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Statement of the Asia-Pacific Network of People living with HIV/AIDS (APN+) on the 12th Round of Regional Comprehensive Economic Partnership (RCEP) Agreement Negotiations

Concerns over impact of Intellectual Property and Investment Provisions in RCEP negotiations on Public Health and Access to Medicines

"Some Member States have expressed concern that trade agreements currently under negotiation could significantly reduce access to affordable generic medicines. If these agreements open trade yet close access to affordable medicines, we have to ask: Is this really progress at all, especially with the costs of care soaring everywhere?"

-Dr. Margaret Chan, Director General,
World Health Organisation

Bangkok, 22 April 2016 - Negotiators from 16 countries will meet in Perth, Australia, 24 April onwards for the 12th round of negotiations of the Regional Comprehensive Economic Partnership Agreement (RCEP). The RCEP negotiating countries include developed countries (Japan, Australia, New Zealand, Singapore and South Korea), developing countries (China, India, Malaysia, Indonesia, the Philippines, Thailand, Vietnam and Brunei Darussalam) and least developed countries (Myanmar, Cambodia and Laos). The RCEP negotiating countries have established working groups on different areas of the trade negotiations including a working group on intellectual property and a working group on investment.

Today, the draft investment chapter being negotiated as part of RCEP was leaked. And earlier in the week the draft intellectual property chapter was also leaked. After a legal review of these leaked chapters dated October 2015, APN+ is issuing this urgent statement to highlight our grave concerns over the potential adverse impact of these negotiations. Specifically, we are greatly concerned that intellectual property provisions being proposed, by Japan and South Korea in particular, at the RCEP negotiations include those that go far beyond the WTO's TRIPS Agreement and will have a severe, adverse impact on public health and access to medicines in the region and globally.

Asia-Pacific Countries, access to medicines and high priced patented medicines

According to UNAIDS, around 1.63 million people living with HIV in the Asia–Pacific region had access to antiretroviral therapy in 2014, which accounts for only one in three people living with HIV. In addition, HIV-positive pregnant women in South Asia have the world's lowest rate of access to the antiretroviral medicines needed to prevent mother-to-child transmission of HIV. While the region has seen an overall decline in new infections, in several countries—including China, Indonesia, and the Philippines—rates of new infections are increasing. In Indonesia, AIDS-related deaths have quadrupled since 2005. Also, HIV rates among key populations—people who inject drugs (PWID), men who have sex with men (MSM), transgender individuals, and sex workers—are far higher than among the general population, and rising.

For developing countries in the Asia-Pacific region, as they are categorized as middle income countries by the World Bank, their access to funding from the Global Fund is decreasing while at the same time multinational pharmaceutical companies are withdrawing lower prices for their medicines and excluding several of these countries from voluntary licenses with generic companies.

It is not only HIV medicine prices that are of concern to us. For people living with hepatitis C, access to directly acting antivirals (DAAs) like sofosbuvir, ledipasvir and daclatasvir, has been severely hampered by high prices and restrictive voluntary licensing by the patent holders. In the case of sofosbuvir and ledipasvir, Gilead has issued voluntary licenses to generic companies to produce low cost versions that exclude China, Brunei, Malaysia, the Philippines and Thailand among the developing countries in the RCEP negotiations. In the case of daclatasvir, BMS and the Medicines Patent Pool have issued voluntary licenses to generic companies that exclude China, Brunei, Malaysia, and Thailand. For the countries excluded Gilead and BMS are negotiating extremely high prices with patients in Malaysia, for instance, paying anywhere between US$12,000 to US$100,000 for a 12 week course of sofosbuvir. Indian generics are selling 12 week courses of sofosbuvir for US$324; of daclatasvir for US$183; and of sofosbuvir and ledipasvir for US$615.

Like much of the developing world, the incidence of non-communicable diseases (NCDs) is also on the rise in the Asia-Pacific region. As pointed out by Dr. Margaret Chan, Executive Director, WHO, "Developing countries now account for around 70% of all cancer deaths. Many of these people die without treatment, not even pain relief…The same is true for heart disease, diabetes, and chronic lung diseases. In some middle-income countries, diabetes treatment alone is now absorbing nearly half of the entire health budget."

