

## **CHAPTER 12**

### **SECTORAL ANNEXES**

#### **Article 12.1: Sectoral Annexes**

1. In addition to other applicable provisions of this Agreement, this Chapter contains provisions with respect to chemical substances, cosmetic products, information and communication technology, energy performance standards, medical devices, and pharmaceuticals, as defined therein.

2. The rights and obligations set out in each annex to this Chapter shall apply only with respect to the sector specified in that annex, and shall not affect any Party's rights or obligations under any other annex to this Chapter.

## ANNEX 12-A

### CHEMICAL SUBSTANCES

#### Article 12.A.1: Definitions

For the purposes of this Annex:

**chemical mixture** means a combination or a solution composed of two or more chemical substances in which they do not react;

**chemical substance** means any organic or inorganic substance of a particular molecular identity or a mixture of substances,<sup>1</sup> including:

- (a) any combination of those substances occurring in whole or in part as a result of a chemical reaction or occurring in nature; and
- (b) any element or uncombined radical;

**hazard** means the potential adverse human health, physical, or environmental effects caused by a chemical substance or chemical mixture;

**risk-based approach** means the evaluation of a chemical substance or chemical mixture that includes the consideration of both the hazard and exposure; and

**safety data sheet** means written or printed material that provides comprehensive information about chemical identity, hazards, precautions, and response actions for a particular chemical substance or chemical mixture for use in a workplace chemical control regulatory framework.

#### Article 12.A.2: Scope

This Annex applies to the preparation, adoption, and application of technical regulations; standards; conformity assessment procedures; measures relating to hazard communication, labeling, and communication of information on the use and storage of chemical substances and chemical mixtures, and on response in the workplace to hazards and exposures; and import and

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<sup>1</sup> “Mixture of substances” do not include any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction.

export permits for chemical substances and chemical mixtures by a Party's central level of government:<sup>2</sup>

- (a) applied for the purposes of protecting the environment or human health from chemical substances and chemical mixtures;
- (b) that may significantly affect trade between the Parties; and
- (c) which is not:
  - (i) a sanitary or phytosanitary measure,
  - (ii) a measure relating to pesticides, pharmaceutical products, veterinary drugs, cosmetic products, nuclear material, or food products, including food additives, or
  - (iii) a measure relating to the control of chemical precursors in order to prevent the production of illegal narcotics and psychotropic substances.

#### **Article 12.A.3: Competent Authorities**

Each Party shall publish online the following information with respect to each of its competent authorities at its central level of government that has responsibility for implementing and enforcing measures regulating chemical substances and chemical mixtures:

- (a) a description of each authority, including the authority's specific responsibilities; and
- (b) a contact point within each authority.

Each Party shall promptly notify the other Parties of any material changes to this information and update the information online.

#### **Article 12.A.4: Enhancing Regulatory Compatibility**

1. The Parties recognize that the principal objective of regulating chemical substances and chemical mixtures is the protection of human health and the environment.

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<sup>2</sup> The Parties recognize that the obligations in this Annex do not preclude a Party from implementing obligations under existing international agreements relating to chemical management or entering into any new international agreement relating to chemical management.

2. The Parties also recognize the importance of developing and implementing measures in a manner that achieves their respective level of protection without creating unnecessary economic barriers or impediments to technological innovation.

3. Each Party shall endeavor to use a risk-based approach to the assessment of specific chemical substances and chemical mixtures, where appropriate. Each Party also intends to encourage, as appropriate, a risk-based approach to regulating chemical substances and chemical mixtures both in international fora and in its relations with non-Parties.

4. The Parties shall endeavor, if appropriate, to align their respective risk assessment methodologies and risk management measures for chemical substances and chemical mixtures provided that alignment does not prevent a Party from determining and achieving its levels of protection. In its alignment efforts, each Party shall strive to continue to improve its levels of protection.

5. Each Party, when developing, modifying, or adopting a measure concerning chemical substances or chemical mixtures, shall endeavor to consider how a measure adopted by another Party could inform its decision-making.

6. The Parties shall strengthen their cooperation on chemical substances and chemical mixtures, including through the use of fora in existence. To that end, the Parties recognize potential areas of cooperation include:

- (a) their respective implementation of the United Nations Globally Harmonized System for Classification and Labeling of Chemicals (GHS);
- (b) the use and content of safety data sheets, including with respect to the information requirements for identical or similar chemical substances, without reducing the level of safety or protection for workers;
- (c) compatibility of respective requirements for presentation of information protected as confidential business information on safety data sheets;
- (d) coordination, compatibility, and, if appropriate, development of chemical inventories;
- (e) coordination and collaboration on chemical risk assessment and risk management methodologies, tools, and models, and on the development of specific chemical assessments; and
- (f) if appropriate, scientific criteria used for the reliability of scientific data underpinning regulatory decisions.

If the Parties identify differences in practice with respect to paragraphs (b) and (c) they shall cooperate with a view to minimizing the differences in the use of safety data and safety data sheets by the competent authorities of each Party.

