Talking TTIP: Pharmaceuticals and Healthcare

Fact Sheet by campaign group “SMEs Against TTIP”; (German: “KMU gegen TTIP”)

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WORKING GROUP: “SMEs Against TTIP” (*KMU GEGEN TTIP*)

The aim of this working group is to explain to Germany’s small and medium-sized enterprises the planned features and the effects of the TTIP free-trade deal. As well as providing this information, the working group will also play its part in giving greater strength to the critical voices in the SME sector which continue to be absent from the European Commission’s public statements.

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What TTIP Means for the Health Sector: Unchecked Costs and Greater Pressure to Privatise

In their position paper on TTIP the presidents and chairs of the German Medical Association (**Bundesärztekammer (BÄK)**), the German National Association of Statutory Health Insurance Physicians (**Kassenärztliche Bundesvereinigung (KBV)**), the German Dentists Association (**Bundeszahnärztekammer (BZÄK)**), the Federal Union of German Associations of Pharmacists (**Bundesvereinigung Deutscher Apothekerverbände (ABDA)**) and the German National Association of Statutory Health Insurance Dentists (**Kassenzahnärztliche Bundesvereinigung (KZBV)**) made the following joint declaration: "We demand a *positive list* which clearly states that TTIP shall not apply to the health service and the healing professions."[1] The statement demonstrates that Germany's main health professionals are clearly opposed to TTIP being applied to the health sector.

Background: The German health service is not a free market. In a European context we understand this to mean that every patient has the right to a treatment that is best for him/her and that meets his/her medical needs. This basic principle of solidarity is fundable because refundable services are regulated by Germany's self-governance principle[2] (according to which all stakeholders – including patients - are called on jointly to play their part in ensuring the effective functioning of the public health insurance system.) But within the framework of these regulations, commercial competition is both provided for and considered desirable.

By contrast the US health system is highly market-orientated and has considerably fewer solidarity elements.

Given that the health system is part of the public services provision, there is a plan to exempt health services from TTIP altogether – by way of an exemption clause. This clause states that TTIP shall not impinge on the freedom of the parties to the TTIP Agreement to set their own health policies; to structure their health services; and to provide medical care.[3] The problem however is that the public and private sectors are both closely intertwined with the health service – and it is not always possible clearly to separate these sectors, even from a legal point of view. As such this may seriously limit the effect of the proposed exemption clause.

[1] Joint Position Paper, 19.05.2015: www.bundesaerztekammer.de/presse/pressemitteilungen/news-detail/vielfalt-des-europaeischen- gesundheitswesens-und-freiberuflichkeit-bewahren/ (available in German only)
[2] www.bmg.bund.de/themen/gesundheitssystem/selbstverwaltung/selbstverwaltung-im-ueberblick.html (available in German only)
[3] cf. also: www.bmwi.de/BMWi/Redaktion/PDF/S-T/ttip-schutz-der- daseinsvorsorge,property=pdf,bereich=bmwi2012,sprache=de,rwb=true.pdf (available in German only. For background in English see EC Trade)

The threats posed by TTIP to the health care system are the following:

I. Pressure to privatise part of the health service could increase
II. Costs, particularly for drugs, could rise steeply
III. Licensing requirements for registered doctors and pharmacists could be weakened resulting in increased unfair competition

Any redistribution of health care costs that favoured large pharmaceutical companies would be at the expense of small and medium-sized enterprises. There would be increased cost pressures on doctors, dentists, pharmacists, hospitals and medium-sized producers of medical products. Once specific regulations were enshrined in TTIP, they could not be reversed by national parliaments.

The Arguments in Detail:

I. Unchecked Pressure to Privatise

a. Scope of proposed exemption clause in TTIP covering public utilities is unclear

According to the so-called 'Public Utilities' clause, public utilities are to be exempted from TTIP regulations. But it remains unclear as to whether or not, in this context, Germany's social insurance funds would be deemed to be 'public utilities'. In June 2015 Germany's Green Party posed the following parliamentary question on this very issue: "In the government's opinion, is the exemption clause ("Public Entities") adequate to exempt fully the German social insurance system from TTIP regulation, given the 'self-governance' principle that applies here in Germany?" They went on to ask: "What is the impact on the scope of the exemption clause of the fact that statutory health insurance funds here in Germany are in competition with one another?"
Germany's secretary of state, Matthias Machnig, replied that while TTIP would not impact on how Germany's social insurance system functioned, the government "could not yet say definitively which detailed regulations would be written into the TTIP agreement in order to ensure that there would indeed be no impact". The same problem affects commercial services funded by the statutory social insurance system; and similarly it also affects long-term care insurance and accident insurance, given that these are entirely – or almost entirely – funded by contributions made by the person insured.
In the foreword to their parliamentary question, the German Green Party noted the following: "If these exemptions turn out to be ineffective, then potentially these services may not be exempted either from the law on national treatment or the law on market access; and it could then be left to private arbitration tribunals to interpret these exemptions from a legal point of view." An example of this might be the following: private foreign medical insurance funds could take legal action against the existing risk equalisation systems which enable financial transfers from insurers with low-risk profiles to insurers with high-risk profiles.[4]

