

Tracking Federal Regulatory Initiatives

Regulatory Affairs

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Patented Medicine Prices Review Board Rules

This Order establishes general rules for regulating the practice and procedure of hearings of the Patented Medicine Prices Review Board (PMPRB), replacing the draft rules of practice and procedure used in prior proceedings. The proposed rules will come into effect on the day they are approved by the federal cabinet.

The cover such things as the quorum, procedures and evidence, time limits, giving of notice or service, filings, notices and records of hearings, interventions, including interventions by Ministers, access to evidence, confidentiality, hearings, submissions, directions, decisions and orders.

The PMPRB, which has certain powers, rights and privileges of a superior court of record, monitors the price at which patentees sell patented medicines, and may, following a public hearing, issue a remedial order with respect to excessive pricing. The Board may also issue an order to require a patentee to file prescribed information or to address a failure to comply with a previous Board order.

Contact: Sylvie Dupont-Kirby, Secretary of the Patented Medicine Prices Review Board, Standard Life Centre, Suite 1400, 333 Laurier Avenue W, Ottawa, Ontario K1P 1C1. Tel: 613-954-8299; Fax: 613-952-7626.

Patent Act, subsection 96(2)

Published in Canada Gazette May 9, 1998

Proposed Regulations

for Pre-Publication in Part I, Canada Gazette

Statutory Authority

Assets (Foreign Companies) Regulations, amendment

As a result of the promulgation of Bill C-82, section 666 of the *Insurance Companies Act* was deleted and accordingly foreign insurance companies can no longer determine their level of assets maintenance based on that section. Therefore, assets maintenance will be determined in accordance with accounting principles referred to in subsection 331(4) of the *Insurance Companies Act*.

The amendment to the Regulations will reflect the change made to the *Insurance Companies Act*.

Contact: Charles P. Johnston, Legislation Officer, Legislation and Precedents Division, Office of the Superintendent of Financial Institutions, 255 Albert Street, Ottawa, Ontario, K1A 0H2. Tel: 613-990-7472; Fax: 613-998-6716.

Insurance Companies Act, section 610

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Exempt from Pre-Publication and Approved

Statutory Authority

Income Tax Regulations, amendment (SOR/98-281, OIC 1998-782)

These amendments to provisions relating to labour-sponsored venture capital corporations are consequential to amendments to the *Income Tax Act*.

More specifically, the changes:

- amend the definition of “small business security” in subsection 5100(2) to exclude from the definition unsecured or subordinated debt issued by eligible corporations that are prescribed labour-sponsored venture capital corporations (LSVCCs) in Part LXVII of the Regulations. This is appropriate because the amount of small business investments required to be made by LSVCCs depend on their equity capital, rather than the amount of debt they issue.
- amend paragraphs 6700(d) and 6701(d) to eliminate references to the definition of “registered labour-sponsored venture capital corporation” in section 204.8 of the Act. These references are no longer appropriate as a consequence of the addition of the definition to subsection 248(1) of the Act which defines this expression for all purposes of the *Income Tax Act* and *Income Tax Regulations*.
- amend section 6706 to provide that a registered LSVCC may redeem Class A shares of its capital stock if it withholds an amount from the proceeds of the redemption in accordance with Part XII.5 of the Act.

The amendments were announced in a press release accompanying a Notice of Ways and Means Motion amending the *Income Tax Act* that was tabled December 5, 1996.

Contact: Simon Thompson, Tax Legislation Division, Department of Finance, L'Esplanade Laurier, 140 O'Connor Street, Ottawa, Ontario, K1A 0G5. Tel: 613-992-0049.

Income Tax Act, section 221

To be published in Canada Gazette May 27, 1998

Public Service Official Languages Exclusion Approval Order, amendment; Public Service Official Languages Appointment Regulations, amendment (SOR/98-276, OIC 1998-769)

The amendments remove, as of April 2003, the right for unilingual federal public service executives to remain in positions whose language requirements they do not meet, while also making it possible for them in the meantime to acquire the required second language proficiency.

Public Service Employment Act, subsection 37(1) and 41(2)

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Exempt from Pre-Publication and Approved

Statutory Authority

The amendments also remove the right of unilingual candidates of any age in the same designated regions to be appointed to bilingual positions in the Executive Group without having to undergo language training at government expense for attaining the level of second language competency required for the bilingual position. The amendments also facilitate their access to this training by removing their obligation to demonstrate at the outset, their potential for second-language learning.