#### **Article 12.A.5: Data and Information Exchange**

1. The Parties shall endeavor to periodically exchange information concerning respective methodologies for assessing chemical substances, both generally and with respect to particular chemicals.
2. Upon request of another Party, a Party shall share any available data or assessments on particular chemical substances, such as full data studies or robust data summaries.<sup>3</sup> Each Party shall adopt or maintain procedures to prevent the disclosure of confidential information that appears in the data or assessments, including procedures to remove or recall any confidential information that is inadvertently disclosed.
3. The Parties shall exchange, as appropriate:
  - (a) information related to their respective activities to disseminate information to the public concerning the safety of chemical substances; and
  - (b) scientific data and technical information, on new and emerging issues related to the management of chemical substances, with a view to accumulating the best available scientific data or technical information, including peer-reviewed studies.

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<sup>3</sup> A Party may fulfill this obligation by making the data or assessments requested publicly available and informing the Party that made the request how to access the information.

## ANNEX 12-B

### COSMETIC PRODUCTS

#### Article 12.B.1: Definitions

For the purposes of this Annex:

**cosmetic product** means:

- (a) for Canada, a product that constitutes a “cosmetic” as defined under section 2 of the *Food and Drugs Act*, R.S.C., 1985, c.F-27, as amended, and that is regulated solely under the *Cosmetic Regulations*, C.R.C., c. 869, as amended;
- (b) for Mexico, a product covered as “cosmetics” as defined under article 269 *Ley General de Salud* (Health General Law) and article 187 *Reglamento Control Sanitario de Productos y Servicios* (Regulation Sanitary Control of Products and Services) as amended; and
- (c) for the United States, a product covered as a “cosmetic” under 21 U.S.C. § 321(i), as amended;

**marketing authorization** means the process or processes by which a Party approves or registers a cosmetic product in order to authorize its marketing, distribution, or sale in the Party’s territory on the basis of the Party’s safety, efficacy, and quality requirements;

**ICI Dictionary** means the International Cosmetic Ingredient Dictionary and Handbook, published in Washington, DC by the Personal Care Products Council;

**INC** means the International Cosmetic Ingredient Nomenclature Committee, which develops the INCI names; and

**INCI name** means the International Nomenclature Cosmetic Ingredient name assigned to an ingredient in the ICI Dictionary.

#### Article 12.B.2: Scope

This Annex applies to the preparation, adoption, and application of technical regulations, standards, conformity assessment procedures, and notification procedures by a Party’s central level of government that may affect trade in cosmetic products between the Parties, other than sanitary

or phytosanitary measures or technical specifications prepared by a government body for production or consumption requirements of that body.

### **Article 12.B.3: Competent Authorities**

1. Each Party shall publish online the following information with respect to each of its competent authorities at its central level of government that has responsibility for implementing and enforcing measures regulating cosmetic products:

- (a) a description of each authority, including the authority's specific responsibilities; and
- (b) a contact point within each authority.

Each Party shall promptly notify the other Parties of any material changes to this information and update the information online.

2. Each Party shall avoid adopting or maintaining unnecessarily duplicative regulatory requirements with respect to cosmetic products, including by periodically examining whether its authorities are engaged in duplicative activities.

### **Article 12.B.4: Enhancing Regulatory Compatibility**

1. The Parties shall seek to collaborate to improve the alignment of their respective regulations and regulatory activities for cosmetic products through work in relevant international initiatives, as appropriate, such as those aimed at harmonization, as well as regional initiatives that support those international initiatives.

2. In developing or implementing regulations for cosmetic products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.

3. If a Party prepares or adopts good manufacturing practice guidelines for cosmetic products, it shall use relevant international standards for cosmetic products, or the relevant parts of them, as a basis for its guidelines unless those international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

4. Each Party shall endeavor to share information:

- (a) from post-market surveillance of cosmetic products; and

- (b) on its findings regarding cosmetic ingredients that may affect trade between the Parties.

#### **Article 12.B.5: Application of Regulatory Controls**

1. Each Party shall ensure that for a measure it applies to ensure the safety, effectiveness, or quality of cosmetic products, including marketing authorizations, notification procedures, and elements of either, products imported from the territory of another Party be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country, in a comparable situation.

2. In developing a regulatory requirement for a cosmetic product, each Party shall consider its available resources and technical capacity in order to minimize the likelihood of implementing requirements that could:

- (a) inhibit the efficacy of procedures for ensuring the safety, effectiveness, or quality of cosmetic products; or
- (b) lead to substantial delays for cosmetic products becoming available in that Party's market.

