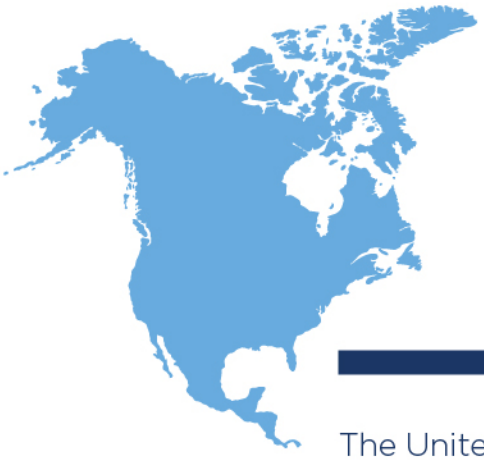
TLC asociados

Fiscal, Administrative, Foreign Trade and Customs Law
Law Suit, Audit, Consultancy and Training

USMCA 360°

FIND OUT ABOUT THE IMPACT AND RECOMMENDATIONS IN THE MEDICAL DEVICES SECTOR

www.tlcasociados.com.mx | tlc@tlcasociados.com.mx | 01(55) 5280.3267



MEDICAL DEVICES

The United States – Mexico – Canada Agreement (USMCA) represents in principle an agreement that concludes the NAFTA's renegotiation, which started on August 2017. While it is true that the USMCA has been described as a new trade agreement replacing the North American Free Trade Agreement (NAFTA), several chapters contained by this "new agreement" allude to the same matters, since several provisions have not been changed at all.

Despite the attention has focused on the changes of the rules of origin concerning the automotive sector, since this sector produces a large proportion of the Mexican exports towards the United States, other fields of the manufacturing activity also present changes that have a propensity to increase the regional content in their production.

It establishes significant changes concerning the rules that regulate trading between the three countries, changes represent an adjustment in the supply chain of several industries, such as: automotive, agriculture, textile and clothing items, alcohol beverage, medical device and chemical industry, among other. As long as the regional content is complied with, the products may be traded, as duty and quota free, among the three members.

In addition, the new agreement does not eliminate the American tariffs concerning steel and aluminum, in accordance with Section 232 of the trade Expansion Act of the United States in 1962.

The tariffs between 18 and 23% are not mentioned either, which were imposed to the Canadian woods by the American government by the end of 2017. This represented a conflict, between these two countries, which started during the eighties, when the American logging companies framed their counterparts for receiving subsidies granted by their government, who possess plenty of territories where the Canadian wood is extracted.

USMCA is an agreement that includes 34 chapter, 13 annexes and 13 parallel letters, which contain new regulations details. It is relevant to remark that the USMCA shall not come into force instantaneously, since the legislative processes of each party still remain. It is expected to come into force in 2020, meanwhile, the NAFTA shall continue to be applied to trade of three countries.

One of the significant changes, established by the USMCA, concerns the increase of the required level of automobiles and auto parts regional content to export duty-free automobiles to the United States. Canada also performed concessions by opening one part of its dairy market to the American imports. Concerning oil and gas industry, Canada shall not be subjected any longer to the proportionality provisions within the energy chapter of the NAFTA.

Basically, the USMCA seems to comply the objectives established by the American government. The most relevant aspect concerns the fact that it eliminates the uncertainty caused by the current negotiations. In case the agreement is adjusted, it will maintain the relationship between three economies for, at least, the next 16 years.

The Specific Rules of Origin for furniture may be found in Chapter 4: Rules of Origin and Specific Rules of Origin of the new United States – Mexico - Canada Agreement (USMCA). It is relevant to remark that not all Specific Rules of Origin were updated, however, according to the Economy Department, the Chapter intended to update the origin regulations to make them congruent with more contemporary disciplines negotiated by Mexico in other Agreements.

Particularly, some modifications are related with the following matters:

- De Minimis. Taking into consideration that global chains have become a fundamental characteristic of our economic reality, in order to provide the enterprises with the necessary balance to access to a global inputs supply and promote the use of regional components, De Minimis regulation was updated in order to increase the current percentage up to 10%, which corresponds to the established percentage of our trade partners.

- Sets. Additionally, taking into consideration that some goods tend to be submitted in sets, which represents a new market strategy increasingly extended, new regulations concerning sets were incorporated.

- Principle or Clause concerning "accumulation", which permits to recognize as originating the materials of the signatory countries, as well as the procedures performed in any of their territories. In this context, the regional value chains are reinforced.

