86TH CEDAW PRE-SESSIONAL WORKING GROUP
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CRITICAL ISSUES AND QUESTIONS
FOR THE
MALAYSIAN GOVERNMENT
UNDER ARTICLE 12 CEDAW

NGO SUBMISSION BY

TWN
Third World Network

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ADDRESSING PARAGRAPH 80 OF MALAYSIA’S 6TH PERIODIC REPORT ON THE BASIS OF ARTICLE 12 OF CEDAW AND CEDAW GENERAL RECOMMENDATIONS NO.24: ARTICLE 12 OF THE CONVENTION (WOMEN AND HEALTH)\(^1\)

1. The impact on diverting resources from non-communicable diseases, including female-related cancers, to COVID-19 pandemic management

In Paragraph 80 of Malaysia’s 6\(^{th}\) Periodic Report submitted under Article 18 of CEDAW, the Ministry of Health admits that ‘increasing health threats and changing demographics pose several challenges towards Malaysia’s healthcare system. The rise in non-communicable diseases and the necessity to handle the COVID-19 pandemic, which includes the deployment of the National COVID-19 Immunisation Programme, has put a strain on the healthcare system. In addition, Malaysia is preparing itself to meet the challenges towards aged nation by 2030.’

COVID-19 is a grim reminder of what happens when systems fail: a global moral catastrophe where those who need assistance the most are forsaken\(^2\). \textbf{It revealed that pandemics disproportionately affect women worldwide.} In Malaysia, the adverse impacts on women and girls led to exacerbation of mental health issues, domestic violence, period poverty, as well as negative consequences arising out of limited or inflexible occupational arrangements and socio-economic empowerment\(^3\). The gendered pattern of COVID-19 impact is broadly similar to those witnessed during the HIV/AIDS, Ebola, and Zika outbreaks\(^4\), further underscoring the need for non-discriminatory public measures that fulfils women’s right to health during both COVID-19 (whose effects continued to be felt) and future pandemics.

In particular, the COVID-19 pandemic exposed and tested the limits of the Malaysian public healthcare sector, where the Malaysian Government had to decant many of the non-COVID patients to the private sector. Overall, the management of non-communicable diseases (NCDs) deteriorated throughout the course of the pandemic. As the pandemic struck there was a diversion of human and financial resources away from NCD patients to concentrate on managing COVID-19 in acute settings. Consequently, between March and June 2020, diabetes, hypertension and cancer patients faced up to two-month appointment delays, increasing to 6 months in some

\(^{1}\) Specifically paragraphs 1, 9, 10, 11, 13, 24, 29, 30 and 31.
cases when the second wave of the pandemic struck Malaysia. In relation to NCDs specifically, paragraph 84 of the 6th Report points out that female-related cancers, including breast and cervical, have led to hundreds of thousands of premature deaths among women. In fact, breast cancer (among women) has the highest incidence rate in Malaysia. The link between the deterioration of healthcare during the pandemic and gender-based discrimination cannot be ignored. Indeed, as noted by the CEDAW Committee in its Guidance Note on CEDAW and COVID-19, “Gender bias in the allocation of resources and diversion of funds during pandemics worsen existing gender inequalities, often to the detriment of women’s health needs.”

2. Trade-Related Aspects of Intellectual Property Rights Agreement (“TRIPS”) and its impact on equal right to health in Malaysia

a. TRIPS and the ongoing COVID-19 pandemic

According to General Recommendation 24, in relation to international agreements, “States parties should take steps to ensure that these instruments do not adversely impact upon the right to health. Similarly, States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health.” In this regard, General Recommendation references international financial institutions, such as the International Monetary Fund and World Bank, requiring State parties that are members of these institutions “to pay greater attention to the protection of the right to health in influencing the lending policies, credit agreements and international measures of these institutions.” By analogy, State parties that are members of the World Trade Organisation (WTO), such as Malaysia, are required to pay greater attention to protection of the right to health when engaging with its procedures and agreements, and ensure no adverse impacts.

In particular, what stands in the way of a timely response to the pandemic, and to non-communicable diseases as well, is the monopoly afforded to pharmaceutical companies under the Trade-Related Aspects of Intellectual Property Rights Agreement (“TRIPS”) before the WTO.

TRIPS was the result of lobbying by pharmaceutical, biotechnology and chemical industries which sought to ensure that governments entrenched the globalisation of intellectual property protection that disproportionately favours big business. Today, there is widespread concern that the current intellectual property system designed by corporations and developed country governments has become a serious impediment. For decades, TRIPS has exacerbated the problem of timely, equitable, and affordable access to life-saving medicines, with COVID-19 revealing the deadly impact on a global scale.

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Governments often refer to “flexibilities” within TRIPS as a countermeasure to alarms raised about corporate-driven intellectual property regime. These flexibilities include the right to determine what can be excluded from patentability, what can be patented (an “invention” is to be defined by national law), the right to determine patentability criteria (new, inventive step and industrial applicability are defined by national law), the right to establish opposition procedures, to issue compulsory licences to import or manufacture generic versions of a patented product, to parallel import, and others.

