Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

REGULATORY **ROADMAP** FOR HEALTH PRODUCTS AND FOOD

APPENDIX A

SUMMARY OF WHERE WE ARE

ROADMAP

Canada

Appendix A – Summary of Where We Are

Food and Drugs Regulations - Part A (Administration)

Purpose

Part A of the *Food and Drug Regulations* provides a home for those prohibitions, powers, definitions and obligations that generally apply throughout the regulations.

Design

Prohibitions

The importation of a food or drug, the sale of which in Canada would violate the Act or Regulations is prohibited unless the importer gives an inspector notice of the importation and that the food or drug will be relabelled or otherwise modified to enable its sale to be lawful in Canada.

An export certificate for the purposes of Section 37 of the Act must be signed and issued in the form prescribed by the regulations.

Labelling requirements are provided for foods or drugs contained in pressurized containers. Labelling text, language and labels, size and placement are specified. Some of these labelling standards are incorporated by reference to the *Consumer Chemicals and Containers Regulations.*

The sale or import of certain drugs for human use that are available to the general public is prohibited unless the drug is contained in a security package that provides assurance to the consumer that the package was not previously opened.

Exemptions from prohibitions on advertising and sale at the level of the Act allow for the labelling and advertising of a drug with preventative representations.

Powers-Analysts; Inspectors

Certain activities that may be conducted by an inspector in the administration of the *Food and Drugs Act* and *Regulations*, are indicated where and of what photographs may be taken are indicated, the examination and sampling of any food or drug intended for import, the provision of samples to an analyst for examination,

The authority of an inspector is clearly indicated as extending to the whole of Canada. As well the certificate of designation for an inspector is required to include the name of the person, that the inspection authority is for the purpose of administering the *Food and Drugs Act* and be signed by the Director and the person named in the certificate.

Obligations

Obligations on the regulator are included for the provision of certain documents upon request. These include, copies of official methods referred to in the regulations for the purposes of analysis under the Act and Regulations. Also, upon request, the regulator is obligated to comment on the acceptability of any method that has been submitted.

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An inspector must notify the importer and collector of customs that of any food or drug intended to be imported if they are of the opinion following examination or analysis that the import would constitute a violation of the Act or Regulations.

An inspector must inform the owner or person from whom a sample is being that it will be submitted for analysis and if possible divide the sample into 3 sealed and identified parts of which the owner shall retain one part.

Fees

Fees for the analysis of a sample other than for the purpose of the Act but for a department of the government of Canada for the purpose of legal action are set at $15.

Interactions

- Parts B, C and D of the *Food and Drug Regulations*
- *Food and Drugs Act*
- *Broadcasting Act*
- *Consumer Chemicals and Containers Regulations*
- Official Methods
- *Consumer Packaging and Labelling Regulations*

Food and Drug Regulations - Part B (Food)

When an article is manufactured, sold or represented for use as a food or drink for human consumption, it is defined as a "food" and is regulated under the *Food and Drugs Act* (Act) and Part B of the *Food and Drug Regulations* (FDR).

There are two basic categories of food under Part B: new or higher risk foods (e.g. *Novel Foods*, new additives or foods for special diets) that pose potential/unknown harm, and foods that are not new (e.g. foods with long-standing use and established standards).

DIVISION 1

Introduction

This is a general division that applies to all of Part B. It sets out various prohibitions (general & specific), standards, labelling and packaging requirements as well as authorization mechanisms that may lead to a regulatory amendment.

Purpose

The purpose of this division is to prevent the sale of food containing harmful substances (e.g. by establishing compositional tables, listing substances (including drugs) that cannot be added to a food, and including authorization mechanisms for new or higher risk foods), to prevent fraud (e.g. by prescribing acceptable labelling of nutrition content claims) and to provide health information to the general public (e.g. by specifying acceptable labelling of health claims).

Design

Prohibitions

In Division 1, prohibitions generally relate to the labelling and advertising of food; however, specific prohibitions (e.g. against the sale or importation of food that contains specified risk materials, such as specific parts of cattle aged 30 months or older) are also included.

Rules of General Application

As a rule of general application, this Division sets out the information that must appear on the label of a food (e.g. common name, list of ingredients, identity and principal place of business of the person by or for whom the food was manufactured or produced, and irradiated food symbol if applicable), including the requirement for this information to be in both English and French, unless there is a specific exception.

Also provided are reference standards for a nutrient, the basis for and the way to express a serving of a food, nutrition labelling for pre-packaged products (including the content and format of a nutrition facts table), and nutrition content claims as well as other permitted statements or claims.

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Temporary or Interim Marketing Authorization

In this Division, authorization mechanisms allow for the temporary or interim sale of a food that is not currently captured by the general rule (e.g. in a table or standard) while the regulator revises the regulations to include this food based on evidence that the food will not be harmful to health. It specifically provides for a Temporary Marketing Authorization Letter (TMAL) where the food or the packaging, labelling or advertizing of the food does not comply with the requirements of the FDR, and for an Interim Marketing Authorization (IMA) to allow the sale of the food until the regulations are amended to capture that food in the general rule. This mechanism exempts the food from specific requirements of the Act and regulations to permit its sale.

Interactions

- NHP/Food health claims

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DIVISIONS 2-14 & 17-22

Specific Food Standards

These Divisions set out the standards for the following specific food products:

Division 2 (Alcoholic beverages); Division 3 (Baking Powder); Division 4 (Cocoa & Chocolate Products); Division 5 (Coffee); Division 6 (Food Colouring); Division 7 (Spices, Dressings and Seasonings); Division 8 (Dairy Products); Division 9 (Fats and Oils); Division 10 (Flavouring Preparations); Division 11 (Fruit, Vegetables, Their Products and Substitutes); Division 12 (Pre-packaged Water and Ice); Division 13 (Grain and Bakery Products); Division 14 (Meat Products & By-products); Division 17 (Salt); Division 18 (Sweetening Agents); Division 19 (Vinegar); Division 20 (Tea); Division 21 (Marine & Fresh Water Animal Products); and Division 22 (Poultry Products & By-products)

Purpose

The purpose of these Divisions is to prevent fraud, to protect health and safety and to ensure the nutritional quality of foods (e.g. by establishing standards that a food must meet for commerce purposes, by setting out the food additives that may be added to foods and by setting out the vitamins and mineral nutrients that may or must be added to certain foods), as well as to prevent the sale of food containing harmful substances (e.g. by prohibiting the sale of cocoa unless it is free from *Salmonella*). In addition, Division 8 (Dairy) also identifies certain additions to food for public health reasons (e.g. Vitamin D added to milk).

Design

Prohibitions

In these Divisions, prohibitions are included to prevent the sale of food containing harmful substances (e.g. food colours cannot contain arsenic), and also extend to the processing/manufacturing of foods (e.g. prohibition against selling meat that was not killed for the purpose of food, or that was infected with disease).

Rules of general application

Standards have been established for the specific types of food included in these Divisions; however, these Divisions do not include detail about the possibility to add to or change these standards. The labelling and advertising requirements are also tailored to the type of food product (e.g. for meat, there are advertising provisions related to grading, origin and price; for flavouring preparations, there are requirements for labelling 'artificial' or 'imitation'). Some Divisions also reference good manufacturing practices.

Pre-Market Certification

Unique to the food standards Divisions is Division 6 (Food Colouring) in that partial prohibitions are included to prevent the sale or import of a synthetic colour unless the regulator certifies that it meets certain requirements restricting the amount of arsenic, lead and heavy metals.

Post-market Oversight

Obligations

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Unique to the food standards Divisions is Division 8 (Dairy Products) in that product tracing requirements are included.

Interactions

- AAFC's commodity regulations under CAPA, MIA and FIA

DIVISIONS 15

Adulteration

This Division provides safety oversight with respect to substances that may be introduced into a food from various sources if the substances do not exceed the prescribed amount.

Purpose

The purpose of this Division is to prevent the sale of food containing harmful substances (e.g. by establishing tables listing substances – and their maximum residue limits – that can be added to food). An example is that the maximum residue limit for nicotine on certain fruits and vegetables cannot exceed 2 parts per million, or the food would be considered to be adulterated.

Design

Prohibitions

The Division provides certain exemptions from the Act's prohibition on the sale of food that is adulterated (e.g. a particular food which does not have present in it a particular agricultural chemical that exceeds a prescribed maximum residue limit).

Rules of general application

Designed as a rule of general application, this division establishes maximum limits for individual substances that can be added to foods, determines when a food is adulterated by a substance regulated as a pest control product or agricultural chemical, and sets out that maximum residue limits for the use of vet drugs.

Interactions

- PCPA

DIVISIONS 16

Food Additives

This Division provides safety oversight for substances the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food

Purpose

The purpose of this Division is to prevent the sale of food containing harmful substances (e.g. by establishing tables listing food additives, the foods they may be added to and their maximum level of use. Examples would be that the maximum level of use of gelatin in cottage cheese cannot exceed 0.5%, or that the maximum level of use of caffeine in cola type beverages cannot exceed 200 parts per million in the finished product.

Design

Prohibitions

This Division prohibits the sale of a food containing a food additive unless it contains a permitted prescribed food additive as listed in Tables I through XV. Also included are prohibitions linking to other Divisions of Part B to specify when an ingredient is considered a food additive for a specified purpose.

Rules of general application

Designed as a rule of general application, this Division includes limitations of safe use for each individual additive, and includes reference to good manufacturing practices. This Division requires a quantitative statement of the amount of each additive present or direction for use that, if followed, will produce a food that will not contain such additives in excess of the prescribed maximum levels of use to be shown, grouped together with the list of ingredients, of any substance or mixture of substances for use as a food additive.

