



TTIP and Affordable Medicines

How TTIP may obstruct progress towards
sustainable access to medicines

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I. Introduction

The Transatlantic Trade and Investment Partnership (TTIP) negotiations pose serious risks to Europeans' access to medicines and affordable healthcare. TTIP is likely to help entrench a broken medical innovation system rather than seize today's opportunities to advance medical innovation and affordable access to medicines for all.

Pharmaceutical corporations charge European Union (EU) Member States and the United States (U.S.) increasingly higher prices for medicines. EU Member States and the U.S. are facing a looming access to medicines crisis as they struggle to afford new, patented, high-priced medicines. At the same time, since the 1980s, no new truly valuable antibiotics have reached the market.¹ Despite stringent intellectual property (IP) rules and continued lengthening market monopolies, there has been a striking lack of medical innovation.²

EU Member States have therefore rightly questioned whether excessive IP rights and additional market monopolies, which are now at the disposal of the pharmaceutical industry, function well as drivers for pharmaceutical innovation in their 2016 Council Conclusions.³ The Dutch Health Minister leading these Conclusions has called for a new balance between IP protection and affordable and sustainable access to medicines, prioritizing the exploration of alternative research and development (R&D) models.⁴ Leading public health institutions, academics and the World Health Organization (WHO) have questioned the current monopoly-driven incentive model for biomedical innovation for more than a decade, while exploring alternatives that focus on sharing knowledge rather than granting market monopolies.⁵ Most recently, the UN High Level Panel on Access to Medicines has also called for investment in alternative models of innovation.⁶ At the same time, EU Member States are calling for more effective pricing and reimbursement strategies to counter pharmaceutical companies' monopoly pricing strategies and ensure sustainable access to medicines.

TTIP could impede change towards affordability, needs-driven innovation and alternative incentive structures. TTIP may add to existing monopoly protections for medicines; reinforce the current trend of industry claiming trade secret protection to limit access to crucial information on medicines' safety, efficacy and development; reign in the freedom of national governments to make decisions on pricing and reimbursement to ensure affordability; and establish global standards that are harmful for developing countries.

We will first discuss how the argument for strong monopoly protections as a driver for pharmaceutical innovation is seriously flawed. Then, based on key EU, U.S. and pharma position and proposal documents on TTIPⁱ, we critically assess how:

- TTIP may lock in or even expand monopolistic intellectual property rules.
- TTIP runs the risk of limiting public access to information about the medicines we take.
- TTIP may constrain a government's effective medicines pricing and reimbursement policies.
- TTIP could enable structural pharmaceutical industry mingling in domestic & EU medicines and IP policies.
- TTIP's standards would harm access to medicines in developing countries.

ⁱ EU positions on IP and Pharmaceuticals for TTIP; US and EU negotiating positions in recent other trade agreements including the Trans Pacific Partnership agreement (TPP); Pharmaceutical industry submissions filed to the EU and US for TTIP.

1. Needs-based and affordable R&D: what role for exclusive rights?

Moving towards open and collaborative forms of innovation

The past two decades have seen revolutionary changes in economic production, much of it stemming from new forms of collaboration in the creation and sharing of knowledge.⁷ Open and collaborative innovation is increasingly made possible by digital technologies.⁸ The sharing of data and the embrace of open innovation have spurred innovation in software, but also other fields, such as biomedical research and development (R&D). Examples include drug discovery and data sharing platforms, collaborative product development partnerships and the Medicines Patent Pool.⁹ In the development of urgently needed new antibiotics, open and collaborative innovation models are now generally championed as the way forward.¹⁰

The sharing of knowledge has brought significant economic and social benefits as knowledge goods have taken a central role in our wellbeing. Medical knowledge is a prime example. Given the low marginal costs of sharing knowledge today, policies should promote greater access to knowledge instead of using exclusive rights to limit access.

EU and U.S. assumptions on IP and economic growth

At the same time, EU and U.S. trade policies remain based on the assumption that our economic growth and wellbeing depend on a further strengthening of exclusive property rights. In its revised Strategy on the Protection and Enforcement of IP in Third Countries (July 2014), the European Commission set out its vision and plans for the management of its knowledge assets globally, and here it identifies IP as *'a key driver for growth and innovation'*.¹¹ Also, in the EU IP Position for TTIP,¹² the European Commission maintains IP is key and plans to agree with the U.S. on *'General principles stressing the importance of IP as a tool for innovation, growth and jobs.'*

Here, the European Commission based its position on a 2013 study on the contribution of IP to economic performance and employment in Europe. This study has been exposed as flawed by independent researchers, pointing to logical fallacies and methodological biases. Patents filed were taken as a direct measure of innovation without checking the quality of the patents. Also, the study showed no causal link between IP protection and claimed contributions to gross domestic product (GDP) and employment.¹³

In 2012, the U.S. Department of Commerce published a similar study on IP and the U.S. economy. According to the report, the number one IP-intensive industry in terms of employment is "grocery stores," with 2.5 million jobs.¹⁴ A recent study from George Mason University dismantles most of these claims. As seen with the grocery store example, jobs created in an IP-intensive industry (within the grocery store) should not be interpreted as economic benefits from stringent IP protection. Jobs within that industry may not be dependent on IP protection. Even if brand-name foods did not exist, grocery stores still would. With this in mind, the report urges U.S. policymakers to consider the impact that other incentives, including prizes, awards, assurance contracts, and donations for research, may have on innovation and job creation.

Key concerns with the current patent-driven biomedical innovation model

...relentless drive by pharma to charge higher prices

New medicines come at a huge cost to health systems and their percentage of total pharmaceutical expenditure has been rising.¹⁵ EU Member States are currently facing a looming access to medicines crisis as they struggle to afford new medicines with excessive price tags, such as for cancer and

hepatitis C.¹⁶ The current biomedical innovation model based on patent monopolies relies on high prices of the resulting medical technologies used by patients. In Europe, similar to the U.S., on top of the 20-year patent protection period, additional market exclusivity, data exclusivity, and supplementary protection certificates further delay price-lowering generic competition.

In the meantime, prices are set in a way that bears no relation to the cost of R&D or production, but rather according to the maximum of what we will pay to care for our sick, while the real costs of R&D remain unknown.¹⁷ The pharmaceutical industry is the most profitable in the world.¹⁸ Take, for example, prices for sofosbuvir, a medicine that is part of a 12-week treatment for hepatitis C. Although the cost of producing the medicine is US\$68–\$136, the company that holds the patent set the launch price at US\$84,000.¹⁹

“When new effective medicines emerge to safely treat serious and widespread diseases, it is vital to ensure that everyone who needs them can obtain them,” WHO Director-General, Dr. Margaret Chan said in May 2015.²⁰ With current medicine price tags, we will never reach this goal of universal access.

...while patents drive innovation towards markets that can pay

Patents are routinely taken as an indicator for innovation. Yet, many patents are defensive and designed to block innovation, or belong to patent trolls serving only to litigate, and never lead to anything new coming on the market. Research suggests patents on medicines are proving an expensive way for societies to stimulate innovation.²¹ The European Commission has also recognized that IP protection can, in fact, inhibit innovation because excessive patenting of both compounds and research tools hinders follow-on public and private research.²²

The current biomedical innovation model, based on patent monopolies, relies on high prices of the resulting medical technologies. Driven to seek markets that guarantee high prices and speedy recovery of assumed investment, originator companies have gradually shifted their focus from needs-driven innovation towards market-driven innovation, promotion, wide patenting, litigation against competitors and the development of “me too” medicines of little therapeutic advantage.

