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**U.S Introduction to Proposed TBT Annexes on Medical Devices,
Pharmaceutical Products and Cosmetic Products**

Derived From: Classification Guidance
dated March 4, 2010

Reason: 1.4(b)

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INTRODUCTION

The United States is introducing three additional proposed annexes for the TBT Chapter during the Chicago Round. These three annexes would cover certain regulatory aspects of the trade among the TPP Parties in cosmetic products, pharmaceutical products and medical devices.

OBJECTIVES

The United States believes that these annexes would benefit TPP partners by better aligning our respective regulatory regimes for covered goods over time. Greater alignment would reduce unnecessary regulatory divergences, which would make it easier to do business in the region and, in turn, enhance economic growth and promote job creation, without sacrificing the public health protections our regulators and citizens expect. Many TPP partners already manufacture and export cosmetic products, pharmaceutical products and medical devices and other TPP partners could make themselves more attractive as places to do business by adopting these disciplines.

Currently, five TPP partners each export more than half a billion USD annually of medical devices; five TPP partners export at least \$120 million USD annually of pharmaceutical products; and three TPP partners export more than half a billion USD annually of cosmetic products, with three other partners also exporting sizable quantities of cosmetic products. In all three product areas, seven of the TPP partners export to the United States.

In addition to the economic benefits that would accompany greater regulatory alignment, better alignment could help our respective regulators to their jobs more efficiently – namely, protecting the health and safety of patients and consumers and ensuring that only the highest quality goods are placed on the market. These proposals recognize that, in an increasingly globalized world, effective regulation does not stop at one's own border. Regulators need to work together to accomplish their objectives, and these annexes have the potential to enhance such current cooperation in the field of public health regulation. Nevertheless, the draft proposed annexes are sufficiently general so as to provide sufficient flexibility for each TPP Party to ensure that it is able to determine its own appropriate level of public health protection.

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Provisions Common to All Three Annexes

The core provision of all three annexes is the collaboration obligation. The annexes strongly encourage better alignment of regulatory approaches by requiring our respective regulators to collaborate through existing and future regulator-to-regulator international initiatives in each product area, to consider relevant guidance documents developed by such bodies when regulating, and to explain any deviations from such guidances. This proposal encourages our regulators to utilize the internationally developed best practices and work collaboratively in the regulation and oversight of cosmetic products, medical devices and pharmaceutical products, with resulting benefits for facilitating trade in these goods, enabling greater convergence in regulatory approaches, and assuring requisite levels of public health protection.

Crucial to a country's ability to more effectively collaborate is for each country to have one regulatory authority at the central government level responsible for oversight of each of these goods and to define clearly the scope of goods that are subject to that regulatory authority's jurisdiction. Ensuring that there is only one regulator also makes it easier to do business because it eliminates the potential for two central government regulators in the same country to be regulating for the same purpose in redundant or inconsistent ways, which unnecessarily increases supplier costs, burdens and delays to market.

If a Party maintains a marketing authorization process that suppliers must complete before being able to market their goods within a Party's territory, we've also set out several general rules that each Party would need to follow to ensure that the process is transparent, timely, impartial, objective, reasonable and without conflicts of interest. The U.S. proposals would provide Parties with much flexibility in terms of how to implement these provisions, such as in the choice of appeals mechanism, the flexibility to determine the reasonable period of time for a marketing authorization determination, and the discretion to determine what would be "just cause" for requiring re-authorization of a good. Under the U.S. proposal, it is not even required that a Party maintains a marketing authorization process; the United States, for instance, does not maintain such a process for cosmetic products.

Moreover, the United States is proposing that each TPP Party consider any resource capacity constraints it might have when determining the appropriate marketing authorization procedure to put in place. Inadequate resource capacity can inhibit the effectiveness of a marketing authorization assessment procedure in fulfilling regulatory public health objectives and lead to delays for suppliers and manufacturers trying to market their goods.

