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THE RECOMMENDATIONS

FOR THE

MEDICAL DEVICES

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Medical Devices.

The United States - Mexico - Canada Agreement (USMCA) represents an agreement in principle that concludes the renegotiation of NAFTA, which began in August 2017. Although the USMCA has been described as a new trade agreement to replace the North American Free Trade Agreement (NAFTA), many of its chapters cover virtually the same issues, many of the provisions remain unchanged.

Although attention has focused on changes in the rules of origin for the automotive sector, since this sector generates a large part of Mexican exports to the United States (US), other branches of manufacturing activity also have changes aimed at increasing the regional content in their manufacturing.

It establishes significant changes in the rules governing trade between the three countries, changes that involve an adjustment in the supply chains of several industries, including automotive, agriculture, textiles and clothing, alcoholic beverages, medical devices, and chemicals. As long as the regional content is met, products can be traded free of quotas and tariffs between the three partners.

It does not refer to the 18-23% tariffs imposed on Canadian timber by the U.S. government at the end of 2017. A conflict between the two nations that originated in the 1980s, when U.S. timber companies accused their counterparts of receiving subsidies from their government, which owns much of the land from which Canada's timber originates.

The USMCA is an agreement comprising 34 chapters, 13 annexes and 13 parallel letters, which contain details of the new rules. It is expected to enter into force on July 1, 2020. In the meantime, NAFTA will continue to apply to trade between the three countries.

Among the important changes established by the USMCA is the increase in the required level of regional content of automobiles and auto parts to export duty-free cars to the U.S. Canada also made concessions, by opening up part of its dairy market to imports from the United States. In the oil and gas industry, Canada will no longer be subject to the proportionality provisions in the energy chapter of NAFTA.

Overall, the USMCA appears to meet the objectives set by the U.S. government. Most importantly, it puts an end to the uncertainty caused. If ratified, the agreement will maintain the three linked economies for at least the next 16 years.

The specific Rules of Origin for furniture are contained in Chapter 4: Rules of Origin and Specific Rules of Origin of the USMCA. It is important to note that not all of the Specific Rules of Origin were updated; however, according to the Secretariat of Economy (SE), the objective of the chapter was to modernize the rules of origin to make them compatible with more modern disciplines, which Mexico has already negotiated in other Agreements.

Specifically some modifications were related to the following issues:

- De Minimis. Taking into account that global value chains have become an essential feature of our economic reality, in order to provide the necessary balance required by companies to access a global supply of inputs, and at the same time, encourage the use of components from the region, the provision on De Minimis was updated to increase the current percentage to 10%, which corresponds to that established with the rest of our trading partners.

- Games or Assortments. Also, taking into account that there is a trend towards presenting goods in game or assortment, where it has become an increasingly common marketing strategy, new provisions related to games and assortments were incorporated.
- Principle or Clause on "accumulation", which allows to recognize as original both the materials of the signatory countries and the processes carried out in any of their territories. With this, regional value chains are strengthened.

It is important to remember that, the 2013 amendments to the Rules of Origin affected a wide variety of items such as: mineral fuels, plastics, optical and medical instruments, furniture and smoking pipes.

However, it is important to review the Rules of Origin for each product, as well as the changes in the methodology for calculating the Regional Content Value (RCV).

In order to make the procedures for the inclusion of pharmaceutical products and medical devices in health care programs transparent, a Sectoral Annex, not negotiated in NAFTA, was established. The new Annex, in accordance with the SE contains:

- It recognizes the importance of research and development related to pharmaceutical products and medical devices.
- It emphasizes the need to promote timely and cost-effective access to pharmaceuticals and medical devices.
- It includes transparency provisions for listing new pharmaceuticals and medical devices in health programs operating under reimbursement schemes.
- It excludes public procurement of pharmaceuticals and medical devices.

It is important to note that the Annex makes no changes to the Industry Rules of Origin, the current ROE's remain the same; medical devices may qualify for duty free treatment if the North American content is at least 50% using the net cost method or 60% using the transaction value method.

The inclusion of this Annex is a positive development for medical device manufacturers. It commits the parties to avoid imposing or maintaining duplicative regulatory requirements, and will periodically review whether authorities are involved in duplicative activities. In addition, the parties have agreed to coordinate efforts to harmonize regulatory activities through international forums.

With respect to the inspection of manufacturers' "quality management systems", the parties agree to improve cooperation on inspections and will recognize audits that are in accordance with the requirements of the Medical Device Single Audit Program (MDSAP).

