Vol. 3, No. 2 Fall 1997

MEDICAL DEVICES BULLETIN

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

Editorial

We would like to thank you for providing input into the Medical Devices Bulletin – both by following up with the staff members identified in the various articles, and by forwarding ideas for new articles in upcoming issues. Keep up the good work – the Bulletin is intended to serve you, and your continued input and interaction will enable it to do so!

You were informed in the last issue that in January 1997, the Medical Devices Programme merged with the Drugs Programme and now this combined organization has a new name. On April 1, 1997, this amalgamation was formalized under the new names Therapeutic Products Directorate and Therapeutic Products Programme (TPP), the latter including the five regional offices. The Medical Devices Sector of this Programme includes the Medical Devices Bureau in Ottawa and the inspectors and other personnel of the Medical Devices Units of the five regional offices. The new names better cover the scope of products the Programme deals with, and better convey the integration of two existing Programmes into one dynamic entity.

Just a reminder – we are still the same people you are accustomed to dealing with or hearing from, doing the same jobs, at the same locations. You can reach us the way you always have – by telephone, fax, E-mail or regular mail. We look forward to continuing to work with you as we move towards the 21st century and all the challenges that will entail.

All comments received in response to the publication of the proposed Medical Devices Regulations in Canada Gazette Part I in February 1997 have now been reviewed. The Regulations will be finalized with their publication in Canada Gazette Part II, scheduled for February 1998.

Continuing its open dialogue policy with industry, the TPP members met with representatives of Medical Devices of Canada (MEDEC) on June 16, 1997. A number of issues related to medical devices, such as new Medical Devices Regulations, cost recovery initiative and the Mutual Recognition Agreement with the EU, were discussed.

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Can fall be in the air already? It must be since we are working on the next issue of the Bulletin that will include an update on Mutual Recognition Agreements and much more. These are busy times for the Programme, and until we are in touch again, make sure to get all those naughty leaves raked up and to get everyone registered for those upcoming winter (brrrr!) activities.

"Medical Device" – What's in a Name?

Quite a lot, possibly, if you're a manufacturer wondering whether your product falls under the legal definition of a medical device. When Canada's proposed new Medical Devices Regulations come into effect, devices will have to be registered and establishments which import or distribute devices, and manufacturers that distribute other company devices, will have to be registered. All devices will be classified into four risk classes, with the degree of regulatory requirements for a given device determined by the device's risk class.

But before a risk classification can be assigned to a product, and the regulatory requirements followed, it must be determined whether the product is a device at all. The definition of a "device" is stated in the *Food and Drugs Act*. A definition of "medical device" has been proposed in the new Medical Devices Regulations published in the Canada Gazette, Part I, on February 15, 1997. The definitions are equivalent except that the definition of "medical device" in the proposed Regulations does not include veterinary devices. Several of the key terms in the definition are broad enough to allow a range of interpretations, and this has caused headaches for manufacturers and Programme staff for over twenty years.

Specifically, the definition in the proposed Regulations states that a "medical device" is:

"an article, instrument, apparatus or contrivance, including a component, part or accessory of one, that is manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in a human being;

(b) the restoration, correction or modification of a body function or the body structure of a human being;

(c) the diagnosis of pregnancy in a human being; or

(d) the care of a human being during pregnancy and at and after the birth of a child, including the care of the child.

It includes a contraceptive device but does not include a drug."

The definition contains several terms which are crucial in deciding whether a product is a device. The first is the phrase "for use in diagnosis, treatment" etc. What constitutes "use" in treatment? Is a wheelchair "used" in treating patients? Some interpretations argue that it is not, since the wheelchair itself does not bring about any change in the patient's condition. Others argue that the wheelchair is "used in treatment" because it is used in handling patients undergoing treatment in a health care facility.

Another problem phrase is "prevention of a disorder or abnormal physical state." Does this mean that helmets, steel-toed boots, safety goggles and seat belts are medical devices because they prevent a "disorder or abnormal physical state", namely an injury?

And what about components, parts, or accessories of a medical device? Is a screwdriver, supplied by the manufacturer to service a diagnostic monitor, an "accessory" to the monitor, and hence a medical device?

