Healthcare and
social benefits for all

POSITION PAPER

Transatlantic Trade and Investment Partnership (TTIP)

28 June 2014

Further information

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Summary of the key points from of mutual benefit societies and health insurers:

Transparency

- Mutual benefit societies and health insurers call for a greater involvement of the public in the TTIP negotiations.

Exclusion of services of mutual benefit societies/ health insurance funds from trade agreements

- Health insurance services provided by statutory health systems/health mutual benefit societies must be clearly and unambiguously defined and excluded from the scope of free trade agreements.
- Health services (hospitals, nursing homes, etc.), social services and other services carried out by mutual benefit societies or other not for-profit organizations should also be excluded.
- The service chapter should only apply to services which are explicitly mentioned ('positive list').

Investment protection and Investor-State-Dispute Settlement

The Investor-to-State Dispute Settlement Mechanism should be excluded from the TTIP negotiations because

- Both the EU and the US have strong legal mechanisms in place to reassure investors.
- It can be expected that private for-profit-health -insurers from the U.S. might sue national governments of the EU in order to challenge national health protection systems regarding pricing and reimbursement measures, or access to compulsory health protection services provided by public entities or private organizations carrying out these activities on behalf of Member States.

If ISDS was to be included

- Intellectual Property (IP) should be excluded from the definition of investment.
- A positive list approach, where only especially mentioned service sectors will be subject to Investor-State-Dispute Settlement (ISDS) should be adopted.
- Strong provisions should be included to safeguard the public interest (e.g. health and social interests) U.S. investors should follow EU rules. "Indirect expropriation" and "fair and equitable treatment" should be precisely and narrowly defined to protect legitimate government regulations in support of public health (e.g. pricing and reimbursement measures, access to medicines) from challenge by foreign investors.

Public Procurement

If the EU opens up its markets to public procurement in the TTIP, every commitment should be binding for *all* EU Member States and for *every* U.S. State because

- Of the risk that EU Member States investors and its entities would not have the same access to the U.S. market as the U.S. entities/investors to the EU market.
- Commitments at U.S. Federal level might not be respected by sub-level government entities.

Commitments in the field of health protection/social services should be made via a 'positive list'.

Pharmaceuticals

1. **Pricing and reimbursement**

- Pricing and reimbursement is a highly sensitive topic and a national competence; it should be definitely excluded from the TTIP negotiations.
- Reimbursement procedures should not be shortened. The current legislation at EU level guarantees affordable and cost-effective medicines and ensures access to pharmaceuticals for patients.

2. **Advertisement regarding healthcare services and pharmaceuticals**

- Patients should only have access to objective information of high quality, which is independent of the manufacturers.
- In fact, only objective information empowers the patient to discover and to decide, what is best for him. Therefore direct-to-consumer pharmaceutical advertising of medicines on prescription should be excluded in the TTIP.

3. **Internet Sales and safety of medicines**

- National regulations of the Member States with strong rules for internet sales should be maintained and not undermined.

4. **Limiting Clinical Trial Transparency: Undermining EU Public Health Policy**

- Transparency of clinical trial data is necessary to ensure the safety and efficacy of pharmaceuticals
- The progress gained in the EU legislation on clinical trials should be guaranteed.

5. **Intellectual property rights**

- Member States should have the possibility to exclude patents available for interventions for diagnostic, for therapeutic and surgical methods for the treatment of humans as is foreseen in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization.
- Patent protection and data exclusivity should in any case not be extended as it will lead to an increase in price for pharmaceuticals, which will limit patients' access to affordable medicines.
- The right of using the International Non-proprietary name (INN) for biological products should be guaranteed.

6. **Medical Devices**

- In the U.S., the Food and Drug Administration's (FDA) standards for the premarket approval of medical devices are higher than Europeans'. This issue should be included in TTIP's negotiations in order to raise patients' safety in Europe.