The Sectoral Annex also commits the parties to classify medical devices with a clear focus on safety and risk and prohibits searching for sales, pricing or financial data used in device marketing. This will create a more transparent regulatory framework for exporters.

Finally, the parties have committed to a provision that will allow imported devices that have been mislabeled at a port of entry, not to be returned to the exporting party, the importer may re-label the device prior to sale.

The USMCA was signed on November 30, 2018, in Buenos Aires, Argentina, by then President of Mexico, Enrique Peña Nieto; Prime Minister of Canada, Justin Trudeau; and President of the United States, Donald Trump. Once it enters into force, it will replace the North American Free Trade Agreement (NAFTA).

June 19, 2019, the full Senate of the Republic approved, with 114 votes in favor; 4 against, and 3 abstentions, the United States - Mexico - Canada Agreement (USMCA).

In response to the demands of the Democrats in the U.S. House of Representatives and the American unions, the Modifying Protocol was negotiated. These petitions revolved around 4 themes:

a. protection of the environment;
b. data protection for biological medicines;
c. protection of labor rights; and
d. monitoring and enforcement.

On December 10, 2019, the signing of the Protocol of Amendment to the United States - Mexico - Canada Agreement (USMCA) took place in Mexico City. This protocol reforms some of the disciplines originally agreed in the USMCA, including a provision recently proposed by the U.S., on rules of origin for the automotive and steel sectors.

The US was the last partner to notify its counterparts that it had completed the internal procedures necessary for the entry into force of the USMCA on 24 April 2020. Canada and Mexico did the same earlier this month.

The Protocol amending the USMCA provides that the agreement will enter into force on the first day of the third month after the last partner notifies the completion of its internal procedures. This deadline was set for July 1st.

A. USMCA

Chapter 12: Sectoral Annexes, consists of:

- Article 12.1: Sectoral Annexes
  - Annex 12-A: Chemicals
  - Annex 12-B: Cosmetic Products
    - Appendix: Improving Regulatory Compatibility for Products Recognized as Cosmetic and Drug Intermediaries
  - Annex 12-C: Information and Communication Technologies
  - Annex 12-D: Energy Efficiency Standards
  - Annex 12-E: Medical Devices
  - Annex 12-F: Pharmaceuticals

- 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 to authorize its marketing, distribution or sale in the Party's territory based on the Party's safety, efficiency, and quality requirements; and

    Medical device refers to:

    (a) for Canada: a product which constitutes a "device" as defined in section 2 of the Food and Drugs Act, R.S.C.,
    1985, c. F-27, as amended, and which is regulated as a "medical device" under the Medical Devices Regulations, SOR/98-282, as amended;

    (a) for Mexico: a product covered by Article 262 of the General Health Law, as amended; and

    (b) 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 development, adoption, and application of a Party's central level of government technical regulations, standards, conformity assessment procedures, trade authorization, and notification procedures that may affect trade in medical devices between the Parties, other than sanitary or

phytosanitary measures or technical specifications prepared by a government agency for that agency's production or consumption requirements.

- Article 12.E.3: Competent Authorities.

  1. After the entry into force of this Agreement, each Party shall make available online the following information with respect to each of its competent authorities at its central level of government that have responsibility for implementing and enforcing measures regulating medical devices

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

  (b) a contact point within each authority.

  Each Party shall promptly notify the other Parties of any substantial changes to this information.

  2. Each Party shall avoid imposing or maintaining unnecessary duplicative regulatory requirements with respect to medical devices, including periodically reviewing whether its authorities are engaged in duplicative activities.

- Article 12.E.4: Improvement of regulatory compatibility.

  1 Each Party shall define "medical device" in accordance with its laws and regulations in a manner consistent with the meaning assigned to the term "medical device" in the Definition of the Terms "Medical Device" and "In Vitro Diagnostic Medical Device (IVDM) approved 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 on relevant international initiatives, such as those aimed at harmonization, including the International Forum of Medical Device Regulators, as well as regional initiatives that support these international initiatives, as appropriate.

  3 The Parties shall seek to improve their cooperation in the inspection of the quality management systems of medical device manufacturers. To this end, each Party shall recognize the quality management system audits of device manufacturers that meet the requirements of the Single Medical Device Audit Program (SMPAD) and are carried out by audit organizations authorized by the regulatory authorities participating in the SMPAD to audit in accordance with the requirements of the SMPAD.

4 When developing or implementing regulations for the 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 any measure it implements to ensure the safety, efficacy or quality of medical devices, including marketing authorizations, notification procedures and elements thereof, accords treatment to products imported from the territory of another Party no less favorable than that accorded to like products of domestic origin and to like products originating in any other country, in a comparable situation.