Pre-market submission linked to Interim Marketing Authorization

This Division sets out the process to request that a food additive be added to, or a change be made in, Tables I through XV. A pre-market submission and notification process is included whereby the regulator decides whether or not to proceed with a regulatory amendment to change or make a rule of general application.

Interactions

- Refers to Codex (B.01.045) and FAO/WHO Expert Committee

DIVISIONS 23 & 27

Food packaging (general & specific)

These Divisions provide safety oversight of harmful substances that may be introduced to a food from its packaging. Division 23 (Food Packaging Materials) provides general food packaging requirements, and Division 27 (Low-Acid Foods Packed in Hermetically Sealed Containers) includes specific food packaging requirements for foods packed in containers that are intended to be secure against the entry of microorganisms.

Purpose

The purpose of these Divisions is to prevent the sale of food containing harmful substances (e.g. by establishing requirements related to the proper packaging of foods).

Design

Prohibitions

The sale of a food in a package that may introduce a harmful substance is expressly prohibited, as well as the sale of low-acid food packaged in hermetically sealed container unless it is commercially sterile and the label bears a code or lot number.

In Division 23, a number of harmful substances are identified that are not allowed in food packaging, and others which may be present within specific limits. Reference to acceptable testing methods are also provided. Exceptions related to a product's sterility are included in Division 27 when low-acid food is kept refrigerated or frozen.

Post-market Oversight

Interventions

In Division 23, post-market authorities include the ability to issue a notice requesting evidence that the processes used to manufacture, process and package the food is commercially sterile, and the ability to stop sale.

DIVISIONS 24-25

Special Dietary & Infant Foods

Division 24 sets out the -requirements-for formulated liquid diets, meal replacements, nutritional supplements, gluten-free foods, pre-packaged meals, foods sold by weight reduction clinics and foods represented for use in very low energy diets; Division 25 sets out the requirements for infant foods, human milk substitutes and foods containing human milk substitutes. These Divisions cover special purpose foods: foods for special dietary use and foods for medical purposes.

Purpose

The purpose of these Divisions is to prevent fraud (e.g. by establishing standards that these special purpose foods must meet), to prevent the sale of food containing harmful substances (e.g. by prescribing labelling requirements such as for gluten-free foods).

Design

Prohibitions

Partial prohibitions are included throughout both Divisions related to the sale and advertising of special purpose foods. Division 24 expressly prohibits the advertisement to the general public of a formulated liquid diet and of a food for use in a very low energy diet.

Rules of general application

These Divisions set out prescribed information to be on, and prescribed claims not permitted to be on, the label and/or advertisement of special purpose foods covered under these Divisions. Specific labelling requirements and amounts of minerals and vitamins required to be in the food are included for these special purpose foods.

Pre-Market Context

Written Order

For foods to be used in a very low energy diet there is a need for oversight; the regulations reflect this need by requiring a written order from a physician (i.e. similar to prescription drug).

Notification

Manufacturers of the following types of foods must give prior written notice to the regulator of its intention to sell or advertise for sale: **foods for use in very low energy diets** (or such food that has undergone a major change), and **new human milk substitutes** (or such substitutes that have undergone a major change). The notification timeframe is specified as 90 days prior to sale or advertisement.

Post-Market Oversight

Interventions

Post-market authorities for formulated liquid diet, meal replacement or food for use in a very low energy diet include the ability to request evidence with respect to that product, which results in a stop sale until sufficient evidence is submitted.

Interactions

- References Canada's Food Guide to Healthy Eating (1992)

DIVISIONS 26

Irradiated Foods

This Division pertains to food that has undergone radiation, and provides safety oversight of harmful substances that may be introduced to a food from its radiation.

Purpose

The purpose of this Division is to prevent the sale of food that has been irradiated unless specifically allowed for.

Design

Prohibitions

This Division includes a general (partial?) prohibition on the sale of a food that has been treated with ionizing radiation unless the food has been irradiated as prescribed in the table (e.g. by a permitted source of ionizing radiation, for a permitted purpose and at a permitted maximum absorbed dose).

Rules of general application

As a rule of general application, the manufacturer and importer are required to keep records (like a post-market obligation) with the prescribed information, for at least two years after the date of the irradiation.

Submission to Change the Table

This Division sets out the submission process to request that a food be added or a change be made to the table.

Interactions

- Does the submission process link to an IMA while the table gets revised?

DIVISIONS 28

Novel Foods

This Division provides safety oversight over substances that do not have a history of safe use as a food, including genetically modified foods or foods that have been altered by other novel means. This includes a pre-market notification scheme for manufacturers who must meet certain requirements and submit certain information prior to sale.

Purpose

The purpose of this Division is to prevent harm associated with the consumption of a new food or a food that does not have a history of safe use as a food (e.g. by requiring manufacturers to submit information and notify the regulator prior to sale or advertisement of a novel food).

Design

Prohibition linked to Pre-Market Notification

This Division includes a partial prohibition on the sale or advertisement of a novel food, which gives rise to a pre-market notification scheme (e.g. no person shall sell, *unless*). The notification process allows the regulator to evaluate evidence supporting the safety of the novel food prior to its sale or advertisement. If the evidence is found to be acceptable, the regulator authorizes the food by providing notice to the manufacturer or importer. A list of authorized novel foods is not maintained in the Regulations, and there are no additional labelling requirements specific to novel foods.

Interactions

- A novel food is similar in concept to a "new drug" as defined in Part C, Division 8 of the Food and Drug Regulations.

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Food and Drug Regulations - Part C (Drugs)

DIVISION 1
General

Purpose

Drugs by nature produce a pharmacological effect on the body including both desirable effects and the potential for undesirable side effects. These side effects as well as other risks introduced through the manufacturing process must be considered in the context of the desired benefit. The standards in Division 1 have been established over time to address these risks without the need to provide additional evidence of a drugs safety, effectiveness or quality.

Division 1 applies generally to all of Part C providing a mechanism to authorize the sale or importation of drugs (for human or veterinary use) that are not *New Drugs* and a linkage to the authorization requirements for *New Drugs* in Division 8. Division 1 includes compositional, dosing, labelling, packaging and testing standards as well as providing limits on the advertising and distribution of samples of a drug. Substances requiring the supervision of a practitioner are included on Schedule F and the sale is further controlled by the requirement for a prescription. Post-authorization obligations, most notably for the reporting of adverse drug reactions (ADR) are also included in this Division. The regulator has the ability to intervene to gather information and take action to address unforeseen risks associated with a drug once it has entered the market.

Design

Prohibitions on sale - General

The sale of any drug, unless otherwise exempted, is prohibited unless a Drug Identification Number (DIN) has been assigned and has not been cancelled. This prohibition gives rise to most of the authorization schemes for drugs in Divisions 1 and 8. Prohibitions on the sale of a drug also apply (including distribution of samples) unless its composition, labelling and packaging conforms to the standards included in this division. An important prohibition on the sale of a drug unless pursuant to a prescription is linked to those drugs specifically named in Schedule F.

Prohibitions on sale - Composition

All drugs have risks, some more than others. Many of these risks are mitigated by giving oversight over what substances can be included in drugs. Substances are managed in different ways in Division 1, depending on known risks associated with them. This is achieved by prohibiting certain substances in any circumstance, specifying substances that may be used for specific purposes (colouring agents), defining acceptable levels, specifying methods of preparation, specifying limits of dosage and controlling access by requiring a prescription for sale.

Prohibitions on sale -Labelling

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Labelling requirements reflect the risks associated with a product and take into account whether the product is intended for selection and use by the consumer or under the supervision of a practitioner. Basic information concerning the identity of the medicinal ingredients and any preservatives, the strength, directions for use, expiry date and net amount in the container is required for all drugs. In addition, the manufacturers name and address and the lot number must appear on the label to facilitate traceability and corrective action such as recall. Further labelling is required to identify a prescription or controlled drug or a drug that is sterile. Specific text is also required to be included on the labels of certain human and veterinary drugs.

Prohibitions on sale - Packaging

There is a prohibition on the sale of a few specified drugs under certain conditions unless they are contained in a child resistant package as defined by regulations. Additionally, there are requirements for the type of container and materials of construction for a drug for parenteral use reflective of the unique risks associated with this form of drug delivery.

Prohibitions - Samples

Except for narcotics, controlled drugs or unauthorized drugs (not issued a Notice of Compliance under Division 8), samples may be distributed only by a registered and practicing physician, dentist, veterinary surgeon or pharmacist as long as they are labelled according to the regulations and records of their distribution maintained.

Prohibitions - Importation for sale

The importation for sale of any drug is prohibited unless there is a person responsible for the drug in Canada and the name and address of the importer appears on the label. The importation of a Schedule F drug for human use is prohibited except by a practitioner, a drug manufacturer, a wholesale druggist, a registered pharmacist, or a resident of a foreign country while a visitor in Canada.

Prohibitions - Advertising

Advertising of most drugs for human use that appear on Schedule F is prohibited other than representations on name, price and quantity.

Prohibitions – Dissemination of promotional literature to practitioners

The dissemination to a practitioner of promotional literature about certain drugs is prohibited unless the prescribed cautionary statements are included in the literature.

Prohibitions – Standards

Numerous standards are prescribed within Division 1 either in explicit language or by reference. These include standards that are prescribed by any statute of the Parliament of Canada or regulation made under them such as standards in publications listed in Schedule B to the *Food and Drugs Act* and the standards listed in Division 6(Canadian Standard Drugs) of the *Food and Drug Regulations*. Other standards that have been incorporated by reference including from the Canadian Standards Association, European EN standards, ISO standards, and standards found in foreign legislation or regulation such as the *Code of Federal Regulations* of the United States.