In the past, such questions were handled by the Programme almost on a case-by-case basis, with the assistance of a legal opinion from the

Department of Justice. However, it is now apparent that a systematic approach is needed. The Programme has therefore established a task force to develop a guidance document for interpreting the definition. The document will help in resolving the majority of questions on product status. It could also be used to produce a list of products deemed to be medical devices, for the guidance of manufacturers and Programme staff. For general questions regarding the guidance document, please contact Dr. Peter Uhthoff of the Medical Devices Bureau at (613) 954-1330 (tel.), (613) 941-4726 (fax) or **peter_uhthoff@inet.hwc.ca** (email). For questions on specific product status, please contact your local Regional Office as listed elsewhere in the Bulletin.

Don't Let Low-Cost "Hearing Aids" Fool You

In the last few years there has been an increase in the advertising of low cost "hearing aid" type devices in Canada and the United States. While these products resemble actual behind-the-ear hearing aids, they make unrealistic hearing-enhancing claims, trying in many cases to convince consumers that the devices are actually state-of-the-art products with advanced sound processing technology.

These devices may retail for as little as $30 and are often sold through mail-order companies or via some U.S. television stations, although at least one brand is known to have been sold in a large retail store chain in Canada. Advertisements and literature for such devices often claim that your hearing will be improved, you'll hear things you never did before, you'll be able to hear a small object being dropped at great distances, or that you'll also be able to hear sounds in adjoining rooms.

Some of these devices may state that they are not to be used to correct hearing impairment. However, because of their low cost, claims to greatly improve the wearer's hearing – claims which are often unsubstantiated – and their similar appearance to true hearing aids, consumers may buy one only to find that they have bought a product which is unsatisfactory after having been misled. Health Canada is concerned that consumers suffering from hearing loss may purchase such devices instead of a proper hearing aid fitted with the assistance of a recognized hearing care professional.

Health Canada has evaluated two of these hearing devices and has concluded that such devices are often of poor quality and that **they can generate sound levels which could, over time, damage the wearer's hearing.**

On Sept 10, 1996, Industry Canada's Competition Bureau issued a news release announcing that the company selling one of these devices, the Micro Ear 2000, was found guilty of six counts of misleading advertising under the *Competition Act*. In this case, the claim that the device could tune out background noise and enable one to hear clear crisp sound was proven false by experts. In the U.S., Telebrands Corporation, the company marketing another such device, the Whisper XL, has been ordered to pay over $500,000 to settle consumer fraud suits for falsely advertising the product and selling it without the approval of the Food and Drug Administration (FDA). Telebrands must also refund the purchase price to any purchaser who requests a refund. As well, between 1994 and 1996, the FDA issued warning letters to several other manufacturers of similar products that made unsupported claims for their devices.

In view of the above, Health Canada urges the public to be wary of the quality and claimed performance of such devices, especially when they are being sold for a fraction of the cost of a true hearing aid, which normally costs several hundred dollars. If you would like to report an injury as a result of the use of such a device, or report a case where you believe that the device does not meet its claimed performance, please call the Medical Devices Hot-Line at 1-800-267-9675. You may also contact your

regional Health Protection Branch office listed elsewhere in the Bulletin. For information, contact Denis Roy at (613) 954-0365 (tel.), (613) 993-0281 (fax) or **denis_g_roy@inet.hwc.ca** (email).

If you suspect that you have a hearing loss that requires correction, Health Canada encourages you to seek proper medical attention by consulting your physician, who will provide you with referrals to recognized hearing care professionals.

No More Calls About Air Cleaners, Please

The medical devices toll-free hotline was swamped with calls this spring after the March publication in a number of Canadian newspapers of an article about home air cleaners that produce ozone. The reporter interviewed Dr. Philip Neufeld of the Medical Devices Bureau and gave the medical devices hotline number for readers to call if they wanted further information. By the end of May, the hotline staff had responded to approximately 1 500 calls. The voice-mail message buffer, which can store 24 messages, was permanently full and the batteries in the hotline cordless phone ran down because the phone was never on the receiver long enough to recharge during the day.

