As we strive to achieve SDG Target 3.3 by 2030—ending the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases, and combating hepatitis, water-borne diseases, and other communicable diseases—it is more crucial than ever to eliminate barriers preventing access to existing and emerging health technologies. This involves leveraging existing structures such as the Medicines Patent Pool (MPP) to ensure no one is left behind. Unfortunately, the MPP faces challenges in meeting the needs of upper middle-income countries (UMICs). Addressing these shortcomings is essential to ensuring equitable access to life-saving treatments and technologies for all.

Reflecting on a decade of Dolutegravir (DTG), it is crucial to consider the lessons learned. DTG's simple formulations and lower risk of drug resistance have demonstrated remarkable results in helping both adults and children achieve an undetectable viral load, significantly reducing mortality and preventing HIV transmission. The good news is that with the efforts of civil society and subsequently the MPP, with funding support provided by the Global Fund and PEPFAR, many low- and middle-income countries were quickly able to put patients on DTG-based first-line treatment regimens long ago. However, other countries, particularly UMICs, have struggled. For instance, it took 10 years for countries like Belarus, Kazakhstan, and Malaysia to even gain some access to generic DTG, although at prices significantly higher than those available to the Global Fund. For example, the tenofovir/lamivudine/dolutegravir (TLD) combination is available to the Global Fund for less than US$45 per person per year, while prices in UMICs are much higher.

A decade ago, advocacy efforts in Kazakhstan, Belarus, and Malaysia were initiated by communities aiming to secure compulsory licenses—a legal mechanism allowed under the TRIPS Agreement to access affordable generic DTG, as the voluntary license excluded these countries from accessing affordable quality generics. At that point, the MPP initiated a special license agreement with ViiV. Initially, it appeared to offer a faster and simpler route to access, but this was a misconception. Consequently, preparations for compulsory licenses were halted, as governments were led to believe that the MPP license with ViiV provided a better solution towards affordable access to DTG-based treatment regimens.

The UMIC MPP-ViiV DTG license was a departure from good practices. Non-disclosure agreements (NDAs) required by ViiV as part of this license arrangement with MPP kept critical information, including the royalty applied, confidential. Community representatives involved in the negotiations as members of the advisory group were restricted by confidentiality agreements and could not share crucial information with colleagues and communities, potentially impacting treatment access negatively. The license also limited the number of suppliers, as only three generic companies were granted the license to manufacture and supply to UMICs, adversely affecting robust generic competition that would have enabled further price reduction. The UMIC MPP-ViiV license for Belarus, Kazakhstan, Azerbaijan and Malaysia also contained different and complex royalty calculations based on the Product Access Percentage (PAP), which is calculated based on the procured quantity and numbers of PLHIV on treatment in the country, and not on the cost of production.

Thus, access to DTG in these countries was slow. For example, in Belarus, only 12.8% of patients on ARV treatment regimens included DTG at the end of 2022. Community representatives were unaware of the exact price but were told by the government it was significantly higher than previous first-line regimen prices. As a result, DTG was not included in national guidelines, despite WHO recommendations, because the country could not afford to transition to DTG-based regimens due to higher prices. Significant progress was observed in Belarus only at the beginning of 2024, with almost 60,5% of patients on treatment switching to DTG-based regimens, and a plan for 75% to switch by the end of 2024. Kazakhstan experienced a similar process, with only 47% of patients transitioning to DTG-based combinations by 2024.

In Malaysia, the shift from more toxic treatment regimens to DTG-based treatments has been limited. Although the UMIC VL was signed in November 2020, only in 2024, the remaining two generic manufacturers registered the combination of tenofovir/lamivudine/dolutegravir (TLD). Furthermore, due to the much higher price of DTG and related combinations (i.e.,almost 10 times the Global Fund price), scaling up treatment has been extremely challenging.

It took these countries 10 years to come closer to having DTG-based first-line treatment widely available. For the future, we urge the MPP to consider the following lessons learned:

1. Transparency: We request that MPP make all license text fully available, including information on royalty rates and other relevant details.