Authorization

A drug manufacturer, authorized representative or importer of a drug may make an application for a DIN in order to sell or import a drug in Canada. The basic information that is normally required to be submitted with

the application is not of the level required to conduct a full and comprehensive analysis of the drugs safety, effectiveness or quality. Where this type of information is necessary a submission must be filed in accordance with Division 8 respecting *New Drugs.* An application for a Notice of Compliance in Division 8 is considered to be an application for a DIN.

If the application requirements of either Division 1 or 8 are met, the Director shall issue a document to an applicant that contains the assigned DIN (s) associated with the manufacturer's name, pharmaceutical form, route of administration, premises of use if the drug is a disinfectant, list of medicinal ingredients and the brand name.

The regulator may refuse to issue a DIN where he believes on reasonable grounds that the product is not a drug or it is a drug the sale of which would: cause injury to the health of consumers or purchasers or violate the Act or Regulations.

The applicant may request the regulator to reconsider the refusal to issue by providing additional information.

Where there has been a change to certain information submitted in the DIN application, a new DIN application is required to be submitted. The sale of the changed drug is prohibited until a DIN has been assigned in respect of the new application. Other changes to the information are allowed without the filing of a new application provided that the applicant has given notification of the change.

Post-authorization Obligations

Notification of commencement or discontinuance of sale
The person to whom a DIN has been assigned for a drug must notify the regulator within 30 days of either commencing or discontinuing the sale of drug in Canada. Upon notification of discontinuance, the regulator must cancel the DIN. Samples of the labels as well as confirmation of the correctness of the application information must also be provided with the notification of commencement.

Annual notification to confirm information
The manufacturer of a drug must annually and before October 1 provide notification to the regulator to confirm that information previously submitted with respect to that drug is correct. Failure to notify may result in the cancellation of the DIN.

Adverse Drug Reaction Reporting
A manufacturer is prohibited from selling a drug unless the requirements respecting adverse drug reactions (ADR) have been followed. This includes the reporting of serious and serious unexpected adverse drug reactions to the regulator that occur within or outside of Canada respectively, within 15 days.

Annual Summary Report
The manufacturer must prepare an annual summary report including information relating to ADR and serious ADR during the previous 12 months and identify whether any significant change to the benefits and risks of the drug based on this information. The manufacturer must also notify the regulator of any significant change identified in the preparation of the annual summary report.

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Maintenance of Records
Manufacturers are required to maintain records of ADR reports, annual summary reports and issue-specific reports.

Recalls
A manufacturer or importer who sell a drug in dosage form who commences a recalls of a drug is required to notify the regulator immediately by providing information respecting the circumstances of the recall including the identity and quantity of drug implicated, the reason for the recall and any other action taken.

Post-authorization interventions

Request for evidence and stop sale
The regulator may request that the manufacturer provide evidence to establish the safety of the drug under the conditions of use recommended and the effectiveness of the drug for the purposes recommended. The manufacturer must stop the sale of drug if the evidence is not provided within the timeline specified in the request or if the regulator has notified the manufacturer that the evidence submitted is not sufficient.

Cancellation of a DIN
The regulator *must* cancel a DIN when a DIN holder notifies the regulator of discontinuation of sales of a drug; a NOC has been suspended or the product that was assigned the DIN is not a drug. The regulator *may* cancel a DIN if the manufacturer fails to submit an annual notification or provides insufficient evidence when requested by the regulator to establish the safety of the drug under the conditions of use recommended and the effectiveness of the drug for the purposes recommended.

Request for annual summary reports and case reports
The regulator has the ability to request, for the purpose of assessing the safety and effectiveness of the drug, annual summary reports and case reports relating to ADR and serious ADR know to the manufacturer, within a specified time.

Request for issue-related summary reports
The regulator has the ability to request, for the purpose of assessing the safety and effectiveness of the drug, issue-related summary reports, within a specified time or a period less than 30 days if the drug poses serious or imminent risk to human health.

Request for information - site, rate or extent of release or availability of a drug
A manufacturer must conduct investigations prior to making representations regarding the site, rate or extent of release to the body or availability to the body of a medicinal ingredient of a drug. The records of these investigations may be requested by the regulator but is not required to be submitted with a DIN application.

Request for information – manufacturer's standard:
If a manufacturer's standard is used for a drug, the manufacturer must provide, on request by the regulator, details of the standard and method of analysis.

Request for information - drugs intended for animals that may be consumed as food
Where a manufacturer intends to sell a drug for use in a food producing animal, the regulator may request information regarding the tests and results to determine the drug residues. These residues are prohibited from

exceeding the limits set out in the Regulations and the drug must be labelled with the withdrawal period specified by the regulator.

Interactions

- The *Food and Drug Regulations*: Part A, Part C (all divisions), Part D, Division 5 (Minerals in Drugs), Part G (Controlled Drugs)
- *Narcotic Control Regulations*
- *Benzodiazepines and Other Targeted Substances Regulations*

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DIVISION 1A
Establishment Licences

Purpose

Activities associated with a drug may impact the quality of a drug and comprise safety. Division 1A provides a mechanism to authorize the conduct of certain activities associated with drugs. The purpose of this division is to provide oversight such that activities associated with a drug meet good manufacturing practices (GMP) standards of Division 2 of these regulations.

Design

Prohibition

The conduct of certain activities is prohibited unless it is authorized by an establishment licence. These activities include: the fabrication and importation for sale, packaging, labelling, and distribution of drugs, the wholesaling of drugs listed in Schedule C or D to the Act or in Schedule F to these Regulations, controlled drugs and narcotics as well as the performing of tests and examinations required under Division 2. These requirements apply to drugs in dosage form including bulk process intermediates of drugs listed in Schedule C or D to the Act but not to other active pharmaceutical ingredients.

Activities associated with drug compounding by a licensed professional, manufacturing of antimicrobial agents (disinfectants) or drugs for clinical trials as well as wholesaling of veterinary drugs to be mixed with feeds are not subject to the requirements of this division. Drugs that are natural health products are also not subject to these requirements.

Authorization

A person who wishes to conduct these activities must submit an application for an establishment licence (EL) that includes information regarding the category of drugs and dosage form class for each activity and the buildings where activities will be conducted and records maintained. In the case of importers, information supporting the conduct of activities in a recognized country for which a mutual recognition agreement (MRA) with Canada exists must be provided.

This information is examined by the regulator, and if necessary, additional information, samples or building inspection may be requested prior to issuing a licence. If necessary to ensure the health of or to prevent injury to

the consumer, the licence may also indicate a specific record retention period or additional terms and conditions.

In order to continue conducting activities authorized under a licence, EL holders must submit an application for the review of their licence before April 1 of each year. The application is subject to the same requirements and process as for the original licence.

EL holders must amend their licence by submitting the applicable information to the regulator prior to implementing any major change such as adding an activity, category of drugs or building to a licence. An application for amendment is subject to the same requirements and process as for the original licence.

The regulator may refuse to issue or amend a licence, in whole or in part, if the application contains false or misleading information or if an EL was previously suspended. The regulator must refuse to issue or amend an EL, in its entirety or in part, if there is reasonable grounds to believe that it would result in a risk to the health of the consumer. The applicant must be notified of the reasons for the refusal and given an opportunity to be heard.

Post-authorization Obligations

The EL holder must comply with the terms and conditions indicated in the licence and applicable requirements of Divisions 2 to 4.

The regulator must be notified within 15 days of a change (such as a change in address and contact information, dosage form class or building address) or an event that contravenes GMP requirements that may affect the quality, safety or efficacy of a drug.

EL holders must also notify the regulator of changes that may impact GMP (change to building plans and specifications, equipment and procedures) by providing sufficient information to assess the safety of the drug, taking into account the change. The conduct of these activities must cease if the regulator notifies the EL holder that the change is not acceptable.

Importers of a drug that is fabricated, packaged, labelled or tested in an MRA country at a recognized building must immediately notify the regulator when a valid permit no longer exists at a building where these activities are conducted. The regulator will amend the EL accordingly.

Post-authorization interventions:

The regulator has the ability to amend terms and conditions of a licence if necessary to prevent injury to the health of the consumer by giving at least 15 days notice to the EL holder indicating the reasons for the amendment and effective date.

The regulator may suspend, by notice, an EL, with or without giving an opportunity to be heard prior to the suspension depending upon the severity of the grounds for suspension. The EL may be reinstated after consideration of additional information.

The regulator must cancel an EL if it has been suspended for a period of more than 12 months or if the holder did not submit an application for the review of their licence.

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Interactions

- *Food and Drug Regulations*: Part A, Part C - Divisions 2-4, 8, Part G
- *Narcotic Control Regulations*

DIVISION 2
Good Manufacturing Practices

Purpose

The safety and effectiveness of a drug depends on the continued assurance of its quality. Control over all aspects of the manufacturing through the application of good manufacturing practices (GMP) is a critical component to achieving this. Division 2 sets out the GMP standards that apply to all activities in the drug supply chain: fabricating, testing, importing, packaging, labelling, storing, and transporting. The purpose of this division is to prevent the sale of drugs that are adulterated or manufactured under unsanitary conditions.

Design

Prohibition

The sale of a drug is prohibited unless it has been fabricated, packaged, labelled, tested and stored according to the requirements of this division. This division provides for controls on all aspects of the manufacturing of a drug (fabricating, packaging, labelling, testing, storing and importing) specific to the premises (design, construction, maintenance), equipment used (cleaning, contamination, function), personnel (including training and qualifications), sanitation (health and hygiene), testing (raw material, packaging, finished product and stability testing), manufacturing controls, quality control department (organizational structure), record keeping, and sample retention.