Lastly, we would prohibit a Party from requiring prior authorization of a good in another Party's territory or in the country of manufacture as a condition of market access. (At the same time, we would continue to encourage each Party to accept prior authorization of a good in another market as evidence that a good may meet its regulatory requirements – we know that many TPP partners already do this.) Prior authorization requirements in other markets have caused trade distortions for several reasons. Defining the country of manufacture can be challenging where the good's supply chain spans more than one country. In addition, some suppliers manufacture goods solely for export to specific countries so

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requiring them to undergo the marketing authorization process in another market imposes unnecessary costs, burdens and delays to the market, which can negatively impact consumers and industry in the importing country. Requiring prior authorization in another jurisdiction as a condition of entry also incentivizes production of cosmetic products, medical devices and pharmaceutical products to shift to countries with the fastest regulatory authorization times, which could negatively impact the safety and quality of the products.

Annex-specific Provisions

The United States is also proposing a number of provisions that are annex-specific:

For medical devices, we are proposing that each Party should put in place a system for priority review of new and innovative medical devices, and that the Parties should attempt to align their Unique Device Indicators (UDI) systems to the extent possible.

Alignment of UDI systems to identify medical devices will yield benefits to public health (e.g., in tracking and tracing, identifying substandard or fake products, alleviating shortages, post-market surveillance, facilitating recalls, and enhancing patient care); benefits to industry (e.g., allowing manufacturers to use a single UDI to meet all TPP requirements, improving the efficiency and effectiveness of recalls, as well as logistics throughout the supply chain); and benefits to regulators (e.g., generating better data on product performance, improving use and understanding of suspected adverse event reports and understanding the risks of specific devices for certain patients and certain uses, which could help expedite marketing authorizations).

For pharmaceutical products, the United States is proposing that each Party accepts the marketing authorization format set out in the ICH Common Technical Document, recognizing that this format allows for additional information requirements to meet local needs, but it does harmonize the format of a large portion of the marketing application. This provision would enable suppliers to follow the same core application format in all nine of the TPP Parties, which should simplify the marketing authorization process in the TPP region, while allowing each Party to tailor the information required to its specific regulatory needs.

For cosmetic products, the United States is putting forward provisions that would restrict requiring the use of most animal testing for assessing safety when other validated methods to establish safety exist and encourage each Party to adopt good manufacturing practice guidelines as part of their approach to ensure that cosmetic products are consistently manufactured and controlled to assure safety and quality.

Regarding medical devices and cosmetic products, each Party would be required to regulate on the basis of a risk-based approach. For example, one would approach the regulation of a bed pan quite differently from the regulation of a pacemaker because the risks of non-fulfillment of legitimate public health objectives are radically different with respect to those two products.

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Further, we propose that each Party allows suppliers to supplement existing labels with country-specific labeling information at any time prior to the goods entering the Party's customs territory. Absent this provision, a supplier would need to design country-specific labels for each market and adjust its production line accordingly, which adds unnecessary costs to the production process. It would also enable greater flexibility in supply chains because goods could be diverted from a market where demand has been met to a market where demand exceeds supply and then re-labeled for that market. This could not happen if the good already carries a label that is specific to a particular market.

With respect to medical devices and pharmaceutical products, the United States proposes that each Party ensures that its marketing authorization process considers generally-accepted international scientific best practices and supports an assessment of product safety, effectiveness and quality that form the basis for a final benefit-to-risk assessment. In addition, a Party would only be able to consider information related to the safety, efficacy, manufacturing quality and labeling of the medical device or pharmaceutical product as the basis for making its marketing authorization determination; extraneous factors that are unrelated to these considerations would not generally be allowed in marketing authorization determinations. These disciplines would help ensure that Parties render decisions that are consistent (within their jurisdiction), and predictable science-based determinations and are less likely to create unnecessary obstacles to trade.

