



21 October 2014

(14-6036)

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Committee on Technical Barriers to Trade

Original: English/French

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	Notifying Member: <u>CANADA</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2.	Agency responsible: Health Canada Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Canada's SPS & TBT Notification Authority and Enquiry Point Foreign Affairs, Trade and Development Canada Technical Barriers and Regulations Division (TIB) 111 Sussex Drive Ottawa, ON K1A 0G2 Canada Telephone: (343) 203-4273 Fax: (613) 943-0346 E-mail: enquiry@international.gc.ca
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Synthetic drug (ICS: 11.120, 71.060)
5.	Title, number of pages and language(s) of the notified document: <ul style="list-style-type: none">• Order Amending Schedule I to the Controlled Drugs and Substances Act (Tapentadol)• Regulations Amending the Narcotic Control Regulations (Tapentadol) (1 page, English and French)
6.	Description of content: The purpose of this initiative is to add the substance Tapentadol to Schedule I to the Controlled Drugs and Substances Act (CDSA) and to the Schedule to the Narcotic Control Regulations (NCR). Tapentadol is a synthetic opioid used for pain relief that has been marketed under the brand name NUCYNTA® since 2011 in immediate and controlled/extended-release (IR and CR/ER) formulations that, due to its opioid properties, may pose health and safety risks. While opioids like tapentadol are generally safe and effective, they can lead to physical and/or psychological dependence, abuse and/or addiction. Studies have shown that tapentadol has abuse liability potential comparable to hydromorphone, and is five times more potent for pain relief than intravenously-injected morphine. Both hydromorphone and morphine are already listed in Schedule I to the CDSA and the schedule to the NCR due to their diversion and abuse potential. In February 2011, a Notice to Interested Parties proposed to add tapentadol, its salts and its related analogues under Schedule I of the CDSA and to the NCR. The proposed wording for the addition to the schedules has been modified since the NOI was published. As such,

	<p>the proposed amendment would add tapentadol (3-[(1R, 2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl]-phenol), its salts, derivatives and isomers, and salts of derivatives and isomers to Schedule I to the CDSA and the Schedule to the NCR.</p> <p>Scheduling tapentadol under the CDSA and the NCR will mitigate the risk of the potential diversion of tapentadol to an illicit market or use while allowing access for legitimate medical purposes. This proposed amendment is supported by the sole manufacturer and importer of tapentadol in Canada and is consistent with the Government of Canada's continued commitment to address prescription drug abuse.</p>
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health
8.	Relevant documents: Canada Gazette, Part I, 26 February 2011, Pages 656-657 (available in English and French)
9.	<p>Proposed date of adoption: The date of adoption will be the date of entry into force</p> <p>Proposed date of entry into force: Canada is proposing a delayed coming into force period of 90 days. This 90 day period will allow licensed dealers time to apply to add tapentadol to their licences and take the steps necessary to come into compliance by the coming into force date. Health Canada consulted with the association representing pharmaceutical manufacturers and distributors, as well as the market authorisation holder of tapentadol in Canada. These parties indicated they are supportive of this 90 day coming into force transition period.</p>
10.	Final date for comments: 21 November 2014. A 30-day period is deemed to be sufficient given the following: Health Canada published a Notice to Interested Parties in February 2011 soliciting comments on the proposed amendment. Comments received indicated that stakeholders were fully supportive of this regulatory initiative, including the sole manufacturer of tapentadol for the Canadian market. No significant trade impacts are anticipated. The global developer/manufacturer has requested that tapentadol be placed under international control by having it scheduled under the UN Single Convention on Narcotic Drugs, 1961 as a precautionary measure.
11.	<p>Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>The electronic version of the regulatory text can be downloaded at:</p> <p>http://canadagazette.gc.ca/rp-pr/p1/2011/2011-02-26/pdf/g1-14509.pdf</p> <p>http://canadagazette.gc.ca/rp-pr/p1/2011/2011-02-26/html/notice-avis-eng.html</p> <p>http://canadagazette.gc.ca/rp-pr/p1/2011/2011-02-26/html/notice-avis-fra.html</p>

Vol. 145, No. 9 — February 26, 2011

DEPARTMENT OF FOREIGN AFFAIRS AND INTERNATIONAL TRADE

CONSULTATIONS ON POSSIBLE NEGOTIATIONS FOR A COMPREHENSIVE ECONOMIC PARTNERSHIP AGREEMENT WITH JAPAN

The Government of Canada is seeking the views of Canadians on the scope of a possible comprehensive economic partnership agreement between Canada and Japan.