This division does not apply to the fabricating, packaging, labelling, testing, storing and importing of antimicrobial agents (disinfectants).

Interactions

- Part C: Divisions 1A, 3, 4
- Part A

DIVISION 3
Schedule C Drugs

Purpose

Radiopharmaceuticals are unique in that their therapeutic and diagnostic utility derives from short lived radioactive decay. As a consequence, unlike other drugs, many radiopharmaceuticals are prepared at the time of use, normally in a hospital setting. The primary purpose of this division is to provide requirements, supplementary to Divisions 1, 1A, 2 and 8, respecting the safe storage, handling and use of radiopharmaceuticals, drugs sold or represented for use in the preparation of radiopharmaceuticals and radionuclide generators (i.e. Schedule C drugs).

Design

Prohibition

The sale of a Schedule C drug is prohibited unless it has been fabricated, packaged, labelled, tested and stored according to the requirements of this division. Additionally, the sale of any lot of a drug for which the testing protocol or sample fails to meet the requirements of the Regulations is prohibited. Prohibitions also extend to the sale of a drug derived from unhealthy infectious animals.

Unique labelling requirements include requirements to label as radioactive with appropriate warning symbols and precautions, to indicate the strength in terms of radioactivity, the useful life, and to indicate the Establishment Licence (EL) number but not the Drug Identification Number (as radiopharmaceuticals are not issued a Drug Identification Number).

Some of the standards for labelling (from *Atomic Energy Control Regulations*) and testing (Schedule B monographs) have been incorporated by reference.

Powers

The regulator has the ability to request protocols of tests and samples prior to the sale of a Schedule C drug.

Interactions

- Part C: Divisions 1, 1A, 2, 8
- Part A
- Schedule C of the *Food and Drugs Act*

DIVISION 4
Schedule D Drugs

Purpose

Biologics (Schedule D drugs) generally differ from other pharmaceuticals in that they are usually sourced from living organism and may contain living material or have a high risk of being contaminated with pathogens or other undesirable substances. Given the nature of these drugs, this division provides controls on their manufacturing, packaging, labelling, storing and testing supplementary to the requirements in Divisions 1, 1A, 2 and 8. These additional controls are necessary to provide adequate oversight of the safety, effectiveness and quality of these drugs.

Design

Prohibition

The sale of a Schedule D drug is prohibited unless it has been fabricated, packaged, labelled, tested and stored according to the requirements of this division. Additionally, the sale of any lot of a drug for which the testing protocol or sample fails to meet the requirements of the Regulations is prohibited. Prohibitions also extend to the sale of a drug derived from unhealthy infectious animals. Specific prohibitions are included intended to reduce the risk of contamination from various sources.

This division provides specific requirements for the fabrication, packaging, labelling, testing and storing of named vaccines, bacteriophages, toxins, toxoids, antitoxins and antisera, preparations from human sources, human plasma, insulin and anterior pituitary extracts. These include requirements for composition (including prohibited substances), methods of preparation, testing standards (test methods and limits), specific expiration periods, premise design and conditions and qualification of personnel. Additional requirements to protect human blood donors include screening for donor suitability and obtaining consent from donors prior to collection.

This Division does not apply to a drug in oral dosage form that contains micro-organisms if the drug is recommended solely for restoring, normalizing or stabilizing the intestinal flora.

Authorization

Fabricators must request written permission from the regulator prior to manufacturing other drugs in areas or premises in which polio-virus vaccines are manufactured.

Prior to selling an insulin preparation, a fabricator must file a submission containing test protocols and reports related to that preparation, as well as any additional information requested by the regulator. The fabricator may sell the preparation if a notice from the regulator indicating that the information contained in the submission meets the requirements is received.

Obligations

Prior to sale, fabricators of virus and rickettsial vaccines must submit to the regulator details of the source of strains used, methods of their propagation and fabrication of the vaccine, and testing methods for sterility, safety, identity and potency.

Fabricators of B.C.G. vaccines are also required to examine pathologically all test animals used and immediately report to the regulator any evidence of active, progressive tuberculosis in any such animals.

Fabricators of source plasma are required to notify the regulator of any serious adverse reaction and report any recalls of source plasma.

Fabricators of Schedule D drugs must keep additional records as indicated in this division.

Powers

The regulator may request that protocols of tests together with samples of any lot of a drug be submitted before a drug is sold**.**

The regulator may request, with respect to each lot of virus or rickettsial vaccine, when ready for sale, detailed protocols of sterility, safety, identity, potency, and of any other tests required by these Regulations.

The regulator may request a copy of records pertaining to plasmapheresis, specific immunization or source plasma in order to prevent injury to the health and safety of donors and recipients of products manufactured from source plasma.

Interactions

- *Food and Drug Regulations*, Part C - Divisions 1,1A, 2, and 8
- Schedule D of the *Food and Drugs Act*

DIVISION 5
Drugs for Clinical Trials Involving Human Subjects

Purpose

Clinical trials are used to discover the effects of a drug and ascertain its safety and efficacy. Division 5 provides a mechanism to authorize the sale or importation of drugs to be used for the purposes of clinical trials involving human subjects. The purpose of this division is to protect human clinical trial subjects and others involved.

Design

Prohibition

The sale or importation of a drug for the purposes of a clinical trial is prohibited unless the trial is authorized and has not been suspended or cancelled. Applicable prohibitions from Division 1 are extended to this division. This division also allows for the trial of drugs containing substances that are prohibited for sale in drugs in Division 1. A clinical trial of an authorized drug within the existing conditions of use is not subject to the requirements of this division.

Authorization

A clinical trial sponsor (a person responsible for the conduct of a trial) must obtain authorization from the regulator to conduct a clinical trial in Canada in respect of a drug for use in humans that involves human subjects. Application requirements include the submission of information such as a protocol describing the objectives, design, methodology, statistical considerations and organization of the clinical trial, preclinical and clinical data and chemistry and manufacturing information. This information is examined by the regulator, and if necessary, additional information or samples may be requested. The regulator must notify the applicant within 30 days of receipt of the application if there are any concerns with the proposed trial.

Sponsors must obtain an authorization prior to implementing any major change to a previously authorized trial and must notify the regulator of minor changes within 15 days of implementation.

Post-authorization Obligations

Sponsors must follow good clinical practices designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons. These include the supervision by a qualified investigator and approval by a research ethics board at each clinical trial site, obtaining informed consent from participants, record keeping (25 years), and that the drug is manufactured according to good manufacturing practices.

Sponsors must also ensure that investigational drugs are labelled according to specific requirements, report serious unexpected adverse drug reactions, notify of the discontinuance of a trial in whole or in part for any reason.

Post-authorization interventions

The regulator has the ability to suspend or cancel, in whole or in part, an authorization to sell if the sponsor has contravened the Act or Regulations, has failed to comply with their obligations or to prevent injury to the health of a clinical trial subject or other person.

Interactions

- Division 1, 2-4, 8

DIVISION 6
Canadian Standard Drugs

Purpose

This division sets standards (test methods including Official Methods, United States Pharmacopeial references, source, and composition) for six specified drugs (conjugated estrogens, digitoxin, digoxin, esterified estrogens, gelatin and thyroid). The incorporation of specific standards in this division and throughout the regulations provides the controls necessary to prevent harm in a manner that has already been well established.

Design

Prohibition

Any of the drugs named in this division shall be the drugs that correspond to the prescribed standards. The prohibition restricting the sale of drug for which a standard is prescribed in this division unless labelled as such, is found in Division 1 of the *Food and Drug Regulations*.

Interactions

The United States Pharmacopoeia (USP), Official Methods, Division 1.

DIVISION 7
Sale of Drugs for the Purposes of Implementing the General Council Decision

Purpose

The General Council Decision of the World Trade Organization enables a drug under patent protection to be manufactured and sold for humanitarian purposes by someone other than the patent holder. In support of this decision**,** this division provides the mechanism for a manufacturer to export a drug that cannot be sold in Canada due to patent restrictions. Regulatory activities through the application of this division are to the immediate benefit and protection of persons outside of Canada

Design

Prohibition

This division requires the filing of a New Drug Submission, Abbreviated New Drug Submission or Drug Identification Number Application under the *Food and Drug Regulations* and confirmation of the intent to file a separate application to the Commissioner of Patents to satisfy the requirements of the *Patent Act*. The drug must meet all the pre-authorization requirements that any other drug to be sold in Canada must meet. Specific labelling and product marking requirements are intended to prevent unauthorized sale of the drug in Canada.

Authorization

The Minister of Health must notify both the manufacturer and the Commissioner of Patents when an application meets all requirements of this division and must assign an export tracking number to each authorized drug. The manufacturer may sell the drug only when authorization is received form the Commissioner of Patents.

Post-Authorization Obligations

The same post-authorization record keeping and reporting obligations for *New Drugs* sold in Canada also apply to these drugs. The manufacturer must notify the Minister before commencing the manufacture of the first lot of an authorized drug and before the exportation of each subsequent lot.

Powers

The Minister must notify the Commissioner of Patents if the authorized drug no longer meets the requirements of the Act and Regulations.

Interactions

- Division 1, 8
- *Patent Act*
- *Food and Drugs Act*

DIVISION 8
New Drugs

Purpose

New drugs are drugs that may consist of new substances for new indications or in new combinations that have not been established to the extent that risks associated with their manufacture and use can be adequately controlled through the application of pre-existing regulatory standards. In these instances, information regarding the safety, efficacy and quality of the drug is necessary in order to determine the risks and benefits associated with the drug and allow a determination by the regulator regarding its acceptability for sale. This division sets out the general pre-authorization application and post-authorization record keeping and reporting requirements for new drugs both for human and veterinary use. It supplements the requirements found in Division 1. Also included is an authorization scheme and specific requirements regarding the sale of drugs for veterinary use for the purpose of clinical testing and experimental studies. The purpose of this division is to provide a means by which evidence supporting the safety, efficacy and quality of a drug may be submitted to the regulator with the intent of allowing the sale or advertising of that drug for the desired purpose.

