

# Modernising the EU-Mexico Free Trade Agreement

## Recommendations for an ambitious new trade and investment relationship

### Our position

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2016, directly supports more than 4.5 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

## Executive Summary

The American Chamber of Commerce to the EU (AmCham EU) welcomes the ongoing negotiations between the EU and Mexico to modernise the trade pillar of the existing EU-Mexico Global Agreement (the EU-Mexico Free Trade Agreement, FTA). Bringing the current EU-Mexico FTA in line with the most recently concluded FTAs by the EU and Mexico will benefit consumers and industry in both regions. Preliminary analysis demonstrates that a modernised agreement could have a particularly positive economic impact on Mexico<sup>1</sup>. The decision to include a chapter dedicated to maximising benefits for small and medium-sized enterprises (SMEs) is also encouraging.

The US business community underscores that the benefits to the EU and Mexican economies from the modernised agreement can only be realised once the FTA has been signed, ratified, and properly implemented by both parties. Swift conclusion and ratification is therefore essential.

### 1. Introduction - general considerations

AmCham EU welcomes the ongoing negotiations between the EU and Mexico to modernise the trade pillar of the EU-Mexico Global Agreement. The effect and impact of the existing EU-Mexico FTA has been well-documented: bilateral trade in goods between the EU and Mexico expanded significantly after its entry into force. Exports and imports have more than doubled and the EU is today Mexico's third biggest trade partner, after the US and China. In 1999, the EU's share of Mexican exports was 3.8%; by 2013 it had risen to 4.9%. Meanwhile, Mexico's share of EU exports increased from 0.5% to 0.7%; EU exports to Mexico increased by 19 percent; and Mexican exports to the EU increased by 15 percent. Mexico's GDP is estimated to be 0.34% higher due to the FTA, while the EU's GDP is estimated to be 0.01% higher.<sup>2 3 4</sup>

Since the negotiations for and the entry into force of the EU-Mexico FTA in 2000, global trade has changed dramatically and so has the trade relationship between the EU and Mexico. Building on the 2000 EU-Mexico FTA, the modernisation should reflect these new and changed trade and investment patterns. Bringing the EU-Mexico FTA up to the standards of the most recently concluded FTAs by the EU and Mexico will benefit both economies and their consumers. The modernisation of the FTA should reflect the significant reforms achieved by Mexico in key economic sectors (e.g. energy, taxation, telecommunications sector, and banking) over the last few years and through the *Pacto por México*, to create new opportunities for trade between the EU and Mexico.

Including a strong digital trade chapter should be a key priority to make sure the modernised FTA is fit for purpose for today's business models. Commitments should promote the growth of ICT goods and services, telecoms, cloud computing, and e-commerce, and ensure that the digital ecosystem and the data that flows through it remains open to innovation, economic growth, and commerce globally.

AmCham EU supports the European Commission's aim to conclude a highly ambitious agreement with Mexico in the coming months and commends the parties for their continued progress in these negotiations. Rapid signature and ratification of the agreement is key to ensuring that all sectors and consumers can take advantage of the benefits of the agreement.

### 2. National treatment and market access for goods

<sup>1</sup> London School of Economics Enterprise, Sustainability Impact Assessment (SIA) in support of the negotiations for the modernization of the trade pillar of the Global Agreement with Mexico – Inception Report, November 2017, [http://www.siaeumexico.com/uploads/1/0/9/7/109735155/eu-mexico\\_draft\\_inception\\_report.pdf](http://www.siaeumexico.com/uploads/1/0/9/7/109735155/eu-mexico_draft_inception_report.pdf)

<sup>2</sup> Speech by Cecilia Malmström, European Commissioner for Trade UNAM University, Mexico, 9 May 2017, [https://eeas.europa.eu/delegations/mexico/25814/node/25814\\_be](https://eeas.europa.eu/delegations/mexico/25814/node/25814_be)

<sup>3</sup> European Commission, COM(2017) 654 final, 9 November 2017, <http://ec.europa.eu/transparency/regdoc/rep/1/2017/EN/COM-2017-654-F1-EN-MAIN-PART-1.PDF>

<sup>4</sup> Ecorys, Ex-post evaluation of the implementation of the EU-Mexico Free Trade Agreement Final Report, February 2017, <http://www.trade-sia.com/wp-content/uploads/2015/09/EU-MEX-FTA-ex-post-evaluation-final-report.pdf>

AmCham EU commends efforts to eliminate tariff and non-tariff trade barriers and to cover all goods. We highlight below some specific points of attention.