Despite continued strengthening of market exclusivities for pharmaceutical companies in Europe, there has been a striking lack of truly valuable medicines being brought to the market over the last decade. Independent drug bulletin *La Revue Prescrire* has rated new patented medicines that were brought onto the market from 2000-2013 and concluded that only 9% offer a therapeutic advantage as compared to existing products on the market.²³ At the same time, companies are pulling out of R&D for new antibiotics at a time when society most needs it and investment in neglected diseases is still poor.

This demonstrates how the industry’s use of the terms “innovation” and “innovative medicines” are misleading, for they do not necessarily refer to a drug that does something new or treats something differently, but simply to *any* new medicine on the market. More patent protection and additional market exclusivities serve this type of “innovation” where innovation comes to mean selling new medicines.²⁴ For medicines, true innovation should mean added therapeutic benefit compared to existing medicines on the market. Unfortunately, there are currently few incentives built into the institutional environment for adding therapeutic benefit.

...and the real costs of R&D remain unknown

Admittedly, biomedical research is costly and a great deal of investment is needed to bring a product to the market. Yet the real costs of R&D remain unknown and estimates by the industry and independent analysts vary greatly. Industry sometimes estimates the cost of developing a new medicine at more than a billion dollars.²⁵ But the Drugs for Neglected Diseases initiative (DNDi), a

non-profit organization that develops new medicines, has spent far less: €100–150 million (approximately U.S. \$113–\$169 million), to develop a new chemical entity.²⁶

Furthermore, we should not forget that large portions of the investment come from public sources through research at public universities and grants given by government programs. Increasingly, the public sector is also supporting late stage research.²⁷ The public also supports biomedical R&D through tax breaks and other incentives intended to spur development. All-in-all, approximately 80% of all funds for basic research for medicines and about 30-40% of all R&D for global health is publicly funded.²⁸ This means that, under the current innovation model, the public ends up paying multiple times for their medicines throughout the development phase and for the final monopoly price charged for the medicine.

Change is needed

The balance is lost: current incentives are not producing the health technologies required by society and act as a barrier for access to the products that it does produce. We have a historic opportunity to advance medical innovation and access at the same time through the use of proven and emerging policy solutions. Non-profit collaborative approaches have shown it is worthwhile to explore alternatives.²⁹ A recent mapping of the alternative biomedical R&D landscape surveys a wealth of alternative approaches to innovation.³⁰

Many leading voices in public health from the non-profit, corporate and governmental sectors, as well as the United National High Level Panel on Access to Medicines, call for new innovation models that embrace the principle of the delinkage as the way forward. De-linkage describes the idea that temporary monopolies and the associated high drug prices should not be used to fund pharmaceutical research and development, as well as a set of policy proposals that would replace monopolies and high prices with alternative incentives based upon cash rewards and expanded funding for research, drug development, and clinical trials through a combination of grants, contracts, tax credits, and other subsidies. Collectively, de-linkage would transform the business model of the pharmaceutical industry in order to expand access, improve outcomes and reduce costs.³¹

Health Action International, Commons Network and Public Citizen are concerned that TTIP would entrench the failed models of the past, which have produced limited medical breakthroughs while rationing access to care through excessive pricing. In addition, TTIP could restrain governments' abilities to mitigate the impact of resulting high prices through effective pricing and reimbursement strategies.

The EU and U.S. should explore and encourage alternatives to a patent-based system needed to stimulate therapeutically valuable innovation. Instead of locking in current practices, a different type of transatlantic cooperation could aim to unleash a more open and participatory R&D culture, the creation of public knowledge goods and pricing and reimbursement strategies that result in more affordable health systems.

2. TTIP may lock in, or even expand, intellectual property protection

Instead of moving toward the change that is needed, TTIP could add another layer of enforceability to existing IP rules on both sides of the Atlantic and block the path toward future cost-cutting reforms in domestic IP standards. Moreover, TTIP could strengthen monopoly protection periods for health technologies and further delay price-lowering generic competition. Pharmaceutical industry filings show that it is pushing for harmonized patentability standards across the Atlantic.

Although the EU has said that it aims to mostly confirm patent standards already in place in the U.S. and the EU, TTIP will add a layer of enforceability for these practices. Confirming or acknowledging current standards or practices by means of an international trade agreement will block the possibility to change these practices in the future.

Legal obligations for patentability standards in TTIP

European Commission position paper on IP:

- “Recalling established practices on patent procedures and patentability criteria including regarding secondary use or incremental innovation; interference of regulatory entities; provisional protection of patent applications.”³²

Pharma company submissions:

European Federation of Pharmaceutical Industries and Associations (EFPIA)³³

- Joint commitment to existing high-level standards of IP protection and enforcement and establishment of joint high-level IP principles.

Biotechnology Industry Organization (BIO)³⁴:

- “it is essential that TTIP encompass patentability provisions [...] that promote greater substantive harmonization between the EU and U.S.”
- “TTIP represents an opportunity [...] to establish a clear standard requiring broad patent eligibility for all inventions [...] including gene-based inventions, medical process inventions [...]” (p. 11)
- “important that TTIP sets a clear, high and harmonized standard establishing that ‘second medical use’ [...] and in vivo diagnostic and ‘method of treatment’ claims are protectable through patents.”

Pharmaceutical Research and Manufacturers of America (PhRMA)³⁵:

- “impose no limits on inventions, including improvement and selection inventions, beyond normal standards applied to determine patentability.” (p.9)

i) Differences in patentability standards

There are important differences between EU and U.S. patentability standards.³⁶ In several areas, the European Patent Convention (EPC) contains stricter patentability standards, while in other areas the U.S. has stricter standards. Strict patentability standards typically result in fewer patents and more generic competition. This is key for the affordability of medicines and promotion of innovation that provides added therapeutic benefits. Patentability criteria are not (entirely) harmonized across EU Member States, and in principle, the European Commission does not have the competence to negotiate this area of policy.³⁷ However, we have seen instances where in trade negotiations the EU has pursued provisions going beyond the EPC.³⁸ Furthermore, the agenda of the United States Trade Representative (USTR) and the pharmaceutical industry are not minor pressures, and intentions of the European Commission in terms of not changing EU IP standards do not preclude changes being made in the course of the negotiations.

Moreover, even if no harmonization of IP standards is pursued, creating mutual obligations on existing practices in TTIP is already problematic, as the following examples will explain.

ii) Secondary patenting allows for harmful evergreening practices

A key example is that the EU position paper on IP³⁹ refers to the need to confirm current practices on “secondary use or incremental innovation.” The U.S. trade negotiators pushed for the same in previous trade negotiations, most recently in the Trans-Pacific Partnership (TPP). Patenting on the basis of secondary use and incremental innovation already takes place in the U.S. and the EU. Although one could argue that valuable incremental innovation merits protection, there are important drawbacks of the procedure. For instance, the length of an additional patent awarded for such incremental innovation is 20 years, just like the original patent.

Extending IP monopolies by patenting for secondary use or incremental innovation allows for “evergreening”. Evergreening refers to the myriad ways in which companies use the law to extend their patent protection by making small changes to an existing medicine, such as new forms of release or new combinations, and using business strategies to maintain market share. Granting full protection for minor modifications results in keeping prices for medicines high much longer than is reasonable in terms of the public health gain offered.⁴⁰

Corporations file for additional defensive patents to thicken the protection around their original base patents. These additional patents rarely represent anything new or inventive in terms of science. Instead, their purpose is to prolong a company’s monopoly, and consequently, its ability to charge high prices for its drugs. Some drugs have dozens of secondary patents.⁴¹ Through evergreening, the patent system is structurally abused to retain high revenues on medicines for which the original patent protection has ended. Industry often refers to this as “lifecycle management”.

