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Joint position

The Transatlantic Trade and Investment Partnership (TTIP): A Civil Society Response to the Big Pharma wish list

The analysis of the 5 most worrying proposals of the pharmaceutical industry's wish list for the EU-US trade agreement reveals a real threat to European public health systems and democracy.

Secret negotiations give Big Pharma a unique chance to push its agenda

The European Union is currently negotiating a trade agreement with the United States, the Transatlantic Trade and Investment Partnership (TTIP). Like many contemporary trade agreements, the TTIP is expected to have little to do with tariffs, the traditional focus of trade agreements. Instead, the US and the EU want to address non-tariff regulatory measures affecting EU-US trade, including setting standards and legal frameworks for technical regulations, intellectual property rights, and investment protection measures.

Reducing regulatory obligations to the lowest standards found on either side of the Atlantic. While the European Commission claims the treaty would boost the European economy, the details of the provisions are secret, except to well-connected lobbyists working for large companies. There is no independent analysis of the TTIP's contributions to economic growth or job creation.[i] Many consumer organisations, Members of the European Parliament, trade unions and health groups have expressed concerns that the agreement will lower standards for consumer protection, undermine health and environmental policies, and transfer even more political power to corporations. Many expect the harmonisation of regulations to effectively result in a race to the bottom, thus reducing regulatory obligations to the lowest standards found on either side of the Atlantic.[1] Furthermore, the agreement's global standard setting could also negatively affect developing economies.

[i] The study regularly quoted by the Commission as an 'independent' report was commissioned by the EC and written by the London Based Centre for Economic Policy Research (CEPR). The CEPR is funded by some of the world's largest banks which stand to benefit from the proposed trade deal. The European Parliament has already pointed to a number of methodological flaws in the assessment, as have others. See: http://www.europarl.europa.eu/RegData/etudes/etudes/join/2013/507492/IPOL-ENVI_ET(2013)507492_EN.pdf and http://opendemocracy.net/ourkingdom/clive-george/whats-really-driving-eu-us-trade-deal

Negotiated in secret to benefit commercial interests of a few multinational firms. Even though the agreement is likely to affect nearly one billion European and US citizens as well as many others beyond that, it is being negotiated in secret. The lack of transparency undermines the legitimacy of the negotiations and runs counter to the democratic notion that citizens should know what their governments are doing on their behalf. Also, the secrecy reinforces the asymmetric influence of the general public and big corporations. Many big corporations have direct and regular access to the negotiators on both sides of the Atlantic, and hundreds of industry lobbyists serve on US trade advisory boards where they have privileged access to the text being negotiated.[2] Only a few Members of the European Parliament have occasional and limited access to the negotiation texts. Member States have limited insight into texts, while national parliaments, civil society or trade unions are mostly excluded from the process. This asymmetry in access to the negotiating text and corporate pandering by trade officials reinforces our concerns that the agreement is being designed to promote the particular commercial interests of large multinational firms over the general interest of citizens and consumers.

A unique chance for big pharma to push its agenda. The pharmaceutical industry is one of the most powerful corporate actors on both sides of the Atlantic and these companies perceive the agreement as a unique chance to put forward their agenda. The EU Commission has referred on multiple occasions to the pharmaceutical industry wish-list, promising 'to take it to the negotiation table'. The wish-list was leaked to civil society.[ii] Here we shall unpack and analyze a selection from this list and discuss the implications of this agenda for access to medicines, European health systems, patients and the rest of the world.[iii]

Industry Wish List Implications for Public Health

A reading of the industry wish list reveals the extent of the industry's ambition for TTIP. Apart from the intention to expand the periods of monopoly through patents and other intellectual property measures, on several accounts it clearly seeks to undermine regulations set by European Member States to protect public health. Also, this agenda directly attacks the

[ii] Full list: http://openmedicineeu.blogactiv.eu/files/2013/12/TTIP-AGENDA.pdf There is also this submission of PhRMA to USTR from last year with similar demands (published): See comments PhRMA submitted to the Office of the U.S. Trade Representative (USTR), available at: http://www.regulations.gov/contentStreamer?objectId=09000064812d9cad&disposition=attachment&contentType=pdf

