Joint response to the public consultation on investment protection and ISDS in TTIP

Brussels, 11 July, 2014

The inclusion of investor-to-state dispute settlement (ISDS) in Transatlantic Trade and Investment Partnership (TTIP) would undermine public health

1. INTRODUCTION

In July 2013, the European Commission began negotiating a free trade agreement with the United States (US), called the "Transatlantic Trade and Investment Partnership" (TTIP). The agreement includes provisions on the controverted 'investment protection' and 'investor-to-state dispute settlement' (ISDS).

At the end of March, 2014, following growing opposition from civil society and members of national and European parliaments about the potential inclusion of ISDS in TTIP, the European Commission launched a public consultation to establish "a possible approach to investment protection and ISDS in the TTIP" that would attempt to strike "the right balance between protecting investors and safeguarding the European Union's right and ability to regulate in the public interest," and keep ISDS within the proposed agreement.

Health Action International (HAI) Europe, the Commons Network, Knowledge Ecology International (KEI) Europe, Health GAP (Global Access Project), Salud por Derecho, the International Society of Drug Bulletins (ISDB), the Medicines in Europe Forum (MiEF) and Universities Allied for Essential Medicines (UAEM) welcome the opportunity to submit a response to this consultation. We believe, however, that this consultation, which aims to *improve* ISDS, is asking the wrong questions. ISDS cannot be improved. The real question is whether ISDS should be included in TTIP at all. The answer, very simply, is no.

Our key concern is that ISDS will have a negative impact on public health, especially for long-term, sustainable access to medicines in Europe and, in turn, low-and middle-income countries. By default, the inclusion of ISDS in TTIP will set a new global standard for other trade agreements.

Despite our view that this flawed consultation is not asking the right questions, we offer commentary on several sections to illustrate the problems that ISDS presents for public health and demonstrate that the proposed adjustments do not adequately address these concerns.

Moreover, this consultation does not eliminate our concerns about TTIP, in general, and the undemocratic nature by which this agreement is being developed and negotiated. For more information on this, please refer to our previous statement.

2. CONCERNS ABOUT THE INCLUSION OF ISDS IN TTIP

A. ISDS is neither needed, nor justified, in TTIP

According to the European Commission's definition, ISDS is a procedural mechanism in international agreements on investment that allow an investor from one country to bring a case directly against the country in which they have invested before an arbitration tribunal.

ISDS therefore allows companies to challenge legislative and administrative measures—even judicial decisions taken by EU Member States to safeguard public health and other public interest concerns. By using ISDS, companies are allowed to seek compensation for the benefits that they cannot make due to these public interest protection measures. In short, companies can ask to receive financial compensation because of anticipated harms to speculative expectations to future profits.

ISDS fundamentally changes the power balance between companies and states. The ISDS mechanism elevates companies and investors to a higher legal standing than states, since states are not permitted to take investors to arbitration. In contrast, foreign investors may challenge states before private arbiters.[i]

Moreover, the system does not allow a judicial oversight since decisions on the interpretation of ISDS and potential conflicting principles of law are taken by three arbitrators outside the judicial system. This process is especially threatening for the democratic legal system as there is no prospect of judicial review by an independent court since decisions are final and binding on countries. In short, ISDS fundamentally changes the power balance between companies and states. The dynamics of ISDS create pressure on policy space and human rights, and there is a serious risk of a one-sided decision-making process that leads to inequitable outcomes with no legislative feedback loop, leaving the system without corrective, majoritarian input.

We therefore strongly oppose the position that ISDS should be part of TTIP, or any other trade agreement, as have numerous multi-sectorial stakeholders from around the world, including trade unions and academics. We also request the exclusion of vague concepts such as 'expectation of gain or profit' and 'the assumption of risks' from the scope of the definition.

Furthermore, the EU and US have well-developed administrative and judicial systems and there is no evidence of systemic deficiencies in either system that would justify the need for ISDS. Moreover, international commitments by the US to EU investors can be enforced in US courts and even confer a right of action to individuals[ii].

