulations respecting the use of samples in the marketing of drug products. For example, the regulations or guidelines could clarify which methods of distribution constitute sampling and which methods of distribution are acceptable.

With respect to the two for one promotion, as long as the second item is the same product as the first one, it should not be considered sampling, even if the second item is marked as “free” or for a marginal cost e.g. one cent. The idea is that the consumer is paying for a drug and he is merely getting more of the same drug for a promotional price. The same would apply to additional quantity of a product in a larger container for “free”.

A package containing several drugs would not be considered as containing samples as long as the reason for these drugs to be marketed together served a health purpose (e.g. first aid kit containing an antibacterial ointment, and an analgesic, etc.), or as long as the drugs had to be used in complement of each other (e.g. a contact lense starter kit containing a disinfecting solution and a cleaning solution). Promotional offers of one drug with a trial size or regular size of another drug (e.g. an analgesic and an anti-diarrheal) would be considered as sampling because they encourage the use of a product that the patient may not have a use for.

The regulations or guidelines could also describe how market research to test consumer acceptance could be done, and could provide more guidance on whether or not different marketing schemes constitute sampling or not.

There are risks associated with the unrestricted sampling of drugs. For example, the uncontrolled sampling of consumer drugs could lead to products being accumulated in cars, the home, being improperly stored, left in purses, getting into children’s hands with the risk of potential serious injury, increasing the use of unnecessary medication, having samples getting back into the chain of commercial products or of samples being disposed of in an unsafe manner, etc.

Products left on the doorstep or in the mail box could result in a child picking it up and

ingesting it. Vitamins and minerals are in the low risk category when used as intended, but an entire bottle could cause serious injury to a child. This would also be true of benzoyl peroxide lotions and fluoride mouthwashes.

In the case where sampling was allowed, the sampling could be limited to adults only. Or, to prevent mass distribution in general public areas such as streets and malls, sampling could be limited to personal distribution in drugstore, retail establishments, department stores, beauty and hair salons, or through mail distribution to homes. The Department would have to be notified in advance of the time, place, quantity and lot numbers of the products sampled.

2.3.5 Violations of the Sampling Prohibition

Compliance action is considered when a case of non-compliance is brought to the attention of the Department by a complainant.

2.4 What We Have Heard

2.4.1 Health Professionals and Associations

2.4.1.1 Public Health Departments

The representatives of several Ontario Public Health Departments have asked that Health Canada amend section 14 to allow for the distribution of sun screens that have DINs. They argue that the provision of sun screens by day care centres, schools, recreational facilities (i.e. day camps) and workplaces with outdoor employee assignments, is one of the crucial ways of supporting human health against the sun's harmful rays. Section 14 of the *Food and Drugs Act* prevents these groups from adopting this protective strategy.

2.4.1.2 Canadian Pharmacists Association

The Canadian Pharmacists Association has a position paper on the subject entitled "Taking Patient's Interests to Heart - Reforming Sampling Practices". The Association's position refers to the samples provided by health professionals. The Association raises the issue that the distribution of clinical evaluation packages (samples) by physicians in their offices is not part of the patient's medication profile accessible to the health care professionals who need it. Other concerns raised in their position paper are that a drug may be used because it is free and readily at hand thus leading to less than optimal therapy, as well as improper storing conditions, and outdated samples.

The Canadian Pharmacists Association proposes that the distribution of samples be done through pharmacies: physicians would write a prescription for a drug (for which the manufacturer has a sampling program), the patient would obtain the sample from the pharmacist who would add the prescription on the patient profile, and the

pharmacist would submit a claim to the manufacturer for the provision of this service.

However, the patient profile argument is limited by the fact that pharmacies cannot usually share patient information among themselves because of personal privacy concerns. Consequently, a patient profile in any individual pharmacy may be far from complete if the customer chooses to frequent other establishments.