However, COVID-19 showed that TRIPS Flexibilities would not be sufficient to respond to a pandemic.

On 2nd October 2020, the Governments of India and South Africa made a joint submission (IP/C/W/669) (“the Waiver Proposal”) to the World Trade Organization seeking a waiver from certain provisions of TRIPS (patents, trade secrets, copyright and industrial designs) in relation to the containment, prevention and treatment of COVID-19. The scope covered diagnostics, vaccines, therapeutics, medical masks, other personal protective equipment, ventilators and other needed medical products. The Waiver Proposal was co-sponsored by 63 other countries including Malaysia and received global support from most of the other developing countries and the international community.

Unfortunately, there was a failure to deliver on a comprehensive Waiver. Instead, a “TRIPS Decision” was adopted in June 2022 that only grants increased access to vaccines in a limited way. Developed countries fought and diluted the original proposal while deferring the application of the Decision to diagnostics and therapeutics. There is now an ongoing battle for the extension of the Decision to these much-needed medical tools.

**WHO Director-General, Dr. Tedros Ghebreyesus**, at his opening remarks at the media briefing on COVID-19, on the 12th January 2023 emphasised that it is the obligation of global leaders “to ensure that breakthrough treatments, as well as reliable tests, are available in all countries. To end the acute stage of the pandemic, the highly effective tools science has given us need to be shared fairly and quickly with all countries of the world. Vaccine inequity and health inequity overall were the biggest

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10 Paragraph 8 of the Decision reads: “No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.” Ministerial Decision on the TRIPS Agreement. WTO Ministerial Conference, 12th Session, 17 June 2022, [https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True)
failures of last year... I call on citizens of the world, including civil society, scientists, business leaders, economists and teachers to demand that governments and pharmaceutical companies to share health tools globally and bring an end to the death and destruction of this pandemic... We need vaccine equity, treatment equity, test equity and health equity and we need your voices to drive that change. Equity, equity, equity.”

In line with the above and its responsibilities under Article 12 and General Recommendation 24 of CEDAW, Malaysia must now continue to fight for the Decision to be extended to diagnostics and therapeutics without any dilution.

b. TRIPS and barriers to affordable medicine created by Malaysia’s patent system

Likewise, the TRIPS regime impacts equitable healthcare in Malaysia. In 2017/2018, the Malaysian Competition Commission carried out a market review of the pharmaceutical sector.

Of the laws and guidelines mentioned above, patents issued under the Patents Act 1983 (which incorporates TRIPS in Malaysia) were identified as a major barrier to affordable pharmaceutical products, due to the manner in which patents are granted in the country and the resulting product monopolies afforded to

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Each patent that is granted provides 20 years of monopoly from the date of application for a patent.

It is very important and central to the integrity of a patent system that it only grants high quality, deserving patents. As stated above, TRIPS does not restrict Members’ right to define what constitutes patentable subject matter. Malaysia must adopt strict standards of patentability including provisions that explicitly exclude new uses and forms from patentable subject matter. Rigorous patentability standards in national patent law and in guidelines would:

- exclude new forms, uses, indications of known compounds from patenting in the patent law
- exclude patents on combinations, admixtures, and arrangements or rearrangements
- exclude naturally occurring substances even if isolated and purified

In contrast, Malaysia’s Patents Act and Patent Examination Guidelines allow for a broad range of secondary patents for pharmaceuticals that have been excluded in some countries because these have an “evergreening effect” which can have anti-competitive impact on entry of generics or biosimilars, in the case of biological products, driving high prices of treatment for longer and extended periods.

As in the response to COVID-19, the entry and availability of generics/biosimilars is crucial to recovery and upholding the right to health. Generics/biosimilars expand affordable, timely supply making treatment available for all and is central to the sustainability of health systems. A recent example in Malaysia is the case of trastuzumab, a drug for the treatment for HER-2 positive metastatic breast cancer, sold under the brand name of Herceptin by Roche.

In 2017, one month’s treatment of trastuzumab cost an average of RM8,600, making it clearly unaffordable for most Malaysians. In December 2018, a biosimilar version of...
Trastuzumab was approved in Malaysia. Following this, the Ministry of Health called for an open tender for the supply of trastuzumab for public use. The biosimilar was approximately 50% of the price of the originator. Roche which participated in the tender, shockingly dropped the cost of Herceptin by 52% overnight. Before the competition from the biosimilar Roche has resisted reducing its price.

The price reduction allowed the Ministry of Health to increase patient access in the public health system. With this reduction in price, Malaysia included trastuzumab in the 5th Edition of its Essential Medicines List. In contrast, trastuzumab was included in the WHO Essential Medicines List in 2015 and in neighbouring Thailand in 2014 but the prohibitive pricing by Roche delayed this in Malaysia.

