



Transatlantic Trade and Investment Partnership (TTIP)

Position of the *European Social Insurance Platform (ESIP)*

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About the *European Social Insurance Platform* (ESIP)

The *European Social Insurance Platform* (ESIP) represents over 40 national statutory social insurance organisations (covering approximately 250 million citizens) in 16 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

Statement regarding positions submitted by ESIP: *ESIP members support this position in so far as the subject matter lies within their field of competence.*

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Preliminary remarks and key issues

ESIP welcomes the intention of the European Union (EU) to facilitate trade arrangements for European companies through a Transatlantic Trade and Investment Partnership (TTIP) with the United States of America (US) and thereby to promote employment and growth in Europe.

At the same time, ESIP observes with some concern the changing nature of the “new free trade agreements” such as the TTIP. Unlike existing EU multi- and bilateral trade agreements, the scope of TTIP will be extended to include rules governing investment, public procurement, services and intellectual property rights (TRIPS-plus) as well as reducing regulatory (non-tariff) barriers to free trade.

In this context, ESIP is particularly concerned about the treatment of public services in the services negotiations and the impact of investment protection and investor to state dispute settlement chapters on social security and public health, as well as issues surrounding healthcare products and product standards.

Therefore in the context of further negotiations, ESIP calls for the following **key points to be taken into account**:

- **Social insurance schemes** as well as **services provided or paid for by the statutory social insurance institutions** must be clearly and unambiguously excluded from the scope of the TTIP regardless of the way they are organised or financed.
- Provisions governing **investment protection** are not necessary since sufficiently strong legal mechanisms already exist in the EU and in the US. Further, it should be ensured that the standards, organisation and financing of social security and social protection are not jeopardised.
- When considering further compatibility/convergence between the different regulatory systems for **pharmaceuticals** the highest standards should be maintained to ensure patient safety; mutual recognition of market authorisation must be excluded. Issues of pricing and reimbursement are a Member State competence and should not be subject to discussion under the TTIP.
- Rules on **intellectual property** within TTIP should not lead to longer periods of patent protection or marketing exclusivity in the pharmaceutical sector.
- For better regulatory compatibility in the field of **medical devices** EU approval and surveillance requirements should be aligned with the higher standards of pre-market approval for high-risk medical devices demanded in the US.

- EU-wide and national provisions governing the **safety and health of workers** must remain outside the scope of negotiations.
 - **Product standards** must continue to support the legislation consistently and without contradiction, thereby avoiding distortions in competition and contributing to the high level of safety called for in the EU.
 - Closer relations between the EU and the US regarding **conformity assessment of products** do not require mutual recognition, rather common principles and technical harmonisation.
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The key issues in detail:

1. Public services

ESIP is concerned about the impact that TTIP and further liberalisation of public services could have on national social security systems and the benefits and services funded and delivered by the competent institutions in this context. Above all, we recall that in the field of trade in social, education and health services Article 207 4b of TFEU must be respected.

Although the mandate for negotiations contains an exemption clause based upon Article I.3 of the GATS, according to which certain public services are excluded from negotiations, the scope of the services delivered by public administrations and covered and protected by this article is not clearly defined. It is currently unclear whether statutory social insurance schemes as such and the services delivered or funded by the statutory social insurance institutions fall within the exemption clause. Firstly, the scope of Article I.3 (b) whereby "services supplied in the exercise of governmental authorities" are excluded from the GATS is defined very narrowly and covers only typical state functions. Secondly, Article I.3 (c) constrains the exemption further in that it covers only services that are supplied neither on a commercial basis, nor in competition with one or more service suppliers. In many social security systems it is difficult to say whether services are supplied on a commercial basis or in competition with one or more services suppliers, since it is not clearly defined what is meant by the terms "commercial basis" and "competition".

ESIP therefore calls for a precise formulation of the text over and above that of Article I.3. of the GATS that clearly and unambiguously excludes all kinds of social security systems and benefits funded and delivered by social security institutions, to be included in the *body text* of the agreement and that of the financial services and other relevant chapters of all trade agreements, including TTIP. Stand-still provisions and in particular ratchet clauses that leave social security systems, benefits and services open to potential future liberalisation are not acceptable.

