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MEDICAL DEVICES BULLETIN

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

PROGRESS IN MUTUAL RECOGNITION AGREEMENTS

Canada and the European Union (EU) have moved forward in Mutual Recognition Agreement (MRA) negotiations. Once operational, the agreement will allow the EU and Canada to accept the conformity assessment approvals issued by the other party without further reassessment.

The MRA has three main purposes:

- to ensure the safety and effectiveness of devices marketed in Canada without devices having to undergo any unnecessary evaluation in both jurisdictions;
- to provide Canadians with quicker access to new technology developed by EU companies; and
- to allow Canadian device manufacturers quicker and easier access to the large markets represented by the EU.

Under the proposed agreement, the EU and Canada would undertake a transitional confidence-building phase leading to an operational phase.

Confidence-Building Phase

The confidence-building phase is aimed at establishing comparability of two aspects of each party's review process: pre-market evaluation procedures respecting technical device-related submissions; and quality audit methodology and interpretations.

Pre-market evaluation procedures will undergo an inter-comparison exercise, using a select sample of devices (minimum of 10 cases) representative of different device technologies in high and medium risk classes. Each test case submission will be evaluated in parallel by Health Canada and at least one other participating EU Conformity Assessment Body (CAB). The evaluation will be made against the regulatory requirements of the market for which the device is intended. The reports and recommendations of each CAB, including Health Canada, will then be compared. During this phase, and after resolution of all relevant issues, final approval will be issued by the CAB responsible for the market for which the device is intended.

Procedures for confidence building with respect to quality system audits are in the preliminary stages of development.

After some 18 months of experience in this phase, both sides will have an opportunity to evaluate the results and, on the basis of establishing satisfactory mutual confidence, to make the decision to move to the operational phase.

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Operational Phase

In the operational phase, the CABs that have been accepted as part of the agreement will conduct full assessments of medical devices to the requirements of the other party. The approvals issued by participating CABs pursuant to these conformity assessments will be mutually recognized without the need for further assessment.

Terms of the MRA

The MRA would ensure recognition by one party of conformity assessments made by the other. Terms of the agreement will include:

- Manufacturers must continue to adhere to all other regulatory requirements applicable to medical devices within the territory in which they are marketed (registration requirements, post-market reporting requirements, etc.).
- Each party will notify the other of any confirmed problems reported and of corrective actions or recalls related to products evaluated under the MRA.
- Each party will share with the other any information, generated within the framework of its regulatory system, that is relevant to the operation of conformity assessment procedures.

In future issues of the Bulletin, we will keep you updated on further developments regarding MRAs. For more information, contact Don Boyer at (613) 957–7090 (tel.) or at don_boyer@isdtcp3.hwc.ca (e-mail).

SALES OF DEVICES FOR INVESTIGATIONAL TESTING

In Canada, investigational testing is required for devices that currently do not have safety and effectiveness data available. These devices can only be sold in Canada under the provision of the section 15.2 of Part I of the Medical Devices Regulations.

The Regulations were amended on December 27, 1995, to consolidate specific requirements for investigational testing (formerly called a clinical trial) of medical devices. Prior to this amendment, the requirements for conducting clinical trials for Part V devices under section 35(3) were not well defined. The Medical Devices Program feels that it has addressed this shortcoming by requiring that all investigational testing (clinical trials), including those for Part V devices, be conducted in accordance with well-defined requirements.

Investigational testing is conducted by qualified health care professionals, with the approval of the ethics committee at the hospital where the testing is to be carried out. Before initiating testing, the manufacturer of the device must file an investigational testing submission with the Medical Devices Program. Program clinicians or scientists review the submission to ensure that the device can be used for investigational testing without seriously endangering the life or health of the patient on whom it is to be used, or the user of the device.

The Program also provides guidance to manufacturers on the design of investigational tests. Such guidance includes requirement to ensure that the investigational patient population is representative of age and sex of the ultimate population for which the device is intended. For devices used by both sexes, inclusion criteria list both men and women. In the testing of devices used mostly by older age groups, more women than men are enrolled due to population demographics. Studies involving gender-specific devices such as intrauterine devices are, of course, limited to the relevant gender.