User concern centred on the safety and legality of generating ozone for home air purification. Health Canada regards air-borne ozone as a pollutant. The Medical Devices Regulations contain a standard (Schedule VIII) which prohibits the sale of a medical device designed to produce air-borne ozone to which humans may be exposed – this would automatically exclude devices such as ozone-generating home air cleaners. Part 2 of Schedule VIII prohibits the sale of a device that generates ozone incidental to its normal operation at a level in excess of 0.05 ppm – which would again exclude ozone-generating air cleaners since the production of ozone is not incidental to their operation. (The U.S. Food and Drug Administration has similar regulations).

However, an air cleaner must first be considered a medical device, as defined in the *Food and Drugs Act*, before the Regulations apply, and that decision rests largely on the medical claims, or absence of medical claims, made for the air cleaner. Most air cleaners are deemed not to be medical devices because their manufacturers are careful not to make claims which would cause their products to be subject to the Regulations.

Health Canada has no regulations at present to govern the safety of air cleaners that are not medical devices. Such air cleaners would be classed as consumer products and would fall within the mandate of the Product Safety Bureau of Health Canada. The Department is reviewing the safety aspects of non-medical air cleaners to determine whether regulations are necessary.

Health Canada has prepared a fact sheet on air cleaners that generate ozone which is available through our regional offices. Consumers with questions or concerns regarding home air cleaners are asked to contact a Product Safety Inspector in any of the Health Protection Branch's regional offices across Canada and give the hotline phone a chance to cool off.

The telephone numbers for the Product Safety regional offices are:

Vancouver	(604) 666-5003
Edmonton	(403) 495-2480
Calgary	(403) 292-5613
Saskatoon	(306) 975-4028
Winnipeg	(204) 983-5490
Toronto	(416) 973-4705
Hamilton	(905) 572-2845
Montreal	(514) 646-1353
Quebec	(418) 648-4327
Moncton	(506) 851-6638
Dartmouth	(902) 426-8300
St. John's	(709) 772-4050

Risk of Fire with Use of Polyurethane Foam Mattress Pads

A few months ago, a Canadian hospital informed us of its concerns regarding the use of polyurethane foam mattress pads in a hospital setting. A biomedical engineer had accidentally discovered that the kind of mattress pad used in the facility ignited very easily – like a sheet of paper – with a match, despite the note on the label that the material used in the mattress pads had been treated to be flame retardant. Following this observation, the hospital discontinued use of the mattress pads.

While the Therapeutic Products Programme has received no reports of mattress pads igniting in hospitals in Canada, the U.S. Food and Drug Administration has received reports of two deaths related to fires of two different brands of foam mattress pads.

In Canada, the Product Safety Bureau regulates the advertisement, sale and importation of hazardous products under the *Hazardous Products Act*. The Act's Hazardous Products (Mattresses) Regulations set out the flammability requirements of a mattress exposed to a lighted cigarette. However, these Regulations do not contain any requirements regarding the flammability of mattress pads.

Product Safety Bureau staff found no reports in their files of fires involving use of these mattress pads, in either a hospital or a home setting. As well, provincial fire authorities and chief coroners were contacted, but all responded that there was no data available to connect a fire to the use of a foam mattress pad.

Standard CA TB 117[1] of the State of California consists of an open flame test. This test seems most appropriate at this time for checking the degree of flammability of polyurethane foams. It appears that the polyurethane foams that are customarily used to make mattress pads can easily meet standards for resistance to smouldering fires.

To minimize the risk of fire when using polyurethane foam mattress pads, the Programme recommends that you:

- use a mattress pad that meets standard CA TB 117 of the State of California, or an equivalent standard using an open flame test with the sample in a vertical position;
- cover the mattress pad with a sheet meeting Canadian Standard CAN 2-4.162[2];
- secure the sheet well so that the mattress pad remains covered at all times; and
- ensure that no part of the mattress pad is exposed vertically.

For further information, please contact: Francine Jacques, a medical devices inspector with the Québec Region at 1-800-561-3350 (tel.), or (514) 928-4105 (fax), or Denis Roy at (613) 954-0365 (tel.), (613) 993-0281 (fax), or **denis_g_roy@inet.hwc.ca** (email).

