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MEDICAL DEVICES BULLETIN

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

Welcome...

We are pleased to welcome you to the second issue of our *Medical Devices Bulletin*. We'd also like to thank all of you who took the time to write in with your comments on our first issue. The response was very positive and we are taking your suggestions into consideration as we plan upcoming issues.

In line with your comments, we are striving to provide you with the most up-to-date information on the issues at hand. In this issue, we're highlighting many timely subjects including updates on alerts, the dental amalgam study, international harmonization efforts and the latest developments in our cost recovery initiative.

We hope you find this issue informative and helpful. Included in many of our articles is a name and number for additional information. Please continue to send in your comments. They will be helpful as we continue to strive to keep our key audiences as fully informed as possible about our business.

ALERTS RESPOND TO PUBLIC HEALTH NEEDS

Each year, the Medical Devices Program receives over 300 reports from health care professionals and the public on problems related to medical devices.

Most problems reported are resolved by direct interaction between the Health Protection Branch (HPB), the manufacturer and the user, without the need for a public advisory.

However, in cases where the hazard is judged to be urgent and widespread (about two percent of problem reports), the Program issues *Medical Devices Alerts*. *Alerts* are sent to all Canadian hospitals and to selected nursing homes and individual health care professionals in order to recommend corrective action for the user and to describe measures being taken by the manufacturer and the government to address the problem.

Hazards reported in *Alerts* must meet the following criteria:

1. The device has been implicated in a death or serious injury, or in an incident with the potential to cause death or serious injury and there is a reasonable probability of recurrence.

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2.The hazard has been confirmed by HPB scientific and clinical evaluation and/or testing.

3.The device is used by a sufficient number of hospitals or physicians to justify informing all potential users by an *Alert* rather than contacting individual users.

4.The manufacturer is unable or unwilling to identify and contact all users of the device to issue a warning or conduct a product modification or recall.

5.The corrective action recommended, or the increased user awareness generated by an *Alert*, will significantly reduce the risk of recurrence of the problem.

Wherever possible, an *Alert* will identify the device, including trade name, model number, serial or lot numbers, and particulars about the manufacturer. If the problem is common to more than one manufacturer, a list of trade names or a generic description of the device type is provided. All manufacturers affected are informed of the *Alert*'s text before publication.

Alerts have been well-received by Canadian hospitals. Two contract surveys reported that nearly all hospitals are familiar with *Alerts* and use them in their safety programs. *Alerts* are also abstracted in industry newsletters and journals in the United States.

Alerts are currently distributed, according to topic, to about 4,500 hospitals, nursing homes, physicians and interested individuals throughout Canada and the United States. An average of six have been issued annually over the past 18 years. As of February 1995 (*Alert No. 106*), the procedure of faxing *Alerts*, wherever possible, was started. While faxing will reach most institutions, only about a third of physicians' offices currently have fax machines.

Because *Alerts* are not published on a regular schedule, some recipients may wonder if they have missed an issue. A printed list of all 107 *Alert* titles, with their date of issue, may be obtained by contacting Kathy Bird, Research and Surveillance Division, Medical Devices Bureau, Room 225, 775 Brookfield Road, Postal Locator 6302B, Ottawa, Ontario, K1A 1C1, Tel. (613) 954-0287, Fax (613) 993-0281. Current issues can also be found on HPB's WWW site at http://hpb1.hwc.ca/datahpb/dataehd

PREVENTIVE MAINTENANCE FOR ANAESTHESIA AND OTHER MACHINES WITH WHEELS

The Montreal regional office recently investigated an incident report where one of the wheels of an anaesthesia machine broke, tipping the unit over and causing a hand injury to a technician.

The investigation revealed that the manufacturer of the device had known of the potential for wheel breakage since 1989 and had initiated a protocol of wheel inspection/replacement at that time. However, only those operators who had purchased an after-sales service contract with the distributor were contacted about the inspection/replacement protocol. Such a contract was recommended at the time of purchase and included a complete check of the apparatus, including the wheels, three times per year. Only three-quarters of the distributor's eastern Canada clients purchased a service contract. At HPB's recommendation, the distributor informed the remainder of its clients of the potential for wheel breakage and provided them with inspection/replacement procedures.

Our review of the USFDA problem report database revealed a similar incident in which a hospital employee suffered a serious injury. Should this type of incident occur during a surgical procedure, potential exists for the patient to suffer serious injury.

HPB recommends that all operators of anaesthesia machines, as well as all other wheeled devices, ensure that the wheels/casters are checked on a regular basis, either through an after-sales service agreement with the manufactur-

er/distributor, or through their own biomedical engineering unit. Any problems should be brought to the immediate attention of one of the HPB regional offices listed in this bulletin, or by calling the *Medical Devices Hot-line* at 1-800-267-9675.