For further information on investigational testing of a specific device, contact the relevant Section Head of the Device Evaluation Division:

- Musculoskeletal Devices -
  Dr. Mary-Jane Bell at (613) 954-0377
- In Vitro Diagnostic Devices -
  Dr. Christian Choquet at (613) 954-0387

• General Restorative Devices -
Dr. David Clapin at (613) 954-0942

• Cardiovascular Devices -
Dr. Kathleen Magwood at (613) 954-0295

Note: Fax number : (613) 941-4726

CONDOMS

Changes to Regulations

Schedule I of the Medical Devices Regulations is a standard for the design, performance, testing, advertising, labelling and packaging of condoms in Canada. In June 1996 the Schedule was amended to ensure that female condoms and synthetic plastic male condoms sold in Canada provide adequate protection against disease and pregnancy. Latex male condoms must continue to pass the detailed requirements in the Schedule. However, manufacturers of female condoms and synthetic male condoms must also obtain the Medical Devices Program's approval of the test methods for these products prior to selling the condoms in Canada.

The manufacturer must also have a monitoring system in place to ensure that the quality of the condoms is being checked, and demonstrate that the material used to make the condoms provides a good barrier to micro-organisms and sperm.

Details on the approval process can be obtained from Dr. David Clapin at (613) 954-0942 (tel.) or david_clapin@isdtcp3.hwc.ca (e-mail).

Illegal Sales

On June 19, Health Canada issued a public warning concerning the sale of expired Aegis, Adonis, and Maxima condoms. From the information available, it appears that these condoms were sold primarily through vending machines in Quebec.

An investigation conducted by the Program's Quebec Regional Office revealed that the condoms were manufactured before 1989. These condoms have expired and are believed to be unfit for use because they may provide inadequate protection for contraceptive purposes or against sexually transmitted diseases.

A previous investigation in 1994 revealed that Distributions Cofalb Inc. (Distribution R. Pagé Inc.) had re-labelled Aegis and Adonis condoms with a new lot number to extend the expiry date of the condoms. In Canada, sale of condoms after their expiration date — a date that must not be more than five years after their manufacture — is prohibited. The condoms were offered for sale under new brand names, such as "Adam et Eve". As a result of this investigation, 2.5 million Aegis and Adonis condoms were seized by the Program and destroyed.

Recently, the Program has become aware that Distributions Cofalb Inc. had resumed selling Aegis and Adonis condoms. A follow-up investigation prompted the Program on May 17, 1996 to obtain an injunction in Federal Court ordering the firm to stop selling the expired condoms, to stop re-labelling expired condoms to modify the expiration date, to hand over all condoms in stock to Health Canada, and to provide a list of locations where the condoms have been sold or offered for sale.

Aegis and Maxima condoms are apparently no longer being produced, but small quantities of these brands, distributed by a different company, may still be available in retail stores or vending machines. Health Canada advises consumers not to use Aegis or Maxima condoms, or Adonis condoms with lot number 910615 and expiration date May 1994, and lot number 910315 and expiration date February 1994.

For further information, contact Benoit Toupin, Quebec Regional Office of the Medical Devices Program at 1-800-561-3350.

BLOOD GLUCOSE MONITORS

Medical Devices Program scientists have studied the safety and effectiveness of blood glucose monitors since 1983. Studies have continually demonstrated deficiencies, resulting in Program negotiations with manufacturers to obtain corrective action. For example:

- The complexity of some monitors and their operating manuals was found to decrease their clinical reliability. Manufacturers responded by simplifying the design and labelling of the devices.

- It was discovered that the monitors did not produce clinically reliable results without proper calibration, and that some monitors did not function if they were not calibrated before use. As a result of corrective action, current monitors are easier to calibrate, and instruction manuals now warn users of relevant models of the need for calibration prior to each use.

- Abnormal hematocrit and lipemia were found to dramatically affect the results obtained with some monitors, making them unsuitable for monitoring neonates. As a result of Program input, manufacturers now advise users of limitations by putting warnings in the package inserts for relevant models.