This notice is part of the Government of Canada's domestic consultation process with business, citizen-based organizations and individual Canadians, as well as with provincial and territorial governments, to obtain advice and views on priorities, objectives and concerns to help outline the parameters of this initiative.

Background

Japan is a global economic power with significant influence in Asia, and one of Canada's most important economic and commercial partners. It is Canada's largest bilateral foreign direct investment (FDI) partner in Asia. In 2009, Japan's foreign direct investment stock in Canada totalled \$13.1 billion. The stock of Canadian direct investment in Japan at the end of 2009 stood at \$3.6 billion. Japan is also Canada's fifth-largest partner in two-way merchandise trade (second in Asia after China). Canada's exports of merchandise to Japan totalled \$8.3 billion in 2009 while imports from Japan were \$12.3 billion. The largest single Canadian merchandise export item to Japan is coal, valued at \$1.8 billion, followed by canola seeds (\$932.6 million). Canadian exports of services to Japan in 2009 totalled \$1.0 billion.

Japan is a priority market in the Government of Canada's Global Commerce Strategy. It is home to 64 Fortune Global 500 corporations and is the world's largest exporter to China. It thus represents not only a large and lucrative market in itself, but also a gateway to mainland Asia. Japan has often been characterized as one of the world's most innovative countries. Japan is thus a country that represents a range of trade, investment and innovation cooperation opportunities for Canadian firms.

The Government is actively seeking ways to support two-way investment and to facilitate joint Canada–Japan innovation projects and partnerships, with emphasis on advanced materials, information and

communication technologies (ICT), aerospace and defence, environmental industries, agriculture, food and beverages, forest-based building products, consumer products and medical technology.

In November 2005, the Canadian and Japanese prime ministers signed an Economic Framework designed to reinforce existing commercial ties and address new and emerging challenges and opportunities. A joint study by Canada and Japan, concluded in October 2007, highlighted positive economic relations between Canada and Japan and indicated that more could be done to strengthen our commercial ties. To supplement the previous study, the Government of Canada is seeking the views of Canadians in this second exercise with the Government of Japan to examine the possibility and scope of a possible comprehensive economic partnership agreement.

Japan has completed negotiations and signed economic partnership agreements (EPA) with Singapore (2002), Mexico (2004), Malaysia (2005), the Philippines (2006), Chile (2007), Brunei (2007), Thailand (2007), Indonesia (2007), the Association of Southeast Asian Nations (ASEAN — 2008), Vietnam (2008), and Switzerland (2009). Japan has also launched negotiations and joint studies with several other countries, including Australia and Mongolia. Japan and Canada have already concluded a number of bilateral agreements designed to facilitate closer trade. Japan and Canada signed a science and technology cooperation agreement in 1986 and an air services agreement was extended in 2009.

Additional information on Canada's relationship with Japan can be found at

Department of Foreign Affairs and International Trade Canada

Web site of the Embassy of Canada to Japan (www.canadainternational.gc.ca/japan-japon/index.aspx?lang=eng)

Science and Technology Agreement (www.treaty-accord.gc.ca/text-texte.asp?lang=eng&id=102070)

Canadian Trade Commissioner Service

Canadian Trade Commissioner Service in Japan (www.tradecommissioner.gc.ca/eng/office.jsp?oid=146)

Contact information for the Embassy of Japan in Canada

Embassy of Japan, 255 Sussex Drive, Ottawa, Ontario K1N 9E6, 613-241-8541 (telephone), 613-241-2232 (fax)

General email: infocul@embjapan.ca

Contact information for the Embassy of Canada to Japan

7-3-38 Akasaka, Minato-ku, Tokyo 107-8503, Japan, (011-81-3) 5412-6200 (telephone), (011-81-3) 5412-6249 (fax)