3. Each Party shall apply a risk-based approach to regulating the safety of cosmetic products for human health, taking into account relevant scientific factors. In applying this approach, each Party shall take into account that cosmetic products generally present a lower potential risk to human health or safety than medical devices or pharmaceutical products. Accordingly, no Party shall require:

- (a) a marketing authorization for a cosmetic product, unless a Party identifies a human health or safety concern, and a less trade-restrictive alternative, such as a notification or post-market surveillance, is not reasonably available to effectively address the risks at issue;
- (b) re-testing or re-evaluating of a cosmetic product that differs only with respect to shade extensions or fragrance variants, unless conducted for human health or safety purposes;
- (c) a cosmetic product to be labeled with a notification number;
- (d) a cosmetic product to receive a marketing authorization from a regulatory authority in the country of manufacture, as a condition for being placed in its market;<sup>4</sup> or

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<sup>4</sup> For greater certainty, this subparagraph does not prohibit a Party from accepting a prior marketing authorization issued by another regulatory authority as evidence that a product may meet its own requirements.



- (e) a cosmetic product to be accompanied by a certificate of free sale as a condition of marketing, distribution, or sale in the Party's territory.

4. If a Party requires a manufacturer or supplier of a cosmetic product to indicate information on the product's label, the Party shall permit the manufacturer or supplier to indicate the required information by relabeling the product or by using supplementary labeling of the product in accordance with the Party's domestic requirements after the importation but prior to offering the product for sale or supply in the Party's territory.

5. No Party shall require that a cosmetic product be tested on animals to determine the safety of that cosmetic product, unless there is no validated alternative method available to assess safety. This paragraph, however, does not preclude a Party from considering the results of animal testing to evaluate the safety of a cosmetic product.

#### **Article 12.B.6: Labeling**

1. The Parties recognize the importance of the International Nomenclature Cosmetic Ingredient (INCI) in providing consistent, standardized information about the ingredients in cosmetic products to consumers, health practitioners, and other interested persons.

2. To that end, the Parties shall continue efforts to seek closer alignment of cosmetic ingredient labeling and, no later than one year after the date of entry into force of this Agreement, to report progress to the Commission toward this goal.

3. The Parties shall also endeavor to participate in the INC process for developing, revising, and simplifying the ICI Dictionary.

## APPENDIX 1

### ENHANCING REGULATORY COMPATIBILITY FOR PRODUCTS RECOGNIZED AS BEING AT THE INTERFACE OF COSMETICS AND DRUGS

1. This Appendix applies only as between Canada and the United States. Accordingly, for the purposes of this Appendix, “Party” or “Parties” means Canada or the United States, singly or collectively.

2. This Appendix applies to toothpastes, mouthwashes, personal care use antiseptic skin cleansers, sunscreens, anti-dandruff shampoos, diaper-rash creams, antiperspirants, medicated skin care products,<sup>5</sup> and acne products as set out in the following subparagraphs:

- (a) for Canada, products that:
  - (i) are for topical use in the oral cavity or on unbroken skin that act in a localized and non-systemic manner,
  - (ii) are authorized for sale in Canada,
  - (iii) are a non-prescription drug product or a natural health product, and
  - (iv) meet the definition of a “cosmetic” in section 2 of the *Food and Drugs Act*, R.S.C., 1985, c.F-27, as amended;
- (b) for the United States, products that conform to an over-the-counter drug monograph or an approved new drug application before the product can be placed on the U.S. market.

3. For the purposes of this Appendix:

**facts table** means a standard labeling format containing prescribed information as provided under each Party’s law;

**monograph** means the regulatory requirements setting forth the permissible conditions for marketing of certain over-the-counter drug products, including use and labeling requirements, such as dose, intended use, directions for use, warnings, active ingredients and combinations thereof;

**non-prescription drug product** means a pharmaceutical product, as defined in Article 12.F.1 (Definitions), that is safe and effective for use as directed on the label, is available for direct sale

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<sup>5</sup> Medicated skin care products do not include antifungals, antivirals, antibiotics, corticosteroids, counterirritants, and analgesics.

to a consumer, is permitted to be sold without a prescription, and is not intended to be administered solely under the supervision of a health care practitioner;

**security packaging** means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase; and

**tamper-evident packaging** means an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred.

4. If an importing Party has authorized for sale a product covered by paragraph 2, the importing Party shall allow the product to be shipped directly to retailers or wholesalers without subjecting the product to re-testing or quarantine unless done pursuant to:

- (a) an identified human health concern with regard to that specific shipment; or
- (b) an established system of random or risk-based inspection applied for the purpose of protecting human health.

5. The Parties shall endeavor to strengthen their cooperation in the regulation of products covered by paragraph 2. To that end, the Parties shall consider cooperating in areas including:

- (a) alignment of the requirements for tamper-evident packaging in the United States and security packaging in Canada with respect to dermatological and dentifrice products, subject to the consideration of any human health or safety concerns; and
- (b) alignment of facts table requirements.

6. If a Party authorizes for sale a product covered by paragraph 2, the Party shall permit the distribution of samples in that Party's territory under conditions set out in that Party's law.