Compelling data from the ACTION study carried out in Malaysia discovered that 45% of the population experienced financial catastrophe within a year following cancer diagnosis. Specifically for private hospitals, direct medical care costs were the main driver for catastrophic payments. Further, a study on avoidable deaths showed that out of the 2500 women who died of breast cancer in Malaysia in 2012, 50% of these deaths were premature on account of lack of access to screening and treatment services. The poor bore the brunt of the failure.

In a further study published in 2022, the team found that “in our study, despite both men and women experiencing comparable costs following cancer diagnoses, there is a hint that women were more vulnerable in terms of coping with the financial strain of cancer-related costs, including that of indirect costs. Previous studies have indeed reported a higher proportion of women who experienced income loss or employment disruption after a cancer diagnosis...Even before their cancer diagnosis,


women have been reported to be less likely to own adequate health insurance coverage, more likely to be unemployed, or employed in low-wage jobs or informal sectors, to have fewer saving and have poorer social support…Coupled with pre-existing economic inequalities, it is conceivable that a diagnosis of cancer may render women more financially vulnerable due to their lack of access to economic resources. Nonetheless, we acknowledge that the male participants may have not fully disclosed the extent of their financial hardship due to cultural norms and societal expectations.”

Multinational pharmaceutical companies tout that the high cost of medicines are directly related to high research and development costs. However, these claims do not hold water and have been repeatedly proven untrue27. In an investigation into the American pharmaceutical industry, Roosevelt Institute found “Contrary to the industry’s claims, unaffordable prescription drugs are not the price we must pay for the industry to find cures and innovate affordable medicines; rather, it is the price tag we pay for an industry that values profits over patients and public health. This profit-seeking is built in part by the rules that govern the industry and, more broadly, our economy that creates wealth for shareholders and executives at the expense of patients. Today’s pharmaceutical industry arises from the rules that govern it; the complex structure of laws, regulations, and institutions that shape corporate decision-making and drive runaway profits.”

Knowing that, it is beholden on the Malaysian Government to critically review its laws and regulations to ensure that these do not entrench a system where society bears the cost, paying for it with their lives.

As described above, the Patents Act has not incorporated the full extent of flexibilities available under TRIPS. Malaysia needs to amend its patent law and guidelines to adopt stricter criteria to determine what is patentable. Furthermore, the Malaysian Government has not sufficiently utilised TRIPS flexibilities such as compulsory licences to ensure timely access to affordable treatment for its population.

Indeed, members of the WTO affirmed in the 2011 Doha Ministerial Declaration that: “We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.

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27 See for eg. Hill, Andrew M et al. Estimated Costs of Production and Potential Prices for the WHO Essential Medicines List, Volume 3, Issue 1, https://gh.bmj.com/content/3/1/e000571
In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.  

The incoherencies between the right to health, trade, intellectual property and public health objectives can only be resolved using robust and effective accountability frameworks that hold all stakeholders responsible for the impact of their decisions and actions on innovation and access to health technologies.

As stated in General Recommendation 24, “The realization of women’s right to health requires the removal of all barriers interfering with access to health services”.

The global intellectual property regime, upheld by the WTO, is among the strongest structural barriers to accessible, affordable and non-discriminatory healthcare services in Malaysia and across the globe. Therefore, in accordance with Malaysia’s responsibilities under Articles 2 and 12, and General Recommendation 24, of CEDAW to take all appropriate measures to eliminate discrimination in the field of healthcare, we call on the Government of Malaysia to continue to proactively support an extension of the TRIPS Decision to cover COVID-19 diagnostics and therapeutics.

We also request that the Government to detail the measures which Malaysia is taking to:

- move towards self-sufficiency of pharmaceutical supply in Malaysia to reduce its reliance on imports. The COVID-19 pandemic taught Malaysians that dependency on (vaccine) imports could potentially become a national security issue;
- use TRIPS flexibilities (including compulsory licenses) to overcome insufficient access to health treatments especially in the case of highly priced medical treatments such as that for cancer;
- ensure that the spirit of Doha Declaration and the full flexibilities under TRIPS are incorporated into Malaysia’s patent regime;
- support the local pharmaceutical industry for production of generics and biosimilars, vaccines and medical devices towards ensuring self-resilience in Malaysia’s health system.

“As from a human rights perspective, access to medicines is intrinsically linked with the principles of equality and non-discrimination, transparency, participation, and accountability. There remains an intrinsic link between poverty and the realization of the right to health, where developing nations have the greatest need and the least access to medicines. States are obliged to develop national health legislation and policies, and to strengthen their national health systems”

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29Declaration on the TRIPS Agreement and Public Health. DOHA WTO Ministerial 200, 20 November 2001, [https://www.wto.org/english/theewto_e/minist_e/min01_e/mindecl_trips_e.htm](https://www.wto.org/english/theewto_e/minist_e/min01_e/mindecl_trips_e.htm)