General email: TOKYO.CC@international.gc.ca

Submissions by interested parties

The Government is embarking on a public consultation process to allow all interested stakeholders an early opportunity to provide comments and advice on a possible comprehensive economic partnership agreement with Japan. It is essential that the Government of Canada be fully aware of the interests and potential sensitivities of Canadians with respect to this initiative. We welcome advice and views on any priorities, objectives and concerns relating to a possible comprehensive economic partnership agreement with Japan. In particular, we are seeking views with respect to the following:

Opinions on areas of goods export interest, including products that would benefit from the removal of tariffs and other barriers by Japan. The Government is also seeking views on the liberalization of access for Japanese products to the Canadian market, including input on the elimination of tariffs on specific products (e.g. tariff phase-outs).

Advice and views on trade in services, particularly the identification of sectors/activities of export interest for Canadian service providers, and opinions on domestic regulatory measures that restrict or otherwise affect market access for Canadian service providers.

Advice, views and experiences regarding the temporary entry of business persons from Canada into Japan and into Canada from Japan (e.g. impediments to entering or working in Japan on a temporary basis including licensing or certification requirements at the border).

Advice, views and experiences regarding measures affecting exports destined for Japan including non-tariff barriers (such as import licensing), technical barriers to trade (including technical regulations, standards and/or conformity assessment procedures) and sanitary and phytosanitary measures.

Views on general rules of origin and on appropriate rules of origin for specific products or sectors.

Advice on “trade facilitation” issues (e.g. significant impediments related to import procedures).

Advice, views and experiences with customs procedures and with commercial goods entering and/or leaving Japan.

Advice, views and experiences regarding investment barriers faced by Canadian investors in Japan, including restrictions imposed on foreign ownership or entry to market, questions of transparency of regulation, performance requirements (i.e. local content requirements, use of local labour and services, etc.), and any other impediments/barriers.

Advice and views on priority government procurement markets for Canadian suppliers in Japan, including the government entities or enterprises of interest to Canadian suppliers and the goods, services or construction services that Canadian suppliers are interested in selling to those government organizations.

Advice, views and experiences regarding barriers (e.g. availability and transparency of information, domestic preferences) when selling or attempting to sell to governments in Japan.

Views and experiences with the protection of intellectual property rights.

Advice and views on competition policy matters, including development of possible cooperation mechanisms.

Views on ways to reflect the interests and values of Canadians in the area of sustainable development, environmental protection and conservation.

Views on ways to reflect the interests and values of Canadians in the areas of workers' rights, human rights, transparency in business and commercial practices and other social concerns, as they relate to Japan.

Advice and views on ways to enhance the bilateral economic relationship, such as cooperation on science and technology.

Advice and experiences regarding trade remedies (i.e. anti-dumping and countervailing measures) taken on trade between Japan and Canada.

Views on other related issues not mentioned above.

All interested parties are invited to submit their views by March 26, 2011. Please be advised that any information received as a result of this consultation will be considered as public information, unless explicitly stated otherwise. Submissions should include

the contributor's name and address and, if applicable, his/her organization, institution or business;

the specific issues being addressed; and

precise information on the rationale for the positions taken, including any significant impact it may have on Canada's domestic or foreign interests.

Contributions can be sent by email, fax or mail to consultations@international.gc.ca (email), 613-944-3489 (fax), or Trade Negotiations Consultations (Japan), Foreign Affairs and International Trade Canada, Trade Negotiations Division (TPE), Lester B. Pearson Building, 125 Sussex Drive, Ottawa, Ontario K1A 0G2.

[9-1-o]

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties — Proposal regarding the regulation of tapentadol, its salts and its related analogues under the Controlled Drugs and Substances Act

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add tapentadol (phenol, 3-[(1R,2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl]-), its salts and its related analogues to Schedule I to the Controlled Drugs and Substances Act (CDSA) and to the schedule to the Narcotic Control Regulations (NCR).