[iii] We do not address all the points in the original list, yet the problematic ones having clear implications.

praiseworthy yet long overdue EU move towards transparency on clinical trials which would enhance public safety.[iv]

Reprint of a selection of Pharmaceutical Industry Wish List

I. Regulatory issues

Greater regulatory convergence:

- a built-in agenda allowing for progressive greater regulatory convergence over time.
- a Working Group on Pharmaceutical and Medical Devices as platform to discuss implementation issues and address joint approaches to future compatibility topics.
- Single development plans
- address duplicative clinical testing requirements (via revision of ICH E5)

Other areas of convergence

- establish harmonized list of clinical trial result data fields & agree on which may be disclosed to the public (uniform protection of confidential commercial info & trade secrets)
- add a pharmacovigilance cluster to conduct work on post-marketing testing & risk management requirements

II. IPR

- PhRMA: seek patent term adjustments for patent office delays in the EU
- PhRMA: seek forms of patent linkage in the EU
- EU/US aligned approach re disclosure of clinical trials data (impact on commercial opportunities in third countries should also be considered)
- Include commitment to shared principles regarding patentability standards
- Extension of data exclusivity (DE) on biologics in EU up to 12 years (despite in US it is 4ys DE and 8ys Market Exclusivity)
- Establish a benchmark for not limiting the use of trademarks other than to protect public health

III. Market Access & Transparency

- pricing & reimbursement (P&R) policies should take into account innovation
- when products are grouped for pricing & reimbursement (P&R) purposes, it should only take into account bioequivalent products
- To avoid that pricing & reimbursement (P&R) policies hamper trade between EU/US
- include a pharma annex on P&R policies that promote transparency principles in processes & and reward innovation
- Procedural safeguard in government P&R
- legal remedies for applicants

IV. Other chapters:

- Third countries: coordinated approach for trade policy objectives in third countries: joint principles on regulatory harmonization, transparency measures, IP and tariff elimination and coordinated approach to be leveraged at multilateral level when feasible: WTO, OECD, ICH, WIPO

[iv] The European Medicines Agency (EMA) is developing a policy on the proactive publication of clinical-trial data. At the same time the European Commission has developed a new regulation on Clinical trials which also enhances transparency
See:www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp
and Council of the European Union "Consolidated text of the draft regulation on Clinical trials on medicinal products for human use as approved by the Permanent Representatives Committee (Part 1) on 20 December 2013"
http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=ST%2017866%202013%20INIT

Implications for Public Health and Access to Medicines

Generic competition and government pricing policies are essential to keeping medicines affordable.[3] At present, several EU public health systems already cannot provide access to medicines to all patients in need. High prices are an important obstacle and the crisis has made this situation particularly difficult. Countries hardest hit by the crisis, including Portugal, Spain and Greece, have been forced to dramatically cut their pharmaceutical spending.[4] The effects of these budget cuts on access to medicines and health services are already visible: In Greece for example more than 6,000 children are now without vaccination.[5]

The EU Commission's own 2008 Inquiry into the pharmaceutical sector showed that the balance between providing incentives for innovation and guaranteeing affordability to health products has been lost.[6] In fact, the EU Commission's Inquiry revealed that companies structurally abuse intellectual property rights limiting generic competition, hurting innovation and costing European health systems billions.[v] The TTIP proposals would aggravate this problematic state of affairs.

At the same time, although the sector has produced many key medicines for a broad variety of disease areas, the business model of Big Pharma is to a large extent based on innovation of little therapeutic value.[7] Many new medicines are neither safer nor more effective than those already available.[8] To keep this model profitable industry needs high hurdles of protection which are not oriented on usefulness but prevent as much competition as possible.[9] Furthermore, it has become clear that shrouding clinical trial data in secrecy (non-disclosure) damages both public health as well as innovation, and is ethically unacceptable.[10] Citizens, medical practitioners and researchers have the right to have access to full information on the medicines they take or prescribe.

