Submission by the South Centre to the Office of the United Nations High Commissioner for Human Rights on Inputs for the comprehensive report on ensuring access to medicines, vaccines and other health products (HRC resolution 50/13)

The South Centre presents this submission in response to the call for contributions to a comprehensive report, including new developments, on ensuring access to medicines, vaccines and other health products (HRC resolution 50/13), Reference: TESPRDD/DESIB/ESCR/KH.

I. *What challenges or barriers have emerged or intensified in your efforts to ensure access to essential health products over the past two years, and what human rights implications do these pose? What are recommendations to address these challenges or barriers?*

The Covid-19 pandemic intensified existing systemic challenges and barriers for governments to advance access to health products as part of their human rights obligations (i.e. low availability, lack of affordability, weak health technology assessment and price control practices, concentration of production capacity for vaccines and new medicines, regulatory and intellectual property and other market exclusivity barriers to develop and procure lower cost generics) and caused further significant disruptions to health services including provision of access to medicines and routine immunization services.

Additional challenges include:

- Increasing resistance to essential antibiotics and other antimicrobials is increasing healthcare costs and deaths associated to and as a result of antimicrobial resistance (AMR). A recent study suggests that bacterial AMR will cause 39 million deaths between 2025 and 2050 (Nagvani et al, Global Burden of Bacterial Antimicrobial Resistance 1990-2021: A Systemic Analysis with Forecasts to 2025, The Lancet, 404:10459, 1199-1226). There is need for increased attention to ensuring access to essential antibiotics,

vaccines and diagnostics, alongside antimicrobials stewardship, infection prevention and control and universal access to water, sanitation and hygiene (WASH) to contain antimicrobial resistance.

- Promoting geographically diversified production of vaccines has become an important priority for many governments and multilateral institutions, such as the World Health Organization (WHO) and regional agencies such as the Pan American Health Organization (PAHO) and the African Union (AU). This is a response to the dependency on vaccines from few producers and countries and, as during Covid-19, the hoarding of vaccines by rich countries when global supply was limited. The efforts to increase regional production capacities are being hindered by insufficient funding and barriers to access to technology and know-how imposed through intellectual property rights and insufficient collaboration from industry. To support vaccine production in developing countries, there is need for sustained multilateral cooperation for transfer of technology and know-how, addressing intellectual property barriers, providing financing and market shaping including through pooled procurement mechanisms.

- Access to medicines and technologies that are essential for sexual and reproductive health care is limited by barriers such as cost, misinformation, social stigma and restrictive policies and regulations. In the past years there were some alarming developments in abortion bans and decreased access to prescription birth control and emergency contraceptives as well as reduced access to family planning services (Qato DM, Myerson R, Shooshtari A, Guadamuz JS, Alexander GC, Use of Oral and Emergency Contraceptives After the US Supreme Court's *Dobbs* Decision, *JAMA Netw Open*. 2024;7(6):e2418620. doi:10.1001/jamanetworkopen.2024.18620). Countries should advance fundamental human rights to healthcare for all, including access to medicines and technologies needed for sexual and reproductive health care.

- Countries continue to face challenges in aligning their public health goals with their policies and legislations on intellectual property rights. In the past years, voluntary licensing by the pharmaceutical industry has not been sufficient to ensure availability and affordability of essential medicines. In the past years the overall number of companies with voluntary licensing agreements decreased and there has also been a decline in the number of new non-exclusive voluntary licenses (Access to Medicines Index 2024, Access to Medicines Foundation). Moreover, in the granted voluntary licenses, such as for Lenacapavir (for HIV treatment), many middle-income countries are excluded.

- Compulsory licenses remain an important mechanism for advancing access to medicines. The compulsory licence granted by Colombia for advancing treatments to HIV/AIDS is a very welcome development. This case example shows that the use of compulsory licencing is a viable and effective mechanism, and also calls attention to the undue legal actions of industry against compulsory licensing.

- Generic medicines have an important role in advancing affordable access. The advancements in biologics, including monoclonal antibodies, offers significant potential for improved health outcomes, but these are very expensive and production is concentrated in few countries. The market entry of lower-cost biosimilars, the equivalent of generics for small-molecule drugs, is slow. There are more challenges for biosimilar development and regulatory approval as compared to generics. Moreover, extensive patent protection and in addition marketing exclusivity for biologics, further delays market entry of biosimilars. Countries should advance policies to facilitate biosimilar market entry, which may include establishing guidelines for examination of patents for biologics that provide for stringent implementation of patentability criteria, that can limit the number of patents granted.

II. What steps have you taken to strengthen pandemic preparedness and response and how are human rights principles incorporated into these strategies?

The South Centre provides policy advice and technical assistance to developing countries and support in international negotiations including on the WHO pandemic treaty.

There is a need for sustained investment in public health, to strengthen healthcare systems, including infrastructure and primary healthcare, towards ensuring universal health care for all, as a core foundation for strengthened pandemic preparedness and response. It is critical that countries can maintain essential services during pandemics and other health emergencies and to ensure access to essential health services including ensuring access to medicines and vaccines, in full respect for human rights.

The South Centre provided support to developing countries in the negotiation of amendments to the WHO International Health Regulations (IHR). The agreed amendments to the IHR in 2024 now recognise the importance of equitable access to medicines, vaccines and other relevant health products for countries to prepare and respond to health emergencies and pandemics, though the amendments fall short of setting up concrete legal obligations for enhancing access as was proposed by developing countries.

Extensive and sustained scarcity and inequity of medicines, vaccines, diagnostics and other health products during pandemics can be prevented. The South Centre supports negotiations for a WHO pandemic treaty that is grounded on human rights obligations, including to ensure access to medicines, vaccines and other health products and essential health services, with no discrimination and special attention to the protection of vulnerable groups and populations. The pandemic treaty must set the framework for

advancing global solidarity and equity for timely access to vaccines and other health products during pandemics, including by advancing transfer of technology and know how and suspending during a pandemic the enforcement of intellectual property rights in instances when these create barriers to the manufacture or supply of health products for prevention, diagnostic or treatment. The pandemic treaty should also support equitable and affordable access to medicines and other health products by requiring greater transparency in the costs of research and development (R&D), public sector support for R&D, and prices of medicines and other health products, aligned to the WHO Resolution WHA72.8 on improving the transparency of markets for medicines, vaccines, and other health products. The pandemic treaty should also include commitments for countries to require access conditions for government-funded R&D for new medicines and other health products, such as affordable pricing, non-exclusive licencing, and obligations on product registration and distribution.