A new policy of the Treasury Board raises the language requirements for all Assistant Deputy Minister level positions in the federal public service, as well as those for most other Executive Group positions in the regions designated as bilingual for language-of-work purposes under the *Official Languages Act*. These amendments give effect to the new policy.

The changes are effective May 1, 1998.

Contact: Régis Gaudreault, Policy Advisor, Resourcing Policy and Legislation Directorate, Policy, Research and Communications Branch, Public Service Commission of Canada. Tel: 613-992-9706.

Order repealing the Eskimo Economic Development Guarantee Order (SOR/98-283, OIC 1998-784)

The Order revokes the Eskimo Economic Development Guarantee Order, OIC 1978-18, SOR/78-61, since the Department of Indian Affairs and Northern Development no longer has a mandate to guarantee loans for Inuit economic development.

The changes are effective May 7, 1998.

Direction to the CRTC (Reservation of Frequencies for Toronto) Order (SOR/98-284, OIC 1998-800)

The purpose of this regulatory initiative is to fulfil a commitment made by the Government on October 23, 1997, to respond to public demand for another radio station on the FM band in Toronto, by requesting the Canadian Radio-television and Telecommunications Commission (CRTC) to reserve an FM frequency for this purpose.

This commitment was made at the same time as the Government announced it had upheld CRTC Decision 97-362, allowing the Canadian Broadcasting Corporation (CBC) to move CBL, its English-language Radio One station in Toronto, from 740 on the AM band to FM 99.1. This will free up 740 on the AM band once the CBC completes the approved change.

As well, the CBC has applied to the CRTC for approval to move its CBC Radio One frequency in the Peterborough area from FM 93.5 to FM 98.7. If this application is approved, the frequency FM 93.5 would be available for use in Toronto. The joint use of AM 740 and FM 93.5 in Toronto was a concept discussed in April 1997 at the CRTC public hearing which preceded Decision 97-362 and remains an option to be explored.

Contact: Larry Durr, Director, Regulatory Policy Broadcasting Policy Branch Department of Canadian Heritage Hull, Québec, K1A 0M5. Tel: 819-997-8143; Fax: 819-997-7435.

Appropriation Act No. 1, 1976, subsection 30(1)

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Broadcasting Act, paragraph 26(1)(b)

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Pre-Published and Approved With comments or changes

Statutory Authority

Medical Devices Regulations, amendment (SOR/98-282, OIC 1998-783)

The new regulations replace the *Medical Devices Regulations* which have been in force since 1975.

The new Regulations stem from a 1991-1992 review of the Department's Medical Devices Program (MDP) which recommended that the MDP should focus on regulating medical devices on a risk assessment and risk management basis.

The scope of application of the new regulations remain virtually unchanged: all medical devices will be subject to the Regulations with the minor exception of medical devices for use on animals which will only be subject to the Act.

The major difference is the focus of the new Regulations and their emphasis on the risks inherent in medical devices. Under present requirements only 5 - 10% of medical devices are subject to pre-market scrutiny prior to marketing in Canada, whereas under these Regulations, approximately 50% of medical devices will undergo some form of premarket scrutiny before authorization for sale in Canada is granted. A significant portion of this pre-market scrutiny is in the area of quality system audits.

In brief, the Regulations:

- set out a system for classifying medical devices into one of four classes; class I representing the lowest risk devices and class IV representing the highest risk devices.
- require that device manufacturers register the devices they sell in Canada and insert specified information. Sale of unregistered devices are prohibited.
- require that device importers and distributors register their establishments. Sale of devices by unregistered importers and distributors are prohibited.
- require that devices imported or sold in Canada be labelled and meet 11 fundamental safety and effectiveness requirements, which manufacturers must provide assurance the requirements have been met. The degree of information which must be submitted to provide that assurance is proportional to the class of the device.
- require that manufacturers must provide evidence that the devices they sell in Canada are produced in accordance with a certified quality system. Class I devices are exempt unless they are sterile or provide a measuring function, in which case the sterilization process and measuring function must be validated.
- require manufacturers, importers and distributors to keep distribution records and to have written procedures to investigate problems and to recall defective devices from the market.
- require manufacturers and importers report serious problems which have occurred involving the use of devices they sell.
- provide for the tracking of certain implanted devices so that recipients of those implants may be notified of pertinent post-implant information. Schedule II to the regulations will identify devices subject to this requirement.
- provide for exemptions for custom-made devices and devices for emergency use from most of the requirements of the Regulations. The provisions set out the conditions that must be met in order to qualify for the exemptions.
- require manufacturers to obtain authorization from the Health Department prior to conducting investigational testing involving Class II, III and IV devices.

