

WHO Prequalification of Vector Control Products

Overview of the WHO Prequalification Assessment of Vector Control Products



World Health
Organization

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1. Abbreviations

CIP	Cataloguing-in-Publication
CRO	Contract Research Organization
DoL	Declaration of Labelling
GLP	Good Laboratory Practices
ISO	International Organization for Standardization
IVM	Integrated Vector Management
LoA	Letter of Agreement
NRA	National Regulatory Authority
PCC	Pre-Submission Coordination Committee
PQT/VCP	Vector Control Product Assessment Team in the Prequalification Unit
PPQC	Post-Prequalification Change
SOP	Standard Operating Procedure
UN	United Nations
VCAG	Vector Control Advisory Group
VCP	Vector Control Product
WHO	World Health Organization

2. Introduction

The World Health Organization (WHO) prequalification assessment process for vector control products (VCPs) is coordinated through the Regulation and Prequalification Department in the Access to Medicines and Health Products Division. These procedures are carried out by the Vector Control Product Assessment Team in the Prequalification Unit (PQT/VCP).

WHO prequalification does not imply any approval by WHO of the product and manufacturing site(s). Moreover, prequalification does not constitute any endorsement or warranty by WHO of the fitness of any product for a particular purpose, including its safety, quality or performance.

WHO prequalification of VCPs is a comprehensive assessment of individual VCPs through a standardized procedure aimed at determining whether the product meets WHO prequalification requirements.

The prequalification assessment process includes:

- review of submitted product dossiers; and
- inspection of manufacturing sites.

Products submitted for prequalification assessment that meet, as determined by WHO, the WHO prequalification requirements are included in the WHO list of prequalified VCPs. The duration of the validity of the prequalification status of a product is dependent on the manufacturer's fulfilment, within the applicable deadlines, of its post-prequalification obligations and requirements, including:

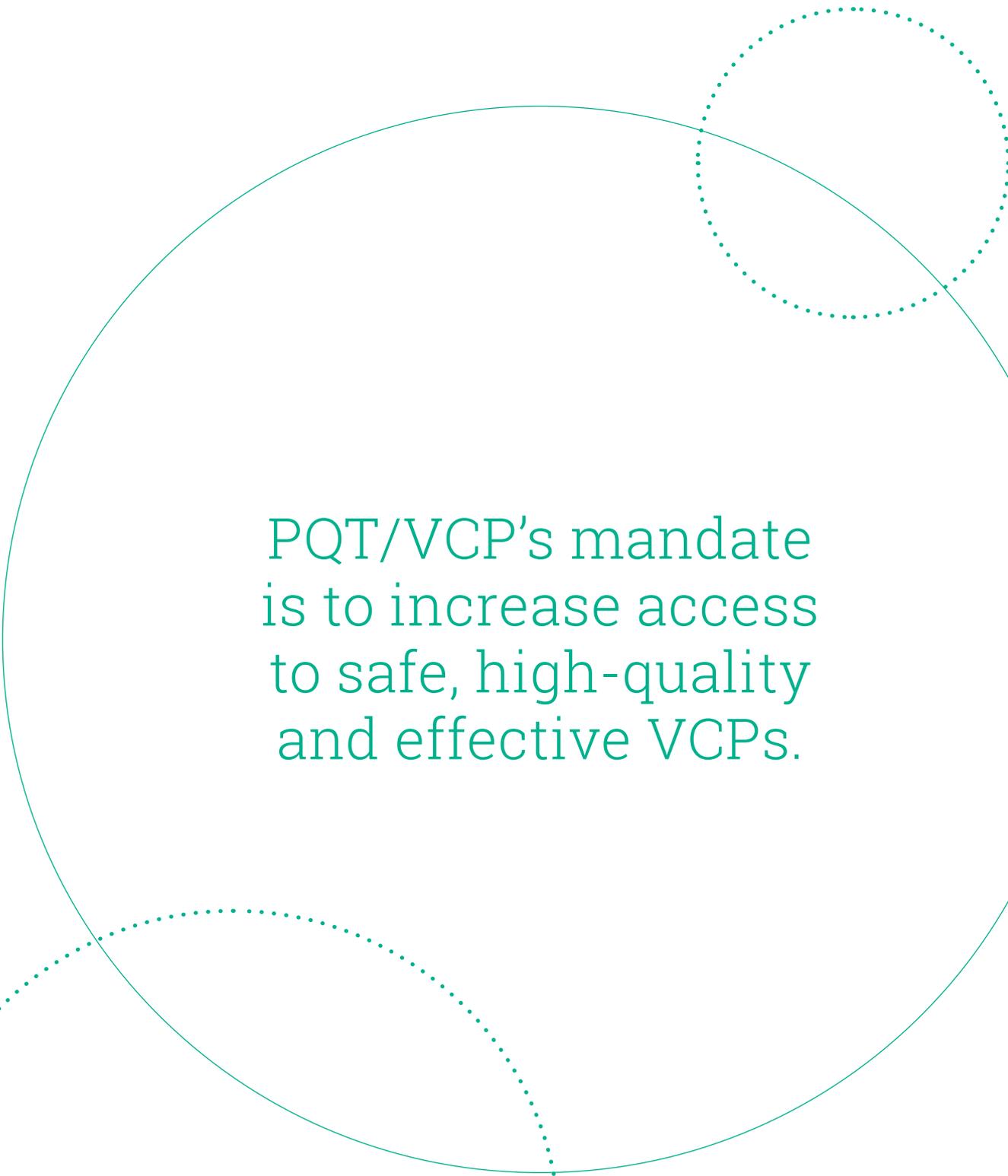
- fulfilling prequalification commitments;
- reporting of changes;
- post-market surveillance obligations;
- receiving inspections/re-inspections; and
- continued compliance with established WHO specifications.

The findings of WHO prequalification are based on the assessment of the safety, quality and efficacy of VCPs for the purpose of providing guidance to interested United Nations (UN) agencies and WHO Member States in their procurement decisions.

Once a product has been prequalified, it is included in the WHO list of prequalified VCPs and becomes eligible to participate in the procurement processes of UN agencies. WHO Member States are encouraged to use the WHO list of prequalified VCPs for their respective procurement decisions. Nevertheless, UN agencies and WHO Member States using information from the WHO prequalification of VCPs process should not exclusively rely on WHO prequalification assessment and should make their own assessment before purchasing products included in the WHO list, including but not limited to steps such as ensuring the supplier's financing stability and standing, the ability to supply the required quantities of the product, security of the supply chain, quality control testing and other relevant aspects.

3. Intended audience

This document has been developed to provide manufacturers with an overview of the WHO prequalification assessment process for VCPs. Manufacturers wishing to apply for WHO prequalification of their product(s) should read this document before applying so that they can be aware of and prepared for all aspects of the prequalification assessment process.



PQT/VCP's mandate is to increase access to safe, high-quality and effective VCPs.

4. Vector control products

The primary purpose of a VCP is to control pests (e.g. insects, molluscs, rodents, etc.) which transmit diseases to humans either directly or indirectly. VCPs may include formulated chemical pesticide products (natural or synthetic), physical devices, microbials and genetically modified organisms used in the control of pests that cause vector-borne diseases. These tools, which provide effective management/control of vectors, may be used as part of a resistance management programme. VCPs for use in public health are a component of an integrated vector management (IVM) programme. IVM relies on a suite of diverse interventions and implementation of best practices to manage the vector and chemical/behavioural resistance.