If you would like to know more about federal requirements for the flammability of mattresses (excluding mattress pads) or other products with textile content that are not medical devices, please contact a regional representative of the Product Safety Bureau (see list of regional Product Safety Bureau offices at the end of the article on air cleaners in this issue).

For information concerning provincial requirements for the flammability of textiles used in hospitals, please contact your provincial health department.

1. "Requirements, Test Procedure and Apparatus for Testing the Flame Retardance of Resilient Filling Materials Used in Upholstered Furniture"

2. "Hospital Textiles – Flammability Performance Requirements"

Electronic Communications

Medical Devices electronic access has under- gone a number of changes. As discussed in the Spring 1997 Bulletin, the BBS no longer exists. Relevant information that was available on the BBS has now been moved to the website.

Our "home page" is now that of the **Therapeutic Products Programme** (TPP). The URL **www.hc-sc.gc.ca/hpb/drugs** is still valid. However, in accordance with Treasury Board guidelines, and in response to our recent organizational re-alignment, our new web address is **www.hc-sc.gc.ca/hpb-dgps/therapeut**.

The Therapeutic Products Web (TP-Web) contains the Public Access Database, migrated BBS information, a link to our previous web address at **www.hc-sc.gc.ca/datahpb/dataehd** and any new postings. In the near future, data still at the previous address will be moved to the new site.

On all new postings, and as old postings are revised, a Programme contact name, phone number, and e-mail address will be clearly stated for every document or subject. These contacts can interpret the document as it relates to Medical Devices Sector or any other business line of the Therapeutic Products Programme. Technical problems with the website (broken links, database malfunctions, etc.) can be e-mailed to the TP-Webmaster (fr: PTWeb-gestionnaire) link which appears on most navigation pages. Also you may contact Pete Nilson at 613-941-1601 or Ivor Jackson at 613-941-0436. Ivor jackson can also be contacted at **ijackson@inet.hwc.ca** (email).

There is considerable pressure to make changes to different aspects of our web site, and we have certainly learned a lot ourselves about how to present TPP information better. We hope to be in a position to make some of these recommended changes in the months to come. Should you have comments, suggestions, praise or complaints that might help us – now is the time to make your views known. E-Mail the Webmaster, or fill out the on-line survey. The survey can be accessed by clicking the feedback (fr: Commentaires) button at the bottom of the English or French TP-Web/PT-Web menus.

Medical Device Manufacturers Survey

The Medical Devices Sector of the Therapeutics Product Programme is conducting a survey of all firms on the medical device database to update information regarding their status as a manufacturer and/or distributor and/or importer of medical devices in Canada. The definition of a manufacturer of a medical device can be found in the interpretation section of the proposed new Medical Devices Regulations that appeared in the Canada Gazette Part I on February 15, 1997.

"Manufacturer" of a medical device means a person who sells the medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

The reason that this survey is being conducted at this time is so that the Programme will have accurate information regarding the status of all Canadian manufacturers, distributors and importers of medical devices in Canada. This survey should be completed before the promulgation of the new Medical Devices Regulations, scheduled to appear in Canada Gazette Part II in February 1998.

The manufacturer survey involves medical devices inspectors contacting each firm by phone in their respective regions and asking a series of questions on the status of the firm's medical devices.

The results of this survey will give the Programme a more accurate count of Canadian manufacturers, distributors and importers of medical devices. For further information contact any of the Programme staff at HPB Regional Offices, telephone numbers are given on page 8.

Electronic Registration

New Medical Devices Regulations are scheduled to be implemented in February 1998. Under the new Regulations, medical devices will require registration before being sold in Canada. A registrant will be required to submit specified information to the Therapeutics Products Programme (TPP) to register. In an effort to better serve all clients, the Programme is in the initial stages of designing an electronic registration system for medical devices. The new system is expected to enhance the Programme's efficiency, which will benefit all parties.

The ultimate goal is to provide the industry with the option to register their products, pay required fees and obtain information on the status of a device electronically. With a view to have users' opinion and an insight about what is needed in this type of system, a preliminary workshop was held in January 1997. Participants included both industry representatives and Programme staff. Currently, the Programme is preparing for the next step, which is to conduct a detailed analysis of users' needs.

The various features of the electronic registration system will be phased in over a certain period. Initially the plan is to allow for registration of Class II devices and renewal of registration for Class II, III and IV electronically.

