CRS Verification Review of Biotherapeutic Products: Product Eligibility Criteria

To be eligible for verification review, each product submitted to the CARPHA/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/eml/more)).

   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.pharma-caribbean.org) for TECHPHARM Terms of Reference).

2. **Market Authorization by a Stringent Regulatory Authorities of Reference**

   a. The product has valid market authorization from one of the stringent regulatory authorities (SRA) of reference recognized by the CRS for originator and similar biotherapeutic products (Table 1), 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 1: Stringent Regulatory Authorities of Reference for Biotherapeutic Products

<table>
<thead>
<tr>
<th>Zone</th>
<th>Country: National Regulatory Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional</td>
<td>Canada: Health Canada or Santé Canada&lt;br&gt;United States of America: US Food and Drug Administration, US FDA</td>
</tr>
</tbody>
</table>

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 using email [crsregistration@carpha.org](mailto: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, and
- Proof of payment of the User fee, with a note identifying the relevant product.