AmCham EU welcomes the wording of the EU's textual proposal on motor vehicles<sup>5</sup>, which:

- promotes compatibility and convergence of regulations based on international standards;
- promotes recognition of approvals based in particular on approval schemes applied under the agreements administered by the UNECE World Forum for Harmonization of Vehicle Regulations (WP.29); and
- provides for future regulatory cooperation on new technologies.

**Remanufactured goods** continue to face many barriers including:

- Tariff barriers, including for example excessive fees or taxes that significantly increase the customer's cost of choosing a viable remanufactured product;
- Non-tariff barriers, including categorising remanufactured goods as 'used' goods, which cannot be imported under any circumstance or can only be imported after complying with special inspection, certification, licensing or other onerous requirements.

Similar barriers are often faced when customers seek to export their cores (end-of-life components) and return them to the manufacturer in exchange for a remanufactured engine or component. The inclusion of an article on remanufactured equipment and parts in the motor vehicles annex<sup>6</sup> to the Agreement is therefore a welcome development.

Countries participating in the global economy should treat remanufactured products the same as new goods. The Trans-Pacific Partnership (TPP) and NAFTA agreements contain language on remanufacturing that could be reproduced in the modernised EU-Mexico FTA:

*TPP National Treatment and Market Access chapter<sup>7</sup>*

*Article 2.11: Remanufactured Goods*

1. For greater certainty, Article 2.10.1 (Import and Export Restrictions) shall apply to prohibitions and restrictions on the importation of remanufactured goods.
2. If a Party adopts or maintains measures prohibiting or restricting the importation of used goods, it shall not apply those measures to remanufactured goods.

*TPP Rules of Origin<sup>8</sup>*

*Article 3.4: Treatment of Recovered Materials Used in Production of a Remanufactured Good*

1. Each Party shall provide that a recovered material derived in the territory of one or more of the Parties is treated as originating when it is used in the production of, and incorporated into, a remanufactured good.
2. For greater certainty:
  - (a) a remanufactured good is originating only if it satisfies the applicable requirements of Article 3.2 (Originating Goods);
  - and (b) a recovered material that is not used or incorporated in the production of a remanufactured good is originating only if it satisfies the applicable requirements of Article 3.2 (Originating Goods).

<sup>5</sup> EU textual proposal 'Annex Motor Vehicles and Equipment and Parts thereof', October 2017, [http://trade.ec.europa.eu/doclib/docs/2017/october/tradoc\\_156331.pdf](http://trade.ec.europa.eu/doclib/docs/2017/october/tradoc_156331.pdf)

<sup>6</sup> EU textual proposal 'Annex Motor Vehicles and Equipment and Parts thereof', October 2017, [http://trade.ec.europa.eu/doclib/docs/2017/october/tradoc\\_156331.pdf](http://trade.ec.europa.eu/doclib/docs/2017/october/tradoc_156331.pdf)

<sup>7</sup> TPP chapter on National Treatment and Market Access, <https://ustr.gov/sites/default/files/TPP-Final-Text-National-Treatment-and-Market-Access.pdf>.

<sup>8</sup> TPP chapter on Rules of Origin and Origin Procedures, <https://ustr.gov/sites/default/files/TPP-Final-Text-Rules-of-Origin-and-Origin-Procedures.pdf>.

NAFTA 19 CFR 181.132<sup>9</sup>

(a) Treated as production. For purposes of implementing the rules of origin provisions of General Note 12, HTSUS, and Chapter Four of the NAFTA, except as provided in paragraph (b) of this section, disassembly is considered to be production, and a component recovered from a good disassembled in the territory of a Party will be considered to be originating as the result of such disassembly provided that the recovered component satisfies all applicable requirements of Annex 401 and this part.

(b) Exception; new goods. Disassembly, as provided in paragraph (a) of this section, will not be considered production in the case of components that are recovered from new goods. For purposes of this paragraph, a “new good” means a good which is in the same condition as it was when it was manufactured and which meets the commercial standards for new goods in the relevant industry.