Vector control interventions contribute substantially to controlling and eliminating vector-borne diseases. The 2019 World Malaria Report shows the number of countries with fewer than 100 indigenous malaria cases at 27 countries in 2018, from 17 countries in 2010, with malaria deaths reducing by about 140 000 worldwide in that same time period. Recent studies indicate that 69% of cases averted were due to the use of insecticide-treated bednets, and a further 10% due to indoor spraying of insecticides. The use of VCPs is also critical in the prevention of the transmission of other vector-borne diseases.

Major vector-borne diseases

- Chagas disease
- Chikungunya
- Dengue
- Human African trypanosomiasis
- Leishmaniasis
- Lymphatic filariasis
- Malaria
- Onchocerciasis
- Schistosomiasis
- Zika

5. Prequalification of vector control products

WHO prequalification of VCPs primarily benefits populations most affected by vector-borne diseases by facilitating access to these prevention-focused tools. The vector-borne diseases include malaria and neglected tropical diseases such as dengue, chikungunya, Zika, Chagas disease, lymphatic filariasis, leishmaniasis, human African trypanosomiasis, onchocerciasis and schistosomiasis.

The Global Malaria Programme and the Department for Control of Neglected Tropical Diseases are responsible for the establishment of WHO recommendations for product classes in relation to priority vector-borne diseases and do this on the advice of the Vector Control Advisory Group (VCAG). The WHO recommendations are developed through the Guidelines Development Group. Only when a WHO recommendation is in place can a decision for product prequalification be implemented. (For more information, refer to the [Vector Control Product Norms and Standards Document](#), December 2020).

The decision to prequalify a product consists of two components: determination of public health values and the prequalification process.

Determination of public health value is evaluated in cases where a WHO recommendation has not been established. It is supported by the VCAG. A product or product class has public health value if it has proven protective efficacy to reduce or prevent infection and/or disease in humans. The VCAG can assist applicants in the development and evaluation of product data to determine public health value.

Figure 1. WHO evaluation of VCPs

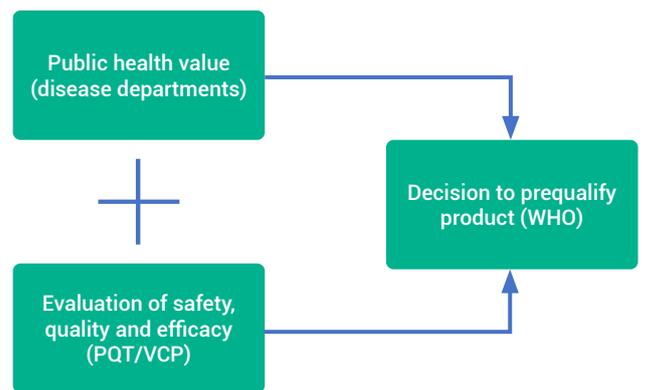
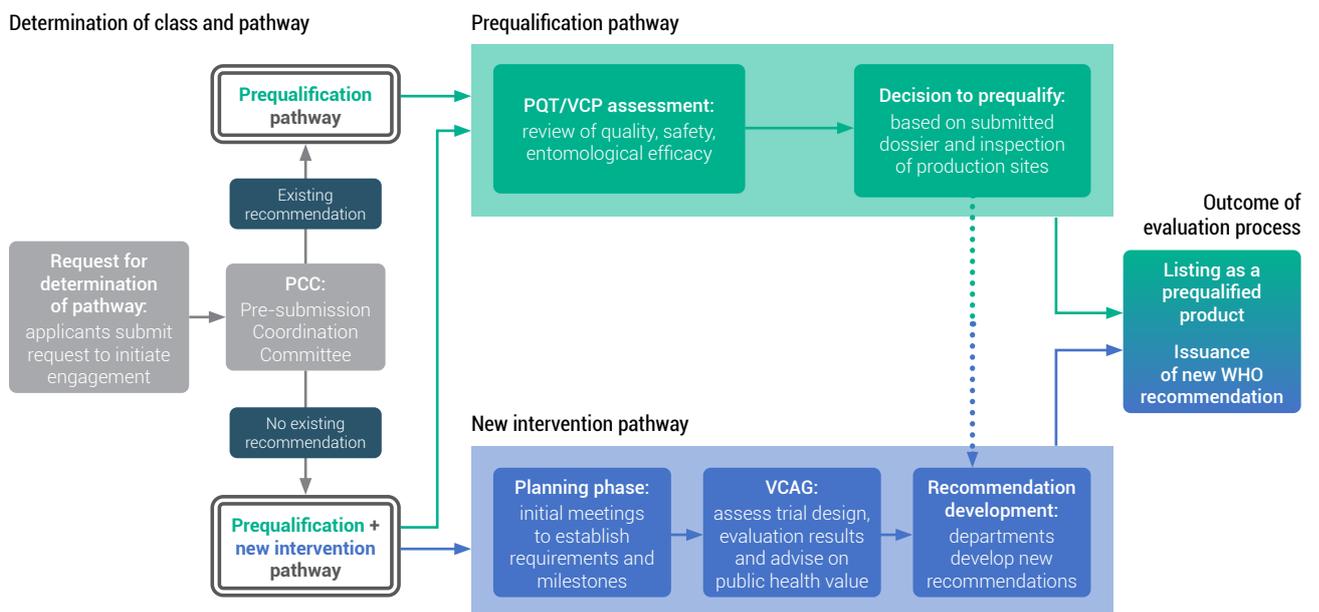


Figure 2. Pathway to prequalification



5.1. Mandate

The mandate of WHO prequalification of VCPs is to increase access to safe, high quality, effective VCPs.

5.2. Purpose

The purpose of PQT/VCP is to:

- prequalify VCPs that are safe, effective and manufactured to a high quality, and publish a list of these prequalified products;
- provide guidance to interested UN agencies and WHO Member States in their procurement decisions;
- ensure prequalification validity of products throughout their life cycle; and
- contribute to building assessment capacity of Member State national regulatory authorities:
 - training of assessors from Member States through the actual WHO assessments;
 - harmonizing quality and regulatory systems; and
 - supporting collaborative registrations.

5.3. Applicants and their obligations

6.3.1. Legal manufacturer

Application for WHO prequalification of 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 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.

5.4. Eligibility for participation in the WHO prequalification assessment process

All products intended for use in vector control are eligible for submission and there are no restrictions on the timing of submissions. Each proposed product must undergo Determination of Pathway and apply for Prequalification or New Intervention + Prequalification assessment according to current WHO policies and procedures and the decision of the PCC.

The WHO prequalification process consists of:

- Applicant submits a Request for Determination of Pathway.
- Pre-submission Coordination Committee (PCC) reviews the application, determines the appropriate pathway for the proposed product and informs the applicant.
- Once the pathway is determined, the applicant develops and submits a product dossier which includes data and information to support the safety, efficacy and quality requirements appropriate to the product type and generated according to good laboratory practices (GLP) and appropriate quality management system.
- Submission is screened for completeness. Only complete applications are accepted for assessment.
- Once an application is determined to be complete, two parallel activities will commence:
 - assessment of the application by experts as part of the Assessment Session for Vector Control Products and Joint Meeting for Pesticide Specifications (as needed); and
 - inspection of the manufacturing facilities to ensure compliance with WHO-recommended quality standards.