2. Investment protection and Investor-to-State Dispute Settlement (ISDS)

The mandate for negotiations also covers investment protection and discussions have included the introduction of an Investor-to-State Dispute Settlement (ISDS) mechanism. This mechanism enables foreign investors to initiate international legal proceedings (including redress to an international arbitration tribunal) against national authorities when they believe the international rules on investment protection have been broken i.e. they have been treated differently as foreign investors compared to national investors. As a consequence of such mechanisms, public (health) policy objectives have been challenged in some countries (e.g. Philip Morris vs. Australia), forcing national governments to pay compensation to the amount of millions of dollars or encouraging them to open their markets to avoid potentially costly trials.

The consequences of introducing an ISDS mechanism applicable to national statutory social security systems could be far-reaching, as illustrated by the case above and the following cases: "Centurion Health vs. Canada", "Eli Lilly vs. Canada", "Achmea vs. Slovak Republic"¹. For example, to avoid possible compensation claims, national governments might forgo improvements in the social / health sectors or align existing measures with those applied elsewhere, reducing national standards to do so. In addition, institutions considered to have a monopoly in the area of statutory social insurance could be challenged. Private for-profit-social-insurers from the US could feasibly sue national governments of the EU in order to challenge national social protection systems regarding pricing and reimbursement measures or access to compulsory social protection services provided by public entities or private organisations carrying out these activities on behalf of Member States.

ESIP argues that in the case of the EU and the US sufficiently strong legal mechanisms are already in place to reassure foreign investors and that the ISDS mechanism is both unnecessary and potentially destabilising. As such ISDS should be excluded from the TTIP negotiations.

3. Health related aspects

3.1. Pharmaceuticals

When considering possible further convergence between the regulatory systems governing pharmaceuticals in the US and the EU, ESIP stresses the need to retain the highest standards. In our view current EU procedures ensure a higher level of patient safety which has been achieved steadily through a series of improvements to legislation over the last 10 years.

The process of **market authorisation** of medicinal products and the decisions taken by the European Medicines Agency (EMA) in the EU and the FDA in the US are and should remain independent. While mutual recognition of market authorisation should not be allowed, the unrestricted exchange of clinical data between the competent authorities can contribute to greater patient safety and should be supported.

Issues of **pricing and reimbursement** fall within the competence of the Member States and should not be subject to discussion under the TTIP. The national health systems need to

¹ See: http://www.esip.eu/files/TOP%20ISDS%20in%20health%20care%20_Eisenbarth.pdf

maintain their control over the pricing and reimbursement of pharmaceuticals and the instruments of value control such as the assessment of the benefits of new drugs and negotiated agreements.

While the U.S. allows **direct-to-consumer pharmaceutical advertising**, advertising of prescription-only medicines directly to consumers is prohibited in the EU. This constraint has been reaffirmed during the debates surrounding proposals put forward in 2008 by the European Commission to amend EU legislation governing information to patients on prescription medicines which it was forced to abandon. While patient empowerment requires that patients have access to high-quality, objective and independent information direct-to-consumer advertising of prescription-only medicines must be excluded from discussion under the TTIP.

Complete transparency and full access to **clinical trial data** is crucial to ensure the safety and efficacy of pharmaceuticals and to assess their therapeutic added-value (an important element of evidence-based medicine). "Commercial confidentiality" is often misused to prevent the publication of important trial data. In the EU, transparency of the approval, conduct and publication of detailed clinical trials data has recently been improved through new legislation (Regulation (EU) No. 536/2014) which entered into force earlier this year. The provisions of this new Regulation should not be undermined by the TTIP negotiations.

Likewise, recently adopted EU provisions aimed at combatting **falsified medicines** (Directive 2011/EU/62 and implementing Regulation (EU) No. 699/2014, which entered into force in July this year) as well as national rules governing Internet sales of pharmaceuticals should not be jeopardised.

3.2. Intellectual property rights

According to reports, the US seeks to impose medical procedure patents on other countries. Currently the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)² allows members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals. In this context, the conditions of the TRIPS should be upheld.

Strengthening intellectual property rights for pharmaceuticals (by increasing the scope or length of patents and data exclusivity) would lead to increased costs for health care systems and reduced access to medicines for patients. Access of patients to innovative treatments depends on the early introduction and wider use of generic drugs and biosimilars which provide affordable health care for all. Extended patent protection delays and discourages the entry of generics and biosimilars onto the market and should not therefore be supported. In addition, the right to use the International Non-proprietary Name (INN) for biological products should be guaranteed.

3.3. Medical Devices

In seeking better regulatory compatibility in the medical devices sector the TTIP negotiations offer a number of opportunities to improve the level of European patient safety, in particular in view of regulations governing market access and surveillance.

