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?