  2. Each Party shall classify medical devices on the basis of risk, taking into account relevant scientific factors. Each Party shall ensure that the regulatory requirements it imposes on medical devices to ensure the safety and efficacy of the device are based on a risk assessment of the medical device.

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

  (a) inhibit the effectiveness of procedures to ensure the safety, efficacy or quality of medical devices; or

  (b) result in significant delays in making medical devices available on that Party's market.

- Article 12.E.6: Trade Authorizations.

  Each Party shall determine whether to grant a marketing authorization for a specific medical device on the basis of information that is necessary to assess the safety, efficacy and quality of the medical device. Such information may include:

  (a) clinical data and information, if appropriate, on safety and efficacy.

  (b) information on the performance, design and quality of the device; and

  (c) labelling information related to the safety, efficacy, quality and use of the device.

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

2. Each Party shall administer its marketing authorizations:

(a) reasonably, including:

(i) avoiding duplicative applications or requests for unnecessary information from the applicant

(ii) promptly communicating any deficiencies, and the reasons for those deficiencies, to the applicant, if such deficiencies would prevent or delay consideration of the application; and

(iii) provide an applicant seeking a marketing authorization for a medical device with its determination within a reasonable period of time;

(b) objectively, by applying published criteria;

(c) in an impartial manner, including by adopting or maintaining procedures to manage any conflicts of interest; and

(d) in a transparent manner, including the publication of a checklist or other guidance regarding the information to be provided in any application.

3. Each Party shall ensure that measures are maintained to allow an applicant for a marketing authorization to seek review or reconsideration in the event that the application is rejected.

4. Where a Party requires a periodic re-authorization of a medical device that has previously received a marketing authorization from the Party, the Party shall allow the medical device to remain on its market in accordance with the terms of the prior marketing authorization pending a decision on the periodic re-authorization, unless a Party identifies a significant safety, efficacy or quality issue.

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

6. A Party may accept a prior marketing authorization issued by another regulatory authority as evidence that a medical device meets its requirements. Notwithstanding paragraph 5, if the Party faces regulatory resource constraints that restrict its ability to grant marketing authorizations, a Party may require a marketing authorization from a reference country as a condition of 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 medical device meets its requirements.

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 re-label the device or use supplemental labeling in accordance with the Party's requirements after importation, but prior to offering the device for sale or supply in the Party's territory.

Additionally, the following chapters should be observed:

- Customs and Trade Facilitation:
  - It incorporates provisions on customs cooperation and enforcement, including:
    - Regional and bilateral cooperation, to improve coordination between customs and promote initiatives to detect and prevent customs offences.
    - Exchange of information to prevent customs crimes.
    - Verifications through collaboration between customs authorities to obtain documents and carry out visits to companies.
    - Establishment of a Customs Sub-Committee, which will address issues of potential or actual customs crime, as well as discuss joint initiatives on issues of mutual concern.

- Public Sector Purchases:
  - The Mexico-Canada relationship will be governed by the provisions of the CPTPP once it enters into force.
  - Disciplines are established between Mexico and the US, in particular:
    - The obligation to define purchasing requirements on the basis of objective and international criteria and not with the aim of creating unnecessary obstacles to trade between the Parties is maintained.
    - The obligation not to impose countervailing conditions on covered purchases, such as local content requirements, is maintained.
    - The power of entities to disqualify suppliers for matters such as bankruptcy, false declarations or disqualifications for poor performance in the performance of a government contract is recognized.

- Investment:
  - It is divided in two sections:
    - The first contains the disciplines on the protection of foreign investment.
    - The second contains the investment arbitration mechanism (Investor-State)
  - Investors in any sector may have recourse to an arbitration procedure in case of violations in the disciplines: National Treatment, Most Favored Nation Treatment, Direct Expropriation.
  - The Investor-State dispute settlement mechanism does not apply to Canada.

- Labor:
  - Specific provisions are included for Mexico on collective bargaining, which seek to guarantee this right.
  - Cases of sustained or recurrent action or inaction in the application of labor law by a government will be subject to the dispute resolution mechanism.