I. Introduction

Over the past years, an increasing number of countries have negotiated at international level in order to remove barriers to trade in services and goods. It is considered that a free market economy increases competition, which forces suppliers to reduce prices and increase the quality of their goods and services. At the same time it is believed to lead to allocative and productive efficiency and create sustainable development, integrating environmental, social and economic concerns.[1] More and more countries are initiating new trade agreements between two countries or amongst a group of countries, the so-called free trade agreements ("FTAs"). They are promoted to provide significant economic benefits to signatory countries. Regional FTAs are often seen as a way to move liberalisation forward and to increase market access in addition to that achieved at multilateral level in the WTO. The EU and the US in particular are promoting bilateral FTAs implementing existing international trade rules.[2] The most recent negotiations are the trade agreements between the EU and Canada, known as CETA (Comprehensive Economic and Trade Agreement) and between the EU and the USA, called TTIP (Transatlantic and Investment Partnership). However, TTIP will contain rules which will go beyond the multilateral achievements, such as investment rules, public procurement, services and intellectual property rights (TRIPS-plus) in order to make regulations the least trade-distortive. Mutual benefit societies and health insurers are worried about the changes of the nature of the "new free trade agreements": the "positive/negative list approach" in the services negotiations, the increasing inclusion of chapters on investment and on investment protection and their impact on public health and access to medicines, the increasing protection of intellectual property rights, and the lowering of standards (for example food standards).

II. Transparency – greater involvement of the public

Mutual benefit societies and health insurers call for a greater involvement of the public in the TTIP negotiations, which started in June 2013. Even though regular information events and hearings for the Civil Society have been organized and a public consultation on the Investor-to-State Dispute Settlement has been launched, AIM and its members think that the

1 AIM Background paper „Globalization on health care".

2 The Potential Impact of Free Trade Agreements on Public Health | UNDP, UNAIDS; http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2349_Issue_Brief_Free-Trade-Agreements_en.pdf

involvement is not sufficient. Without the text being made publicly available, it is almost impossible for Civil Society to contribute in an appropriate way. Publication of concrete provisions and key documents allows understanding of the agreement's full impact and is the only was to facilitate real contribution.

III. Inclusion of health mutual's and statutory health fund's services in trade agreements?

At a first glance, health insurance services of statutory health funds as well as of health mutuals, when delegated by the state, seem to be excluded from plurilateral and free trade agreements. The General Agreement on Trade in Services (GATS), negotiated in 1994 under the WTO, covers virtually all service activities with some exemptions: It excludes "services supplied in the exercise of governmental authorities" (Article 1.3). The exemption is defined as "any service, which is supplied neither on a commercial basis, nor in competition with one or more service suppliers". Similar phrases can be found in the first abstract of TTIP.[3]

In many health systems of different countries it is difficult to say whether health insurance services are supplied on a commercial basis or in competition with one or more services suppliers, as definitions in the GATS are vague and uncertain. There is no further guidance; terms and concepts such as "public services" or "services of general interest" do not exist in the GATS.[4]

It should be noted that, currently, health insurance services provided by statutory health insurers and mutual benefit societies carrying out government functions are to some extent protected against the General Agreement on Trade in Services (GATS). However, it is becoming more and more difficult to remove health insurance benefits and health insurance related financial services from the scope of the liberalisation obligations of the GATS. The reason is that some health insurers in Europe are becoming more and more competition oriented and are being approached by profit-oriented private health insurers.[5] This argument is even more crucial when it comes to TTIP: This agreement is designed to go beyond the GATS.

Exceptions to commitments related to market access in the GATS exist only for those financial services that are not in *"competition with a public entity or a financial service supplier".*[6] As a consequence of the liberalisation commitments in the insurance sector, the apparent similarity between statutory health insurers (as well as mutual benefit societiescarrying out government functions) and private for profit health insurers could lead

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3 Article 1, paragraph 4 (j) TTIP abstract from 02/07/2013: "*services includes any service in any sector <u>except</u> services supplied in the exercise of governmental authority".*
(k) "services supplied in the exercise of governmental authority" are "any services which is supplied neither on a commercial basis, nor in competition with one or more service suppliers".