In addition, academic evidence suggests that the inclusion of ISDS would, on balance, not be advantageous for the EU[iii]. There is indeed significant potential for harm in allowing foreign investors to bypass domestic courts, including their appeal systems, and in allowing them to assert rights and seek remedies beyond those allowed in national law, including those enshrined in national constitutions. Treaty-based arbitration rights extend rights to foreign investors well beyond the rights of competing domestic investors[iv]. According to a study from the London School of Economics, "The content of international investment law remains contested and uncertain, and it is possible that an

ISDS tribunal formed under an EU-US investment chapter would grant a US investor significant damages for conduct that would normally be actionable under domestic law."[v]

At the European level, the European Parliament has passed a resolution[vi] calling for reforms to the investment dispute settlement process, including a requirement that foreign investors exhaust domestic legal remedies before bringing an investor-state claim. This recommendation, however, is not in the Commission's proposal.

Lessons should be learned from experience in third countries. Numerous EU and third countries, including Germany, France, Indonesia, Australia, Japan, South Africa, Brazil, as well as many countries in South America, have already expressed their opposition to ISDS[vii]. These objections are based on experience gained about the use of this mechanism by companies that have been particularly detrimental in the field of public health. Several countries, such as Bolivia, Ecuador, Venezuela and South Africa, have gone so far as to withdraw from existing ISDS investment agreements.

B. Public health will be jeopardised if ISDS is included in TTIP

ISDS includes intellectual property (IP) in the definition of 'investment'. Using ISDS, US pharmaceutical companies could sue any EU Member State, arguing that the government's measures to promote access to medicines (such as price controls, reimbursement decisions, marketing approvals and pharmacovigilance decisions, or stricter patentability standards) will damage their investments protected by IP rights in the EU.

The potential for US pharmaceutical companies that invest in the EU to use this form of arbitration against EU Member States and challenge pro-public health measures is evident from recent challenges by major US, Canadian and French companies that have led to a number of arbitration decisions under ISDS provisions in investment treaties[viii].

In this context, we anticipate that US pharmaceutical companies could harm public health policies in four ways by:

i. Damaging EU Member States' public health policies to protect affordable access to medicines by claiming that a government's health regulations undermine enjoyment of their IP-related 'investments'.

As a reminder, the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), adopted in 1994, mandated global IP rules, including a minimum 20-year patent term for medicines. It was a major victory for rich countries and the pharmaceutical industry, representing the single-greatest expansion of IP protection in history. Both the EU and US have adopted a standard of IP protection and enforcement that goes well beyond the 20 years mandated by TRIPS, including monopoly protections on regulatory data that impede or prevent regulatory approvals of generic equivalents and patent term extensions[ix].

ISDS, as proposed by the EU and US, includes IP in the definition of 'investment', drawing on multiple sources of IP rights, including many that are TRIPS-plus[x]. Accordingly, investment clauses incorporating IP investor and investment rights can greatly expand the scope of substantive protections, and ISDS adds yet another remedy beyond private enforcement, border measures, criminal prosecutions, and state-to-state dispute resolution. ISDS therefore adds yet another, and unnecessary, means of strengthening and enforcing IP rights for pharmaceutical companies.

Two examples are particularly instructive:

Example 1:
Foreign pharmaceutical companies have started to use ISDS to challenge decisions to grant, deny or withdraw patent applications or other forms of IP protection on medical technologies.

The Eli Lilly case against Canada clearly demonstrates that a pharmaceutical company can challenge states' routine patent validity decisions under ISDS pursuant to investor rights in a free trade agreement. In 2013, the US-based company, Eli Lilly, accused Canada of violating its obligations to foreign investors under the North American Free Trade Agreement (NAFTA) by allowing its courts to invalidate patents for two of its drugs based on a lack of proof of their ineffectiveness in relation to what was promised in the patent application. Eli Lilly is claiming indirect (regulatory) expropriation and a violation of minimum standards of treatment and is demanding $500 million in compensation for the invalidation of two patents, as well as challenging Canada's legal doctrine for determining a patent's validity[xi].