## ANNEX 12-C

### INFORMATION AND COMMUNICATION TECHNOLOGY

#### Article 12.C.1: Definitions

For the purposes of this Annex:

**cipher** or **cryptographic algorithm** means a mathematical procedure or formula for combining a key with plaintext to create a ciphertext;

**cryptography** means the principles, means or methods for the transformation of data in order to conceal or disguise its content, prevent its undetected modification, or prevent its unauthorized use; and is limited to the transformation of information using one or more secret parameters, for example, crypto variables, or associated key management;

**electromagnetic compatibility** means the ability of a system or equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances with respect to any other device or system in that environment;

**electronic labeling** means the electronic display of information, including required compliance information;

**encryption** means the conversion of data (plaintext) through the use of a cryptographic algorithm into a form that cannot be easily understood without subsequent re-conversion (ciphertext) and the appropriate cryptographic key;

**information and communication technology good (ICT good)** means a product whose intended function is information processing and communication by electronic means, including transmission and display, or electronic processing applied to determine or record physical phenomena, or to control physical processes;

**information technology equipment product (ITE product)** means a device, system, or component thereof for which the primary function is the entry, storage, display, retrieval, transmission, processing, switching, or control (or combinations thereof) of data or telecommunication messages by means other than radio transmission or reception;

**key** means a parameter used in conjunction with a cryptographic algorithm that determines its operation in such a way that an entity with knowledge of the key can reproduce or reverse the operation, while an entity without knowledge of the key cannot;

**supplier's declaration of conformity** means an attestation by a supplier that a product meets a

specified standard or technical regulation based on an evaluation of the results of conformity assessment procedures; and

**terminal equipment** means a digital or analog device capable of processing, receiving, switching, signaling, or transmitting signals by electromagnetic means and that is connected by radio or wire to a public telecommunications transport network at a termination point.

### **Article 12.C.2: ICT Goods that Use Cryptography**

1. This Article applies to ICT goods that use cryptography.<sup>6</sup> This Article does not apply to:
  - (a) a Party's law enforcement authorities requiring service suppliers using encryption they control to provide unencrypted communications pursuant to that Party's legal procedures;
  - (b) the regulation of financial instruments;
  - (c) a requirement that a Party adopts or maintains relating to access to networks, including user devices, that are owned or controlled by the government of that Party, including those of central banks;
  - (d) a measure taken by a Party pursuant to supervisory, investigatory, or examination authority relating to financial institutions or financial markets; or
  - (e) the manufacture, sale, distribution, import, or use of the good by or for the government of the Party.
  
2. With respect to an ICT good that uses cryptography and is designed for commercial applications, no Party shall require a manufacturer or supplier of the good, as a condition of the manufacture, sale, distribution, import, or use of the good, to:
  - (a) transfer or provide access to any proprietary information relating to cryptography, including by disclosing a particular technology or production process or other information, for example, a private key or other secret parameter, algorithm specification, or other design detail, to the Party or a person in the Party's territory;
  - (b) partner or otherwise cooperate with a person in its territory in the development, manufacture, sale, distribution, import, or use of the product; or
  - (c) use or integrate a particular cryptographic algorithm or cipher.

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<sup>6</sup> For greater certainty, for the purposes of this Annex, an ICT good does not include a financial instrument.

### **Article 12.C.3: Electromagnetic Compatibility of ITE Products**

1. This Article applies to requirements regarding the electromagnetic compatibility of ITE products.
2. This Article does not apply to a product:
  - (a) that a Party regulates as a medical device, a medical device system, or a component of a medical device or medical device system; or
  - (b) for which the Party demonstrates that there is a high risk that the product will cause harmful electromagnetic interference with a safety or radio transmission or reception device or system.
3. If a Party requires positive assurance that an ITE product meets a standard or technical regulation for electromagnetic compatibility, it shall accept a supplier's declaration of conformity,<sup>7</sup> provided that the declaration satisfies the Party's requirements regarding testing, such as testing by an accredited laboratory, in support of a supplier's declaration of conformity, registration of the supplier's declaration of conformity, or the submission of evidence necessary to support the supplier's declaration of conformity.

### **Article 12.C.4: Regional Cooperation Activities on Telecommunications Equipment**

1. This Article applies to telecommunications equipment.
2. The Parties are encouraged to implement the APEC *Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment* of May 8, 1998 (MRA-TEL) and, with respect to each other, the APEC *Mutual Recognition Arrangement for Equivalence of Technical Requirements* of October 31, 2010 (MRA-ETR), and to consider other arrangements to facilitate trade in telecommunications equipment.
3. In accordance with the *Mutual Recognition Agreement between the Government of the United States and the Government of the United Mexican States for the Conformity Assessment of Telecommunications Equipment*, done on May 26, 2011 at Paris, France the United States and Mexico shall accept test reports provided by a recognized testing laboratory designated by the other Party under terms and conditions no less favorable than those it accords to test reports produced by testing laboratories in its territory, and without regard to the nationality of the supplier or manufacturer of the telecommunications equipment, or the country of origin of the equipment for which a test report has been produced.