Adding another layer of enforceability through a trade agreement on existing practices in the EU and U.S. on secondary patenting will block the possibility to change these disputed IP practices in the future. For example, in India, minor variations to existing products are not considered inventive when there is no significant difference in its properties with regard to efficacy, which means that India does not allow for secondary patenting.⁴² The EU currently does not have this requirement. However, from a public health and cost-savings perspective, this would be a rational practice for the EU or individual Member States to adopt, because it would encourage generic competition, which brings down medicines prices.⁴³ EU governments are increasingly looking for ways to encourage meaningful and affordable medical innovation. EU Member States have now asked the European Commission to critically examine to what extent current patent protections and additional monopoly protections actually result in meaningful pharmaceutical innovations.⁴⁴ However, revising current EU patent standards as a result of this study would be ruled out if these were enshrined in TTIP.

iii) Entrenching current additional protections will block path to future reform

Another area where we are concerned about the impact of locking in or strengthening current protection levels is data exclusivity and market exclusivity. Data exclusivity and market exclusivity may prolong the monopoly protection period for the originator companies after the patent has expired, or grant exclusivity where there is no (or weak) patent protection. During the data exclusivity period, generic manufacturers may not refer to the marketing authorization data when seeking to register their generic medicines. Impact studies confirm that data and market exclusivity have a direct impact on medicines prices.⁴⁵ Moreover, instead of spurring innovation, long periods of exclusivity may block innovation as they prohibit incremental innovation by competitors.

For example, for biologic medicines, the EU currently has eight years of data exclusivity plus two years of market exclusivity plus one extra year for new indications (8+2+1 years – total 11 years). The U.S. has four years of data exclusivity and eight years of marketing exclusivity for biologics (4+8 years – total of 12 years). In the area of biologic medicines, competition provided by biosimilars – generic versions of biologics - is even more crucial than for “traditional” medicines. Biologics are expensive and prices far exceed the most costly classic small molecule medicines – on average 20 times more.⁴⁶ In 2014, biologic medicines accounted for 27% of the pharmaceutical sales in Europe and their percentage of the pharmaceutical drug market is expanding.⁴⁷ Biosimilar market entry generally results in significant cost savings as biosimilars are on average 30% lower in price.⁴⁸

Should the EU and U.S. decide to harmonise exclusivity periods for biologics, this may lead to one additional year of exclusivity in the EU. Given the high price tag of new biologics, any extra year of monopoly will result in huge extra costs for societies.

Even if TTIP would only confirm the current EU and U.S. levels of data and market exclusivity, this would lock in existing terms for both the U.S. and EU for the future. This is unacceptable at a time when EU Member States have explicitly asked the European Commission to revisit patent and market/data exclusivity rules due to serious concerns regarding their impact on innovation and affordable access.⁴⁹ Meanwhile in the U.S., bipartisan legislation has been introduced to reduce the exclusivity period for biologics from 12 years to seven,⁵⁰ and the White House repeatedly has proposed reducing the period to seven years in its annual budget. Any agreement to extend or lock in current levels of data exclusivity protection in the EU and U.S. in TTIP would make it harder to address this issue in the future in order to manage the unsustainable industry pricing of medicines.

3. TTIP runs the risk of limiting public access to safety and efficacy data of the medicines we take

To extend their monopoly protection on pharmaceuticals, the pharmaceutical industry uses a mix of strategies. In addition to patents and other exclusivities, corporations use *trade secret protection* and *confidential commercial information (CCI)* classifications to justify secrecy on data relating to the safety, efficacy, manufacturing and development of medicines. We are concerned that any increase of the protection of such information through TTIP may have a chilling effect on future disclosures by the European Medicines Agency and national medicines agencies out of fear of being sued. Access to this information protects our health – any proposal that may further limit such public scrutiny should be a non-starter.

At a time when the competition authorities and EU Member States are questioning whether current monopoly protections on medicines provide the appropriate incentives, companies should not be provided with another way to avoid sharing the results of pharmaceutical research.

Benefits of data sharing

Access to medicines safety and efficacy data for researchers, doctors and patients is critical to protecting patient safety. Incomplete knowledge of a medicine's safety profile can lead to use by patients for whom the risk is too high. Many adverse drug reactions, including deaths, can be avoided when the public knows about the undisclosed effects of these medicines. Data secrecy also raises concerns from an ethical perspective, because the clinical trial participants have undertaken risks to make a contribution to improving medical knowledge.⁵¹

Currently more than half of all clinical trials are never fully published.⁵² Scientific knowledge about the safety and efficacy of these medicines is lost forever. The good news is that in the EU there have been important developments towards increased transparency of this data. The 2014 EU Clinical Trials Regulation requires mandatory trial registration, the proactive publication of trial summary results for all trials and the publication of clinical study reports submitted for marketing authorisation. Notably, the Regulation states that clinical trial data in general should not be considered commercially confidential information.⁵³ Data redaction on the grounds of commercial confidentiality is to be understood as an exception, which, by no means, can apply whenever there is an overriding public interest in disclosure.⁵⁴ The United States is making modest progress as well.

Companies invoke trade secrets to justify data secrecy

In spite of all the evidence of the public health benefits of access to medicines safety and efficacy data, the pharmaceutical industry continues to argue that disclosure of information relating to the safety, efficacy and development of their medicines poses a risk to innovation, because it gives competitors access to companies' alleged trade secrets and proprietary information.⁵⁵

Health Action International, Public Citizen and Commons Network are concerned that TTIP would strengthen pharmaceutical industry claims that this public interest data should be considered trade secrets and/or CCI. Trade secrets and CCI may feature in TTIP chapters on regulatory cooperation in the area of pharmaceuticals as well as in the intellectual property chapter. The EU seems ambitious in its position paper on pharmaceuticals and identifies protection of CCI as a cross-cutting issue, stating that "*TTIP could entail legal provisions allowing the exchange of confidential information in the horizontal chapter as well specific confidentiality provisions in the pharmaceuticals annex.*"⁵⁶

i) Trade secrets protection

An industry coalition has lobbied the EU and U.S. governments to harmonise trade secret protection domestically.⁵⁷ Uniform trade secrets standards within the EU and U.S. may make it easier to include a broader and more substantive provision in TTIP. We are concerned that this will strengthen the pharmaceutical industry in their attempts to use trade secret protection as a justification for not releasing important data about the safety and efficacy of medicines.

European Commission position paper on IP⁵⁸:

- “Once harmonized in the EU, trade secrets protection will be discussed in TTIP in the IP chapter.”

U.S. in TPP:

- TPP includes a provision on trade secrets protection.⁵⁹

Pharma company submissions:

American Chamber of Commerce (AmCham) EU:

- “A commitment to strengthen and better harmonise protections for trade secrets both within the EU and U.S. and in third countries.”(p.33)⁶⁰

PhRMA:

- “urge the US government to engage with the EU in every available venue to resolve this issue [EMA practice of disclosure of clinical trial data].”(p. 12)⁶¹

The EU has recently harmonized trade secret protection through the new EU Trade Secrets Directive. This paves the way for the EU to discuss trade secrets as part of TTIP. The new Directive’s broad definition of what constitutes a “trade secret”⁶² and its lack of clarity on exceptions to unlawful use or disclosure create legal uncertainty.