[4] cf. also: www.zeit.de/wirtschaft/2016-05/ttip-freihandel-risiko-kapital-sozialdienste (available in German only)

b. Financial transfers from the public sector to private service providers will become more difficult

At present, if a municipal hospital gets into debt, the municipal authorities can settle the debt. But in future, US competitors could sue in such circumstances on the grounds of distortion of competition. This issue was also the subject of a parliamentary question in the German parliament; and here too the responsible Secretary of State, Mr Machnig, side-stepped the issue. The Munich Environmental Institute (*Umweltinstitut München e.V.*) points out that once an American investor has a financial stake in a European company, the investor then has an automatic right to take a case to an arbitration tribunal. "US investment banks already hold equity stakes in Germany's large hospital groups, namely Fresenius and Rhön-Klinikum AG."[5]

II. Cost Increases in the Health Service (particularly for drugs)

Between 1992 and 2015 expenditure on drugs by Germany's statutory health insurance funds doubled, and now stands at approximately €35bn per year.[6] On 17 June 2016 the EU Health Ministers discussed the issue of drugs being too expensive.[7] Pressure is mounting for action to be taken. But TTIP could reduce the options available.

Doris Pfeiffer, the Chair of the Board of Germany's National Association of Statutory Health Insurance Funds (*GKV*), was recently interviewed by the German daily newspaper, the *Frankfurter Rundschau*. In the interview she said: "In Germany and in many other European countries we have a great many rules designed to limit cost increases in health insurance. Pharmaceutical companies are not simply at liberty to set prices as they see fit: they are subject to certain rules. So, for example, the price of new drugs is negotiated on the basis of an analysis of the added benefit for patients.
"In addition, health insurance funds can also negotiate discounts with pharmaceutical companies. The danger is that this system could be undermined by a free-trade agreement."[8]

Examples:

a. Investor Protection

Investors could use the investor protection provisions included in TTIP to take legal action, through an international arbitration tribunal, against laws designed to reduce the cost of drugs. In their statement of May 2015, the presidents and chairs of Germany's healing professions jointly declared that "even though considerable obstacles would have to be overcome before a case could be brought before such tribunals, the mere threat of possible compensation claims could be enough to put a stop to certain vital legislation that would benefit public health."[9]

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[5] www.umweltinstitut.org/fragen-und-antworten/freihandelsabkommen/ttip-das-abkommen-mit- den-usa/auswirkungen-von-ttip-auf-den-gesundheitsbereich.html (available in German only)
[6] Source: 'The Information System of the Federal Health Monitoring' http://www.gbe-bund.de/oowa921-install/servlet/oowa/aw92/dboowasys921.xwdevkit/xwd_init?gbe.isgbetol/xs_start_neu/&p_aid=3&p_aid=78176046&nummer=522&p_sprache=E&p_indsp=-&p_aid=40545736
[7] http://www.euractiv.com/section/health-consumers/news/eu-health-ministers-confront-crisis-in-affordability-of-medicines/
[8] www.fr-online.de/wirtschaft/ttip--patientenschutz-ist-gefaehrdet-,1472780,27171618.html (available in German only)

[9] www.bundesaerztekammer.de/presse/pressemitteilungen/news-detail/vielfalt-des-europaeischen- gesundheitswesens-und-freiberuflichkeit-bewahren/ (available in German only)

b. Reversal of burden of proof: now manufacturers of generic drugs have to make the case

Once a drug's patent has expired other pharmaceutical companies are permitted to produce generic versions of the drug. They produce pharmaceutical preparations that have the same active ingredients as the original drug but are usually considerably cheaper – on average they cost a third of the price of the original product. Currently the situation is that if a generic product infringes a patent, the burden of proof lies with the patent owner. But the burden of proof could be reversed under TTIP: in other words, the manufacturer of the generic drug would have to prove that no patent had been infringed. This would be costly and therefore make drugs more expensive.