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<sup>7</sup> For greater certainty, this paragraph does not apply to requirements a Party has adopted for certification by a conformity assessment body.

4. In accordance with the *Mutual Recognition Agreement between the Government of Canada and the Government of the United Mexican States for the Conformity Assessment of Telecommunications Equipment*, done at Honolulu on 12 November 2011, Canada and Mexico shall accept test reports provided by a recognized testing laboratory designated by the other Party under terms and conditions no less favorable than those it accords to test reports produced by testing laboratories in its territory, and without regard to the nationality of the supplier or manufacturer of the telecommunications equipment, or the country of origin of the equipment for which a test report has been produced.

5. If a Party requires equipment subject to electromagnetic compatibility and radio frequency requirements to include a label containing compliance information about the equipment, it shall permit this information to be provided through an electronic label. The Parties shall exchange information, as appropriate, about their respective electronic labeling requirements with a view to facilitate compatible approaches to electronic labeling.

#### **Article 12.C.5: Terminal Equipment**

1. This Article applies to terminal equipment.

2. Each Party shall ensure that its technical regulations, standards, and conformity assessment procedures relating to the attachment of terminal equipment to the public telecommunications networks, including those measures relating to the use of testing and measuring equipment for conformity assessment procedures, are adopted or maintained only to the extent necessary to:

- (a) prevent damage to public telecommunications networks;
- (b) prevent degradation of public telecommunications services;
- (c) prevent electromagnetic interference, and ensure compatibility, with other uses of the electromagnetic spectrum;
- (d) prevent billing equipment malfunction; or
- (e) ensure safety of and access to public telecommunications or services, including for the hearing impaired or other disabled persons.

3. Each Party shall ensure that the network termination points for its public telecommunications networks are established on a reasonable and transparent basis.

4. Each Party shall permit any recognized<sup>8</sup> conformity assessment body to perform the testing required under the Party's conformity assessment procedures for terminal equipment to be attached to the public telecommunications network, subject to the Party's right to review the accuracy and completeness of the test results.

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<sup>8</sup> "Recognized" means recognized pursuant to an act by a regulatory authority under which a conformity assessment body is approved to perform conformity assessment.



## ANNEX 12-D

### ENERGY PERFORMANCE STANDARDS

#### Article 12.D.1: Definitions

For the purposes of this Annex:

**energy performance standard** means a specification, containing performance or energy use requirements for an energy-using product, that specifies the performance (efficiency) or maximum amount of energy that may be consumed by a product when rated in accordance with the specified test procedure; and

**test procedure** means a uniform method established to measure, with respect to a given product, energy use, energy efficiency, water use, or water efficiency.

#### Article 12.D.2: Scope

This Annex applies to the preparation, adoption, and application of technical regulations by a Party's competent authorities at its central level of government, that set out energy performance standards and related test procedures.

#### Article 12.D.3: Competent Authorities

1. Each Party shall publish online the following information with respect to each of its competent authorities at its central level of government that has responsibility for developing, implementing, revising, or enforcing energy performance standards or related test procedures:

- (a) a description of each authority, including the authority's specific responsibilities; and
- (b) a point of contact within each authority.

2. Each Party shall promptly notify the other Parties of any material changes to this information and update the information online.

#### **Article 12.D.4: Enhancing Regulatory Compatibility**

1. The Parties shall cooperate on energy performance standards and related test procedures in order to facilitate trade among the Parties and advance energy efficiency, including through the use of fora in existence.
2. With respect to products for which each Party applies energy performance standards or test procedures on the date of entry into force of this Agreement, the Parties shall endeavor to harmonize:<sup>9</sup>
  - (a) test procedures for those products no later than eight years after the date of entry into force of this Agreement; and
  - (b) energy performance standards for those products no later than nine years after the date of entry into force of this Agreement.
3. When developing or modifying energy performance standards or test procedures for a product, each Party shall give due consideration to adopting:
  - (a) energy performance standards and test procedures adopted by another Party; or
  - (b) industry standards that a standards development organization accredited in the territory of another Party has finalized and published for the product.
4. In developing or modifying test procedures for a product, each Party shall give due consideration to operating conditions that are unique to each Party.

#### **Article 12.D.5: Voluntary Approaches to Promote Energy Efficiency**

1. The Parties recognize that voluntary programs and voluntary mechanisms can contribute to improving energy efficiency for a range of products.
2. The Parties also recognize that voluntary programs and voluntary mechanisms should be open, transparent, and designed in a manner that maximizes benefits to consumers and environmental benefits, and avoids the creation of unnecessary barriers to trade.
3. The Parties shall encourage the use of voluntary programs and voluntary mechanisms and cooperate, as appropriate, to facilitate greater transparency and compatibility among these voluntary programs and voluntary mechanisms.

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<sup>9</sup> The Parties recognize that successful efforts at harmonization should not diminish consumer welfare, consumer protection, or energy efficiency objectives. To that end, the Parties shall take into account, as appropriate, various factors including those relating to climate, geography, household purchasing power, and electricity infrastructure.

