UNITAID IP SUBMISSION: LAW REFORM PLATFORM FOR LDC PHARMACEUTICAL TRANSITION PERIOD

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Least Developed Countries (LDCs) are an area of special focus for UNITAID. LCDs have a unique opportunity and need under the TRIPS Agreement to implement alternatives to the WTO mandated IP system that is increasingly being critiqued for its failures to (1) provide proper incentives for research and development targeted at neglected needs and product adaptation/optimization and (2) ensure access to existing medical technologies. Even where medicines exist, patents and data protections create barriers not just in terms of affordability but also adaptability for use in LDCs. Although at least 25 LDCs are estimated to have relied on earlier pharmaceutical transition periods under the WTO TRIPS agreement to allow imports of generic HIV medicines, the need for adoption and further use of a newly granted pharmaceutical transition period (2016-2033) to confront HIV, TB, malaria, and other emerging health crises in LDCs is likely to increase. Despite the significant policy space that WTO LDC members now have under the 2016-2033 pharmacetuical extension to ignore TRIPS requirements, the vast majority of LDCs have not taken full advantage of the pharmaceutical transition period nor have they even adopted the full range of permissible exemptions, definition, limitations, and exceptions allowed by the pharmaceutical extension let alone the even more permissive 2021 general TRIPS extension. By adopting the TRIPS-compliant pharmaceutical transition period, LDCs will be able to meet their medical needs either through the importation of generic medicines or through local production. The option of local production is particularly significant since LCDs will be permitted to produce and even export medicines that may well be patent protected in leading producer countries like India.

This submission identifies a need for the establishment of a Least Development Country (LDC) IP Law Reform Facility focused on the following:

- *Providing pro-development and pro-public health technical assistance*: In reviewing intellectual property (IP) laws, LDCs should receive technical assistance tailored to their socio-economic needs and focused on public health and access to medicines. Such assistance should promote the full use of LDCs flexibilities under the TRIPS Agreement.
- *Promoting full use of the TRIPS and Pharmaceuticals Transition Periods*: The 2021 and 2033 TRIPS transition periods provide LDCs with a critical avenue to review and reverse the standards of IP protection in their countries, particularly on pharmaceuticals and other health technologies including diagnostic. LDCs should accordingly consider making full use of their rights under the transition periods to tailor their IP regimes to their public health, socio-economic, and industrial policy needs. This could include having no IP protection at all, particularly on pharmaceuticals, or protection that is far below what is otherwise required by TRIPS.
- *Promoting review and incorporation of the full range of public health safeguards/TRIPS flexibilities*: LDCs not making full use of the transition periods or no longer benefitting from transition periods, should undertake a full review of their patent and related laws to ensure the incorporation of the full range of TRIPS flexibilities. This would include law reform in relevant regional IP bodies like ARIPO and OAPI.

The Facility would create policy and advocacy documents on the law reforms discussed above and would support LDC governments and civil society organizations in promoting and achieving pharmaceutical IP law reform in LDC as comprehensively as possible and in a coordinated way.