Design

General

This division provides a home for five distinct classes of authorization; general market authorizations allowing a manufacture to market a drug to the consumer; extraordinary use authorizations allowing a manufacturer to sell a drug to government authorities; emergency use authorizations allowing a manufacturer to sell a drug to a practitioner for use with a specific patient; authorizations allowing a manufacturer to sell a drug to qualified investigators for the purpose of clinical testing of drugs for veterinary use and authorizations allowing a manufacturer to sell a drug for the purpose of conducting experimental studies in animals. All these authorization classes require the filing of an application with varying levels of evidence supporting the safety, efficacy and quality of the drug, the issuance of a notice of some kind by the regulator regarding the acceptability of the evidence and obligations on the authorization holder. The regulator has the ability to intervene post-authorization to address safety related issues or violations of the Act and Regulations.

Opportunity for the applicant to provide additional information is incorporated into the design of all these authorization schemes. In the specific cases where the regulator has suspended a notice of compliance (NOC) or refuses to issue an authorization for the sale of a drug for clinical testing for veterinary use, the manufacturer may request reconsideration of that decision through a “new drug committee” which includes members selected by both the regulator and the manufacturer. The regulator is not bound by the recommendations of the committee but may reconsider and reverse the decision as a result.

Definitions

A number of critical definitions are provided that define the scope of this division and the different types of application requirements within. The most important of these is the definition of “new drug”. In essence, a new drug is a drug that requires the provision of evidence to demonstrate its safety, effectiveness and quality beyond that which has already been well established and may be controlled by standards developed over time. This is in direct contrast to the DIN application requirements of Division 1 which generally do not require such new evidence. The definition of “Canadian reference product” gives rise to the abbreviated new drug submission

(ANDS) which is based upon a comparison to a new drug that has received an authorization and is marketed. The ability given to a manufacturer to make such a comparison allows for a reduction in the evidence requirements to support the safety and effectiveness of the drug and brings efficiency to the authorization scheme for new drugs by eliminating the need for redundant testing in humans. Conversely, the definition of "innovative drug" leads to restrictions on when the regulator may accept the filing of an ANDS and when an authorization may be issued. This is the only occurrence in Part C of the regulations where such a restriction on an authorization is applied.

Prohibitions – New Drug Submissions (NDS), Abbreviated New Drug Submissions (ANDS), Extraordinary Use New Drug Submissions (EUNDS) and Supplements

Prohibitions are provided on the sale or advertising of a new drug unless the manufacture has filed a submission containing the required evidence in support of the safety, efficacy and quality of the drug and the regulator has issued a notice of compliance (NOC) in respect to that submission. In the case of an extraordinary use new drug (EUND) an additional prohibition limits the sale of such a drug to municipal, provincial or federal governments. The manufacture must have also provided copies of the final versions of the labels to be used and the proposed date that those labels will be used.

Prohibition - Sale of New Drug for Emergency Treatment

This prohibition restricts the sale of an unauthorized drug for emergency treatment unless an application has been filed by the practitioner that is acceptable to the regulator.

Prohibitions - Clinical Testing of a New Drug for Veterinary Use and Experimental Studies

The prohibitions on sale by a manufacturer to a qualified investigator are similar for these two classes of authorization and restrict the sale unless an application has been submitted to the regulator and determined to be acceptable.

Prohibition - Sale of Medicated Feeds

The sale of a medicated feed is permitted pursuant to a written prescription from a veterinary practitioner if the drug used in the feed has been assigned a DIN or has been authorized for use for the purpose of clinical testing, emergency treatment or experimental studies. The medicated feed must be for the treatment of animals under the direct care of the veterinary practitioner who signed the prescription and must be used for therapeutic purposes only. This prohibition is unique in that it is linked to a drug that has already been authorized through another mechanism.

Authorization - New Drug Submission (NDS)

A new drug submission must contain information necessary to enable the regulator to assess the safety and effectiveness of the new drug. This includes the description and name of the new drug, a qualitative list and specifications of the ingredients, detailed chemistry and manufacturing information, pre-clinical and clinical data including results of tests used to establish the safety and clinical effectiveness of the drug , drafts of labels, recommended route of administration, proposed dosage, claims, contra-indications and side effects, description of the dosage form, and for a drug intended for administration to food-producing animals, the withdrawal period of the new drug.

Authorization - Extraordinary Use New Drug Submission (EUNDS)

A manufacture of a new drug may file a EUND submission only if the drug is intended for use in an emergency situation after exposure to or as preventative use for persons at risk to exposure to potentially lethal substances or pathogens. Additionally, the circumstances of use of the drug would preclude the establishment of the safety and efficacy of the drug in humans without undue serious harm. Other evidence requirements are similar to a NDS.

Authorization - Abbreviated NDS or Abbreviated EUNDS
A manufacturer may file an abbreviated new drug submission (ANDS, AEUNDS), with reduced evidence requirements in comparison to that of a NDS if the drug when compared to the Canadian reference is pharmaceutically equivalent, bioequivalent, has the same route of administration and falls within its conditions of use. Despite the difference in evidence requirements, the evidence must be sufficient to allow the regulator to assess the safety and effectiveness of the drug. Restrictions regarding the time of filing and issuance of the NOC for the ANDS are linked to the date an NOC was issued to the innovator.

Authorization - Supplement to a NDS, ANDS, EUNDS, AEUNDS
Where there has been a significant change to a drug or certain information associated with the drug, a manufacturer must file a supplement including evidence in support of the change. The manufacturer is prohibited from selling the changed drug unless a notice of compliance has been issued.

Authorization - Sale of New Drug for Emergency Treatment
A practitioner may request authorization to sell a new drug for human or veterinary use that has not been issued a NOC for use in the emergency treatment of a patient under his or her care by filing information concerning the medical emergency for which the drug is required, data with respect to the use, safety and efficacy of that drug, the names of all institutions in which the drug is to be used and other data as required by the regulator. Based on this information, the regulator may issue a letter of authorization to a practitioner authorizing the sale of a limited quantity of a new drug. The letter must indicate the name of the practitioner to whom the new drug may be sold, the medical emergency and the quantity of the new drug that may be sold to that practitioner for that emergency. The sale of a new drug is exempt from the provisions of the Act and these Regulations if made in accordance with the authorization.

Authorization - Clinical Testing of a New Drug for Veterinary Use A manufacturer is prohibited from selling a new drug for the purpose of clinical testing for veterinary use unless a preclinical submission containing information regarding the drug and the study has been provided to the regulator and the regulator has not indicated within 60 days that this information is unsatisfactory.

Authorization - Experimental Studies
An experimental study is a limited test of a new drug in animals carried out by an experimental studies investigator. Prior to selling a drug to an investigator a manufacturer must file an application for an experimental studies certificate. Application requirements include information about the drug and quantity to be used in the study; study objectives, premises and facilities; qualification of investigators; results of toxicological or pharmacological studies; species, number and production type of animals. Where a food-producing animal is involved in the study, a written agreement not to sell the animal or its products without prior authorization from the investigator must be obtained from the owner of the animals and included in the application. Additional information or samples may be requested by the regulator.

If satisfied that the proposed study can be conducted without undue foreseeable risk to humans or animals, the regulator must issue an experimental studies certificate, specifying the quantity of the new drug that may be sold to the investigator.

Post-authorization Obligations - General

Obligations apply to the manufacturer, practitioner, qualified investigator or other person as the case may be to conduct certain activities including collecting information about the drug and its effects, maintaining records and reporting to the regulator certain information on a regular basis, upon request of the regulator or when the safety of persons or animals exposed to the drug has or could be compromised.

Post-authorization Obligations - Sale of New Drug for Emergency Treatment

The practitioner to whom the authorization applies must report results of the use of the drug in the medical emergency and any adverse reactions to the manufacturer and regulator. Additionally, on request of the regulator, the practitioner must account for the quantities of drugs received under the authorization.

Post-authorization Obligation - Clinical Testing of a New Drug for Veterinary Use

Prior to selling a new drug for veterinary use to a qualified investigator for the purpose of clinical testing, the manufacturer must ensure that the investigational drug is labelled according to specific requirements, that every qualified investigator has the facilities and the necessary information to conduct the testing, that written agreement is obtain from qualified investigators regarding the use and quantities of the drug and the reporting serious adverse drug reactions. The manufacturer must keep records and report to the regulator all information respecting serious adverse reactions.

Post-authorization Obligations – Experimental Studies

A drug proposed for use in animals for the purpose of an experimental study must be labelled according to specific requirements and an experimental studies investigator must report all serious adverse drug reactions, maintain records, and report study results on request by the regulator.

Post-authorization interventions/Powers

Generally, the regulator has the ability to intervene after the sale of the drug has been authorized in order to protect the health of humans or animals exposed to the drug or otherwise safeguard public or animal health or to promote public safety. Interventions are normally triggered by the provision of information additional to that in the application that may become available to the regulator. An intervention may include a request from the regulator for additional information and can result in the suspension of an NOC (and the requisite cancellation of the associated DIN) or the suspension or cancellation of other types of authorizations found within this division. Action may also be taken to suspend or cancel an authorization if the requirements of the Act and Regulations are not met.