It is relevant to keep in mind that the modifications, applied to the Rules of Origin 2013, affected a wide variety of articles, such as: mineral fuels, plastics, optical and medical instruments, furniture, and pipes.

Nevertheless, it is relevant to review the Rules of Origin of each product, as well as the changes to the Regional Value Content (RVC) calculation methodology.

For the purposes of the transparency of procedures to include pharmaceutical products and medical devices in health care programs, a Sectoral Annex was included, which is not negotiated within NAFTA. According to the Economy Department, this new Annex contains the following aspects:

- It recognizes the importance of research and development related to pharmaceutical products and medical devices.

- It emphasizes the necessity of promoting the pertinent and economic access to pharmaceutical products and medical devices.

- It includes provisions of transparency to enlist new pharmaceutical products and medical devices into the health programs that operate under reimbursement schemes.

- It excludes the public procurement of pharmaceutical products and medical devices.

It should be emphasized that this Annex has no changes regarding the Rules of Origin of the current sector, the current SRO (Specific Rules of Origin) still be the same ones; the medical devices may qualify for a duty-free treatment in case the North American content corresponds, at least, to 50% by using the net cost method, or the 60% by using the transaction value method.

Including this Annex represents a positive development for the medical devices manufacturers. The parties are committed to avoid imposing or maintaining the doubled regulatory requirements and, it shall be examined periodically in case the authorities are involved in duplicative activities. In addition, the parties have agreed to implement reinforcements to harmonize the regulatory activities through international forums.

Concerning the inspection of "quality management systems" of the manufacturers, the Parties agree to improve the cooperation during the inspections and the audits shall be recognized, which agree with the requirements established by the Medical Device Single Audit Program (MDSAP).

The Sectoral Annex compromises the Parties as well to classify the medical devices with a clear approach regarding security and risk, and it prohibits the search of sales, prices or financial data used during the device marketing. This shall create a more transparent regulatory framework for the exporters.

Finally, the Parties have committed to a provision that shall enable the imported devices, which have been incorrectly labeled in a port of entry, to not be handed back to the exporting Party, the importer shall be able to label the device one more time before the selling.

A. USMCA

Chapter 12: Sectoral Annexes, it is composed of:

- Article 12.1: Sectoral Annexes
  - Annex 12-A: Chemical Substances
  - Annex 12-B: Cosmetic Products
    - Appendix: Improvement of the Regulatory Compatibility for Products Recognized as Intermediaries of Cosmetics and Drugs.
  - Annex 12-C: Information and Communication Technologies
  - Annex 12-D: Energy Efficiency Regulations
  - Annex 12-E: Medical Devices
  - Annex 12-F: Pharmaceutical Products

Annex 12-E: Medical Devices.

- Article 12.E.1 Definitions.

For the purposes of this Annex:

Marketing Approval concerns the process or processes by which a Party approves or registers a medical device to authorize its marketing, distribution or sale in the territory of this Party on the basis of safety, efficiency and quality requirements of the Party; and

Medical Device is defined:

(a) for Canada as: a product that represents a "device", according to Section 2 within the Food and Drugs Act, R.S.C, 1985, c. F-27, with its amendments and, which is regulated as a "medical device" in accordance with the Medical Devices Regulations, SOR/98-282, with its amendments;

(a) for Mexico as: a product covered by article 262 of the General health Law, as it may be amended; and

(b) for the United States as: a product for the human use covered as a "device" under the 21 U.S.C. § 321 (h), as it may be amended.

- Article 12.E.2: Field of Application.

This Annex shall apply the manufacturing, implementation and enforcement of technical regulations, standards, assessment procedures of compliance, marketing approval, and notification procedures of the central level of the government of a Party that may affect the medical devices trade among the Parties, without being sanitary or phytosanitary measures, or technical specifications prepared for a government agency for the production or consumption requirements of this agency.

- Article 12.E.3: Competent Authorities.

1. Once this Agreement comes into force, each Party shall provide, via online, the following information regarding each competent authorities of its central level of government that must implement and comply with the measures that regulate the medical devices:

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

(b) a point of contact within every single authority.
Each Party shall notify promptly any significant change of this information to the other Parties.

2. Each Party shall avoid imposing or maintaining unnecessary doubled regulatory requirements regarding medical devices, including examining periodically the participation in doubled activities by its authorities.

- Article 12.E.4: Improvement of Regulatory Compatibility.

1 Each Party must define "medical devices" in accordance with its laws and regulations in a way that is compatible with the meaning assigned to the term “Medical device” within the definition of the terms “Medical device” and “In vitro Diagnostic Medical Device” (IVDMD) approved, on May 16th 2012, by the Working Group on Global Harmonization, with its amendments.