In 1987, Program scientists warned of the risk of finger injuries and infections as a possible complication of home-use blood glucose monitoring, and developed guidelines to reduce such risks. In 1991, the Program alerted health care professionals about the risk of infection from spring-loaded lancet devices used with glucose monitors (Medical Devices Alert No. 95). Program guidelines have been incorporated into national and international standards and guidelines. The Program has also collaborated with the Canadian Standards Association (CSA) to establish a comprehensive performance standard for blood glucose monitors.

The Program has continued its research into the performance and limitations of glucose monitors and has conducted numerous investigations over the past 13 years. Problems experienced with a monitor or any accessories should be reported to the nearest regional office listed in the Bulletin, or by calling the Medical Devices Hot-line at 1-800-267-9675.

Health care professionals responsible for blood glucose testing or training diabetes patients in self-monitoring should be aware that glucose monitors may give unreliable results in patients with certain clinical conditions. For further information, contact Abbey Klugerman at (613) 957-3144 (tel.) or at abbey_klugerman@isdtcp3.hwc.ca (e-mail).

REGULATORY PROPOSALS UPDATE

The Medical Devices Program received numerous constructive and helpful comments on last December's regulatory proposals. These comments were discussed at the January 1996 consultation workshops held in Vancouver, Toronto, Montreal, and Washington D.C.

Soon after the workshops, a Program Working Group met to consider changes to the proposals based on the comments received. The group made its recommendations for changes to senior Program management last March.

A second working group on workload estimation examined the proposals in light of the Program's ability to deliver the services associated with the proposals. Additional changes were recommended to Program managers for consideration at a managerial meeting held in June.

As a result of these meetings, the following changes have been made to the Regulatory proposals:

- The Program will not make bar coding a mandatory requirement for medical devices. While the intent of the proposal remains valid (i.e., each medical device be uniquely identified to permit accurate and efficient identification of the device), the Program agreed with the comments to be more flexible with

respect to how the intent is implemented. Accordingly, the option of placing either a catalogue number or a bar code on the label of a device will be incorporated into the labelling requirements of the new Regulations.

• In response to comments that the Program would not be able to handle the workload associated with device registration in a timely manner, requirements will be phased rather than implemented all at once. Upon promulgation of the new Regulations, only risk class II, III, and IV devices will be required to be registered. Meanwhile, the Program will investigate other means to obtain sufficient information to identify companies selling Class I devices. Phasing in the requirements should significantly reduce the Program's workload respecting device registration, as it is estimated that Class I device registrations account for approximately 45 percent of all device registrations.

• The submission of an investigational testing application for Class I devices will not be required under the new Regulations, but manufacturers conducting investigational testing with Class I devices will be expected to adhere to the investigational testing requirements.

• There will be no requirement for Establishment Registration by manufacturers, as information on these establishments will be controlled through Device Registrations, renewable every three years. Additionally, foreign manufacturers will be allowed to designate an authorized agent to act on their behalf in all aspects of Device/Establishment Registration. Default times for service delivery will appear in service standards rather than in the Regulations.

Lawyers from the Regulatory Section (Justice) have written the proposals into regulatory text. Regulations are expected to be approved and published in the Canada Gazette, Part I, in October.

Copies of the December 1995 version of the regulatory proposals or the relevant Canada Gazette may be obtained from Erika Lindig at (613) 954-0287 (tel.) or (613) 993-0281 (fax). The Canada Gazette is also posted on the Environmental Health Directorate website. For address see page 8.

WHAT'S NEW IN NOTIFICATION AND TRACKING?

The enhanced Medical Devices Database was implemented in April 1996. Users should be aware that, since the database is now relational and number-oriented, some changes have been made in terminology and manufacturer codes:

• The term "Device I.D. Number" replaces the previous "Accession Number". In any correspondence with the Medical Devices Program concerning a specific device, manufacturers and health care professionals should quote the Device I.D. Number(s).

• The three-letter company code previously used in all correspondence with device manufacturers has been replaced by a six-digit code. Correspondents are requested to continue using their three-letter code until they are advised of the new six-digit code. (Note that individual Device I.D. Numbers and manufacturer codes are both six-digit codes.)