Interactions

- *Food and Drug Regulation*s: Part A, Part C (all divisions), Part D, Division 5 (Minerals in Drugs), Part G (Controlled Drugs)
- *Narcotic Control Regulations*
- *Benzodiazepines and Other Targeted Substances Regulations*
- *North American Free Trade Agreement Implementation Act*

Appendix A – Summary of Where We Are

- *World Trade Organization Agreement Implementation Act*

DIVISION 9
Non-prescription Drugs

Purpose

This division sets out additional compositional and labelling standards for a few commonly used non-prescription analgesic drugs for human use.

Design

Prohibition

Prohibitions restrict the sale of the named drugs unless the prescribed labelling, packaging, composition and dosage requirements are met. These prohibitions supplement those found in Division 1. There is also an absolute prohibition on the sale of certain drugs in combination. Although the application of this division is to non-prescription drugs available for self selection to the consumer, unique labelling requirements are included to consult a physician if exceeding recommended doses or when underlying conditions persist.

Interactions

Division 1 of the *Food and Drug Regulations*

Natural Health Products Regulations

A natural health product (NHP) includes substances that can be found in living organisms or a synthetic duplicate of those substances, minerals or a live microorganisms as listed in Schedule 1 but excludes the substances listed under Schedule 2 of the Regulations. Substances that require prescription or administration by injection are regulated under the *Food and Drug Regulations*.

PART 1
PRODUCT LICENCES

Purpose:

The purpose of this Part is to provide a mechanism to authorize the sale of NHP through the application of a licensing scheme.

The Regulations apply to NHP for human use only. The level of evidence necessary for the regulator to authorize a NHP by issuing a product licence depends on the nature of product and recommended use. Where a NHP is composed of commonly used medicinal ingredients for which their safety and efficacy is already established through a standard, additional evidence to support the safety and efficacy of the NHP may not be required.

Design:

Prohibition

The sale of a NHP is prohibited unless it has been issued a product licence and that licence has not been suspended or cancelled or the sale of the licensed NHP has not been directed to be stopped.

Authorization

An application for a product licence includes information such as medicinal ingredients, source, dose, potency, non-medicinal ingredients, recommended use(s), proposed labels, and supporting safety, efficacy and quality information.

If an application relates to a NHP for which its safety and efficacy is already established according to a standard in the compendium of monographs published by the Department of Health, the regulator must dispose of the application within 60 days by either issuing a licence or refusing to issue.

Authorization must also be obtained prior to selling a NHP affected by a change. Fundamental changes such as a change in the dose, medicinal ingredient, dosage form or route of administration require the filing of a new product licence application. Other major changes require the filing of an application to amend a product licence. Minor changes must be notified to the regulatory within 60 days of implementation.

Additional information or samples may be requested by the regulator if necessary to determine whether to issue or amend a licence. The regulator issues or amends a product licence if the application meets the requirements, does not include false or misleading statements and is not likely to result in injury to the health of a purchaser or consumer. A product number assigned to each licensed NHP.

If refusing to issue or amend, the regulator must notify the applicant of the reasons for the refusal. The applicant may make a request for reconsideration within 30 days and have an opportunity to be heard. If refusing to issue or amend again, the regulator sends the applicant a final notice.

Post-authorization Obligations

The licensee must provide the regulator with certain information prior to commencing the sale of the NHP, including information related to the site at which certain activities associated with the manufacturing of the NHP are conducted.

Licensees must also maintain certain records and report adverse reactions.

Post-authorization interventions

The regulator can request additional safety information if the regulator believes that the NHP may no longer be safe when used under the recommended conditions of use.

The regulator can stop the sale of a NHP if its safety information is not provided when requested or if it fails to demonstrate its safety or does not meet good manufacturing practices, packaging and labelling standards. The direction to stop the sale can be lifted if sufficient evidence demonstrating the safety and quality of the NHP is provided.

The regulator may suspend, by notice, a product licence, with or without giving an opportunity to be heard prior to the suspension depending upon the severity of the grounds for suspension. The licence may be reinstated or cancelled after consideration of additional information.

Interactions:

- Parts 2 and 3 of the *Natural Health Products Regulations*

PART 2
SITE LICENCES

Purpose:

Activities associated with a NHP may impact its quality and comprise its safety. Part 2 provides a mechanism to authorize the conduct of certain activities associated with NHPs. The purpose of this Part is to provide oversight such that activities associated with a drug meet good manufacturing practices (GMP) standards of Part 3 of these regulations.

Design:

Prohibition

The conduct of certain activities is prohibited unless it is authorized by a site licence that has not been suspended or cancelled and that these activities are conducted in accordance with the GMP standards set out in Part 3. These activities include: the manufacturing, packaging, labelling or importation for sale of a NHP. A site licence is not required for a NHP used for the purpose of a clinical trial.

Authorization

A person who wishes to conduct these activities must submit an application for a site licence that includes information regarding the activities and the buildings where activities will be conducted and a report from a quality assurance person demonstrating compliance with the GMP standards of Part 3.

Site licence holders file an application to amend their licence prior to implementing any major change such as adding an activity or building to a licence or to relinquish any part of their licence. An application for amendment is subject to the same requirements and process as for the original licence.

Unless renewed, a site licence expires one year after its issuance or at the end of the renewal period. If necessary, the regulator may request additional information prior to issuing, amending or renewing a site licence.

Post-authorization Obligations

Licensees must report any recalls of a NHP.

Changes in contact information or that affect GMP must be notified within 60 days of implementation.

Post-authorization interventions

The regulator may suspend, by notice, a site licence, with or without giving an opportunity to be heard prior to the suspension depending upon the severity of the grounds for suspension. The licence may be reinstated or cancelled after consideration of additional information.

Interactions:

- Part 3 of the *Natural Health Products Regulations*

Appendix A – Summary of Where We Are

PART 3
GOOD MANUFACTURING PRACTICES

Purpose

The safety and efficacy of a NHP depends on the continued assurance of its quality. Control over all aspects of the manufacturing through the application of good manufacturing practices (GMP) is a critical component to achieving this. Part 3 sets out the GMP standards that apply to the manufacturing, packaging, labelling, importation, distribution and storage of a NHP. The purpose of this division is to prevent the sale of NHPs that are adulterated or manufactured under unsanitary conditions.

Design

Prohibition

The sale of a NHP is prohibited unless is has been manufactured, packaged, labelled, imported, distributed or stored according to requirements set out in Part 3, however, the sale of a NHP is permitted if the above activities are conducted according to requirements that are equivalent to those set out in Part 3.

This Part provides for controls on aspects of the manufacturing of a NHP (manufacturing, packaging, labelling, importation, distribution and storage), specific to the premises (design, construction, maintenance), equipment used (cleaning, contamination, function), personnel (including training and qualifications), sanitation (health and hygiene), operations (standard operating procedures; control system for purposes of recall); quality assurance (measures to assure product quality), stability (determination of expiry date and recommendation of storage), record keeping, sterile NHPs (additional requirements), and ophthalmic use (preservatives and sterility testing requirements in the *Food and Drug Regulations*)

Obligations

Manufacturers, importers or distributors that commence a recall of a NHP are required to provide the regulator information relating to the recall.

Powers

The regulator has the ability to request lot and batch samples if believed to result in injury to the health of a purchaser or consumer.

Interactions:

- *Natural Health Products Regulations*, Parts 1 and 2
- *Food and Drugs Regulations*, Part C - Division 1

PART 4
CLINICAL TRIALS INVOLVING HUMAN SUBJECTS

Purpose

Clinical trials are used to discover the effects of a product and ascertain its safety and efficacy. Part 4 provides a mechanism to authorize the sale or importation of NHPs to be used for the purposes of clinical trials involving human subjects. The purpose of this division is to protect human clinical trial subjects and others involved.

Design

Prohibition

The sale or importation of a NHP for the purposes of a clinical trial is prohibited unless the trial is authorized and has not been suspended or cancelled. A clinical trial of a licensed NHP within the existing conditions of use is not subject to the requirements of this division.

Authorization

A clinical trial sponsor (a person responsible for the conduct of a trial) must obtain authorization from the regulator to conduct a clinical trial in Canada in respect of a NHP for use in humans that involves human subjects. Application requirements include the submission of information such as a protocol describing the objectives, design, methodology, statistical considerations and organization of the clinical trial, preclinical and clinical data, chemistry and manufacturing information. This information is examined by the regulator, and if necessary, additional information or samples may be requested. The regulator authorizes the trial by sending a notice to the sponsor.

Sponsors must obtain an authorization prior to implementing any major change to a previously authorized trial and must notify the regulator of minor changes within 15 days of implementation.

Post-authorization Obligations

Sponsors must notify the regulator 15 days prior the commencement of sale or importation of a NHP for the purpose of a clinical trial at a site.

Sponsors must follow good clinical practices designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons. These include the supervision by a qualified investigator and approval by a research ethics board at each clinical trial site, obtaining informed consent from participants, record keeping (25 years), and that the NHP is manufactured according to good manufacturing practices.

Sponsors must also ensure that investigational NHPs are labelled according to specific requirements, report serious unexpected adverse drug reactions, notify of the discontinuance of a trial in whole or in part for any reason.

Post-authorization interventions

The regulator has the ability to suspend or cancel, in whole or in part, an authorization to sell if the sponsor has

contravened the Act or Regulations, has failed to comply with their obligations or to prevent injury to the health of a clinical trial subject or other person.

Interactions

- *Food and Drug Regulations*, Division 1

PART 5
GENERAL

Purpose

This is a general part that applies to all of the *Natural Health Products Regulations* unless specifically exempted. It allows for the use of electronic signatures and electronic record keeping and sets out various labelling and packaging standards, and references specific requirements from the *Food and Drug Regulations*. It also exempts the advertising of a NHP for preventative purposes or the sale when labelled or advertised as such for the diseases listed in Schedule A to the *Food and Drugs Act*.

