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THERAPEUTIC PRODUCTS PROGRAMME

MEDICAL DEVICES BULLETIN

Health Canada's mission is to help the people of Canada maintain and improve their health.

A Message from the Director General – TPP

With the publication of new Medical Devices Regulations in Canada Gazette Part II on May 27, 1998, and their implementation on July 1, the management and staff of the Therapeutic Products Programme (TPP) would like to express our appreciation to all those stakeholders who took the time to participate on advisory groups or in consultation workshops or to provide their comments through the various stages of developing these Regulations. I would also like to thank TPP staff, and especially the Medical Devices Bureau staff, who worked diligently, but patiently, to develop a regulatory framework of which Canada can be proud.

By now, many of our industry stakeholders already know that Ms. Beth Pieterson became the Acting Director of the Medical Devices Bureau when her predecessor, Dr. Richard Tobin, left the Programme in November 1997 to participate in the government's senior management development programme. I would like to congratulate Ms. Pieterson for successfully stepping in and managing the completion of the task so ably started by Dr. Tobin.

Promulgation of the new Medical Devices Regulations is only one of the milestones that TPP has successfully achieved this year. Other major accomplishments include the Commercial Hemp Regulations, a major Clinical Trial Regulation Review, and progress on various International Mutual Recognition Agreements (EU, Switzerland, EFTA, Australia, Japan, USA). Additionally, in April, 1998, the Bureau of Compliance and Enforcement was created within the Programme to strengthen our inspection and investigation capabilities.

With many challenges still facing us as we move forward towards the 21st century, I seek your continued cooperation and assistance in developing the Therapeutic Products Programme into one of the most efficient and effective regulatory agencies in the world. It is our shared responsibility to continue to ensure that the therapeutic products made available to Canadians are safe, effective and of high quality.

Dann Michols

In This Issue

Editorial – Director MDB

As the Acting Director of the Medical Devices Bureau since November 1997, I would like to add my appreciation in addition to that of Dann Michols regarding the effort put in by medical device stakeholders and TPP staff in finalizing the new Medical Devices Regulations.

The goal of the new Regulations is to implement a risk-based framework that is consistent with the contemporary regulatory framework in place with our major trading partners. This global harmonisation of activities regulating medical devices will ultimately speed up the review process for new devices and device technology and allow easier and quicker access both to Canadian and foreign markets through Mutual Recognition Agreements.

The classification system provides for the premarket review of a greater range of devices than under the previous Regulations – with the degree of review based on the class of the device rather than whether it was included in the short table to Part V.

A series of guidance documents explaining various Sections of the Regulations prepared by TPP staff have been posted on our website. Stakeholders affected by specific Sections of the Regulations are encouraged to view the relevant guidance document.

We realize that the medical device industry faces an array of challenges in complying with the new Regulations. TPP staff are making every effort to make this transition as easy as possible through a variety of information providing activities such as guidance documents and frequently asked questions on the website, dedication of most of this issue of the *Bulletin* to the Regulations and the creation of an in-house phone number and e-mail address to act as a focus point for any further questions you may have. In addition to these activities, a number of Regulatory Workshops, in collaboration, with the medical device industry are being conducted by the TPP staff.

Year 2000 (Y2K) is fast approaching. Given the number of devices that are now computer or micro-processor controlled, the Programme is preparing a Y2K page on our website to assist device users in determining if the potentially affected devices they use are Y2K compliant or not. A letter has been issued to manufacturers requesting data on relevant devices which will be posted on our website.

The TPP website is becoming increasingly important as a means of providing information, in a timely and economical fashion, to all stakeholders, including the general public. As a result, the website itself is being updated so you may notice changes in its design. The end result should be a website that is client focussed and user friendly.

Cooperative efforts have seen us to the finalization stage of the Regulations, our continued cooperation will see us through the implementation phase, past the Y2K hurdle and on to new challenges that await.

Beth Pieterson

Frequently Asked Questions Concerning the New Medical Devices Regulations

Q 1 Where can I get a copy of the New Regulations?

A. Copies of the new Medical Devices Regulations can be down loaded from our website at: hc-sc.gc.ca/hpb-dgps/therapeut/ Select the Index heading, then select Regulations. The new Regulations are listed under Schedule 1101. The Regulations can also be found at: www.canada.gc.ca/gazette. Please note that you may need to have a pdf file reader capability (eg. Adobe Acrobat Reader), or an unzip file capability to accomplish this. Alternatively, hard copies

can be purchased by contacting: Canada Communications Group, Publishing, Ottawa, Ontario, K1A 0S9 (Tel) 819 956 4802 (Fax) 819 994 1498. Please quote issue number: Canada Gazette Part II, Volume 132 # 11, dated 27 May, 1998. Copies are $3.50 each plus shipping and applicable taxes.

Q 2 Under the new Regulations, medical devices are classified into four classes. How will I know which class my device belongs in?

A. Manufacturers will be able to classify their devices according to the rules of the Risk-Based Classification System (RBCS) as per Schedule I *"Classification Rules for Medical Devices".* Part 1of the Schedule is applicable to non IVDDs, while Part 2 is for IVDDs. Programme staff have prepared a guidance document to assist manufacturers in determining the correct classification for their devices, including listings of typical Class I, II, III and IV devices. Classifications assigned by the manufacturer will be reviewed by TPPstaff. The TPP retains the authority to assign the appropriate device classification.

Q 3 My device may be classified into more than one class, which classification will apply?

A. Where a medical device can be classified into more than one class, the device will be assigned to the higher of the two classes, i.e. Class IV will be applied rather than Class III, etc.

Q 4 What if I do not agree with the classification indicated by the rules of the RBCS, or the TPP?

A. There will be provisions for manufacturers to appeal a device classification to the Medical Devices Bureau Director. Manufacturers are encouraged to contact the Bureau to discuss their device classification prior to submitting a licence application if they are uncertain of the device's classification.

Q 5 Do I have to obtain a licence for devices in each of Classes I, II, III and IV?

A. Manufacturers will have to obtain a device licence for each device in Class II, III and IV. Class I devices will not require a device licence. However, a manufacturer of Class I devices will be required to obtain an establishment licence and submit a generic listing of Class I devices to TPP, if he is not selling devices through a licensed importer or distributor.

Q 6 Do I have to obtain a licence for a device that is already on the market and is in compliance with the old Regulations (i.e. the device is notified under Part II or has a Notice of Compliance under Part V, if applicable)?