AMALGAM SAFETY BECOMES FOCUS OF RECENT ATTENTION

The safety of dental amalgam (tooth fillings containing mercury) has received considerable public attention in the past few years as a result of controversial television documentaries such as *60 Minutes* and the BBC's *Panorama*, as well as articles in magazines like *Consumer Reports*. Research claiming to show a link between dental mercury and a wide range of illnesses has also been published.

Sweden has proposed the gradual discontinuation of amalgam on environmental grounds, while Germany has recommended restrictions on its use. However, the U.S. Public Health Service, in a major review published in January 1993, concluded that it was inappropriate to recommend any such restrictions.

The Medical Devices Bureau is conducting an extensive review of available data on dental amalgam in order to establish a basis for the Department's position on the subject. A preliminary report, which reviews available scientific information and includes an exposure and risk assessment, has undergone scientific peer review by a group of national and international experts. While the report will not contain recommendations on the use of amalgam, it will be used as the basis for a departmental position on amalgam safety.

The report will be released this fall to stakeholders in order that they may discuss possible policy options. Stakeholders include provincial health ministries, the Canadian Dental Association, the International Academy for Oral Medicine and Toxicology, the dental products industry, and various citizens groups. When released, the report can be obtained by contacting Kathy Bird at (613) 954-0287.

SEPTEMBER WORKSHOP FURTHER DIALOGUE ON PROPOSED REGULATORY CHANGES

A two-day workshop hosted by the Medical Devices Program in September featured presentations and discussions concerning proposed changes to the Medical Devices Regulations.

The workshop held in Ottawa on September 11 and 12 was attended by Program staff, industry representatives and members of the recently formed Ad Hoc Stakeholders Group advising on the finalization of the Regulatory Proposals. The Ad Hoc Group, which consisted of representatives from industry, health care professionals and consumers, was established to provide immediate feedback on revisions to the regulatory proposals.

On the first day of the workshop, subject experts made presentations on issues concerning proposed regulatory changes, including ISO 9000 Quality System Standards, third party assessments, bar coding, mutual recognition agreements, and European Medical Devices Directives. On the second day, the Ad Hoc Stakeholder Group met with Program representatives to discuss outstanding issues and concerns. These meetings will continue throughout the fall to ensure the broadest possible understanding and acceptance of the final regulatory proposals.

The workshop followed the recent completion of the Business Impact Test (BIT). The BIT was used to identify direct cost to firms applicable to the regulatory proposals, as well as how the proposed regulations impact on the way firms operate, organize and innovate. For a copy of the final report, contact Debbie Clark at (613) 957-7285.

The program expects to have the next version of the proposed requirements finalized by mid November, at which time it will be available to interested stakeholders for review and comment. As well, regional workshops are proposed for January, to provide further opportunity for comments prior to the March 1996 publication of the proposals in the Canada Gazette Part I.

ELECTRONIC COMMUNICATIONS UPDATE

BBS (Health Information Net)

The electronic bulletin board service (BBS) can now be accessed by direct dial-up with a modem or by Internet using Telnet, Gopher, or World Wide Web (WWW).

For modem access, the numbers are (613) 941-0979, 941-1139, 941-0810, 952-9597 (five modems) or 954-6151 (three modems). 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.

For Internet access, login using the same instructions outlined above. 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. The address for Telnet or Gopher is **hpb1.hwc.ca**. For Gopher, select the HPB BBS Information topic once the menu is displayed.

EHD World Wide Web (WWW) Site

The Environmental Health Directorate WWW site offers access to information for program areas under its auspices, including the Medical Devices Program. The URL for the site is **http://hpb1.hwc.ca/datahpb/dataehd**. Look for further developments in the coming months.

UPDATE ON BACKFLOW FROM LAPAROSCOPIC INSUFFLATORS

Medical Devices Alert No. 106 (February 3, 1995) warned hospitals of the possibility of laparoscopic insufflators becoming contaminated with patient fluids, resulting in the danger of infection to patients and damage to the insufflator. HPB has undertaken regulatory action with insufflator manufacturers to correct the problem. Manufacturers have now stopped the sale of insufflators that can allow backflow under normal operating conditions. One manufacturer has offered to replace contaminated units free of charge and has developed a retrofit for new units, or existing units that have not been contaminated.

Following the *Alert*, some hospitals reported finding contamination that may have been previously undetected because of the small amount of fluid involved. Hospitals are advised to inspect their units carefully.

The *Alert* recommended the use of disposable hydrophobic bacterial filters as an extra level of protection. Several users have asked the Branch to recommend suitable filters. While HPB is currently testing representative filters, the many different insufflators and filters on the market do not allow us to suggest ones that will be compatible. Preliminary test results, however, indicate that some filters, including some recommended by insufflator manufacturers, are not suitable. Findings will be reported once testing is complete. For further information on findings contact Kathy Bird at (613) 954-0287.

