



NOTIFICATION

1.	<b>Notifying Member:</b> <u>CANADA</u> <b>If applicable, name of local government involved:</b>
2.	<b>Agency responsible:</b> Health Canada
3.	<b>Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):</b> Veterinary health products (ICS Code: 11.220)
4.	<b>Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5.	<b>Title of the notified document:</b> Proposed changes to <i>Food and Drug Regulations</i> to address Antimicrobial Resistance (AMR) related to veterinary drugs <b>Language(s):</b> English and French <b>Number of pages:</b> 51
6.	<b>Description of content:</b> Health Canada is proposing changes to the <i>Food and Drug Regulations</i> (FDR) to address the problem of antimicrobial resistance related to veterinary drugs. Currently the FDR do not provide adequate controls to help mitigate the risks of AMR.  Canada is seeking comments on proposed changes to: <ul style="list-style-type: none"><li>- restrict the importation of certain veterinary drugs;</li><li>- require manufacturers and importers to follow stricter rules with regards to the quality of the active ingredients used in the fabrication of antimicrobials;</li><li>- require manufacturers to provide sales information so that Health Canada can better monitor the use of antimicrobial drugs; and</li><li>- introduce an easier way to access low-risk veterinary health products.</li></ul> Canada has also notified this measure to the TBT Committee (G/TBT/N/CAN/491).
7.	<b>Objective and rationale:</b> <input type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input checked="" type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests. The overall objective of this proposal is to limit risks to human health by reducing the likelihood of resistance to antimicrobials in humans as a result of the use of antimicrobials for veterinary purposes.
8.	<b>Is there a relevant international standard? If so, identify the standard:</b> <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text) <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number) <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number) <input checked="" type="checkbox"/> None

<p><b>Does this proposed regulation conform to the relevant international standard?</b>  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b> There are no international standards; however the proposed regulations align with the International Conference on Harmonisation (ICH) Q7 Guideline: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (APIs). The Guideline, which has international adoption and acceptance, provides guidance regarding good manufacturing practice (GMP) for the manufacturing of APIs under an appropriate system for managing quality. It is also intended to help ensure that APIs meet the requirements for quality and purity that they purport or are represented to possess.</p>	
9.	<p><b>Other relevant documents and language(s) in which these are available:</b></p> <p><i>Food and Drug Regulations</i>  <a href="http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html">http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html</a> (English)  <a href="http://laws-lois.justice.gc.ca/fra/reglements/C.R.C.%2C_ch._870/index.html">http://laws-lois.justice.gc.ca/fra/reglements/C.R.C.%2C_ch._870/index.html</a> (French)  <i>Canada Gazette</i>, Part I, 2 July 2016, Pages 2357-2407 (available in English and French)</p>
10.	<p><b>Proposed date of adoption (dd/mm/yy):</b> Normally approximately twelve months following publication in the <i>Canada Gazette</i>, Part I.</p> <p><b>Proposed date of publication (dd/mm/yy):</b></p>
11.	<p><b>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy):</b> These Regulations would come into force six months after the day on which they are published in <i>Canada Gazette</i> Part II.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
12.	<p><b>Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy):</b> 15 September 2016</p> <p><b>Agency or authority designated to handle comments: <input type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b></p>
13.	<p><b>Text(s) available from: <input type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b></p> <p>The electronic version of the proposed policy document can be downloaded at:  <a href="http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/pdf/g1-15027.pdf">http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/pdf/g1-15027.pdf</a>  <a href="http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/html/reg2-eng.php">http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/html/reg2-eng.php</a> (English)  <a href="http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/html/reg3-eng.php">http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/html/reg3-eng.php</a>  <a href="http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/html/reg2-fra.php">http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/html/reg2-fra.php</a> (French)  <a href="http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/html/reg3-fra.php">http://www.gazette.gc.ca/rp-pr/p1/2016/2016-07-02/html/reg3-fra.php</a></p>