Tapentadol is a novel opioid analgesic that was co-developed by Johnson & Johnson Pharmaceutical Research and Development (J&JPRD) and Grünenthal GmbH. In December 2010, Health Canada issued a notice of compliance for NNUCYNTA TM* CR, a new drug product containing tapentadol to be sold in Canada in controlled release tablet formulations of 50, 100, 150, 200 and 250 mg. NNUCYNTA TM* CR has been approved for use in the treatment of moderate and chronic nociceptive and neuropathic pain.

Although tapentadol is not currently included in any of the United Nations drug control conventions, studies of abuse liability indicate its potential for abuse and thus its susceptibility to diversion and trafficking. Several countries, e.g. United States, Germany, Lithuania, France, and Ireland, have already elected to regulate tapentadol as a controlled substance under their legislation in a manner similar to other opioids such as morphine and hydromorphone.

The addition of tapentadol, its salts and its related analogues to Schedule I to the CDSA and to the schedule to the NCR would prohibit its possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production except as authorized under the NCR.

The scheduling of tapentadol will mitigate the potential for its diversion, trafficking and abuse while not preventing its availability for legitimate medical reasons. Scheduling will also enable law enforcement to take action in instances of suspected illegal activity.

The publication of this notice begins a 30-day comment period. If you are interested in this process or have comments on this proposal, please contact Mr. Nathan Isotalo, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater Street, Ottawa, Ontario, Canada K1A 0K9, by fax at 613-946-4224 or by email at OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca.

February 17, 2011

CATHY SABISTON

Director General

Controlled Substances and

Tobacco Directorate

[9-1-o]

DEPARTMENT OF INDUSTRY

RADIOCOMMUNICATION ACT

Notice No. SMSE-003-11 — New issue of RSS-123

Notice is hereby given that Industry Canada is releasing the following revised document:

Radio Standards Specification 123 (RSS-123), Issue 2: Licensed Low-Power Radio Apparatus sets out the requirements for certification of licensed low-power radio apparatus operating in various frequency bands, such as low-power auxiliary equipment and wireless cameras.

General information

RSS-123, Issue 2, will come into force as of the date of publication of this notice.

This document has been coordinated with industry through the Radio Advisory Board of Canada (RABC). The Radio Equipment Technical Standards Lists will be amended to reflect the above changes.

Any inquiries regarding RSS-123 should be directed to the Manager, Regulatory Standards, 613-990-4699 (telephone), 613-991-3961 (fax), res.nmr@ic.gc.ca (email).

Interested parties should submit their comments within 120 days of the date of publication of this notice. Soon after the close of the comment period, all comments received will be posted on Industry Canada's Spectrum Management and Telecommunications Web site at www.ic.gc.ca/spectrum.

Submitting comments

Respondents are requested to provide their comments in electronic format (WordPerfect, Microsoft Word or Adobe PDF) to the Manager, Regulatory Standards, along with a note specifying the software, version number and operating system used.

Written submissions should be addressed to the Director General, Engineering, Planning and Standards Branch, Industry Canada, 300 Slater Street, Ottawa, Ontario K1A 0C8.

All submissions should cite the Canada Gazette, Part I, the publication date, the title and the notice reference number (SMSE-003-11).

Obtaining copies

Copies of this notice and of documents referred to herein are available electronically on Industry Canada's Spectrum Management and Telecommunications Web site at www.ic.gc.ca/spectrum.

Official versions of Canada Gazette notices can be viewed at www.gazette.gc.ca/rp-pr/p1/index-eng.html. Printed copies of the Canada Gazette can be ordered by telephoning the sales counter of Publishing and Depository Services at 613-941-5995 or 1-800-635-7943.