## ANNEX 12-E

### MEDICAL DEVICES

#### Article 12.E.1: Definitions

For the purposes of this Annex:

**marketing authorization** means the process or processes by which a Party approves or registers a medical device in order to authorize the marketing, distribution, or sale of the product in the Party's territory on the basis of the Party's safety, efficacy, and quality requirements; and

**medical device** means:

- (a) for Canada, a product that constitutes a "device" as defined under section 2 of the *Food and Drugs Act*, R.S.C., 1985, c. F-27, as amended, and that is regulated as a "medical device" under the *Medical Devices Regulations*, SOR/98-282, as amended;
- (b) for Mexico, a product covered under article 262 of the *Ley General de Salud* (General Health Law ) as amended; and
- (c) for the United States, a product for human use covered as a "device" under 21 U.S.C. § 321(h), as amended.

#### Article 12.E.2: Scope

This Annex applies to the preparation, adoption, and application of technical regulations, standards, conformity assessment procedures, marketing authorization, and notification procedures of a Party's central level of government that may affect trade in medical devices between the Parties, other than sanitary or phytosanitary measures or technical specifications prepared by a government body for production or consumption requirements of that body.

#### Article 12.E.3: Competent Authorities

1. Each Party shall publish online the following information with respect to each of its competent authorities at its central level of government that has responsibility for implementing and enforcing measures regulating medical devices:

- (a) a description of each authority, including the authority's specific responsibilities; and

- (b) a contact point within each authority.

Each Party shall promptly notify the other Parties of any material changes to this information and update the information online.

2. Each Party shall avoid adopting or maintaining unnecessarily duplicative regulatory requirements with respect to medical devices, including by periodically examining whether its authorities are engaged in duplicative activities.

#### **Article 12.E.4: Enhancing Regulatory Compatibility**

1. Each Party should define “medical devices” under its laws and regulations in a manner that is consistent with the meaning assigned to the term “medical device” in the *Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’* endorsed by the Global Harmonization Task Force on May 16, 2012, as amended.

2. The Parties shall seek to collaborate to improve the alignment of their respective regulations and regulatory activities for medical devices through work in relevant international initiatives, such as those aimed at harmonization, including the International Medical Device Regulators Forum, as well as regional initiatives that support those international initiatives, as appropriate.

3. The Parties shall seek to improve their cooperation on inspections of medical device manufacturers’ quality management systems. To this end, each Party shall recognize audits of device manufacturers’ quality management systems that are in accordance with the requirements established by the Medical Device Single Audit Program (MDSAP) and conducted by auditing organizations authorized by the regulatory authorities participating in MDSAP to audit under the MDSAP requirements.

4. When developing or implementing regulations for marketing authorization of medical devices, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.

#### **Article 12.E.5: Application of Regulatory Controls**

1. Each Party shall ensure that for a measure it applies to ensure the safety, effectiveness, or quality of medical devices, including marketing authorizations, notification procedures, and elements of either, products imported from the territory of another Party be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country, in a comparable situation.

2. Each Party shall classify medical devices based on risk, taking into account relevant scientific factors. Each Party shall ensure that any regulatory requirements it imposes on medical devices for purposes of assuring the device's safety and effectiveness are based on an assessment of the medical device's risks.

3. When developing a regulatory requirement for a medical device, each Party shall consider its available resources and technical capacity in order to minimize the likelihood of implementing requirements that could:

- (a) inhibit the efficacy of procedures for ensuring the safety, effectiveness, or quality of medical devices; or
- (b) lead to substantial delays for medical devices becoming available in that Party's market.

#### **Article 12.E.6: Marketing Authorizations**

1. Each Party shall make a determination whether to grant marketing authorization for a specific medical device on the basis of information that is necessary to evaluate the safety, effectiveness, and quality of the medical device. This information may include:

- (a) clinical data and information, if appropriate, on safety and effectiveness;<sup>10</sup>
- (b) information on performance, design, and quality of the device; and
- (c) labeling information related to safety, effectiveness, quality, and use of the device.

To this end, no Party shall require sales data, pricing data, or other financial data concerning the marketing of the medical device in making the determination.

2. Each Party shall administer its marketing authorizations:

- (a) reasonably, including by:
  - (i) avoiding duplicative requests or requests for unnecessary information from the applicant,

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<sup>10</sup> For the purposes of evaluating the safety of a medical device, a Party may require information concerning the volume of devices sold in another jurisdiction and any reported problems or recalls of the medical device.

- (ii) promptly communicating any deficiencies, and the reasons for those deficiencies, to the applicant, if that deficiency would prevent or delay consideration of the application, and
  - (iii) providing an applicant that requests marketing authorization for a medical device with a determination within a reasonable period of time;<sup>11</sup>
- (b) objectively, through application of published criteria;
  - (c) impartially, including by adopting or maintaining procedures to manage any conflicts of interest; and
  - (d) transparently, including by publishing a checklist or other guidance concerning the information that must be provided in any application.