4 Rudolf Adlung, Trade in Services Devision, WTO Secretariat, Geneva, Switzerland, p. 229.

5 Examples: German statutory health fund (GKV) and private health insurers (PKV);

6 Annex on financial services in GATS: 1. b) (ii) (c); article 57 of the abstract of TTIP from 02/07/2013: "*Nothing in this Title shall be construed to prevent a Party, including its public entities, from exclusively conducting or providing in its territory activities or services forming part of a public retirement plan or statutory system of social security, except when those activities may be carried out, as provided by the Party's domestic regulation, by financial service suppliers in competition with public entities or private institutions."*

to an activation of international liberalisation commitments.[7] Furthermore, the increasing "quasi-economic" structuring of statutory health insurance services can fall within the field of public procurement. According to statements from the EU Commission, the EU is trying to integrate public procurement in the negotiations with the U.S. (TTIP).

Impact on mutual benefit societies and health insurers at national level and the risks:

As Free Trade Agreements are considered as instruments of international law, they rank higher than national law and even European Law (Article 216 Paragraph 2 of the Lisbon Treaty). As a consequence, international trade rules would override national social and public health provisions in case of conflict. In a sector such as health care this could become a particular concern.

There is a risk that health insurance services provided by mutual benefit societies and health insurers might be included in the free trade agreements. As a consequence, national provisions of the Member States of these services could be seen as trade barriers. Thus, free trade agreements could limit the ability of states to restrict access to public health services. Profit oriented U.S. providers might enter the market for public health services in the EU and be able to compete with the health services of statutory health insurances or health mutuals.

Health services are part of the general good. They generate benefits for the population such as universal access to healthcare, increased life expectancy, as well as security, social cohesion and solidarity. If health care were to be organised on the sole basis of profit oriented enterprise and individual protection it would definitely not serve in the same way these values. Non-profit-oriented mutual benefit societies and health insurers are built upon the principle of solidarity. They guarantee safety and quality of supplied health care coverage and ensure access to health care services for the whole population, irrespective of financial and health status. This is achieved through providing services according to needs.

Moreover, not only do mutual benefit societies provide services delegated by the state, such as compulsory health insurance, but they also offer affordable health services and other services. As an example, they provide dental care, optical care and long-term care. Their activities can currently be ruled by European laws on service of general economic interest (SGEI). In that context, activities in the field of health and social services' specificities are more and more taken into account by European laws. Both activities specificities must be kept and not be overruled by international law. In order to continue providing affordable, resilient and high-quality services, activities in the field of health and social services should be excluded from the TTIP.

An opening of the statutory health services to profit oriented health insurers as well as the introduction of competitive elements into health systems, the creeping privatisation of the public health care sector and the shift towards more cost-sharing and privately funded health care provisions could lead to the mere promotion of commercial interests instead of the improvement of health outcomes and health services. Suppliers of services across borders

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7 Doctors thesis, Iordanka Iungareva, February 2009, Grenzüberschreitende Gesundheitsnetzwerke im Lichte der EG-Grundfreiheiten und des europäischen Wettbewerbs-, Beihilfe- und Vergaberechts: Eine neuinstitutions-ökonomische und evolutionsökonomische Analyse des Managements transnationaler Gesundheitsnetzwerke; p.120. 121, http://d-nb.info/993584012/34 (German), (access 15 April 2014).

or via information technologies might escape from national authorities' control, safety, quality and social standards, which could not be imposed on them.

Mutual benefit societies and health insurers request:

- Health insurance services (provided by statutory health systems or health mutual benefit societies) must be clearly and unambiguously defined and excluded from the scope of free trade agreements.
- Health services (hospitals, nursing homes, etc.), social services and other services carried out by mutual benefit societies or other not for-profit organizations should also be excluded.
- The service chapter should only apply to services which are explicitly mentioned ('positive list' approach).

