WHO Prequalification of Vector Control Products

Use of third-party agents for communication and interaction with WHO PQT/VCP

Background

The World Health Organization (WHO) Prequalification of Vector Control Products (PQT/VCP) allows manufacturers to rely on third-party agents to represent the manufacturer in relation to activities and interactions with PQT/VCP, such as submission of applications. Sections 5.3.1 and 5.3.2 of the Overview of the WHO prequalification assessment of vector control products describe the definitions and requirements.

5.3.1 Legal manufacturer

Applications for WHO prequalification of vector control products (VCPs) are accepted only from the legal manufacturer of the products. The legal manufacturer of the VCP is the entity which is entirely responsible for the manufacturing of the submitted VCP. Legal manufacturers are required to ensure that all product dossier information on file with WHO is current and correct, including authorized points of contact. The legal manufacturer is ultimately responsible for ensuring that the prequalified product is manufactured in accordance with the information provided to WHO to support the prequalification assessment. This responsibility extends beyond the manufacturing of the product in facilities owned by the legal manufacturer and includes all contractual or toll manufacturing facilities. Legal manufacturers are also required to submit and maintain current information on the rebranding or supplemental distribution of their products to WHO.

5.3.2 Use of authorized agents

Legal manufacturers of VCPs may rely on an authorized agent(s) to submit applications for prequalification to WHO and/or communicate with WHO on their behalf. The legal manufacturer must provide a Letter of Authorization identifying the authorized person(s) with whom WHO may communicate and the specific product(s) or application(s) to which the authorization applies.

Purpose

The purpose of this document is to provide additional clarification on the use of third-party agents (hereafter agents) and to highlight the need for inclusion of legal manufacturer representatives on all communication.

Identified need for additional guidance

PQT/VCP has identified several situations where:

- the defined relationship between the legal manufacturer and the agent(s) is unclear;
- the scope of the delegated authority of the agent(s) granted by the legal manufacturer is limited to specific meetings, activities and/or technical areas, while it seems that communication with WHO from the third-party agent goes beyond the scope of the delegated authority;
- agent(s) may be authorized to represent multiple legal manufacturers concurrently; and/or
- it is unclear if the agent is communicating on behalf of the legal manufacturer or in its own name.

These situations can cause a significant resource burden to WHO where additional time and effort must be spent ensuring that appropriate authority has been granted regarding the specific activities or topics on which the agent(s) may be engaging.

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https://extranet.who.int/prequal/vector-control-products

Advice

To ensure that written and meeting engagements with legal manufacturers and their agents are handled in accordance with the procedures for the WHO prequalification assessment of VCPs, the following should be adopted by the responsible individuals and organizations.

- In all written communication with PQT/VCP, agents are required to:
  - identify the legal manufacturer on whose behalf they are communicating with WHO;
  - include the appropriate point of contact of the legal manufacturer in copy;
  - attach a copy of the proxy pursuant to which the agent has been granted delegated authority to represent the legal manufacturer.
- For all meetings, in-person and virtual, it is preferred that when agents may be leading the meeting on behalf of the legal manufacturer, that participation include direct representation of the legal manufacturer as well unless WHO has received written evidence (such as a proxy) that the agent(s) has received delegated authority to represent the legal manufacturer at a particular meeting. If participation of the legal manufacturer is not possible, such written evidence or proxy should be sent to WHO in good time to allow WHO enough time to review the scope of the proxy received.

This advice does not limit nor prohibit the availability of PQT/VCP to provide general guidance regarding the policies and procedures of WHO to any individual who may wish to understand more about the WHO evaluation of VCPs.

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