Once WHO confirms that the prequalification assessment process is complete for the relevant product, that the product meets WHO prequalification requirements, and that the product aligns with the existing WHO recommendation based on the potential public health value, the product, as manufactured at the declared manufacturing site(s), will be included in the WHO list of prequalified VCPs.

6. Dossier development and pre-submission activities

WHO requires that product dossiers be developed using the following established module-based approach. The modules are defined as follows:

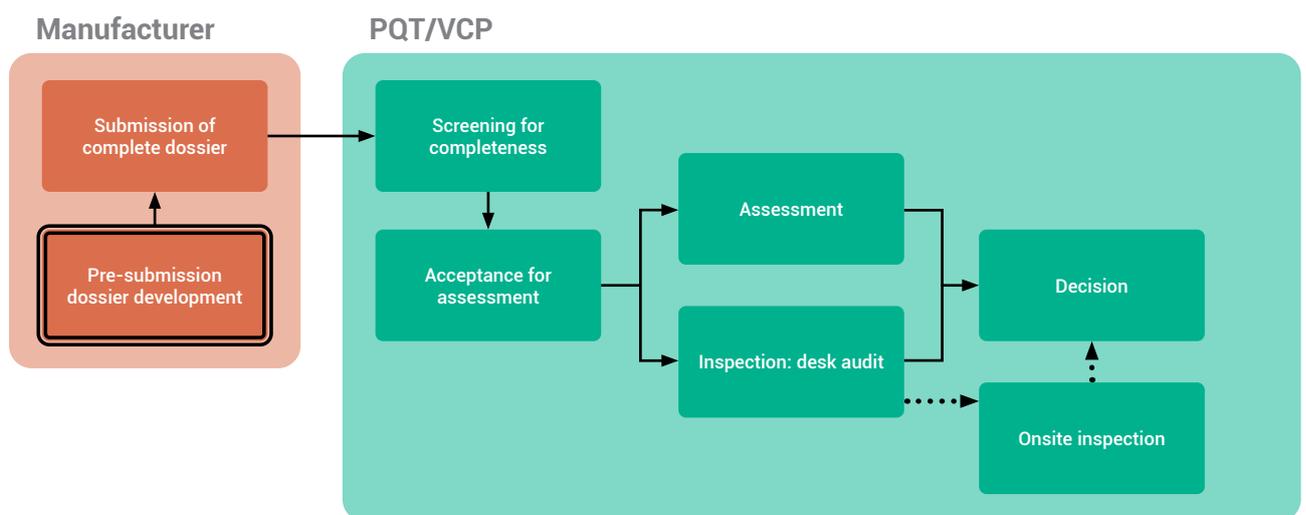
- **Module 1:** Administrative information and labelling
- **Module 2:** Discipline summaries
- **Module 3:** Quality dossier
- **Module 4:** Safety dossier
- **Module 5:** Efficacy dossier
- **Module 6:** Inspection dossier.

Further information on the modules and specific dossier requirements are available on [PQT/VCP website](#).

Manufacturers interested in the prequalification of a VCP are invited to contact WHO PQT/VCP prior to the submission of their application. PQT/VCP offers pre-submission meetings to ensure clarity and understanding of the prequalification process and data requirements, either generally or within the context of a particular proposed product.

Additionally, manufacturers may voluntarily submit testing protocol(s) intended to be employed in the generation of supporting product information. PQT/VCP will review the proposed protocol(s) and provide advice to be considered by the manufacturer. Note: PQT/VCP does not approve testing protocols. The manufacturer may choose to incorporate the provided feedback, if appropriate. The review of testing protocol(s) and considerations provided do not have any impact on the review of the data/information generated using the reviewed protocol. The review of submitted protocol(s) does not guarantee, nor have any bearing on the acceptability of any generated data/study reports, nor the assessment of the product.

Figure 3. Prequalification process for manufacturers



7. Applying for WHO prequalification

To ensure that WHO can prequalify VCPs as efficiently as possible, manufacturers should be fully prepared for the prequalification assessment process when they apply for WHO prequalification. Applications should be submitted to WHO in a manner to ensure the security of the submission.

Only complete applications will be accepted for prequalification assessment. Once the product dossier has been received by WHO, it will be screened for completeness by WHO staff before being reviewed. This screening is aimed at ensuring that all requisite sections of the product dossier have been submitted; it does not take into consideration the technical appropriateness of all the information provided in the product dossier. If the application is incomplete, the manufacturer may be informed in writing that an incomplete application has been received and be requested to provide the necessary information to complete the dossier. Alternatively, in cases where deficiencies in the product dossier are found to be of critical nature, WHO may issue a Screening Failure Letter, effectively cancelling the review of the submission. If a Screening Failure Letter is issued, the applicant may resubmit the application at a later time once the identified deficiencies have been addressed. The new application will be considered without prejudice.

If an application is found to be complete, the application will be accepted for prequalification assessment, and WHO will inform the manufacturer in writing. Additionally, and before the prequalification assessment of a product may commence, manufacturers must deliver to WHO a signed and completed Letter of Agreement, which will serve: (i) as an agreement between WHO and the manufacturer on the participation of the product in the WHO prequalification assessment process, and (ii) as the manufacturer's acceptance of and commitment to comply with the provisions of the prequalification assessment process.

After an application has been accepted for prequalification assessment by WHO, it will be published on the PQT/VCP website in the pipeline of applications under assessment.

7.1. Prequalification assessment of products

For applications which have been accepted for prequalification assessment, the information submitted in the application will be assessed by external experts (assessors) appointed by WHO. Assessors involved in the dossier review must have appropriate qualifications and expertise in the relevant fields and must comply with the confidentiality and conflict of interest rules of WHO. The assessors will act as temporary advisers to WHO. The assessment of product dossiers will be conducted in accordance with standard operating procedures (SOPs) established by WHO for that purpose to ensure uniformity in evaluation and timeliness of assessment activities. If needed, WHO may provide training to the assessors.

The assessment of prequalification applications will be conducted as per the following criteria:

- **Quality** – Assess product formulation, manufacturing process and physical/chemical characteristics and establishment of WHO specifications.
- **Safety** – Assess acute toxicology and hazard, exposure and risk based on the formulation and intended use of the proposed product.
- **Efficacy** – Assess supporting information substantiating the impact of the product on the target vector(s) in conditions/settings applicable to the intended use of the product.

Any deficiencies in the documentation submitted and/or in the data that are identified in the product dossier review will be communicated in writing to the manufacturer by WHO. WHO may request that a corrective action plan that details the amendments needed to correct the deficiencies (i.e. responses to comments, documentation and/or data that is missing) and target times for their submission be provided by the manufacturer to WHO.