IV. Investment protection and Investor-State-Dispute-Settlement

Free Trade Agreements and Bilateral Investment Treaties include powerful dispute settlement mechanisms dealing with claims before arbitration tribunals outside national court systems. These mechanisms enable foreign investors to initiate international legal proceedings against national authorities when they believe their interests are being affected. As a consequence, public policy objectives have been challenged, forcing national governments to pay compensation in the amount of millions of dollars or to reconsider political decisions.[8]

Canada and the United States were among the first states to be sued by foreign investors under the investment provisions of NAFTA´s Chapter 11. The investment chapter was especially criticized with regard to the weakened sovereignty of host states and the high rate of taxes as well as the ad hoc nature of the tribunals and lack of clarity in NAFTA proceedings. Furthermore, NAFTA gave greater rights to foreign investors than it did to domestic investors and the provisions enabled investors to bring an action against State governments so as to discourage them from enacting otherwise legitimate laws.[9] A lawsuit against governments could oblige taxpayers to pay millions of dollars, as happened in the case of *"Metalclad v Mexico"*, where the government of Mexico was held liable to pay damages of $ 15.6m. This burden was ultimately shifted to Mexico´s taxpayers.[10] In consequence, both states added certain restrictions related to fair and equitable treatment and expropriation in order to safeguard their own policies in the field of environmental and social affairs.[11]

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8 Oxfam Discussion paper „Sleeping Lions" 2011, p. 4; http://www.oxfam.org/sites/www.oxfam.org/files/dp-sleeping-lions-260511-en.pdf (access on 17/04/2014).

9 J. Byrne, „NAFTA Dispute Resolution: Implementing True Rule Based Diplomacy through Direct Access" (2000) 35 Texas International Law Journal 415, 434.

10 Metalclad Corporation v United Mexican States (2001) ICSID Case No ARB(AF)/97/1, 40 ILM 36.

11 Oxfam Discussion paper „Sleeping Lions" 2011, p. 8; http://www.oxfam.org/sites/www.oxfam.org/files/dp-sleeping-lions-260511-en.pdf (access on 17/04/2014).

Impact on mutual benefit societies and statutory health insurers:

Investment provisions can seriously limit the health policy space of Member States. Since the Lisbon treaty came into force, direct foreign investment has become a key part of the EU's external trade policy and is no longer the sole competence of individual EU countries.

Investor-to-state dispute settlements can re-establish rights or market access giving investors of the signatory country the same investment rights as those given to domestic or third-country foreign investors. Compensation in the case of expropriation can require public authorities to pay full and prompt compensation to investors. Usually there are only minor exceptions included where expropriation is justified (national security). Compensation in the case of expropriation becomes problematic when investors consider that they must also be compensated when they have been expropriated from "expected profits".

Cases in the health sector have already been initiated by foreign investors. In the Case *"Centurion Health v. Canada"* under Chapter 11 of NAFTA, a U.S. national and his company Centurion Health sued Canada in order to open a private health care facility in Vancouver, Canada, which was supposed to offer private surgical services ranging from cosmetic and reconstructive plastic surgery to general surgery. The claimant sought $ 160 million (plus interest and costs). The tribunal never decided the claim because the investor did not pay $100.000 deposit as required by the arbitration tribunal to proceed. It is not sure whether the claim would have succeeded if there had been a decision by the tribunal. However, in this case the Canada Health Act and publicly-funded health care services were challenged.[12]

In another case, Eli Lilly, one of the largest pharmaceutical companies in North America, sued the Canadian Government for $ 500 million. Under the North American Free Trade Agreement (NAFTA), a company can sue another NAFTA country if that nation's laws affect its expected future profit. In this case, Eli Lilly claimed losing profit because Canadian regulators denied patents on two of Eli Lilly's drugs.[13]

In the case of the United Kingdom, there is a very concrete threat for the National Health System. Indeed, the Health and Social Care Act 2012 introduced a requirement for competitive tendering in the health sector, opening the door to the private sector. The House of Commons and British MPs have pointed out that an ISDS mechanism within TTIP could make it impossible to repeal the Act and could potentially have major repercussions for the NHS.[14] Indeed, private companies could bring legal proceedings against the UK government in that case as a change to this legislation would be interpreted as discrimination of private companies

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12 Case Centurion Health v. Canada.