An important point is that Canada's highest courts had refused Eli Lilly's patent claims. The company lost its invalidation appeal at the Appeal Court level, and the Supreme Court of Canada has declined to hear its further appeal. Eli Lilly's claim at a North American Free Trade Agreement (NAFTA) panel is therefore an attempt to appeal a decision of the highest courts and to use the ISDS system to get around binding judicial precedent. The Canadian government is consequently insisting in the Comprehensive Trade and Investment Agreement (CETA) talks with the EU that IP protections be circumscribed in an effort to avoid similar challenges of the courts' authority in future disputes.

It has been reported that negotiations are currently stuck as a result of Canada's request to exclude certain IP policies from the scope of the ISDS mechanism. Europe will face similar challenges of its laws and regulations by Canadian and US investors if CETA and TTIP investor rights provisions proceed as contemplated.

Example 2:
ISDS might be used to challenge legitimate use of TRIPS flexibilities. In 2001, the WTO ministerial conference adopted the Doha Declaration on TRIPS and Public Health. It affirms that WTO rules on IP should not prevent countries from taking measures to protect public health.[xii] Such measures are known as 'TRIPS flexibilities'[xiii] (such as transition periods, compulsory licensing, government use, strict standards of patentability, exceptions and limitations to patents).

For example, low-and middle-income countries, like Thailand, Brazil, Ecuador, Indonesia, and India, as well as many sub-Saharan countries, including least-developed countries, have effectively used TRIPS flexibilities to issue compulsory government-use licences and extend the grant and/or enforcement of medicine patents to gain access to generic medicines and reduce medicine prices[xiv]. The EU has also implemented paragraph 6 of the Doha Declaration, which allows production for export of medicines under a compulsory license to developing and least-developed countries that lack production capacity. Millions of people living with HIV/AIDS are alive today because they can access cheaper medicines through generic competition.[xv]

In its consultation document, the European Commission proposes to exclude one specific TRIPS flexibility—compulsory licensing—from the scope of ISDS, but it is not a sufficient safeguard. That exclusion is vaguely defined and does not take into account that Member States may use other legitimate TRIPS flexibilities (e.g., strict standards of patentability, exceptions and limitations to

patents) to ensure access to medicines for all. Moreover, the exclusion does not cover other limitations and exceptions to other IP rights. Instead, overly broad interpretations of fair and equitable treatment (FET), indirect expropriation, or national treatment and most favoured nation status can be interpreted to protect almost any alleged IP-based expectation of profit so long as IP rights are included in the definition of investment.[xvi]

ii. Challenging EU Member States' or regulatory bodies' decisions on marketing authorisation, pricing, reimbursement and medicines data transparency

We are also very concerned that ISDS can challenge EU Member States' or regulatory bodies' decisions on marketing authorisations, pricing and reimbursement of medicines and data transparency.

The Apotex case is demonstrative of challenges made to a governmental decision on marketing authorisation. Apotex, a Canadian generic pharmaceutical corporation, has previously alleged that US courts wrongly interpreted federal law, and that such errors violated the NAFTA's national requirement. Apotex claimed that it was subject to mistreatment by the US, its agencies (particularly the US Food and Drug Administration) and its federal courts in the course of the company's efforts to market generic versions of the antidepressant medicine, sertraline (Zoloft), and the anti-cholesterol medicine, pravastatin (Pravachol), in that country. Apotex asserted that the FDA treated other US investors and US-owned investments more favourably in not subjecting these other investors to a measure as severe as the import alert imposed on the Apotex products. The US objected to the jurisdiction of the NAFTA Tribunal on the grounds, *inter alia*, that Apotex did not qualify as an 'investor' that had made an 'investment' in the US for the purposes of NAFTA. The Tribunal ultimately dismissed all the claims and ordered Apotex to pay the legal fees and arbitral expenses of the US, but ISDS claims can still be used to challenge routine regulatory decisions.