Industry wish list would worsen the situation. Even if only a section of the industry's agenda is implemented, the consequences for European health systems and access to medicines would be significant. And given the pharmaceutical industry impressively successful track record in

[v] Strategies include excessive use of litigation, patent clusters, and practices like patent settlements; as well as misleading claims by originators about inferior quality of generics in decisions on product authorisation and pricing and reimbursement status; and the launching of follow-on products in order to displace generic medicines based on the original product. The Commission noted that on entry to the market, generic versions are 25 % less expensive than originator versions. After two years in the market, generic medicines are cheaper on average by 40%, due to competition.

pushing its agenda in international and bilateral trade negotiation,[vi] it is very likely that an important share of these proposals will end up in the negotiation text.[vii]

The 5 most worrying proposals of industry wish list

Most 5 worrying proposals of industry wish list	Implications
1. Changes in intellectual property regulations	Longer monopoly periods, higher prices and more new drugs with limited therapeutic value.
2. Limits on pricing and reimbursement policies	Undermining government policies to organise and contain cost of medicines in their national health systems.
3. Attempts to limit transparency of clinical trials	A strategy to undermine the new European Medicines Agency's (EMA) policy and neutralize the New EU Clinical Trials Regulation policy, which call for clinical trial disclosure for public safety.
4. Increased corporate involvement in policy making + Dispute resolution mechanisms	Private sector interests trumping legitimate public policy making
5. Setting a global standard	Negative impact on third countries

1. Intellectual Property: Longer Monopolies, Higher Prices

The World Trade Organization (WTO) agreement on the Trade Related Aspects of Intellectual Property Right (TRIPS) globalised standards for intellectual property protection and has been a source of controversy with regards to access to medicines since its creation in 1994. In fact, patent and other IP protections limit the availability of low cost generic medicines.[11] TRIPS includes some public health safeguards, yet bilateral trade agreements like TTIP offer new opportunities for the pharmaceutical industry lobby to demand further IP protections and lengthen the period of market exclusivity for its products. EU Commission position papers have made it clear that the Transatlantic Trade and Investment Trade Partnership (TTIP) is meant to include bolstering of bilateral intellectual property rules.[12] The industry wish list includes several proposals to achieve strengthened intellectual property rules

[vi] Most blatantly in GATT negotiations and the resulting agreement on Trade related Aspects of Intellectual Property (TRIPS) in 1994.

[vii] Some of these provisions also appear in the Trans Pacific Partnership agreement (TPP) the US is negotiating with Pacific Rim countries. The leaked text has the details and has provoked much controversy and serious concerns about access to medicines for the negotiating countries like Peru and Vietnam.

'Seek patent term adjustments for patent office delays in EU'. This is a provision that extends the patent term beyond the set 20 years, to compensate for supposed 'delays' in the granting of a patent. In the EU there are already supplementary patent certificates (SPC) to compensate for delays in the granting of marketing authorization. Patent term adjustments extend the period of monopoly, regardless of the profitability of products, and consequently delay the availability of more affordable generic medicines. [13] If patent terms extensions are included in the trade agreement, it becomes more difficult for the EU or the US to reform their domestic laws, including by limiting such extensions when revenues and profits are already large, relative to investments in Research & Development.

'Seek forms of patent linkage in the EU'. Patent linkage refers to the linking of marketing authorisation for a medicine to its patent status. A market authorisation agency's function is to assess the efficacy and safety of medicines. Linkage to patent status causes delays in generics reaching the market and generally places generic medicines at a disadvantage on the market. Regulatory authorities would only be able to start the licensing process when the patent is terminated. It is currently forbidden in the EU; the European Court of Justice has maintained that it is an anti-competitive mechanism.[viii] Yet apparently industry still seeks to bypass that, using trade agreements.

'Include commitment to shared principles regarding patentability standards'. This refers to the harmonization of EU and US patentability standards. There are important differences between EU and US patentability standards.[14] In several areas, the EU has stricter patentability standards, meaning among other things, fewer patents and more competition; key for affordability and useful innovation. Some differences concern the patentability of bioethics of life forms. There is also the difference of requirements in utility (US) versus industrial application standards (EU); utility is generally a lower standard and makes it easier to get a patent, particularly in thriving areas such as biotech innovation. So this allusion to harmonization would in practice mean: laxer standards for patentability for 'new' inventions, more patents and less generic competition for Europe.[15] Industry would never push for upward (more stringent) harmonisation of regulations in the area of patentability. Although implicit, the objective in this particular case is clear when

[viii] Patent linkage is in contradiction with EU Directive 2001/83/EC, on the Community code for medicinal products for human use, which states " the processing of marketing authorization procedures can be carried out without being affected by the protection of industrial and commercial property interests".

considering the context: Downgrade patentability standards in the EU and then further export this to the rest of the world, similarly to what the US is already doing in other trade agreements.