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**U.S Textual Proposal for the TBT Chapter:
Annex on Cosmetic Products**

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ANNEX III: COSMETIC PRODUCTS

1. This Annex applies to any cosmetic product.
2. The Parties shall seek to collaborate, including through relevant regulatory collaboration initiatives, such as the International Cooperation on Cosmetics Regulations (ICCR), as appropriate, to improve the alignment of their respective cosmetic products regulations and regulatory activities with the objective of promoting and protecting public health while not creating unnecessary obstacles to trade.
3. Each Party shall consider relevant, internationally-developed guidances when developing or implementing laws and regulations regarding cosmetic products. A Party shall, upon request, explain its consideration of such guidelines and provide a rationale for any deviations.
4. Each Party shall ensure that only one regulatory body at the central government level in the Party's jurisdiction has the authority to regulate cosmetic products with respect to the protection of human health and safety.
5. Each Party shall define the scope of the products subject to its regulatory requirements for cosmetic products in its territory and make such information publicly available.
6. Each Party shall make regulatory decisions with respect to cosmetic products on the basis of a risk-based approach. Each Party recognizes that the burden of providing sufficient information on which a Party makes regulatory determinations rests with the cosmetic product manufacturer.
7. Each Party shall ensure that any marketing authorization process it maintains for cosmetic products is administered in a timely, reasonable, objective, transparent, and impartial manner and without conflicts of interest.
 - (a) If a Party requires marketing authorization for a cosmetic product, that Party shall provide the cosmetic product marketing authorization applicant with its determination regarding marketing authorization within a reasonable period of time.
 - (b) If a Party requires marketing authorization for a cosmetic product and the Party determines that a marketing authorization application for a specific cosmetic product under review in its jurisdiction has deficiencies that will lead to a non-authorization decision, that Party shall notify the marketing authorization applicant and provide a detailed written description of the deficiencies.
 - (c) If a Party requires marketing authorization for a cosmetic product, that Party shall ensure that any marketing authorization determinations are subject to an appeal process that may be invoked at the request of an applicant directly affected by such determination. That Party may maintain an appeal process that is either internal to the regulatory body, such as a dispute resolution or other supervisory process, or external to the regulatory body, at the discretion of the Party.

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- (d) Once a Party has granted full marketing authorization for a cosmetic product in its territory, that Party shall not require periodic re-authorization assessments, without cause, as determined by the Party's regulatory authority.
- 8. When determining the appropriate regulatory procedures, including any marketing authorization procedures, for cosmetic products, a Party shall take into account whether it has any capacity constraints that could:
 - (a) Inhibit the effectiveness of the procedure for ensuring the safety or manufacturing quality of cosmetic products, or
 - (b) Lead to substantial delays in the marketing authorization decision, if required, regarding cosmetic products for sale on its market.
- 9. No Party shall require, as a condition for any marketing authorization of a cosmetic product in its territory, prior marketing authorization of the product by another Party or by the country of manufacture of the cosmetic product.
- 10. If a Party requires that cosmetic product manufacturers provide information on labels that are affixed to their products, it shall permit manufacturers to comply with such requirements by re-labeling their products or providing supplementary labeling for a Party's territory prior to admission into commerce in that territory.
- 11. No Party shall require animal testing for determining the safety of cosmetic products, unless there is no validated alternative method available to otherwise assess safety. A Party may, however, consider the results of animal testing in determining the safety of a cosmetic product.
- 12. Each Party shall adopt good manufacturing practice guidelines to ensure that cosmetic products are consistently manufactured and controlled to the specified quality.
- 13. For purposes of this Annex, a cosmetic product is an article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, excluding products regulated as pharmaceutical products (as defined in Annex IV (Pharmaceutical Products) to Chapter XX) or medical devices (as defined in Annex V (Medical Devices) to Chapter XX) in a Party's territory. The term cosmetic product generally includes, but is not limited to, skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, certain shampoos, permanent waves, hair colors, certain toothpastes and mouthwashes, deodorants, as well as any material intended for use as a component of a cosmetic product.