Although the EU Trade Secrets Directive states that it will not affect the application of public disclosure obligations by the EMA and EU Member States’ national medicines agencies, the implications of this provision in practice remain uncertain. Agencies may take a safe course of action in their interpretation of what constitutes commercially confidential information and become less inclined to disclose information – such as clinical trial data – that is in the public interest. Trade secret protection has long been a recurring argument by the pharmaceutical industry to justify data secrecy. In fact, the trade secrets argument was used recently by the company sponsoring the clinical trial in France where one person died and others were injured.⁶³

In the U.S., trade secrets are primarily governed by state law, but norms for trade secret protection are perhaps more consistent and widespread in the U.S. than they were in the EU before harmonisation.⁶⁴ Some pharmaceutical information related to development or manufacturing processes may qualify for trade secret protection. But clinical trial data, in at least some circumstances, does not qualify.⁶⁵ Like the EU, the U.S. has recently established a uniform standard for trade secret misappropriation at the federal level through the “Defend Trade Secrets Act”.⁶⁶ Opponents of the act have stated that it may have ancillary negative impacts on access to information.

The legal uncertainty and overly broad protection that the U.S. and EU trade secrets legislation will bring is unacceptable since it runs the risk of restricting access to crucial data about the safety and efficacy of the medicines we take. This uncertainty and blurring the line of what is a trade secret and commercially confidential information may have a chilling effect on medicines regulators, who may be less inclined to disclose information on medicines safety and efficacy out of fear of being sued.

It is therefore important that trade secret protection does not become harmonised across the Atlantic through TTIP. Any negative consequences that may arise from such harmonised trade secret protection will then be difficult to repeal through democratic processes. At a minimum, biomedical research data, and particularly clinical trial and pharmacovigilance data, must be excluded from any

definition of what constitutes a trade secret or commercially confidential information in TTIP, or must be explicitly excluded from the standard.

ii) Protection of information shared between regulators

European Commission proposal annex medicinal products (May 2016)⁶⁷

- “Article 8.1 - Parties shall ensure that their competent authorities are allowed to exchange relevant regulatory information, including confidential and trade secret information related to the authorization and supervision of medicinal products;
- Article 8.3 – A Party shall not publicly disclose confidential information of commercial, technical or scientific nature, including trade secrets, which is not in the public domain, and which it has received from the other Party, if and in so far as that information is protected under its applicable legislation on access to information or access to documents.”

Pharma company submissions:

PhRMA:

- “Include provisions that allow for protection of commercially confidential information exchanged between EU regulators and the U.S. Food and Drug Administration (FDA).”⁶⁸

BIO:

- “ensure non-disclosure of all commercial confidential information.”⁶⁹

The European Medicines Agency and the U.S. Food and Drug Administration have had confidentiality arrangements between them in place since 2003, allowing for the exchange of confidential information as part of their regulatory and scientific processes. The current confidentiality agreement was signed in 2010 and is now effective for an indefinite period.⁷⁰ The FDA also has several bilateral confidentiality agreements in place regarding information sharing with different EU Member States’ medicines regulatory agencies.⁷¹ It seems that the EU and U.S. are now seeking to codify these confidentiality obligations in TTIP.

The May 2016 EU proposal for an annex on medicinal products mentions how information exchanged will be protected to the extent applicable under its Access to Documents legislation. This sounds reasonable, but the EU Access to Documents Regulation,ⁱⁱ Article 4(1) identifies “the protection of public interests as regards international relations” as one of the exceptions under which access to a document shall be refused. The European Commission has confirmed that under the current confidentiality agreements, the EMA – in case of a request of access to information obtained from the FDA – assesses on a case by case basis whether this exception applies. After this assessment by the EMA, the information is shared with the FDA for review and agreement on whether this information can be released to the requester, and if so, whether further redaction of information at the request of the FDA is needed.⁷² It seems that under this article in the EU Access to Documents Regulation, in principle, the FDA will have the last say in marking information shared as CCI. It therefore works as a *de facto* safe harbour for information provided by the FDA to the EMA.

The same process applies when the FDA receives a Freedom of Information Act (FOIA) request for information shared by the EMA with the FDA. When the FDA makes reference to any non-public information shared by the EMA under the FDA’s confidentiality commitments, it must stipulate in the review that the information was shared under FDA’s confidentiality commitments so that future readers know the source of information is confidential.⁷³

The EU and U.S. are now seeking to codify this information sharing including confidentiality obligations in TTIP. In principle, increased information sharing between the FDA and EMA and EU Member States regulatory agencies is a good thing. However, only if it is ensured that information relating to the safety and efficacy of the medicines we take would not be covered by the confidentiality obligation that covers information exchanged between regulators in TTIP. This includes

ⁱⁱ The assessment of access to documents regulations in place governing EU Member State level regulatory agencies is beyond the scope of this paper.

not only safety and efficacy data submitted by the relevant company, but also the FDA or EMA's *risk assessment* of adverse drug reactions reported after a medicine has been introduced on the market and the *analysis* of the safety and efficacy data, in the context of an application for marketing authorisation.

Given this risk, the EU and U.S., when discussing information exchange between medicines regulators across the Atlantic in TTIP, should ensure:

- that information shared between EU/U.S. regulators, even if marked commercial confidential, can always be released if there is an overriding public interest in disclosure and that the relevant medicines agency makes this assessment on a case-by-case basis for each third-party information request. This is to prevent the creation of a safe harbour for protection of information as CCI that could be relevant for the public assessment of the safety and efficacy of the medicines we take.
- that EU/U.S. regulators will always request all data needed for a comprehensive assessment of marketing authorization directly from the relevant company, even if the data has already been obtained from other sources. This is needed to ensure that such information remains, in principle, available for public access under existing EU/U.S. regulations governing access to medicines safety and efficacy information and does not fall under the safe harbour of EMA/FDA information exchange.

4. Pricing and Reimbursement policies under attack in TTIP

The freedom of EU Member States and the U.S. to tailor their pricing and reimbursement policies to contain costs of pharmaceutical expenditure may be jeopardized under TTIP. TTIP could offer the pharmaceutical industry a bigger say in governments' decisions on pricing and reimbursement. It could weaken the negotiating power of governments to make medicines affordable for patients by imposing cumbersome procedural requirements on public authorities that attempt to enact cost-containment measures.⁷⁴

EU and U.S.:

- The U.S. and EU have a track record of negotiating provisions that can affect the freedom of governments to tailor pricing and reimbursement policies to meet public health needs. The U.S. has negotiated a so-called "Transparency Annex" in its trade negotiations with South Korea and in the Trans-Pacific Partnership (TPP). The EU has also negotiated a "Pharmaceutical Annex" in its free trade agreements with South Korea and Singapore. When comparing the text of previous annexes negotiated by the EU and U.S. with South Korea, the similarity of the provisions is striking.

European Commission May 2016 proposal annex medicinal products:

- nothing in TTIP "shall affect the powers of the competent authorities either as regards the setting of prices of medicinal products or their inclusion in the scope of national health insurance scheme, on the basis of health, economic and social conditions."⁷⁵

Pharma company submissions:

EFPIA⁷⁶

- TTIP can help promote fair, predictable and transparent policies on pricing and reimbursement processes. A pharmaceutical annex in TTIP [...] could promote principles around transparency in pricing and reimbursement processes, and reflect the value new medicines can bring to patients, healthcare systems, and society.