2 The Parties shall intend to cooperate in improving the orientation of their corresponding regulations and regulatory activities for medical devices through working in pertinent international initiatives, as the ones destined for harmonization, including the International Forum of Medical Devices Regulators, as the regional initiatives that support these international initiatives, as the case may be.

3 The Parties shall intend to improve their cooperation during the inspections of quality management systems of the medical devices manufacturers. For that purpose, each Party shall recognize the audits of the quality management systems of the medical devices manufacturers that comply with the requirements established by the Medical Device Single Audit Program (MDSAP) and performed by the auditing agencies authorized by the participating regulatory authorities within MDSAP for auditing in accordance with the requirements of MDSAP.

4 When regulations are created or implemented, which are intended for marketing approval of medical devices, each Party shall consider scientific documents or technical orientation documents as "pertinent" or "developed" through international cooperation efforts. Each Party is encouraged to consider scientific documents or technical orientation documents as "regionally manufactured" complemented with international efforts.

- Article 12.E.5: Implementation of Regulatory Controls.

1. Each Party shall ensure that any measure applied to guarantee security, effectiveness, or quality of medical devices, including the marketing approvals, notification procedures and the elements from any of these aspects, provide the products imported from the territory of another Party with an advantageous treatment as well as the treatment for similar products of national origin and similar originating products from any other country, in a similar case.

2. Each Party shall classify the medical devices according to the risks, considering the pertinent scientific factors. Each Party shall make sure that the regulatory requirements, applied to the medical devices in order to guarantee security and effectiveness of the device, are based on a risk assessment of the medical device.

3. Once a regulatory requirement is created for a medical device, each Party shall take its resources and technical capacity available into consideration in order to reduce the probabilities of implementing requirements, that may:

(a) inhibit the effectiveness of the procedures that ensure security, effectiveness or quality of the medical devices; or

(b) generating significant delays for the medical devices to be available in the market of the Party aforementioned.

- Article 12.E.6: Marketing Approvals.

1. Each Party shall determine whether it provides a marketing approval for a specific medical device based on the information required to assess security, effectiveness and quality of the medical device. This information may include:

(a) clinical information and data, in case it is appropriate, regarding security and effectiveness;

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

(c) information regarding labeling related to security, effectiveness, quality and usage of the device.

For this purpose, no Party shall require sales, prices, or financial data related to marketing of the medical device, once the resolution is accomplished.

2. Each Party shall manage its marketing approvals:

(a) rationally including:

(i) avoiding doubled requests or unnecessary information requests of the applicant;

(ii) notifying promptly any defect, as well as the reasons derived from those defects, to the applicant, in case this defect would inhibit or delay the contemplation of the request; and

(iii) providing an applicant that requests a marketing approval for a medical device, with his/her resolution within a reasonable period of time;

(b) objectively, through the implementation of published criteria;

(c) impartially included through the implementation or preservation of procedures to manage any conflict of interests; and

(d) in a transparent manner, including the publication of a checklist or another guide related to the information that must be provided in any implementation.

3. Each Party shall ensure that the measures, which enable a marketing approval applicant to search for a review or a reassessment in case the requests is rejected, are preserved.

4. In case a Party requires a periodical reauthorization of a medical device that has received previously a marketing approval of the Party aforementioned, the Party shall enable the medical device to remain in its market according to the conditions of the prior marketing approval, awaiting a decision regarding the periodical reauthorization, unless a Party identifies a significant security, effectiveness or quality problem.

5. No Party shall require a medical device to receive a marketing approval from a regulatory authority in the manufacturing country as a condition for the medical device to receive a marketing approval from the Party aforementioned.

6. A Party shall be able to accept a prior marketing approval issued by a regulatory authority as evidence of the compliance of the requirements by a medical device. Despite the part established in the 5th paragraph, in case the Party faces limitations of regulatory resources that inhibit its capacity to provide marketing approvals, a Party shall be able to require a marketing approval from a reference country as a condition for the marketing approval, as long as the Party has established and published a list of countries, from which it shall accept a marketing approval as evidence of the compliance of the requirements by a medical device.

7. In case a Party requires a medical devices manufacturer or supplier to provide information through the labelling, the Party shall enable the manufacturer or supplier to relabel the device, or to use an additional labelling in accordance with the requirements of the Party after importation, but before offering the device for sale or supply within the territory of the Party aforementioned.

