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.

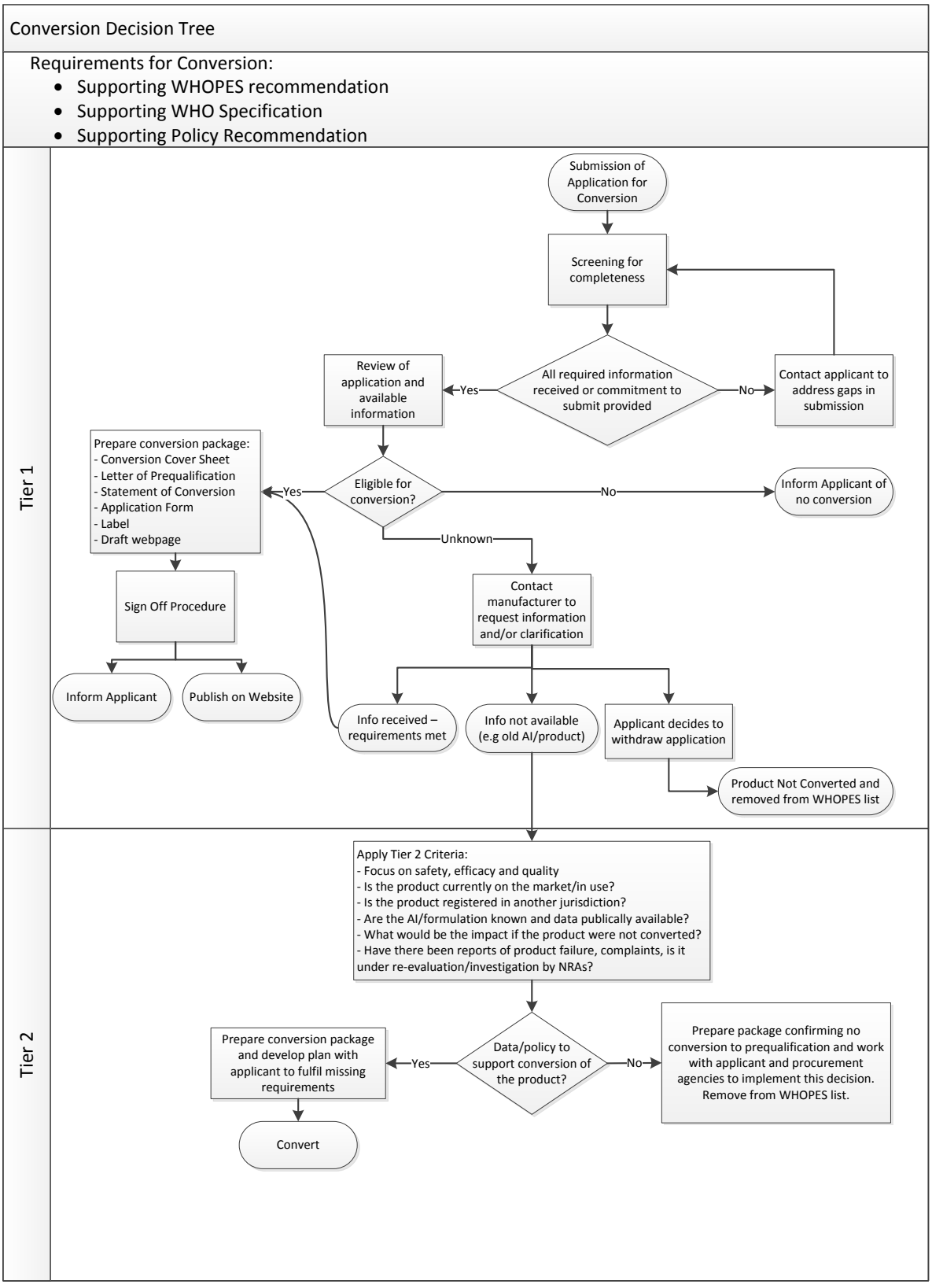
The approach to the conversion process is to convert, where appropriate, all WHOPES recommended products to a PQ listing. This approach will:

- 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.