Your comments and questions are valuable in the system development process. Please participate and let your needs be known. You may contact Marc-André Côté at (613) 954-1083 (tel.), (613) 957-7318 (Fax) or at **marc-andre_cote@inet.hwc.ca** (email).

Cost Recovery Stakeholder Workshop

A very successful multi-stakeholder consultation workshop was held in Aylmer, Quebec on August 24-26, 1997. The purpose of the workshop was to obtain a broad range of input into cost recovery and related regulatory issues. The meeting was attended by approximately 30 people, representing a cross-section of the medical device industry, trade associations, device users, and the public. The workshop resulted in a useful interchange of ideas and a better understanding of the various concerns that industry and users have. Comments from participants will assist the Programme in developing important elements of the cost recovery framework associated with medical devices.

One of the most lively workshop topics was the interpretation of exactly what constitutes a 'registrable device' for device registration purposes. A draft guidance document prepared by the Programme served as a starting point for the discussion. Excellent points were made by industry representatives that underlined the complexity of this issue. As a result of the discussions, the Programme agreed to convene a small working group to address this issue in depth in a short period of time, and develop a revised guidance document.

Other achievements of the workshop included the development of a matrix for fee reduction and fee exemptions. Background documents and the 'as was said' document from the workshop will be available on the Therapeutic Products Programme's web site – the address is given on page 6. For more information on the Cost Recovery Workshop, please contact Louise Labonté-Lloyd at (613) 941-8906 (tel.) or (613) 941-3331 (fax) or **louise_labonte-lloyd@inet.hwc.ca** (e-mail).

How to contact the Medical Devices Sector Staff

Should you have any questions regarding Medical Devices Regulations or compliance issues, please contact a regional office by email or by telephone. E-mail address:

Atlantic: **herbert_sooley@inet.hwc.ca**
Quebec: **benoit_toupin@inet.hwc.ca**
Ontario: **jerry_holatko@inet.hwc.ca**
Central: **robert_scales@inet.hwc.ca**
Western: **keith_hutcheon@inet.hwc.ca**

Telephone Numbers:
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

Medical Devices Bureau Hotline 1-800-267-9675

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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.

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 "*****"@inet.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 @inet.hwc.ca.

Canadian Medical Devices Bulletin Questionnaire for Readers Input: October 1997

Purpose - To acquire opinion from medical device sector clients and stakeholders on the effectiveness of the Medical Devices Bulletin and to receive client input in order to improve the publication.

Please answer the following questions. Your input will assist us in improving the Bulletin.

Do you or the employees in your organisation read the Bulletin?	Yes G	No G
Do you find the Bulletin is useful to you or to your organisation?	Yes G	No G
Do you find the length of the Bulletin is adequate?	Yes G	No G

Please make any additional comments regarding the above questions:

_____

_____

Using the scale below, please indicate your level of interest in the contents of the Bulletin by circling the appropriate score:

1. High 2. Moderate 3. Low 4. None

In terms of :				
Articles regarding device problems	1	2	3	4
Articles regarding recalls	1	2	3	4
Information on Medical Device Regulations	1	2	3	4
Information on cost recovery	1	2	3	4
Articles on medical device sector's operating procedures	1	2	3	4
Update on the Mutual Recognition Agreement	1	2	3	4
Updates on the Programme's organisational structure	1	2	3	4
Announcement of upcoming events	1	2	3	4

If you wish to see any specific topics, please provide your comments:_____

_____

_____

Should the Medical Devices Bulletin remain a stand alone publication or should information concerning all therapeutic products be combined in a proposed Theraeutic Products newsletter?

Stand alone G Combined G

Presently the Bulletin is published twice a year. Should this be changed?

Yes G No G

If yes, what frequency of the publication would you suggest? _____

Information about you; please check all those or complete where indicated:

Manufacturer G Others (Specify)_____

Distributor G Speciality (Specify)_____

Hospital G Province (Specify)_____

Nursing Home G

Thank you for taking the time to complete this questionnaire. Please send your response by Dec. 31 to: Editor, Medical Devices Bulletin by mail (address on reverse) or by fax at (613) 954-0941.

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Additional Comments