13 http://italaw.com/sites/default/files/case-documents/italaw1172.pdf (access on 17/04/2014).

14 House of Commons Note on Investor-state dispute settlement (ISDS) and the Transatlantic Trade and Investment Partnership (TTIP), 2013.

Mutual benefit societies and health insurers request:

The Investor-to-State Dispute Settlement Mechanism should be excluded from the TTIP negotiations because

- Both the EU and the US have strong legal mechanisms in place to reassure investors.
- It can be expected that private for-profit-health-insurers from the U.S. might sue national governments of the EU in order to challenge national health protection systems regarding pricing and reimbursement measures or access to compulsory health protection services provided by public entities or private organizations carrying out these activities on behalf of Member States.

If ISDS was to be included

- Intellectual Property (IP) should be excluded from the definition of investment.
- A positive list approach, where only investments from especially mentioned sectors will be subject to Investor-State-Dispute Settlement (ISDS) should be adopted.
- Strong provisions should be included to safeguard the public interest (e.g.health and social interests). U.S. investors should stick to EU rules. "Indirect expropriation" and "fair and equitable treatment" should be precisely and narrowly defined to protect legitimate government regulations in support of public health (e.g. pricing and reimbursement measures, access to medicines) from challenge by foreign investors.

V. Public Procurement

During the TTIP negotiations, the EU plans to integrate rules on public procurement. The preparatory process is intended to start immediately. In the U.S., sometimes only the Federal state is bound to multilateral agreements such as the General Public Procurement Agreement (GPA). The individual constituent States are covered to varying degrees by the GPA. This means that only goods and supplies of some States in the U.S., which themselves have signed this agreement, would be treated on equal footing with other U.S. domestic products for procurement opportunities with State-level entities. However, the Government Procurement Agreement under the World Trade Organisation does not give open access to sub-federal level entities and the municipal level.

Impact on mutual benefit societies and health insurers:

The U.S. investors and its individual State entities, including subfederal level entities and the municipal level entities would have open access to EU health services and EU health products. In contrast, the EU Member States investors and its entities would not have the same access to U.S. health services and health products.

Mutual benefit societies and health insurers request:

If the EU opens their market to public procurement in the TTIP, every commitment should be binding for *all* EU Member States and for *every* US State because

- EU Member States investors and its entities would not have the same access to U.S.

health services and health products as the U.S. entities/investors to EU services and products.

- Commitments at U.S. federal level might not be imposed by sublevel government entities and municipal level.

Commitments in the field of health protection and social services should be made by means of an explicit 'positive list'.

VI. Pharmaceutical Sector

1. Pricing and Reimbursement

The U.S. has requested the inclusion of pricing and reimbursement procedures in the TTIP negotiations. In recent years, many Member States have been facing rising health expenditure. Hence, governments have applied policies in order to control healthcare and pharmaceutical expenditure. Some countries have implemented cost-containment measures regarding pharmaceuticals. Members States need to improve public health to ensure access to healthcare such as therapies and pharmaceuticals and, at the same time, to control health expenditures. That is why Member States need to have the flexibility to cut prices and health expenditure to guarantee affordable and available medicines. The examples of increasing prices for different pharmaceuticals in the different Member States show how important pricing and reimbursement policies are, in order to ensure affordable and available medicines for the patients of Europe. The pricing and reimbursement procedures fall within national scope and Member States must keep control of those procedures. Patented new drugs, e.g. cancer, multiple sclerosis or 'orphan drugs', have come into the EU markets with unacceptably high prices.[15] Member States have enacted reforms to ensure that the so-called innovative medicines really bring new benefit to the patient.[16]