The prequalification assessment procedure is usually suspended (WHO will not undertake any further action) until a complete response has been submitted by the manufacturer. In certain cases, WHO may agree, in its sole discretion, to permit the manufacturer to correct specific deficiencies after prequalification, provided that the manufacturer commits in writing to correct them by an agreed upon deadline. Such a commitment to prequalification will be reflected in the WHO prequalification public report and will be monitored for completion. Failure to comply with prequalification commitments within agreed deadlines may result in suspension of the prequalification or delisting from the WHO list of prequalified VCPs. The manufacturer may request a hearing or meeting with WHO to clarify issues identified during the assessment. If the application/product successfully meets WHO prequalification requirements, a summary of the assessment will be included in the WHO prequalification public report.

If the product dossier does not meet WHO prequalification requirements or if any of the other conditions outlined under section 9.3 (Cancellation of the application) is met, the prequalification application will be cancelled.

7.1.1. Labelling considerations

The labelling information submitted to WHO in support of the assessment and prequalification of a product is referred to as the 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 of the product relevant to WHO. The DoL may not be a comprehensive product label. The product may be authorized for additional or different uses by NRAs. The product label authorized by an NRA may therefore differ from the DoL based on the country or regional labelling requirements.

7.1.2. Verification of WHO recommendation supporting public health value

Finalization of the product assessment is dependent upon the existence or establishment of an applicable disease-related policy recommendation.

7.2. Inspection

WHO will plan and coordinate, in accordance with established SOPs and based on quality management principles, the performance of inspections of the site(s) of manufacture of the VCPs, and where needed, site(s) of manufacturer of source materials and the contract research organizations (CROs). The following factors will be considered when planning inspections:

- results of previous inspection(s) by WHO or an NRA and history of compliance of the company or facility with WHO-recommended standards;
- outcome of the assessment of data submitted to WHO;
- complexity of the site, processes and product;
- number and significance of known quality defects (e.g. complaints, recalls);
- major changes to the manufacturing or research facility (e.g. buildings, equipment, processes, key personnel); and
- site experience with manufacturing and testing of a product.

If serious or critical nonconformities of public health concern are identified in connection with an inspection, WHO reserves the right to use, publish, issue, share with relevant authorities of WHO Member States as well as with UN agencies and other relevant intergovernmental organizations, and/or make publicly available (in each case, pursuant to the provisions of this document, including provisions regarding the protection of any commercially sensitive confidential information of the manufacturer) any outcomes, reports and/or results, whether in draft or final form, and whether positive or negative, arising from or relating to the prequalification assessment process. This includes, without limitation, any WHO Notices of Concern, WHO Notices of Suspension and WHO Information Notices for users.

7.2.1. Manufacturing sites

The inspections of the manufacturing site(s) are conducted to assess compliance with WHO-recommended quality standards (ISO-9001:2015). The initial inspection of the manufacturing site will be performed in two stages. The stage 1 inspection, usually a desk audit,¹ will evaluate the documentation related to the quality management system to ensure readiness for the stage 2 inspection. General information about the documented quality management system (including the quality manual and manufacturing processes, organigram, workflows, critical suppliers and floor plan)² will be reviewed during the stage 1 inspection to establish the readiness of the manufacturer's quality management system and to prepare for an on-site visit. Any issues of concern will be communicated to the manufacturer.

The stage 2 inspection will comprehensively evaluate the effective implementation of the quality management system and production processes through an on-site(s) inspection. The inspection team is composed of WHO staff, external experts (inspectors) appointed by WHO as well as, potentially, interpreters and observers. The inspectors involved in the on-site(s) inspection(s) should have appropriate qualifications and expertise in the relevant fields, must comply with the confidentiality and conflict of interest rules of WHO and will act as temporary advisers to WHO. Representatives of the NRAs and/or additional WHO employees may accompany the inspection team to the manufacturing site(s) as observers or for training purposes.

If time allows, a preliminary nonconformance report detailing issues of concern (if any) will be provided to the manufacturer on the final day of the inspection. A final inspection report, including the graded nonconformities will be issued to the manufacturer after the inspection of the manufacturing site(s).

All nonconformities must be corrected by the manufacturer through suitable corrective actions addressing the root cause of each nonconformity. Depending on the nature and number of nonconformities, objective evidence of the effective implementation of proposed corrective actions may be required. WHO will assess the information provided and decide whether the corrective action plan can be accepted. Conformity with prequalification requirements will be established based on assessment of such information. In some instances, the number and criticality of nonconformities may require that the effective implementation of proposed corrective actions be verified in a follow-up inspection before the nonconformities can be closed off.

A summary of the findings of the inspection of the manufacturing site(s) will be included in the WHO prequalification public report, if the product successfully meets WHO prequalification requirements. In certain cases, WHO may agree, in its sole discretion, to permit the manufacturer to correct specific nonconformities after prequalification, provided that the manufacturer commits in writing to address them by an agreed upon deadline. Such a "commitment to prequalification" will be reflected in the WHO prequalification public report and will be verified during the re-inspection. Failure to comply with prequalification commitments within agreed deadlines may result in the suspension of the prequalification or delisting of the product from the WHO list of prequalified VCPs. If the manufacturer does not meet WHO prequalification requirements or if any of the other conditions outlined in section 9.3 (Cancellation of the application) are met, the prequalification application will be cancelled.

7.2.2. Contract research organizations

The inspection of CROs may be carried out to assess compliance with GLP, or relevant standard(s), and to perform verification of data.

¹ The stage 1 inspection may also be performed on-site.

² See Site Master File Guidance.

8. Outcome of the prequalification assessment

8.1. Reporting and communication of the results of the prequalification assessment

As part of the prequalification assessment process, WHO may share the manufacturer's application and related information with interested NRAs, subject to WHO entering into an appropriate confidentiality undertaking with each such NRA. Furthermore, the outcome of any joint review of information by WHO and NRA(s) may be used by WHO, at its discretion, as part of the prequalification assessment process.

Each assessment report (including WHO specifications) and manufacturing site(s) inspection report will be finalized according to the relevant SOPs and format established by WHO, describing the findings and including requests and recommendations to the manufacturer. The assessment reports will be communicated in writing to the manufacturer. If any additional information is required, or if corrective action has to be taken by the manufacturer, WHO will postpone its decision on the acceptability of the product and/or manufacturing site(s) concerned until, as applicable: (i) such information has been provided by the manufacturer, assessed and found satisfactory by WHO, and/or (ii) such corrective action has been taken by the manufacturer and found satisfactory by WHO, in light of the specified standards.

As WHO is responsible for the prequalification assessment process, the ownership of the reports arising from or relating to the prequalification assessment process lies with WHO. Thus, WHO shall be entitled to use and publish such reports subject to the protection of any commercially sensitive confidential information of the manufacturer.

Confidential information in this context means:

- confidential intellectual property, know-how, and trade secrets (including formulas, processes or information contained or embodied in a product, unpublished aspects of trademarks, patents, etc.); and
- commercial confidences (e.g. structures and development plans of a company).

Subject to the protection of commercially sensitive confidential information, WHO will publish on the WHO website and make publicly available the following information in connection with the prequalification assessment process:

- names of products submitted for prequalification, associated manufacturer(s) and the prequalification status of each application;
- certain product attributes depending on the product type, for the purpose of identifying product specific characteristics;
- manufacturing sites associated with the formulation/production of the VCP;
- WHO prequalification public report summarizing the findings of the prequalification assessment; and
- any negative outcomes of the prequalification assessment, including product alerts such as WHO Information Notices for users, WHO Notices of Suspension and/or WHO Notices of Concern.