**Agricultural raw materials**, such as sugar, should be incorporated in FTAs, as should high value-add processed products based on agricultural raw materials e.g. in the agrifood and chemicals sectors. Particular attention should be paid to enabling trade through the removal of tariffs and the application of workable rules of origin.

Finally, as part of the tariff commitments, Mexico should join the expansion of the **Information Technology Agreement (ITA)**.

#### Recommendations

- AmCham EU welcomes the wording of the EU’s textual proposal for an Annex on motor vehicles;
- The two parties should continue efforts to eliminate tariff and non-tariff trade barriers on remanufactured goods; the Trans-Pacific Partnership (TPP) and NAFTA agreements contain language on remanufacturing that could be reproduced in the modernised EU-Mexico FTA;
- Agricultural raw materials, such as sugar, should be included in any modernisation of the EU-Mexico FTA, as should high value-add processed products based on agricultural raw materials;
- Mexico should join the expansion of the ITA.

### 3. Rules of origin

The European Commission’s proposed language on ‘**cumulation of origin**’ is to be welcomed,<sup>10</sup> including provisions on cumulation which support the economic reality of global value chains. This is especially relevant for Mexico, which is highly integrated into the North American economy. The similarities and differences in the rules of origin protocols of different agreements that do not overlap between the EU and Mexico must also be taken into account. For the automotive industry in particular, the EU should apply the standard rule for the sector (EU Added Value Calculation Method based on ex-works price) in all EU FTAs with third countries, and include a 55% threshold for originating material/local content.

Mexico should also **reduce any unnecessary administrative burdens** specifically related to the legalisation of documents by the International Chamber of Commerce (ICC) and the Mexican consulate, as well as burdensome invoice procedures.

#### Recommendations

- The Rules of Origin chapter should include provisions which allow cumulation or origin;
- For trade agreements that do not overlap between the EU and Mexico, the different rules of origin protocols should be taken into account;

<sup>9</sup> NAFTA agreement – Title 19, Chapter 1, Part 181, <https://www.law.cornell.edu/cfr/text/19/part-181>.

<sup>10</sup> EU textual proposal ‘Annex concerning the definition of the concept of “originating products” and methods of administrative co-operation’, November 2016, [http://trade.ec.europa.eu/doclib/docs/2016/december/tradoc\\_155169.pdf](http://trade.ec.europa.eu/doclib/docs/2016/december/tradoc_155169.pdf)

- The agreement should include the EU standard rules of origin for the automotive industry and a 55% threshold for originating material/local content.

#### 4. Cross-border trade in services

**Quantitative restrictions** on the supply of cross-border services **should be prohibited** and provisions should prevent the requirement that suppliers from the other party adopt specific forms of entities or joint ventures to provide services in the territory. Similarly, no requirement to establish a domestic office or affiliate to access the markets of the other party should be permitted. AmCham EU supports the language included in the EU's textual proposal on Market Access and Performance Requirements for services (article 2.2 and 2.6)<sup>11</sup>.

A **'negative list' approach** for cross-border trade in services with no exceptions or carve-outs for 'new services' would ensure that the modernised EU-Mexico FTA remains future-proof, which is especially relevant for the fast-evolving technological and digital services. Furthermore, strong commitments on digital trade are essential to bring the EU-Mexico FTA up-to-date and welcomes the recognition by both parties in their Joint Statement from the VII EU-Mexico Summit of the importance to expand cooperation on the digital agenda<sup>12</sup>.

Ensuring the chapter includes a provision on **data flows** is a key priority, but other provisions in the EU offer could also be further strengthened (whether in the digital trade chapter or in horizontal Technical Barriers to Trade (TBTs), regulatory cooperation etc.). It is crucial that any provision on data flows base its exception on GATS article XIV and does not reverse the burden of proof whereby it would be up to industry to provide evidence of 'bad faith' on part of the trading party undertaking an infringing measure in order to obtain relief.

In addition to including the general principle of free flow of data, the new FTA should also include a **restriction on imposing localisation requirements** that force businesses to place computer infrastructure, manufacturing or service facilities in the market in which they seek to operate. Cross-border data flows are essential to the global digital economy, and governments should ensure that these are predictable and interoperable.