A. Devices that are already notified and in compliance with Parts II and V of the old Regulations, as applicable, by June 30, 1998, will not require a device licence until February 1, 1999. There is a five month grace period (September 1, 1998 - February 1, 1999. September 1, 1998 is the initial date device licence applications for previously notified devices will be accepted) to obtain licences for devices that are already notified as of June 30, 1998. The device licence is renewable every year thereafter.

Q 7 Will Class II, III and IV devices, that are being sold prior to July 1, 1998 and are in compliance with Parts II or V, if applicable, of the old Regulations, have to undergo a premarket review of safety and efficacy as required for these device classes under the new Regulations?

A. No. Devices that are in compliance with Parts II or V of the old Regulations prior to July 1, 1998 are deemed to be in

compliance with the requirements for Class, II, III or IV devices under the new Regulations. No further proof of safety or efficacy will have to be submitted, unless specifically requested by the TPP. However, all of these devices must be licensed by February 1, 1999. The device licence is renewable every year thereafter.

Q 8 Can a device licence be refused?

A. Yes. A device licence can be refused if:

- the applicant does not comply with these Regulations or any provisions of the Food and Drugs Act relating to medical devices;
- a false or misleading statement was made in the device licence application;
- the manufacturer has not supplied requested information, or has not provided sufficient evidence to support safety and efficacy requirements for Class II, III or IV devices; or,
- the medical device does not comply with the labelling requirements set out in Section 21.

Effective July 2001, a device licence can be refused if the device is not manufactured under specified quality system requirements as stated in ISO 13488 for Class II devices and ISO 13485 for Class III and IV devices.

Q 9 Can a device licence be suspended?

A. Yes. A device licence can be suspended if the device licencee is found to have contravened any provision of the Food and Drugs Act or the Regulations, or if, after the device licence has been issued, the device is no longer considered to be safe or effective, or the labelling is later found to be false, misleading or incomplete.

The licence may be suspended with or without an appeal by the licencee depending on the hazard that is presented by the device. Following a review and any corrective action required by the manufacturer, a suspended device licence may be reinstated if the reason for the suspension has been corrected, or if the reason for the suspension was unfounded.

Q 10 Were applications for a device licence accepted before July 1, 1998? Is there a transition period?

A. No. The old Regulations remained in effect until June 30, 1998. Device licence requirements did not come into effect until the new Regulations were implemented July 1, 1998.

Q 11 As an importer or distributor, can I obtain a device licence on behalf of the manufacturer?

A. Yes, an importer or distributor, or any other individual designated by the manufacturer, can submit an application for obtaining a device licence. However, the designated party is required to submit the authorization from the manufacturer, in writing, on the form prescribed by the Programme. This policy will be detailed in a guidance document on how to obtain a device licence.

Q 12 If Class I devices do not require a device licence, how will the TPP know which Class I devices are on the market, or investigate a mandatory problem report involving a Class I device?

A. Manufacturers of Class I devices, or their Canadian importer or distributor, will have to acquire an establishment licence and provide the TPP with certain information on the type of Class I devices they sell. Manufacturers and importers of Class I devices are subject to safety and effectiveness requirements as stipulated in the Regulations and are required to have procedures in place to report incidents to the TPP which meet the definition of a mandatory report. The fact that a Class I

device does not require a device licence does not remove the obligation of the manufacturer and importer to comply with other parts of the Regulations including mandatory reporting, reporting of recalls, investigation of incidents and maintaining records of these incidents.

Q 13 How will the TPP deal with the bundling of several similar devices that differ only in size or identifier number with respect to a device licence – could one licence cover several similar devices?

A. Some provision will be made for bundling of similar devices under one licence, but this will depend to some extent on the devices in question. A guidance document on device type is available but beyond that, for the purpose of device bundling, the TPP would have to consider the indications for use, label names and significant change aspects of the various devices to be included in the bundle.

Q 14 Is it acceptable to submit clinical data to establish device safety and efficacy that was obtained at a foreign site?

A. Clinical data generated at a foreign site may be acceptable provided the data came from a recognized site, was collected under a strict protocol, involved ethics committee review as part of the protocol, and clarification is provided if money was an issue during the investigational testing. Verification of foreign site testing, or approval of data previously produced during foreign site testing, will be confirmed with the TPP on a case-by-case basis.

Q 15 Does the device label have to be bilingual?

A. No. The device label can be in a minimum of English **or** French. Should the directions for use be supplied in only English or French at the time of sale, the directions have to be available from the manufacturer in the other language should they be requested by the purchaser of the device. However, for devices that are sold at a self-service display such as at a drug store or grocery store, the directions for use must be in both English **and** French.

Q 16 Who requires an establishment licence?

A. Device importers and distributors are required to hold an establishment licence by January 1, 1999. Additionally, manufacturers of Class I devices, unless they have a Canadian importer or distributor, are also required to hold an establishment licence by January 1, 1999.

Q 17 Will I have to obtain an establishment licence? If yes, under what circumstances?

A. All Canadian importers and distributors of medical devices will be required to obtain an establishment licence prior to initiating sale of medical devices in Canada. Manufacturers of Class II, III and IV devices are not required to obtain an establishment licence – unless they also manufacture Class I devices. Manufacturers of Class I devices are required to obtain an establishment licence unless they have a Canadian importer or distributor.

Where a manufacturer also distributes devices that are not manufactured by their company, they are required to licence their establishment as a distributor.

There will be a phase-in period for obtaining the initial establishment licence from November 1, 1998 to January 1, 1999. All establishments must be licensed by January 1, 1999. The establishment licensing fees will be payable starting January 1, 1999.

Q 18 If I am a manufacturer, and also import or distribute a device that is not manufactured by my company, do I have to obtain an establishment licence?

A. Yes. In this case, you are considered to be acting as an importer or distributor on behalf of the manufacturer, and you will be required to obtain an establishment licence. A guidance document will clarify what is required from a company applying for an establishment licence.

Q 19 If I am a Canadian subsidiary and licence a device manufactured at a foreign site, am I also required to apply for an establishment licence?

A. It depends on how you wish to take responsibility for the device. If you choose to be labelled as the 'manufacturer' on the device label, i.e your company's name and address appear on the label, then you must apply for the device licence. If you choose to be the importer or distributor only for the device, then you must obtain an establishment licence. A foreign manufacturer must apply for the device licence.

Q 20 Since manufacturers of Class II, III and IV devices are not required to hold an establishment licence, how will the TPP keep track of these manufacturers?

A. Manufacturers of Class II, III and IV devices will be required to obtain a device licence for each device they sell. The information provided to the TPP in the application for the device licence, such as device name, device identifier, manufacturer's name, address, etc. will be maintained in the TPP's medical devices database. The database will continue to be an important tool to track all devices and their manufacturers.

