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MEDICAL DEVICES BULLETIN

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

Snow has mostly disappeared from the grounds of Canada's capital and the signs of spring have started to appear. It makes us envious of those who are already in the middle of spring. Nonetheless, all of us are entering a new fiscal year, which always brings us new challenges as well as new opportunities, and 1997 is no exception. If we reflect back, it is evident that last year's challenges have become our achievements. We will share some of these with you in this Issue.

The long-awaited, new Medical Devices Regulations have been published in Canada Gazette Part I, February 15, 1997. You can find the Regulations on our web site. A substantive agreement on mutual recognition in the medical devices sector has been concluded between the European Union and Canada. The accord comes as a result of over two years of negotiations. The Medical Devices Bureau and the Centre for Devices and Radiological Health, US Food and Drug Administration (FDA), have initiated a pilot project for joint reviews of Part V devices submissions. Canada has moved to an average of 68 days on approval of Part V submissions on medical devices, and is rated among the fastest in the world. Read on for details on all these topics.

The latest news concerning the organization of the Programme is that, as of January 1, 1997, two Programmes of the Health Protection Branch, the Medical Devices Program and the Drugs Programme, have merged into one. The combined Programme will be referred to as the Drugs and Medical Devices Programme. Therefore, until further notice, please use this new name in your correspondence. It is anticipated that in the joint venture, Medical Devices will be one of several business lines. Managers are working as a team, to ensure a smooth transition.

Editors

New Regulations in Canada Gazette Part I

On February 15, 1997, the proposed new Medical Devices Regulations were published in Canada Gazette, Part I, to provide early notice of Health Canada's (HC) intention to revise the existing Regulations and to solicit comments from stakeholders.

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Canada

The publication of these Regulations comes at the end of an extremely cooperative and productive consultation process between HC representatives and all affected parties. This initiative began with the recommendations from the Medical Devices Review Committee (Hearn 1992) followed by the development of the Department's Plan for an Improved Medical Devices Regulatory Program (1993). Between 1994 and 1995, valuable advice and a number of recommendations were received from various external advisory committees and internal working groups, which assisted in shaping the content of the new Regulations. Further input came as a result of workshops held in Montreal, Vancouver, Toronto and Washington at the beginning of 1996.

Although an immense amount of work has been accomplished thus far, the process of introducing improved Medical Devices Regulations that work well for all affected parties is far from complete. The Regulations are scheduled to come into force in February 1998, when they are published in the Canada Gazette, Part II. Between now and then, the Programme will consider all comments on the new Regulations and, based on these comments, the Regulations will be revised prior to publication in Canada Gazette, Part II. All comments should be forwarded to the Director, Medical Devices Bureau, either by fax (613) 957-7318, by mail at the address provided in the Bulletin or by email at **Bill_Wallace@inet.hwc.ca** before June 1, 1997.

During the same time period, the Programme is committed to performing a comprehensive benefits and cost study respecting the Medical Devices Regulations. The study will also take into account another major regulatory initiative which will impact on medical devices - new Fees Regulations. Discussions with industry on new Fees Regulations will resume based on the Canada Gazette, Part I, version of the Medical Devices Regulations.

Dr. R. Tobin, Director, Medical Devices Bureau, would like to take this opportunity to thank all those who have taken the time to participate and contribute in the development of these new Regulations. In our opinion, your contributions are reflected in the quality of the work completed thus far. We look forward to continuing this partnership.

To receive a copy of the proposed Regulations as published in Canada Gazette, Part I, visit our Web site at **http://www.hwc.ca/hpb/drugs**, or contact the Planning Division secretary at (613) 957-7285.

Quality Systems Course
ISO 13485/ISO 13488 Standards

Under the proposed Medical Devices Regulations, published in Canada Gazette Part I (February 15, 1997), manufacturers of medical devices intended for the Canadian market will be required to implement Quality Systems Standards ISO 13485/ ISO 13488, which were released by the International Organization for Standardization in February 1997.