The inclusion of **no forced disclosure of source code** is a step in the right direction. The EU and Mexico should make sure the exception is clearly defined and narrow in scope to national and public security.

Market access should not be contingent upon **forced transfers of technology** and must reinforce the principle of companies not being required to transfer their technology, production processes, or other proprietary information to persons or governmental bodies in other countries.

Updating the EU-Mexico agreement provides a further opportunity to address **standardisation and interoperability** issues in digital trade. To avoid conflicting standards, provisions should ensure that foreign services providers can rely on global technology standards developed through voluntary and industry-led processes. Such standardisation brings about greater efficiency in business operations and the ability to provide services globally in a more cost-effective manner.

We would also suggest adding a provision regarding **'commercial encryption'** (likely in market access/TBT whether horizontal or ICT specific). In order to offer the products with the highest security standards, the import, use, and sale of products containing cryptographic capabilities should be largely unrestricted. It is therefore necessary to include commitments that prevent parties from requiring makers or suppliers of goods that use encryption for commercial applications to transfer or disclose proprietary encryption technology, production processes or other information to government or a domestic partner, or to partner with a domestic partner, or

<sup>11</sup> EU textual proposal 'Investment and Trade in Services Title', May 2016, [http://trade.ec.europa.eu/doclib/docs/2017/may/tradoc\\_155521.pdf](http://trade.ec.europa.eu/doclib/docs/2017/may/tradoc_155521.pdf)

<sup>12</sup> Joint Statement from the VII EU-Mexico Summit, Brussels, 12 June 2015, <http://www.consilium.europa.eu/media/23736/joint-eu-mex-final-clean.pdf>

to use a particular type of encryption, as a condition of being able to make, import, sell, distribute or use these goods.

The modernised agreement should require the **license-free export of items on the Wassenaar Dual Use List** (including those with encryption) between and among Mexico and the EU.

Last but not least, the updated agreement should **reinforce cybersecurity cooperation**. This will build the capacity to help prevent cyber-attacks and thwart the distribution of malware.

#### Recommendations

The modernised EU-Mexico FTA should use a 'negative-list' approach for trade in services, with no exceptions for 'new services'. Negotiators should include provisions in the cross-border trade in services chapter to:

- Prohibit quantitative restrictions for service providers;
- Support the free flow of data and strengthen the digital economy;
- Restrict localisation requirements for computer infrastructure, manufacturing or service facilities;
- Prohibit forced disclosure of source code or transfers of technology;
- Enable the use of global technology standards;
- Ensure license-free export of dual-use items;
- Reinforce cybersecurity cooperation.

## 5. Technical Barriers to Trade (TBTs)

It is important that the agreement provides 'national treatment' to each other's **conformity assessment bodies**, so testing and certification performed by a qualified conformity assessment body will be accepted as consistent with another party's requirements.

#### Recommendations

- 'National treatment' should exist between Mexico and EU's conformity assessment bodies.

## 6. Customs and trade facilitation

The priority should be to develop a **commercially meaningful agreement** that allows companies to compete on a level playing field and applies competitive principles which include electronic customs clearance, a *de minimis* regime, 24/7 automated customs processing, flexible hours, low-value thresholds and risk assessment.

**A level playing field for *de minimis*:** The Mexican Post can benefit from a \$300 *de minimis* at import while private express delivery companies can only benefit from a \$50 *de minimis*. The Mexican General regulation on Foreign Trade (Regulation 3.7.1.) stipulates that import operations of goods carried out by the postal service whose customs value is equal to or less than \$300 are not subject to taxation (IGI, DTA, and IVA)<sup>13</sup>, provided that such goods are not subject to regulations or non-tariff restrictions or when the goods are for personal consumption and not for sale. According to Regulation 3.7.3, express delivery companies may clear goods without payment of taxes (IGI and IVA) where the consigned goods value does not exceed the equivalent in local or foreign currency to \$50. This means that private express delivery companies are at a clear competitive disadvantage. This is a growing concern for SMEs that rely on e-commerce.

<sup>13</sup> IGI (Impuesto General Indirecto – general import tax); DTA (Derecho de Trámite Aduanal - Customs Processing Fee); IVA (Impuesto al Valor Agregado – VAT)

**Linking imported goods with HTS tax codes:** Mexico is currently drafting an e-commerce regulation obliging express companies to link incoming merchandise with the relevant HTS tax codes. This would be an additional administrative burden for these companies.