Germany has introduced with the AMNOG-Reform a mandatory Health Technology assessment-procedure (based on added clinical value) for new drugs. After the HTA-evaluation, the pharmaceutical manufacturer must undergo price negotiations with the umbrella organization of public funds. In Belgium, several procedures exist to evaluate the added value: in addition to the standard reimbursement procedures, specific procedures have been put in place to allow early access to drugs with proven **therapeutic and social added value** and which respond to unmet medical needs: it is possible to start the reimbursement procedure before the final opinion of the Committee for Medicinal Products for Human Use at EMA (European Medicines Agency); it is possible to provide early access, via the Solidarity Fund, to drugs which do not have marketing authorization yet but which present therapeutic and social value and responding to the priorities set by the General

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15 In Germany, expenditure for medicines for public sick funds had nearly doubled during the last 10 years. In Belgium, considerable room for manoeuvre has been identified over the past decade regarding the budget for reimbursement of innovative life-saving treatments. Thus, the reimbursement of anti-cancer drugs has multiplied by 3,2 between 2002 and 2012[15]. Today, anti-cancer drugs represent the highest category of drugs expenditure, costing € 283,3 million. The number of patients treated increased by 55%, but it is in particular the doubled of the costs of treatment which explains the growth of spending. Reimbursement of 'orphan drugs' through compulsory insurance quadrupled from 2005 to 2012[15]. In France, a 2008 negotiation between industrial and governmental authorities agreed that the total cost of an 'orphan drug' treatment could not exceed 50000€/patient/year.

16 Germany: AMNOG law from 2011 to limit the rise of costs of pharmaceuticals during the past years; Belgium: Reform of the legislation "Unmet Medical Need", which will be implemented in December 2014 and which will allow that those patients will benefit earlier from real innovative medicines; France: Reintegration of out-DRG drugs in DRG in France for cost-containment measures.

Council of the NIHIDI.

Impact on mutual benefit societies and statutory health insurers:

The inclusion of pricing and reimbursement in the TTIP negotiations would enable the U.S. to influence national pricing and reimbursement policy. If a national authority of a Member State wants to exclude a drug from reimbursement, it could be challenged by a U.S. pharmaceutical company before an Investor-to-State Dispute Settlement tribunal. [17] Moreover, pricing and reimbursement procedures could be shortened due to the request of pharmaceutical companies in order to give patients faster access to their medicines. By contrast, national pricing and reimbursement procedures are necessary to ensure that patients will get value for their money and that medicines are affordable to them.

Mutual benefit societies and health insurers request:

- Pricing and reimbursement is a highly sensitive topic and a national competence; it should not be subject to the TTIP negotiations.
- Reimbursement procedures should not be shortened. The current legislation at EU level guarantees affordable and cost-effective medicines and ensures access to pharmaceuticals for patients.

2. Advertisement of healthcare services and pharmaceuticals

Advertisement of medicines on prescription aimed at consumers is prohibited in many Member States in the EU or is only allowed in professional networks (e.g.doctors or pharmacists).[18] In some Member States, the publication of package inserts for medicines on prescription on the Internet is permitted.

The U.S. allows direct-to-consumer pharmaceutical advertising (DTCPA), where a pharmaceutical company is allowed (usually via popular media) to promote its prescription products directly to patients. Even though the U.S.'s Food and Drug Administration (FDA) regulates DTCPA, the rules are criticised as being too relaxed and inadequately enforced. Direct-to-consumer pharmaceutical advertising (DTCPA) has grown rapidly during the past few decades and is now the most prominent type of health communication that the U.S. public encounters.