Challenges to EU Member States' decisions on pricing and reimbursement are also concerning. New patented medicines introduced on the market are increasingly expensive, and the rise in expenditure on patented medicines outpaces savings brought through the use of generics.[xvii] At the beginning of the 21st century, affordability of treatment became a problem, even in developed countries, especially for serious conditions such as cancer.

To date, EU Member States have exclusive competence to determine and negotiate the price and extent of reimbursement of (new) medicines. The organisation of their health system is, in fact, a national prerogative and the subsidiarity principle applies. Member States can use their competence to negotiate a price and design a reimbursement scheme and procurement practices that best meets their citizens' public health needs. For example, they can use this competence to impose price cuts and/or fixed price and reimbursement decisions based on the added therapeutic value of new drugs compared to existing medicines in the market.[xviii]

Through TTIP, the Pharmaceutical Research and Manufacturers of America (PhRMA) is putting pressure for limiting the influence of European health technology assessment bodies. PhRMA requires "that in the framework of pricing and reimbursement decisions, countries shall not duplicate the assessment conducted by regulatory agencies for market approval purposes"[xix].

The subsidiarity of Member States may be seriously jeopardised since ISDS can be used to challenge, for instance, recent policies where Member States have cut medicine prices when faced with the need to cut public spending in times of austerity.[xx] These challenges are

particularly likely when a country adopts new measures that frustrate companies' expectations of being able to impose monopoly prices. Pharmaceutical companies' submissions to the Office of the US Trade Representative (USTR) in the context of the Special 301 consultations[xxi] show that these concerns are real.

iii. Challenging new EU transparency requirements and expanding pharmaceutical control over clinical data

Despite the adoption of a new regulation on clinical trials to improve transparency in the EU in April 2014[xxii], the pharmaceutical industry continues to strongly oppose mandatory public disclosure of detailed clinical trial results.

Two US pharmaceutical companies have sued the European Medicines Agency over its decision to grant access to clinical trial data on one of their medicines[xxiii]. Despite being a public good[xxiv], the industry claims that clinical trial data is commercially confidential—even a trade secret—and requires the "establish[ment of a] harmoni[s]ed list of clinical trial result data fields and agree[ment] on which may be disclosed to the public (uniform protection of confidential commercial info and trade secrets)."[xxv]

If implemented, ISDS will most likely enable companies to sue governments against their decision to grant public access to clinical trial data undermining the protection of public health.

iv. Challenging other public health-related measures implemented by EU Member States

Health is a fundamental human right, which governments have the obligation to fulfil. ISDS can, however, challenge public health-related measures implemented by EU Member States.

As an example, in Achmea v. the Slovak Republic in 2012, the Dutch health insurer sued the Slovak Republic under a bilateral investment treaty and was awarded €22 million in compensation from Slovakia. Slovakia was, indeed, punished for reversing its health privatisation policy.[xxvi]

More recently, at the 67th World Health Assembly in Geneva in May, 2014, Professor David Price of Queen Mary University suggested that national policies, such as planning the number of hospital beds, might be removed under pressure of TTIP, with the aim of increasing competition for health service providers and attracting foreign investment[xxvii].

C. Other concerns not addressed by the consultation

We underline two additional concerns:

First, the most-favoured nation (MNF) provision is missing from the consultation text. MFN provisions create the possibility for foreign investors to shop for stronger forms of investor rights by using or establishing a subsidiary company. This enables them to claim greater rights than are provided under the free trade agreement and bilateral investment treaty agreed to by the US and EU. This loophole could lead to an even larger and more tangled web of excessive international investor protections where investors could pick the most advantageous standards. Those could include dispute settlement mechanisms that bypass obligations to seek a remedy through the domestic courts. As a newly revealed danger, if other agreements provided for non-violation complaints because unanticipated government action violated the spirit but not the letter of that agreement's IP protections, foreign companies could bring an amorphous non-violation complaint as well.

