Summary of Service Codes

Service Code	Name	Target Review Time
PQ100	Request For Determination of Pathway	2 months
PQ200	Protocol Review	3 months
PQ300	New Product	12 months
PQ301	New Equivalent Product	12 months
PQ400	New Specification for Source Material (TC/TK or other)	12 months*
PQ401	Extension of Existing Specification for Source Material (TC/TK or other)	12 months*
PQ500	PPQC: Major	7 months*
PQ501	PPQC: Minor	3 months
PQ510	Change to Specification/Production of Source Material (TC/TK or other)	12 months*

* For those actions which include JMPS review, established submission/review schedules should be followed. As such, the target review time may vary.

PQ100 – Request for Determination of Pathway (RDP)

Description – All new vector control products in development for which the manufacture is interested submitting to WHO for evaluation should submit a request for determination of pathway.

Contents – RDP Form, Cover Letter, and label (if available)

Timeline – 2 months

Purpose:

- Inform applicants of data requirements and relevant WHO review processes
- Determine eligibility for PQ decision making

Considerations

- If a new product application is submitted without having first submitted an RDP, or if there are significant differences between the submitted product and a previously submitted RDP, the determination of pathway process will be completed based on the submission.
- The determination of pathway is based on the product type/use, active ingredient/mode of action, target vector, disease intended to be impacted. The determination is made by the relevant disease program
- One RDP may result in multiple responses depending on varying use/vector/disease combinations
- RDP(s) may be necessary for expanded uses and/or target vectors

Pre-submission Request

PQ200 – Protocol Review

Description - Prior to submitting an application for a new product or change to a listed product, the applicant may submit protocol(s) for review by PQT-VC. PQT-VC does not approve protocol but can provide comments to be considered by the study sponsor/investigator.

Contents –Cover Letter (including list of documents provided), Proposed Protocol(s)

Timeline – 3 months

Considerations:

- The submission of protocol for which studies have already been initiated/completed is not a good use of time/resources
- Protocol designed to investigate public health outcomes through clinical trials are within the purview of VCAG. However, PQT-VC may be requested to review methodologies to investigate entomological outcome within such trials.

Submissions for Prequalification

PQ300 – New Product

Description - This service code is for new products submitted for prequalification.

Contents – Modules 1-6

Timeline – 12 months

Considerations:

- See slides on Modules
- This service code is also applicable for products which are progressing through VCAG. A PQ300 submission can be made at any time; however, a prequalification decision may be dependent on the outcome of the policy recommendation development process for GMP and/or NTD.

PQ301 – New Product claiming Equivalence

Description - This service code is for new products submitted for prequalification which claim equivalence to another prequalified product.

Contents – Modules 1-3, 5, 6

Timeline – 12 months

Considerations:

- The PQT-VC policy for validation of a claim of equivalency is under review

Submissions for Specifications

PQ400 – New Specification for Source Material (TC/TK or other)

Description – This service code is to support the establishment of WHO specifications for source materials of active ingredients or synergists to be used for the formulation of vector control products.

Contents – See FAO/WHO Manual for the development of pesticide specifications, Declaration of Manufacturing Sites

Timeline – 12 months

Considerations:

- The source materials (TC/TK and others) of active ingredients and synergists used for formulating prequalified vector control products must be supported by an evaluation report confirming adherence to established WHO specifications.
- In some cases, the source material may be a formulation (ex. SC). In this case, the source must be supported by a evaluation report and the applicant must provide verification that the preceding TC/TK is also supported by an evaluation report.

PQ401 – Extension of Existing Specification for Source Material (TC/TK or other)

Description - This service code is for the submission of applications requesting assessment of the production of source materials of active ingredients or synergists to be used for the formulation of vector control products to demonstrate accordance with existing WHO specifications.

Contents – See FAO/WHO Manual for the development of pesticide specifications, Declaration of Manufacturing Sites

Timeline – 12 months

Considerations:

- In the event that a reference specification changes, manufacturers may be required to submit additional information for the continued extension of the specification

Change Submissions – PQ Products and/or Specifications

PQ500 – PPQC: Major

Description - An applicant may submit a variation application to amend a prequalified product or active ingredient manufacturing site. This service code is for any change request which requires the review of data.

Contents – Module 1, Modules 2-6 as needed depending on change

Timeline – 7 months*

PQ501 – PPQC: Minor

Description - An applicant may submit a change application to amend a prequalified product or active ingredient manufacturing site. This service code is for any change request which does not require the review of data.

Contents – Module 1, Modules 2-6 as needed depending on change

Timeline – 3 months

PQ510 – Change to Specification/Production of Source Material (TC/TK or other)

Description - An applicant may submit a change application to amend a specification or evaluation report supporting a WHO evaluated source materials (TC/TK or other).

Contents - See FAO/WHO Manual for the development of pesticide specifications, Declaration of Manufacturing Sites

Timeline – 12 Months*