- The Protocol of Amendment establishes:
    - Language that made it difficult to prove that business partners were not committed to protecting workers from workplace violence was removed.
    - It creates a presumption that a labor violation affects trade and investment, so the other government must prove otherwise.
    - In order to ensure that the U.S. government will effectively monitor compliance with labor obligations in Mexico:
        - A committee is created to oversee the implementation of labor reform and compliance in Mexico.
        - There will be labor attachés in Mexico in order to have real information on labor practices.
    - Rapid response mechanism for the settlement of labour disputes entering into force immediately. This mechanism provides for the establishment of panels of experts on labor matters in the event that a Party believes that a Covered Plant (Plant) is denying workers' rights relating to union elections and collective bargaining.
    - It will apply to plants in the manufacturing, service and mining sectors. It will have a short time period established to issue a resolution.
    - Sanctions may include the suspension of preferential tariff treatment for goods manufactured in the defendant company or the imposition of sanctions on goods manufactured or services provided by the defendant company.
    - In cases where a company incurs at least two denials of duties, sanctions may include the suspension of preferential tariff treatment for such goods; the imposition of sanctions on such goods or services; or the denial of entry of such goods.

- Environment:
    - Some harmful fisheries subsidies, mainly to vessels and operators involved in poaching and illegal fishing, are prohibited.
    - Includes a commitment to prevent and reduce marine debris, promote sustainable forest management, and prevent commercial whaling.
    - Intentional transnational trafficking in protected wildlife species is criminalized as a serious offence.
    - Robust and modern mechanisms for public participation and environmental cooperation
    - Disciplines that seek to improve the effectiveness of customs inspections of shipments containing wildlife at ports of entry.
    - Disciplines are established to protect air quality, and ensure appropriate procedures for environmental impact assessments
    - Cases of sustained or recurrent action or inaction in the enforcement of labor laws by a government will be subject to the dispute resolution mechanism.
    - The Protocol of Amendment establishes:
        - It creates a presumption that an environmental violation affects trade and investment, so the other government must prove otherwise.
        - The Montreal Protocol is covered.

- A commitment is added that all Parties will adopt, implement and maintain 7 multilateral environmental agreements, other agreements may be added to the list. Non-compliance with any of these agreements will be subject to the State-State dispute settlement mechanism, which could lead to the eventual adoption of retaliation.
- A committee is created to monitor the implementation of the obligations acquired in the agreements, as well as the recommendations. It will be the platform through which the American government will coordinate its support and financing of projects to implement the best practices in environmental matters.
- There will be environmental attachés in Mexico in order to have real information about regulations and practices.
- It adds a new customs verification mechanism to guarantee that only legally harvested and taken flora and fauna are traded through Mexico.
- A new North American Development Bank authorization and funding for EPA, loans under the Border Water Infrastructure Program to address pollution on the U.S.-Mexico border; and additional funds to the Trade Control Trust Fund to be used for focused environmental efforts.

- Technical Barriers for Trade:
  - It incorporates provisions relating to the transparency of the processes of elaboration, adoption and application of the standards, technical regulations and conformity assessment procedures of the Parties.
  - Provisions for the conclusion of mutual recognition agreements.

- Procedure of Origin:
  - The certificate of origin may be issued by the exporter, producer or importer.
  - The format of the certificate is eliminated, and certification is allowed on the invoice or on any commercial document, provided that minimum information is declared.
  - In the event that importers fail to comply with the stipulations regarding the origin of the goods, each country will determine whether to apply a civil, criminal or administrative sanction.

- Propiedad Intelectual:
  - Robustece el sistema de protección de indicaciones geográficas.
  - Se prevén disciplinas para marcas notoriamente conocidas.
  - Las autoridades podrán detener los bienes que sospechen que han sido falsificados en toda entrada o salida del país.
  - Implementación de medidas en contra de bienes falsificados y piratería a escala comercial.
  - The Protocol of Amendment establishes for biotechnological:
    - The provision requiring Parties to provide at least 10 years of exclusivity for biologicals was deleted.
    - The provision requiring parties to confirm that patents would be available for new uses of known products was deleted.
    - The provision requiring three additional years of exclusivity for clinical information was deleted.

- Trade remedies:
    - Safeguards: an exclusion for partners subject to certain conditions (not being in the first 5 exporters) from the overall safeguard measures is maintained.
    - Anti-dumping and subsidies: WTO rights are recognized in these areas. Additional rules were agreed to promote transparency.
    - Combating circumvention: a cooperation mechanism is established to prevent the evasion of countervailing, anti-dumping and safeguard duties.
    - Binational Panels: the mechanism of Chapter XIX of NAFTA is maintained.

Fuente:

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6. IQOM

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DE COMERCIO EXTERIOR Y ADUANAS PARA BRINDAR
TRANQUILIDAD Y ASERTIVIDAD A LA CONTINUIDAD
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