It should also be noted that this provision will not only apply to any other bilateral treaty already in force, but also for US and Canadian investors through NAFTA and its jurisprudence.

Secondly, ISDS intends to become a global standard that will apply to other trade agreements all over the world. We should not forget that the EU has been a frontrunner in increasing IP enforcement standards.[xxviii] Similar concerns about ISDS therefore apply to EU free trade agreements with other countries, including those with Thailand, Myanmar, and China.

3. CONCLUSION

Including ISDS in TTIP is unnecessary and unjustified. Its clauses pose an enormous risk to public health objectives and, in particular, to ensuring access to affordable medicines.

ISDS can, in fact:

- Force the development of an unnecessary and potentially abusive arbitration system lacking democratic control when well-developed legal and court systems already exist in both the EU and US.
- Further strengthen the level of IP protection enjoyed by the pharmaceutical industry by providing a means for them to challenge EU Member States' or regulatory bodies' use of legitimate TRIPS flexibilities (e.g., patent reform, compulsory licensing).
- Provide the pharmaceutical industry with a means to challenge EU Member States' marketing authorisation, pricing and reimbursement and procurement policies. This will jeopardise the freedom of Member States to tailor these policies to ensure long-term, sustainable access to affordable medicines for their citizens.
- Potentially lose public policy space that governments need for addressing increasing domestic and global health threats.
- Have a chilling effect on the possibility of adopting measures necessary to protect public health and ensure affordable access to medicines without fearing costly legal battles.

We therefore strongly oppose the inclusion of ISDS provisions in the TTIP and urge the European Commission to refrain from leading the EU down this dangerous path, which will jeopardise public health. We also request that IP be completely excluded from the definition of 'investment' in TTIP and any trade agreement.

Further information is available from the co-signatory organisations:

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ANNEX 1: ONLINE RESPONSES TO CONSULTATION QUESTIONS

(NOTE: Only the five first questions were deemed pertinent to answer)

Question 1: Scope of the substantive investment protection provisions

Based on the fact that the definition of 'investment' in free trade agreements and bilateral investment treaties is much broader than the real property rights and other specific interests in property that are typically protected under domestic property rights law, including IP rights, we have serious concerns that the definition of investment will be similar in TTIP.

An excessively broad definition will allow expansive interpretation by arbitrators, including the inclusion of all kinds of IP rights. By defining investments as "every kind of asset having an economic value," pharmaceutical companies may file claims arising from investments that are based purely on their IP rights, marketing approvals, licensing agreements, import permits, and other contracts in the foreign jurisdiction at issue independent of the real benefit of the product for the patient.

An overly broad definition of investments will therefore allow companies to undermine national public health policies used to ensure affordable access to medicines by claiming that a government's health regulations detract from the enjoyment of their IP-related 'investments' by: Challenging decisions to grant, deny or withdraw patent applications or other forms of IP protection on medical technologies and challenging the legitimate use of TRIPS flexibilities. (See above)

We strongly recommend that IP be totally excluded from the definition of 'investment' in TTIP and any trade agreement. We also request the exclusion of the vague concepts such as 'expectation of gain or profit' and 'the assumption of risks' from the scope of the definition.

Question 2: Non-discriminatory treatment for investors

The right of governments to introduce policies that protect public health must be safeguarded because it constitutes a necessary mechanism in meeting their 'duty of care' to citizens. In some cases, discrimination against certain investors may be necessary to achieve public health goals. In other words, non-discriminatory treatment of investors is not a principle that serves public health goals and should not take priority over public health.

Moreover, vaguely worded provisions that guarantee foreign investors a 'minimum standard of treatment', including fair and equitable treatment, open the door to investor-state claims over a wide range of government measures that are otherwise permissible under nations' constitutions and legal systems. Furthermore, companies will not only be able to use the substantive investment protection provisions in TTIP, but can cherry-pick protection from any other investment agreement that the EU or EU Member States signed or will be signing.

