EARLY ACCESS TO Dolutegravir-based HIV Treatments in Low- and Middle-income Countries

Issues
Despite progress in scaling up antiretroviral therapy (ART) worldwide, approximately 38% of adults and 46% of children living with HIV still lack access to ART. Among people on ART, many are still on suboptimal treatment, often for lack of access to affordable versions of optimised treatments. Access-oriented licences on patented medicines facilitate access to affordable, quality-assured generic medicines, benefiting millions of people in low- and middle-income countries (LMICs).

The Medicines Patent Pool (MPP)’s public health-oriented licences allow the distribution of affordable versions of patented medicines in LMICs and the development of new treatments (e.g., paediatric formulations and fixed-dose combinations). Competition among multiple manufacturers brings prices down, supporting scale-up.

The MPP strikes licences with companies to ensure access to affordable DTG-based ART in LMICs.

Africaregion - Overall data
- 35,900,000 PLHIV
- 16,500,000 (60%) on ART
- 4,150,000 patients-years of DTG-based treatment

Lessons learned
The DTG licence nominally covers 94 countries; in addition to this territory, countries where DTG is not patented may also procure DTG-based products from MPP licensees. The non-exclusive nature of the DTG licence has promoted strong generic competition (with prices for TLD already below USD 70 per person per year).

As of June 2019, six MPP licensees had received stringent regulatory approval (SRA) on DTG and/or TLD, and had made them available in 74 countries (including 34 in Africa). These licensing arrangements have facilitated an unprecedented acceleration in the availability of an important new medicine in LMICs, with nearly 1.5 million people living with HIV (PLHIV) in LMICs now having access to generic DTG-based products since DTG’s initial U.S. Food and Drug Administration (USFDA) approval in 2013.

Next steps
Tenofovir alafenamide (TAF) + FTC or emtricitabine, FTC + DTG is now recommended by WHO for adults in special circumstances, i.e., for people with established osteoporosis and/or impaired kidney function, as an alternative first-line regimen for children, and in some cases for second-line treatment. TAF may have safety advantages over TDF and enable further cost savings. The territory covered by both TAF and DTG licences is 87 countries. As of June 2019, one MPP licensee had received SRA approval for TAF/TD/DTG. Early licensing of DTG has enabled prompt access to quality, affordable generic versions of TLD and other promising treatment options, setting new standards in promoting access to important new medicines. It is now important, in order to enable implementation of WHO guidelines, that countries update their national guidelines and switch to DTG-based products, while ensuring that generic manufacturers register these products in all licensed countries.

REFERENCES
- World Health Organization, Key Facts: www.who.int/news-room/fact-sheets/detail/hiv-aids
- UNAIDS Fact Sheet: www.unaids.org/en/resources/fact-sheet

NEW Medicines
Six quality-assured generic manufacturers are ready to supply TLD to PLHIV in LMICs.

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