3. Each Party shall ensure that it maintains measures that permit an applicant for a marketing authorization to seek review or reconsideration in the event the application is denied.<sup>12</sup>

4. If a Party requires periodic re-authorization for a medical device that has previously received marketing authorization from the Party, the Party shall allow the medical device to remain on its market under the conditions of the previous marketing authorization pending a decision on the periodic re-authorization, unless a Party identifies a significant safety, effectiveness, or quality concern.<sup>13</sup>

5. No Party shall require that a medical device receive a marketing authorization from a regulatory authority in the country of manufacture as a condition for the medical device to receive marketing authorization from that Party.

6. A Party may accept a prior marketing authorization that is issued by another regulatory authority as evidence that a medical device meets its requirements. Notwithstanding paragraph 5, if the Party faces regulatory resource limitations that restrict its ability to provide marketing authorizations, a Party may require a marketing authorization from a reference country as a condition for the marketing authorization, provided that the Party has established and made public a list of those countries from which it will accept a marketing authorization as evidence that a medical device meets its own requirements.

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<sup>11</sup> The Parties recognize that the reasonable period of time required to make a marketing authorization determination may be affected by factors such as the novelty of a product or regulatory implications that may arise.

<sup>12</sup> This provision does not preclude a Party from imposing a deadline by which review must be sought.

<sup>13</sup> For greater certainty, the Parties recognize that an application for reauthorization that is not filed in a timely manner, that contains insufficient information, or that is otherwise inconsistent with a Party's requirements, is deficient for the purposes of the reauthorization decision.

7. If a Party requires a manufacturer or supplier of a medical device to provide information through labeling, the Party shall permit the manufacturer or supplier to relabel the device or use supplementary labeling in accordance with the Party's requirements after the device's importation but prior to being offering for sale or supply in the Party's territory.

## ANNEX 12-F

### PHARMACEUTICALS

#### Article 12.F.1: Definitions

For the purposes of this Annex:

**marketing authorization** means the process or processes by which a Party approves or registers a pharmaceutical product in order to authorize the marketing, distribution, or sale of the product in its territory on the basis of the Party's safety, efficacy, and quality requirements; and

**pharmaceutical product** means:

- (a) for Canada, a product destined for human use that constitutes a "drug" as defined under section 2 of the *Food and Drugs Act*, R.S.C., 1985, c. F-27, as amended, and that is regulated as a "drug" under the *Food and Drug Regulations* C.R.C., c. 870, as amended;
- (b) for Mexico, a product covered as human "drugs," "biologics," and "biotechnology" under articles 221, 222 bis, 224, and 224 bis of the *Ley General de Salud* (General Health Law ) as amended; and
- (c) for the United States, a product for human use covered as a "drug" under 21 U.S.C. § 321(g)(1), as amended, or as a "biologic" under 42 U.S.C. § 262(i), as amended.

#### Article 12.F.2: Scope

This Annex applies to the preparation, adoption, and application of technical regulations, standards, conformity assessment procedures, marketing authorization, and notification procedures of a Party's central level of government that may affect trade in pharmaceutical products between the Parties, other than sanitary or phytosanitary measures or technical specifications prepared by a government body for production or consumption requirements of that body.

#### Article 12.F.3: Competent Authorities

1. Each Party shall make available online the following information with respect to each of its competent authorities at its central level of government that has responsibility for implementing and enforcing measures regulating pharmaceutical products:



- (a) a description of each authority, including the authority's specific responsibilities; and
  - (b) a point of contact within each authority.
2. Each Party shall promptly notify the other Parties of any material changes to this information and update the information online.
  3. Each Party shall avoid adopting or maintaining unnecessarily duplicative regulatory requirements with respect to pharmaceutical products, including by periodically examining whether its authorities are engaged in duplicative activities.

#### **Article 12.F.4: Enhancing Regulatory Compatibility**

The Parties shall seek to collaborate to improve the alignment of their respective regulations and regulatory activities for pharmaceutical products through work in relevant international initiatives as appropriate, such as those aimed at harmonization, as well as regional initiatives that support those international initiatives.

#### **Article 12.F.5: Application of Regulatory Controls**

1. Each Party shall ensure that for a measure it applies to ensure the safety, effectiveness, or quality of pharmaceutical products, including marketing authorizations, notification procedures, and elements of either, products imported from the territory of another Party be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country, in a comparable situation.
2. When developing a regulatory requirement for a pharmaceutical product, each Party shall consider its available resources and technical capacity in order to minimize the likelihood of implementing requirements that could:
  - (a) inhibit the efficacy of procedures for ensuring the safety, effectiveness, or quality of pharmaceutical products; or
  - (b) lead to substantial delays for pharmaceutical products becoming available in that Party's market.
3. The Parties shall seek to improve their collaboration on pharmaceutical inspections. Accordingly, each Party shall, with respect to a good manufacturing practice surveillance inspection of a manufacturing facility for pharmaceutical products within the territory of another Party:

- (a) notify the other Party prior to conducting an inspection, unless there are reasonable grounds to believe that doing so could prejudice the effectiveness of the inspection;
- (b) if practicable, permit representatives of the other Party's competent authority to observe the inspection; and
- (c) notify the other Party of its findings as soon as possible following the inspection and, if the findings will be publicly released, no later than a reasonable time before release.

