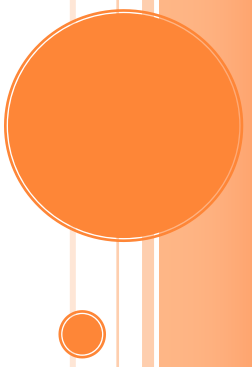
CARIBBEAN REGULATORY SYSTEM

FOCAL POINTS TERMS OF REFERENCE



INTRODUCTION

- The CRS has requested countries/territories to provide officially nominated government focal points to engage with the CRS. The following are terms of reference for focal point responsibilities.

GENERAL

- The CRS will review dossiers of generic essential medicines already approved in PAHO-designated reference authorities, and if favourable, issue a recommendation for registration/marketing authorization in CARICOM countries/territories on its website and through a formal communication to CRS focal points.
    - The recommendation will include a CRS assessment report for the country/territory's information and to help their understanding of the rationale for the recommendation.
    - To further understanding of CRS recommendations, and to provide a forum for asking questions, the recommendation will also be discussed in a monthly teleconference with CRS staff where focal points or designees are invited to participate. This is voluntary for focal points. Each teleconference will include a review of the CRS recommendations made for the month.
- The CRS will also carry out pharmacovigilance and postmarket surveillance on all CRS recommended products. The CRS requires that companies report pharmacovigilance and postmarket issues.

CRS TECHNICAL WORK- REGISTRATION

- CRS focal points are requested to shepherd the CRS recommendation and assessment through the proper government channels to achieve a decision on marketing authorization within 60 calendar days.
    - The country/territory has sovereign authority over this decision and does not have to agree with the CRS. However, the focal point must communicate the decision back to the CRS. If the decision is counter to the CRS recommendation, the rationale of the decision should be communicated to the CRS.
- CRS focal points are requested to act as a liaison to the CRS staff on questions related to technical information on CRS recommended products.
- The CRS will liaise with companies on variations or other issues with products that it recommends, including on variations, and will communicate this information to focal points.

CRS TECHNICAL WORK- PHARMACOVIGILANCE AND POSTMARKET SURVEILLANCE

The CRS will liaise with companies on pharmacovigilance and postmarket surveillance of CRS recommended products and will notify the country/territory of information as appropriate.

- CRS focal points are requested to share relevant pharmacovigilance and postmarket surveillance information with the CRS as appropriate.

CRS COMMUNICATIONS

CRS focal points are requested to serve as a liaison for bi-directional communication and information flow related to CRS activities, including act to further disseminate information to relevant officials in-country/territory as appropriate, and within confidentiality parameters, and share relevant information with the CRS staff on CRS- recommended products.

- Communications could include the confidential sharing of information such as related to the following:
  - CRS assessment report
  - Pharmacovigilance or other postmarket surveillance information

CONFIDENTIALITY

CRS focal points are requested to sign confidentiality agreements with the CRS related to information sharing and facilitate doing this with other officials in the country/territory as appropriate.