

WORLD TRADE ORGANIZATION

G/TBT/N/CAN/52
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(02-6764)

Committee on Technical Barriers to Trade

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French

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>CANADA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Department of Health Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Canadian Enquiry Point, 200-270 Albert Street, Ottawa, Ontario, Canada, K1P 6N7 Tel.: +1 613 238 3222, Fax.: +1 613 569 7808, E-mail: info@scc.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): Substances which require a prescription for both human and veterinary use (ICS : 11.120, 11.220)
5.	Title, number of pages and language(s) of the notified document: Proposed Amendment to the Food and Drug Regulations (1286 – Schedule F) (pages 3514-3518; English and French)
6.	Description of content: The Therapeutic Products Directorate (TPD) of Health Canada intends to update Schedule F to the <i>Food and Drug Regulations</i> of the <i>Food and Drugs Act</i> by adding 17 medicinal ingredients to Part I of Schedule F. Schedule F is a list of medicinal ingredients, the sale of which are controlled specifically under sections C.01.041 to C.01.049 of the <i>Food and Drug Regulations</i> . Part I of Schedule F lists medicinal ingredients that, when contained in a drug, are sold on prescription for both human and veterinary use. The review and introduction of new drugs onto the Canadian market necessitates periodic revisions to Schedule F. It is proposed that the following 17 medicinal ingredients be added to Part I of Schedule F: 1. Aminolevulinic acid and its salts and derivatives - a photodynamic therapy photosensitizer - in combination with blue light irradiation, indicated for the treatment of single and multiple non-hyperkeratotic actinic keratoses of the face and scalp.

2. Amlexanox and its salts and derivatives - an anti-inflammatory, anti-histaminic, leukotriene-inhibitor agent - indicated for the treatment of aphthous ulcers in people with normal immune systems.
3. Argatroban and its salts and derivatives - an antithrombotic - indicated as anticoagulant therapy in patients with heparin-induced thrombocytopenia syndrome.
4. Eflornithine and its salts and derivatives - a hair growth inhibitor - indicated for the condition of excessive facial hair growth (hirsutism) whose use is restricted to hirsute women.
5. Entacapone - an adjunct to levodopa and DDC inhibitor/COMT-inhibitor - indicated as an adjunct to levodopa/carbidopa to treat patients with idiopathic Parkinson's Disease who experience signs and symptoms of end-of-dose "wearing-off".
6. Etanercept - a biological response modifier - indicated for reduction in signs and symptoms of moderately to severely active rheumatoid arthritis in patients who have an inadequate response to one or more disease-modifying antirheumatic drugs.
7. Fomepizole and its salts - a synthetic alcohol dehydrogenase inhibitor - indicated as an antidote for ethylene glycol (antifreeze) poisoning, or for use in suspected ethylene glycol ingestion.
8. Gatifloxacin and its salts and derivatives - an antibacterial agent - indicated for treatment when susceptible bacteria cause community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis, acute sinusitis, uncomplicated skin and skin structure infections, uncomplicated urinary tract infections (cystitis), complicated urinary tract infections, pyelonephritis, and uncomplicated urethral, rectal and cervical gonorrhoea.
9. Infliximab - a biological response modifier - indicated for the treatment of severe, active Crohn's disease in adult patients who have not responded to a full course of therapy with corticosteroid and/or an immunosuppressant, and for treatment of fistulising Crohn's disease in adult patients who have not responded to a full course of therapy with conventional treatment.
10. Linezolid and its salts - an antibacterial agent - indicated in adult patients for the treatment of:
 - intra-abdominal, urinary tract, and skin and skin-structure infections (including cases associated with concurrent bacteremia) caused by Vancomycin-resistant *Enterococcus faecium* (VREF);
 - nosocomial pneumonia or community-acquired pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and methicillin-resistant strains) or *Streptococcus pneumoniae* (penicillin-susceptible strains only, including community-acquired cases with concurrent bacteremia);
 - complicated skin and skin-structure infections caused by *Staphylococcus aureus* (methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes*, or *Streptococcus agalactiae*; and
 - uncomplicated skin and skin-structure infections caused by *Staphylococcus aureus* (methicillin-susceptible strains) or *Streptococcus pyogenes*.
11. Lopinavir - a Human Immunodeficiency Virus (HIV) protease inhibitor - in combination with ritonavir, indicated in conjunction with other antiretroviral agents for the treatment of HIV infection.

	<p>12. Moxifloxacin and its salts and derivatives - an antibacterial agent - indicated for treatment when susceptible bacteria cause community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis, and acute sinusitis.</p> <p>13. Perflutren - a contrast enhancing imaging agent - indicated for contrast-enhanced ultrasound imaging of cardiac structures and function in adults with suboptimal echocardiograms, and for contrast-enhanced ultrasound imaging of the liver and kidneys in adults to improve the evaluation of pathology.</p> <p>14. Rabeprazole and its salts - a H^+, K^+ - ATPase inhibitor - indicated in the treatment of conditions where a reduction of gastric acid secretion is required.</p> <p>15. Sirolimus and its derivatives - an immunosuppressive agent - in combination with cyclosporine and corticosteroids, indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants.</p> <p>16. Tegafur and its salts - an antineoplastic agent and folic acid derivative - in combination with uracil and its salts, indicated for the treatment of metastatic colorectal cancer.</p> <p>17. Uracil and its salts - an antineoplastic agent and folic acid derivative - in combination with tegafur and its salts, indicated for the treatment of metastatic colorectal cancer.</p>
7.	<p>Objective and rationale, including the nature of urgent problems where applicable: Protection of human health</p>
8.	<p>Relevant documents: Canada Gazette, Part I, 23 November 2002</p>
9.	<p>Proposed date of adoption: } Not stated Proposed date of entry into force: }</p>
10.	<p>Final date for comments: 6 February 2003</p>
11.	<p>Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: The electronic version of the regulatory text can be downloaded at:</p> <p>http://canada.gc.ca/gazette/part1/pdf/g1-13647.pdf</p>