TACD Resolution on Medicinal Products and Medical Devices in the TTIP Agreement

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Trans-Atlantic Consumer Dialogue (TACD) Resolution on Medicinal Products and Medical Devices in the Transatlantic Trade and Investment Partnership Agreement (TTIP)

The World Health Organisation (WHO) defines health technologies as including: 'devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives'.1 Medicines and medical devices play an important role in improving health outcomes and improving the quality of life of patients. However, providing affordable and equitable access to quality, safe and effective health technologies is increasingly a challenge both in the EU and the US and may be further challenged by provisions in TTIP.
TTIP should respect the principle of Universal Health Coverage and must ensure coherence between public health and trade in the field of health technologies. It should not reinforce the monopoly power of pharmaceutical corporations, or their ability to withhold information on medicine safety and efficacy. Nor should it limit the freedom of national governments to tailor decisions on pricing and reimbursement to ensure affordability, or to revise current intellectual property protection terms to spur affordable access to important drugs.
It is important to stress in the context of health technologies that trade agreements should not undermine the treatment and protection of sensitive health data

TACD Recommendations on Medicines

Investment protection
Recommendation 1:
Referring to the concerns expressed by TACD, in light of the Eli Lilly case3 the exclusion of any form of investment protection measures is relevant in the context of health technologies.

Regulatory cooperation
Recommendation 2:
With regard to regulatory cooperation on human medicines, there is no need for a specific annex on regulatory cooperation in TTIP.

Recommendation 3:
However, if such an annex is included, it is essential that provisions on regulatory cooperation in TTIP should explicitly protect the EU's exercise of the precautionary

principle and similar US safeguards, and essential that the primary aim of regulatory cooperation on medicinal products is stated to be improving health outcomes and reducing health inequalities.

Pricing and reimbursement

Recommendation 4:

Pharmaceutical pricing and reimbursement – including enhanced transparency and/or improved procedural rights in relation to these decision making processes – must be excluded explicitly from TTIP as the current rights and processes are sufficient.

Intellectual property

Recommendation 5:

Intellectual property rights (IP) and related exclusivities for health technologies must be explicitly excluded from all relevant sections of TTIP.

Recommendation 6:

If IP provisions and related exclusivities on health technologies are included in TTIP, they should not:

– regulate the standards or entrench established practices for granting patents on pharmaceuticals, in particular on secondary patenting and other patentability standards.

– strengthen or entrench the terms and scope of data or marketing exclusivity on pharmaceuticals, including particularly in the area of biologics.

Safeguarding access to information on development of health technologies, including clinical trial data

Recommendation 7:

Ongoing EU commitment to increased transparency of clinical trials data of pharmaceuticals must be firmly restated in TTIP.

Recommendation 8:

TTIP should not include trade secret protection.

Recommendation 9:

If trade secret protection is included, safeguards and exceptions should be in place to ensure that data in the public interest, and in particular information related to safety, efficacy and development of medicines, cannot be protected as trade secrets.

Recommendation 10:

If confidentiality provisions to facilitate information exchange between medicines regulators across the Atlantic are included, TTIP needs to:

– stipulate that access to information to be shared between EU/US regulators – even if marked commercially confidential – can always be requested, and should always be granted, if there is an overriding public interest in disclosure.

– stipulate that EU/US regulators will always request all data needed for a comprehensive assessment of marketing authorisation directly from the applicant, even if the data has already been obtained from other sources through this information exchange.

Medical Devices

Recommendation 11:

The reduction of tariffs on medical devices (bringing these into line with pharmaceutical products where there are no tariffs) is welcome – provided that the reduction in tariffs is reflected in lower prices for purchasers and not higher profits for manufacturers.

Recommendation 12:

With regard to regulatory cooperation on medical devices, there is no need for a specific detailed annex in TTIP.

Recommendation 13:

However, if a detailed annex on medical devices is included, the primary aim of regulatory cooperation should be explicitly stated as improving health outcomes and reducing health inequalities, with increased trade a secondary aim.

Direct-to-Consumer Advertising of Medicines and Health Technologies

Recommendation 14:

Nothing in TTIP should affect the ban on direct-to-consumer advertising of medicines and health technology products in the EU, or limit the US from regulating or restricting direct-to-consumer advertising in the future. This must be explicitly stated in the final text of TTIP.

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