The Quality Systems Standards ISO 13485/ ISO 13488, specifically directed to medical devices, identify quality assurance requirements in the design/development, production, installation and servicing of medical devices. These standards also include all requirements currently set out in the generic quality assurance Standards, ISO 9001 and ISO 9002 which were issued in 1994.

To facilitate understanding and implementation of ISO 13485/ ISO 13488, the Medical Devices Bureau, in partnership with Accademia Qualitas Inc., has developed a course on this series of standards. This three-day course is intended for the medical devices industry, HC staff and any other client interested in under-

standing the underlying concepts, structure and application of the ISO standards. The course will provide information on how to apply these standards for compliance with the new Medical Devices Regulations as well as for general business improvement.

The course is offered by Accademia Qualitas Inc, a private Canadian company dedicated to training in management systems based on recognized standards. The Programme has agreed to a partnership with Accademia Qualitas in the delivery of this course. To this end, one staff member has already been trained as an instructor for Accademia Qualitas, and will initially act as instructor for this course.

The course will be offered several times during 1997 in different cities across Canada. For more information on the course content and schedule, contact Accademia Qualitas Inc. at 1-800-263-0128 (tel.), (514) 333-5768 (fax) or at assist@accademia.com (email)

For technical information concerning ISO 13485/13488, contact Pierre Landry at (613) 957-3837, (613) 957-7318 (fax); or **plandry@hpb.hwc.ca** (email).

Progress in Mutual Recognition Agreement

On October 23, 1996, the members of the negotiating teams from the European Union (EU) and Canada concluded a substantive agreement on mutual recognition in the medical devices sector. The accord comes as a result of over two years of negotiations. The document will be one of the sectoral annexes attached to an overall framework agreement between EU and Canada, still to be finalized and ratified by both parties.

A mutual recognition agreement (MRA) with the EU will mean mutual recognition of the ability of each party to perform conformity assessment to the regulatory requirements of the other. The agreement covers all devices except *in vitro* diagnostic devices, silicone-gel filled breast implants and devices containing drugs.

The agreement provides for a transitional (confidence-building) phase and an operational phase. The confidence-building phase of approximately 18 months will involve participation by regulatory authorities and Conformity Assessment Bodies of both parties. It will feature a variety of information exchange activities which have already begun and a series of inter-comparison exercises involving double blind evaluations of medical device technical submissions by each regulatory authority to the requirements of the other jurisdiction. As soon as Health Canada has finalized its requirements for conformity assessment of quality systems, a confidence-building exercise with the EU addressing these requirements will be conducted. At the end of this phase, there will be an opportunity for both parties to assess the progress made and, if satisfactory, to move to the operational phase of the agreement.

In the operational phase, the Conformity Assessment Bodies of the exporting party will be authorized to evaluate and certify conformity of the products with the regulatory requirements of the other party. There are opportunities to challenge the decision of the other party, with just cause, or to obtain the technical data in the case of problems with the device. Each party will continue to have the authority to carry out its regulatory mandate, including post-market surveillance. Any problems encountered with devices subject to this agreement will be communicated to the other party through a two-way alert system.

Health Canada believes that this agreement will continue to ensure the safety and effectiveness of medical devices in Canada, will result in regulatory efficiencies and cooperation between Canada and the European Union and will ensure that new medical devices can enter the marketplace without undue delay. For more information contact Don Boyer at (613) 957-7090 (tel.) or **Don_Boyer@isdtcp3.hwc.ca** (email).

Biotechnology Products to Require Environmental Assessments

The 1988 *Canadian Environmental Protection Act* (CEPA) requires that all substances new to Canadian commerce be notified to Environment Canada for assessment of their potential impact on the environment. The New Substances Notification Regulations (NSNR) have been in force since 1994 for chemicals and polymers, and will be amended in the near future to include biotechnology products.

The federal government has called for the establishment of a regulatory framework to perform similar assessments for all new products of biotechnology. Health Canada, under the authority of the *Food and Drugs Act*, has assumed responsibility for developing this regulatory framework for environmental assessment for new products of biotechnology which are regulated under the *Food and Drugs Act*.

