BRIEFING NOTE

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN

RCEP: IMPACT ON ACCESS TO MEDICINES

THE REGIONAL COMPREHENSIVE ECONOMIC PARTNERSHIP (RCEP) TRADE AGREEMENT INCLUDES PROVISIONS THAT THREATEN ACCESS TO MEDICINES

The Regional Comprehensive Economic Partnership (RCEP) trade agreement is being negotiated in secret, without input from public health stakeholders. A leaked draft of the negotiating text has revealed some proposed provisions that could undermine access to price-lowering generic medicines, and thus, life-saving treatment for millions of people in the developing world.

Since 2012, the RCEP trade agreement has been under negotiation between the ten members of the Association of South East Asian Nations (ASEAN) (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam) and the six countries that have existing trade agreements with ASEAN: Australia, China, India, Japan, New Zealand and the Republic of Korea. Notably, the RCEP countries are home to nearly 50% of the global population, including some of the world's most impoverished and marginalised communities.

The leaked draft of RCEP's negotiating text on intellectual property (IP) and investment reveals proposals that apply to pharmaceutical products which could affect access to affordable medicines and biomedical innovation across the Asia Pacific region.[1]

According to the leaked text, Japan and the Republic of Korea are pushing for provisions that go far beyond international trade rules (known as TRIPS-plus rules) to extend drug corporations' patent terms and introduce the most damaging form of clinical trial data monopolies. Further, the proposed elevated levels of IP enforcement would delay generic competition and translate into higher prices for lengthier periods of time, which would, in turn, prevent the flow of affordable generic medicines from producer to patient. These provisions offer pharmaceutical corporations a blank cheque for abuse. In developing countries, where people rarely have health insurance and must pay for medicines out of pocket, high prices keep life-saving medicines out of reach – and this is often a matter of life and death.

As a medical humanitarian organisation working in nearly 70 countries, Médecins Sans Frontières (MSF) is concerned that proposed provisions in the IP and investment chapters could potentially restrict a government's capacity to initiate and execute policies to protect public health and ensure affordable access to medicines for all, in particular in developing countries where most of MSF's operations are based.

A DANGEROUS NEW GLOBAL NORM

RCEP's damaging provisions are similar to those included in the Trans Pacific Partnership (TPP) trade agreement between the United States and eleven other Pacific Rim countries. The TPP was signed in February 2016 after years of secretive negotiations, but it has not yet been ratified or implemented in any of the member countries.

Seven countries are common to both the TPP and the RCEP. The TPP has been repeatedly referred to as "the worst trade deal ever for access to medicines." MSF has expressed concern that the RCEP negotiating countries—in particular, Japan, Australia and New Zealand—have increasingly framed the RCEP as a 'stepping stone' towards a convergence with the TPP and towards a vision of an all-encompassing 'Asia Pacific Free Trade Area'.[1] It is disquieting that Japan and the Republic of Korea (who are also part of the TPP) are seeking to include similar damaging IP provisions in a trade agreement that includes many more developing countries.

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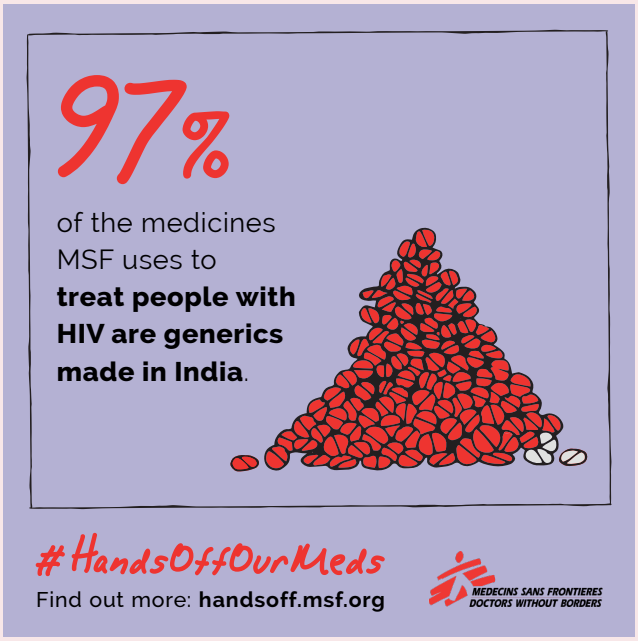
INDIA: PHARMACY OF THE DEVELOPING WORLD