c. Tightening up of patent protection rules: patent term and data exclusivity

In the EU the patent term for drugs is usually ten years. In the USA the term is sometimes considerably longer. Were the systems to be harmonised this could lead to longer patent terms in the EU. But it is not just patent terms that are different in Europe and the USA: there is another reason why TTIP could complicate or at least delay the development of generic drugs. Research-based pharmaceutical companies want to use TTIP to rule that, even once a patent has expired, they do not have to publish the results of their research, deeming the results to be trade secrets. This form of 'data exclusivity' is problematic for two reasons: not only would it make it more expensive – or even impossible – to develop generic versions of a drug; it would also restrict scientific progress.
The European Commission has agreed that the subject of patent law should be discussed within the framework of the TTIP negotiations. This emerged from the negotiation documents that were leaked in May this year.[10]

d. Pseudo-Innovations

According to details from *Barmer GEK* (a company that provides statutory health insurance) expenditure on so-called pseudo-innovations accounts for 20 to 30 percent of medical insurance companies' expenditure.[11] TTIP could lead to a further major increase in the number of innovations approved. The reason for this is the difference in the European and US approaches to market logic for drugs. In Germany in order for an innovation to be approved and thus be funded by the statutory health insurance funds, its added benefit must be demonstrated by academic studies. This is not the case in the USA. In America, pharmaceutical companies can, by and large, set prices themselves allowing the market to dictate the price. American studies, therefore, do not include the additional benefits details available in Germany. Were the EU to recognise the American approval procedures, patients would perhaps gain quicker access to certain drugs, but there would be far more pseudo-innovations on the market.[12] Trying to intervene to control the situation could, potentially, be very difficult. The US pharmaceuticals company El Lilly is demanding US$500 million

compensation because two of the company's patents were declared invalid in Canada as they were deemed not to be true innovations.[13]

[10] www.correctiv.org/recherchen/ttip/blog/2015/10/16/ttip-leak-das-protokoll-der-zehnten- verhandlungsrunde/ (available in German only)
[11] Quote from: http://www.tagesspiegel.de/wirtschaft/medikamente-wie-scheininnovationen-die-preise-nach- oben-treiben/9959124.html (available in German only)
[12] http://www.handelsblatt.com/unternehmen/industrie/big-pharma-und-freihandel-macht-ttip- medikamente-teurer/11941782.html (available in German only)
[13] http://www.umweltinstitut.org/fragen-und-antworten/freihandelsabkommen/ttip-das- abkommen-mit-den-usa/auswirkungen-von-ttip-auf-den-

e. Compulsory Health Insurance Thresholds and Discount Agreements

If healthcare costs rise, the statutory health insurance funds (in German: *GKV*) can adjust the compulsory health insurance threshold accordingly. In recent years this threshold has risen annually by 2.5% and now stands at €4,575 per month. This is the minimum income an employee must earn before s/he is entitled to leave the statutory health insurance system and purchase private insurance. Consequently, more high-earners remain in the statutory health insurance scheme and their contributions support the solidarity system. But under TTIP, US private insurance companies could take legal action against any further increases in these thresholds as they could deem such increases harmful to their investments, given that the effect could be a reduction in the number of potential clients. Were this interpretation to be accepted by an arbitration tribunal, then a large percentage of the rising costs experienced by the statutory health insurance funds could no longer be apportioned to the high-earners; instead they would have to be divided among those people who pay into the statutory insurance funds based on a one-time permanent setting of the insurance threshold.[14]
Similarly, the legally set discounts or additional discount agreements between the various health insurance funds and the pharmaceuticals industry could be overturned by arbitration tribunals if these tribunals rule that the resulting lower profits represent obstacles to investment.

III. Blurring entry requirements for doctors, dentists and pharmacists

In Germany to work as a doctor, dentist or pharmacist and run your own practice or pharmacy, strict conditions have to be met. Only qualified pharmacists are permitted to open pharmacies and they cannot own and operate more than four. Furthermore, the pharmacies must be in close proximity to each other. This ensures that the qualified pharmacist personally supervises the business.

The ban on third-party and multiple ownership of pharmacies ensures that pharmacies are run and personally supervised by fully liable pharmacists who qualified in Germany. Equally the pharmacy market is regulated by law. In Germany most drugs are available from authorised pharmacies only. As such pharmacists play a major role in advising patients.