Notwithstanding any of the foregoing, WHO reserves the right to use, publish, issue, share with relevant authorities of WHO Member States as well as with UN agencies and other relevant intergovernmental organizations, and/or make publicly available (in each case, in accordance with the provisions of this document, including provisions regarding the protection of any commercially sensitive information of the manufacturer) any outcomes, reports, notices and/or results, whether in draft or final form, and whether positive or negative, of the prequalification assessment process. This includes, but is not limited to, the assessment and/or manufacturing site inspection, and includes any confidential information to which WHO may gain access in the course of the prequalification process.

8.2. Successful prequalification

Once WHO is satisfied that the prequalification assessment process is complete for the relevant product, and that the product meets WHO prequalification requirements, the product bearing a specific product name, as manufactured at the declared manufacturing site(s), will be included in the WHO list of prequalified VCPs. The WHO list of prequalified VCPs will be compiled in accordance with an SOP established by WHO for final decision-making on inclusion in that list. The list will be published on the WHO website and will specify the prequalified product name, relevant product attributes/characteristics, the manufacturer's name, the manufacturing site(s), the date of prequalification and the current prequalification status.

The manufacturer will receive a letter of prequalification from WHO informing it of the outcome of the overall prequalification assessment of the product. Once the product is included in the WHO list of prequalified VCPs, the manufacturer will be responsible for:

- fulfilling prequalification commitments;
- reporting of changes;
- post-market surveillance obligations;
- receiving inspections/re-inspections; and
- continued compliance with established WHO specifications.

The decision to include the product in the WHO list of prequalified VCPs is made based upon information available to WHO at the time of the prequalification assessment, including information obtained as a result of the product dossier application and the inspection of manufacturing site(s) and/or the labelling review conducted by WHO. This decision is subject to change on the basis of new information that may become available to WHO.

NOTE: If serious or critical nonconformities or concerns (including with respect to quality, safety and/or efficacy) are identified in connection with the prequalification assessment of a product and/or a prequalified product, WHO reserves the right to use, publish, issue, share with relevant authorities of WHO Member States as well as with UN agencies and other relevant intergovernmental organizations, and/or make publicly available (in each case, pursuant to the provisions of this document, including provisions regarding the protection of any commercially sensitive information of the manufacturer) any outcomes, reports, notices and/or results, whether in draft or final form, and whether positive or negative, arising from or relating to the prequalification assessment process and/or prequalified product. This includes, without limitation, any WHO Notices of Concern, WHO Notices of Suspension and WHO Information Notice to end users. Consequently, WHO may delist the product after evaluation of the evidence and risk-benefit assessment or may suspend the product until results of further investigations become available and are assessed by WHO. WHO may re-list the product only after the aforementioned evidence, risk-benefit and other assessments, and investigation results are considered acceptable by WHO.

USE OF WHO NAME AND/OR EMBLEM:

Manufacturers must understand and agree that it is not WHO's mandate to issue any approvals, certificates or licences for VCPs. This responsibility lies with the NRA of each country. Furthermore, WHO does not, as a matter of policy, endorse any specific commercial product over others. As mentioned above, the purpose of WHO prequalification of VCPs is to provide guidance to interested UN agencies and WHO Member States in their procurement decisions. In this regard, the results of the prequalification assessment, participation in the WHO prequalification assessment process, inclusion of any product in the WHO list of prequalified VCPs, and/or the WHO name and emblem **MAY NOT BE** used by manufacturers or any other party for commercial and/or promotional purposes. WHO will not accept any liability or responsibility whatsoever for an injury, death, loss, damage or other prejudice of any kind that may arise as a result of or in connection with the procurement, distribution and use of any product as to which WHO has published the assessment results and/or that is included in the WHO list of prequalified VCPs.

8.3. Cancellation of the application

WHO reserves the right to cancel the application for a specific product at any time or stage of the prequalification assessment procedure if:

- the product dossier does not contain all of the required information or does not meet WHO prequalification requirements; and/or
- the manufacturer is not able to, or fails to, provide the required or requested information within a specified deadline; and/or
- the product does not meet the standards for prequalification; and/or
- the manufacturer is not able to, or fails to, implement any corrective actions which WHO may require within a specified deadline; and/or
- the information supplied is inadequate to complete the prequalification assessment in a timely manner.

After cancellation, the manufacturer may re-apply for WHO prequalification assessment once the issues have been addressed.

8.4. Withdrawal from the prequalification assessment

WHO provides the manufacturer with the right to withdraw its application for prequalification assessment at any time. To exercise this right of withdrawal, the manufacturer must provide WHO with written notice specifying the product(s)/application(s) to be withdrawn. After withdrawal, the manufacturer may re-apply for WHO prequalification assessment at any time.

8.5. Reporting and communication of outcomes after withdrawal or cancellation of an application

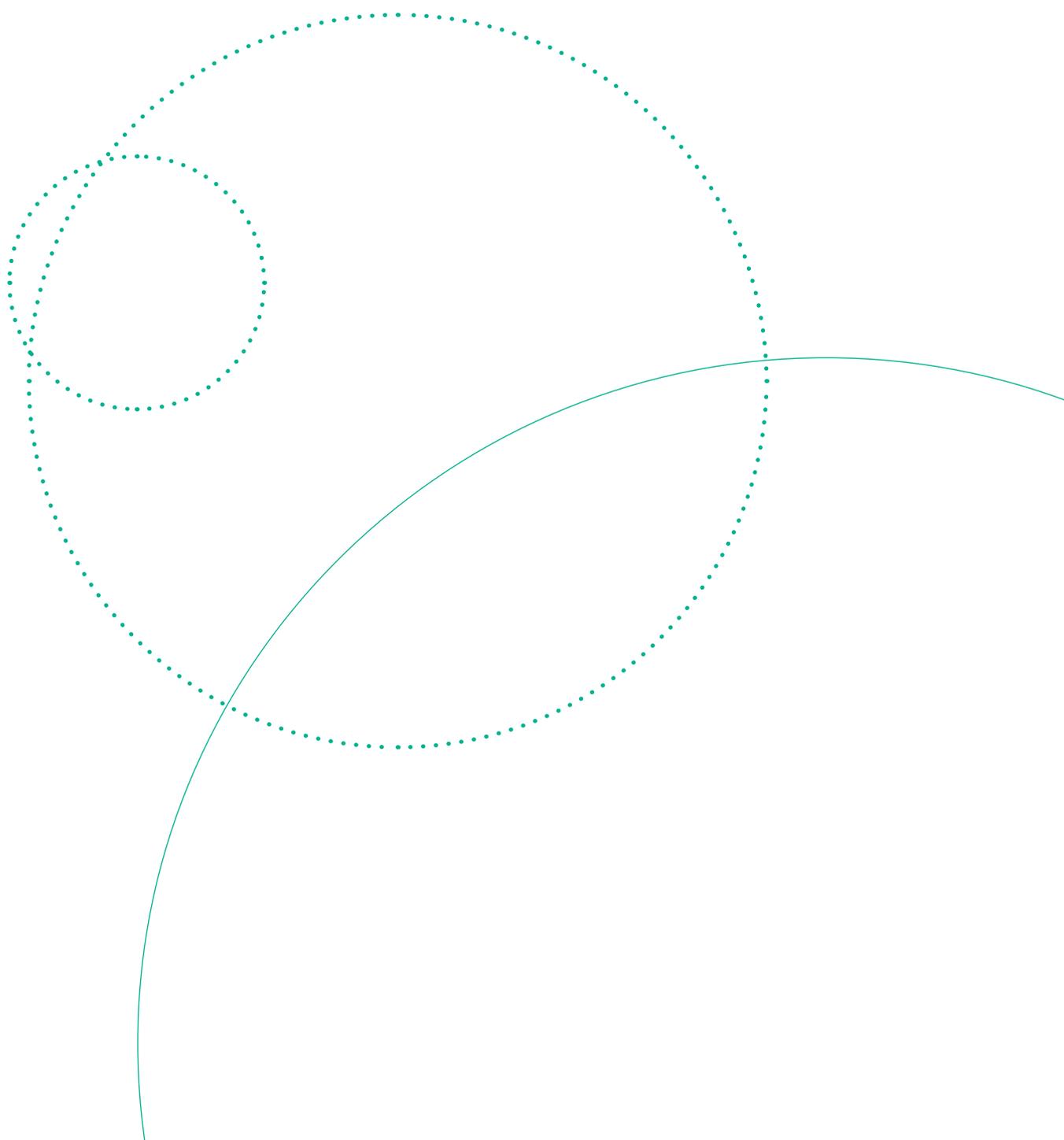
The cancellation or withdrawal, at any time and for any reason, of an application for prequalification assessment of a specific product will not prejudice or otherwise affect WHO's rights to use, publish, issue, share with relevant authorities of WHO Member States as well as with UN agencies and other relevant intergovernmental organizations, and/or make publicly available (in each case in accordance the provisions of this document, including provisions regarding the protection of any commercially sensitive information of the manufacturer) any outcomes, reports, notices and/or results, whether in draft or final form, and whether positive or negative, arising from or relating to the prequalification assessment process, including without limitation any WHO Notices of Concern, WHO Notices of Suspension and/or WHO Information Notices for users.

