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To: Hospital Administrators
Hospital Risk Managers
Hospital Infection Control Practitioners
Hospital Biomedical Engineering Departments
Provincial Hospital Associations
Canadian Healthcare Association
Provincial Health Ministries
Canadian Medical Protective Association
Canadian Medical Association
Colleges of Physicians and Surgeons
Canadian Dental Associations

Subject: UPDATE ON REPROCESSING AND REUSE OF SINGLE-USE MEDICAL DEVICES

Dear Sir/Madam:

On July 30, 2004, and April 29, 2005, Health Canada issued advisory letters to health care facilities providing background information on the issue of the reuse of single-use medical devices. This letter is to advise you of recent developments on this issue.

BACKGROUND

Single-use devices (SUDs) are those labelled by their manufacturer as being intended to be used once and then discarded. Since the 1970s, health care institutions have been reusing SUDs in order to save the cost of buying a new device for every procedure.

In recent years, health care organizations have expressed increasing concern about the safety of this practice, since manufacturers of SUDs provide no instructions for proper cleaning and sterilization. The design of many SUDs makes them impossible to disassemble for cleaning, and some components cannot withstand the heat and chemicals used in sterilization.

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In 2005, Health Canada established a Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD), which submitted its recommendations on the reuse of SUDs in February, 2005. The SAP-RMD recommended that the reuse of SUDs not be allowed unless it is regulated by Health Canada[1].

Health Canada also held a meeting of stakeholders on June 9, 2005. The consensus of this consultation was that Health Canada should regulate the reprocessing of SUDs[2].

RECENT DEVELOPMENTS

Health Canada

In response to its consultations with stakeholders, Health Canada undertook a review of its authority to regulate the reprocessing of single-use medical devices by hospitals or third parties. This review has concluded that the *Food and Drugs Act*, from which the *Medical Devices Regulations* derive their authority, is not intended to apply to the use of a device after its sale. Therefore, Health Canada does not have the authority to regulate reuse.

The delivery of health care and the establishment of policies and standards of practice in patient care have traditionally been the responsibility of Provincial and Territorial health ministries and hospital boards. Several Provinces and Territories have recently published guidance documents on the reuse of SUDs.

Ontario

In 2006, the Ontario Ministry of Health and Long Term Care endorsed a guidance document developed by its Provincial Infectious Diseases Advisory Committee (PIDAC) advising that critical and semi-critical SUDs must not be reprocessed and reused unless the reprocessing is done by a licensed reprocessor[3].

Manitoba

Since 1999, Manitoba has not permitted its hospitals to reuse “critical contact” single-use devices (those that contact the bloodstream or a sterile body cavity).

Northwest Territories

The Northwest Territories Department of Health and Social Services revised its *Hospital and Health Care Facility Standards Regulations* in 2005 to require that “a disposable device intended to be used on a patient during a single procedure shall not be used on a patient for more than one procedure and shall not be used on another patient”[4].

British Columbia

British Columbia has issued a policy to its health authorities stating that by January 1, 2008, all health authorities must eliminate the reprocessing and reuse of critical contact single-use devices unless they have been reprocessed by a licensed third-party reprocessor certified by a national regulatory authority such as Health Canada or the US Food and Drug Administration[5].

NEXT STEPS

Health Canada has convened a working group of representatives of the Provincial and Territorial health ministries to develop a pan-Canadian position on this issue. The Working Group held its first meeting on June 12, 2007, and plans to develop a framework based on evidence collected by such organizations as the Canadian Agency for Drugs and Technologies in Health (CADTH) and Health Canada, and recommendations already published by health care associations and the Provincial and Territorial health ministries.

References

1. Health Canada Scientific Advisory Panel on Reprocessing of Medical Devices. http://hc-sc.gc.ca/dhp-mps/md-im/activit/sci-consult/reproc-retraite/index_e.html

2. Health Canada Stakeholders' Conference on the Reprocessing of Single Use Medical Devices, June 9, 2005. http://hc-sc.gc.ca/dhp-mps/md-im/activit/sci-consult/reproc-retraite/saprmd_rep_gcsrmm_rap_2005-06-09_e.html

3. Ontario Ministry of Health and Long Term Care, Best Practices for Cleaning, Disinfection, and Sterilization in All Health Care Settings, April, 2006. http://www.health.gov.on.ca/english/providers/program/infectious/diseases/ic_ds.html

4. Northwest Territories, *Hospital and Health Care Facility Standards Regulations*, R-036-2005, Section 62, 2005. http://www.canlii.org/nt/laws/regu/2005r.036/20070717/whole.html

5. British Columbia Ministry of Health, Policy Communiqué, Reprocessing of Medical Devices and Patient Care Equipment, 2007.

Yours sincerely,

Original signed by

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