The new Regulations, with some exceptions, take effect on July 1, 1998, with some transitional rules.

Food and Drugs Act, sub-sections 3(3), 30(1) and 37(1)

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Pre-Published and Approved With comments or changes

Statutory Authority

As a result of comments received following prepublication of the proposals in the Canada Gazette, Part I, on Feb. 15, 1997, a number of changes were made, including:

- modifying the requirements for class I medical device manufacturers so that manufacturers of class I medical devices will not be subject to device licensing requirements under the framework. Manufacturers of class I devices who do not import or distribute solely through a person who holds an establishment licence will be required to hold an establishment licence to import or sell medical devices in Canada.
- requiring the manufacturer to file an amendment to their existing medical device licence rather than require a new licence for changes to that device. The amendments will include changes that are significant or administrative.
- classifying most In-Vitro Diagnostic Devices (IVDDs) as either class I or class II rather than the higher-risk categories Class III and IV.
- adding breast implants and tissue expanders to the table in rule 16 and classifying them as Class IV devices.
- changing the term “catalogue number” to “medical device identifier” which will be defined as follows: “a unique series of letters and numbers or any combination of those or bar code assigned by the manufacturer that uniquely identifies the device as different from other similar devices.”
- including an annual renewal system for device licensing rather than requiring the manufacturer to submit a new initial application for a medical device licence every three years. On November 1st of each year, the manufacturer will be required to submit a statement to the TPP that all the information previously supplied with respect to that device licence is correct.
- the addition to Schedule II (in addition to heart valves) of annuloplasty rings; active implantable device systems, e.g., implantable pacemakers and leads, implantable defibrillators and leads, artificial heart, implantable ventricular support system, and implantable drug infusion systems; devices of human origin, e.g., human aura mater and wound covering containing human cells.
- adding a new rule to the risk-based classification system, namely “any device that is a material that is intended to be sold to a health care professional or dispenser for the specific purpose of configuration into a mould or shape to meet the needs of an individual is considered to be a medical device and is classified in the class that would apply to the product in its finished form”. Under this rule, dental casting alloys are medical devices and the devices made from them are medical devices.
- classifying contact lens products as class II devices except those that fall under Rule 14.
- removing the requirement for a medical device licence for class I medical devices

Contact: Nancy Shadeed at nancy_shadeed@hc-sc.gc.ca or Julie Gervais at julie_gervais@hc-sc.gc.ca Policy Division Bureau of Policy and Coordination Therapeutic Products Programme Health Protection Building Address Locator: 0702B1, Tunney's Pasture Ottawa, Ontario, K1A 0L2 Tel: 613-957-0372; Fax: 613-941-64586.

Ministerial Orders Approved

Statutory Authority

Public Service Employment Regulations, 1993 (SOR/98-275)

The amendments change the rules for merit-based appointments to the Executive Group of the federal public service, especially in relate to appointments to the level of assistant deputy minister.

One change is made to one of the prescribed circumstances that provide for merit to be based on the competence of an employee as measured by a standard of competence rather than as measured against the competence of other individuals. This amendment will enable the consideration of a larger candidate population in selection processes for positions at the level of assistant deputy minister.

Under the existing provision, the names of qualified employees in the Executive Group are placed in a pool from which appointments may be made to positions at the level of assistant deputy minister. Names may also be removed from the pool for reasonable cause or if the individuals are not appointed within two years from the date their names were placed in the pool. The amendment extends these same measures to candidates not in the Executive Group who may be found qualified for inclusion in the pool.

A further change is being made to similarly exclude from appeal rights the appointments of persons who are not in the Executive Group to positions at the level of assistant deputy minister. This will ensure that all candidates for assistant deputy minister positions are treated in an equal manner. Appointments of employees to the Executive Group are subject to right of appeal, although appointments of employees within the Executive Group to other positions in that group are not.

Contact: Edith Kehoe, Policy Advisor, Resourcing Policy and Legislation Directorate, Public Service Commission. Tel: 613-947-9871

Public Service Employment Act, subsections 10(2) and 35(2)

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Quebec Wood Producers' Levies (Interprovincial and Export Trade) Order (SOR/98-277)

This order imposes a levy on producers of wood in the Quebec Region in the Province of Quebec, for wood produced in that region and marketed by the producers in interprovincial and export trade.

Under the Order, producers must pay all levies payable pursuant to section 2 to the Commodity Board at its headquarters in Quebec City, within the time limits set out in the applicable regulations referred to in that section.

The Order comes into force May 1, 1998.

Quebec Wood Order, 1983, sections 3 and 4

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