'Extension of Data Exclusivity (DE) on biological medicinal products in EU up to 12 years (despite in US it is 4 years DE and 8 years Market Exclusivity*)'*. Data exclusivity may prolong the market exclusivity for the originator firms after the patent has expired. It does this by not allowing generic manufacturers to refer to the marketing authorization data when aiming to register their generic medicines. Inclusion of data exclusivity term of 12 years for biologics - avoiding reference the information available about the original clinical trials for biological branded products- would lock in this term for both the US and EU (EU currently has 8+2+1 years). Although the 12 years have not made it through the policy process in the US and President Obama proposed 7 years instead, the Office of the United States Trade Representative (USTR) has tried this same strategy in the Trans Pacific Partnership Agreement.

'Establish a benchmark for not limiting the use of trademarks other than to protect public health'. This measure is likely to be related to the ongoing debate on using the International Nonproprietary name (INN) for biologicals, favoured by governments and the World Health Organization for public health reasons. Originator companies would rather use their trademark or proprietary name. This could limit the use of generics and of biosimilar medicines, the potential substitution by the doctor or the pharmacist – and so hampering affordability.[16]

2. Pricing and Reimbursement: Undermining Member States' Medicines Policies

Policies in pricing and reimbursement give EU Member States the flexibility and instruments to limit expenditure in public health systems, enabling them to grant broad and affordable access to medicines and even to protect public health (not reimbursing medicines with a questionable benefit harm ratio (i.e. pioglitazone in France and Germany) minimises the population exposed to its adverse reactions). If adopted, this could for example damage recent policies where Member States have cut medicines prices when faced with the need to cut public spending in times of austerity. The US in its trade policy has a record of seeking to limit government price controls in other countries, for instance by influencing pricing and reimbursement policies.[17] This allows for pharmaceutical companies to increase their profits on the medicines they market in a given country. The wish list illustrates how the pharmaceutical industry intends to undermine these price-controlling policies in the EU, just as they have inserted this into the US negotiation on Trans Pacific Partnership agreement (TPP).[18]

'Pricing & Reimbursement policies should take into account innovation'. This refers to price control through pricing and reimbursement agencies. It implies prices should be high and 'reward innovative products' or new medicines. But pharmaceutical companies have a too broad definition of "innovation", including everything just "new" instead of rewarding only therapeutic progress (i.e. medicines that represent a tangible therapeutic advance for patients).

'When products are grouped for Pricing & Reimbursement purposes, it should only take into account bioequivalent products'. This measure aims to exclude biosimilars. Copies of biological medicines (i.e. proteins) fulfilling the same therapeutic function can be proven to be similar but not necessarily strictly bioequivalent as is the case for chemical compounds. That demand would imply an unjustified reduction of the number of products that are comparable in order to establish the minimum reimbursement price. This would undermine Member States' subsidiarity in terms of its health systems organisation and pro-access policies.

'To avoid that pricing & reimbursement (P&R) policies hamper trade between EU/US include a pharma annex on P&R policies that promote transparency principles in processes & and reward innovation.' This is in line with the first point, that there should be high prices for 'innovative products' and insight & voice for the industry, with more industry control over the pricing and reimbursement policies established at national level.

'Procedural safeguards in government P&R.' This refers to companies having a voice in the internal pricing policies of governments through 'procedural safeguards'. For instance, tacit agreements coming into force when deadlines are not met or penalties applicable to Member States per day of delay, among others.

'Legal remedies for applicants.' This is much like 'procedural safeguards'. Companies would like to be able to take a government to court to contest a pricing and/or reimbursement decision. Investor to states dispute mechanisms (ISDS) could be such a legal remedy which would be beyond any democratic control (see point 4).