Additionally, the following chapters must be examined:

- **Customs Administration and Trade Facilitation:**

  - It integrates provisions concerning customs cooperation and compliance, intending to accomplish the following points:
    - Regional and bilateral cooperation to improve the customs coordination and it promotes initiatives to detect and prevent customs offenses.
    - Information exchange that prevents customs offenses.
    - Verifications by collaborating with customs authorities to obtain documents and conduct visits to enterprises.
    - Establishing a Customs Subcommittee, which shall handle matters concerning potential or real customs crimes, as well as propose joint initiatives concerning reciprocal issues.

- **Public Sector Purchases:**

  - The relationship between Mexico and Canada shall be ruled by the stipulated part in the CPTPP (Comprehensive and Progressive Agreement for trans-Pacific Partnership) once it comes into force.
  - Some disciplines between Mexico and the United States are established, in particular:
    - Defining the requirements of a purchase is imperative, based on objective and international criterions and with no purposes of creating unnecessary obstacles to trading among Parties.
    - Not imposing compensatory conditions, concerning open purchases, is imperative, as local content requirements.
    - The authority of entities to disqualify suppliers for issues as

bankruptcy, false declarations or disqualifications caused by a poor performance in the compliance of a governmental agreement, is recognized.

- Establishing a Customs Subcommittee, which shall handle matters concerning potential or real customs crimes, as well as propose joint initiatives concerning reciprocal issues.

- **Investment:**

  - It is divided in two sections:
    - The first one contains the disciplines of protection to foreign investment.
    - The second one contains investment arbitration mechanism (Investor – State).
  - The investors of any sector may perform an arbitral procedure in case of infringements of the disciplines: National Treatment, Most-Favoured-Nation Treatment, Direct Expropriation.
  - The Disputes Settlement Mechanism "Investor - State" is not applicable for Canada.

- **Labor sector:**

  - Certain specific provisions are included for Mexico, in terms of collective bargaining, intending to guarantee the current right.
  - The cases of sustained or frequent action or inaction, while implementing the labor law by a government, shall be subjected to the disputes settlement mechanism.

- **Environment:**

  - Certain prohibitions are established concerning some subsidies that affect fishing, especially ships and operators involved in illegal fish poaching.
  - Preventing and reducing marine debris, promoting the sustainable forest management and preventing whaling with commercial purposes are commitments included in this context.

- Trafficking transnationally and intentionally wildlife protected species shall be considered as a felony.
- Large and contemporary public participation and environmental cooperation mechanisms.
- Disciplines that intend to improve the effectiveness of the customs inspections of shipments that contain wildlife at the inbound ports.
- Certain disciplines are established to protect the air quality index, and ensuring the proper procedures for the environmental impact assessment.
- The cases of sustained or frequent action or inaction, while implementing the labor law by a government, shall be subject to the disputes settlement mechanism.

- **Technical Obstacles for Trading:**

  - It integrates provisions related to transparency of the following procedures: manufacturing, implementation and enforcement of the regulations, technical regulations and assessment procedures in accordance with the Parties.
  - Provisions for celebrating reciprocal recognition agreements.

- **Origin Procedures:**

  - The origin certificate may be issued by the exporter, manufacturer or importer.
  - The certificate format is removed, and the invoice certification or any other commercial document is permitted as long as minimum data of the information is declared.
  - In case of a non-compliance, by the importers, of the stipulated part concerning the origin of the goods, each country shall determine whether a civil, criminal or administrative penalty shall be applied.

- **Copyright:**
  - The geographical indications protection system is reinforced.
  - Certain disciplines are prevented for well-known trademarks.
  - The authorities may intercept the goods in case they suspect these inbound or outbound goods have been counterfeit.
  - Implementing measures against counterfeit goods and piracy on a commercial scale.

- **Trade Remedies:**
  - Safeguards: an exclusion, subjected to certain restrictions, is maintained for members (not being listed within the first 5 exporters) of the worldwide safeguard measures.
  - Anti-dumping and subsidies: the rights of the WTO (World Trade Organization) are recognized concerning these matters. Certain added regulations, that provides benefits for transparency, were established.
  - Fight against avoidance: A cooperation mechanism is established to prevent compensatory duties avoidance, anti-dumping and safeguard.
  - Binational Panels: The mechanism of Chapter XIX of NAFTA remains.