• A risk class (0, 1, 2, 3, 4) has been added to the Preferred Name Code (PNC) data set: 0 indicates that a risk class has not been assigned; 1 indicates the lowest risk class; and 4 indicates the highest risk class. For example, 74LWS—Defibrillator, automatic implantable cardioverter, risk classification 4.

Approximately 95 percent of the PNCs currently used to identify medical devices in the database have been assigned a risk class. The classification of the in vitro diagnostic preferred name codes is currently being validated.

A final version of the Guide to the Preparation of a Notification Pursuant to Part II of the Medical Devices Regulations will soon be

released. The final version reflects user feedback and the latest changes to the database. This Guide is intended to clarify the notification process and includes a sample of the Device Notification Form. Users are encouraged to keep this form as an original and to make copies of it for future notification purposes. A copy of the Guide can be obtained through one of the regional offices or by contacting Christine Reissmann, Head, Notification and Tracking Section at (613) 957-1909 (tel.) or (613) 957-7666 (fax) or at christine_reissmann@isdtcp3.hwc.ca (e-mail). The Guide can also be downloaded from the Health Canada Bulletin Board Services. Please find BBS address on page 8.

COST RECOVERY INITIATIVE UPDATE

Cost Recovery Statistics for Part V Devices

Since the Medical Devices Fees Regulations were implemented on January 1, 1996, the Program has received 53 new device submissions and 96 supplementary device submissions.

In general, service standards were either met or surpassed during the first six months of the cost recovery initiative. Performance was noticeably better in the second quarter of the cost recovery initiative (April 1–June 30):

- 98.8 percent of submissions were acknowledged within 7 days, compared with 47.2 percent in the first quarter. Average turnaround for acknowledgement was 2 days per submission, compared with 13 days in the first quarter.
- 81 percent of submissions were screened within 21 days, compared with 50 percent in the first quarter. Average turnaround to screen submissions was 18.5 days, compared with 22.9 days in the first quarter.
- Average total elapsed time – from date of receipt of a file to the date a Notice was issued – was 50 days, compared with 75 days in the first quarter.

Fee Application Procedures for Part V Submissions

The Program is striving to monitor and continuously improve its procedures and processes. To make it easier to process fees and submissions:

- Manufacturers should send cheques or money orders in Canadian funds, as indicated in the *Fee Application Procedures*. Cheques written on U.S. or other foreign currency accounts create inefficiencies and lengthy delays in processing submissions.
- Manufacturers should send the submission and application form, with the fee attached, to the Medical Devices Program.
- Manufacturers should send the fees with their invoice for outstanding balances to the Medical Devices Program, not to HPB Financial Services. This is a change in procedure in response to manufacturer feedback, and will expedite the submission process. The cost recovery initiative package will be updated to reflect this and other procedural changes.

To avoid excess use of paper, it is no longer necessary to send more than one copy of the submission.

New Devices Regulations and Cost Recovery

The new Medical Devices Regulations are expected to be published in the Canada Gazette, Part 1, in October 1996. The processes, services and respective costs related to the proposed new regulations are being assessed by the Program. Further details will follow.

The Industry Consultative Committee representing industry associations, the Canadian Healthcare Association, Industry Canada and the Program, on the second phase of the cost recovery, continues its discussions on cost recovery based on the new Regulations. The first meeting of the Committee was held in May. Suggestions and feedback from the Committee were appreciated.

To ask questions, or to provide feedback, on the Medical Devices Program cost recovery initiative, contact Linda Bierbrier, Medical

Devices Bureau at (613) 957-1594 (tel.) or at linda_bierbrier@isdtcp3.hwc.ca (e-mail).

DENTAL AMALGAM

Health Canada's position statement entitled *The Safety of Dental Amalgam* was officially released at a technical briefing for the news media on August 21, 1996. The recommendations were mailed the same day as a "Dear Doctor" letter to all Canadian dentists. Copies of the letter have been distributed through the Canadian Medical Association Journal to Canadian physicians in early September.