Design

Prohibitions

The sale of a NHP is prohibited unless it is labelled and packaged according to the regulations. This Part provides specific information that must be included on the package labelling as well as placement on the packaging, including basic information concerning the identity of the ingredients, the strength, recommended use, product number, lot number, expiry date and storage conditions. It also provides requirements on security packaging, as well as general requirements for pressurized containers, cautionary statements and child resistant packages and medicinal ingredient representations set out in the *Food and Drug Regulations*.

Specific prohibitions and requirements of the *Food and Drug Regulations* are referenced so that they apply to NHPs, including rules on importation; inspectors' functions, duties and responsibilities; sampling; export certificates; tablet disintegration times; and sale for emergency treatment.

Exemptions from prohibitions on advertising and sale at the level of the Act allow for the labelling and advertising of a NHP with preventative representations.

Interactions

- *Food and Drugs Act*
- *Food and Drug Regulations:* Part A, Part C

PART 6
AMENDMENTS, TRANSITIONAL PROVISIONS AND COMING INTO FORCE

This Part is no longer applicable. With the creation of a new regulatory framework for NHPs, some consequential amendments to the *Food and Drug Regulations* were required. The *Natural Health Products Regulations* came into force on January 1, 2004. A transitional period (up to December 31, 2009) was necessary for products that were formerly regulated under the *Food and Drug Regulations*.

Medical Devices Regulations

INTRODUCTION

There are four classes of medical devices covered by the *Medical Devices Regulations* (MDR), which are classified according to risk:

- **Class I devices** present the lowest potential harm, e.g. toothbrushes and band-aids. These devices do not require a licence, but manufacturers, distributors and importers are required to obtain an establishment licence in order to sell.

- **Class II devices** present the next level of potential harm, e.g. denture material, contact lenses and latex condoms. These devices require a licence, as well as a quality management system (QMS) certificate.

- **Class III devices** present the next level of potential harm, e.g. insulin infusion pumps, MRI machines and tracheal stents. These devices require a licence, a QMS certificate as well as additional information such safety and effectiveness evidence.

- **Class IV devices** present the highest potential harm, e.g. defibrillators, pacemakers and HIV test kits. These devices require a licence, a QMS certificate as well as additional information such safety and effectiveness evidence, risk assessment analysis and evaluation and detailed information regarding relevant studies.

PURPOSE

The purpose of the MDR is to **prevent harm** to humans associated with the use of medical devices and can be further defined by the following:

- preventing the sale of products that are unsafe, ineffective and of poor quality
- preventing the sale of devices manufactured under unsanitary conditions
- protecting clinical trial subjects and others involved
- providing information on the safe use of medical devices
- preventing the sale of unauthorized devices in Canada
- monitoring the safety of devices

Each provision of the regulations is designed to achieve one or more of these purposes.

STRUCTURE

The regulations and application requirements are structured around the four classes of devices within five Parts and three Schedules:

Appendix A – Summary of Where We Are

Interpretation, Application and Classification of Medical Devices
Part 1 – General application to medical devices
Part 2 – Custom-made devices and devices to be imported or sold for special access
Part 3 – Medical devices for Investigational Testing (clinical trials) involving human subjects
Part 4 – Export certificates
Part 5 – Transitional provisions, Repeal and Coming into force
Schedule 1 – Classification rules
Schedule 2 – Implants
Schedule 3 – Export certificate for medical devices (form)

DESIGN

The MDR include various mechanisms for regulating the safety, effectiveness and quality of medical devices; these mechanisms reflect the risk and level of oversight required, and include the following design features:

Prohibitions

A prohibition is a general rule forbidding certain activities. In the MDR, there are both general and specific prohibitions that are either absolute or partial in effect. General prohibitions related to sale and advertising are covered under sections 26 to 27. Partial prohibitions (e.g. prohibitions that include an "if" or "unless") give rise to the potential to establish other requirements. For example, in the MDR, the labelling requirements are designed as a partial prohibition – "No person shall import or sell a medical device unless the device has a label that sets out the following information…".

Rules of General Application

Part 1 of the MDR contains rules of general application through general obligations, including manufacturer's obligations, safety and effectiveness requirements, quality management systems requirements, labelling and advertising requirements and prohibitions.

Authorizations

The partial prohibition in section 27 on the sale or import of Class II, III or IV devices without a licence gives rise to the pre-market authorization/licensing scheme established under section 32. Generally, the authorization process involves an application, a decision by the regulator, and an opportunity for representation. An authorization cannot exempt a provision of the Act or the Regulations. There are several types of applications for authorization under the MDR:

- Class II licence
- Class III licence
- Class IV licence
- Licence Amendment
- Establishment Licence
- Investigational Testing (device clinical trials in humans)
- Custom-made devices and SAP devices

Appendix A – Summary of Where We Are

Note: Class I devices do not require a licence, but manufacturers, distributors and importers are required to obtain an establishment licence in order to sell Class I devices in Canada.

Post-Authorization Obligations
The holder of an authorization must fulfill certain requirements in order to maintain an authorization to sell a device.

Post-Authorization Interventions
Certain abilities are available to the regulator to monitor and address risks related to an authorized device and Class I devices.

Appendix A – Summary of Where We Are

INTERPREATATION
APPLICATION
CLASSIFICATION

The *Medical Devices Regulations* (MDR) begin with general sections directed to definitions of terms within the regulations (Interpretation), the Application of the regulations and general Classification provisions:

Interpretation (s. 1) – This section defines terms used within the MDR.

Application (ss. 2 to 5) – This section sets out what the MDR do and do not cover. For example, the MDR apply to sale, advertising and importation, but do not apply to importation for personal use.

- **MDRs apply** to sale, advertising and importation; to in vitro diagnostic product that is a drug or contains a drug (classification purposes); and certain sections apply to dispensers

- **MDRs do not apply** to importation for personal use, or drugs listed in Schedule E or F of the Act, Part G or J of the FDR, schedules to the CDSA or NCR, medical gas piping system as part of health care facilities (ISO standards)

Classification (s. 6 to 7) – These sections include the general rules to explain the risk classes and to specify that in cases where a device meets more than one class, the higher risk class applies.

Appendix A – Summary of Where We Are

PART 1 – GENERAL

Purpose

The term 'medical device' covers a great variety of products used in health care facility settings as well as at home. Examples include: toothbrush, bandages, knee implant, blood glucose meter, surgical instruments, condom, contact lenses, pacemaker, and hospital information systems. To be a 'medical device' (and not a consumer product, for example), these products must be for use in treating, mitigating, diagnosing, or preventing a disease or abnormal physical condition.

Faced with the challenge of regulating such a large spectrum of products, the regulations include **rules** to help classify devices into four risk classes, and the regulatory requirements are proportional to the risk class and level of oversight required. This risk-based approach allows Part 1 to address the purpose of **preventing harm** to humans associated with the use of medical devices; preventing the sale of products that are unsafe, ineffective and of poor quality; preventing the sale of devices manufactured under unsanitary conditions; providing information on the safe use of medical devices; preventing the sale of unauthorized devices in Canada; and monitoring the safety of devices once they are on the Canadian market.

Design

Rules of General Application

Part 1 of the MDR contains rules of general application through general obligations, including manufacturer's obligations, safety and effectiveness requirements, quality management systems requirements, labelling and advertising requirements.

A prohibition is a general rule forbidding certain activities, and the MDR contain both general and specific prohibitions that are either absolute or partial in effect. General prohibitions related to sale and advertising are covered under sections 26 to 27. Partial prohibitions (e.g. prohibitions that include an "if" or "unless") give rise to the potential to establish other requirements.

Prohibitions on Sale or Import – Labelling

Part 1 includes a partial prohibition on sale that gives rise to the prescribed labelling requirements for medical devices. Basic information concerning the device and its intended use, packaging, directions for use, expiry date, and storage conditions are required for all devices. In addition, the manufacturers name and address and the device identifier must appear on the label to facilitate traceability and corrective action such as recall. Further labelling is required to identify a device that is sterile. Device labels are also required to be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.

Prohibition on Sale or Import – General

The sale or import of any device is prohibited unless a medical device licence or amended device licence has been assigned. This prohibition gives rise to the authorization schemes in the MDR. Another important prohibition on sale relates specifically to a lot of unlicensed in vitro diagnostic devices (IVDDs) based on terms and conditions set out pursuant to section 36.

Appendix A – Summary of Where We Are

Prohibition on Sale – Advertising

The advertising for sale of any Class II, III or IV device is prohibited unless a medical device licence or amended device licence has been assigned, or the advertisement includes a warning that the device may not have been licensed for sale in Canada.

Prohibition on Sale or Import – Establishment Licensing

The sale of any device is prohibited unless an establishment licence has been issued.

Authorization

The partial prohibition in section 27 on the sale or import of Class II, III or IV devices without a licence gives rise to the pre-market authorization/licensing scheme established under section 32. Generally, the authorization process involves an application, a decision by the regulator, and an opportunity for representation. An authorization cannot exempt a provision of the Act or the Regulations. There are several types of applications for authorization under Part 1:

- Class II licence (s. 32.(2))
- Class III licence (s. 32.(3))
- Class IV licence (s. 32.(4))
- Licence Amendment (s. 34)
- Establishment Licence (ss. 44 to 51)

Note: Class I devices do not require a licence, but manufacturers, distributors and importers are required to obtain an establishment licence in order to sell Class I devices in Canada.

Part 1 also includes a process for the mutual recognition of other country's regulatory review/authority and conformity assessment body (s. 33).

Requirements for manufacturers seeking authorization to export their devices for the purposes of implementing the General Council Decision are included in ss. 43.2 to 43.6.