2.4.1.3 Conference of Pharmacy Registrars of Canada

The Conference of Pharmacy Registrars of Canada, which is composed of 10 Registrars of provincial regulatory bodies, has a position paper on sampling which also deals with prescription drugs. They maintain that major problems exist in the distribution of drug samples in Canada:

- Oversupply: samples are distributed in an uncontrolled manner, filling closets and drawers in medical clinics to overflowing;
- Diversion by non-professional staff: security is non-existent, with samples stored in unlocked cabinets freely accessible to non-medical staff, i.e. receptionist and cleaning staff, and perhaps patients;
- In a Canadian Pharmacists Association survey, 30% of pharmacists admitted receiving samples from doctors and 58% were in exchange for stock. This fact is felt to be sufficient to warrant a complete rethinking of the provision of samples;
- Given the amount of samples which are sold or bartered to pharmacies or disposed of, far fewer samples are put to their intended use (distribution to patients) than assumed by the manufacturers. Manufacturers are likely overrating the marketing benefits of sampling programs.
- Samples are not disposed properly by a significant proportion of physicians: 41% of physicians throw them in the garbage and 21% of the pharmacists do the same. Only 2.7% of physicians return their unwanted samples back to the supplier, as requested by the Pharmaceutical Manufacturers Association of Canada Code of Marketing Practice. Perhaps the industry believes that sampling is a good marketing tool because of this small return.
- Lack of complete patient profile at the pharmacy level, and in the case of several provinces, the computer network. An incomplete patient medication profile can lead to complications when monitoring for drug interactions.
- Irrational use by patients: as samples usually bear dosage instructions, the patient who was instructed to comply with a different dosage schedule might be confused.
- Lack of control of outdated samples: when samples are bartered or sold to pharmacies, there is a loss of the lot # and expiry dates when these drugs are mixed with the regular stock (in case of a recall, there is no standardized way of tracing the samples bartered). There is also some evidence that physicians do not check expiry dates with the same seriousness as pharmacists.

The Conference of Pharmacy Registrars suggests a few alternatives to the current system. They are:

a) Discontinue sampling completely. However, the Conference points out that there is no way short of federal legislation that would convince manufacturers to accept this solution;
b) Sample through pharmacists. This is the method currently in use in New Jersey. It is similar to the model proposed by the Canadian Pharmacists Association described above;
c) Strict enforcement of the Code of Marketing Practice. Though this would result in a better system, it does not deal with the handling of samples once they are in the possession of the physicians. Federal and provincial laws need to deal with the handling of sampling;
d) Third party controlled sampling. This refers to programs such as the Physicians Sample Hotline in which physicians request various samples from third parties representing various drug companies. The Registrars approved in principle this method as an alternative to current sampling policies, on condition that it would be the only method of receiving samples.

The Conference of Pharmacy Registrars favors option b) above. If the status quo is selected, they suggest that the following laws be considered at the federal and provincial levels:

- making it mandatory for physicians and dentists to account for all samples received;
- making it an offense against the *Food and Drugs Act* to sell or barter samples;
- making it an offense to dispose of samples other than methods acceptable to environmental officials.

2.4.1.4 Canadian Dermatology Association

The Canadian Dermatology Association has requested that Health Canada amend “the existing Section 14 of the *Food and Drug Act* that prohibits the distribution of any drug as a sample to the general public in order that sun screens, with a DIN or GP number on the label, can be provided as samples."

The association pointed out that it had been involved in health promotion activities, and indicated that the distribution of free sun screen samples accompanied by health information would be a good way to educate the public. It also mentioned that not only would it be useful to be able to distribute samples of sun screens, but that it would allow campaigns such as the large campaigns done in Australia in which sun screen dispensers have been put on beaches and are free for people to access. At the moment, section 14 prohibits them from doing any of these health promotion activities for what they consider a very significant health problem and one which could be

prevented if sun screens were more readily available to those who have forgotten them or cannot afford them.