8.6. Reporting and communication of outcomes after delisting or suspension of a product

If the prequalification assessment and/or a prequalified product is suspended or delisted, at any time and for any reason, such suspension or delisting will not prejudice or otherwise affect WHO's rights to use, publish, issue, share with relevant authorities of WHO Member States as well as with UN agencies and other relevant intergovernmental organizations, and/or make publicly available (in each case, in accordance the provisions of this document, including provisions regarding the protection of any commercially sensitive information of the manufacturer) any outcomes, reports, notices and/or results, whether in draft or final form, and whether positive or negative, arising from or relating to the prequalification assessment process, including without limitation any WHO Notices of Concern, WHO Notices of Suspension and/or WHO Information Notices for users.

9. Prequalification fees

Currently there are no fees required to be paid by the manufacturer in association with the submission of an application.



10. Post-prequalification activities

10.1. Fulfilment of prequalification commitments

Commitments to prequalification must be fulfilled by the manufacturer within the agreed deadlines in order to keep the prequalification status of the product. Failure to meet prequalification commitments within the agreed deadlines may lead to suspension of the prequalification or delisting of the product(s) from the list of prequalified VCPs.

10.2. Changes

The manufacturer of product(s) included in the WHO list of prequalified VCPs are obligated to report to WHO changes related to the quality, safety and/or efficacy of the prequalified product or its design, labelling or manufacture.

To determine whether a change to the product, including its design, labelling and manufacture, or to the quality management system, requires reporting to WHO, the manufacturer should evaluate the potential effect this change may have on the quality, safety and/or efficacy of the product.

For all reportable changes to a prequalified product, the manufacturer must submit to the WHO PQT/VCP team a Post-Prequalification Change Application (PPQC) including the supporting information/data, as applicable. The manufacturer must communicate to WHO its intent to introduce a change well in advance (i.e. early in the process of designing and validating the change) in order to allow sufficient time for WHO to assess the change before its implementation. WHO will not approve any changes without due assessment. Depending on the type of change, the assessment may also include an inspection of the manufacturing site(s).

Once the PPQC application is received by WHO, it will be screened for completeness and, provided all the required information has been supplied, will undergo assessment by WHO. If any aspect of the supporting documentation is incomplete, the manufacturer will be informed in writing and requested to complete it within a specified deadline set by WHO.

WHO will inform the manufacturer in writing of the outcome of its assessment of the change. The manufacturer will also be notified if WHO deems (based on the nature of the change and its potential impact on the quality, safety and/or efficacy of the product) that an inspection of the manufacturing site(s) is also required, or if a new product application may be necessary depending on the severity of the change.

Once WHO is satisfied that the prequalification change assessment of a product is complete and provided that the overall findings demonstrate, as determined by WHO, that the product continues to meet all WHO prequalification requirements, then the WHO list of prequalified VCPs will be updated, as necessary, to reflect the relevant change accepted by WHO. If the submitted documentation supporting the change does not meet WHO prequalification requirements or if all the requested information is not provided by the manufacturer within the specified deadline, WHO will reject the change. The impact of such a decision on the prequalification status of the prequalified VCP will be communicated to the manufacturer in writing by WHO.

Failure to submit a PPQC to WHO, which may impact the quality, safety and/or efficacy of a prequalified product, may lead to suspension of the prequalification or delisting of the product(s) from the list of prequalified VCPs.

10.3. Routine re-inspections

Routine re-inspections will be conducted to ensure continued compliance with prequalification requirements. Routine re-inspections will typically take place every three years, and up to five years, after prequalification of a product unless an earlier re-inspection is deemed necessary by WHO.

10.4. Post-market surveillance

10.4.1. Handling of complaints

In the case of a complaint, WHO will verify the validity of the information submitted and may request the manufacturer to provide further information relating to the complaint, including details regarding the investigation undertaken and any preventive and corrective actions taken. When necessary, WHO will conduct an investigation in relation to the complaint(s), which may include use of established procedures for assessment and/or inspection. Based on the findings of the investigation, WHO may determine that it is necessary to issue a suspension of the prequalification until the identified issues are addressed or product is brought into compliance. Alternatively, WHO may determine that the product should be delisted and removed from the list of prequalified VCPs. WHO may also notify, depending on the nature of the complaint, NRAs, relevant authorities of any interested Member States and/or interested UN agencies of the complaint.

Depending upon the severity of the complaint(s), WHO may determine that it is necessary to issue a suspension of the prequalification pending the outcome of investigation.

10.5. Compliance with established WHO specifications

Manufacturers are expected to maintain compliance with the relevant WHO specifications for the VCP and source materials, as appropriate. Compliance with the established WHO specifications may be verified during inspection/re-inspection and/or post-market or quality assurance testing by a third party. Failure to comply with the relevant WHO specifications will require the manufacturer to take corrective actions to ensure compliance or submit the necessary application/information to establish new/revised specifications. Such noncompliance may lead to suspension of the prequalification until the product is brought into compliance or delisting of the product(s) from the list of prequalified VCPs.