LATEX ALLERGY PROJECT UPDATE

HPB's intention to require that all sterile medical gloves be labelled with material of manufacture by June 1996 was published in *Information Letter No. 814* (June 16, 1995). The requirement will assist users in avoiding inadvertent exposure

to natural rubber latex, and make it easier to distinguish among the different types of synthetic sterile gloves. Non-sterile medical gloves are already required to be labelled with material of manufacture (*Information Letter No. 777, April 13, 1990*). All medical gloves certified by the Canadian General Standards Board are labelled with material of manufacture.

The Bureau is working with the Ontario Hospital Association on a one-day educational seminar on latex allergy, to be held in Toronto on December 6, 1995. Registration information will be available in mid October from Carol Castella, Ontario Hospital Association, 150 Ferrand Drive, Don Mills, Ontario, M3C 1H6, Tel. (416) 429-2661, ext. 5600, Fax (416) 429-5651, Email: Carol_Castella@OHA.com.

The Bureau has prepared an email information package on latex allergy that may be obtained by writing adouglas@hpb.hwc.ca. The hard copy publications *Medical Glove Quality in Canada* and *Latex Allergy* may be obtained by calling 1-800-267-9675.

VANCOUVER HOSTS INTERNATIONAL HARMONIZATION ACTIVITIES

A series of events held in Vancouver last June will have a significant impact on the international harmonization of requirements for medical devices. The Medical Devices Bureau was involved in all of the activities, serving as host, sponsor, or participant.

The Global Harmonization Task Force met June 22-25 to continue discussions on opportunities for harmonization of regulatory requirements, quality systems, and audit procedures. The task force reviewed Canada's proposed regulations and provided valuable comments aimed at furthering harmonization of proposals with other jurisdictions.

The International Organization for Standardization (ISO) Technical Committee 210 held its second meeting June 22-24. The meeting furthered the development of draft standards for the application of ISO 9000 series of standards to medical devices.

The inaugural meeting of the Medical Devices Industry Association of British Columbia (MEDIA-BC) was held on June 27. Guest speaker, Dr. Richard Tobin, Director of the Medical Devices Bureau, spoke on the proposed regulations as well as cost recovery. The members of the association—largely small device manufacturers, distributors, or representatives of user groups—are enthusiastic about participating in the development of the regulations and ensuring that cost recovery is applied equitably.

The Fifth Global Medical Devices Conference, held June 25-28, attracted about 350 participants from around the world, making it the most successful meeting to date. The focus of the conference was international harmonization of regulatory requirements and globalization of the market place. Presentations by Canadian industry and by representatives of the Medical Devices Program demonstrated that Canada wants to be a player in this arena.

In preparation for more formal meetings in Ottawa this fall, an informal meeting of the Trilateral (USA, Mexico, Canada) Working Group on Quality Systems was held on June 21. While at different stages in their development of the process, all three countries espouse the principle that the implementation of quality systems in the manufacture and distribution of medical devices is fundamental to assurance of their safety and effectiveness.

COST RECOVERY INITIATIVE UPDATE

The Medical Devices Program has consulted extensively over the summer with the Industry Consultative Committee in an effort to identify equitable terms for implementing cost recovery.

The Committee is comprised of representatives from the following medical device associations: *Association québécoise des fabricants de l'industrie médicale*, Medical Devices Canada (MEDEC), Dental Industry Association of Canada, Electro Federation, Canadian Association of Technological Advances, Association of Ontario Medical Manufacturers and Medical Device Industry of British Columbia. The Manitoba Health Organization, Calgary Association for Medical Products and Healthcare Opportunities Metro Edmonton have given their proxy to MEDEC. The Committee has also representatives from the Medical Devices Program, HPB, and Industry Canada.

Extensive changes have been made to the proposal published on June 10, 1995 in Canada Gazette, Part 1. The changes include lower fees (for new devices and supplementary submissions) and a fee reduction schedule for low volume products. The implementation date has been changed to December 1, 1995.

Information about the cost recovery program may be obtained from Linda Bierbrier, Medical Devices Bureau, Tel. (613) 957-1594.

ISO 9000 HANDBOOK NOW AVAILABLE TO MEDICAL DEVICES INDUSTRY

Information Letter #791, issued in 1991, confirmed the intention of the HPB to adopt ISO 9001 standards for quality of medical devices. Since that time, HPB has been active in pursuing this goal. Staff have participated in the Global Harmonization Task Force, the ISO Technical Committee #176 (which developed the ISO 9000 series of standards), the ISO TC #210 (which is developing an international approach to adapt ISO 9001 to the medical device sector), and numerous consultations and analysis activities with industry and foreign health authorities.