February 26, 2011

MARC DUPUIS

Director General

Engineering, Planning and Standards Branch

[9-1-o]

DEPARTMENT OF PUBLIC SAFETY AND EMERGENCY PREPAREDNESS

CRIMINAL CODE

Designation as fingerprint examiner

Pursuant to subsection 667(5) of the Criminal Code, I hereby designate the following persons of the Vancouver Police Department as fingerprint examiners:

Malcolm John Newlands

Denise Lynne Kask

Stephen Lawrence Haras

Ottawa, February 11, 2011

RICHARD WEX

Assistant Deputy Minister

Law Enforcement and Policing Branch

[9-1-o]

BANK OF CANADA

Statement of financial position as at January 1, 2011

(Millions of dollars) Unaudited

31 December 2010

Canadian GAAP Effect of transition to IFRS

1 January 2011

IFRS

ASSETS

Cash and foreign deposits

4.7

—

4.7

Loans and receivables

Securities purchased under resale agreements

2,062.4

—

2,062.4

Advances to members of the Canadian Payments Association

22.5

—

22.5

Advances to Governments

—

—

—

Other receivables

2.1

—

2.1

Investments

2,087.0

—
2,087.0

Treasury bills of Canada

24,906.1

—

24,906.1

Government of Canada bonds

33,550.6

—

33,550.6

Other investments

38.0

272.7

310.7

58,494.7

272.7

58,767.4

Property and equipment

123.4

29.6

153.0

Intangible assets

25.9

—

25.9

Other assets

149.1

29.0

178.1

60,884.8

331.3

61,216.1

31 December 2010

Canadian GAAP Effect of transition to IFRS

1 January

2011

IFRS

LIABILITIES AND EQUITY

Bank notes in circulation

57,874.2

—

57,874.2

Deposits

Government of Canada

1,869.4

—

1,869.4

Members of the Canadian Payments Association

47.5

—

47.5

Other deposits

639.9

—

639.9

2,556.8

—
2,556.8

Liabilities in foreign currencies

Government of Canada

—
—
—

Other

—
—
—
—
—
—

Other liabilities

Securities sold under repurchase agreements

—
—
—

Other liabilities

323.8

44.5

368.3

323.8

44.5

368.3

60,754.8

44.5

60,799.3

Equity

Share capital

5.0

—

5.0

Statutory and special reserves

125.0

—

125.0

Available-for-sale reserve

(1.7)

272.7

271.0

Actuarial gains reserve

—

14.1

14.1

Retained earnings

1.7

—

1.7

130.0

286.8

416.8

60,884.8

331.3

61,216.1

Effective January 1, 2011, the Bank of Canada adopted International Financial Reporting Standards (IFRS).

I declare that the foregoing return is correct according to the books of the Bank.

Ottawa, February 16, 2011

S. VOKEY

Chief Accountant

I declare that the foregoing return is to the best of my knowledge and belief correct, and shows truly and clearly the financial position of the Bank, as required by section 29 of the Bank of Canada Act.

Ottawa, February 16, 2011

M. CARNEY

Governor

[9-1-o]

BANK OF CANADA

Statement of financial position as at January 31, 2011

(Millions of dollars) Unaudited

ASSETS

Cash and foreign deposits

5.2

Loans and receivables

Securities purchased under resale agreements

—

Advances to members of the Canadian Payments Association

—

Advances to Governments

—

Other receivables

2.6

2.6

Investments

Treasury bills of Canada

23,218.2

Government of Canada bonds

34,581.4

Other investments

310.7

58,110.3

Property and equipment

152.3

Intangible assets

26.5

Other assets

182.4

58,479.3

LIABILITIES AND EQUITY

Bank notes in circulation

54,850.2

Deposits

Government of Canada

1,964.2

Members of the Canadian Payments Association

25.1

Other deposits

746.8

2,736.1

Liabilities in foreign currencies

Government of Canada

—

Other

—

—

Other liabilities

Securities sold under

repurchase agreements

—

Other liabilities

469.4

469.4

58,055.7

Equity

Share capital

5.0

Statutory and special reserves

125.0

Available-for-sale reserve

279.5

Actuarial gains reserve

14.1

Retained earnings

—

423.6

58,479.3

Effective January 1, 2011, the Bank of Canada adopted International Financial Reporting Standards (IFRS).

I declare that the foregoing return is correct according to the books of the Bank.

Ottawa, February 16, 2011

S. VOKEY

Chief Accountant

I declare that the foregoing return is to the best of my knowledge and belief correct, and shows truly and clearly the financial position of the Bank, as required by section 29 of the Bank of Canada Act.

Ottawa, February 16, 2011

M. CARNEY

Governor

[9-1-0]

Date modified:

2011-10-01