10.6. Product review

At WHO's discretion, a product review may be initiated related to a subset of products which share certain attributes. A product review process includes:

- identification of the relevant products based on the issue;
- review of existing information;
- identification of new information/data gaps to be addressed;
- applicant submission of information based on the identified needs; and/or
- evaluation of product integrating new information.

Manufacturers are required to provide all requested information within specified timelines. Failure to comply with such requests may lead to suspension of the prequalification or delisting of the product(s) from the list of prequalified VCPs.

10.7. Product re-assessment

WHO may initiate a partial or complete re-assessment of a single product, resulting from:

- conclusions of a product review;
- submission of complaints and/or suspension of the prequalification;
- proposed changes to a product having been prequalified based on the procedures established for conversion of products at the time of transition to prequalification;
- inspection findings; and/or
- other relevant criteria.

Manufacturers are required to provide all requested information within specified timelines. Failure to comply with such requests may lead to suspension of the prequalification or delisting of the product(s) from the list of prequalified VCPs.

11. Confidentiality

WHO assessors, inspectors and the designated evaluating sites will treat all information to which they will gain access during the assessments and inspections, or otherwise in connection with the discharge of their responsibilities in regard to this prequalification procedure, as confidential and proprietary to WHO or parties collaborating with WHO in accordance with the terms set forth below. WHO assessors and inspectors will take all reasonable measures to ensure that confidential information:

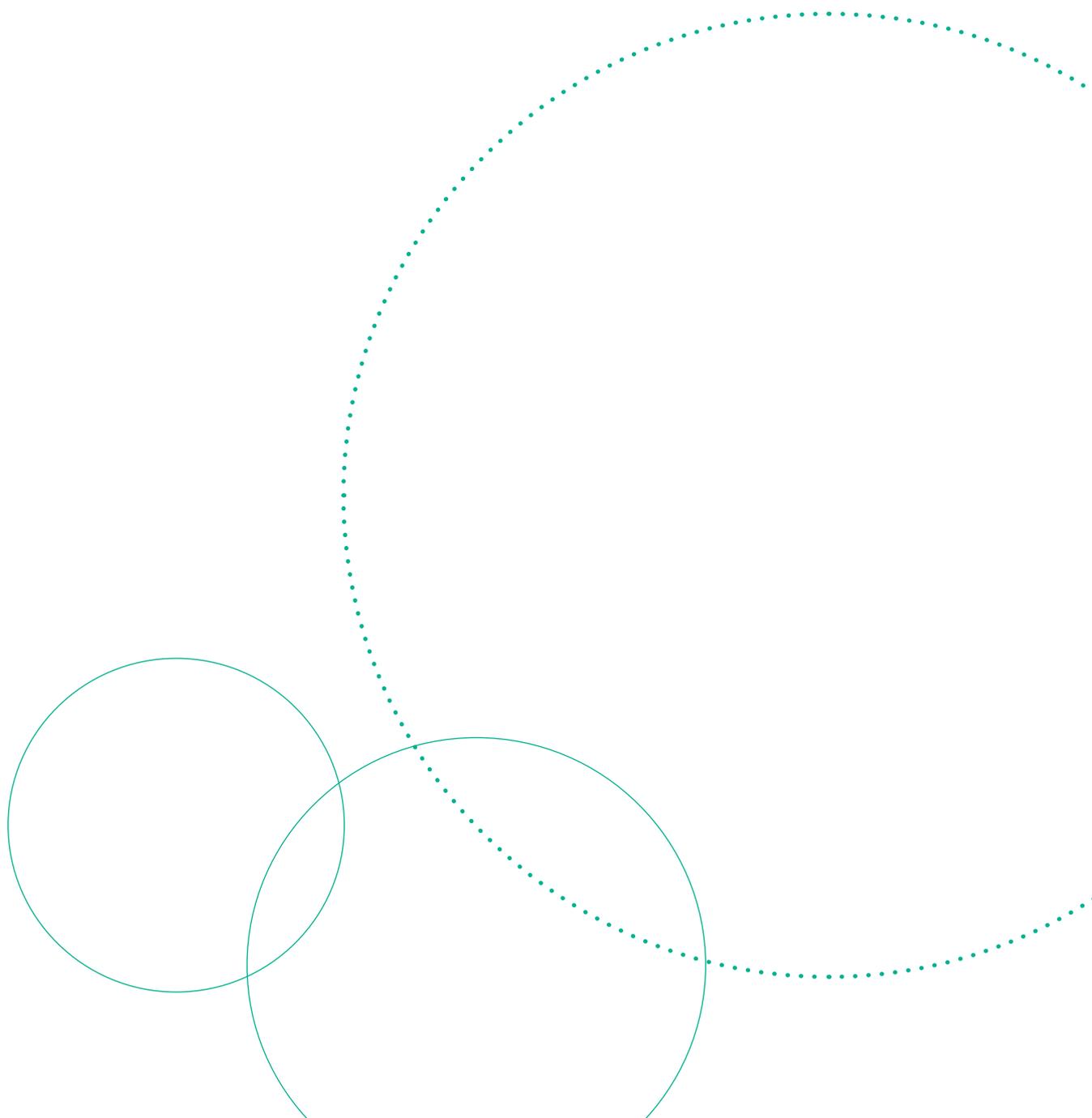
- is not used for any purpose other than the assessment and inspection activities described in this document; and
- is not disclosed or provided to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

WHO assessors and inspectors will not, however, be bound by any obligations of confidentiality and non-use to the extent they are clearly able to demonstrate that any part of the confidential information:

- was known to them prior to any disclosure by or on behalf of WHO (including by the manufacturers); or
- was in the public domain at the time of disclosure by or on behalf of WHO (including by the manufacturers); or
- has become part of the public domain through no fault of theirs; or
- has become available to them from a third party not in breach of any legal obligations of confidentiality; or
- was subsequently and independently developed by or on behalf of WHO, as shown by written records, by persons who had no knowledge of such confidential information; or
- is required to be disclosed by law, provided that WHO shall in such case immediately notify the manufacturer in writing of such obligation and shall provide adequate opportunity to the manufacturer to object to such disclosure or request confidential treatment thereof (note, however, that nothing contained herein shall be construed as a waiver of the privileges and immunities enjoyed by WHO and/or to submit WHO to any national court jurisdiction).

12. Conflict of interest

Before undertaking the work, each external inspector and assessor will also (in addition to the above-mentioned confidentiality undertaking) be required to complete and sign the WHO Declaration of Interests Form. If, based on the above-mentioned declaration of interests, it is felt that there is no risk of a real or perceived conflict of interest (or it is felt that there is only an insignificant and/or irrelevant conflict of interest), and it is thus deemed appropriate for the assessor or inspector in question to undertake the work, then he/she will discharge his/her functions exclusively as adviser to WHO. In this connection, each assessor and inspector is required to confirm that the information disclosed by him/her in the declaration of interest is correct and complete, and that he/she will immediately notify WHO of any change in this information.