² Negotiated by the World Trade Organisation (WTO) and signed 1994.

Various scandals have shown the failures and limits of the European certification system for medical devices; devices that were refused approval by the U.S. Food and Drug Administration (FDA) were first marketed in Europe and then later withdrawn as safety issues became apparent. ESIP believes that superior standards for the pre-market approval of high-risk medical devices, such as those applied by the FDA, should be adopted in Europe.

In view of facilitating surveillance, greater transparency should be applied to important data on safety and efficacy, as well as information about requirements and restrictions in cases of identified potential risk as is the case in the US. Finally, adoption of a globally recognised unique device identification system (UDI) would ensure the traceability of implanted medical devices in cases of serious incidents.

4. Occupational health and safety at work related aspects

4.1. Safety and health of workers at work

Occupational health and safety is regulated in the EU Member States subject to Article 153 of the TFEU essentially by transposition of the relevant EU Directives into national law. These Directives constitute a minimum standard for occupational safety and health throughout the EU that is democratically legitimised and unique in the world.

Should provisions e.g. under the EU OSH Framework Directive governing the safety and health of workers at work be aligned with those of the US, we could expect standards to be reduced to the lowest common denominator. In addition, the role of national and regional governments and in particular the social partners in defining the content of provisions governing the safety and health of workers at work is unlikely to be respected. Consequently, not only would the level of safety and health of workers probably be reduced, but the provisions governing their safety would be less relevant to the field and would no longer meet with acceptance within companies.

ESIP demands that it is clearly stated in TTIP that EU-wide and national provisions governing the safety and health of workers at work are not subject to negotiation, nor do they constitute grounds for lawsuits in ISDS.

4.2. Technical harmonisation

According to the EU mandate harmonisation of technical product standards and conformity assessment procedures will be subject to negotiations as they are regarded as technical barriers to trade.

European and international standards very often constitute the basis for safe and healthy work equipment and personal protective equipment. They have a major role to play in preventing occupational accidents and diseases. Since work on product standardisations is increasingly being conducted at international level, ESIP considers that ISO/IEC standards represent a sound basis for agreements reached within the TTIP. Mutual recognition of European and US statutory provisions, standards and specifications is not acceptable or feasible (demonstrating equivalence of safety standards is extremely difficult and may not even be sufficient due to the different underlying concepts in the EU and the US).

The close relationship between European legislation and standardisation needs to be respected: the legislation sets out essential health and safety requirements (for machinery, electrical products, pressure equipment) which together with the (voluntary) application of standards, especially harmonised standards, provides to satisfy the essential health and safety requirements set out in the Single Market directives.

ESIP therefore expects the high level of safety demanded by the EU Treaties to be observed in the trade of products. At the same time, standards must continue to support the essential health and safety requirements of the EU Single Market directives under the rules of the new Legislative Framework³. Further, bilateral documents formulating safety requirements must be drawn up in accordance with the principle of consensus.

4.3. Conformity assessment

The EU's mandate to negotiate an agreement on conformity assessment calls for onerous testing and certification requirements to be reduced and for confidence in the respective opposite party's conformity assessment bodies to be enhanced. Testing and certification requirements are nevertheless indispensable for products presenting a risk.

In this context we highlight the importance of independent testing and independent certification bodies. Many products submitted for testing fail to satisfy essential health and safety requirements when tested for the first time. Conformity assessment performed by independent bodies serves to identify non-compliant products and prevent them from being placed on the market thus supporting fair competition, increasing purchasers' confidence in the products, and easing the burden on market surveillance authorities.

In order to align conformity assessment procedures in the EU and the US, a common base must be established (including accreditation and monitoring of bodies; joint application and further development of methods for testing and for interpretation of product requirements). Simple mutual recognition of existing conformity assessment bodies is not acceptable.

Conformity assessment procedures are based on product requirements and methods of testing as defined in the legislation and standards. Lack of alignment in technical specifications is an obstacle to alignment in conformity assessment: different requirements or test methods not only lead to different results, but also prevent fair competition between manufacturers and between conformity assessment bodies.

³ Adopted in July 2008, the New Legislative Framework (NLF) updated the New Approach by three texts: Regulation (EC) 764/2008 on the free circulation of products in the non harmonised area, Regulation (EC) 765/2008 on the accreditation of conformity assessment bodies and on the organisation of market surveillance and Decision 2008/768/EC on general principles that the Parliament and Council should follow in the future for legislation covering the free circulation of products (definitions, rights and obligations of the various players, and conformity assessment modules)