Q 21 Do I have to obtain an annual establishment licence?

A. Yes. Establishment licences will be renewed annually for the period from January 1st to December 31st. The first establishment licence renewal will occur in January 2000.

Q 22 Can an establishment licence be refused?

A. Yes. An establishment licence will be refused where the applicant has made a false or misleading statement in relation to the application for the licence.

Q 23 Can an establishment licence be suspended?

A. Yes, suspension of the establishment licence will result if:

- the licencee has contravened any provision of the Food and Drugs Act or the Regulations; or,
- the establishment licence application is found to contain a false or misleading statement.

An appeal process will be available. An establishment licence may be reinstated if the reason for the suspension is corrected, or if the reason for the suspension was unfounded.

Q 24 Will there be an appeal process if my application for a device or establishment licence is rejected?

A. Yes. The appeal process will be detailed in a guidance document.

Q 25 The ISO 13485/13488 (ISO 9001/9002) system is not related to device Class, but is being used in the new Regulations in a risk-based context. Why is the TPP using the ISO system in a manner that appears inappropriate?

A. The quality system standard ISO-13485 is more stringent than the ISO-13488, as the former incorporates design control requirements for medical devices. The rules of the Classification Systems classify all medical devices on the basis of the hazard they present to patients. The quality system requirements are related to the Class of the device. Therefore, quality system requirements for manufacturing Class II devices are less stringent than

those for manufacturing Class III and IV devices. Nevertheless, based on good business practices, all manufacturers are encouraged to incorporate the design controls included in ISO-13485.

Q 26 If the device is manufactured in the US under the FDA Quality System Regulations, or bears the CE mark for Europe, will either satisfy the Canadian ISO 13485 or 13488 requirement?

A. No. Manufacturers must comply with Canadian Regulations (as they will with US or European requirements). Canadian Regulations require conformity with ISO 13485 or 13488. The assessment of quality systems must be conducted by an organization that is acceptable to Health Canada. At this time, quality system assessment decisions by foreign organizations are not considered acceptable to demonstrate compliance with Canadian Regulations. The acceptability of foreign assessment decisions will be addressed through Mutual Recognition Agreements (MRAs) which will allow reciprocity of decisions – a device that is in compliance in one country will deemed to be in compliance in another country. MRAs are progressing but are not expected to be fully in place for several years. In the mean time, Canadian Regulations must be complied with.

Q 27 Are MRAs a dream? When will they be signed?

A. MRAs are not a dream any longer! **A Mutual Recognition Agreement between Canada and the European Community was signed on May 14, 1998 at the EU-Canada summit in London, UK.** For details on this first MRA, please see the article on Page 14. Additionally, discussions/negotiations are underway with Switzerland, the EFTA EEA states (Norway, Iceland, Liechtenstein) and Australia/New Zealand using the MRA model developed with the EU.

Q 28 Why are Canadian requirements being harmonized with those of foreign regulatory authorities?

A. Canadian requirements are being harmonized with those of foreign regulatory authorities in order to:

- eliminate regulatory requirements that are unique to Canada to the extent possible;
- raise the level of regulatory scrutiny for devices sold in Canada to the same level of scrutiny that is currently being exercised by Canada's major trading partners; and,
- facilitate the development and implementation of MRAs.

At present, no country accepts device approvals from any other country. MRAs will facilitate access to foreign markets for domestic manufacturers. Harmonization should reduce the burden of 'unique to Canada' information requirements so that, in principle, domestic manufacturers would not have to generate any new information solely to meet Canadian requirements. The same would apply for Canadian manufacturers preparing to sell devices outside of Canada. Once MRAs are in place, state-of-the-art devices should be available quickly, on a global basis, to all partners of the MRA.

Q 29 Who has to maintain distribution records?

A. Distribution records for each device must be maintained by manufacturers, importers and distributors to allow, if necessary, rapid withdrawal of the product from the market or modification of the device at the location it is being used.

Q 30 How long do distribution records have to be maintained?

A. Distribution records have to be maintained for whichever is longer, the projected useful life of the device (long

term durable devices such as x-ray machines, etc.) or for two years after the device is shipped (short life devices or single use devices such as syringes, etc.).

For further information contact the Bureau: tel: (613) 957-1909, or **mdb-bmm@hc-sc.gc.ca** (e-mail).

Guidance Documents to the New Medical Devices Regulations

In the last few months, a number of guidance documents have been appearing on the TPP website to assist manufacturers in acquiring a better understanding of the statutory requirements of the new Medical Devices Regulations, which were implemented on July 1, 1998. The creation of the guidance documents was initiated following a number of consultative meetings with industry representatives and stakeholders, where the need for such documents was expressed by all interested parties.

Postings began in February and will be completed by the end of July. These documents were initially posted in draft form, consideration was given to all comments received in writing, which led to the revised versions. Topics of the guidance documents posted to date include: interpretation of significant change, how to determine device licence type, complaint handling and recalls, classification rules for devices (IVDDs and Non-IVDDs), device and establishment licensing, labelling, preparation of a premarket review submission for Class III and IV devices, special access programme for devices and custom devices, etc.

Documents range in length from 5 to 30 pages, based on the complexity of the topic covered. All guidance documents are uniquely numbered and include a cover memo with a contact name. For ease of reading, efforts have been made to keep uniformity in their layout. Where needed for clarity, diagrams, flow charts, theoretical examples and forms for licence applications and mandatory problem reporting are included.

All guidance documents are available at **www.hc-sc.gc.ca/hpb-dgps/therapeut/**. The documents are posted as zipped WordPerfect 6.1 files and as PDF files. To read them requires an unzip capability or a PDF file reader such as Adobe Acrobat. *Bulletin* readers are encouraged to consult the website on a regular basis as the website becomes the prime resource centre for TPP publications.For further information contact the Bureau: tel: (613) 957-1909, or **mdb-bmm@hc-sc.gc.ca** (e-mail).

Transitional Provisions

Transitional provisions describe the time frames and any requirements that will permit devices that were in compliance as of June 30, 1998, with Parts II or V, as applicable, of the old Medical Devices Regulations, to be merged with the new Regulations that came into effect July 1, 1998. The provisions establish time frames to have these devices licensed under the new Regulations, and for their manufacturers, importers and distributors to obtain an establishment licence, meet quality system requirements, etc.

All devices marketed prior to July 1, 1998, i.e. those devices that were notified and in compliance with Parts II or V, as applicable, of the old Regulations, and that fall into Class II, III or IV of the new Regulations, will require a device licence under the provisions of the new Regulations by February 1, 1999.

