WHO Prequalification of Vector Control Products

# Data requirements table – Module 1

| DR code | Requirement | Description/notes | Method[1]/reference | Form/template |
|---|---|---|---|---|
| 1.0 | Module 1 index | Identification of supporting information included within Module 1 to address the data requirements. | | • Template Module 1 index |
| 1.1 | Cover letter | Ensure that the "request" is clearly stated by referencing the proposed Service Code. | | |
| 1.2 | Application form | Ensure that the application form is complete and signed. | PQT/VCP product application form<br>PQT/VCP post-PQ change application form | |
| 1.3 | Authorized contacts | Identification of those persons who are authorized by the legal manufacturer to communicate with WHO in relation to the application. | | |
| 1.4 | Table of contents | Ensure that the file names in the dossier match the titles provided in the table of contents.<br>The table of contents should be a living document. If additional information is provided or documents revised, an updated table of contents should be provided for the particular action. | PQT/VCP dossier table of contents | |

[1] Methods identified should be used for the generation of data. Additional and/or alternative methods may be proposed by applicants provided that complete description of the method and validation is included.

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|---|---|---|---|---|
| 1.5 | Declaration of labelling (DoL) | The DoL is the responsibility of the applicant. It is intended to provide information to support the assessment of the product quality, safety and efficacy, for those uses relevant to WHO. The DoL may not be a comprehensive product label. The product may be authorized for additional or different uses by National Regulatory Authorities (NRAs). The product label authorised by an NRA may therefore differ from the DoL based on the country or regional labelling requirements.<br>The DoL submitted in association with the product will be published as part of the prequalification listing. | Guidance on declaration of labelling<br>Example DoL for ITN | |
| 1.6 | Other related information | To be proposed by applicant as necessary. | | |