HEALTH GAP (Global Access Project)

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**Health GAP Applauds New Pediatric Drug Deal with Patent Pool, and Condemns GlaxoSmithKline’s Threats to Obstruct Access to Critical New HIV Medicine**
Activists from Health GAP (Global Access Project) welcomed a new voluntary license agreement on pediatric formulations of the antiretroviral medicine abacavir (ABC). The group welcomed improvements of the license between the drug company ViiV (a venture between Pfizer, GlaxoSmithKline and Shiongoni) and the Medicines Patent Pool (MPP) compared with a deal previously negotiated between MPP and Gilead, which contained more onerous restrictions. The terms and conditions of the new agreement will extend unfettered generic competition to more than 99% of children with HIV in low- and middle-income countries--an improvement in geographic coverage over Gilead medicines for adults. The license also comes without harmful restrictions on the physical location of manufacturers, sourcing of active pharmaceutical ingredients (APIs), use of compulsory licenses, or data exclusivity. The agreement directly covers 118 countries with 98.7% of the developing world's children with HIV. In addition, explicit provisions in the agreement allow sale in additional countries where there are no policy blocks in place to extend generic coverage to 99.4% of the pediatric epidemic. Health GAP asserts that, unless similar provisions are agreed by ViiV’s shareholders in upcoming license agreements, these improvements will appear to be merely a calculated public relations move, given the shrinking pediatric HIV market.

MPP is still in negotiations with ViiV on dolutegravir (DTG)--an even more important medicine that is part of entirely new class of anti-AIDS drug called integrase inhibitors. In spite of the step forward on ABC, drug giant and 76.5% majority ViiV shareholder, GlaxoSmithKline currently limits ViiV’s adult voluntary licenses to only 69 least developed, low-income, and sub-Saharan African countries.

"The agreement on pediatric ABC is a significant step up over previous MPP licenses, but the children's antiretroviral market is small and fragmented. A license on the small children's ARV market with low commercial value cannot be used by ViiV or GSK as PR cover for restrictive licensing on critical newer drugs for adults like dolutegravir," said Health GAP's Senior Policy Analyst Brook Baker, a professor of law at Northeastern University. "Glaxo must back away from its current geographical limitations on adult ARV voluntary licenses, or they will expose the new ViiV license as a public relations gesture that is good for children but deadly for their parents."

Health GAP strongly cautioned against any deadly limitations on access to DTG. "Glaxo is threatening to profoundly restrict adult access to critically needed newer medications," said Health GAP's Nairobi-based Paul Davis. "This improved voluntary license on abacavir must be the floor for GSK, not the ceiling. We need integrase inhibitors here and everywhere in the developing world, and GSK must cease its efforts to gouge monopoly profits out of people with AIDS."

"The improvements in the pediatric ABC license over the Gilead license show that we can improve over the flaws of previous licenses ," said Asia Russell from Health GAP in Kampala. "We call on the Patent Pool, ViiV and GSK to replicate and expand the terms and conditions of the pediatric ABC license for adult and pediatric dolutegravir."

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