MEXICO – EU FTA
KEY ISSUES FOR EFPIA-AMIIF TELECON. FEB 10th 2017

EFPIA – AMIIF ENGAGEMENT

- Interlocutors for both Associations (potential WGs): news alert system, maximizing dialogue opportunities. Setup of regular coordination channel/calls
- Sector Priorities (milestones?) for 3rd and 4th rounds
- Mexico's representation in Brussels
- EU Delegation in Mexico
- Identification of EFPIA/AMIIF member companies willing to help?

KEY ISSUES FROM EU PHARMA SIDE

Investment and economy

- General economic climate, investment figures of pharma companies, growth figures

IP environment

- Weak enforcement IP rights legislation (difficult to prove infringement and/or preliminary injunctions). Obligations of Mexico as NAFTA member.
- No regulatory data protection or patent term extensions (though a reference is made in early EU proposals published in November 2016). COFEPRIS does not consider national birthdates for a product.
- No clear rules for patentability of subsequent medical inventions (incremental innovation, variations).
- Lack of early resolution mechanisms for patent disputes.
- Import of patent protected raw materials for "experimental use" with no time limits (abuse of "Bolar" exemption).
- Role of local manufacturers associations (potential infringements?).Local association: ANAFAM (though Abbot and Teva are members….) what's their relationship with AMIIF if any? Role of CANIFARMA.

Regulatory issues

- Foster regulatory dialogue COFEPRIS – EMA, liaison with EAMI at all?
- Alignment with international standards (ICH). MoUs with other countries/agencies.
- Inadequate biosimilars regulation: Additions and updates to the regulations covering approval of non-innovative biologics (biosimilars) lack clarity.
- Avoid additional, burdensome reviews for imported medicines.
- Need to develop 2-pager on regulatory issues.
- Pharmacovigilance plans.
- Setup of dedicated bilateral regulatory dialogue

Market Access

- Significant barriers to the public market for medicines remain due to the lengthy, non-transparent, and unpredictable sanitary registration release process, despite recent improvements to the marketing approval process for pharmaceutical products by COFEPRIS.
- Role of New Molecules Committee.

- Role of National Committee on Health (transparency of process, participation of companies).
- Pharmaco-economic assessments: are they legally binding?), experienced in multiple layers (for each public institution?

Procurement

- Lengthy timelines for batch release controls impacting access to procurement process?

STRATEGIC VISION 2017: Preserve and improve the standard of protection of Industrial Property of the Pharmaceutical Industry of Innovation.

AGREEMENTS WITH EUROPE

I. EU-Mexico Free Trade Agreement.

- EU text proposal published on November 2016.
- Meetings with the negotiators of Mexico (Secretary of Economy) hold in December and January.
- AMIIF sent comments and articles proposal this week.

II. European Free Trade Association (EFTA). *Iceland; Liechtenstein; Norwaw and Switzerland.*

✓ 1. Meeting with local authorities (SE) in order to know the texts proposals.

✓ 2. Sending the documents to SE with AMIIF comments.

3. Participation in negotiation meetings (**Cuarto de Junto*)

**the possibility in the law for the private sector to be Heard and Provide information with the Delegates of the Mexican Government when discussing a free trade agreement.*

The comments by AMIIF to the EFTA text are the following:

PATENTABILITY:

• AMIIF agrees with the wording that allows the patentability of new uses of products, known methods and new processes.

EFFECTIVE COMPENSATION:

• AMIIF agrees that the wording for compensation of patent validity should continue, although it is preferred to distinguish with the proper clarity between the regulation and the regulation of the patents and the being clearer possible to define the assumptions that cause the compensation and what is the term.

DATA PROTECTION:

• Preserve the wording of "at least ____ years of protection".

• 5 years at least in chemical synthesis products.

• It is also worth 3 years at least for new uses / indications.

• The wording that biotechnology deserves protection should be remained, but we suggest including more than chemicals, we suggest 12 years.

• Significant efforts should not be included in the text, so that it is implanted in the health regulation in Mexico.

ENFORCEMENT OF RIGHTS:

We suggest including a text stating that countries do not bind the parties to incur two administrative and one civil proceedings to obtain compensation or redress for infringement of industrial property rights.