Frequently Asked Questions

General

Registration process

Question: Is the registration process only for multi-source or generic drugs?

Answer: Currently, the registration process is only for multi-source/generic priority medicines. This is for a number of reasons, including 1) to increase generic competition and improve access and affordability of medicines in the CARICOM market, and 2) because evaluation of generic medicines is less regulatory complex than review of innovator medicines, and the CARPHA/CRS is taking a step-wise approach to strengthening regulatory capacity in the region. In the future, the CARPHA/CRS may expand to innovator products, but that would require a policy decision by CARICOM's ministerial level body for health, the Council for Human and Social Development (COHSOD). COHSOD has only approved a scope of generic medicines at this time.

Question: How will the CARPHA/CRS share dossier related information?

Answer: If the CARPHA/CRS evaluates a product favorably, it will recommend the product to CARICOM Member and Associate Member States. This will trigger a process where the CARPHA/CRS staff will work with the country's designated CARPHA/CRS focal point(s) to share information, including an assessment report completed by the CARPHA/CRS for that product, as well as any other dossier related information that the national authority requests. It is important to mention that confidentiality will be maintained throughout this process and focal points will be required to sign confidentiality forms.

Question: Is there a prequalification process for bio-similars and innovator products?

Answer: Currently, the CARPHA/CRS does not offer a prequalification or registration process for biosimilars or innovator products (see answer above about scope). However, one benefit of the CARPHA/CRS focus on generic priority medicines is that this can relieve pressure on Ministries of Health/regulatory authorities to evaluate these products, thus freeing up their resources to focus on other high priority regulatory activities.

Question: Is there a CARICOM policy on generic drugs and biosimilars?

Answer: There is no specific policy on generic drugs or biosimilars other than the Caribbean Pharmaceutical Policy which discusses lines of action or strategies that encourage Member State uptake of generic medicines, as both a strategy to improve patient access, and a strategy to reduce health system costs.

Question: Will the CRS website include information on drugs undergoing consideration, drugs registered and bioequivalent drugs (like the Orange and Purple books of the FDA)?

Answer: Yes- CARPHA recently launched a CRS webpage which will include public information about recommended products, much like WHO's prequalification program webpage.

PRIORITY MEDICINES

Question: Can you provide further information on the priority drug listing e.g. the mechanism and criteria for adding or deleting drugs by member states.

Answer: Currently, CARPHA/CRS priority medicines include all generic medicines on WHO's Essential Medicines List or PAHO's Strategic Fund. Ministries of Health or their national procurers can also suggest medicines to prioritize, such as those where there are cost, quality, availability, or other regulatory issues. CARICOM's Technical Advisory Group on Pharmaceutical Policy (TECHPHARM) approves additional medicines to add to the priority list. Countries are periodically surveyed for priority medicines and the first priority list was developed and approved by TECHPHARM in 2015 containing 10 medicines, mostly those treating non-communicable diseases.

USER FEES

Question: Can you elaborate on the system of user fees? Has the CARPHA/CRS agreed on a schedule of fees and/or financial arrangements a country will be asked to provide?

Answer: The user fee system will apply to companies submitting dossiers. This is a common practice for generating resources and sustainability for regulatory work and many regulatory systems around the world charge user fees to companies. CARPHA is currently working to develop a user fee system for CRS sustainability, but it has not been implemented yet. There will be a grace-period to companies who submit dossiers to the CARPHA/CRS in its early stages. The intention is for the national authority to be able to charge its own user fees (separate from what the CRS charges) during the 60-calendar day period when the country has received the CARPHA/CRS recommendation and is determining whether to issue a marketing authorization. It is possible that in the future, all fees could be combined up-front, with reimbursement to Member States as appropriate thereafter- but this would need more discussion and further fleshing out with Member States.

PHARMACOVIGILANCE/POSTMARKET SURVEILLANCE

Question: Will the CARPHA/CRS have a role / process for the recall of drugs?

Answer: The CARPHA/CRS will conduct pharmacovigilance/postmarket surveillance on all recommended products in concert with the CARPHA Drug Testing Lab and will require that companies submit compliance or other adverse event related information on these products. If product failures emerge, CARPHA will disseminate this information and a corresponding recommendation to CARPHA/CRS national focal points to take appropriate action based on their sovereign authority and national laws.

For Governments and CRS Focal Points

Question: Will there be training of the CRS Focal Points on dossier evaluation?

Answer: Yes- one of the planned short to medium-term activities is to invite representatives from CARICOM Member State Ministries of Health and/or National Regulatory Authorities to joint sessions where reference authorities and PAHO/WHO experts will review dossiers. These sessions will occur periodically as dossiers are submitted. In the medium term, it may also be possible to host Member State pharmaceutical/regulatory staff at CARPHA to partake in reviews of dossiers.

FOR INDUSTRY

Question: Can I submit the dossier and/or packaging/labelling in another language besides English?

Answer: No, at this time, all dossier/packaging/labelling materials must be submitted in English.

Question: What climate zone do I need to submit stability data for? And if this differs from the Reference Authority zone, what do I do?

Answer: WHO's prequalification program has guidance on this (http://apps.who.int/prequal/info_general/documents/guidelines/Storage_June2015.pdf) and the CRS follows this approach. Generally, zone IVb stability data (data generated at 30□2□C/75□ 5%RH) on the primary or production batches of the product in the same packaging as approved for marketing of the finished product in the Reference Authority (RA) country, should be provided.

If these zone IVb data are not available at the time of submission, applicants should initiate as soon as possible long-term stability testing at these conditions in the same packaging as approved by the RA. When complete, the full long term data (at minimum 12 months) should be submitted to the CRS team. Questions regarding this matter can be directed to CRSregistration@CARPHA.org

Question: What happens if my product is recommended by the CRS?

Answer: A positive CRS review is posted on the CARPHA/CRS website, and triggers a process whereby the CRS notifies CARICOM Member States and Associate Member States, as well as regional and national procurers, of the recommendation. Pertinent dossier information, such as the assessment report compiled by the CRS, is then shared with focal points in each of these entities, and the clock begins to tick for sovereign countries to turn the recommendation into a marketing authorization. The goal is 90 calendar days.