**Customs checks:** packages carried by private express delivery companies are currently being opened at customs to compare the content with the manifest. This practice is a result of the lack of preclearance and risk assessment by customs (Servicio de Administración Tributaria, SAT) to identify potential violations of customs regulations. This slows down and complicates the operations of private express delivery companies and affects their service to Mexican customers (big and small businesses, and private consumers).

**Weight limitations for non-Mexican operators:** the Mexican law limits the weight of packages handled by non-Mexican operators (package weight limit of 31.5 kg). The law equally limits the weight of the vehicles used by non-Mexican operators (and a vehicle total weight limit of 10 metric tons).

**Vaccines Batch Release:** every new batch of approved vaccines that is imported to Mexico needs to undergo a specific laboratory analysis by the Mexican National Laboratory (CCAYAC, part of the regulatory agency COFEPRIS). The full process, depending on the vaccine, means that the products can be held up for four to six months once it arrives in Mexico. The lengthy timelines for batch release impacts the possibility to participate in public procurement as it can affect capability to meet tender deadlines. While efforts have been made to simplify it, the current release process is complex, long and has onerous documentation requirements. Meanwhile, the 'fast track' procedure currently in place (*'Liberacion Simplificada'*) also contains unnecessarily complex requirements.

#### Recommendations

A separate chapter on postal and courier services should be included. The chapter should *inter alia* include provisions to:

- assure a level-playing field with the universal service provider;
- ensure equal treatment and border services for national and international express delivery companies;
- set one common *de minimis* level for duties at a minimum \$200 for all goods entering Mexico;
- limit the physical inspections of goods at import and apply a data-based risk assessment procedure in line with article 7 of the WTO Trade Facilitation Agreement for all goods entering Mexico regardless of the operator;
- eliminate the difference in treatment for foreign parcel delivery operators and bring Mexico's practices in line with its WTO obligations;
- guarantee license application processes which are transparent, non-discriminatory, and based on objective criteria; and
- safeguard the independence of the regulatory body.

The Commission should also simplify and streamline the process for vaccines batch release.

## 7. Investment

Following the May 2017 European Court of Justice (ECJ) ruling on the EU-Singapore FTA, AmCham EU calls for clear processes and procedures to be adopted which allow the EU to continue pursue and conclude trade agreements that secure the many benefits of trade liberalisation in parallel with essential investment protection mechanisms, including dispute resolution. The EU should consider dealing with investor disputes separately.

In the period where the EU's pursuit of an Investor Court System (ICS) or subsequent multilateral court system starts to gain international support, increased transparency and consultation provisions will address many public

concerns and misconceptions around investment-related dispute settlement. While the EU's ICS approach and any weakening of investment protection provisions – as compared to existing Bilateral Investment Treaties – remains a concern, Mexico seems to be supportive of reforms to the current ISDS system. However, further diversification away from existing levels of investment protection under ISDS or the ICS proposals would be a step in the wrong direction. In effect, investors would need to work with multiple, overlapping systems. The EU should strive to ensure coherence in this regard.

#### Recommendations

- The EU should consider dealing with investment protection separately;
- The increased transparency and consultation provisions included in the proposed Investor Court System (ICS) may help to address the concerns and misconceptions around investment-related dispute settlement, but should not further diversify from the existing levels of investment protection.

## 8. Telecommunications

The Telecommunications Chapter should ensure that service providers will have access to and use of the **public telecommunications services**, including leased circuits, on reasonable and non-discriminatory terms and conditions.

The modernised agreement should not treat a telecommunications company as a regulated telecommunications provider when supplying an **internet protocol service**. Telecommunications companies should be regulated as such only to the extent that they are providing telecommunications services.

The **Telecommunications Chapter of the TPP** includes 'WTO-plus' obligations for all public telecommunications services suppliers, including interconnection and number portability. More rigorous commitments apply to major suppliers regarding affiliate relationships, competitive safeguards, resale, interconnection, leased circuits, co-location, and access to poles and other structures.