Devices that were notified prior to July 1, 1998 will qualify for grand-fathering of requirements for Class II, III and IV under the new Regulations if their manufacturers have a valid notification, or have submitted a notification for their devices under Part II of the old Regulations

as of June 30, 1998, **or**, if the manufacturers have a valid Notice of Compliance. Unless specifically requested by TPP, no further documentation to substantiate claims made for these devices will be required.

Importers and distributors, manufacturers of Class I devices who do not have a Canadian importer or distributor, and manufacturers that distribute devices that they do not manufacture, will be able to apply for an establishment licence under the new Regulations as of November 1, 1998. They will have to hold an establishment licence by January 1, 1999.

The quality system requirements for manufacturers will come into force on July 1, 2001. All applications must then contain the attestations required under Part I, *Class II, III and IV Medical Devices* of the new Regulations.

NOTE: All new devices introduced to the market on or after July 1, 1998 will be subject to the new Regulations, **including** device licence requirements. For further information contact the Bureau: tel: (613) 957-1909, or **mdb-bmm@hc-sc.gc.ca** (e-mail).

Device & Establishment Licensing

The new Medical Devices Regulations contain provisions governing the sale, importation, clinical testing and advertisement of medical devices in Canada. The level of regulatory scrutiny to be applied in these areas is based on risk management principles. Devices will be classified into four classes using a rules-based system, with Class I representing the lowest risk devices and Class IV the highest. The Regulations will prohibit the importation or sale of a Class II, III or IV device unless the manufacturer holds a valid licence for that device.

The new Regulations will also introduce establishment licensing to provide a mechanism to assure that regulatory requirements with respect to postmarket activities are met, and to provide information on the individual establishments responsible for the importation, distribution or sale of medical devices in Canada.

Medical Device Licensing

Upon implementation of the new Medical Devices Regulations, effective July 1, 1998, every medical device imported into and/or sold in Canada, with the exception of Class I devices, will be required to be licensed within time frames specified in the Regulations. This device licence requirement applies immediately to new devices coming onto the market on or after the July 1, 1998 implementation date, and, through transitional provisions, to any device previously notified and in compliance with Parts II and V, as applicable, of the old Regulations as of June 30, 1998.

In the case of devices in compliance with the old Regulations as of June 30, 1998, the device licence requirement becomes effective as of February 1, 1999.

One device licence will be issued to the device manufacturer for each licence application submitted, on condition that the application conforms with the regulatory information requirements, and that the device is determined by the TPP, on the basis of review of the information submitted, to meet the safety and effectiveness requirements of the new Regulations. Manufacturers should note that, under the new Regulations, **device licensing is now a premarket requirement**, i.e. no one may import or sell a Class II, III or IV medical device in Canada unless the device has a valid device licence.

The device licence is issued to the device manufacturer for the device name as it appears on the label, and unless a licence amendment is issued, the device licence will remain valid until November 1, 1999. November 1 represents the annual renewal date for device licences.

Should sale of a device be discontinued, the holder of the device licence is required to inform the TPP, in writing, within 30 days of the device being withdrawn from sale.

Significant changes to a device could result in the requirement for application for an amended licence. A guidance document on significant change is available on our website. It is the device manufacturer's responsibility to ensure that each device marketed is in compliance with the device class requirements for that device as specified in the new Regulations.

A valid device licence gives the licence holder the right or privilege to sell or import a medical device in/into Canada, and is issued to the manufacturer of the device, or a person/company that has been designated by the manufacturer to act on their behalf. See the guidance document on device licensing on our website. For further information contact the Bureau: tel: (613) 957-1909, or **mdb-bmm@hc-sc.gc.ca** (e-mail).

Establishment Licensing

Importers, distributors and manufacturers of Class I devices that do not have a Canadian importer or distributor, will be able to apply for an establishment licence under the requirements of the new Regulations as of November 1, 1998. They will be required to hold an establishment licence by January 1, 1999 to enable them to import, sell or distribute medical devices in Canada.

An establishment licence is issued for a specified activity or combination of activities including importing, distributing or direct sale of Class I devices.

Barring any changes which may require an amendment, an establishment licence will be valid until December 31, the annual renewal date. At that time, if the regulatory information requirements are met, the establishment licence will be renewed until the following December, or until an establishment licence amendment is required.

An application to amend an establishment licence must be submitted in the case of a change to either: the name or address of the licensed establishment; or, the name, title, phone number of the licensed establishment's representative, within 15 days of the change.

A valid establishment licence gives the holder the right or privilege to import, distribute or sell a medical device in Canada. With the exception of manufacturers of Class I devices, manufacturers who sell directly, i.e. not through a Canadian importer or distributor, are exempt from establishment licensing. Manufacturers of Class I devices are subject to establishment licensing, unless they do business through a licensed Canadian importer or distributor.

Where a manufacturer also distributes devices that they do not manufacture, they are required to licence their establishment as a distributor.

Canadian retailers and health care facilities are exempt from establishment licensing. For further information contact: Kim Dix at (613) 954-6666 (tel), (613) 954-0941 (fax) or **kim_dix@hc-sc.gc.ca** (e-mail).

What Constitutes a Significant Change in a Medical Device?

All Class II, III or IV medical devices sold in Canada are required to be licensed under Section 32 of the new Medical Devices Regulations. An amended application for a device licence is required under Section 34 if a *significant change* has been made to a licensed Class III or IV medical device. This amended licence application must be accepted prior to the modified device being offered for sale in Canada.

Significant change means a change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to one of the following:

(a) the manufacturing process, facility or equipment;

(b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the materials or the device;

(c) the design of the device, including its performance characteristics, principles of operation and specification of materials, energy source, software or accessories; and,

(d) the intended use(s) of the device, including any new or extended use, any addition or deletion of a contraindication for the device, or a change to the time period used to establish the expiration date of that device.

A guidance document *"Guidance for the Interpretation of Significant Change"*, available on the TPP website, is intended to aid manufacturers in determining when a *significant change* has been made to a medical device. The document uses flowcharts and examples to provide assistance to the decision making process that manufacturers will use to determine when a significant change is made to a device.

For further information please contact Mary-Jane Bell at: (613) 954-0377 (tel), (613) 957-1596 (fax) or **mary-jane_bell@hc-sc.gc.ca** (e-mail).

Importation of Medical Devices

Under the new Medical Devices Regulations medical device importers will be required to obtain an establishment licence, report serious incidents involving the devices they import, maintain distribution records, and establish written procedures regarding investigating incidents and recalling defective devices from the market.