BIO⁷⁷:

- "provide that during the patent term or term of regulatory [data] exclusivity [...], the government price for that product should be based on the value of that product and never be set by references to prices for generic products."(p.7)
- "require that the final reimbursement notice should advise the applicant of its rights and the relevant timelines for seeking an independent review of the reimbursement decision."(p.8)

PhRMA⁷⁸:

- "recognize that prices of medicines should be based on a variety of criteria that reflect such considerations as benefits to patients [...]"(p.5)
- "consistent with [...] the EU-Korea free trade agreement clarify that the obligation to address substantive comments in writing and explain and substantive revisions made to proposed regulations should be completed before the proposed regulations are adopted."(p.7)
- "include [...] of the EU-Korea free trade agreement requiring that the final reimbursement notice should advise the applicant its rights and the relevant timelines for seeking an independent review of the reimbursement decision."(p.7)

We welcome the EU commitment not to include provisions that may affect EU Member States' pricing and reimbursement decisions. However, the EU and U.S. have negotiated harmful provisions in so-called pharmaceutical/transparency annexes in the past. Moreover, the U.S. has indicated in public forums and private meetings that it may be obligated to pursue a review of EU pharmaceutical pricing rules through the TTIP negotiations. Pharmaceutical industry comments to the U.S. Trade Representative and the European Commission indicate a strong interest in challenging European pricing rules.

Moreover, some provisions, which at first glance only deal with *transparency* or *procedure* of pricing and reimbursement proceedings, may have an impact on the ability of governments to tailor domestic pricing and reimbursement policies. This gives rise to concern about whether the EU will be able to uphold its commitment throughout the course of the negotiations.

Importance of effective pricing and reimbursement policies

In the EU, Member States have the exclusive competence to negotiate the price and determine the extent of reimbursement of (new) medicines.⁷⁹ EU Member States can and should use their competence to negotiate a price and design a reimbursement scheme that best meets their citizens' public health needs. Small differences in how pricing and reimbursement policies are organised at a national level may have considerable impacts on cost containment for pharmaceuticals and on health budgets overall.

Germany has, for example, recently changed its reimbursement policy (2011) in order to take into account the cost/benefit compared to existing treatments before treatments can be successfully reimbursed.⁸⁰ By only reimbursing medicines that actually offer a meaningful improvement over existing treatment options with respect to outcomes for patients, costs can be kept lower and pharmaceutical manufacturer pricing behaviour can be moderated.

Key concerns of a pharmaceutical/transparency annex in TTIP

A. Conditions for price setting and reimbursement decisions

In previous trade agreements, the EU and the U.S. have included principles that prescribe what elements governments should take into account in medicines pricing and reimbursement decisions. For example, both proposed a principle stating that, when taking pricing and reimbursement decisions, governments should take into account the value of the patent on the medicine.⁸¹

This principle seems to assume that newly patented medicines have an inherent value for public health, which is not always the case.⁸² Whilst a small number of new medicines have changed disease prognosis and patient outcomes, the vast majority of new drugs (between 70-95%) are “me-too” that offer no improvement over existing treatment options.⁸³ If adopted, such a principle could, for example, damage Germany's recent policy where it takes into account the cost/benefit compared to existing treatments before treatments can be successfully reimbursed regardless of the patent status of the product.⁸⁴

B. Conditions on transparency in decision-making process

A second type of provision that the EU and U.S. have negotiated in previous trade deals focus on “the transparency of the decision-making process on pricing, reimbursement and pharmaceutical policy”.⁸⁵ Of course, transparency of pricing and reimbursement processes is, in principle, desirable in order to increase accountability. Yet, the EU and U.S. have previously negotiated that pharmaceutical companies and other stakeholders should have “*reasonable opportunities to comment on any proposed rules on any matter related to the pricing, reimbursement or regulation of pharmaceutical products or medical devices.*” We are concerned that transparency, from this perspective, means corporations could have more opportunities to attempt to influence the outcomes of agency deliberations.

Corporations may argue that for every (however minor) step in the regulatory decision-making process – whether on pricing, reimbursement or any other regulation relating to pharmaceuticals – the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA) or relevant agency in an EU Member State is obligated to allow third parties to comment.

Implementing such a practice may raise transaction costs of these (most often public) bodies. More worrying is that by requiring public consultation for *every* (however minor) step in the decision making process, pharmaceutical companies obtain many opportunities to put pressure on the relevant decision making bodies. This would increase the risk of further politicizing the process of approval and reimbursement of medicines: a largely technical process that is based on public criteria and

guidelines developed through public consultation. In particular, this may facilitate pharmaceutical industry-sponsored lobbying by patient groups or individual patients.

The risk of industry using their influence to politicize these processes is not hypothetical. In 2013, a leaked memo from the European Federation of Pharmaceutical Industries and Associations (EFPIA) showed their strategy of mobilizing patient groups to lobby against increased transparency of clinical trial data.⁸⁶ This is especially worrying because many patient groups receive funding from the pharmaceutical industry.⁸⁷ Also in 2013, in Belgium, pharmaceutical company Alexion hired a public relations company to convince a young patient to lobby the Belgium government for access to a highly priced medicine, Soliris, produced by Alexion for his rare kidney disease.⁸⁸

C. Appeal procedure

Another type of provision featured in previously negotiated EU and U.S. trade agreements is “*the obligation for governments to make available ‘a judicial, quasi-judicial or administrative tribunal or other independent review process that can be invoked by anyone directly affected by a pricing or reimbursement decision’*.”⁸⁹ The introduction of a formal appeal or review mechanism could help pharmaceutical companies, for example, to overturn pricing and reimbursement decisions.

Moreover, the heavily criticised dispute settlement mechanism (investor-to-state dispute settlement (ISDS) or the newly proposed Investment Court System (ICS)) which may be included in TTIP would give such a tribunal very strong teeth. Using investor to state arbitration, pharmaceutical companies could sue any EU Member State/the US, arguing that the government’s measures damage their investments.⁹⁰ This could include price controls, reimbursement decisions, marketing approvals and pharmacovigilance decisions, or stricter patentability standards.

Such an appeal procedure, depending on how it is implemented, increases the risk of undermining the scientific rigour exercised by expert regulatory agencies, such as the EMA or FDA, by allowing their decisions to be reviewed by lesser expert bodies.⁹¹ Combined with increased transparency obligations to consult with stakeholders in every step of the decision-making process – this creates many consultation moments that, if comments are not taken into account by the regulatory agency, could subsequently be appealed by industry. The existence of such an appeals mechanism could have a chilling effect on medicines agencies decision-making processes.⁹²

Conclusion

These provisions and examples demonstrate how a pharmaceutical annex could constrain EU Member States/U.S. to tailor their pricing and reimbursement policies to contain costs of pharmaceutical expenditure. Even if provisions only seem to deal with transparency of proceedings or procedural issues, they could have a chilling effect on the possibility of adopting measures necessary to protect public health and ensure affordable access to medicines out of fear for costly legal battles. If adopted, provisions such as the appeal procedure combined with the increased opportunities to comment could be used by pharmaceutical companies to challenge pricing and reimbursement decisions.

5. Ongoing Opportunities for Corporations to Disrupt the Public Interest

European Commission May 2016 proposal annex medicinal products.⁹³

“Article 9 | Regulatory cooperation between the Parties [NB: this Article may need to be adjusted as discussions on the Regulatory Cooperation Chapter proceed]

1. A Working Group for the regulatory cooperation on medicinal products between the Parties shall be established. The EU shall be represented in the Working Group by the European Commission with the support of the European Medicines Agency. The US shall be represented by the U.S. Food and Drug Administration and the U.S. Department of Agriculture.

