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Director
DG Trade
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BELGIUM

Daniel Mullaney
Assistant USTR for Europe and the Middle East
United States Trade Representative
Washington, DC 20503
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Dear Mr Bercero and Mr Mullaney:

On behalf of the Trans-Atlantic Business Council (TABC), we would like to express our strong support of the life sciences industry for the current negotiations for a comprehensive and ambitious Trade and Investment Partnership (TTIP) between the US and the EU.

The TABC includes as members innovative companies in the life sciences sectors, notably pharmaceuticals, biopharmaceuticals, medical devices, and over-the-counter medicines. Our sectors represent a significant share of trade and innovation on both sides of the Atlantic, accounting for more than 80% of global sales of new medicines and 75% of global R&D in life sciences. At the same time, differences in approval standards and the lack compatibility of processes and standards create unnecessary barriers to further development.

It is our hope that a robust and enforceable agreement that tackles these barriers will drive progress in the global race for R&D, and support innovation, job growth and the development of innovative products to improve health. It would also enhance alignment in broader engagement with third countries. In order to achieve this, US and EU policymakers, negotiators and regulators should work together to encourage open market access, greater regulatory compatibility, investment, as well as strengthened intellectual property rights, and the removal of tariffs.

Regulatory issues:

An enhanced EU-US relationship could represent a unique opportunity to seek even greater compatibility and to create streamlined processes and procedures between the EU and the US. To this end, specific regulatory compatibility proposals are as follows:

- Increase efforts to co-ordinate and avoid unnecessary duplication between the FDA and EMA, notably by each side **mutually recognizing manufacturing site (GMP) inspections**, as well as **parallel scientific advice**. The latter should expand to be

applicable to all medicines, and grant sponsors the right to receive it upon request. More consistent regulatory requirements for trial data for approval of medicines.

- Strengthen EU-US collaboration within the ICH framework in a number of areas, including: greater compatibility in scope, content and timing of submission of **paediatric plans**, requiring only a single plan for submission in both territories, and efforts to harmonize both the structural framework and methodology for **benefit-risk assessments**, and on approaches to post-approval variation submissions for manufacturing changes.
- Establish a procedure for collaborative development of scientific and other **regulatory guidelines for specific therapeutic areas**.
- Harmonize practices by EMA and FDA on the clearance and acceptance of drug names. One common brand (where legally appropriate) will also facilitate PV surveillance and thus contribute to patients' safety.
- Regarding **Over-the-Counter (OTC) medicines**, greater recognition of Rx-to-OTC switch by the EMA and FDA in each other's market, and greater acceptability of foreign trial data by the EMA and FDA in support of a Rx-to-OTC switch. Particularly due to the fact that a Rx-to-OTC switch in the US means the product is available outside the pharmacy, these data should be considered strong evidence of potential safe OTC use in EU. Consider allowing open access to over-the-counter medicines, and allowing the placement of them "in front of the counter" at pharmacies. Implement common EMA and FDA practices on the clearance and acceptance of medicine names.
- Work collaboratively to eliminate counterfeit and substandard medicines. Harmonize approaches and policies regarding verification of prescription medicines (e.g. serialization) in the EU and the US. In order to protect patient safety, pharmaceutical products should have unique identifier to allow them to be recognized by the manufacturer, wholesaler and pharmacy. Unique product identifier will enable customs to identify products internally. Customs should include (high risk) products in the World Customs Organization (WCO) database to be entered following WCO's Interface Public-Members (IPM) rules.
- Apart from harmonizing regulations, continue and increase the exchange of personnel between the respective medicines agencies could also help support this objective.

Sharing of clinical trial data information and public disclosure of data contained in marketing authorization dossiers for medical products by the competent regulatory authority:

- In light of increasing data disclosure requirements, the EU and the US should be willing to adopt an aligned, responsible and balanced approach to data sharing, which protects both patients' and companies' interests while fostering innovation. The TTIP should therefore ensure that both the EU and the US maintain uniform protection of patient privacy, regulatory process integrity and commercial interests in their respective clinical trial data and marketing authorization application disclosure programs.

Market Access:

The life sciences sectors face unique market access challenges. This is due to strict regulatory approval standards, as well the dependence on obtaining positive pricing and reimbursement (P&R) decisions from governments and other authorities.

Following precedents set with the KORUS and EU-Korea FTAs, TABC urges the **adoption of a Pharmaceutical Annex** that would respond to these challenges, notably by emphasizing that procedures and all P&R decisions must be governed by transparent, verifiable and enforceable rules, should adequately recognize the value of the product, and reward innovation.

- Recognition that **International Reference Pricing** (IRP) should only be applied between countries with similar socio-economic levels, populations, disease burdens and health care systems; furthermore, there should never be reference to countries subject to economic crisis measures (e.g. IMF intervention) or mandating measures such as price cuts.
- To appropriately recognize innovation, the **government price for an innovative product should never be set by reference to prices for generic products**.

