ViiV Healthcare

Fostemsavir was developed specifically as part of salvage regimens for people with multidrug-resistant HIV, and access to it is particularly important in places where access to drug resistance testing is limited or nonexistent.

The World CAB urges you to make fostemsavir available to people in low-and middle-income countries (LMIC) who have urgent need, at an affordable price. In Brazil, it will cost 6% of the entire budget for antiretrovirals to cover 500 people – an amount which could cover first-line treatment for 40,000 people. ViiV chose to develop fostemsavir, despite the limited market, and reaped revenue of £82 million in 2022; surely it does not believe that the people who desperately need this drug do not deserve to benefit from innovation because of where they live. It is unfair to hold their lives hostage to what you may consider a poor business decision and to offer options, such as compassionate use, for countries where the drug has already been registered.

The World CAB requests that if results from phase IIIB trials determined that there is no need for a lead-in with oral CAB, and that bridging with alternative products is effective, to please adjust your labeling in accordance with this information rapidly. This change will avoid additional delays in, and expenses for registration of generic versions of the long-acting formulation.

The World CAB requests that you also conduct trials of long-acting products for first-line treatment, rather than in people who are already virally suppressed. Today CAB-LA is a “switch” regimen for high-income countries. Introducing it as a first-line treatment will truly allow people to benefit from this innovation. Furthermore, we request that you include countries where you have conducted trials on CAB-LA, and have contributed to its development, such as in Brazil, in VL agreements.

- Make fostemsavir available to all people living with multidrug-resistant HIV in low-and middle-income countries at an affordable price.
- Respond with a plan that will ensure access to affordable fostemsavir.
- Do not place limitations on the number of sublicensees who can produce CAB-LA and other ViiV products.
- Conduct trials of long-acting products for first-line treatment, rather than in people who are virally suppressed.
- Adjust labeling for a lead-in with oral CAB, and note that bridging with alternative products is effective.
- Supply CAB-LA to countries who are seeking to conduct demonstration projects.
- Empowered generics companies to make their own decisions about market sustainability.
- Include countries where you have conducted clinical trials in VL agreements, such as Brazil, which contributed to the development of CAB-LA.

TB Alliance

The World CAB expresses its dissatisfaction with TB Alliance on pretomanid. The belief among members is that there is little transparency and openness in response to key questions related to access to treatment. CAB members did not receive satisfactory answers to important questions regarding the reasons for patenting drugs developed with public funds and the lack of transparency in voluntary licensing agreements.

The World CAB believes that voluntary licensing agreements should be made available to the public. Especially, as a non-profit organization who receives government funding, TB Alliances unwillingness to disclose the terms and conditions of its VLs is unacceptable. TB Alliance's patenting strategy is of particular concern to our members; filing secondary patents and patents on combinations with linezolid and bedaquiline by a non-profit fully funded by donors. We remain highly skeptical to any notion that patents protect drug quality and rational use – this is the domain of regulatory agencies. This has drawn more apprehension among CAB members towards TB Alliance considering its not-for-profit status.

The World CAB is also concerned about the inclusion of linezolid in a trial for people with DS-TB. Although we understand the need for a pan-TB regimen, it should not include drugs with the potential to cause permanent harm to people who have other treatment options.

- Make your voluntary licensing agreements public.
- Stop filing evergreening patents of combinations with linezolid and bedaquiline.
- Stop including linezolid in clinical trials for people with DS-TB.
- Stop asserting that patents and quality are linked.
- Announce the non-enforcement of patents on pretomanid.

MPP/mRNA Hub

The World CAB does not consider that the recent licensing agreements concluded by the Medicines Patent Pool (MPP) meet public health needs or provide quick and affordable access to life-saving treatment. Recent licenses have demonstrated that the practice of limiting suppliers leads to increased prices and delays in product roll-out, thus putting access to treatment at risk. These licenses also contain, what the CAB deems to be, unnecessary and excessive requirements on licensees, such as restrictions on API, use of data, and technology transfer, which contribute to further delays and high prices. For example, the UMICs DTG license, which resulted in slow roll-out in Belarus, and in Malaysia the majority of patients are still not on DTG-based regimens. In addition to being an inadequate solution to access issues, it undermines efforts to use TRIPS flexibilities such as compulsory licenses. We ask the MPP to seek to broaden existing licenses in a transparent and non-restrictive manner.

An area for increased transparency is the inclusion of governments and civil society at all stages of negotiation between the MPP and companies. In particular, for civil society representatives, they must be able to share information with the communities they represent, especially in regard to any aspects that will impede treatment access.

- Make the full license text available, including royalty rates and any other information that pharmaceutical companies might see as commercially sensitive.
- Do not to agree to any language restricting the number of potential suppliers.
- Avoid signing any agreements that contain other limitations that make the roll-out of products more difficult.
- Do not seek "special" UMIC solutions that undermine efforts to use TRIPS flexibilities.
- Include governments and civil society in license negotiations.
- Enumerate redlines for licenses and reject licenses or stop negotiations when licenses do not meet these criteria.
- Ensure timely inclusion of countries when they transition to lower income categories.
- Advocate for the use of additional criteria beyond World Bank classification for inclusion in licenses.