13. Disputes – privileges and immunities of WHO

In the event of any dispute or disagreement between the manufacturer and WHO arising from or relating to the prequalification assessment process, an SOP established by WHO for the handling of such disputes and disagreements will be followed to discuss and resolve the issue. By virtue of WHO's status as a specialized agency of the UN, WHO, its officials and experts performing missions for WHO (including for example, the prequalification assessors and inspectors) enjoy privileges and immunities under national and international laws and conventions, including the Convention on the Privileges and Immunities of the Specialized Agencies, adopted by the General Assembly of the United Nations on 21 November 1947 (the 1947 Convention). Nothing contained in or relating to this document or the prequalification assessment will constitute or be deemed as a waiver of any of the privileges or immunities which WHO, its officials and/or experts performing missions for WHO enjoy pursuant to the 1947 Convention or otherwise under any national or international law, convention or agreement, and/or as submitting WHO, its officials and/or experts aforesaid to any national court jurisdiction.

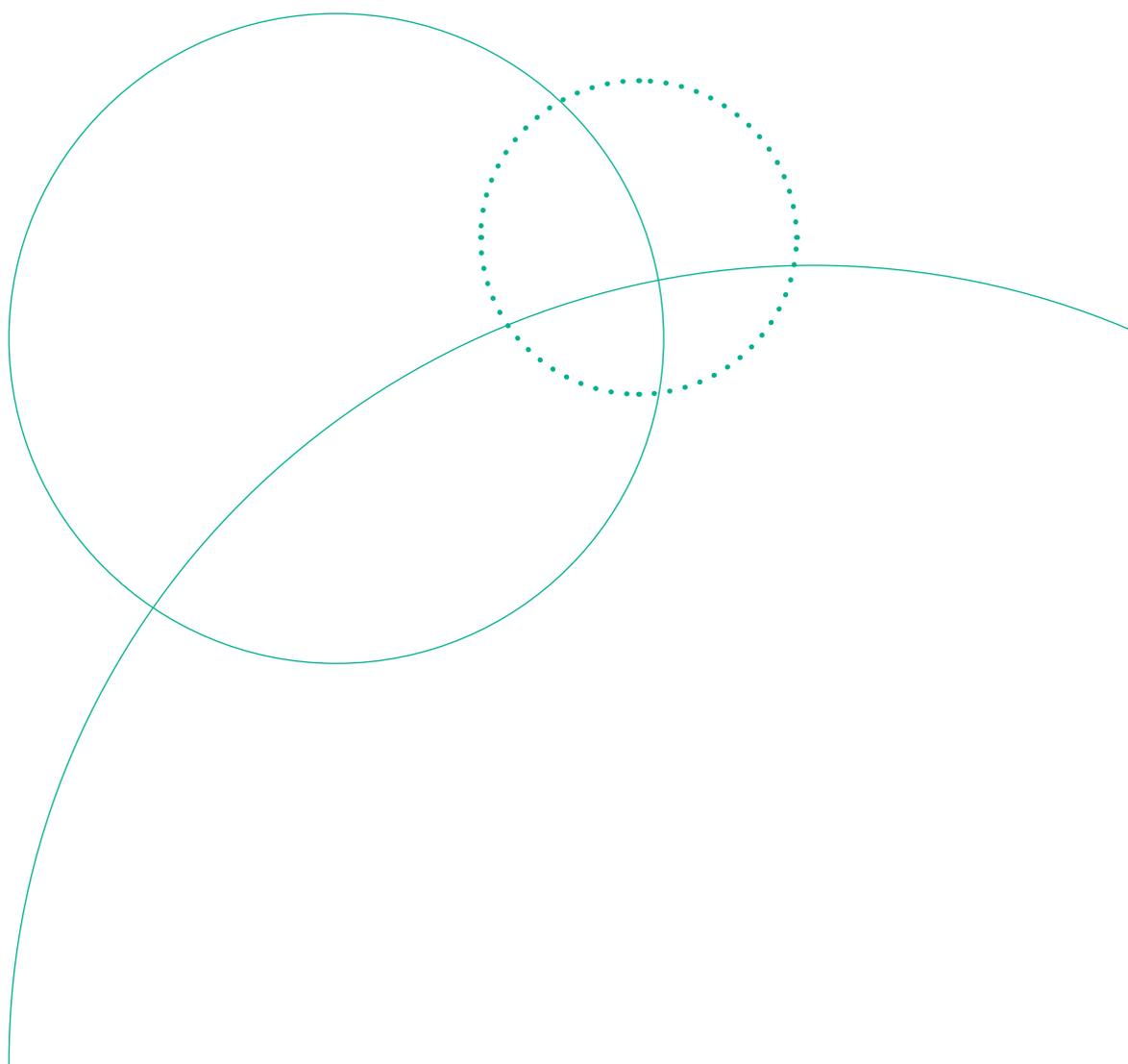
14. Additional information

For further information about applying for prequalification, the prequalification process or the PCT-VCP team, please visit the following websites:

- [WHO Prequalification Team: Vector Control Products](#)
- [VCP Norms and Standards Documentation](#)
- [WHO Global Malaria Programme](#)
- [WHO Neglected Tropical Diseases](#)
- [Vector Control Advisory Group](#)

Any enquiries regarding WHO prequalification of VCPs should be addressed to:

pqvectorcontrol@who.int



15. Definitions

Active Ingredient	The ingredient of a product formulation providing the pesticidal action.
Applicant	The party who submits an application for prequalification assessment.
Contract Research Organization	An organization (commercial, academic, or other) to which an applicant may transfer some of its tasks and obligations in relation to the conducting of studies to generate data for the product dossier.
Declaration of Labelling	The labelling information submitted to WHO in support of the prequalification assessment of a product.
Dossier Review	Review and assessment of documentation, including data, protocols, reports, procedures, etc., submitted to support the quality, safety and efficacy of a product for the purpose of WHO prequalification.
Good Laboratory Practices	A quality system concerned with the organizational process and the conditions under which nonclinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.
Inspection	Inspection of the manufacturing site(s) of a product undergoing or having undergone prequalification assessment.
Manufacturer	Any party with responsibility for design and/or manufacture of a VCP with the intention of making the VCP available for use, under the party's name, whether such a VCP is designed and/or manufactured by that party or on behalf of another party.
National Regulatory Authority	The government agency or agencies responsible for regulating public health pesticides and/or VCPs.
Pest	Any destructive organism (including insects and other arthropods, molluscs, plants, etc.) that acts as a vector of human or animal disease, creates nuisance conditions or causes harm to or otherwise interferes with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feed stuffs.

Pesticide	Any substance, mixture of substances, microorganism (including viruses), biological agent or device intended to repel, destroy or control a pest.
Product Claim	A product claim is a statement of something as a fact or an assertion about the product, intended for inclusion on a label. For VCPs, this may include statements about the formulation, benefit, impact or effect of the product.
Product Class	A product class in vector control is a group of products that share a common entomological effect by which it reduces pathogen transmission and thus reduces infection and/or disease in humans.
Public Health Value	Proven protective efficacy to reduce or prevent infection and/or disease in humans.
Screening	A systematic process to ensure all sections of the dossier/application have been submitted.
Site Master File	A site-specific dossier provided by the manufacturer detailing information necessary for inspections of the manufacturing facility.
Vector Control Product or VCP	A product used to control vectors of disease, which has undergone all stages of manufacture, including packaging and labelling.
WHO Recommendation	A position statement, recommendation, information note or other guidance document issued by WHO. The most recent of these takes precedence over any previously issued recommendations.



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**WHO Prequalification of Vector Control Products:
<https://extranet.who.int/pqweb/vector-control-products>**