3. Limiting Clinical Trial Transparency: Undermining EU Public Health Policy

'EU/US aligned approach regarding disclosure of clinical trial data (impact on commercial opportunities in third countries should also be considered).'

'Establish harmonized list of clinical trial result data fields & agree on which may be disclosed to public (uniform protection of confidential commercial information & trade secrets)'

Currently over half of all clinical trials are never fully published (not registered and/or results are not available) and scientific knowledge about the safety and efficacy of these pharmaceutical products is lost forever. In Europe there is now a strong push towards transparency on clinical trials data spearheaded by the public health community.[19] Granting full access to clinical trial data is crucial for evidence-based medicine.[20]The recently revised EU Clinical Trials Regulation includes more transparency on the approval, conduct, and publication of detailed results of clinical trials.[21] The European Medicines Agency (EMA) announced that it will change its policy and proactively publish detailed clinical trial data provided by industry when applying for marketing approval (clinical study reports, CSR)[ix] However, the pharmaceutical industry does not agree and is fighting the EMA's policy in court (European Court of Justice).[22]

The European federation of pharmaceutical industries and associations (EFPIA) and the US pharmaceutical industries organisation (PhRMA) have developed joint principles for 'responsible data sharing,' which basically maintain the current status quo, by using 'commercial confidentiality' agreements as barriers to transparency. Moreover, welcoming the new EU Directive proposal on trade secrets published end of November 2013, EFPIA calls for clinical data to fall into the definition of trade secrets.[23] Enshrining such an 'aligned approach' in the TTIP would lock in the status quo for EU and US law, and undermine efforts by the EMA, European Parliament and Member States to disclose clinical trial data for public health reasons.[24] In practice that could mean that any information which is "unfavourable" for a drug (lack of efficacy, harms) could be considered confidential because its publication will definitely mean a commercial disadvantage.

[ix] This is partly a consequence of the Tamiflu scandal where EMA authorized it without having seen the full scientific data itself, and a consequence of other pharmacovigilance disasters(Vioxx, Acomplia) where an independent reanalysis of the data show that adverse drug reactions could have been identified at time of marketing authorisation but where dissimulated by the marketing authorisation holder.

4. Private sector interests to trump legitimate public policy regulations

'Procedural safeguards in government P&R.*'* This refers to companies having a voice in the internal pricing policies of governments through 'procedural safeguards' (see point 3).

'Legal remedies for applicants.' This is much like 'procedural safeguards'. They would like to be able to take government agencies to court to dispute pricing decisions.

Investor-to-state-dispute mechanisms could provide such a procedural safeguard or legal remedy. Both the US and the EU are planning to include dispute resolution mechanisms in this agreement. As in many other bilateral investment treaties, investor-to-state dispute settlements (ISDS) would be part of the investment chapter. ISDS allows companies to bring claims against a government in a judicial form outside the national courts, often seeking monetary compensation for allegedly illegal behaviour that negatively affected their business. Intellectual property rights would be subject to ISDS measures in the bilateral investment chapter, yet ISDS can also concern price control policies, and other pro-public health policies that limit the profits of pharmaceutical companies.

ISDS has on many occasions been targeted at government's public health and environmental policies and can hamper a governments' regulatory freedom, leading to a'chilling' effect on regulatory processes.[25] Multinational companies in both the US and the EU have been using these instruments to attack government policies all over the world. Dutch insurer Achmea recently won a 22 million Euro award against the Slovak Republic because the country had reversed the privatisation of its national health system to contain costs. US Pharma company Eli Lilly is suing the Canadian government over its patentability standards for $500 million US dollars.[26] In another IPR-based claim, US tobacco giant Philip Morris is suing Uruguay and Australia over their-anti smoking laws, on the basis that warning labels on cigarette packs and plain packaging interfere with its trademark, causing a substantial loss of market share.[27] The pharmaceutical industry will not shy away from using such an instrument to attack national public health or cost-saving policies in order to maximize profits. Companies are already well protected under EU law. Enshrining power for corporations in this agreement and enabling US companies to challenge

public health regulations means that the healthy balance between public and corporate interest is forever lost.[x]