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Annex on Pharmaceutical Products**

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ANNEX IV: PHARMACEUTICAL PRODUCTS

1. This Annex applies to any pharmaceutical product.
2. The Parties shall see to collaborate, including through regulatory collaboration initiatives, such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and various regulatory collaborative initiatives of the World Health Organization (WHO), as appropriate, to improve the alignment of their respective pharmaceutical products regulations and regulatory activities with the objective of promoting and protecting public health while not creating unnecessary obstacles to trade.
3. Each Party shall consider relevant, internationally-developed guidances, such as those developed by ICH or WHO technical committees, when developing or implementing laws and regulations on the marketing authorization of pharmaceutical products. A Party shall, upon request, explain its consideration of such guidelines and provide a rationale for any deviations.
4. Each Party shall ensure that only one regulatory body at the central government level in the Party's jurisdiction has the authority to regulate pharmaceutical products regarding their safety, effectiveness, and manufacturing quality and to grant marketing authorization for pharmaceutical products in the territory of the Party.
5. Each Party shall clearly define the scope of the products subject to its regulatory requirements for marketing authorization as pharmaceutical products in its territory and make such information publicly available.
6. Each Party shall make its determination on whether to grant marketing authorization for a specific pharmaceutical product solely on the basis of information related to the safety, efficacy, labeling, and manufacturing quality of the product. Each Party recognizes that the burden of providing sufficient information on which a Party makes regulatory determinations rests with the pharmaceutical product marketing authorization applicant or holder.
7. Each Party shall ensure that any marketing authorization process it maintains for pharmaceutical products is administered in a timely, reasonable, objective, transparent, and impartial manner and without conflicts of interest.
 - (a) Each Party shall provide a pharmaceutical product marketing authorization applicant with its determination regarding marketing authorization within a reasonable period of time.
 - (b) If a Party determines that a marketing authorization application for a pharmaceutical product under review in its jurisdiction has deficiencies that will lead to a non-authorization decision, that Party shall notify the marketing authorization applicant and provide a detailed written description on the deficiencies.
 - (c) Each Party shall ensure that any marketing authorization determinations are subject to an appeal process that may be invoked at the request of an applicant directly affected

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by such determination. Each Party may maintain an appeal process that is either internal to the regulatory body, such as a dispute resolution or other supervisory process, or external to the regulatory body, at the discretion of the Party.

- (d) Once a Party has granted full marketing authorization for a pharmaceutical product in its territory, the Party shall not require periodic re-authorization assessments, without cause, as determined by the Party's regulatory authority.
8. Each Party shall seek to ensure that any marketing authorization process it maintains for pharmaceutical products:
- (a) takes into consideration generally-accepted international scientific best practices, such as the ICH guidances, and
 - (b) supports an assessment of product safety, effectiveness, and manufacturing quality.
9. With respect to applications for marketing authorization, a Party shall accept safety, efficacy, and manufacturing quality information submitted by a manufacturer in a format that is consistent with the principles found in the ICH Common Technical Document (CTD), recognizing that the CTD does not necessarily address all aspects relevant to a Party's determination to grant marketing authorization for a particular product.
10. When determining the appropriate marketing authorization procedure for pharmaceutical products, a Party shall take into account whether it has any capacity constraints that could:
- (a) inhibit the effectiveness of the procedure for ensuring the safety, efficacy, or manufacturing quality of pharmaceutical products, or
 - (b) lead to substantial delays in the marketing authorization decision regarding pharmaceutical products for sale on its market.
11. No Party shall require, as a condition for any marketing authorization of a pharmaceutical product in its territory, prior marketing authorization of the pharmaceutical product by another Party or by the country of manufacture of the pharmaceutical product. Nothing in this provision prohibits a Party from accepting a prior marketing authorization by another Party as evidence that a pharmaceutical product may meet its own requirements.
12. For purposes of this Annex, a pharmaceutical product is a human drug, including biologics, or animal drug that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals or intended to affect the structure or any function of the body of a human or other animals and achieves its intended purpose by means that do not all within the definition of medical device set forth in Annex V (Medical Devices) to Chapter XX.

