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To,

China, India, Australia, New Zealand, Myanmar, Lao, Cambodia, Indonesia,
Thailand, Vietnam, Malaysia, Brunei, Philippines, Singapore, Japan, South Korea

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RCEP Investment Chapter Presents a Grave Threat to Access to Medicines

We are writing on behalf of Médecins Sans Frontières (MSF) to express serious concern over provisions under negotiation in the Regional Comprehensive Economic Partnership (RCEP) investment chapter that threaten to restrict access to affordable medicines for millions of people. MSF has previously expressed concern with the RCEP intellectual property (IP) chapter. Details are available on our website.¹

MSF is an independent international medical humanitarian organization that delivers medical care to people affected by armed conflicts, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries. In order to fulfil our mission, MSF requires access to affordable medicines.

MSF has been closely following the negotiations of the RCEP Agreement, and is concerned that proposed provisions in the leaked draft investment chapter² and its intersection with other proposals on intellectual property (IP) could potentially undermine a national government's capacity to implement 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 medical operations are based.

Much of the RCEP investment text replicates, often word-for-word, the most controversial terms found in US-led trade agreements, and especially in the Trans-Pacific Partnership Agreement (TPP).³

Investment, IP and access to medicines

In the context of access to medicines, countries and their courts have the right to seek a balance between the imperatives of the right to health with the IP system, often necessitating steps to limit the abuse of the patent system by multinational pharmaceutical corporations. Countries can do so by using currently available 'TRIPS flexibilities' to address high drug prices and promote generic competition. Yet this balance is now under threat as foreign corporations would have the power under the draft investment chapter of RCEP to challenge any domestic regulation or judicial decision in secret arbitration proceedings, whenever they claim the regulation or decision, including those within the remit of TRIPS flexibilities, has affected enjoyment of the companies' investments and expectations of potential profits.

¹ MSF RCEP IP Chapter Technical Analysis, November 2016, available at <https://www.msfaccess.org/rcep-ip-chapter-analysis>.

² Draft text of the investment chapter and respective proposals are published by RCEP Legal, available at: <https://rceplegal.files.wordpress.com/2016/08/03-rcep-wqi10-draftconsolidated-investmenttext.pdf>

³ Chapter 9, Investment, The Transpacific Partnership Agreement, available at <https://ustr.gov/sites/default/files/TPP-Final-Text-Investment.pdf>.

These regulations and decisions could be challenged even if they are aimed at protecting public health and access to medicines.

Investment rules proposed in the RCEP investment chapter and included in some previous trade agreements and bilateral investment treaties (BITs) problematically link investors' rights with IP protection. These types of provisions can and have been used by pharmaceutical companies to sue governments in non-transparent, international arbitration tribunals – outside of domestic courts – under the controversial investor-state dispute settlement (ISDS) mechanism. ISDS tribunals typically do not meet standards of transparency, consistency or due process, or provide fair, independent or balanced venues for resolving IP disputes. Most importantly, they do not have to take the obligation to protect the right to life and health into consideration.

Several such disputes have already been filed by corporations against governments under existing ISDS provisions, in an effort to reverse pro-public health laws, policies and judicial decisions, including those protecting access to affordable generic medicines. For example, in the context of tobacco control and public health warnings and regulations,⁴ the threat of launching expensive ISDS proceedings against a government has been frequently used as an effective tactic by tobacco corporations.

Similarly ISDS cases or threats of cases are now being used by pharmaceutical corporations to pressure governments to give in to demands to put company profits before people's access to affordable medicines, due to prohibitive costs of arbitral hearings and the risk of excessive damages should they lose.

Examples of the use or threat to use ISDS by pharmaceutical companies in the past decade

- In 2013, Eli Lilly, the US pharmaceutical company, launched a \$500 million claim against the Government of Canada to the North American Free Trade Agreement (NAFTA) arbitral tribunal. Eli Lilly is challenging the decision of invalidation by Canadian courts on secondary patents related to the previously-known active ingredients atomoxetine and olanzapine, drugs used to treat mental illness. Eli Lilly brings its case under Chapter 11, NAFTA's investment chapter – not the IP chapter – arguing that Canada violated the provision that guarantees fair and equal treatment to foreign investors and protects them from expropriation of their investments.⁵
- In 2016, while the Government of Colombia was taking measures to address the exorbitant prices of cancer medicines in the country, Colombia considered issuing a compulsory license to open up generic competition on the leukemia drug imatinib. In response, the Swiss-based pharmaceutical company Novartis threatened to sue Colombia's government using the ISDS mechanism contained in the Colombia-Switzerland BIT.⁶
- In January 2017, US pharmaceutical corporation Gilead Sciences threatened to use investment rights and ISDS provisions under the US-Ukraine BIT to launch a claim for more than \$820 million damages from the Ukrainian government over Ukraine's registration of a more affordable generic version of the lifesaving hepatitis C (HCV) medicine sofosbuvir. Ukraine

⁴ Examples of the use or threat to use ISDS on national tobacco control policies could be found from Tobacco Free Kids, "Fact Sheets on TPP, ISDS and Tobacco Control", available at: https://www.tobaccofreekids.org/content/what_we_do/federal_issues/trade/ISDS_TFK_ACS_CAN_Fact_Sheet_May_2015.pdf.