India – often known as the 'pharmacy of the developing world' for its wide-scale production of generic medicines – supplies life-saving, affordable medicines needed to treat communicable and non-communicable diseases to Sub-Saharan Africa and many other developing countries.

As a medical treatment provider, MSF relies on affordable, quality generic medicines to treat many diseases. In fact, two-thirds of the medicines we use to treat people with tuberculosis, malaria, and HIV/AIDS are generic medicines from India.

MSF is not alone in its reliance on affordable generic medicines: other major international treatment initiatives and agencies, including the Global Fund to Fight AIDS, Tuberculosis and Malaria; the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program; UNITAID and UNICEF also depend heavily on affordable generic drugs for their urgently-needed treatment programs. For example, 97% of the antiretroviral medicines purchased by PEPFAR to treat HIV/AIDS are low-priced, quality-assured generic medicines.[1]



ROBUST GENERIC COMPETITION IS A CATALYST FOR AFFORDABLE MEDICINES:

Generic competition from India and the availability of affordable active pharmaceutical ingredients (API - the raw material needed to produce drugs) for these medicines from China have ushered in a treatment revolution in developing countries, by bringing down the price of first-line antiretroviral medicines by 99% since 2001.[2] This is a key factor that allowed developing countries to scale up HIV/AIDS treatment to an estimated 17 million people by 2016.[3]

The world is looking to countries like India and China to provide affordable generic medicines and vaccines to address emerging public health challenges including drug-resistant tuberculosis, viral hepatitis, non-communicable diseases and anti-microbial resistance.

The availability of generic medicines in a particular country depends on a complex structure of laws and regulations, especially those that govern patents and other intellectual property rights. Trade and other types of international agreements also influence these regulations. In 1995, the WTO's Trade Related Intellectual Property Rights (TRIPS) agreement,[4] which included the obligation to grant patent monopolies to pharmaceutical products for a period of 20 years, imposed minimum IP standards across the globe for the first time. However, TRIPS also incorporated legal safeguards that gave countries some leeway in overcoming IP barriers when they hampered access to medicines and flexibilities that helped balance the patent system with the right to health.

Since governments are fiscally responsible for public health programs, they must avoid jeopardizing the effectiveness of these programs by ensuring that new roadblocks are not put in the way of introducing generic competition to their markets. A number of governments have made multiple commitments[5] that reaffirm the importance of protecting public health over the commercial interests of pharmaceutical corporations. For example, by referring to and interpreting relevant flexibilities in the TRIPS agreement, India secured health safeguards in its Patent (Amendment) Act, which provided significant benefits that ensured the availability of more affordable generic versions of medicines to its citizens - and to millions of people across the developing world.

Despite these measures, the legal tools and safeguards used to counterbalance commercial interests of pharmaceutical corporations in favour of the right to health are continually under attack. Developing countries that try to promote the use of generics are frequently the target of litigation by pharmaceutical corporations[6] and are also subject to diplomatic pressures such as the threat of sanctions, specifically, by governments seeking to protect the interests of pharmaceutical corporations.[7] Likewise, some countries are attempting to make use of the RCEP agreement to impose aggressive IP standards, known as TRIPS-plus provisions, that further tip the balance towards pharmaceutical corporations and away from public health.

THE WHO DIRECTOR-GENERAL MARGARET CHAN ACKNOWLEDGES THE NEGATIVE IMPACT OF TRADE AGREEMENTS ON ACCESS TO AFFORDABLE GENERIC 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?"*[1]

"Proposed provisions such as data exclusivity are still under negotiation in RCEP, and are just another form of prolonging monopolies. By delaying the registration of generic versions of a medicine by several years, data exclusivity will effectively give a backdoor monopoly status to pharmaceutical corporations, even for older drugs that do not deserve a patent."