'A built-in agenda allowing for progressive greater regulatory convergence over time.' Since 1994, the International Conference on Harmonization (ICH)[28] comprising of the regulatory authorities and pharmaceutical industry of Europe, Japan and the US have harmonized international rules for drugs registration. In fact, the US, EU and Japanese authorities in cooperation with Big Pharma have replaced the WHO in the task of laying down international standards for quality, safety and efficacy of medicines. Even though the majority of the adopted standards are of good quality, the process dodges multilateral decision-making and some new standards serve as mere trade barriers. [29]

'A Working Group on Pharmaceutical and Medical Devices as platform to discuss implementation issues and address joint approaches to future compatibility topics.' Implementation is half the game. This working group would actually be more of a committee of implementation, just as the World Trade Organization's (WTO) TRIPS Agreement has the Council for TRIPS to monitor the operation of this Agreement.[xi] The TTIP would have a committee particularly devoted to pharmaceutical policies and regulations. Implementation issues would concern IP, as well as regulatory issues, pricing and reimbursement. These types of working groups tend to have no public record and totally lack transparency and democratic control – it would institutionalize this type of joint transatlantic pharmaceutical and medical devices industry lobbying.[xii]

'Address duplicative clinical testing requirements (via revision of ICH e5)'. Currently the International Conference on Harmonization (ICH) allows countries to have additional trials because differences in populations (genetic, etc.). Therefore full harmonization could create safety risks for patients.

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[x] Karel De Gucht, European commissioner for trade, announced 21 January that EU negotiators will suspend one part of ongoing trade talks with the United States - a section dealing with investment rules - while the Commission conducts a three month long public consultation. http://kriegspiel/international/business/criticism-grows-over-investor-protections-in-transatlantic-trade-deal-a-945107-2.html

[xi] Article 68, TRIPS Agreement

[xii] The US-South Korea FTA includes such a Working Group and so does the US proposal for the Trans Pacific Partnership (TPP) agreement.

5. Global standard setting

The implications of the TTIP for third countries - especially lower and middle-income countries - are significant, as one of the objectives behind this agreement is to set global standards. Less transparency on the benefit and harm of medicines, longer monopolies, less generic competition and limits on pricing policies are even more harmful for low and middle-income (LMICS) countries where resources are more constrained. Many LMICs have fewer institutions to frame and balance intellectual property protection and higher prices, such as health insurance and strong competition law. Here, the increased power and protection of large corporations will put an even greater burden on public health systems and on citizens, effectively leading to the exclusion of many people from accessing certain medicines. At the same time, some of the demands could create trade barriers for third countries.

The EU should promote the Common Good, not Narrow Commercial Interests

Undoubtedly the pharmaceutical industry has a very ambitious agenda for the TTIP, an agenda that is harmful for access to medicines and for public health in the European Union. Apart from the intention to expand periods of monopoly through patents and other intellectual property measures, there is a clear aspiration to **undermine regulations established by democratically elected governments of European Member States to protect public health**. Also, the European move towards transparency of clinical trial data is directly targeted by this agenda.

The industry wish-list shows a **disrespectful attitude**: disrespectful of countries' democratic processes and public policies, and disregarding the evidence that more intellectual property does not deliver more innovation, as well as the needs of patients who need treatment.

Big Pharma is one of the strongest corporate lobbying forces on both sides of the Atlantic, dwarfing the capacity of public health advocates. The European Commission, including its Trade Directorate General, should refrain from uncritically partnering with Big Pharma on European citizens' behalf. The European Parliament and Member States should also reject this **corporate policy capture**. Exaggerated promises of economic growth cannot be an acceptable trade-off for weakening democratic control over public health policy making.

At present many patients in Europe cannot afford the medicines they need, the present financial crisis has made it even harder. Faced with a financial and economic crisis and ever increasing health care expenditures, EU Member States are struggling to continue to provide universal access to medicines for their citizens.

The EU should not further strengthen the hand of pharmaceutical monopoly holders. Instead, it **should promote the common good**. To this end the EU should redirect companies towards economically sustainable, health-needs driven real innovation; exploring open, collaborative Research & Development models based on affordability instead of consolidating the present system of high monopoly prices.

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End Notes

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