Importers must verify if any of the products they are importing are a medical device or not. Basically, any product that is represented for the diagnosis, treatment, mitigation or prevention of a disease or abnormal physical state in humans is a medical device and therefore subject to the Regulations. Veterinary products are not subject to these Regulations, but are required to meet the general requirements of safety and effectiveness of Sections 19 and 20 of the Food and Drugs Act.

Many medical devices bear the harmonized product code "90.18 – instruments and appliances used in medical surgical, dental sciences". The harmonized coding system is used by Revenue Canada on Customs release documents. If you are uncertain whether a product is a medical device, contact the manufacturer or one of the TPP's regional offices.

Health Canada has a long-standing agreement with Revenue Canada to request importers or their brokers to submit a fourth copy of a customs invoice marked Health Canada with their release papers. The TPP has the opportunity to review this documentation for surveillance purposes.

An Import Alert procedure is available whereby the TPP advises customs officials of devices that may be in violation of the Regulations, and the action to be taken to assist the TPP in achieving correction.

For the future, TPP is working with Canada Customs to examine ways to improve the import surveillance of medical devices by utilising electronic technologies. A possible output of this project will require importers to declare their establishment licence number, and the licence number of each device imported.

For information, contact Jim Moore (613) 954-8186 (tel.), (613) 954-0941 (fax), or **james_h_moore@hc-sc.gc.ca** (e-mail).

Problem Reporting Under the New Medical Devices Regulations

When the new Medical Devices Regulations come into effect July 1, 1998, they will include a requirement for the mandatory reporting, by manufacturers and importers, of serious incidents

involving medical devices to the TPP. Mandatory reporting will enable the TPP to identify, resolve, and monitor these incidents so that device problems may be corrected in a timely manner while minimizing or preventing their recurrence.

Canada's major trading partners have similar device incident reporting requirements. The introduction of a mandatory reporting system here will enable Canada to participate in the international exchange of device incident information and alert systems.

The new Regulations will require a manufacturer or importer to report any incident occurring in Canada where a device failure or labeling deficiency has led to, or created the potential for, death or serious deterioration in the state of health of a patient, user, or other person. Such incidents occurring outside Canada must also be reported if the device is sold in Canada, **and** if the manufacturer has taken corrective action outside Canada **or** has been required to do so by a regulatory authority in the country in which the incident occurred.

Mandatory reports must be submitted to the TPP within certain time frames depending upon the severity of the incident. Preliminary and final reports will be required with specific information to be supplied with each. These reports must notify the TPP of the course of action the manufacturer will follow to resolve the concern, the time frame to complete the investigation and any proposed corrective actions. The TPP will review the reports to determine if further action is required by the reporter or by the TPP.

Manufacturers and importers will be exempt from reporting incidents related to devices obtained under the Special Access or Investigational Testing provisions of the Regulations. However, the Regulations will include compulsory reporting requirements for health care professionals who have obtained devices under these provisions and where the incident meets the criteria for a mandatory report.

Health care professionals and the general public are urged to continue voluntary reporting of all types of device problems to the manufacturer or distributor, and to the TPP. The investigation of voluntary reports will be performed on a risk management basis with higher risk issues given higher priority.

The TPP has prepared a guidance document on mandatory reporting that is available on our web site. For further information, contact Abbey Klugerman at (613) 954-7536 (tel.), (613) 954-0941 (fax) or **abbey_klugerman@hc-sc.gc.ca** (e-mail).

If you would like to file a voluntary problem report with the TPP, please contact one of the regional offices listed in the *Bulletin*.

Managing Problem Investigations and Recalls

The new Regulations require manufacturers, importers and distributors to keep distribution records of all devices they market, and to have written procedures in place on investigating problem reports and recalling defective devices from the market.

The intent of the new Regulations with regard to the management of device problem investigations and recalls is:

- to ensure that device manufacturers, importers and distributors maintain records of problem reports and of the actions they have taken in response to these reports;
- to ensure that manufacturers, importers and distributors establish and implement documented procedures that will enable them to carry out effective and timely investigations of reported problems, and recalls;
- to ensure that defective or potentially defective medical devices are removed from the market or that measures are taken to correct the problem in an effective and timely manner; and,

- to ensure that the TPP is informed of serious device incidents (see article on problem reporting) and all device recalls that are initiated, their results, and of the action taken to prevent recurrence of the problem.

The incident and recall handling requirements in the new Regulations do not apply to a retailer, or a health care facility regarding a device that is distributed for use within that facility. However, a retailer who imports a device would have to meet these requirements, as would a hospital that imports a medical device and then sells it outside the hospital.

Managing Problem Investigations

The new Regulations require device manufacturers, importers or distributors to maintain records of all the reported problems and consumer complaints received (regardless of where they occurred) related to the safety or efficacy of the device. They are also required to maintain records of all actions taken in response to these reports. As stated above, serious incident reports are to be forwarded to the TPP. Manufacturers, importers and distributors are also required to have in place a written procedure for managing problem investigations that details steps to be taken once an incident report or concern is received.

This written procedure should include:

- a detailed description of the problem/incident/concern;
- procedures to enable the determination of the health hazard associated with the problem/incident/concern;
- the determination of whether the device fails to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety;
- the determination of whether the device meets the device-related requirements of the Food and Drugs Act, or the specific requirements of these Regulations such as device licence, etc.;
- the determination of what corrective/preventative action is to be taken based on the above information; and,
- if it is determined that no action is to be taken, a justification for that decision.

Managing Recalls

A recall is defined in the Regulations and includes any action taken by the manufacturer, importer or distributor to recall or correct a device, after becoming aware that the device:

- may be hazardous to the health of a patient or user;
- may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or,
- may not meet the requirements of the Food and Drugs Act or the Regulations.

A recall may include the physical retrieval of the device from the actual users, as well as any form of retrofit or correction made at user institutions, including labelling or instructional changes and user advisories.

Manufacturers, importers and distributors are required to have in place a written recall procedure that will detail the steps to be taken once a problem report investigation has concluded that a recall is necessary to correct all units, or a specific lot(s) or range of serial numbers of the device. The recall procedure will identify all the internal and external personnel involved, their functions and responsibilities, the channels and means of communication and the rapidity that the procedure should be implemented based on the priority assigned to the recall.

For information, see the guidance document, or contact Lindsay Blaney at (613) 957-3842 (tel), (613) 957-7318 (fax) or **lindsay_blaney@hc-sc.gc.ca** (e-mail), or one of the Regional offices.