LEENA MENGHANEY, HEAD-SOUTH ASIA, MSF ACCESS CAMPAIGN

SOME OF THE IP PROVISIONS IN THE LEAKED RCEP DRAFT TEXT THAT WILL KEEP DRUG PRICES HIGH

TRIPS-PLUS RCEP PROPOSALS	IMPACT ON ACCESS TO MEDICINES
Creates **data exclusivity** by preventing drug safety regulators from using or relying on existing clinical data to grant market approval to generic drugs.	Data exclusivity grants a market monopoly status to medicines, even when patents no longer apply or exist. This gives companies a new way to keep prices high for longer periods of time and further delays generic competition. It creates a barrier for entry of generic producers, as they will have to repeat clinical trials to generate a new set of safety and efficacy data if they intended to register before the data exclusivity period expires, a process that is costly and can takes years. In addition, existing generics can be forced off the market when such backdoor monopolies are granted under the drug regulatory system. More importantly, repeating clinical trials solely for registering the generic version is unethical. The WHO recommends against data exclusivity for developing countries, and yet the draft text in RCEP would grant data exclusivity for a period of "no less than five years".
Mandates **patent term extensions** by increasing patent terms beyond 20 years.	At present, patents on drugs in most countries last for 20 years from the date of filing. Thus, a straightforward way to prolong a company's monopoly over a drug is simply to extend the life of the drug's patent beyond 20 years. Extra years ensure that patent holders can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.
Extends **intellectual property enforcement measures** to cover all areas of intellectual property, beyond the obligations of the TRIPS Agreement. RCEP has numerous provisions on border enforcement that could prevent the flow of generic medicines from producer to patient.	Elevated levels of enforcement increase the likelihood of legal actions against legitimate suppliers of generic medicines. RCEP provisions could also widen the scope of IP enforcement and place the generic medicines distribution and supply chain, including treatment providers, at risk of litigation and court cases. Such provisions are not only excessive in their scope, but also stand in contrast to judicial efforts to remedy IP infringements by awarding royalties to patent holders, instead of through enforcement measures that undermine access and competition. In addition, the current RCEP text on border measures does not adequately protect legitimate transport of generic medicines.
Proposes the **premature adoption of intellectual property obligations** by Least Developed Countries (LDCs) in the region.	RCEP trade negotiators have not adequately protected the transition period available to its most impoverished member countries—Cambodia, Myanmar and Lao People's Democratic Republic—that allows them to delay the implementation of the WTO TRIPS agreement vis-a-vis pharmaceuticals. Under this transition period—which may also be extended—LDCs do not have to apply or enforce TRIPS provisions concerning patents and test data protection for pharmaceutical products until 1 January, 2033[8]. The proposed provisions in RCEP, including the mandate to ratify WIPO treaties such as the Patent Cooperation Treaty, may force these countries to prematurely adopt patents and other IP obligations that could hinder supply and registration of low-cost generic medicines.
Intellectual property inclusions in the investment chapter **allow companies to sue governments for public health protections**.	If an investor-state dispute settlement (ISDS) mechanism is agreed to in the RCEP, pharmaceutical companies could sue governments in secret arbitration tribunals and seek huge financial compensation if any IP-related law, policy, rules, regulations, court decisions or other actions interfere with their profits, even when these domestic measures are in accordance with national law and the World Trade Organization's TRIPS Agreement.