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ANNEX V: MEDICAL DEVICES

1. This Annex applies to any medical device.
2. The Parties shall seek to collaborate, including through regulatory collaboration initiatives, such as international coalitions of regulators and other international initiatives, as appropriate, to improve alignment of respective medical device regulations and regulatory activities with the objective of promoting and protecting public health while not creating unnecessary obstacles to trade. For example, the Parties should endeavor to align their Unique Device Indicators (UDI) systems to the extent possible.
3. Each Party shall consider relevant, internationally-developed guidances when developing or implementing its laws and regulations on the marketing authorization of medical devices. A Party shall, upon request, explain its consideration of such guidances and provide a rationale for any deviations.
4. Each Party shall ensure that only one regulatory body at the central government level in the Party's jurisdiction has the authority to regulate medical devices regarding their safety, effectiveness, and manufacturing quality and to grant marketing authorization for medical devices in the territory of the Party.
5. Each Party shall regulate medical devices on the basis of a risk-based approach that distinguishes between classes of medical devices based on their relative risk, intended use, indications for use, and other relevant factors, with requirements appropriate to each class. Each Party recognizes that the burden of providing sufficient information on which a Party makes regulatory determinations rests with the medical device marketing authorization applicant or holder.
6. Each Party shall define the scope of the products subject to its regulatory requirements for marketing authorization as medical devices in its territory and make such information publicly available.
7. Each Party shall make its determination on whether to grant marketing authorization for a specific medical device solely on the basis of information related to the safety, efficacy, labeling, and manufacturing quality of that device.
8. Each Party shall ensure that any marketing authorization process it maintains for medical devices is administered in a timely, reasonable, objective, transparent, and impartial manner and without conflicts of interest.
 - (a) Each Party shall provide a medical device marketing authorization applicant with its determination regarding marketing authorization within a reasonable period of time.
 - (b) If a Party determines that a marketing authorization application for a medical device under review in its jurisdiction has deficiencies that will lead to a non-authorization

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decision, that Party shall notify the marketing authorization applicant and provide a detailed written description of the deficiencies.

- (c) Each Party shall ensure that any marketing authorization determinations are subject to an appeal process that may be invoked at the request of an applicant directly affected by such determination. Each Party may maintain an appeal process that is either internal to the regulatory body, such as a dispute resolution or supervisory process, or external to the regulatory body, at the discretion of the Party.
 - (d) Once a Party has granted full marketing authorization for a medical device in its territory, the Party shall not require periodic re-authorization assessments, without cause, as determined by the Party's regulatory authority.
9. Each Party shall seek to ensure that any marketing authorization process it maintains for medical devices:
- (a) takes into consideration generally-accepted international scientific best practices, and
 - (b) supports an assessment of product manufacturing quality and/or product safety and effectiveness, as appropriate.
10. When developing a new marketing authorization procedure for medical devices, a Party shall take into account whether it has any capacity constraints that could:
- (a) Inhibit the effectiveness of the procedure for ensuring the manufacturing quality and/or safety or efficacy of medical devices, as appropriate, or
 - (b) Lead to substantial delays in the marketing authorization decision regarding medical devices for sale on its market.
11. No Party shall require, as a condition for any marketing authorization of a medical device in its territory, prior marketing authorization of the device by another Party or by the country of manufacture of the medical device. Nothing in this provision prohibits a Party from accepting a prior marketing authorization by another Party as evidence that a medical device may meet its own requirements.
12. Each Party should adopt priority review programs for new and innovative medical technology to accelerate patient access to pioneering medical devices.
13. If a Party requires that medical device manufacturers provide information on labels that are affixed to their products, it shall permit manufacturers to comply with such requirements by re-labeling their products or providing supplementary labeling for a Party's territory prior to admission into commerce in that territory.

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14. For purposes of this Annex, a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory thereof, that is intended –

- (a) for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (b) to affect the structure or any function of the body of man or other animals, and

that does not achieve its primary intended purposes through chemical action within or on the body of a human or other animal and that is not dependent upon being metabolized for the achievement of its primary intended purposes.