⁵ Eli Lilly and Company v. The Government of Canada, UNCITRAL, ICSID Case No. UNCT/14/2 - See more at: <http://www.italaw.com/cases/1625#sthash.YEdm9MNW.dpuf>.

⁶ ISDS Platform, "Investigation: As Colombia pushes for Cancer Drug Price-out and Considers Compulsory Licensing, Novartis Responds with Quiet Filing of an Investment Treaty Notice", available at: <http://isds.bilaterals.org/?investigation-as-colombia-pushes>. The full text of the Colombia-Switzerland BIT is available at: <http://investmentpolicyhub.unctad.org/Download/TreatyFile/803>.

faces one of the highest burdens of liver disease due to HCV and has been making efforts to increase availability of new direct-acting antivirals that dramatically improve cure rates for the disease. Ukraine's drug regulatory authority in the absence of patent barriers registered a generic version of sofosbuvir, refusing to provide 'TRIPS-plus' exclusive rights to the originator company Gilead over test data (data exclusivity) on the drug, which would have entitled Gilead to a market monopoly until October 2020. Gilead first challenged the registration before a Ukrainian court, but the company lost the case in the lower courts. After losing the case, Gilead linked the decision to not enforce data exclusivity on the drug sofosbuvir to the definition of investment and expropriation of its investment and profits under US-Ukraine BIT and threatened an ISDS claim. The Ukrainian government entered into a settlement with Gilead⁷ as a result of this threat and is facing the risk of cancelling the marketing approval granted to a generic competitor.

Recommendations for negotiators

MSF offers the following recommendations on the necessary amendments to the draft investment chapter in RCEP negotiation:

- IP (including goodwill, technical processes, test data and know-how) should be excluded from the definition of "Investment" and other proposed definitions, including intangible property and related/other property rights in RCEP. Investment rights linkage should be removed from any provisions under the IP chapter.
- The ISDS mechanism, which is not required under TRIPS obligations, should be removed from RCEP negotiations. In replacing ISDS, a negotiation and consultation based and state-to-state dispute settlement mechanism should be considered. Such mechanism could provide investor protection through the combination of negotiation and consultation procedures, transparent and constitutional domestic judicial system, and a state-to-state dispute settlement mechanism similar to those commonly used to settle trade disputes under international treaties such as the WTO Dispute Settlement Board.
- The vague Fair and Equitable Treatment Standard of investment treatment and the clauses on Minimum Treatment Standards, which has been repeatedly used in ISDS cases ruling against domestic policies aimed at protecting health and environment, should be removed.
- Expropriation claims should be limited to direct taking of ownership or control of an asset, preventing the possibility of abuse under indirect expropriation claims that may affect the use of price control mechanisms, compulsory license, patent oppositions, revocation and invalidation of patents and other public health safeguards under the TRIPS agreement.
- Parties should recognize and reaffirm that all domestic laws, policies and measures taken are at the discretion of RCEP governments, in compliance with their constitutional obligations, the Doha Declaration on TRIPS and Public Health – including but not limited to patentability criteria, examination procedures and other key public health safeguards – and as such are excluded from the scope of the investment chapter.
- RCEP countries should immediately review and reform all existing BITs to effect the same changes recommended above.

⁷ The decision regarding this settlement was published on Ukrainian government website on January 25th, 2017, available at: <http://www.kmu.gov.ua/control/uk/cardnpd?docid=249699210> (in Ukrainian language only).

There is already awareness in countries including India and Indonesia of the harm such provisions – signed by governments in the 1990s as part of bilateral investment treaties (BITs) – can cause and reforms are in the pipeline. We urge countries negotiating RCEP not to grant pharmaceutical corporations additional avenues to pressure governments to undermine laws, policies or judicial decisions that implement TRIPS flexibilities to protect access to affordable medicines.

We thank you for your attention and are available for further discussions and information.

Sincerely,

A handwritten signature in black ink, appearing to read 'RM', followed by a stylized flourish.

Rohit Malpani
Director of Policy and Analysis