



CARPHA CARIBBEAN REGULATORY SYSTEM

On June 30, the CARPHA/CRS recommended two generic essential medicines for marketing authorization/import permit in CARICOM Member States.

The medicines, used in the treatment of HIV, are Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate [600/200/300mg] tablets (abbreviated EFV/FTC/TDF), and Nevirapine USP 200mg tablets (abbreviated NVP), and are manufactured by Strides Shasun Ltd.

One of the requirements of CARPHA/CRS recommended products is that they have already passed through scrutiny and “approval” by a trusted regulatory entity, such as the US FDA or Health Canada. In these cases, both medicines were reviewed for safety, quality, and efficacy by the World Health Organization, and have received their approval or “prequalification” designation.

The EFV/FTC/TDF medication is known as a triple-fixed dose combination, meaning that three medicines are combined into one daily pill, which improves ease of treatment and adherence for patients. This particular drug is listed as a preferred first-line regimen for adults, pregnant or breastfeeding women, and adolescents, according to the latest WHO guidelines. NVP plays a critical role in alternative regimens as well as in preventing mother-to-child transmission of HIV.

The CARPHA/CRS shares its assessment reports for these products with CARICOM governments to help them make a rapid decision on legal authorization, targeting 60 calendar days for their issuance of marketing authorization/import permit. Adherence to these timelines speeds access to high quality and affordable life-saving medicines for patients.

The CARPHA/CRS has now recommended 9 medicines. For more information, please see: <http://carpha.org/What-We-Do/Laboratory-Services-and-Networks/CRS>