Quality Systems

One of the important features of the new Medical Devices Regulations is the requirement for manufacturers to conform to quality system standards as of July 1, 2001. Under the old Regulations, device manufacturers were not required to comply with any quality system standard. However, under the new Regulations, manufacturers will be required to submit attestations indicating compliance with quality system standards Can/CSA-ISO 13485 for Class III and IV devices, and ISO 13488 for Class II devices. These national standards are based on ISO 9001/9002 respectively.

The quality system standard 13485 is more stringent than the 13488, as the former incorporates design control requirements for medical devices. Therefore, manufacturers of Class III and IV devices will be required to comply with 13485, and manufacturers of Class II devices will be required to comply with 13488. Nevertheless, based on good business practices, all manufacturers are encouraged to incorporate the design controls included in ISO 13485.

The assessment of conformity with quality system requirements and registration of manufacturers' quality systems will be conducted by external third party organizations approved by TPP. The TPP is developing a third party auditing programme for certification to the national quality system standards. The programme will be in place in sufficient time to ensure that industry meets the July 2001 regulatory deadline. For further information contact Pierre Landry at (613) 957-3837 (tel), (613) 957-7318 (fax) or at **pierre_landry@hc-sc.gc.ca** (e-mail).

CSA has recently published a second edition of a practical handbook for implementing the ISO 9000 standards for medical device manufacturers. This second edition also includes ISO 13485 essentials. The book entitled, *"ISO 9000 and 13485 Essentials"*, is available from CSA. Copies can be ordered by contacting:

Canadian Standards Association
178 Rexdale Boulevard
Etobicoke, Ontario Canada
L5B 3C3
1-800-463-6727
1-416-747-4000

Progress on the Canada/ European Community Mutual Recognition Agreement

On 14 May 1998, a Mutual Recognition Agreement (MRA) between Canada and the European Community was signed at the EU-Canada Summit in London, U.K. The agreement will govern approximately $12 billion of annual bilateral trade in six regulated sectors: low voltage equipment, telecommunications terminal equipment, electromagnetic compatibility, recreational craft, medical devices and Good Manufacturing Practice (GMP) for drugs. Upon the exchange of diplomatic notes, expected within the next sixty days, the agreement will come into force commencing with an 18 month confidence building phase.

The MRA Agreement for the Medical Devices sector establishes mutual recognition of each country's ability to assess products to the standards of the other country. Specific categories of medical devices are not included in the agreement such as *in vitro* diagnostic devices, breast implants, devices containing drugs, and devices incorporating tissues of human or animal origin.

While the agreement is expected to reduce unnecessary barriers to trade and eliminate costly duplication, the agreement has been negotiated to maintain Canada's high standards of health and safety. Regulatory Authorities involved will recognize the regulatory programmes and standards of the other(s) only if they provide the same high level of protection and therapeutic product quality. The TPP will manage the

implementation of MRA Agreements for therapeutic products.

The MRA with Europe does not harmonize regulatory programmes and standards, override Canadian legislation and regulations, nor causes the TPP to relinquish any of its authority or responsibilities in regulating the advertising, importation or sale of therapeutic products.

An 18-month transition phase follows the exchange of diplomatic notes and will provide the time needed to assess and determine the equivalency of programmes and standards of the regulatory authorities in the other countries before formal implementation of this agreement. A Joint Sectoral Group, made up of Canadian and European regulators, will monitor the implementation and long-term maintenance of the agreements to ensure that the health and safety of its citizens is not being compromised.

Various safeguards have been built into the agreement including a provision to challenge decisions or request additional information. The TPP will continue to make all decisions concerning therapeutic products sold in Canada. The agreement allows Canada or other countries to end an agreement should the regulatory authorities or standards ever cease to be equivalent.

The MRA will simplify trade by reducing barriers between countries without reducing the high Canadian safety and quality standards for therapeutic products. Canadian products will no longer have to undergo an additional round of local European testing and certification before being placed on the EC market. According to the Department of Foreign Affairs and International Trade, it is estimated that the MRA could eliminate 50% of the product testing and certification costs that exporters currently bear to meet EC regulatory requirements. The MRA could also facilitate the development of new export markets for Canadian therapeutic products.

The MRA also provides an opportunity to increase Canadian-European regulatory cooperation which will result in regulatory efficiencies and ensure that therapeutic products are available to both populations without undue risk or delay, potentially at a lower cost.

The TPP believes that the medical devices sectoral Annex provides the necessary provisions and safeguards for continuing to ensure the safety and quality of medical devices available on the Canadian market. The MRA will enable the TPP to allocate resources to ensuring that therapeutic products coming from non-traditional markets, such as Asia or South America, meet the high Canadian standards of product safety and quality.

The text of the Annexes, once finalized and translated by the Department of Foreign Affairs and International Trade, will be posted on the TPP website. For further information contact Don Boyer at (613) 957-7090 (tel), (613) 941-9672 (fax) or at **don_boyer @hc-sc.gc.ca** (e-mail).

Cost Recovery Update

The TPP held a consultation workshop March 25 to 27, 1998 to discuss the proposed *Fees to be Paid in Respect of Medical Devices Regulations.* More than forty industry and stakeholder representatives were invited to participate at the workshop. The broad issues discussed included the design of the fee structure, implementation issues, fee reduction and fee exemption provisions and the methodology which was used to determine the unit fees. Participants were receptive to the improvements which have been made since the previous consultation meeting in August 1997 and provided the TPP with other suggestions to improve the regulatory proposal. Participants expressed support for the principle of fees for medical devices product and establishment licensing, the component based approach of the fee structure and the exemption from fees for:

- Class I devices;

- medical devices which are custom-made or imported or sold under the special access programme;
- authorisations to conduct investigational testing;
- some of the fee components of the medical device licence application, if an authorization for sale of a medical device has been granted to a qualified investigator in the circumstances referred to in Part III of the new *Medical Devices Regulations* to conduct investigational testing;
- Class II device licence amendment; and,
- "administrative" device licence amendment.

The consultation process provided an opportunity to discuss methods to make the TPP more efficient and cost effective, methods of improving the working relationship between the TPP and stakeholders, and to discuss the positive aspects of the proposed fee schedule, the issues, potential impacts and the most appropriate means of minimizing negative impacts.

The cost recovery Regulations were published in *Canada Gazette* Part I on 13 June 1998 as Schedule 1102. Comments received on the proposed cost recovery Regulations will be collected until the end of a 30-day comment period and will be considered in the development of the final proposal to be published in *Canada Gazette* Part II. For information, contact Julie Gervais at (613) 952-3601 (tel), (613) 941-6458 (fax) or **Julie_Gervais@hc-sc.gc.ca** (e-mail).

