

# CARIBBEAN REGULATORY SYSTEM

## **National Regulatory Authority of Guyana Grants Marketing Authorization for a CARPHA CRS Recommended Medicine**

A CARPHA/CRS recommended medicine was recently granted marketing authorization by the National Regulatory Authority of Guyana, signifying the first time ever a CARICOM Member State has done this in the history of the newly created mechanism. The product, a 1st line triple-fixed dose combination therapy for HIV, manufactured by Mylan, was fast-tracked for marketing authorization through a voluntary agreement between Guyana and CARPHA. The total time from receipt of the application by the CRS to marketing authorization by Guyana was 3 months or 90 calendar days. This is a much-improved timeline over what currently exists in many Caribbean countries, where limited resources hamper regulatory activities, sometimes taking years for products to gain the legal approval needed for access by patients. The CARPHA/CRS recommends only essential medicines that have already been approved by a reference regulatory authority, such as WHO or the US Food and Drug Administration and encourages Member States to grant marketing authorization to these products within 60 calendar days. It is part of a broader effort by partners, including PAHO/WHO, and the Bill and Melinda Gates Foundation, to strengthen regulatory capacity in the region, and improve timely access to strategic and high cost medicines for patients.

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