Bill C-74, an Act to amend CEPA, contains a clause amending section 35 of the *Food and Drugs Act* for the purpose of implementing environmental assessments for foods, drugs, devices and cosmetics. This will have the benefit of providing manufacturers of new biotechnology products with a single "window" since products reviewed by Health Canada would then be exempt from a parallel requirement to submit information under CEPA/NSNR.

Health Canada's area of responsibility for biotechnology products will encompass foods, drugs, drugs regulated as medical devices (e.g., *in vitro* diagnostic devices), medical devices, and cosmetics. The rapid advance of technology in this area presents a special challenge for Health Canada for the development of an effective and efficient regulatory approach. For further information about this initiative, contact Dr. David Clapin at (613) 954-0942 (tel.) or **David_Clapin@isdtcp3.hwc.ca** (email).

Electronic Communications

Medical Devices on the Web

The Programme is consolidating all its public access electronic information offerings in one place - the Canada Health Network web site. Since the Medical Devices Program has now merged with the Drugs Programme, the information is posted under the Drugs web page. Convenient links have been put in place for easy access to medical devices related information. Look for us at **http://www.hwc.ca/hpb/drugs**.

One of the features offered at the new address will be a Public Access Database of devices (PADB). This database provides information on devices legal for sale in Canada, and voluntarily submitted recalls. Conventionally, topics which were too big to fit on HTML pages have been offered to users as large data files for download. The user would download the file, and then scan through it for the information the user is interested in. PADB allows the web user to perform queries from the web, retrieving only the information on device or manufacturer keywords they specify. An upcoming enhancement will allow searching for recalls within a specified time period. Contact the Webmaster, Pete Nilson, at (613) 941-1601 or **pnilson@hpb.hwc.ca** (email).

As of March 31, 1997, all hpb1 addresses (the BBS), and public dial-in phone numbers, have been phased out. The pertinent information on the BBS (telnet or web to hpb1.hwc.ca) and under the EHD Medical Device web page has been ported to **http://www.hwc.ca/hpb/drugs**. For comments or information, call Ivor Jackson a t (613) 941-0436 or **ijackson@inet.hwc.ca** (email).

Update on Cost Recovery Initiative

Cost Recovery Statistics for Part V Devices

The Programme received 67 device submissions in the three-month period from October to December '96. A total of 208 devices were submitted for review in the first three quarters of fiscal year 1996-97 (April to December'96). This compares well with the forecasted volume of 210 for the same period. Revenues from cost recovery are slightly above target.

Performance statistics last quarter were again favorable. The average turnaround time for acknowledgment during the quarter was 3.9 days. The average time to screen submissions was 13.6 days. The average turnaround time for making a decision following the date of receipt of the most recent information from the company was 36 days. The completion of 88.7% of evaluation cycles was accomplished within 60 days. Our aim is to continuously improve our service by finding ways to expedite the processing of submissions without sacrificing quality standards in the review process.

The average turnaround time for fee reduction application review was 15.4 days. There were 15 fee reduction applications submitted during this quarter. Nineteen percent of fee application requests over the last two quarters were withdrawn or rejected due to the lack of sufficient evidence and support for their estimated sales figures.

Fee Application Procedures for Part V Submissions

To facilitate the processing of fees and submissions, we ask again that manufacturers please send cheques or money orders in **Canadian funds** as indicated in the Fee Application Procedures. Cheques that have been drawn on U.S. currency accounts or other foreign currency accounts have in the past created lengthy delays in processing the submissions. We have noted that the number of cheques drawn on foreign accounts has dropped significantly over the last two months. We wish to thank those manufacturers who have responded favorably to this request. We also request that manufacturers send the fees with their invoice for outstanding balances to the Medical Device Bureau, Room 1605, Statistics Canada Main Building, PL 0301H1, Tunney's Pasture, Ottawa ON K1A OL2 and **not** to HPB Financial Services. This change will simplify the procedure and expedite the final processing of submissions.

