UACT Letter to TPP Negotiators

Re: Effects of TPP provisions on cancer patients and their families

July 26, 2015

Dear Trans Pacific Partnership Negotiators,

I am writing to you today on behalf of the Union for Affordable Cancer Treatment (UACT)[1], an international network of people who share the conviction that cancer treatment and care should be available everywhere for everyone, regardless of gender, age, nationality, or financial resources. We are a union of people -- people affected by cancer, their family members and friends, people who take care of people with cancer, health care professionals and cancer researchers -- committed to increasing access to effective cancer treatment and care. I myself am a stage IV HER2 positive breast cancer patient in active treatment since May 2010, and I consider myself extremely fortunate to have access to the most advanced treatment available.

We are particularly concerned about the rapidly escalating cost of cancer medication and we believe that cancer medicines and other essential medical tools, such as diagnostic tests, should be affordable.

We will focus our comments on the effect of some of the proposed TPP language on cancer patients and their families regarding access to the best care available. This includes access to affordable biologic drugs, which are among today's game-changers in cancer treatment.

In this letter to all TPP negotiators we would like to express our concerns regarding proposals that would:

1. Mandate exclusive rights in test data for medicines,
2. Ban statutory limits on remedies including damages for the infringement of patents,

[1] http://cancerunion.org/

3. Create more restrictive standards for using compulsory licenses,
4. Require linkage between drug registration and patent status,
5. Give drug companies access to governments processes for reimbursements, and
6. Create new investors rights, directed against patient interests

A major concern for UACT is a US proposal in the TPP to require the granting of a monopoly on the evidence -- including the data from clinical trials -- that a specific drug is safe and efficacious. The monopoly on data will extend the delays for registration of more affordable products. Biosimilar drugs will be affected by the longest data monopoly in the TPP.

The data monopoly effectively requires generic and biosimilar drug manufacturers to unnecessarily duplicate experiments involving human subjects where the result is known. This conflicts with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.[2]

It is important that the TPP, at a minimum, allows exceptions to rights in test data for cases when prices are excessive and/or a barrier to access, where there are shortages of drugs, when duplicative trials are unethical, or for other legitimate policy reasons.

UACT is also concerned with proposed language that would ban statutory limits on damages for patents on biologic drugs, when drug companies fail to make timely disclosure of assertions that patents are relevant to a biologic drug.[3] This could increase the risk of costly and time-consuming litigation to manufacturers of biosimilar drugs and result in delays in the availability of more affordable drugs. Many cancer patients do not have time to waste.

UACT is concerned that the current TPP text would change the WTO standard for compulsory licensing of drugs, with a new more restrictive standard, and/or create new opportunities for drug companies to challenge compulsory licenses by using the TPP Investor State Dispute Settlement mechanisms (ISDS). The TPP proposes to give drug

[2] World Medical Association (WMA) Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, as amended most recently in October 2013. http://www.wma.net/en/30publications/10policies/b3/. The WMA is an international organization representing physicians founded on 17 September 1947, when physicians from 27 different countries met at the 1st General Assembly of the WMA in Paris. It was created to ensure the independence of physicians, and to work for the highest possible standards of ethical behaviour and care by physicians, at all times. This was particularly important to physicians after World War II, and therefore the WMA has always been an independent confederation of free professional associations. Funded by annual contributions of its members, now numbering 111 National Medical Associations.

[3] Such as the limitation in the United States, under 5 USC 271 (e)(6)(B), which states "the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty." Compare this to the TPP language in Article QQ.H.4: {Civil Procedures and Remedies / Civil and Administrative Procedures and Remedies}.

companies the right to call for and participate in arbitration over the meaning of WTO provisions, something that is not currently possible in the WTO. We are concerned that this will affect patients in all countries where the ever-increasing cost of cancer treatments results in unnecessary rationing and death.

We agree with the World Medical Association (WMA) that the language in the TPP in Article QQ.E.17: {TPP Patent Linkage} is unacceptable. It creates an unwanted linkage between drug registration and patents, a practice that has been rejected in Europe, and is famously abused in the United States and in every country where linkage has been implemented. Drug registration decisions should be based on evidence of a drug's safety and efficacy and quality only, reflecting standards that support the promotion of the public's health. Assessing the validity, scope and relevance of patents involves assertions of private rights -- complex legal topics that drug regulatory agencies should not be asked to evaluate.[4] When linkage mechanisms are abused, the monopoly on the drug is extended, and prices are higher.

The TPP Transparency Chapter Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices is also of concern. This Annex will give drug companies undue influence on government policies and decisions regarding the reimbursement of new drugs, and also give pharmaceutical companies new rights to challenge the reimbursement policies and decisions they do not deem favorable to their interests.

Finally, we would like to point out that the standards and investor rights created by the TPP, under the guise of free trade, will make it more difficult for governments to modify intellectual property rules as well as undertake the future health care reforms necessary to restrain and lower the cost of cancer treatments.

We would like to bring to your attention the WMA Council Resolution on Trade Agreements and Public Health Adopted by the 200th WMA Council Session, Oslo, April 2015 which states that the WMA Council members:

> Oppose any trade agreement provisions which would compromise access to health care services or medicines including but not limited to:
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> - Patenting (or patent enforcement) of diagnostic, therapeutic and surgical techniques;
> - "Evergreening", or patent protection for minor modifications of existing drugs;

[4] The standards proposed by some countries in the TPP draft text go far beyond even the legal mechanisms in the United States. Congress has limited the use of linkage for pharmaceutical drugs, and linkage is not used under the U.S. Biologics Price Competition and Innovation Act.