Source:
1. https://www.gob.mx/tlcan/acciones-y-programas/resultados-de-la-modernizacion-del-acuerdo-comercial-entre-mexico-estados-unidos-y-canada?state=published
2. https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/united-states-mexico
3. https://cnnespanol.cnn.com/2016/08/15/5-razones-por-las-que-canada-es-el-verdadero-enemigo-del-tlcan-y-no-mexico-como-dice-trump/
4. https://www.medtechdive.com/news/medical-device-companies-see-upside-in-nafta-20/538743/
5. https://cdn.ymaws.com/www.medec.org/resource/resmgr/USMCA.pdf
6.IQOM

TLC asociados
Derecho Fiscal, Administrativo, Comercio Exterior y Aduanas
Litigio, Auditoría, Consultoría, Capacitación

USMCA: Recommendations regarding the Enforcement of Rules of Origin

Some relevant aspects, to enforce correctly the rules of origin, are described hereunder:

1. Tariff items of raw materials to be temporarily imported.

Once the goods are entered to the customs systems established by the Customs Law, it is relevant for the tariff items, which correspond to the goods, to be correctly classified, and they shall be used to comply with the production processes.

2. Identifying the origin of the raw materials to be imported into national territory.

Identifying the origin of the goods represents a fundamental element to know whether the raw materials are originating from the USMCA in order to enjoy the tariff preferences or, otherwise, considering them as non-originating as a part of the international agreements regarding trading, which represents a fundamental part to our country.

3. Identifying the direct or indirect transportation method for the goods.

An originating good must be shipped directly from the countries that belong to the Free Trade Agreement, whose tariff preferences are intended to be exploited, or, if the goods are exported by a third country that does not belong to the Free Trade Agreement, this country must be placed under customs surveillance.

4.

Having a certification or declaration of origin of the goods.

The certification or declaration of origin shall be the document par excellence to validate the authenticity of the goods from one of the countries that shares an International Agreement regarding Trading. In addition, in case there are non-originating goods, a sworn statement shall be demanded to clarify that this is not a country subject to the compliance of any regulation or non-tariff limitation.

5.

Enforcement of tariff preferences in Mexico. (Rule 8, Prosec, TLC)

The temporary importation of goods, through Tariff Deferral Programs, is subject to the payment of import taxes in our country, therefore, it is necessary to analyze the different tariff schemes in order to reduce the impact of the customs tax obligation.

The applicable alternatives concern the tariff preferences from the Free Trade Agreements, preferential rates from Sectoral Promotion Programs and from the Prior Permissions of Eight Rules.

6.

Identifying the tariff item of the final product.

Once the product is finished, it is relevant to have all information and documentation in order to obtain a correct tariff classification of the final product, which shall be exported outside the national territory while it received the benefits of tariff preferences in the importing country.

7. Identifying the classification of origin of the final product.

a) **First, knowing the destination country of the goods, in which the parties of the USMCA are described.**

b) **Second, the tariff classification of the final good is a fundamental element to determine the applicable rule of origin from the USMCA.**

c) **Third, it is relevant to compare the rule of origin from NAFTA with the rule of origin from USMCA in order to identify the tangible benefits provided by this new agreement regarding trading.**

d) **Fourth, the rules of origin within USMCA may vary, depending on the final good to be produced, therefore, it is imperative to identify the following rules of origin:**

- Entirely obtained and produced.
- Regional Value Content by Transaction Value or Net Cost Value.
- Accumulation.
- De Minimis.
- Operations that do not provide origin.

NAFTA - R.O.	USMCA- R.O.
3926.90	**39.16-39.26 (1)**
A change of subheading 3926.90 of any other heading, with the exception of recognizable devices for symptoms use from subheading 3006.91, complying with a regional content of not less than: (a) 60 percent, when the transaction value method is used, or (b) 50 percent, when the net cost method is used.	A change from subheading 39.16 to 39.26 of any other heading. (1) If the goods from subheading 3926.90 is used for a motor vehicle from chapter 87, as it is described within the appendix from this Annex, the provisions of Appendix from this Annex shall be enforced.

8. Anticipated resolutions of USMCA.

Finally, according to the guidelines of USMCA, the exporter, manufacturer or importer shall be able to conduct a consultancy regarding the detection of the origin prior to the operation in the presence of customs authorities.

TLC asociados

Derecho Fiscal, Administrativo, Comercio Exterior y Aduanas
Litigio, Auditoría, Consultoría, Capacitación

www.tlcasociados.com.mx

tlc@tlcasociados.com.mx

TELÉFONOS:

Región Norte
01(656) 980.0497

Región Noroeste
01(664) 634.0189
01(664) 682.3901
01(686) 980.0496

Región Centro
01(55) 5280.3267
01(55) 2623.1639

Región Bajío
01(477) 211.6009

U.S.A
(619) 354.3547

TLC.Asociados.SC