2. The Working Group shall monitor the implementation of the provisions of this Chapter and support and further develop existing and future bilateral regulatory cooperation between the competent authorities. [...]”

EU/U.S. proposed working groups for ongoing bilateral coordination on pricing and reimbursement decisions (Working Group for the regulatory cooperation on medicinal products) to be established under TTIP would have the ability to influence domestic medicines and IP policy. A complex institutional infrastructure for ongoing regulatory cooperation, in the context of a trade agreement, inevitably leads to more possibilities for industry to influence national pharmaceutical policies.

The recently leaked text has confirmed widely held concerns that the Regulatory Cooperation chapter poses a major threat to health, safety, environmental, labor, consumer, civil and political rights, and other regulatory protections. The U.S. proposals in the Regulatory Cooperation chapter seek to export many of the worst features of U.S. rulemaking. If the United States succeeds in its project, large corporations, including pharmaceutical companies, would gain enormous power to block, slow, undermine and repeal European regulations.⁹⁴

Taken in their entirety, the U.S. Regulatory Cooperation proposals are affirmatively hostile to the precautionary principle. The precautionary principle counsels taking protective action in the face of uncertainty. But the U.S. cost-benefit standards, demands for consideration of alternative regulatory approaches and expansive analytic requirements counsel for inaction in the face of uncertainty. Moreover, U.S.-style cost-benefit analysis places a premium on industry-provided cost estimates while effectively discounting benefits from action to prevent possible harm.⁹⁵

The EU, in its May 2016 proposal for an annex on medicinal products, includes the proposal to establish a working group for regulatory cooperation on medicinal products with a reference to the TTIP Regulatory Cooperation chapter. Even though there is some more information on the modus operandi of this working group in this proposal, it does not sufficiently deal with the key concerns expressed about including regulatory cooperation in TTIP⁹⁶ and such a working group would potentially create an additional avenue for pharmaceutical companies to influence, slow and undermine European medicines regulations.

6. TTIP's global standard will harm developing countries

European Commission position on IP:

- “point f: Cooperation with regards to multilateral and third-country IP issues.”⁹⁷

Pharma company submission:

EFPIA⁹⁸

- Joint commitment to existing high-level standards of IP protection and enforcement and establishment of joint high-level IP principles to be used as a point of reference in future bilateral and multilateral fora.

BIO⁹⁹:

- “The establishment of harmonized U.S. and EU approaches to these issues [patentability standards] will be meaningful in the development of more clearly applied standards on a global level.”(p. 10)

One of the objectives of TTIP is to set “global standards”. The implications of this for third countries – especially lower and middle-income countries (LMICs) – are significant. The mutual obligations created in TTIP would be exported to third countries where resources are more constrained. This can happen through other trade agreements but also by bilateral pressure, for example through the EU priority country list¹⁰⁰ or the U.S. Trade Representative (USTR) 301 Watch list.¹⁰¹ The EU and the U.S. also use technical assistance programs as a way to export their IP standards, even to least developed countries (LDCs), which are not obliged by WTO law (Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS]) to implement those standards. This exception for LDCs exists specifically because excessive IP protection levels can create serious barriers to access to medicines and undermine technological development and emerging industries.¹⁰²

The consequences of the proposals on the TTIP table discussed in this paper – less transparency on the benefits and harms of medicines, longer monopolies, and pressure on pricing policies – are extremely harmful for LMICs. Most LMICs have fewer institutions to counterbalance strong IP rules and mitigate the impact of higher prices, such as health insurance and strong competition laws. Here, the increased power of large corporations will put an even greater burden on public health systems and citizens.

Conclusion and Recommendations

TTIP would reinforce the monopoly power of pharmaceutical corporations and potentially their ability to withhold information on medicine safety and efficacy, while reining in the freedom of national governments to tailor decisions on pricing and reimbursement to ensure affordability and revise current intellectual property protection terms. TTIP could therefore impede change towards medicine affordability, needs-driven innovation and alternative incentive structures.

We have a historic opportunity to advance biomedical innovation and affordable access at the same time, through the use of proven and emerging policy solutions. TTIP would entrench the failed models of the past, which have produced limited medical breakthroughs while rationing access to care through excessive pricing.

Health Action International, Commons Network and Public Citizen believe that secretive “trade” negotiations are absolutely unacceptable forums for devising binding rules that change national non-trade laws including on intellectual property and medicines regulation. If TTIP negotiations continue, we recommend the following:

➤ **The TTIP Intellectual Property chapter:**

TTIP should not include an Intellectual Property chapter: We fear that the outcome would be an agreement that inflicts the worst of both regimes’ rules on the other party and would freeze legislative progress toward a better model. If an Intellectual Property chapter were included in TTIP it:

- should not regulate the standards, or entrench established practices, for granting patents on pharmaceuticals, in particular on secondary patenting and other patentability standards.
- should not strengthen or entrench the terms and scope of data or marketing exclusivity on pharmaceuticals, especially in the area of biologics.
- should not include trade secret protection.
- should not allow data in the public interest - and in particular information related to safety, efficacy and development of medicines - to be protected as “trade secrets”.

➤ **A ‘Medicinal Products’ or ‘Transparency’ Annex in TTIP:**

- should not include any principles suggesting or prescribing what elements governments should take into account in medicines pricing and reimbursement decisions.
- should not, in the name of enhanced transparency, provide for rights for stakeholders in addition to consultation processes already in place to comment and put pressure on medicines regulatory agencies’ decision making processes regarding pricing and reimbursement.
- should not provide for obligations in addition to review processes already in place for medicines regulatory agencies to make available a (judicial or quasi-judicial) review process that can be invoked by anyone directly affected by a pricing or reimbursement decision.
- if a dispute settlement mechanism like ISDS or ICS is included in TTIP, it should at a minimum explicitly exclude this annex from the scope of application of application of such mechanism.
- the EU and U.S. - if including provisions to facilitate information exchange between medicines regulators across the Atlantic - need to:
 - ensure that access to information shared between EU/U.S. regulators – even if marked commercially confidential – can always be requested if there is an overriding public interest in disclosure.
 - ensure that EU/U.S. regulators will always request all data needed for a comprehensive assessment of marketing authorisation directly from the relevant company, even if the data has already been obtained from other sources, including the FDA.

➤ **Cross-Cutting issues:**

- TTIP should exclude any investor dispute settlement mechanism like ISDS or ICS.
- any provisions on regulatory cooperation in TTIP should explicitly protect the EU's exercise of the precautionary principle.

➤ **TTIP as a Global Standard**

The EU and U.S. should ensure TTIP standards:

- are not instrumentalised to impose EU and U.S. standards of pharmaceutical-related patent protection and related exclusivities on third countries.
- support governments that use available legal measures, including safeguards and flexibilities in the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS), to protect and promote public health.

➤ **Positive Agenda: Promote needs-driven R&D and affordable access**

Instead of re-affirming the current unsustainable biomedical innovation model, the EU & U.S. should explore and encourage the development of alternatives to a patent-based system needed to stimulate therapeutically valuable innovation.