In their joint declaration, the presidents and chairs of Germany's healing professions stated that "one of the key features of the structure of our health system is the protection mechanisms in place. These include the licensing requirements for qualified doctors and dentists; so-called requirement planning, a legal obligation; and the service guarantees by corporations." They went on to state that "these mechanisms should not be broken up by free-trade deals simply to provide profit-oriented companies with opportunities to make

more profit by running medical and dental practices, pharmacies or medical service centres".

Many pharmacists believe that TTIP will result in the abolition of the ban on third-party

gesundheitsbereich.html (available in German only)
[14] GEN, p5 (available in German only)

ownership of pharmacies.[15] If that were to happen, the market would be opened up to American pharmacy chains – and this would represent unfair competition for small enterprises.

IV. Safety at Work

The German Social Accident Insurance Association (*Deutsche Gesetzliche Unfallversicherung - DGUV*) and the German National Insurance Scheme for Agriculture, Forestry and Horticulture (*Sozialversicherung für Landwirtschaft, Forsten und Gartenbau - SVLFG*) point out that TTIP could result in problems relating to safety at work. The problem is less about differing safety levels on either side of the Atlantic and more about the fact that the way in which safety levels are achieved is fundamentally different. The *DGUV* cites two examples to illustrate this point:

a. Respiratory Masks

In principle European product safety laws confer on the manufacturer a high level of responsibility. For products that are particularly safety-sensitive, a manufacturer must obtain relevant certification from an independent inspection body. Accredited inspection bodies have to be registered in advance by an EU member state with the European Commission. Respiratory masks are categorised as life-saving, personal safety equipment. Therefore, before they can be placed on the market, they must be tested by an inspection body. The consumer can rely on the fact that such a test has been carried out and that the mask is correctly sealed. In the USA there is no requirement for a third party to carry out such a test. There, employers are obliged – under work-place regulations - to check that respiratory masks are correctly sealed before they are deployed. "Both approaches can result in the safe use of respiratory masks. But if American masks which have not been subjected to third-party testing are sold in the EU and users are unaware that no third-party seal inspection has been carried out, the consequences could be fatal," according to a statement by the *DGUV.*[16]

b. Safety Notices

In Europe companies must provide their staff with proper safety training. This is not the case in the United States. According to the *DGUV* "in the USA, for statutory liability reasons, each individual location must have a sign showing every conceivable hazardous scenario specific to that location. Consequently, there is an absolute plethora of varying signs tailored to each individual location. Both the safety requirements and prohibitions of any given location can appear together on the same sign."[17] In Europe safety requirement and prohibition notices are strictly separated so that they are easier to identify: requirements appear in blue; prohibitions in red. Thus the *DGUV* concludes that "there are justifiable reasons, on both sides of the Atlantic, for one clear approach to safety notices. But it must be applied consistently. Mutual recognition of the two safety notices systems is simply not an option."[18]

The health sector is just one of many sectors affected by this problem.

[15] https://www.deutsche-apotheker-zeitung.de/news/artikel/2015/05/08/TTIP-rasselt-mit-Apothekenketten (available in German only)
[16] Source: www.dguv.de/de/mediencenter/pm/Pressemitteilung_97856.jsp (available in German only)
[17] From DGUV's position paper on TTIP: www.dguv.de/de/internationales/neues/ttip/index.jsp (available in German only)
[18] From DGUV's position paper on TTIP: www.dguv.de/de/internationales/neues/ttip/index.jsp (available in German only)

Conclusion:

The campaign group "SMEs Against TTIP" (German: *KMU gegen TTIP*) is not in principle opposed to free trade and common markets. Indeed, some of companies owned by the founder members of the campaign group make their living by exporting around Europe and beyond.

As entrepreneurs we also support the European principle that every patient has the right to the treatment that is best suited to him or her; and that the health service should be funded through a statutory health insurance system. It is vital for players involved in the health system – particularly SMEs - that the functionality of the statutory health insurance system survives intact.

We believe that the liberalisation of health provision that could be triggered by TTIP threatens the current system.

As a matter of principle, we therefore call for all public service elements to be removed from the TTIP agreement.

SOURCES:

NGOs and Public Institutions

Joint declaration by the presidents and chairs of the German Medical Association (**Bundesärztekammer (BÄK)**), the German National Association of Statutory Health insurance Physicians (**Kassenärztliche Bundesvereinigung (KBV)**), the German Dentists Association (**Bundeszahnärztekammer (BZÄK)**), the Federal Union of German Associations of Pharmacists (**Bundesvereinigung Deutscher Apothekerverbände (ABDA)**) and the German National Association of Statutory Health Insurance Dentists (**Kassenzahnärztliche Bundesvereinigung (KZBV)**):

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