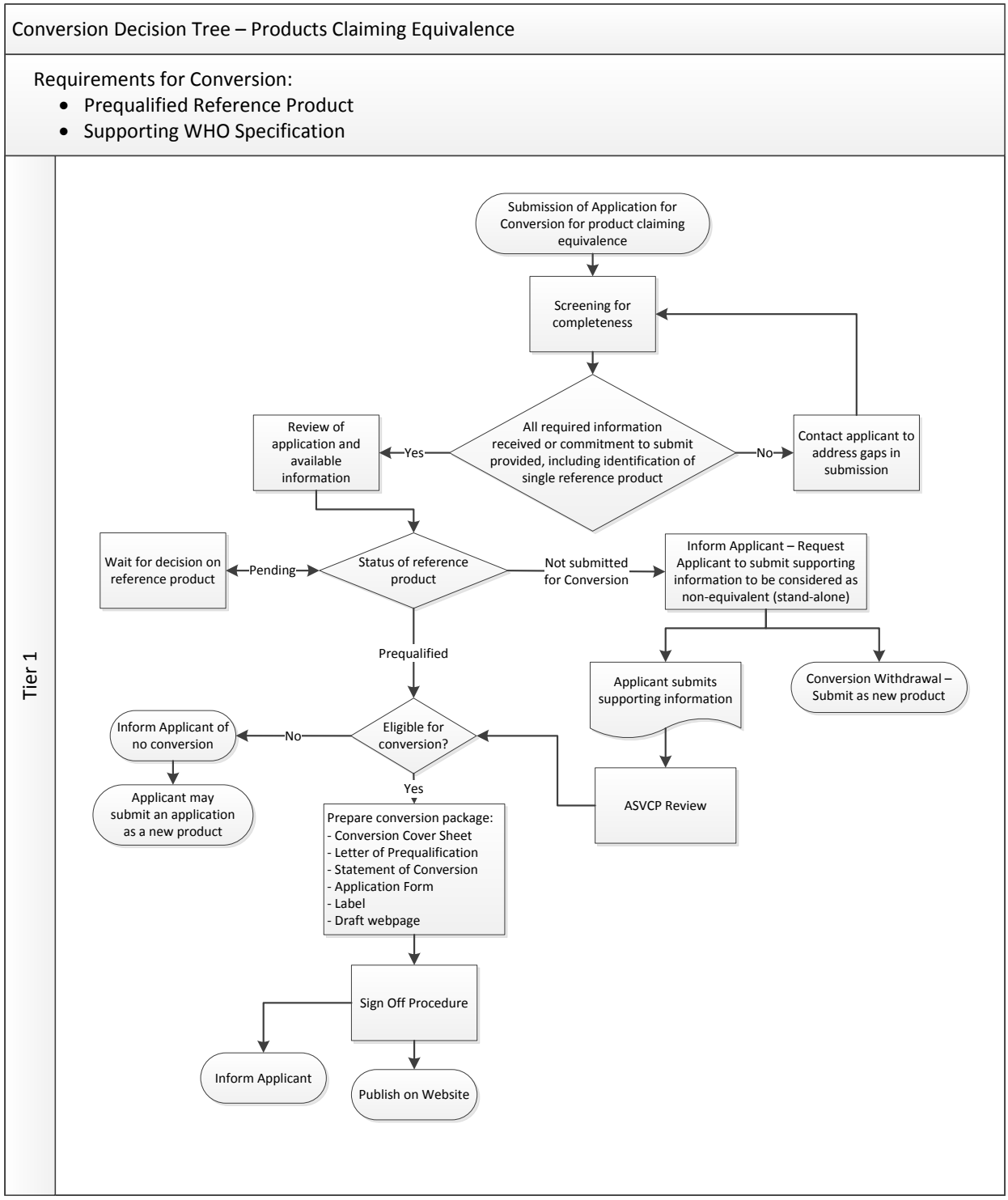
  This approach was adopted to ensure that the transition from WHOPES to PQ would not disrupt the marketplace and hinder access to these vital products and also to ensure a fair and consistent transition for all manufacturers. If PQ has access to any information that would indicate that any of these products 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
Submission of Application for Conversion
Screening for completeness
All required information received or commitment to submit provided
Yes
No
Contact applicant to address gaps in submission
Review of application and available information
Eligible for conversion?
Yes
No
Inform Applicant of no conversion
Unknown
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
Contact manufacturer to request information and/or clarification
Info received – requirements met
Info not available (e.g old AI/product)
Applicant decides to withdraw application
Product Not Converted and removed from WHOPES list
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?
Data/policy to support conversion of the product?
Yes
No
Prepare conversion package and develop plan with applicant to fulfil missing requirements
Convert
Prepare package confirming no conversion to prequalification and work with applicant and procurement agencies to implement this decision. Remove from WHOPES list.

Appendix 2


Conversion Decision Tree – Products Claiming Equivalence
Requirements for Conversion:
Prequalified Reference Product
Supporting WHO Specification
Tier 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
Yes
No
Review of application and available information
Contact applicant to address gaps in submission
Status of reference product
Pending
Wait for decision on reference product
Not submitted for Conversion
Inform Applicant – Request Applicant to submit supporting information to be considered as non-equivalent (stand-alone)
Prequalified
Applicant submits supporting information
Conversion Withdrawal – Submit as new product
Eligible for conversion?
No
Inform Applicant of no conversion
Applicant may submit an application as a new product
Yes
ASVCP Review
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