In particular, the EU and U.S. should:

- recognize the limits of intellectual property protection as a driver of biomedical innovation.
- ensure that innovation and biomedical knowledge, derived in whole or in part from publicly-funded health R&D, results in medical products that are appropriate, affordable and accessible at prices that reflect the public contribution.
- ensure that publicly-funded research results are made publicly available, including by enabling knowledge sharing through intellectual property management that allows for open data and equitable licensing.
- further explore and implement alternative incentive models for biomedical innovation that incorporate the principle of 'delinking' R&D costs from end product prices.

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⁵⁵ Pharmaceutical Research and Manufacturers of America, European Federation of Pharmaceutical Industries and Associations (2013). *Principles for responsible clinical trial data sharing: our commitment to patients and researchers*. Volume 2015, 2013. Available at: <http://transparency.efpia.eu/uploads/Modules/Documents/data-sharing-prin-final.pdf>.

⁵⁶ Position Paper (EC) of May 2014 on pharmaceutical products in TTIP. Available at: http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152471.pdf (Accessed 15 August 2016).

⁵⁷ Corporate Europe Observatory (2015). *Towards legalised corporate secrecy in the EU?* 28 April (Updated: 29 April 2015). Available at: http://corporateeurope.org/sites/default/files/attachments/trade_secrets_protection_lobbying_report_-_final.pdf (Accessed 15 August 2016); The Bureau of Investigative Journalism (2015). *A lobbying masterclass: The inside story of how big business worked with lobbyists to influence the EU in drawing up controversial trade secrets proposals*, 28 April. Available at: <http://labs.thebureauinvestigates.com/a-lobbying-masterclass/> (Accessed 15 August 2016).

⁵⁸ Position Paper (EC) of 20 March 2015 on Intellectual Property in TTIP.

⁵⁹ Article 18.78, Chapter 18 Intellectual Property, Trans-Pacific Partnership Agreement. The TPP provision on trade secrets mirrors the language in TRIPS Article 39.2, which is essentially the same as the language in the proposed U.S. Uniform Trade Secret Act, draft legislation pending before congress now. The text also makes a clear reference to the Paris Convention Article 10, according to which the protection of trade secrets forms part of the general concept of protection against unfair competition. The TPP provision allows parties to limit the availability of criminal procedures and penalties for certain acts for purposes of commercial advantage or financial gain or are intended to injure the owner of such trade secret or are detrimental to a Party's economic interests, international relations, or national defense or national security etc.

⁶⁰ American Chamber of Commerce to the European Union (no date). *AmCham EU's reply to USTR's Request for Comments Concerning Transatlantic Trade and Investment Partnership*. Available at: <http://www.amcham.at/wp-content/uploads/AmCham-EUs-reply-to-USTRs-Request-for-Comments-Concerning-Proposed-TTIP.pdf> (Accessed 16 August 2016).

⁶¹ EFPIA (2015) *EFPIA Position – TTIP Stakeholder meeting*. 27 May. Available at: http://trade.ec.europa.eu/doclib/docs/2015/may/tradoc_153469.PDF (Accessed 16 August 2016); PhRMA (2013). *PhRMA comments to the Office of the U.S. Trade Representative (USTR) on TTIP*. Available at: <https://www.regulations.gov/document?D=USTR-2013-0019-0327> (Accessed 26 September 2016).

⁶² Definition 'Trade Secret' in Article 2 Directive (EU) no. 2016/943 of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure:
(1) 'trade secret' means information which meets all of the following requirements:

(a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
(b) it has commercial value because it is secret;
(c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret;

⁶³ De Pracontal, M. (2016) 'Essai clinique de Rennes: des scientifiques réclament la transparence'. *Le Monde*, 25 January [Online]. Available at: www.lemonde.fr/economie/article/2016/02/25/essai-clinique-de-rennes-l-an-sm-conteste-tout-manque-de-transparence_4871946_3234.html (Accessed 16 August 2016).

⁶⁴ 44 U.S. states have enacted some version of the Uniform Trade Secrets Act (UTSA), a model statute promulgated by the National Conference of Commissioners on Uniform States Laws.

⁶⁵ In the 1980s, Public Citizen sued the FDA under FOIA to obtain safety and effectiveness data that the FDA claimed constituted a trade secret. In *Public Citizen Health Research Group v. FDA*, the D.C. Circuit held that the term "trade secret" should more narrowly be defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Critically, the court clarified that, to qualify for protection, there must be "a direct relationship between the information at issue and the productive process."

⁶⁶ The Defend Trade Secrets Act has now been enacted—in one form or another—by 44 U.S. States and the District of Columbia.

⁶⁷ Proposal (EC) of 24 May 2016 for an annex on medicinal products in TTIP. Available at: http://trade.ec.europa.eu/doclib/docs/2016/may/tradoc_154582.pdf (Accessed 16 August 2016).

⁶⁸ PhRMA (2013). *PhRMA comments to the Office of the U.S. Trade Representative (USTR) on TTIP*. Available at: <https://www.regulations.gov/document?D=USTR-2013-0019-0327> (Accessed 26 September 2016).

⁶⁹ Biotechnology Industry Organization (2013). *TTIP: Comments submitted to USTR docket number: USTR-2013-0019*. Available at: <https://www.bio.org/sites/default/files/BIO%20TTIP%20submission%20May%202013%20final%205%2010%2013.pdf> (Accessed 15 August 2016).

⁷⁰ The EMA and the FDA share information on marketing-authorisation procedures, changes to marketing authorisations and post-authorisation surveillance for products under review both in the US and in the EU.
European Medicines Agency (n.d.), *Regulatory cooperation with the United States*, viewed 6

November 2015,

http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000651.jsp&mid=WC0b01ac058003176e.

⁷¹ For an overview of all FDA bilateral confidentiality agreements with EU Member States see: <http://www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/ucm2016756.htm> (Accessed 26 September 2016).

⁷² Source: email exchange between Health Action International and DG SANTE, d.d. 14 September 2015, available upon request.

⁷³ See FDA (2013) *SOPP 8001.6: Procedures for Parallel Scientific Advice with European Medicines Agency (EMA)* (December), Available at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPs/ucm061218.htm> (Accessed 16 August 2016).

⁷⁴ In response to rising costs of pharmaceuticals governments can for example decide to increase the part that patients will have to pay out-of-pocket for their medicines. This is alarming, because studies suggest that increased co-payments can be associated with lower medicines consumption, worse adherence to treatments and more frequent discontinuation of therapies. Governments can also decide to limit reimbursement to certain groups of patients. Such 'treatment rationing' has occurred in several EU Member States, including France, in response to the high costs of new a Hepatitis C treatment from pharmaceutical company Gilead.

⁷⁵ Proposal (EC) of 24 May 2016 for an annex on medicinal products in TTIP. Available at: http://trade.ec.europa.eu/doclib/docs/2016/may/tradoc_154582.pdf (Accessed 16 August 2016).

⁷⁶ EFPIA (2015). TTIP and Health Care. Available at: <http://www.efpia.eu/uploads/Modules/Documents/efpia-position---ttip-and-healthcare.new.pdf>.

⁷⁷ Biotechnology Industry Organization (2013) 'TTIP: Comments submitted to USTR docket number: USTR-2013-0019'. Available at: <https://www.bio.org/sites/default/files/BIO%20TTIP%20submission%20May%202013%20final%205%2010%2013.pdf> (Accessed 15 August 2016).

⁷⁸ PhRMA (2013). *PhRMA comments to the Office of the U.S. Trade Representative (USTR) on TTIP*. Available at: <https://www.regulations.gov/document?D=USTR-2013-0019-0327> (Accessed 26 September 2016).