The interpretation of non-discriminatory treatment of investors could result in tribunal orders to compensate foreign firms for public health interest policies that appear to be neutral, but that have an inadvertent, disproportionate impact on foreign investors. Moreover, the burden of proof lies on governments rather than investors to justify their actions.

Furthermore, the non-discriminatory treatment will allow investors to challenge other public health-related measures implemented by EU Member States. (See above)

Question 3: Fair and equitable treatment

Introducing a broad basis for protecting the legitimate expectations of an investor adds increased uncertainty and subjectivity to investment arbitrations. Besides, this provision will be extensively interpreted outside domestic courts by tribunals that are not accountable to democratic jurisdictions.

The concept of fair and equitable treatment (FET) may also cover administrative due process and the denial of justice by domestic courts, which are crucial to pharmaceutical companies. They are subject to numerous administrative decisions in order to be able to successfully register their IP rights and have their products approved for sale and distribution, and for pricing and reimbursement[xxix].

As an example, the Apotex case illustrates how a governmental decision on marketing authorisation of generic drug products can be challenged under ISDS. Apotex Inc., a Canadian generic pharmaceutical corporation, has previously alleged that US courts wrongly interpreted federal law, violating NAFTA, based on national treatment. Apotex claimed that it was subject to mistreatment by the US, its agencies (particularly the US Food and Drug Administration) and its federal courts in the course of the company's efforts to bring generic versions of the antidepressant medicine, Zoloft (sertraline), and the anti-cholesterol medicine, Pravachol (pravastatin), to market in that country. Apotex alleged that the FDA accorded more favourable treatment to other US investors and US-owned investments, in that these other investors were not subjected to a measure as severe as the import alert imposed on the Apotex products. The US objected to the jurisdiction of the NAFTA Tribunal on the grounds that, *inter alia*, for the purposes of NAFTA, Apotex did not qualify as an 'investor' that had made an 'investment' in the US. Even though the Tribunal ultimately dismissed all the claims and ordered Apotex to pay the legal fees and arbitral expenses of the US, ISDS claims can still be used to challenge routine regulatory decisions. (See above)

In addition, the proposed text includes two highly problematic provisions that replicate the flaws in prior pacts. First, the list defining FET includes "manifest arbitrariness" as a qualifying criterion. Meanwhile, it defines other criteria in the list more precisely (e.g., "targeted discrimination on manifestly wrongful grounds, such as gender, race or religious belief"); "manifest arbitrariness" is a more open-ended term that tribunals could interpret widely to rule against domestic measures taken in the public interest.

Furthermore, the European Commission's suggestion to allow tribunals to consider an investor's "legitimate expectation" threatens to expose EU member countries to investor-state claims made against policy reforms enacted in the public interest. While the proposal ties the consideration of legitimate expectations to instances in which "a Party made a specific representation to an investor to induce a covered investment," this qualifier is not likely to be sufficient to foreclose the risk to progressive policymaking.

Question 4: (Indirect) expropriation

While the definition of direct expropriation has traditionally been relatively clear, the evolving understanding of indirect expropriation leaves significant flexibility for companies to challenge national regulations by using investment treaty provisions.

Indirect expropriation can be interpreted to mean regulations and other government actions that reduce the value of a foreign investment. Governments can be required to pay compensation based on the impact of the government measure on the value of the investment regardless of whether the measure is essential to protecting public health. While international arbitration tribunals cannot force a government to repeal regulations, the threat of massive damages awards can have a 'chilling effect' on policy-making.

We acknowledge the exception to this provision made for measures to protect legitimate public welfare objectives, but have serious concerns that interpretation of this exception and its application will be left to the discretion of three private sector lawyers with general expertise in investment, not public welfare. It would be inappropriate for them to decide what legitimate public welfare objectives are and whether measures are "manifestly excessive". Thus, they may decide, for instance, that reforming patent law to impose stricter standards of patentability or to allow opposition procedures or to disallow patent term extension will fall outside the scope of a legitimate public policy. Moreover, the definition of legitimate policy and where the burden of proof lies is insufficiently addressed.