Impact on mutual benefit societies and health insurers:

There is a risk that US-style DTCPA might lead to unbalanced information and influence on patients. Furthermore, direct advertisement can also have an impact on doctors, leading to overprescribing of unnecessary, expensive, and potentially harmful medications.

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[17] Similar case Eli Lilly v. Canada (see above under Investor-State-Dispute-Settlement).

[18] For example, in France, advertising to the public of prescription medicines is forbidden. It is allowed for health professionals and pharmacists, if the advertising is controlled and accepted by health authorities. Industrials that bypass the law could be banned from marketing their products. In Germany, misleading advertising to the public regarding pharmaceuticals, medical products, procedures, treatments, etc. is forbidden. Advertisement to health professionals and pharmacists is allowed (Heilmittelwerbegesetz, HWG).

Mutual benefit societies and health insurers request:

- Patients should only have access to objective information of high quality, which is independent from the manufacturer.
- Direct-to-consumer pharmaceutical advertising on medicines on prescription should be excluded in the TTIP, because only objective information can empower the patient to discover and to decide what is best for him.

3. Internet Sales and the safety of medicines

An increasing number of pharmacies are involved in the sale of medicines on the internet to facilitate and accelerate the purchase of medicines. The safety of such medications cannot be guaranteed in all cases because there are risks that some online doctors and pharmacies could exploit regulatory gaps to prescribe and dispense illegal, addictive, or unsafe drugs. The sale of medicines on the internet is not allowed in all EU countries. However, European legislation does not prohibit the sale of medicines online but makes it possible for Member States to individually prohibit online sales of medicines or to adopt at least strong conditions for internet sales.

Mutual benefit societies and health insurers request:

- National regulations of the Member States applying strong conditions for internet sales should be maintained and not undermined.

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

At European level, transparency on the approval, conduct and publication of detailed clinical trials data has been improved through new legislation. These improvements should be kept and should not be undermined. In evidence-based medicine, full access to clinical trial data is crucial. 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) but backpedalled at the last minute[19]. Currently, there are still clinical trials which are not registered, or whose results are not available. Arguments of "commercial confidentiality" are used to prevent the publication of clinical trial data.[20] There is a risk that these arguments will also influence the TTIP negotiations.

Impact on mutual benefit societies and health insurers:

Information such as evidence of lack of efficacy and harm could be hidden from the patient. Clinical trial results are important contributors to scientific knowledge about safety and efficacy of these pharmaceuticals as well as their therapeutic added value.

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[19] See AIM, HAI, ISDB, MiEF and Nordic Cochrane Centre press release: Backpedalling on EMA's "proactive publication of clinical-data" draft policy, published on 20 May 2014.

[20] A Civil Society Response to the Big Pharma wish list; http://commonsnetwork.eu/wp-content/uploads/2014/03/24_03_2014_CivilSocietyResponse_BigPharma_WishList_final1.pdf(access 18/04/2014).

Mutual benefit societies and health insurers request:

- Transparency of clinical trial data is necessary to ensure the safety and efficacy of pharmaceuticals
- The progress gained in the EU legislation on clinical trials should be guaranteed.

5. Intellectual property rights

In some countries the law allows patents on medical procedures but many countries have banned medical procedures. According to reports, the United States seeks to impose medical procedure patents on other countries as they did in the Trans-Pacific Partnership (TPP) with Asian and Latin American countries[21], proposing that "each party shall make patents available for interventions for the following... diagnostic, therapeutic and surgical methods for the treatment of humans or animals."[22] As a concession, patent law in the U.S. limits enforcement of these patents against medical practitioners who perform medical or surgical procedures. Surgeons who perform patented surgical methods should therefore not be liable for patent infringement on these activities.[23]

The exclusion of medical procedure patents can also be found in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)[24], which allows members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals.[25]

Generic drugs are important options that allow greater access to health care for all. According to the US FDA, "A generic drug is identical or bioequivalent to a brand name drug in dosage, form, safety, strength, root of administration and intended use." Often the cost difference between a generic drug and a brand name drug is so much that even well to do people cannot afford a branded drug while the generic version is affordable. Therefore, patent protection should not be extended in such a way as to discourage 'generics' on the market from giving access to more patients.