Developing Countries in the Asia-Pacific are global leaders in use of TRIPS flexibilities, in balancing intellectual property and public interest and production and supply of generic medicines

The importance of generic production and supply in increasing access to medicines across the developing world has been underscored by the HIV epidemic. Today, more than 80 percent of all adult antiretroviral drugs and more than 90 percent of all paediatric antiretroviral formulations in use in developing countries are made by generic companies. An estimated 15 million people in low- and middle-income countries are now on antiretroviral therapy, and the annual number of AIDS deaths has fallen by more than 18 percent since the middle of the last decade and the generic ARVs that have made this possible, come largely from the Asia-Pacific region. In the 1990s, Thailand's Government Pharmaceutical Organisation (GPO) broke new ground with its fixed dose combination of first generation ARVs. Large scale production of fixed dose combination ARVs by Indian generic companies resulted in the dramatic decrease in prices for first line antiretroviral drug regimens in low- and middle-income countries from US$15,000 per person per year in 2001 to less than US$100 in 2014. Meanwhile, a large number of pharmaceutical manufacturers across the world rely on China for supplies of active pharmaceutical ingredients. In fact, nearly all of the developing and least developing countries in the RCEP negotiations have local generic manufacturing capacity that is essential to the health and well-being of their citizens.

Developing countries in the RCEP negotiations are all members of the World Trade Organisation (WTO) and as of 2005 are all implementing the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

With patents increasingly being granted in these countries and the resulting high prices, several developing countries in the Asia-Pacific Region are using TRIPS flexibilities to ensure access to affordable generic medicines.

Among the RCEP negotiating countries, Malaysia (2003), Indonesia (2004, 2007 and 2012), Thailand (2006 and 2008) and India (2012) have issued compulsory licenses to ensure generic competition for medicines for HIV, heart disease and cancer. India and the Philippines have included statutory provisions in their laws that incorporate strict patentability criteria including a prohibition on evergreening – the practice of patent holders to extend monopolies on medicines by filing successive and overlapping patents on new forms and new uses of old medicines. As a result of the use of this and other provisions in India, first and second-line ARVs remain off-patent in India. The patent laws of most RCEP developing countries include several other TRIPS-flexibilities as well such as parallel imports, early working, research and experimental exceptions among others.

RCEP Negotiations should not include TRIPS-plus intellectual property provisions and investment provisions that undermine public health.

In December 2012, all RCEP countries were part of the historic General Assembly resolution that "recognizes the responsibility of Governments to urgently and significantly scale up efforts to accelerate the transition towards universal access to affordable and quality health-care services…"

In 2015, all RCEP negotiating countries also committed to achieving the Sustainable Development Goals (SDGs). In particular Goal 3b includes a commitment to:

> "Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all."

With patents increasingly posing barriers to affordable medicines and decreased access to international aid, the use of TRIPS flexibilities by developing countries is of increasing significance in any effort to scale up universal access to health care. For least developed countries like Myanmar, Cambodia and Laos, the extension available to them from the TRIPS Council for the implementation of the TRIPS Agreement till 2021 and for pharmaceutical products till 2033 is similarly of vital importance for local production of pharmaceuticals, technological advancement and the import of generic medicines.

In this background, APN+ is greatly concerned that the RCEP negotiations may include provisions that override or hamper the use of TRIPS flexibilities by developing and least developed countries in the negotiations. Known as TRIPS-plus provisions, these provisions require developing and least developed countries to agree to intellectual property obligations far in excess of those required by the TRIPS Agreement. We respectfully call on all countries negotiating the RCEP Agreement to ensure that no TRIPS-plus provisions are included in these negotiations. There is considerable evidence

from around the world of the harmful impact that these and other TRIPS-plus provisions can have on access to medicines.

According to the leaked IP and investment chapters, several TRIPS-plus provisions appear to be on the table that adversely impact public health and access to medicines including:

- **DATA EXCLUSIVITY** that prevents governments from relying on clinical trial data to register generic versions of medicines even if they are off-patent, their patents have expired or are revoked & complicates the issuance of compulsory licences;
- **PATENT TERM EXTENTIONS** that extend patent life beyond 20 years and further delay generic entry;
- **WEAKENED PATENTABILITY CRITERIA** that could put restrictions in terms of the time period and content of material that the patent office can take into consideration in determining whether a medicine is actually new or inventive (see provisions on grace periods and worldwide novelty);
- **ACCELERATED PATENT EXAMINATION** that may create undue pressure on already burdened patent offices in developing countries with limited human and financial resources to take hurried decisions on pharmaceutical patent applications that require close, detailed scrutiny;
- **TECHNICAL ASSISTANCE** measures that may result in the indirect introduction of the lower patentability standards of developed countries into developing country patent offices through patent examiner trainings and increasing reliance on patent examination reports and conclusions of developed countries;
- **WEAKENED PATENT EXCEPTIONS** that may impose restrictions on how developing countries in the Asia-Pacific region employ and define research and experimental exceptions to patent rights;
- **BORDER MEASURES** that may deny medicines to patients in other developing countries with custom officials seizing generic medicines that are being imported or exported;
- **INJUNCTIONS AND DAMAGES** that undermine the independence of the judiciary in issuing orders relating to the enforcement of patents in a manner that prioritises the right to health of patients;
- **OTHER IP ENFORCEMENT MEASURES** that put third parties like treatment providers at risk of court cases and draw the whole manufacturing, distribution & supply chain for generic medicines into litigation;
- **WTO-PLUS DISUPUTE SETTLEMENT ON TRIPS** by including TRIPS compliance in the RCEP negotiations, RCEP countries could sue each other for alleged TRIPS violations outside of the WTO Dispute Settlement Body
- **INVESTOR PROTECTION RULES** that allow foreign companies to sue governments in private international arbitration over domestic health policies like compulsory licences, patent revocations or refusals, health safeguards in patent laws, price reduction, negotiation and reimbursement measures & may prevent governments from promoting local production.

RCEP negotiations should set an example among mega-FTA negotiations in prioritizing health over corporate and trade interests; set a positive agenda on intellectual property, research and development and access

APN+ calls on the RCEP negotiating countries to focus their negotiations on a positive agenda on issues related to intellectual property, research and development, increasing access to safe, effective and affordable generic medicines and prioritising the right to health.

APN+ calls on RCEP negotiating countries:

- Not to include any TRIPS-plus provisions in the intellectual property chapter;
- Not to include investment protection provisions that allow companies to sue governments in secret, private arbitration over domestic health policies;
- Commit to the inclusion of the full extent of TRIPS flexibilities in the laws of RCEP countries
- Commit to supporting developing and least developed countries in using TRIPS flexibilities;
- Commit to supporting the full use of the TRIPS implementation extension period till 2021 and the pharmaceuticals transition period till 2033 for LDCs
- Commit to negotiating and implementing a new paradigm on research and development that prioritises research in those diseases and health priorities of developing and least developed countries in the Asia-Pacific region and the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property agreed at the World Health Assembly.
- Commit to supporting technology transfer and local production of generic medicines in RCEP countries

APN+ also calls on the RCEP negotiating countries to release the text for the negotiations on intellectual property and investment and hold broad based public consultations on the text to ensure that these do not undermine public health and access to medicines.

APN+ calls on all RCEP governments to recall their international, regional and national commitments to respect, protect, and fulfill the right to health including the right to access affordable medicines. In their quest for greater economic integration, RCEP negotiating countries must not put the lives and health of millions of people in the Asia-Pacific region at risk.

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NOTES AND REFERENCES FOR EDITORS:

- Leaked RCEP IP and investment chapters: http://keionline.org/node/2474
- The RCEP Negotiations are taking place between 16 countries from the Asia-Pacific region. Guiding Principles and Objectives of the Negotiations: http://www10.iadb.org/intal/intalcdi/PE/CM%202013/11581.pdf
- Previous reports on TRIPS-plus demands in RCEP Negotiations: http://infojustice.org/archives/32024
- Overview of public health related TRIPS-plus provisions in Free Trade Agreement Negotiations can be found here: http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2349_Issue_Brief_Free-Trade-Agreements_en.pdf
- Bangkok Declaration of Public Interest and Public Health Groups on TRIPS-plus provisions in FTAs: http://www.actupparis.org/spip.php?article4560
- Use of TRIPS flexibilities in the Asia-Pacific Region: http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf
- UNDP and UNAIDS Policy Brief on the importance of the TRIPS extention for LDCS: http://www.unaids.org/sites/default/files/media_asset/JC2474_TRIPS-transition-period-extensions_en_0.pdf

- WTO Decisions granting LDCs extension for applying TRIPS Agreement till 2021 (http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm); and for exempting pharmacuetical products from patents and test data protection till 2033: http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm

For information on Indian generic prices for directly acting anti-virals to treat Hepatitis C: http://hepcasia.com/generic-daas-pricing/