2. Competition: MPP must never agree to limit competition by limiting the number of potential suppliers under future license agreements, as the experience with the UMIC DTG license has shown that this practice leads to higher prices and restricted access to new medicines.

3. Standard Licensing: MPP should avoid creating special licenses with opaque and restrictive conditions for UMICs. Instead, MPP should advocate and push where possible for UMICs to be included in standard license agreements.

4. Community Involvement: Any negotiations involving governments should be transparent to community representatives from that country and must not undermine their efforts for a compulsory license. Community representatives should also be involved on a non-confidential basis so that activists can seek advice and fully represent their constituencies.

We hope that these lessons will lead to quicker and more equitable access to the next generation of ARV treatment for all countries, ensuring that no one is left behind.

Signed organizations:

1. AVAC
2. Coalition of women living with HIV and AIDS (COWLHA) Malawi
3. Global Network of People Living with HIV (GNP+)
4. ITPC EECA
5. ITPC Global

6. Third World Network
7. Delhi Network of Positive People (DNP+)
8. Sankalp Rehabilitation Trust
9. Young Health Advocates Ghana
10. International Network of Religious Leaders Living with HIV (INERELA+) Kenya Chapter
11. Ghana Network of Persons Living with HIV/AIDS (NAP+ Ghana)
12. People PLUS (Belarus)
13. Ecumentical Pharmaceutical Network (EPN)
14. Advocacy Core Team (ACT) Zimbabwe
15. Treatment Advocacy and Literacy Campaign (TALC)
16. Union Congolaise des Organisations des PvVIH (UCOP+)
17. Tracy Swan - Independent Consultant/Activist, Spain
18. Asia Pacific Network of People living with HIV (APN+)
19. Network of People Living with HIV/AIDS in Nigeria (NEPWHAN)
20. Among Karsa-Indonesia
21. Health Advocacy Coalition (HAC)
22. Association “Partnership network” Kyrgyzstan
23. Central Asian Association of People Living with HIV (CAAPL), Kazakhstan
24. PF AGEP’C Almaty.Kazakhstan
25. Belarusian Public Association "Positive movement"
26. Indonesia AIDS Coalition
27. ITPC-MENA
28. Brazilian Interdisciplinary AIDS Association (ABIA), Brazil
29. Vietnam Network of People living with HIV (VNP+)
30. Thai Network of People Living with HIV/AIDS (TNP+)
31. National TB Network ,Nepal
32. Assam Network of Positive People, India,
33. Network of Positive Advocates of the Philippines, Inc.
34. PLHIV Network PN+ Bangladesh
35. Pinoy Plus Advocacy Pilipinas Inc., Philippines
36. Jaringan Indonesia Positif (JIP)
37. Association of people living with HIV (APLHIV)- Pakistan
38. Drug User’s Network (DUNE) In Pakistan
39. Positive Female’s Network (Pakistan)
40. Youth Chapter Pakistan
41. Treatment Action Campaign -South Africa
42. Kuala Lumpur AIDS Support Services Society (KLASS), Malaysia
43. All-Ukrainian Network of People Living with HIV/AIDS (CO “100 Percent Life”) - Ukraine
44. Myanmar Positive Group- MPG (National Network of PLHIV)
45. Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
46. Pertubuhan Jaringan Kebajikan Komuniti (JEJAKA), Malaysia
47. Association for people living with HIV/AIDS Laos (APL+)
48. Lhak-Sam - Bhutan Network of People Living with HIV and AIDS (BNP+)
49. Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN)
50. Korean Network of People Living with HIV/AIDS (KNP+)
51. Malaysian AIDS Council (MAC), Malaysia
52. Jeremy Kwan, Independent Advocate & Activist for MSM & Positive Living Community, Malaysia

53. PENGASIH Malaysia
54. Cambodian People living with HIV Network (CPN+)
55. Fundación IFARMA, Colombia
56. Public Foundation “Answer”, Kazakhstan
57. Centre for Women Justice Uganda(CWJU)
58. ITPC MENA
59. Health Equity Initiatives, Malaysia
60. Consumers Association of Penang, Malaysia
61. **Paediatric-Adolescent-Treatment Africa (PATA)**