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CPTTP: PHARMA AND REGULATORY MATTERS

Chapter 8: Technical Barriers to Trade

This chapter provides rules to facilitate trade by eliminating unnecessary technical barriers, improving transparency, and promoting greater regulatory cooperation. It applies to the elaboration, approval and application of technical regulations, standards, conformity assessment procedures and trade authorization for pharmaceuticals, cosmetics and medical devices. The following points were addressed:

• The party's obligations will apply to any product (pharmaceutical, cosmetic or medical device) that the party defines as such. Thus, each party will define the scope of application of the products in accordance with its laws and regulations for each category within its territory, notwithstanding that the treaty establishes certain definitions of its own.
• Each party should identify its authorities to regulate each class of products in the territory. If there is more than one competent authority, measures should be taken to eliminate unnecessary duplication of regulatory requirements.
• In developing and implementing regulations for the commercial authorization of products, each party should consider scientific or technical guidance documents developed regionally or through international collaboration.
• For cosmetic products, parties should ensure that they apply a risk-based approach to the regulation of these products, taking into consideration that they are generally expected to represent a lower potential health risk than medical devices or pharmaceuticals.
• In the case of medical devices, each party should classify them based on their risk and corresponding scientific factors and seek to regulate accordingly.
• It is acknowledged that the applicant is responsible for providing sufficient information for the party to make a regulatory decision about a product.
• A decision on whether to grant a marketing authorization for a specific product will be made based on certain background

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information set forth in the treaty. For this purpose, no party may require sales or financial data, on prices or costs, regarding the commercialization of the product to make the decision.
• Each party will manage its commercial authorization processes in an objective and transparent manner, managing any conflicts of interest to mitigate associated risks. For cosmetics, these processes may be replaced by voluntary or mandatory notification and post-marketing surveillance.
• When developing regulatory requirements, parties should minimize the application of those that inhibit the effectiveness of safety procedures or result in delays of the authorization.
• No party may require that the product must receive marketing authorization from a regulatory authority in its country of manufacture in order to grant its authorization. However, this may be accepted as evidence of the utility of the product [1] .
• For cosmetics, the product may not be required to be tested on animals to determine its safety, unless there is no validated alternative method available.
• Improved collaboration in pharmaceutical inspection will be sought by notifying the performance of an inspection, allowing the other party to observe it and notifying its conclusions.

Chapter 18: Intellectual Property

Regarding measures related to pharmaceutical products, this subsection addresses those aspects of the protection and enforcement of intellectual property rights related to undisclosed test data and the marketing of pharmaceutical products.

It should be noted that the parties agreed to suspend several articles of the original TPP. These are those concerning the protection of undisclosed test data or other undisclosed data and biological products. These suspended provisions are not part of the Treaty and the agreement of all CPTPP members would be necessary for these provisions to be applied in the future.

For purposes of this section, a new drug product means a product that does not contain a chemical entity that has been previously approved in that party. The main points addressed are the following:

• **Exception based on regulatory review.** Notwithstanding the provisions of previous articles on exceptions [2] , each party may adopt and maintain an exception based on regulatory review for

pharmaceutical products.

• **Measures related to the marketing of certain pharmaceutical products.** If a party permits, as a condition of marketing authorization of a product to persons other than the one who originally submitted the safety and efficacy information, to rely on that information for a previously authorized product, that party shall provide:

• A system for providing notice to the patent holder or allowing the patent holder to be notified, prior to marketing the product, that there is another person seeking to market the product during the term of that patent;
• Adequate time and opportunity for the holder to avail himself of available remedies prior to commercialization,
• Procedures for the timely resolution of disputes over the validity or infringement of a patent covering an authorized product.

As an alternative, the party may maintain an extrajudicial system that prevents the granting of authorization to third parties who intend to commercialize a pharmaceutical product subject to a patent without the consent or conformity of its holder.

Alteration of the period of protection. If a product is subject to an authorization system in the territory and is covered by a patent, the party may not alter the period of protection provided in the recently mentioned regulation.

It is noted that, in the case of Chile, the above does not prevent the application of Article 91° of the Industrial Property Law No. 19,039.

Chapter 26: Transparency and procedural equity for pharmaceuticals and medical devices:

This section establishes those definitions, principles, and procedures with the goal of ensuring transparency and procedural equity of the relevant aspects of the parties' applicable systems related to pharmaceutical products and medical devices.

• The importance of protecting and promoting public health is emphasized, recognizing the role of these products in providing quality medical care, in addition to noting the importance of research and development, including innovation associated with these products.

• In addition, there is a need to promote timely and affordable access to these goods through transparent, impartial, and accountable procedures.
• In relation to a party's national health measures that operate or maintain procedures for listing new medical products or devices for reimbursement purposes, or for setting the amount of such reimbursement, under national health programs operated by national health authorities, the party should adopt a series of measures aimed at strengthening the transparency and fairness of the procedures.
• The manufacturer shall make available to health professionals and consumers truthful information about its products approved for that territory.
• Each party shall provide adequate opportunity for the other party to consult as it deems necessary and appropriate with respect to this section.

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[1] A certificate of free sale may also not be required for cosmetics.

[2] Specially Article 18.40°

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