The Medical Devices Bureau, represented by Pierre Landry of the Planning Division, recently combined efforts with the Canadian Standards Association to produce *The ISO 9000 Essentials—A Handbook for Medical Device Manufacturers*. This 173-page handbook, released in May 1995, links all components of the global harmonization approach that are currently being developed for medical devices. Believed to be the first of its kind, the handbook brings together the components necessary to understand the relationships between the ISO 9001 quality requirements and the concepts of applying them to the design, manufacture and installation of medical devices. The Handbook provides:

- the environment of quality systems standards applied to medical devices;
- a conceptual overview of the ISO 9000 series of standards;
- an implementation path;
- the actual requirements from the CAN/CSA-ISO 9001:94 standard, including the current Canadian generic guidelines based on ISO 9000-2;
- the guidelines developed by the GHTF issued in August 1994;
- definitions extracted from CAN/CSA-ISO 8402-94;
- several diagnostic questions to consider when preparing quality system documentation;
- typical audit questions used by quality systems registrars; and
- cross reference tables between ISO 9001 and proposed Good Manufacturing Practices (GMPs) in the United States and Japan.

A copy of the handbook can be purchased for $38.00 from the Canadian Standards Association (CSA) by calling 1-800-436-6727.

NOVEMBER 1 DEADLINE APPROACHES FOR EVALUATION OF *IN VITRO* DIAGNOSTIC KITS

The Medical Devices Bureau is conducting an in-depth evaluation of the performance characteristics of all *in vitro* diagnostic kits sold in Canada for testing blood and blood components intended for transfusion or further manufacture. These measures apply to *in vitro* diagnostic kits intended for the detection of Hepatitis B virus surface antigen, syphilis, antibodies to Hepatitis C virus, and antibodies to Human T-cell lymphotropic virus type 1. *In vitro* diagnostic kits intended for the detection of infection by HIV are not affected by this action as they are already subject to pre-market review in accordance with Part V of the Medical Devices Regulations.

Section 14 of the Regulations stipulates that "No manufacturer of a device or person who has imported into Canada a device for sale shall sell the device unless tests have been conducted in respect thereof and the tests indicate that the nature of the benefits claimed to be obtainable through the use of the device and the performance characteristics claimed for the device are justified as shown by evidence available in Canada to the manufacturer or to the person importing the device." Manufacturers of *in vitro* diagnostic kits as described above have been requested to submit this evidence by November 1, 1995.

The evidence should include:

- information on the intended use, summary of and explanation of the test, biological principles of the procedure, reagents, warnings and precautions, storage instructions, indication of instability or deterioration of reagents, and limitations of the procedure;
- details of the quality control assurance programs used by the firms in the production of these kits; and
- substantiating evidence for performance characteristics, i.e. data with regard to sensitivity, specificity, detectability, reproducibility (intra- and inter-lot and inter-laboratory) and stability.

The information requested should be sent to the Director, Medical Devices Bureau.
For information contact C. Choquet
(Tel. (613) 954-0387) (Fax (613) 941-4726).

NEWS ABOUT BREAST IMPLANTS

Smooth-walled saline-filled implants are currently available on the Canadian market, having either a Notice of Compliance (NOC) or being grandfathered (i.e. was on the market prior to the implementation of premarket review for these products in 1983). The four McGhan products received notices of compliance in 1988; the Mentor device is grandfathered.

Clinical Trial for Textured Saline-filled Implants

Textured saline-filled implants are being considered for clinical trials. They are currently available only under compassionate release for reconstruction and revision surgeries.

Clinical Trial for Trilucent Mammary Implants

LipoMatrix Inc. has submitted a clinical trial protocol to HPB for Trilucent (soybean-oil filled) Mammary Implants. A limited clinical trial of 50 patients is expected to start in Canada within the next six months.

Compassionate Release Program

A moratorium on silicone gel-filled breast implants in Canada was announced on January 8, 1992. In January 1993, the Minister announced the availability of silicone gel-filled breast implants to women in situations where these implants are the best option for their circumstance. In June 1993, a protocol for

compassionate release of such breast implants was introduced and approved by the Minister. Full implementation was complicated by stringent U.S. FDA requirements to permit export of silicone gel-filled breast implants from the United States to Canada.

Since then, The Minister concurred with a recommendation that no silicone gel-filled implants or expanders be sold in Canada for compassionate reasons, effective February 8, 1995.

However, saline-filled textured expanders are now available for compassionate use in Canada.

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

You can also contact us via the Internet at:
"..."@isdtcp3.hwc.ca Replace the "..." with the name of the person you wish to contact (i.e. kamlesh_gupta@isdtcp3.hwc.ca

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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

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

Medical Devices Bureau, Health Protection Branch,
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:_____

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