Provisions to ensure **transparency** with respect to regulatory processes applicable to the telecommunications sector should be included. Parties should ensure that regulatory bodies are separate from, and not accountable to, any supplier of public telecommunications services and that the **regulatory body** does not hold a financial interest or operating role in any supplier. The chapter should provide for enforcement authority, guarantee recourse to regulatory bodies, and specify an appellate process for resolution of domestic telecommunications disputes.

Safeguards on restrictions that regulators can impose on operators' **technology choice** should be included. By limiting the conditions under which parties can specify technology, the chapter would help to avoid the arbitrary denial of technology choice.

Moreover, this chapter presents an opportunity to lock in the forward leaning provisions of the 2013 **Mexican Constitutional reforms in the telecommunications sector** to promote effective competition. The EU should ensure that Mexico meets the following obligations of its telecom reforms, including, but not limited to:

- an independent and autonomous telecom regulator;
- specialised judges and limits on judicial stays of disputed regulation;
- the concept of 'preponderance' as currently defined and the obligation to regulate any preponderant asymmetrically including, without limitation, by imposing specific asymmetric measures sufficient to prevent monopolistic practices and promote competition; and
- a requirement to maintain specific asymmetric measures unless Mexico can demonstrate effective competition exists in the sector, and until there is no longer a preponderant economic agent in the Mexican telecommunications sector.



### Recommendations

Including 'WTO-plus' provisions in the telecommunications chapter of the modernised EU-Mexico FTA will:

- ensure access to and use of the public telecommunications services for telecoms service providers;
- ensure that telecommunications companies, when providing internet protocol services, are not treated as regulated telecommunication providers;
- ensure regulatory transparency and independence;
- avoid the arbitrary denial of technology choice;
- reflect the recent reforms in the Mexican telecommunications sector.

## 9. Energy and raw materials

EU energy trade with Mexico is relatively modest and unlikely to significantly increase in the wake of an update to the EU-Mexico FTA. The most significant impact of NAFTA for the energy sector is the creation of a highly integrated and interdependent North American energy market which is likely to remain Mexico's priority. With this in mind, it would be helpful for the EU to reinforce core internal energy market principles within the Energy Chapter. For example, prohibition of import and export restrictions, eliminating price controls, and reasonable local content requirements. This would further support the recent opening of the hydrocarbons sector in Mexico which is to be applauded. In articles 11-13 of the EU's textual proposal<sup>14</sup>, when referencing 'standardisation' and 'relevant international organisations' (such as ILAC and IAF), care should be taken to include a broader range of international organisations, mindful that the EU is not Mexico's primary energy export market.

### Recommendations

- Reinforce the core internal energy market principles in the modernised FTA;
- Include a broader range of international organisations for cooperation and standardisation of energy and raw materials.

## 10. Intellectual property rights

Mexico continues to be an attractive market for many industries, however, a number of trade barriers remain, notably in relation to Intellectual Property (IP). To uphold the level of IP-protection negotiated in previous FTAs, AmCham EU recommends the inclusion of a comprehensive IP chapter in the modernised agreement.

The updated agreement needs to reflect strong copyright protection and enforcement provisions and commitment to continuously seek an appropriate balance in copyright systems, including through copyright exceptions and limitations.

The agreement should ensure that effective legal remedies are available to address online copyright infringement and provide conditional safe harbours for intermediaries. Limitations of liability should also include provisions such as a 'good Samaritan' clause that facilitates intermediaries addressing and deterring illegal activity conducted over their channels and services.

<sup>14</sup> EU textual proposal 'Energy and Raw Materials', November 2016, [http://trade.ec.europa.eu/doclib/docs/2016/december/tradoc\\_155172.pdf](http://trade.ec.europa.eu/doclib/docs/2016/december/tradoc_155172.pdf)

The agreement should contain provisions strengthening protections against corporate espionage. There should be criminal procedures and penalties for trade secret theft, including by means of cyber theft while preserving domestic laws that protect whistleblowing.