Impact on mutual benefit societies and statutory health insurers:

Medical procedure patents pose substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and blocking medical advancement.

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21 The Trans-Pacific Partnership (TPP) was a trade agreement between Brunei, Chile, New Zealand, and Singapore, which seeks to manage trade, promote growth, and regionally integrate the economies of the Asia-Pacific region. The U.S. joined in 2011 and the agreement was expanded to the Trans-Pacific Strategic Economic Partnership Agreement (TPSEP or P4).

22 http://wikileaks.org/tpp/#start; letter of Public Citizens Global Access to Medicines Program http://www.citizen.org/documents/MedicalProceduresMemo_final%20draft.pdf (access in 24 April 2014).

23 35 U.S.C. 287 ...(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

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

25 The text of TRIPS Art. 27.3:
"Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; ..."
The text of TRIPS Art. 27.2: *"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."*

Strengthening the intellectual property rights (patents, data exclusivity) would lead to an increase of costs for health care systems, which has also an impact on health insurers as well as on patients. Access for all patients to innovative treatments and medicines would be limited. Furthermore, patents on medical procedures still impose significant challenges to medical practitioners in treating patients without fear of infringing those patents.

The pharmaceutical industry is asking to '*establish a benchmark, so the use of trademarks will not be limited except when these limits are introduced to protect public health*'. This request is likely to be related to the ongoing debate on using the International Non-proprietary name (INN) for biologicals, favoured by governments and the World Health Organization for public health reasons.[26] Originator companies would rather use their trademark or proprietary name. This could limit the use of generics and of biological products, the potential substitution by the doctor or the pharmacist – and so hamper affordability.[27]

Mutual benefit societies and statutory health insurers request:

- Member States should have the option to exclude patents available for interventions for diagnostic, therapeutic and surgical interventions for the treatment of humans, as foreseen in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation.
- Patent protection and data exclusivity terms should not be extended, as this would lead to an increase of costs of pharmaceuticals, limiting patients' access to affordable medicines.
- The right of using the International Non-proprietary name for biologicals should be guaranteed.

6. Medical devices

Various scandals have shown the failures and limits of the European certification system for medical devices. Several medical devices that were rejected in the United States thanks to their FDA's high standards were marketed in Europe, and then removed from the market for safety reasons. As an example, the U.S.'s FDA rejected all cardiac constraint devices to treat heart failure. They were approved in the EU based on limited testing. Testing to support US approval showed that the devices were no better than prescription drug therapy, but subjected patients to invasive surgery, a higher risk of operative death, and precluded necessary bypass surgery for some patients.[28]

Mutual benefit societies believe that higher standards for the pre-market approval of medical devices, such as the U.S. FDA's, should be respected in Europe. The Current European laws on medical devices are insufficient to ensure a high level of quality, safety and efficacy of medical devices. Public health dispositions regarding medical devices should be included in

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[26] International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.

[27] The Transatlantic Trade and Investment Partnership (TTIP): A Civil Society Response to the Big Pharma wish list - Commons Network -www.commonsnetwork.eu

[28] Report FDA, Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US, May 2012.

the TTIP negotiations.

Mutual benefit societies and statutory health insurers request:
The issue of medical devices' pre-market approval should be included in TTIP's negotiations in order to increase patients' safety in Europe.

ABOUT US:

AIM
Healthcare and social benefits for all

The Association Internationale de la Mutualité (AIM) is a grouping of autonomous, not-for-profit health insurance and social protection bodies that operate on the principle of solidarity. Currently, AIM's membership consists of 59 national federations representing 27 countries. In Europe, they provide social coverage against sickness and other risks to more than 160 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone. More info: www.aim-mutual.org.
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