Furthermore, arbitrators' rulings are also notoriously inconsistent and unpredictable; therefore, leaving public welfare in their hands poses a real threat. The international tribunals that currently determine investor-state claims lack public accountability, standards, judicial ethics rules and appeals processes.

Almost any law or regulatory measure can be considered as 'indirect expropriation' when it has the effect of lowering future expected profit. Both the Eli Lilly and Apotex cases illustrate this.

Finally, the growing use of ISDS by investors on the grounds of expropriation deters other governments that may consider ambitious regulation in the area of public health protection. If challenged under ISDS, states are forced to spend significant amounts of time and resources defending their regulatory autonomy which can result in the adoption of a wait-and-see approach to public health for fear of resource-draining litigation.

Question 5: Ensuring the right to regulate and investment protection

The "right to regulate" is a basic attribute of sovereignty under international law. It is specifically designed to protect public interest ahead of other interests. TTIP and ISDS provisions should not, in any way, directly or indirectly, restrict the right to regulate. It is the inherent right of the state and not a right granted in the agreement.

ISDS procedures are time-consuming, complex and expensive, even if a state wins a case. Whenever any public health-related proposal is made in the future, multinational companies will be able to threaten to file a complaint under ISDS. Making this possible could have a chilling effect that will prevent measures from being proposed and would generate a strong lobbying tool for multinationals to intimidate democratically-elected lawmakers to legislate in the interests of companies instead of citizens.

The preamble, which is non-binding, limits the right to regulate to "legitimate" objectives. This is an unacceptable limitation. The agreement should include a substantive paragraph that restates the inherent right to regulate. A vague term such as 'legitimate objectives' to define exceptions to this right creates legal uncertainty and is unacceptable.

To date, EU Member States have exclusive competence to determine and negotiate the price and extent of reimbursement of (new) medicines. The organisation of their health system is, in fact, a national prerogative and the subsidiarity principle applies. Member States can use their competence to negotiate a price and design a reimbursement scheme and procurement practices that best meet their citizens' public health needs. For example, they can use this competence to impose price cuts and/or fixed price and reimbursement decisions based on the added therapeutic value of the new drugs compared to existing medicines in the market.[xxx]

Governments also have the right to increase transparency of medicines safety and efficacy data. Under the new clinical trials regulation, clinical study reports submitted for marketing authorisation to drug regulatory agencies must be made publicly available. Despite the many benefits to public health that clinical trial data

transparency brings, the pharmaceutical industry keeps claiming that this information is commercially confidential and cannot publicly disclosed. Taking into account industry's position, governments will most likely end up being challenged under ISDS for their decision to disclose this information. In fact, the European Medicines Agency has already been sued for this very same reason.

[i] Kelsey and Wallach, "'Investor-State' Disputes in Trade Pacts Threaten Fundamental Principles of National Judicial Systems", April 2012
[ii] LSE, Professor Jan Kleinheisterkamp "Is there a Need for Investor-State Arbitration in the TTIP ?, 14 February 2014
[iii] L.Poulsen, J.Bonnitcha, J.W.Jackee, 'Costs and Benefits of an EU-USA Investment Protection Treaty', April 2013 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/260380/bis-13-1284-costs-and-benefits-of-an-eu-usa-investment-protection-treaty.pdf

[iv] IISD Report February 2014 – A Response to the European Commission's December 2013 Document "Investment Provisions in the EU-Canada Free Trade Agreement (CETA)" + LSE paper Kleinheisterkamp
[v] I SE study on costs and benefits of an EU-USA investment treaty, p.27
[vi] European Parliament resolution of 6 April 2011 on the future European international investment policy

[vii] Corporate Europe Observatory et the Transnational Institute "Profiting from injustice - How law firms, arbitrators and financiers are fuelling an investment arbitration boom" Rapport ; November 2012 , p. 76