2.4.1.5 Canadian Association of Optometrists

The Canadian Association of Optometrists has asked that C.01.048 be amended to include optometrists. Again, the reason for this request is that optometrists routinely give to their clients who have purchased contact lenses samples of contact lenses solutions, thereby violating section 14 of the Act. However, it is not possible to amend C.01.048 without first amending the *Food and Drugs* Act which, under section 14, limits the distribution of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists. If sections 14 and C.01.048 were amended to include optometrists, the advantage for them is that they could distribute samples of disinfecting solutions as well as any other products related to their practice.

In the case where the name of a profession was added to section 14 and C.01.048), the named profession, e.g. optometrists, could distribute disinfecting contact lense solutions, as well as any other products related to their practice, i.e. over-the-counter antibiotic ophthalmic drops and ointments, eye decongestants, eye lubricants, artificial tears, etc. On the other hand, if the exemption of a specific product from the application of section 14 was preferred, e.g. disinfecting contact lense solutions exempted from section 14, then anyone could distribute the disinfecting contact lense solutions.

2.4.2 Legislative Renewal National Consultations

The following reflects what was heard about sampling during the first round of the Legislative Renewal national consultations:

- *"Sampling restrictions for lower-risk health products should be removed from the legislation."*
- *"Sampling should be based on the risk of the product. The current sampling restrictions for all drugs, regardless of their risk, unfairly hinders lower-risk health products. Many lower-risk health products, such as dandruff shampoos and fluoride toothpastes, are more similar in risk to that of cosmetic products than drugs. Although cosmetic products are permitted to be sampled to consumers, the lower-risk drug products are not."*
- *"Currently, consumer "sampling" may be conducted with a token monetary charge. Since, sampling is permitted under these conditions, it is inconsistent to maintain broad sampling prohibitions in the legislation."*
- *"Section 14(l) of the Food and Drugs Act states that "No person shall distribute or cause to distribute any drug as a sample." Section 14(2) of the Food and Drugs Act states that "Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists." These provisions that authorize sampling distribution to health professionals only must be retained in any new legislation."*
- *"We strongly support the position that sampling of lower-risk products directly to the consumer should be permitted. Restricting the sampling of products such antiperspirants and fluoridated*

toothpastes is not necessary. These products should not be grouped with the higher risk drugs in this regard."

- *"Another such restriction is the outright prohibition of sampling to consumers regardless of safety. Other consumer products with lower safety profiles are permitted to be sampled to consumers under appropriate regulatory controls. Higher safety products should be permitted greater marketing freedom than lower safety products. This can be accomplished through a regulation rather than a legislated prohibition."*

2.5 International Comparison

2.5.1 United States

Section 503 of the Federal *Food, Drug, and Cosmetic Act*, as amended by the *Prescription Drug Marketing Act*, permits a manufacturer or distributor to distribute samples to a licensed practitioner or pharmacy of a health care entity by mail/common carrier or by other means (through marketing representatives) upon written request. Certain drug sample records must be maintained by manufacturers and distributors, and made available to government officials on request. Manufacturers and distributors must maintain drug samples in a manner that will prevent their contamination, deterioration, or adulteration. They should have systems to monitor and audit the distribution of their drug samples; they must provide FDA with the name and phone number of an individual responsible for responding to requests for information concerning drug samples; and they must maintain lists or representatives and drug sample storage sites. Manufacturers and distributors must notify FDA of significant drug sample losses and known thefts, and of any convictions of their representatives for illegal trafficking in drug samples.

Section 353 of the Federal *Food Drug and Cosmetic Act* prohibits the sale, purchase, or trade or offer to sell, purchase, or trade any drug sample. The term "drug sample" is defined as meaning a unit of a drug which is not intended to be sold and is intended to promote the sale of the drug. However, the distribution of a drug sample to a patient is allowed when performed by a practitioner licenced to prescribe the drug, a health care professional acting at the direction and under the supervision of such a practitioner, or by a pharmacy of a hospital or of another health care entity that is acting at the direction of such practitioner and that received the sample according to the Act.