Glove Barrier Protection and Latex Allergy: Minimizing the Risk

In order to reduce the health risk from latex allergy, Canadian health care facilities are increasingly substituting latex gloves with synthetic ones. Laboratory studies have shown that, when new, both synthetic and latex glove materials are essentially impermeable to HIV and hepatitis virus. Quality brands of new gloves are found to have few pinholes, and generally exceed prescribed and voluntary standards.

However, concerns have been expressed about the durability of non-latex gloves, particularly vinyl, as described in the published literature[1]. A study by TPP staff conducted in Toronto in 1995 showed leakage rates of about 25% for nonsterile vinyl gloves used in a typical hospital ward setting[2]. Most non-vinyl synthetic glove materials have tensile strength and puncture resistance intermediate between vinyl and latex, so one might expect their durability to be greater than vinyl but less than latex: however, few clinical durability studies are reported. Clinical evaluations are needed in order to establish the relative durability of the newer synthetics.

Many latex-sensitive individuals can tolerate an environment in which only low-protein powder-free gloves are used by their co-workers, while the sensitized individuals themselves wear only non-latex gloves. Because of the health risk from latex allergy, one major regulatory agency has recommended that latex gloves in all workplaces should be powder-free[3].

Powder-free latex gloves :

- may reduce the risk of worker sensitization;
- can provide a low-allergen environment that will accommodate allergic workers;
- limit the disadvantages of using non-latex gloves (cost, tactile loss, barrier durability) to those sensitized workers who must avoid all contact with latex; and,
- appear to provide barrier protection equivalent to powder gloves[2].

Occasionally, a worker cannot tolerate the presence of even a powder-free glove. The worker can normally be accommodated if co-workers use only synthetic gloves. However, some workers are sensitive to chemicals found

both in natural rubber latex and in synthetic rubbers and plastics. Accommodation can then only be achieved by transferring the worker to an environment where there is no exposure to gloves or latex.

All gloves, including vinyl, provide substantially more protection than no glove at all[4]. Workers who must use vinyl gloves in high risk situations should double glove, as double gloving has been shown to provide substantially better protection[5] when this type of glove is used.

We cannot yet say that the newer non-vinyl synthetics provide the same barrier durability as latex, but clinical studies may one day show some synthetics to provide durability at least as good as that of natural latex rubber. For more information contact Andrew Douglas at (613) 954-0738 (tel); (613) 993-0281 (fax); or **andrew_douglas@hc-sc.gc.ca** (e-mail).

References:

1. Korniewicz DM, Kirwin M, Cresci K, Larson E. Leakage of latex and vinyl exam gloves in high and low risk clinical settings. Am Ind Hyg Assoc J 1993 Jan; 54(1):22-6.
2. Douglas A, Simon TR, Goddard M. Barrier durability of latex and vinyl medical gloves in clinical settings. Am Ind Hyg Assoc J 1997 58:672-676.
3. Preventing allergic reactions to natural rubber latex in the workplace. June, 1997 DHHS (NIOSH) Publication No. 97-135. NTIS#PB 97-144-109.
4. Olsen RJ, Lynch P, Coyle MB, Cummings J, Bokete T, Stamm WE. Examination gloves as barriers to hand contamination in clinical practice. JAMA 1993 Jul 21;270(3):350-3.
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CSA Standard on Lifting Devices for Persons

In January 1998 the CSA draft standard Z323.5 on *Mechanical/Electromechanical Lifting Devices for Persons* was completed and forwarded to the CSA Technical Committee on Assistive Technologies for Persons with Disabilities for formal approval.

The Standard specifies safety requirements for mechanical/electromechanical devices used in the lifting and moving of a person, and includes requirements for design, construction, maintenance and use of such equipment and accessories, particularly where these are related to the safety of the person being lifted and the operator of the equipment. A July 1, 1998 release date is expected.

The finalization of this Standard marks the culmination of two years of standards development by a CSA subcommittee on lifting devices. The membership of the committee consists of a dedicated group of volunteers, with strong representation from the various stakeholder groups, including health care professionals, manufacturers, workers' compensation boards and the TPP.

To obtain a copy, please contact the Canadian Standards Association at: 1-800-463-6727 (tel), (416) 747-2475 (fax), or **sales@csa.ca** (e-mail). For further information, contact: Denis Roy at (613) 954-0365 (tel), (613) 993-0281 (fax) or **denis_g_roy@hc-sc.gc.ca** (e-mail).

How One Hospital Assures Use of Medical Devices That Are in Compliance With the Regulations

The St. Boniface General Hospital is a tertiary facility of approximately 560 beds in Winnipeg, Manitoba. The operating suite consists of 14 theatres.

The operating room has developed and implemented a comprehensive and effective set of policies and procedures regulating the procurement and use of medical devices, particularly implantable devices that are subject to Part V of the old Medical Devices Regulations, and the majority of which will be subject to Class III or IV requirements under the new Regulations.

The hospital's policies and procedures require that several units within the hospital work in partnership with device vendors and the regional TPP office in Winnipeg to ensure that only devices that are in compliance with the Regulations are used. If there is a question regarding compliance, a request is forwarded to the manufacturer and/or the TPP office requesting confirmation of the device status. A device is not used if there is any question as to its compliance. This record keeping process has also proven an effective process to address product alerts and recalls.

In light of the ever increasing threat of civil litigation, a multidisciplinary team within the hospital has been reviewing in-house policies and procedures to ensure ongoing effectiveness. The team continues to work closely with the local TPP office.

Further details are available by contacting Janet Ridgedale, Equipment Supply Advisor, Operating Room, St. Boniface General Hospital (204) 235-3545 (tel) or Robert Scales of the TPP Winnipeg Regional office at (204) 983-5451 (tel), (204) 983-5547 (fax) or **Robert_Scales@hc-sc.gc.ca** (e-mail).

Year 2000 (Y2K)

The Medical Devices Bureau of Health Canada's Therapeutic Products Programme (TPP) has written to users and manufacturers of medical devices sold in Canada to warn them of the Year 2000 (Y2K) problem. Health Canada is reviewing all areas relating to its internal operations and the products it regulates that could be affected by the Y2K problem.

The letter to users of medical devices provides recommendations on how best to protect themselves against possible malfunction of their devices due to Y2K non-compliance. The letter to manufacturers indicates what the TPP expects manufacturers to do in response to this issue and it requests them to provide information on the Y2K compliance of their devices.

Information provided to the TPP about the status of Y2K compliance of medical devices will be posted on the TPP's web site in an effort to provide users with a central repository of information about this particular aspect of medical devices.