Specifically for the pharmaceuticals industry, Mexico continues to be an attractive market, however, a number of trade barriers remain for pharmaceutical companies operating there, notably in relation to IP. Consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as well as the scope of application of Regulatory Data Protection (RDP) in other EU FTAs, the revised FTA should include **measures guaranteeing that RDP is provided both for small molecules and biologics**. It should be implemented so as to provide effective protection during the RDP term, both in terms of submissions for regulatory approval applications, and subsequent granting of them. Such measures should be specifically defined via legislation, so as to provide certainty to all stakeholders. Protection periods should also be harmonised as much as possible to those provided by EU legislation. To that end, the FTA should include the highest standards of Regulatory Data Protection for both chemicals and biologics.<sup>15</sup> The FTA should also support the introduction of **Supplementary Protection Certificates (SPCs) or a similar form of patent term restoration**. These compensate for some of the patent term lost throughout the long development process of a medicinal product and ensure sufficient protection is available to encourage sustainable and appropriate funding for the next wave of biopharmaceutical R&D.

Given challenges with enforcement of IP protection for pharmaceuticals, we would also strongly support the **inclusion of effective patent enforcement mechanisms** in the revised FTA, including providing for early patent disputes resolution and effective enforcement for medical use and formulations patents.

#### Recommendations

Provisions should:

- Strengthen Regulatory Data Protection (RDP) and patent enforcement for pharmaceuticals;
- Ensure a strong and balanced copyright system;
- Have access to effective legal remedies in case of online copyright provisions;
- Strengthen protection against corporate espionage and trade secrets theft.

## 11. Regulatory cooperation

AmCham EU welcomes the EU's proposal to include provisions on **good regulatory practices** in the modernised FTA<sup>16</sup>. Specific to **pharmaceuticals**, we welcome the renegotiation of the FTA as an opportunity to strive for further alignment with global regulatory standards. To that end, and noting the positive steps by Mexico's regulatory agency – Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) – in regards to regulatory convergence, we encourage **continued focus on global alignment of the agency's processes and full adoption of guidelines of the ICH** (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

Beyond this, the FTA talks should be an opportunity to recommend that any **updated version of Mexico's regulation for biosimilars registration and approval is aligned with international standards**. The **elimination of redundant import testing** of pharmaceuticals (including vaccines), if conditions are met, should also be prioritised. Such conditions might include the provision of evidence by companies that a product was

<sup>15</sup> The EU-Canada CETA agreement has a baseline of eight years of regulatory data protection: a six-year period under which third parties may not rely on the originator's data for authorisation applications, and a two-year period during which the generics may proceed towards market introduction but cannot be marketed and sold.

<sup>16</sup> EU textual proposal 'Chapter on Good Regulatory Practices', April 2017, [http://trade.ec.europa.eu/doclib/docs/2017/may/tradoc\\_155520.pdf](http://trade.ec.europa.eu/doclib/docs/2017/may/tradoc_155520.pdf).

manufactured, tested, stored/distributed under controlled and validated conditions, and proper quality systems that are in place from a compliance viewpoint.

#### Recommendations

The EU's proposal to include provisions on good regulatory practices should be enshrined in the agreement.

Specific to pharmaceuticals, the modernisation of the FTA is an opportunity to strive for further alignment with global regulatory standards and eliminate redundant import testing.

## 12. Conclusion

The ongoing negotiations to modernise the trade pillar of the existing EU-Mexico Global Agreement offer the potential to significantly enhance economic opportunities for businesses and consumers in both regions. At a time of uncertainty about the future direction of world trade, the talks are also an important signal that the EU and Mexico are open for business. In order to maximise the potential of the negotiations, it is critical that the two parties maintain the highest level of ambition.

At the same time, it is equally important that the agreement is concluded as swiftly as possible and that the two parties proceed with urgency towards ratification and implementation. To this end, the two parties should consider laying the groundwork for ratification as early as possible, including by engaging with key policymakers and stakeholders at every opportunity. Meanwhile, the EU and Mexico should also look to begin preparations for implementation of the agreement in advance of ratification, to ensure that its benefits are realised from day one of application. Finally, the two parties should seek to continuously engage with businesses and consumers to raise awareness of the opportunities that the agreement presents and enhance understanding of the role of the FTA in boosting our economies.

AmCham EU continues to play an active and constructive role in ongoing EU trade negotiations, including the modernisation of the EU-Mexico FTA. Our members stand ready and willing to provide input and expertise to negotiators and relevant stakeholders throughout this process, in pursuit of an ambitious agreement that meets the needs of businesses, consumers and society.