2.5.2 Australia

In Australia, the sampling of nonprescription products to the public is not permitted, except for therapeutic devices and sun screens. This restriction applies to members of the general public and not to medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dietitians, biomedical engineers, medical scientists in accredited laboratories, purchasing officers in hospitals, persons designated under section 4 of the Therapeutic Goods Regulations or other health professionals registered under State or Territory legislation or who are engaged in the

business of purchasing by wholesale therapeutic goods or that is intended to be distributed exclusively to or among such persons.

3. OPTIONS ANALYSIS

Regardless of the options chosen, the following should be considered:

- Have an administrative definition of a "sample" contained in a guideline to the effect that a sample is: "a package of a product distributed to a potential customer without cost or at a marginal/ insignificant cost (not related to the production cost of the product or its usual market value)".

- Allow sampling to and by "qualified health practitioners", as defined in the proposed Act. Prescription drugs would be sampled only to those allowed to prescribe them. This would include opticians, optometrists (contact lens disinfectants, over-the-counter eye drops), chiropractors (rubefacients), some alternative practitioners, ...etc.

- Recommend to the Conference of Pharmacy Registrars, the Canadian Association of Pharmacists, the Canadian Medical Association, and the provincial Colleges of Medicine that they adopt in their Code of Conduct a resolution to make illegal the bartering and unsafe disposal of drug samples.

Option 1: Status Quo

Except for the requests to allow the sampling of sun screen, no demands have been received from groups representing the public or health professionals to relax the sampling prohibition. A group representing the pharmaceutical industry (over the counter products) has requested that the restriction on sampling be waived for low risk products. One manufacturer of prescription drugs has asked that the prohibition be maintained the way it is.

If it was retained in its current form, the sampling prohibition could be stated more clearly in the Act and regulations (to avoid the confusion described above) by describing what a sample is, what sampling is, who can do it and how they can do it.

Option 2: Allow the Distribution of Certain Specific Health Products

The proposed Act would establish regulation-making authority respecting the offering of health products as samples.

> *Under the current regime, manufacturers and distributors are not allowed to offer samples of drugs to the general public. The main reason for this provision is to discourage the overconsumption of therapeutic products.*

For example the regulations could:

- prohibit the distribution of drug samples (over the counter drugs and prescription drugs) and establish guidelines as to what constitutes sampling and what does not;

  These guidelines could address issues such as "two for the price of one" promotions; coupons; drug offered with a trial package of another drug; etc.

- allow for the distribution of drug samples to and by qualified health practitioners and establish guidelines to that effect (keeping in mind the provincial jurisdiction over the practice of medicine); or

- designate certain types of non-prescription drugs concerning which distribution of samples would be allowed because their use is generally recognized as contributing positively to public health.

  (E.g. sun screen lotion with a SFP higher than 15)

- The distribution of cosmetic samples, including cosmetics with a structure function claim as per the definition above, would be allowed.

Option 3: Allow the Sampling to the General Public of Over-the-Counter Drugs
The level of risk of over-the-counter (OTC) drugs differs from that of prescription drugs. However, OTC drugs are drugs, inherently risky, and should only be used when absolutely necessary. This option does not send an acceptable message to consumers regarding the consumption of OTC drugs. In addition, no representation was made during the first round of consultations to allow the general sampling of OTC drugs.

Option 4: Prohibit All Sampling
Prohibit all sampling, even that made by health professionals and restrict sampling made to health professionals to minor quantities sufficient to establish the physical identity of the product referred to in the medical and promotional information.

Industry and health professionals might not receive this very well. However, in order to limit the problems and risks associated with the sampling to and by health professionals, it is suggested that the Department recommends to the Conference of Pharmacy Registrars, the Canadian Association of Pharmacists, the Canadian Medical Association, and the provincial Colleges of Medicine that they adopt in their Code of Conduct a resolution to make illegal the bartering and unsafe disposal of drug samples.