⁷⁹ carried out by governments or private insurers.

⁸⁰ Fernando, S., Smith-Parker, J.C. (2012) 'Germany's new drug reimbursement process picks up industry resistance, potential for minor alleviation by authorities'. *Financial Times*, 17 July [Online]. Available at: [http://www.ft.com/intl/cms/s/2/906e131a-d057-](http://www.ft.com/intl/cms/s/2/906e131a-d057-11e1-99a8-00144feabdc0.html#axzz2vZH6LTqs)

[11e1-99a8-00144feabdc0.html#axzz2vZH6LTqs](http://www.ft.com/intl/cms/s/2/906e131a-d057-11e1-99a8-00144feabdc0.html#axzz2vZH6LTqs) (Accessed 15 August 2016).

⁸¹ See for example: article 5.1 - Chapter 5 – Pharmaceutical products and medical devices. US-Korea Free Trade Agreement (FTA). Available at: https://ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file899_12703.pdf (Accessed 15 August 2016); Article 1- Annex 2-D Pharmaceutical products and medical devices. EU-Korea FTA. Available at : <http://old.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:127:0006:1343:EN:PDF> (Accessed 15 August 2016).

⁸² Independent drug bulletin *La Revue Prescrire* has rated new patented medicines being brought onto the market in 2000-2013 and concluded that only 9% offers an advantage as compared to existing products on the market: *Revue Prescrire* (2011) New drugs and indications in 2010: inadequate assessment; patients at risk. *Revue Prescrire*, 20(115).

⁸³ *Revue Prescrire* (2015), 35 (376),; Light and Lexchin, 2012.

⁸⁴ Fernando, S., Sith-Parker, J.C. 'Germany's new drug reimbursement process picks up industry resistance, potential for minor alleviation by authorities', *Financial Times*, 17 July. Available at: <http://www.ft.com/intl/cms/s/2/906e131a-d057-11e1-99a8-00144feabdc0.html#axzz2vZH6LTqs> (Accessed 26 September 2016).

⁸⁵ See for example: Article 5.3 sub 2 (b) - Chapter 5 – Pharmaceutical products and medical devices. US-Korea FTA. Available at: https://ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file899_12703.pdf (Accessed 15 August 2016); Article 3 sub 2 (b) - Annex 2-D Pharmaceutical products and medical devices. EU-Korea FTA Available at : <http://old.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:127:0006:1343:EN:PDF> (Accessed 15 August 2016); article 2 (b,c) and article 3(c) Annex 2-C EU-Singapore FTA. Available at : <http://trade.ec.europa.eu/doclib/press/index.cfm?id=961> (Accessed 15 August 2016).

⁸⁶ Sample, I. (2013) 'Big pharma mobilising patients in battle over drugs trials data'. *The Guardian*, 21 July [Online]. Available at: <http://www.theguardian.com/business/2013/jul/21/big-pharma-secret-drugs-trials> (Accessed 15 August 2016).

⁸⁷ Health Action International (2011) *The Patient & Consumer voice and pharmaceutical sponsorship*. Available at: <http://apps.who.int/medicinedocs/documents/s17767en/s17767en.pdf> (Accessed 15 August 2016).

⁸⁸ Mulder, J. (2013) 'België geschokt door PR schandaal.' *CommunicatieOnline*, 16 May. Available at: <http://www.communicatieonline.nl/nieuws/belgie-geschokt-door-pr-schandaal> (Accessed 15 August 2016).



⁸⁹ See for example: Article 5.3 sub 5 (e) - Chapter 5 – Pharmaceutical products and medical devices. US-Korea free trade agreement; Article 3 sub 4(e) - Annex 2-D Pharmaceutical products and medical devices. EU-Korea free trade agreement.

⁹⁰ Health Action International (2014). *HAI Europe submission to the EU Consultation on ISDS in TTIP and its implications for health*: Available at: http://trade.ec.europa.eu/doclib/docs/2015/may/tradoc_153458.pdf (Accessed 15 August 2016).

⁹¹ Gleeson, D., Lopert, R., Reid, P. (2013). How the Trans Pacific Partnership Agreement could undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand. *Health Policy*, Vol. 112, Issue 3, p. 230.

⁹² Gleeson, D., Lopert, R., Reid, P. (2013). How the Trans Pacific Partnership Agreement could undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand. *Health Policy*, Vol. 112, Issue 3, p. 230.

⁹³ Proposal (EC) of 24 May 2016 for an annex on medicinal products in TTIP. Available at: http://trade.ec.europa.eu/doclib/docs/2016/may/tradoc_154582.pdf (Accessed 16 August 2016).

⁹⁴ Public Citizen (2016) Leaked TTIP Documents: Threats to Regulatory Protections - *Statement of Robert Weissman, President, Public Citizen*. Available at: <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=5880> (Accessed 28 September 2016).

⁹⁵ Public Citizen (2016) Leaked TTIP Documents: Threats to Regulatory Protections - *Statement of Robert Weissman, President, Public Citizen*. Available at: <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=5880> (Accessed 28 September 2016).

⁹⁶ Corporate Europe Observatory (2016) . *TTIP leaks highlight the dangers of regulatory cooperation*- Available at: <https://corporateeurope.org/international-trade/2016/05/ttip-leaks-highlight-dangers-regulatory-cooperation>; BEUC (2015). *Regulatory cooperation: perhaps boring, but the TTIP storm on the horizon* Available at: <http://www.beuc.eu/blog/regulatory-cooperation-perhaps-boring-but-the-ttip-storm-on-the-horizon/>.

⁹⁷ European Commission (18 July 2014), *Transatlantic Working Group discusses Intellectual Property Rights*, viewed 16 August 2016, <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1131>.

⁹⁸ EFPIA (2015). TTIP and Health Care. Available at: [http://www.efpia.eu/uploads/Modules/Documents/efpia-](http://www.efpia.eu/uploads/Modules/Documents/efpia-position---ttip-and-healthcare.new.pdf)

[position---ttip-and-healthcare.new.pdf](http://www.efpia.eu/uploads/Modules/Documents/efpia-position---ttip-and-healthcare.new.pdf).

⁹⁹ Biotechnology Industry Organization (2013) 'TTIP: Comments submitted to USTR docket number: USTR-2013-0019'. Available at: <https://www.bio.org/sites/default/files/BIO%20TTIP%20submission%20May%202013%20final%205%2010%2013.pdf> (Accessed 15 August 2016).

¹⁰⁰ Health Action International / Medicines Sans Frontières – Access Campaign (2015) *Empty Gestures- The EU's commitments to safeguard access to medicines*, p. 5. Available at: <http://haiweb.org/wp-content/uploads/2015/10/Empty-Gestures-The-EUs-Commitments-to-Safeguard-Access-to-Medicines.pdf> (Accessed 15 August 2016).

¹⁰¹ The "Special 301" Report reflects the outcome of a Congressionally-mandated annual review of the global state of intellectual property rights (IPR) protection and enforcement. Available at: <https://ustr.gov/issue-areas/intellectual-property/Special-301> (Accessed 26 September 2016).

¹⁰² Health Action International / Medicines Sans Frontières – Access Campaign (2015) *Empty Gestures- The EU's commitments to safeguard access to medicines*, p. 6. Available at: <http://haiweb.org/wp-content/uploads/2015/10/Empty-Gestures-The-EUs-Commitments-to-Safeguard-Access-to-Medicines.pdf> (Accessed 15 August 2016).