Premarket Review List of Contacts

Once your submission has been acknowledged, the submission will be passed for screening to one of the following individuals:

Dr. Mary-Jane Bell for Musculoskeletal Devices Tel.: 613-954-0377

Dr. Christian Choquet for *In Vitro* Diagnostic Devices Tel.: 613-954-0387

Dr. Dave Clapin for General and Restorative Devices Tel.: 613-954-0942

Dr. Kathleen Magwood for Cardiovascular Devices Tel.: 613-954-0295

Fee reduction applications will be assessed by Linda Bierbrier, Planning Division Tel.: (613) 957-1594

New Devices Regulations and Cost Recovery

The new Medical Devices Regulations were published in Canada Gazette Part I on February 15, 1997. The processes and systems related to the new Regulations are being developed. A Cost Benefit Analysis of the new Devices Regulations and an economic impact analysis of cost recovery under the new Regulations have been initiated.

A copy of the third quarter cost recovery report is available on request. If you require any assistance or would like to provide comments on the Program's cost recovery initiative, please contact Linda Bierbrier at (613) 957-1594 (tel.), (613) 957-7318 (fax) or **Linda_Bierbrier@isdtcp3.hwc.ca** (email).

Pre-clearance of Medical Device Advertisements for T.V. or Radio

All advertisements for medical devices that are to be aired on television or radio must be reviewed by the Medical Devices Bureau and assigned a Continuity Clearance Number prior to broadcast.

Scripts should be submitted in a clean, typed format with the title and length of the advertisement and the name, address, telephone and fax number of the broadcaster or advertiser requesting the Continuity Clearance Number clearly indicated.

It is further required that scripts be submitted for review a minimum of one week prior to planned initial broadcast date. However, advertisers and broadcasters should be aware that if the Programme has questions about the content or claims made in the script that require clarification, a one-week lead time may be insufficient to obtain the Continuity Clearance Number.

It is recommended that advertisers or broadcasters submit scripts prior to production as changes to the scripts are often required before the Continuity Clearance Number is assigned. Additionally, a Continuity Clearance Number will not be assigned to any advertisement that promotes a treatment, cure or preventive measure for any of the diseases, disorders or abnormal physical states that are included in Schedule A of the *Food and Drugs Act*.

The Continuity Clearance Number is valid for a period of one year from the date of approval, and may be renewed for additional one-year increments by resubmitting the unchanged script with the existing Continuity Clearance Number indicated.

To have an advertising script for a medical device reviewed, or for a copy of Schedule A, please contact Kathy Bird at (613) 954-4587 (tel.), (613) 957-1596 (fax) or **Kathy_Bird@isdtcp3.hwc.ca** (email).

Release of A Medical Device on Compassionate Grounds

Health care practitioners should know that there is a provision in the Medical Devices Regulations to allow access to medical devices, which are not currently available for sale on the Canadian market, for the purpose of making a diagnosis or providing care.

Such devices may feature new technology or materials, the benefits of which have not been fully substantiated, or may be undergoing review by the Medical Devices Programme and are thus not available for general use until the review is completed.

Once it is determined that the use of such a device is necessary, the practitioner must apply to the Programme for the sale of the device on compassionate grounds and provide the following:

- the name and model of the device;
- the name and address of the device manufacturer and the importer of the device if applicable;

- a description of the patient's condition and the type of diagnosis or treatment for which the device is required;
- an explanation as to why the device is the one best-suited to meet the needs of the patient rather than one which is already available on the Canadian market.

The practitioner must also agree to:

- inform the patient of the potential risks and benefits associated with the use of the device and obtain the patient's written consent to use the device;
- advise the Programme as to any adverse incidents involving the use of the device that may endanger the health or cause the death of a patient;
- update the Programme and the device manufacturer at specified time intervals as to the outcome of use of the device and any subsequent uses of other units of the same device.

Once the Programme has reviewed all information provided by the practitioner and determined that the potential benefits to the patient appear to outweigh the risks associated with use of the device, the Programme may then authorize the manufacturer to sell a specific number of units of the device to the practitioner.

Practitioners should note that the approval for use of any device on compassionate grounds can be canceled at any time by the Programme following review of an adverse incident report involving use of the device from a practitioner or manufacturer, or review of scientific literature or material produced by a similar regulating agency of a foreign government indicating that continued use of the device would endanger the life or health of a patient.

