CARIBBEAN REGULATORY SYSTEM

CRS Verification Review of Biotherapeutic Products: Product Eligibility Criteria

To be eligible for verification review, each product submitted to the CRS for verification should meet the following criteria:

1. **Essential Medicine**: The product is an essential medicine, as per the most recent Model List of Essential Medicines by the World Health Organization ([WHO EML](https://www.who.int/essentialmedicines/listenationalbasket)).
   
   1.1 The active pharmaceutical ingredient and the dosage form must be the same as the listed medicine. 
   *Note: the dose strength may differ from the listed strengths (e.g. 250mg vs 100mg).*

   1.2 Products that are not listed on the WHO EML may be considered for CRS verification based on the public health need. In these instances, the CRS will consult with CARICOM’s Expanded Committee for Pharmaceutical Policy (TECHPHARM), comprised of Member State representatives for approval (see [Caribbean Pharmaceutical Policy](https://www.caribbeanpharma.org/) for TECHPHARM Terms of Reference).

2. **Market Authorization by a National Regulatory Authority of Reference**

   a. The product has valid market authorization from one of the national regulatory authorities (RA) of reference recognized by the CRS for insulins (Table 1a), or for originator and similar biotherapeutic products (Table 1b), and is on the market of the respective country; or

   b. The product has been favourably assessed by WHO and is included in the WHO list of prequalified medicines (WHOPQ).
<table>
<thead>
<tr>
<th>Type</th>
<th>Countries and National Regulatory Authorities of Reference</th>
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| **1a. Insulin BTPs** | Argentina ANMAT  
Australia: Therapeutic Goods Administration  
Brazil: National Health Surveillance Agency (ANVISA)  
Canada: Biologics and Genetic Therapies Directorate (BGTD), Health Canada  
Cuba: Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED),  
Europe: European Medicines Agency (EMA) or Regulatory authorities of the European Union  
Iceland: Icelandic Medicines Agency  
Japan: Pharmaceuticals and Medical Devices Agency, Ministry of Health, Labour and Welfare  
Republic of Korea: Ministry of Food and Drug Safety  
Liechtenstein: Office of Healthcare  
Mexico: Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)  
Norway: Norwegian Medicines Agency  
Switzerland: Swiss Agency for Therapeutic Products, Swissmedic  
United Kingdom: Medicines & Healthcare Products Regulatory Agency, MHRA  
United States of America: US Food and Drug Administration, US FDA |
| **1b. Non-insulin BTPs** | Australia: Therapeutic Goods Administration  
Canada: Canada: Biologics and Genetic Therapies Directorate (BGTD), Health Canada  
Europe: European Medicines Agency (EMA) or Regulatory authorities of the European Union  
Iceland: Icelandic Medicines Agency  
Japan: Pharmaceuticals and Medical Devices Agency, Ministry of Health, Labour and Welfare  
Liechtenstein: Office of Healthcare  
Norway: Norwegian Medicines Agency  
Switzerland: Swiss Agency for Therapeutic Products, Swissmedic |
3. Payment of the **CRS User Fee**

Before a product dossier is accepted for review, the applicant must pay the relevant user fee according to the type of applicant:

- For importers or distributors: $150 USD per product application;
- For market authorization holders / manufacturers: $300 USD per product application.

Note: The CRS User Fee is subject to change upon review.

Payment may be made via:

(i) PayPal via the application form at: https://carpha.org/What-We-Do/CRS/CRS-Application or using email crsregistration@carpha.org, or

(ii) Bank wire transfer to the Caribbean Public Health Agency. Applicants are advised to include a note to identify the product being paid for, and to submit a copy of the transaction receipt to the CRS as evidence of payment. Contact the CRS for wire transfer information.

**Application**

To be considered complete, an application for product review by the CRS should consist of:

- The product dossier (electronic submission), and
- Proof of payment of the User fee, with a note identifying the relevant product.