[viii] Global Arbitration Review online news, 6 September 2013 – Pharmaceuticals: a new frontier in investment treaty arbitration
[ix] European Commission – Directorate General Competition "Pharmaceutical Sector Inquiry - Final Report" 8 juillet 2009, point 553

[x] In recent years, many developing countries have been coming under pressure to enact or implement even tougher or more restrictive conditions in their patent laws than are required by the TRIPS Agreement – these are known as 'TRIPS plus' provisions. More details at: http://www.msfaccess.org/content/trips-trips-plus-and-doha

[xi] See Notice of Arbitration, available at http://www.italaw.com/sites/default/files/case-documents/italaw1582.pdf.
xii Doha Ministerial Declaration on the TRIPS Agreement and Public Health', WT/MIN(01)/DEC/W/2, 14 November 2001.
xiii Possibility of negative impacts pointed out by the European Parliament: Resolution on the future European international investment policyxiii (point 11): "insists that where intellectual property rights are included in the scope of the investment agreement, including these agreements where draft mandates have already been proposed, the provisions should avoid negatively impacting the production of generic medicines and must respect the TRIPS exceptions for public health."
[xiv] Compulsory licensing for public health is specifically permitted by TRIPS and reaffirmed in the 'Doha Ministerial Declaration on the TRIPS Agreement and Public Health', WT/MIN(01)/DEC/W/2, 14 November 2001. See also: Ellen 'Hoen (2009). The global politics of pharmaceutical monopoly power. AMB Publishers 2009, p. 44-59. Thailand has issued a series of white papers explaining the merits of compulsory licensing to expand health care in the country. See ICTSD (2007) 'Thailand responds to compulsory licensing critics', April 2007 at http://www.iprsonline.org/ictsd/news/bridges11-2.pg17.pdf

[xv] MSF (2013), Untangling the web of Antiretroviral Price Reductions, 15th edition http://www.msf.org/sites/msf.org/files/msf_access_utw_16th_edition_2013.pdf
[xvi] IISD analysis CETA text, p. 10
xvii Care One et all, cost containment measures in the EU p41-42
xviii This is important, because for example medicine bulletin Prescrire found that in 2010 out of 97 new medicines only 4 provided a new therapeutic advantage. Why spend public resources on reimbursing new expensive medicines that provide nothing new compared to what is already on the market?

[xix] PhRMA "Re: Request for Comments Concerning the Proposed Transatlantic Trade and Investment Partnership, 78 Fed. Reg. 19566 (Apr. 1, 2013)" Washington; 10 May 2014:14 pages.

[xx] Presentation Christine Leopold: http://www.epha.org/IMG/pdf/Christine_Leopold-Pharmaceutical_policy_measures_implemented_in_response_to_the_recession_in_Europe_2012-2013.pdf . Greece for example with more than 25% for all reimbursable medicines.

[xxi] The Special 301 Report is an annual review on the adequacy and effectiveness of U.S. trading partners' protection and enforcement of intellectual property rights (IPR) (more information at: http://www.ustr.gov/about-us)

[xxii] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC **(**available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.158.01.0001.01.ENG**)**

[xxiii] Health Action International (HAI) Europe, 'Protecting citizens' health: Transparency of clinical trial data on medicines in the EU'. October 2013. Available at: http://haieurope.org/wp-content/uploads/2013/10/HAI_Protecting-citizenshealth-transparency-of-clinical-trial-data-on-medicines-in-the-EU.pdf

[xxiv] Lemmens T "Access to pharmaceutical data, not data secrecy, is an Essential Component of Human Rights" 8 April 2014: 3 pages.
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[xxvii] At the 67th session of the World Health Assembly in Geneva, 20 May 2014, at the Palais des Nations
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xxx This is important, because for example medicine bulletin Prescrire found that in 2010 out of 97 new medicines only 4 provided a new therapeutic advantage. Why spend public resources on reimbursing new expensive medicines that provide nothing new compared to what is already on the market?