With respect to subparagraph (c), the inspecting Party is not required to notify the other Party of a finding that is subject to treatment as confidential information under the inspecting Party's law.

4. Upon certification by the competent authority in the United States, the competent authorities of Canada and the United States shall establish mechanisms to permit the exchange of confidential information relevant to pharmaceutical inspections, including unredacted Good Manufacturing Practice inspection reports.

5. Upon certification by the competent authority in the United States, the competent authorities of Mexico and the United States shall establish mechanisms to permit the exchange of confidential information relevant to pharmaceutical inspections, including unredacted Good Manufacturing Practice inspection reports.

6. To facilitate the exchange of information pursuant to paragraphs 4 and 5, each Party shall maintain procedures to prevent the disclosure of confidential information that may be necessary for the Parties to permit the exchange.

7. Competent authorities in Mexico and Canada shall strengthen their cooperation in the exchange of information, including through multilateral fora in existence. To that end, Mexico and Canada shall increase collaboration and confidence building exercises in the regulation of pharmaceutical products.

8. When developing or implementing regulations with respect to inspection of pharmaceutical products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts.

#### **Article 12.F.6: Marketing Authorizations**

1. When developing or implementing a regulation for the marketing authorization of a pharmaceutical product, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is further encouraged

to consider regionally-developed scientific or technical guidance documents that are aligned with international collaborative efforts.

2. Each Party shall make a determination whether to grant marketing authorization for a specific pharmaceutical product on the basis of information that is necessary to evaluate the safety, effectiveness, and quality of the pharmaceutical product. This information may include:

- (a) clinical data and information on safety and effectiveness of the product;
- (b) information on the quality of the product, including manufacturing controls for the ingredients of the product; and
- (c) labeling information related to the safety, effectiveness, quality, and use of the product.

3. No Party shall require sales data, or other financial data concerning the marketing of the product in making the determination referred to in paragraph 2. Further, each Party shall endeavor not to require pricing data in making the determination.

4. Each Party shall administer its marketing authorizations:

- (a) reasonably, including by:
  - (i) avoiding duplicative requests or requests for unnecessary information from the applicant,
  - (ii) promptly communicating any deficiencies, and the reasons for the deficiencies, to the applicant, if the deficiency would prevent or delay consideration of the application, and
  - (iii) providing an applicant that requests marketing authorization for a pharmaceutical product with a determination within a reasonable period of time;<sup>14</sup>
- (b) objectively, through application of published criteria;
- (c) impartially, including by adopting or maintaining procedures to manage any conflicts of interest; and
- (d) transparently, including by publishing a checklist or other guidance concerning the information that must be provided in any application.

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<sup>14</sup> For greater certainty, the reasonable period of time required to make a marketing authorization determination may be affected by factors such as the novelty of a product or regulatory implications that may arise.

5. Each Party shall ensure that it adopts or maintains measures that permit an applicant for a marketing authorization to seek review or reconsideration if the application is denied.
6. Paragraph 5 does not preclude a Party from imposing a deadline by which review must be sought.
7. If a Party requires periodic re-authorization for a pharmaceutical product that has previously received marketing authorization from the Party, the Party shall allow the pharmaceutical product to remain on its market under the conditions of the previous marketing authorization pending a decision on the periodic reauthorization, unless the Party identifies a significant safety, effectiveness, or quality concern.<sup>15</sup>
8. No Party shall require that a pharmaceutical product receive marketing authorization from a regulatory authority in the country of manufacture as a condition for the product to receive marketing authorization from that Party.
9. A Party may accept a prior marketing authorization that is issued by another regulatory authority as evidence that a pharmaceutical product meets its requirements. Notwithstanding paragraph 6, if the Party faces regulatory resource limitations that restrict its ability to provide marketing authorizations, a Party may require a marketing authorization from a reference country as a condition for the marketing authorization, provided that the Party has established and published a list of those countries from which it will accept a marketing authorization as evidence that a pharmaceutical product meets its requirements.
10. Each Party shall review the safety, effectiveness, and quality information submitted by the applicant requesting marketing authorization in a format that is consistent with the specifications set forth in the Common Technical Document (CTD) of the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*, as amended.<sup>16</sup>

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<sup>15</sup> For greater certainty, an application for reauthorization that is not filed in a timely manner, that contains insufficient information, or that is otherwise inconsistent with a Party's requirements, is deficient for the purposes of the reauthorization decision.

<sup>16</sup> For greater certainty, the CTD may not address all aspects relevant to a Party's determination to approve marketing authorization for a particular product.