MSF URGES ALL RCEP NEGOTIATING GOVERNMENTS TO:

- **Refuse TRIPS-plus proposals:** RCEP negotiators should not agree to a final text unless all TRIPS-plus provisions, which can severely limit access to medicines in developing countries, are excluded. In its place, RCEP negotiators must insist on language that protects existing public health safeguards and enables developing countries to effectively balance the IP system with the right to health.
- **Increase transparency and release the negotiating text:** Trade negotiations that affect public health must be conducted with adequate levels of transparency and public scrutiny, including providing access to the negotiating texts and conducting a public health impact assessment.
- **Fulfil existing commitments to access to medicines:** RCEP negotiators should ensure that the final text is aligned with global health priorities and that the text specifically mentions and honours relevant public health commitments, including the 2001 WTO Doha Declaration on TRIPS and Public Health; the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property; and the 2015 United Nations Sustainable Development Goals.
- **Refrain from premature adoption of proposals of IP obligations by LDCs:** RCEP negotiators should ensure that the RCEP agreement does not force LDCs to prematurely adopt IP obligations in any form, and should respect their right to fully utilize the pharmaceutical transition periods that have been granted to them vis-a-vis the WTO. The RCEP IP chapter should not impose any TRIPS-plus obligations that will require implementation when countries graduate from LDC status to middle-income status, nor should it interfere with their right to adopt public health safeguards when they adopt the product patent system for pharmaceuticals. The RCEP text should not require LDCs to ratify WIPO treaties such as the Patent Cooperation Treaty, because this could undermine LDC extension granted by rules under the WTO system.
- **Adopt recommendations of the UN High Level Panel on Access to Medicines:** The recent report from the Secretary General's High Level Panel on Access to Medicines advises governments engaged in bilateral and regional trade and investment treaties to ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the rights and public health obligations of its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently, and be made publicly available.

"As we move to Test & Start policies for HIV in South Africa and elsewhere in the region, MSF and governments will continue to require an uninterrupted supply of affordable, quality antiretroviral medicines for a greater number of people living with HIV. India provides the largest volume of medicines to South Africa, and healthcare providers will continue to require this trade partnership to supply affordable medicines – not just for HIV but also to treat other illnesses. We cannot let our patient's lifelines be cut by unjust trade agreements."

DR. AMIR SHROUFI, MEDICAL COORDINATOR FOR MSF IN SOUTH AFRICA

MORE INFORMATION

Visit http://www.msfaccess.org/rcep-ip-chapter-analysis for detailed analysis of RCEP IP chapter.

1 Knowledge Ecology International, RCEP IP Chapter, Washington DC and Geneva: KEI. Available at: http://keionline.org/node/2472

2 MSF, "Untangling the Web of Antiretroviral Price Reductions", 16th edition, July 2013. Available at: http://www.msfaccess.org/content/untangling-web-antiretroviral-price-reductions-16th-edition

3 UNAIDS, "UNAIDS Announces 2 million More People Living with HIV on Treatment in 2015, Bringing New Total to 17 million", May 2016. Available at: http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2016/may/20160531_Global-AIDS-Update-2016

4 The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights.

5 For example:
WTO, "Declaration on the TRIPS Agreement and Public Health", Doha, 2001. Available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
WHO, "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property", 2008. Available at: http://www.who.int/phi/implementation/phi_globstat_action/en/
UNAIDS, "Political Declaration on HIV/AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030", 2016. Available at: http://www.unaids.org/en/resources/documents/2016/2016-political-declaration-HIV-AIDS
In addition, on May 10, 2007, the USA's new trade policy scaled back harsh US government IP trade demands for developing countries, including patent linkage, patent term extensions and data exclusivity. See also, the 2016 CEWG Resolution from 68th WHA and the 2016 Human Rights Council Resolution.

6 For example: MSF. "Novartis, Drop the Case!", 2013. Available at: http://www.msfaccess.org/novartis-drop-the-case
MSF, "India: Bayer Attempting to Block Affordable Patented Drugs", 2012. Available at: http://www.msf.org/en/article/india-bayer-attempting-block-affordable-patented-drugs

7 For example:
MSF, "Doctors Without Borders Responds to Release of 2016 US Trade 301 Watch List Report", 2016. Available at: http://www.msfaccess.org/about-us/media-room/press-releases/doctors-without-borders-responds-release-2016-us-trade-301-watch-

8 TRIPS Council Decision (IP/C/73), World Trade Organization 2015

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