For further information concerning release of a medical device on compassionate grounds, contact Kathy Bird at (613) 954-4587 (tel.), (613) 957-1596 (fax) or **Kathy_Bird@isdtcp3.hwc.ca** (email).

Guidance Documents

Submitter's Guide for Compliance with PART V

The new "Submitter's Guide for Compliance with Part V of the Medical Devices Regulations" is now available. It replaces the previous publication "Guide to the Preparation of a Submission Pursuant to Part V of the Medical Devices Regulations" (84-EHD-107).

This new guide is the result of extensive consultations between industry representatives and Programme staff. It will provide assistance to device manufacturers that are required to forward submissions to the Programme in order to comply with Part V requirements of the Medical Devices Regulations.

For further information contact Kathy Bird at (613) 954-4587 (tel.), (613) 957-1596 (fax) or **Kathy_Bird@isdtcp3.hwc.ca** (email).

What's New in Notification and Tracking

A final version of the Guide to the Preparation of a Notification Pursuant to Part II of the Medical Devices Regulations is now available. A copy of the Guide can be obtained through one of the regional offices or by faxing a request to the Notification and Tracking Section at (613) 941-4726. For further information contact Hripsime Shahbazian at (613) 957-1909 or **Hripsime_Shahbazian@isdtcp3.hwc.ca** (email).

An electronic version of both these Guides is available on the Canada Health Network website; the URL is **http://www.hwc.ca/hpb/drugs/meddev.**

Magnetic Keys for Patient Restraints: A Possible Hazard for Pacemaker Patients?

Magnetic keys are widely used to secure patient restraint vests and belts. The convenient locking system consists of a pin which slips into a button

to lock belts together. To open the lock, a magnetic key is brought near the button. This opens an internal latch and releases the pin.

The Programme has received a report that the Segufix Magnetic Lock may change the programming of an implantable cardiac pacemaker. Since health care workers sometimes carry the magnetic key on a cord around their necks, the key could briefly come near a patient's chest if the worker is bending over the patient. Our *in-vitro* laboratory study has confirmed that at a distance of 3 cm or less, the Segufix magnet can change the programming of a pacemaker to its temporary operation - the fixed rate asynchronous mode. However, when the magnet is removed, the pacemaker returns to its normal operation.

The temporary switch to the asynchronous mode is not in itself a serious hazard to the patient. However, when a pacemaker is in the asynchronous mode, it could, in theory, become susceptible to electromagnetic interference (EMI) which could lead to a permanent change of its programming. If this were to happen, the patient could experience ventricular tachycardia (VT) or ventricular fibrillation (VF) which could be serious.

In order for a permanent programming change to occur, there would have to be a source of EMI capable of reprogramming the pacemaker while the magnet is near the pacemaker. No such cases have been reported to the Programme, and we consider the probability of simultaneous occurrence of two such events to be extremely unlikely. Nevertheless, we suggest that users avoid bringing magnetic keys near a pacemaker.

Hospital workers have also reported that the magnetic keys can erase information on credit cards and computer disks. We have verified that the Segufix key will easily destroy information if it is brought in contact with a computer disk. For further information, contact Dr. Kok-Swang Tan at (613) 954-0380 (tel.), (613) 993-0281 (fax), or **Kokswang_Tan@inet.hwc.ca** (e-mail).

Canada/US Joint Review Initiative

The Device Evaluation Division (DED) of the Canadian Medical Devices Bureau and the Office of Device Evaluation (ODE) in the Center for Devices and Radiological Health, US Food and Drug Administration (FDA), have joined forces in a pilot project that initiates partnership between the review staff of these two organizations.

The pilot project covers specific ear, nose, and throat devices, including cochlear implants, tympanostomy tubes and ossicular prostheses, as well as orthopedic devices. The pilot began January 15,1997, and after one year, the progress of the project will be assessed.