The full statement is a fifteen-page document consisting of two sections:

- a review of the background information, which summarizes the various issues, the evidence, and our conclusions;
- the considerations and recommendations which are addressed to the dental profession.

It must be emphasized that the recommendations contained in the document are not regulations; Health Canada's mandate under the Medical Devices Regulations does not include the regulation of dental practice. Nevertheless, we trust that these recommendations will be useful to dentists and their patients who are concerned over amalgam safety.

The considerations and recommendations of the report are as follows:

Considerations:

1. Although dental amalgam is the single largest source of mercury exposure for average Canadians, current evidence does not indicate that dental amalgam is causing illness in the general population. However, there is a small percentage of the population which is hyper sensitive to mercury and can suffer severe health effects from even a low exposure.
2. A total ban on amalgam is not considered justified. Neither is the removal of sound amalgam fillings in patients who have no indication of adverse health effects attributable to mercury exposure.
3. As a general principle, it is advisable to reduce human exposure to heavy metals in our environment, even if there is no clinical evidence of adverse health effects, provided the reduction can be achieved at reasonable cost and without introducing other adverse effects.

Recommendations:

Health Canada advises dentists to take the following measures:

1. Non-mercury filling materials should be considered for restoring the primary teeth of children where the mechanical properties of the material are suitable.
2. Whenever possible, amalgam fillings should not be placed in or removed from the teeth of pregnant women.
3. Amalgam should not be placed in patients with impaired kidney function.
4. In placing and removing amalgam fillings, dentists should use techniques and equipment to minimize the exposure of the patient and the dentist to mercury vapour, and to prevent amalgam waste from being flushed into municipal sewage systems.
5. Dentists should advise individuals who may have allergic hypersensitivity to mercury to avoid the use of amalgam. In patients who have developed hypersensitivity to amalgam, existing amalgam restorations should be replaced with another material where this is recommended by a physician.
6. New amalgam fillings should not be placed in contact with existing metal devices in the mouth such as braces.
7. Dentists should provide their patients with sufficient information to make an informed choice regarding the material used to fill their teeth, including information on the risks and benefits of the material and suitable alternatives.
8. Dentists should acknowledge the patient's right to decline treatment with any dental material.

Copies of the following documents are available free of charge:

- The complete position statement, *The Safety of Dental Amalgam.*
- The Health Canada report *Assessment of Mercury Exposure and Risks from Dental Amalgam* by Dr. Mark Richardson.
- The report of the Health Canada stakeholder committee on amalgam by Dr. G. Wayne Taylor.

To order them, please contact:

Publications
Health Canada
Address Locator 0900C2
Ottawa, Ontario
K1A 0K9
Tel: 613-954-5995
Fax: 613-941-5366

These Health Canada documents are also posted on the Environmental Health Directorate Website and Health Canada's Health Information Net electronic bulletin board service (BBS).

ELECTRONIC COMMUNICATIONS WITH MDP

Health Information Net BBS

The Health Information Net electronic bulletin board service (BBS) can be accessed by direct dial-up or by Internet using Telnet, Gopher, or World Wide Web (WWW).

Direct Dial-up

For dial-up access, the numbers are (613) 941-0979, 941-1139, 941-0810, 952-9597 or 954-6151. Once a connection is made, login using **hpbnet** (lowercase). Follow the instructions on the screen to register as a new user. A login name and password will be assigned.

Internet Access

The address for Telnet or Gopher is **hpb1.hwc.ca.** For Telnet access, login using the same instructions outlined above for modem access. For Gopher access, select the HPB BBS Information topic once the menu is displayed. The address for the WWW site is **http://hpb1.hwc.ca:8300.** No login is necessary for WWW access as you are automatically logged in as an anonymous user.

Environmental Health Directorate WWW Site

The Environmental Health Directorate (EHD) WWW site offers access to information for program areas under its auspices, including the Medical Devices Program. The address for the site is **http://www.hwc.ca/datahpb/dataehd.**

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

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Head, Notification and Tracking	Christine Reissmann Tel.: 613-957-1909 Fax: 613-941-4726	Notification, information on registering a device, tracking Part V devices
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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.

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