- Patent linkage or other patent term adjustments that serve to as a barrier to generic entry into the market;
- Data exclusivity for biologics;
- Any effort to undermine TRIPS safeguards or restrict TRIPS flexibilities including compulsory licensing;
- Limits on clinical trial data transparency.

As the world population is aging as well as surviving cancer longer, innovation in AND access to new and effective treatments become even more crucial to many of us. Policies that promote uncontrolled escalation in high prices contribute to unnecessary suffering and death.

As we have stated before to USTR -- and we would like all TPP negotiators to hear us on this -- your time and expertise would surely be better spent designing and advancing trade policies that allow all of us to promote rather than impede access to medicines, while expanding funding for medical R&D, including for better cancer drugs and diagnostic tools. This is in every country's interest.

I am available for any questions you may have.

Sincerely,

Manon Ress
On behalf of UACT

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Annex 1: World Medical Association (WMA) Council Resolution on Trade Agreements and Public Health

WMA Council Resolution on Trade Agreements and Public Health
Adopted by the 200th WMA Council Session, Oslo, April 2015

PREAMBLE

Trade agreements are sequelae of globalization and seek to promote trade liberalization. They can have a significant impact on the social determinants of health and thus on public health and the delivery of health care.

Trade agreements are designed to produce economic benefits. Negotiations should take account of their potential broad impact especially on health and ensure that health is not damaged by the pursuit of potential economic gain.

Trade agreements may have the ability to promote the health and wellbeing of all people, including by improving economic structures, if they are well constructed and protect the ability of governments to legislate, regulate and plan for health promotion, health care delivery and health equity, without interference.

BACKGROUND

There have been many trade agreements negotiated in the past. New agreements under negotiation include the Trans Pacific Partnership (TPP),[1] Trans Atlantic Trade and Investment Partnership (TTIP)[2] the Trade in Services Agreement (TiSA) and the Comprehensive Economic and Trade Agreement (CETA).[3]

These negotiations seek to establish a global governance framework for trade and are unprecedented in their size, scope and secrecy. A lack of transparency and the selective sharing of information with a limited set of stakeholders are anti-democratic.

Investor-state dispute settlement (ISDS) provides a mechanism for investors to bring claims against governments and seek compensation, operating outside existing systems of accountability and transparency. ISDS in smaller scale trade agreements has been used to challenge evidence-based public health laws including tobacco plain packaging. Inclusion of a broad ISDS mechanism could threaten public health actions designed to effect tobacco control, alcohol control, regulation of obesogenic foods and beverages, access to medicines, health care services, environmental protection/climate change and occupational / environmental health improvements. This especially in nations with limited access to resources.

Access to affordable medicines is critical to controlling the global burdens of communicable and non-communicable diseases. The World Trade Organization’s Agreement on Trade-Related Aspects of

Intellectual Property Rights (TRIPS) established a set of common international rules governing the protection of intellectual property including the patenting of pharmaceuticals. TRIPS safeguards and flexibilities including compulsory licensing seek to ensure that patent protection does not supersede public health.[4]

TiSA may impact on eHealth provision by changing rules in licensing and telecoms. Its impact on the delivery of eHealth could be substantial and damage the delivery of comprehensive, effective, cost-effective efficient health care.

The WMA Statement on Patenting Medical Procedures states that patenting of diagnostic, therapeutic and surgical techniques is unethical and "poses serious risks to the effective practice of medicine by potentially limiting the availability of new procedures to patients."

The WMA Statement on Medical Workforce states that the WMA has recognized the need for investment in medical education and has called on governments to "…allocate sufficient financial resources for the education, training, development, recruitment and retention of physicians to meet the medical needs of the entire population…"

The WMA Declaration of Delhi on Health and Climate Change states that global climate change has had and will continue to have serious consequences for health and demands comprehensive action.

RECOMMENDATIONS

Therefore the WMA calls on national governments and national member associations to:

Advocate for trade agreements that protect, promote and prioritize public health over commercial interests and ensure wide exclusions to secure services in the public interest, especially those impacting on individual and public health. This should include new modalities of health care provision including eHealth, Tele-Health, mHealth and uHealth.

Ensure trade agreements do not interfere with governments' ability to regulate health and health care, or to guarantee a right to health for all. Government action to protect and promote health should not be subject to challenge through an investor-state dispute settlement (ISDS) or similar mechanism.

Oppose any trade agreement provisions which would compromise access to health care services or medicines including but not limited to:

- Patenting (or patent enforcement) of diagnostic, therapeutic and surgical techniques;
- "Evergreening", or patent protection for minor modifications of existing drugs;
- Patent linkage or other patent term adjustments that serve to as a barrier to generic entry into the market;
- Data exclusivity for biologics;
- Any effort to undermine TRIPS safeguards or restrict TRIPS flexibilities including compulsory licensing;
- Limits on clinical trial data transparency.

Oppose any trade agreement provision which would reduce public support for or facilitate commercialization of medical education.

Ensure trade agreements promote environmental protection and support efforts to reduce activities that cause climate change.

Call for transparency and openness in all trade agreement negotiations including public access to negotiating texts and meaningful opportunities for stakeholder engagement.

Notes

[1] TPP negotiations currently include twelve parties: the United States, Canada, Mexico, Peru, Chile, Australia, New Zealand, Brunei, Singapore, Malaysia, Japan and Vietnam.

[2] TTIP negotiations currently include the European Union and the United States.

[3] CETA negotiations currently include European Union and Canada.

[4] See World Trade Organization, Declaration on TRIPS and Public Health (“Doha Declaration”) (2001)

Annex 2 WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended, most recently, by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013

(Quoted here are paragraphs 1-10, 16-18. The Declaration includes 37 paragraphs in total.)

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this

goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

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Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

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