Health Technology Assessment (HTA):

- Safeguarding the independence of HTA bodies and the involvement of all interested parties, and ensure that HTA is conducted in an objective, fair and transparent manner, with effective means to challenge decisions and adequate remedies available to all interested parties.

Patient Access:

- The time limits for pricing and reimbursement decisions of 180 days established by EU Directive 89/105/EEC are significantly exceeded by several member states. Time to market access measures should be adhered to.
- Any "clawback" or rebate tax levied by a Party in response to an economic crisis should not disproportionately burden innovative pharmaceutical manufacturers (i.e., any tax should be borne by the entire supply chain), and should be subject to a transparent, annual review process that affords those subject to the tax the opportunity to comment on whether it remains necessary to continue the tax. Revenues raised by such taxes should be earmarked to cover healthcare expenditures.

Intellectual Property Rights (IPRs):

IPR is a fundamental element of the life sciences sector. Effective protection and enforcement are essential for the continued investment for the development of innovative pharmaceuticals. The TABC calls for moves to improve upon existing legal standards and further, to harmonize and strengthen protection. The EU and US should:

- Seek to **harmonize and align intellectual property protection and enforcement measures** in the life sciences sector, e.g. by increasing Data Exclusivity (DE) for biologics in the EU to 12 years, and to 10+1 years data exclusivity for small molecules in the US.
- Harmonize approach to patent term adjustment if patent examination was delayed by the patent office.
- Ensure sufficient **IP incentives** for the development of pediatric medicines, orphan medicines, Rx-to-OTC switches (3 year data protection) and other specific needs.
- Provide for **enforcement mechanisms** to prevent patent-infringing products from entering a market while a patent-infringement dispute is ongoing.

- Avoid **imposing restrictions on the use of trademarks** by a) not requiring that only generic names be listed on the packaging of a pharmaceutical; and b) ensure that, on such material, generic names are not given more prominence than proprietary drug names or that use of generic names in prescriptions is given preference over the use of the proprietary drug names.
- Avoid interference with markets stemming from rules and provisions in EU (and EU member states') law giving **privilege or even exclusivity to generic names over proprietary names**.
- Allow for **greater flexibility in umbrella branding** i.e. multi APIs under a single brand.
- **Expand current commitments to align US and EU positions in multilateral dialogues**, to encourage robust third country protection of intellectual property (e.g. establish standard for working interpretation of article 39 TRIPS - what is working and what are working requirements, clarify that compulsory licensing should only be allowed under very tight restrictions). The EU and US already collaborate towards this objective in commitments made in the Transatlantic IPR Working Group's Action Strategy and in the Transatlantic Economic Council. These commitments could be further bolstered by the inclusion of similar mechanisms in a transatlantic agreement.

Medical Devices:

A standstill on any new "buy-national" requirements should be agreed at the outset of the negotiations and the application of export controls to **medical devices** should be clarified to (1) more closely reflect the aims and policy of the Wassenaar Agreement; (2) avoid unnecessary complexity of classification of goods for medical and humanitarian use; and (3) provide consistency of treatment of medical devices, equipment and related software and accessories across the EU and between the EU and US.

TABC supports the following joint priorities for the TTIP put forward by the European and American industry associations for medical technology: 1) maintain harmonization between ISO 13485 and FDA's Quality System Regulation (QSR), 2) a single audit process, 3) harmonized format for product registration submission, and 4) a common way to trace products through a single unique device identification (UDI) process with interoperable databases.

TABC supports the development of regulatory guidance on mobile medical apps. Guidance should be developed analogous to the FDA's Final Guidance on Mobile Medical Applications. The small subset of regulated mobile medical apps should be distinguished from non-medical mobile apps which by definition are not regulated medical devices. Those include common and general health apps that may be used in a healthcare environment, in clinical care or patient management, but are not considered medical devices as they do not present the potential for patient harm. In addition, clarity should be provided for mobile apps that may be considered mobile medical devices but are of such a low-risk to patient harm that enforcement of regulations would be impractical. Guidance should also provide background, regulatory requirements and information on additional resources to help stakeholders in an on-going fashion.

Tariffs:

- Although most finished pharmaceutical products are imported duty-free under the Pharmaceutical Appendix to the Harmonized Tariff Code in the US, the process for adding additional items to the Appendix is time-consuming and uncertain.
- Tariff codes are not sufficiently harmonized between the US and the EU, and thus there are potential conflicts in classifying goods traded between the two. It is not possible to determine an average tariff on exports/imports due to the volume and complexity of the items imported.
- In addition, research and development compounds are generally subject to duties. This can influence the decision whether to import into the US or perform research or development activities elsewhere.
- Eliminate tariffs relating to the shipment of research tools and equipment between trade partners. Reduce possible tariffs that apply to purchased goods.

TABC stands ready to support you and your teams to advance discussion in this important sector for the transatlantic economy and we look forward to working with you as TTIP negotiations move forward.

With kind regards,

Tim Bennett

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Trans-Atlantic Business Council