Both letters are available on the Medical Devices Bureau's web site at **http://www.hc-sc.gc.ca/hpb-dgps/therapeut/mdhtmeng/index.html.** For further information, contact Denis Roy at (613) 954-0365 (tel.), (613) 993-0281 (fax), or **denis_g_roy@hc-sc.gc.ca** (e-mail).

Bulletin Survey Results

The Fall 1997 issue of the *Bulletin* contained a reader survey seeking information as to what readers like about the *Bulletin* and what they want to see included in it. The returns are in, the results have been tabulated and now "The Survey Says..."

The *Bulletin* is distributed to approximately 8000 addressees representing a number of categories of stakeholders. Despite the mail strike, we received responses from over 510 readers, in fact responses are still coming in. Table 1. Gives a breakdown of respondents.

Table 1. Summary of Respondents

Category	No.
Industry	189
Hospitals	108
Long Term Care Facilities	109
HPB Staff	21
*Miscellaneous	12
Not indicated	71
Total	510

* Miscellaneous include public libraries, educational institutions and Health Care Associations

The survey contained a series of questions including if the *Bulletin* is read, if it's useful, if the information is adequate and if the *Bulletin* should be published as a combination newsletter representing all the activities of the TPP, i.e. combined with the Drugs Sector of the TPP. The results of the reader evaluation of the *Bulletin* are featured in Table 2.

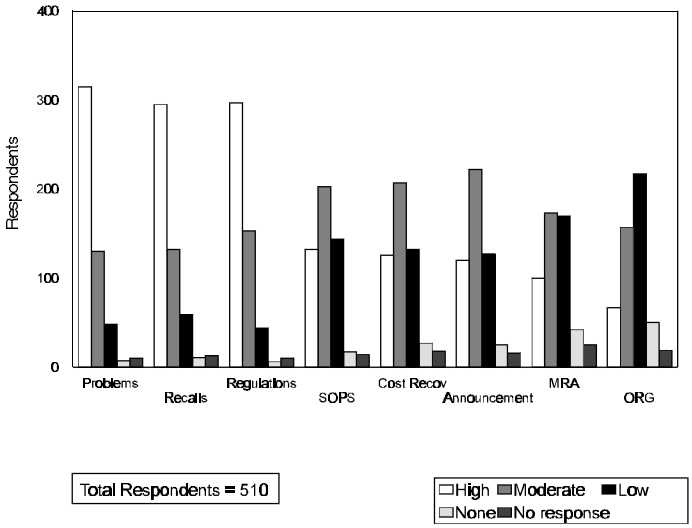
Table 2. Overall Evaluation of the *Bulletin*

Question/Response	Yes	No	No Response
Do you read *Bulletin*?	482	21	7
Do you find it useful?	480	13	17
Is information adequate?	466	16	28
Would you like a combined TPP newsletter?	215	266	29

Readers were asked to indicate their level of interest in the contents of the *Bulletin* by circling a number (1 = high, 4 = none). Categories listed included device problems, recalls, Regulations, cost recovery, TPP's operating procedures, Mutual Recognition Agreements, TPP's organizational structure and announcements of upcoming events. A summary of reader's survey is presented in graph 1.

Graph 1. Reader Survey Summary

Level of readers' interest in various topics



Frequency of publication was broken down as 56% wanted two issues per year (which has been the practice to date), 34.5% would like to see the *Bulletin* issued more frequently i.e. 3 or 4 times a year and approximately 10% did not indicate a preference. At this time, given the ever-increasing demands on TPP resources, it is difficult to make a commitment to increase the frequency of publication, and it would appear that two issues per year will continue.

Many readers provided comments and suggestions. Those who want more information on the Regulations or the inclusion of frequently asked questions will find a bonanza in this issue. Future issues of the *Bulletin* will address other suggestions. Readers are reminded that by looking at Table 1, you can get an idea of the range of the *Bulletin's* readership. While each issue can't be all things to all readers, we are trying our best to meet your needs, and your comments and suggestions will be incorporated wherever possible in future issues.

Please let us know how the *Bulletin* can serve you more efficiently. Your comments and suggestions are always welcome. Our thanks to all those who took the time to participate in the reader survey.

How to Reach Us

You can find the answer to most of your questions by visiting the TPP website at: **http://www.hc-sc.gc.ca/hpb-dgps/therapeut/**. The TPP website includes information on the Programme, the new Regulations and various guidance documents concening the Regualtions. For your convenience, the Medical Devices Bureau has recently established a dedicated phone number: **(613) 957-1909,** and an e-mail address: **mdb-bmm@hc-sc.gc.ca** to act as primary contact points to respond to your questions.

The TPP's Hot Line number (1-800-267-9675) will be automatically routed to the nearest Region, depending upon the area code of the caller. Regional offices of the Bureau of Compliance and Enforcement can be reached by e-mail or by telephone:

	Telephone No.	**E-mail:**
Atlantic:	1-902-426-5575	alicja_kasina@hc-sc-gc.ca
Quebec:	1-800-561-3350	benoit_toupin@hc-sc-gc.ca
Ontario:	1-416-973-1596	jerry_holatko@hc-sc-gc.ca
Central:	1-204-983-5451	robert_scales@hc-sc-gc.ca
Western:	1-604-666-3845	john_wilson@hc-sc-gc.ca

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The *Medical Devices Bulletin* is intended to serve our clients, stakeholders, staff and partners. Please let us know what you would like to see in upcoming issues.

For information contact:

Bill Wallace (613) 954-0736 or Kamlesh Gupta (613) 957-4986. Permission for reproduction in journals in whole or in part is granted. An acknowledgement to Health Canada is requested. Photocopies for in-house distribution may also be made.

For comments and recommendations, or to change/correct an address, please check the appropriate box and return to:

Medical Devices Bureau, Health Protection Branch, Health Canada, Postal Locator 0301H1,
Tunney's Pasture, Ottawa, Ontario K1A 0L2
FAX (613) 954-0941

❑ Address Correction/Change ❑ New Address

Name/Title:_____ Company Name:_____

Old Address:_____

New Address:_____

Comments/Recommendations:_____

_____

_____

_____

All TPP staff can also be contacted via the Internet at "*****"@hc-sc.gc.ca. Replace the "*****" with the name of the person you wish to contact, using the underscore character to fill in the blank space between first name and last name. For instance, to contact Jean-Marc Charron, you would type jean-marc_charron @hc-sc.gc.ca.

OUR MISSION: To ensure that the drugs, medical devices and other therapeutic products available in Canada are safe, effective and of high quality.