Post-authorization Obligations

Obligation to Inform (s. 43) – This section pertains to **annual renewal.** It includes the requirement for manufacturers to inform of their intent to continue selling their devices, and to confirm that there haven't been changes to information or documents from the original application. This section also includes the ability to cancel a licence if the manufacturer doesn't comply, as well as the requirement for manufacturers to inform the regulator within 30 days after the discontinuance, which leads to a cancelled licence

Obligation to submit certificate (s. 43.1) – Sets out the requirement for manufacturers to submit a QMS certificate if it has been updated due to a licence amendment (s. 34).

Distribution records (ss. 52 to 56) – These sections apply to manufacturers, importers and distributors; does not apply to retailer/health care facility; and apply to "implants" (links to implant registration section 67). The purpose of tracking records is explained to facilitate any needed quick and accurate withdrawal of device from

market. Also included is the requirement to retain records for longer of the projected useful life of device and two years after the device is shipped.

Complaint handling (ss. 57 to 58) **–** These sections apply to manufacturers, importers and distributors; does not apply to retailer or health care facility; covers reported problems related to performance and safety, as well as corrective actions; and requirement to establish procedures to enable effective and timely investigation and recall.

Mandatory problem reporting (ss. 59 to 61) – Applies to manufacturers and importers; sets out requirements for the preliminary report (within 10days) and final report (timeline established in preliminary report, plus corrective actions) on incidents (inside or outside Canada) related to: device effectiveness, labelling, directions for use and has lead to death or serious deterioration of health. These sections specify that the preliminary and final reports can be submitted by the importer on the manufacturer's behalf if information from both would be identical

Recall (ss. 63 to 65) – Applies to manufacturers and importers; does not apply to retailers or health care facilities. These sections set out recall requirements (e.g. risk evaluation, reason, number of affected units, proposed action to prevent recurrence, communication issued) and results of the recall. It is specified that this information can be submitted by the importer on the manufacturer's behalf if information from both would be identical

Implant registration (ss. 66 to 68) – Sets out requirements for the manufacturer regarding implant registration cards; requires staff at health care facility to fill out the card with facility information and patient information, then send 1 card to manufacturer and 1 card to patient; includes consent; allows manufacturer to use another method than the implant registration cards, if the method is found sufficient. These requirements pertain to "implants" as listed in Schedule 2 of the MDR

General Council Decision (ss. 43.2 to 43.6) – These sections link to the *Patent Act* and manufacturers are required to notify Health Canada not less than 15 days prior to commencing the manufacture of the device to be exported.

Post-Authorization Interventions

Ability to request evidence of Safety and Effectiveness and Stop Sale

For Class I devices, section 25 includes the ability for regulator to request evidence of safety and effectiveness, as well as ability to require a stop sale.

Ability to request additional information and samples if insufficient safety and effectiveness evidence

For Class II, III and IV devices, section 35 sets out the ability to request additional information if insufficient safety and effectiveness evidence is submitted, as well as ability to request samples.

Issuance (s. 36) – Establishes that if the manufacturer meets the safety and effectiveness requirements (for an application or amendment application), the regulator shall issue a licence, and the ability of the regulator to set terms & conditions on the licence.

Refusal to issue (s. 38) – Establishes a notification scheme with opportunity to be heard in respect of the decision to refuse a device licence application. This section prescribes the basis for refusal: if the applicant does not complying with the Act or regulations; if the application includes a false or misleading statement; if the device does not comply with the labelling requirements; if the applicant has not complied with the request for additional information or samples; and if the applicant doesn't meet the safety and effectiveness requirements.

Additional Information (s. 39) – This post-market ability to request the manufacturer to submit information or samples extends to the case where a report or information is brought forward that is believed (on "reasonable grounds") to question a device's safety and effectiveness.

Suspension (ss. 40 to 42) – Sets out the notification scheme, with considerations prior to suspension, with the opportunity to be heard (unless it is necessary to prevent injury to health or safety). These sections also set out the circumstances that may result in the suspension of a licence; provides the opportunity to request reconsideration; and allows for a licence to be reinstated.

PART 1 – CUSTOM-MADE AND SPECIAL ACCESS DEVICES

Purpose

This Part applies to custom-made devices (defined to be devices, other than mass-produced devices, that are made based on physician's written direction and design, and is for the sole use by a particular patient) and devices to be imported or sold for special access (defined to be for emergency use or if conventional therapies have failed or are unavailable or are unsuitable). The authorization process is different for Part 2 in that it is the health care professional who requests authorization to permit the manufacturer or importer to sell them a custom-made or special access device.

The sections of Part 2 (ss. 69 to 78) address the purpose of **preventing harm** to humans associated with the use of these specific-use medical devices; preventing the sale of products that are unsafe, ineffective and of poor quality; providing information on the safe use of medical devices; preventing the sale of unauthorized devices in Canada; and monitoring the safety of devices once they are on the Canadian market.

Design

This Part contains rules of general application and prohibitions. It sets out the information required for a medical device licence application for these products, and the process that health care professionals and manufacturers must follow to obtain such a licence. For the post-market context, this Part sets out the requirements for distribution records and incident reporting.

Prohibition

General (s. 70) – Prohibition on sale or importation of a **Class III or IV** custom-made device or a device for special access unless the regulator has issued an authorization.

Labelling (s. 75) – Prohibition on sale or import of these devices unless the label stages the name of the manufacturer, name of the device and whether it is custom-made or for special access.

Appendix A – Summary of Where We Are

Authorization

Authorization (ss. 71 to 72) – These sections set out the process to receive authorization, and that the health care professional requests authorization to permit the manufacturer or importer to sell them a device. Application requirements are set out in these sections, and the authorization is given to the manufacturer. There is special mention that this mechanism cannot be used to circumvent Part 1 (regular market authorization route). Also included is the ability to request additional information and the ability to cancel authorization; labelling requirements; distribution record requirements; incident reporting requirements; and implant registration requirements (linked to s. 67).

Post-authorization Obligations and Interventions

Additional Information (ss. 73 to 74) – These sections related to the regulator's ability to request additional information from the manufacturer, importer or health care professional, and issue a cancellation based on prescribed reasons.

Distribution Records (s. 76) – The requirement to maintain distribution records (as set out in ss. 52 to 56) applies to manufacturers or importers of these devices.

Reporting an Incident (s. 77) – This section requires health care professionals to report any incidents as described in section 59 (Mandatory Problem Reporting) within 72 hours to the regulator.

PART 3 – INVESTIGATIONAL TESTING INVOLVING HUMAN SUBJECTS

Purpose

Clinical trials (investigational testing) are used to discover the effects or performance of an unauthorized device and ascertain its safety and efficacy. Part 3 (ss. 79 to 88) provides a mechanism to authorize the sale or importation of devices to be used for the purposes of clinical trials involving human subjects. The purpose of this division is to protect human clinical trial subjects and others involved.

Design

Part 3 contains rules of general application and prohibitions for devices to be used for clinical trial purposes in human subjects. Part 3 also sets out the information required for an investigational testing application, and the process that qualified investigators must follow to obtain such an authorization. For the post-authorization context, this Part lists sections of the regulations that still apply to devices for investigational testing: distribution records, complaint handling, mandatory problem reporting, recalls, and implant registration.

Prohibition

General (s. 80) – Prohibition on sale or importation to a qualified investigator (links to authorization and possession of records) for Class II, III or IV devices; prohibition on sale to qualified investigator (links to possession of records) for Class I, which means that there is no authorization required for Class I devices to be used in IT.

Labelling (s. 86) – Prohibition on sale unless device labels meet prescribed requirements.

Advertising (s. 87) – Prohibition on advertising unless there is an authorization and the advertisement indicates that the device is for investigational purposes.

Authorization

Records (s. 81) – Sets out records required in order to authorize a device for use in a trial, including research ethics boards approval for Class III and IV devices.

Authorization (ss. 82 to 83) – Sets out records requirements specifically for Class II, III and IV devices in order to authorize a trial.

Post-authorization Obligations and Interventions

Additional Information (ss. 84 to 85) – Sets out the ability for the regulator to request additional information and ability to notify regarding requirements to stop sale (Class I) or cancel authorization (Class II, III, IV).

Other requirements (s. 88) – Lists sections of the regulations that still apply to devices for investigational testing: distribution records, complaint handling, mandatory problem reporting, recalls, implant registration.

PART 4 – EXPORT CERTIFICATES

This Part (ss. 89 to 92) links to section 37 of the *Food and Drugs Act* (Exports), and sets out the necessary information needed and the requirements to obtain an export certificate, such as signatures, dates, retention. This Part is also linked to Schedule 3 of the MDR (export certificate form).

PART 5 – TRANSITIONAL PROVISIONS, REPEAL, COMING INTO FORCE

This Part (ss. 93 to 97) is no longer relevant; it covers the transition from the "old regulations" as well as repealed sections.

SCHEDULE 1 – Classification rules

This Schedule includes the 25 rules that help determine the risk class of the medical device, and is separated into two Parts:

- Part 1 – Rules for Devices other than IVDDs: Invasive, Non-invasive, Active and Special Rules
- Part 2 – Rules for IVDDs: Used with respect to transmissible agents, Other Uses, Special Rules

SCHEDULE 2 – Implants

This Schedule sets out the devices considered to be implants under the MDR, and is linked to the implant registration requirements (ss. 66 to 68).

SCHEDULE 3 – Export certificate

This Schedule sets out the export certificate form for medical devices, and is linked to PART 4 of the MDR (Export certificate) and the General Council Decision (ss. 43.2 to 43.6).

Appendix A – Summary of Where We Are