Vector Control Products

Converting from WHOPES Recommendation to Prequalification Listing

Background

As of 1 January, 2017 the WHO evaluation of vector control products has been transitioned from WHOPES to the Prequalification team /unit in RHT /EMP.

Among other activities required to be undertaken to ensure a smooth transfer of this function, one of the most important components includes the conversion of products with an existing WHOPES recommendation to the prequalification listing.

The approach to the conversion process is to convert, where appropriate, all WHOPES recommended products to a PQ listing. This approach will:

- Ensure an accurate and current list of prequalified vector control products. Since manufacturers are responsible to submit a conversion application and request conversion, this will provide a database of products which are available and being manufactured.
- Provide a baseline of information on the safety, efficacy and quality of converted products to inform future activities to be undertaken to ensure that these products are supported by a modern database of evidence and a lifecycle approach is put in place. Only products which are supported by a relevant WHOPES decision document / report and current specifications established through the WHO/FAO JMPS will be prequalified. The submitted labelling will also provide information on the use of the products and the product claims.
- Link products claiming equivalence to an innovator product to an appropriate and relevant database of evidence. Products claiming equivalence will not be prequalified until the reference (generator and owner of the data) has been prequalified. Manufacturers of equivalent products will only be permitted to claim equivalence to one reference product.

This approach was adopted to ensure that the transition from WHOPES to PQ would not disrupt the marketplace and hinder access to these vital products and also to ensure a fair and consistent transition for all manufacturers. If PQ has access to any information that would indicate that any of these products are not safe, efficacious or of high quality, the conversion will not be implemented until an evaluation of the information is undertaken and the product deemed suitable for conversion. During the course of the review of the application documentation and labelling, any issues of interest will be noted and considered at a later date as part of a post market approach.

The detailed process for conversion is described in the Conversion Decision Tree Documents, Appendices 1 and 2.
Appendix 1

Conversion Decision Tree

Requirements for Conversion:
- Supporting WHOPES recommendation
- Supporting WHO Specification
- Supporting Policy Recommendation

Tier 1

<table>
<thead>
<tr>
<th>Preparation of Application for Conversion</th>
<th>Screening for completeness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitting all required information or commitment to submit provided</td>
<td>All required information received or commitment to submit provided</td>
</tr>
<tr>
<td>Contact applicant to address gaps in submission</td>
<td>Contact manufacturer to request information and/or clarification</td>
</tr>
</tbody>
</table>

Tier 2

Apply Tier 2 Criteria:
- Focus on safety, efficacy and quality
- Is the product currently on the market/in use?
- Is the product registered in another jurisdiction?
- Are the AI/formulation known and data publically available?
- What would be the impact if the product were not converted?
- Have there been reports of product failure, complaints, is it under re-evaluation/investigation by NRAs?

Prepare conversion package and develop plan with applicant to fulfill missing requirements

Data/policy to support conversion of the product?

Prepare package confirming no conversion to prequalification and work with applicant and procurement agencies to implement this decision. Remove from WHOPES list.

Convert

Inform Applicant

Publish on Website

Product Not Converted and removed from WHOPES list
Appendix 2

Conversion Decision Tree – Products Claiming Equivalence

Requirements for Conversion:
- Prequalified Reference Product
- Supporting WHO Specification

Tier 1

1. Submission of Application for Conversion for product claiming equivalence

   Screening for completeness

   All required information received or commitment to submit provided, including identification of single reference product

   Contact applicant to address gaps in submission

   Yes

   Review of application and available information

   Yes

   Prequalified

   Eligible for conversion?

   Yes

   Prepare conversion package:
   - Conversion Cover Sheet
   - Letter of Prequalification
   - Statement of Conversion
   - Application Form
   - Label
   - Draft webpage

   Sign Off Procedure

   Inform Applicant

   Publish on Website

   No

   Applicant submits supporting information

   ASVCP Review

   Conversion Withdrawal – Submit as new product

   No

   Applicant may submit an application as a new product

   Inform Applicant of no conversion

   Wait for decision on reference product

   Status of reference product

   Prequalified

   Not submitted for Conversion

   Inform Applicant – Request Applicant to submit supporting information to be considered as non-equivalent (stand-alone)

   Not submitted for Conversion

   Pending

   Wait for decision on reference product

   Inform Applicant – Request Applicant to submit supporting information to be considered as non-equivalent (stand-alone)