It is anticipated that this pilot will result in improved understanding of regulatory procedures in the two jurisdictions, and in the identification of more efficient ways to handle reviews. The pilot project will not delay review times. Equivalent safeguards for proprietary or confidential information exist in both jurisdictions. No information can be disclosed to another party without the proir consent of the sponsor. A formal protocol has been developed for this partnership.

To date, three meetings of reviewers from the FDA and the Canadian Medical Devices Bureau, have taken place, two in Ottawa in September 1996, and one in Washington, DC, in January 1997. Participants in these meetings have been unanimous in their opinion about the great potential of this initiative for success. For information contact: Dr. D. Clapin, General and Restorative Devices, 613-954-0942 (tel.), **Dave_Clapin@isdtcp3.hwc.ca**

An Interim Policy for Class I Devices

The Programme has adopted a new policy governing the processing of device notifications required (pursuant to Part II of the Medical Devices Regulations) to address the increasing backlog in processing notification applications and issuing device identification numbers. Processing of notifications relating to lower risk class (Class I) devices and issuing of device identification numbers to these devices will be delayed until the backlog of higher risk class devices has been eliminated or until the proposed new Regulations come into force. The medical device industry will be advised of this policy by a letter (copy follows) that will be mailed to them together with the acknowledgment card issued for each notification received by the Medical Devices Bureau. For information call Ms. H. Shahbazian at (613) 957-1909 (tel.) or **Hripsime_Shahbazian@isdtcp3.hwc.ca** (email).

TO: Manufacturers and importers of medical devices.

Part II of the Medical Devices Regulations requires manufacturers of all medical devices to notify Health Canada within 10 days from the day on which the manufacturer first sells the device in Canada. Health Canada has historically processed these notifications and provided each manufacturer with a device identification number (formerly called an accession number).

The Drugs and Medical Devices Programme is proposing to replace the Medical Devices Regulations which have been in force since 1975, with a new set of Medical Devices Regulations. The new Regulations stem from a 1991-1992 review of the Programme which recommended that the focus should be on regulating medical devices on a risk assessment and risk management basis.

The proposed Regulations are founded on two principles: 1) that the level of scrutiny afforded a device should be dependent upon the risk that the device presents, and 2) that the safety and effectiveness of medical devices can best be assessed through a balance of quality systems requirements, pre-market scrutiny and post-market surveillance.

The proposed Regulations set out a system for classifying medical devices into one of four classes, with Class I representing the lowest risk devices and Class IV representing the highest risk devices.

Pending the coming into force of the new Regulations and in view of the large backlog of notifications which are in the queue for processing under the existing Regulations, the Programme will implement a risk management approach in processing notifications under Part II of the Medical Devices Regulations. Consequently, devices which will fall into Class II, III and IV will receive notification processing priority over devices which will fall into risk Class I.

This means that notifications for Class I devices, although currently required under the Regulations, will receive lower priority for processing. This will not affect the authority to sell these devices as the Regulations currently permit sale within 10 days of notification. Manufacturers are however advised that receipt of the device identification number indicating that the notification has been processed will be delayed until such time as the backlog has been eliminated or until the new Regulations come into force.

The Programme will continue to issue an acknowledgment card for all notifications received.

Additionally, the Programme will not acquiesce to telephone requests to issue a device identification number for Class I devices in the backlog. Manufacturers wishing to provide evidence to their customers, or others, that their

device is notified are encouraged to use this article, a copy of their completed notification form and the acknowledgment card as an indication that their device is duly notified. It is pointed out that this acknowledgment does not constitute or imply approval of the device(s) notified.

Please note that this is an administrative change only and all the requirements of the current Medical Devices Regulations continue to apply until the new Regulations are in force.

How to contact the Medical Devices Programme

Medical Devices Bureau Hotline 1-800-267-9675

Regional Offices

Western 1-604-666-3845 Central 1-204-983-5451

Ontario 1-416-973-1596 Quebec 1-800-561-3350

Atlantic 1-902-426-5575

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The *Medical Devices Bulletin* is intended to serve clients, stakeholders, staff and partners of the Medical Devices Program. 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.

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 MDP staff can also be contacted via the Internet at "*****"@isdtcp3.hwc.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 @isdtcp3.hwc.ca.