FACTSHEET

Health in TTIP

The health sector is one of the key issues on the table of the Transatlantic Trade and Investment Partnership (TTIP), an EU-US trade agreement under negotiation.

Why is this relevant for consumers? Because a well-designed TTIP could improve the safety of drugs and medical devices. But badly designed, TTIP can lead to higher drug prices – because of slower access to generic medicines and more leeway for pharmaceutical companies – and less transparency on drug safety data.

BEUC believes that **health services** – consultations with doctors, emergency services, hospital care etc. – must be excluded from TTIP. There are concerns across Europe that TTIP will impact health care systems. For example, procurement rules may force national health care providers to outsource services that they may want to keep in-house.

In other areas, i.e. for **pharmaceuticals** and **medical devices**, the main aim for cooperation between regulators should be to enhance consumer safety. But as both the EU and US already cooperate globally or bilaterally on these issues, a politically-charged agreement seeking to advance trade, from the consumer point of view, is *not essential* for promoting better cooperation. References to **pricing** & **reimbursement** in these sectors must be excluded.

What are the potential benefits for consumers?

It potentially makes sense for the EU and US to cooperate more closely on the following matters, when this contributes to enhanced consumer safety.

- **Mutual recognition of inspections.** EU & US authorities inspect companies' facilities on their territories and in third countries to verify product quality and ensure compliance with so-called 'Good Manufacturing Practices'. Closer cooperation could avoid duplicating inspections, achieving a more effective use of scarce human and financial resources. This does not require TTIP: the European Medicines Agency (EMA) already has 'Mutual Recognition Agreements' with some countries e.g. Switzerland, though not with the US.
- **Harmonised medicine authorisation requirements** would mean clinical trials could be recognised on both sides of the Atlantic. As a result, more patients can be spared the risky process of experimenting with medicines. This is especially important for children's medicines. It could also help ensure that medicines are available sooner.
- **Information-sharing on the safety, efficacy and quality of medicines.** EU legislation on the transparency of clinical trials data requires clinical trial results to be made public. This is more restricted in the US as a lot of this information is considered 'commercially confidential'. We therefore support the narrowest definition of commercial confidentiality (and trade secrets) in TTIP. Access to information on clinical trials is essential for better treatment decisions and for medical progress.
- **Convergence of authorisation systems for generics and biosimilars.** Generics are cheaper, unbranded medicines similar to branded medicines whose patents have expired. Biosimilars are similar to other biological medicines[1] already authorised for use. If the authorisation systems could be converged without undermining consumer safety, consumers would get faster access to both.
- **Cooperation on the safety of medical devices.** This includes ensuring that manufacturers observe production requirements and enabling a system that allows medical implants to be traced across borders.

[1] This "is a medicine that contains one or more active substances made by or derived from a biological source"(European Medicines Agency, 2012)

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European consumers *could* benefit from a harmonised approval system for medical devices. In the US, a pre-market approval system allows products such as pacemakers & breast implants to be more closely scrutinised, meaning that consumers get safer devices. This does not exist in the EU. European consumers must be granted the same level of protection as their US counterparts. Regrettably, this is not on the TTIP table.

What should be excluded from TTIP?

Including certain topics into TTIP could negatively impact health care in Europe. BEUC calls for...

- **No health services in TTIP.** The organisation & delivery of health care is legally the sole responsibility of Member States. It should remain so. While EU negotiators have stated that health services will be excluded from TTIP, BEUC calls for this to be formally written into the text (a so-called 'hard exclusion' or 'carve-out').
- **No provisions on pricing & reimbursement of medicines and medical devices in TTIP.** European governments should maintain full autonomy to decide "how much people have to pay or how they're reimbursed". BEUC welcomes the EU's commitment on this.
- **No extension of the intellectual property rights and exclusivities already applied in the EU.** Some medical products have 20 years of patent protection and a number of other exclusivities in the EU. Longer patents delay the introduction of cheaper generics. This keeps medicine prices high, at the expense of healthcare systems and – ultimately – the consumer and so should not be a consequence of TTIP.
- **No changes to EU laws on access to clinical trials data.** BEUC welcomes the EU commitment not to negotiate rules that will impact "in any way" on EU laws giving better access to clinical trial data. European consumers expect the EU's high standards for clinical data disclosure to be safeguarded.
- **No US-style medicine promotion.** In the EU, only non-prescription medicines can be advertised. In the US, this is possible for both prescription & non-prescription medicines. As a result, prescription drugs are consumed more, straining public health budgets. For BEUC, TTIP should not lead to changes to the EU regulations that govern the advertising of prescription medicines or industry's role in providing information to patients.

NOTE: For more information, read our position statement and blog post on health in TTIP.

Other sources: www. tacd.org, www.beuc.eu/blog

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