WHO Coordinated Scientific Advice Procedure for health product research and development
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1. Background and rationale

One of the key World Health Organization (WHO) missions is to enable access to high quality, safe and efficacious/well performing health products (in vitro diagnostics (IVDs), medicines, vaccines, vector control products, medical devices and other products and services) that are suitable for use in populations in greatest need. Two essential elements to achieve this goal are the generation of policy recommendations for health interventions and the WHO Prequalification (PQ) assessment\(^1\) that rely on evidence from well-designed and well-conducted trials with appropriate endpoints, to demonstrate their public health value as well as efficacy/performance and safety of the products. However, limited horizon scanning or interactions with product developers, either in the public or private sector may not allow, at times, appropriate anticipation or systematic planning of relevant policy recommendations and/or timely prequalification assessment and listing for certain products/classes.

In addition, interactions between WHO and developers may depend on individual technical department strategies and modalities and the interaction between technical departments (TDs), product developers and the Prequalification Team (PQT) is not standardized. As a result, some policy recommendations are being issued without any immediate prospects for prequalified products or there may be unnecessary intervals between policy recommendation and availability of prequalified products. Moreover, developers may not be aware of the type of data that are critically needed to enable WHO to make scientifically sound, evidence-based policy recommendations and/or to fulfill PQ requirements, leading to delays in the development of guidelines and issuing of recommendations as well as delays in prequalification assessments and subsequent listings of novel health products.

Some processes for joint TD(s)/PQ activities have been established within WHO (for example, for vector control products, to determine the appropriate assessment pathway for individual products\(^2\)), but there is no such process in place specifically for joint TD(s)/PQ interactions with product developers. A standardized corporate process for interactions between TD(s), PQT and product developers would assist in addressing these issues.

In this context, WHO’s science division (SCI) has developed optimized corporate processes to better link research and product development with access (Box 1). One of these processes is the WHO Coordinated Scientific Advice (CSA) procedure for health product research and development (R&D) whereby product developers may approach WHO and obtain joint advice from the relevant TD(s) and PQT, coordinated by the Science Division (SCI), if the product is likely to meet criteria for public health value (as evidenced by alignment with WHO TPPs or other criteria where no TPPs are available). The present document outlines the basic principles, contents, procedures and outputs of this CSA.

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\(^1\) [https://extranet.who.int/pqweb/](https://extranet.who.int/pqweb/) accessed 29 April 2021

\(^2\) [https://extranet.who.int/pqweb/vector-control-products/determination-pathway](https://extranet.who.int/pqweb/vector-control-products/determination-pathway) accessed 29 April 2021
The scope of the CSA procedure is based on a series of key principles that are outlined below.

**Key principles for WHO’s engagement in CSA procedure**

- **WHO has a responsibility** to communicate the global public health perspective on unmet needs for product development, where this may save lives or prevent disease.
- In areas where product development may fill unmet needs, it is in the **public interest** that WHO engages with developers to better align data generated with WHO’s requirements for both PQ assessment and WHO guideline development: this is the basis for the CSA procedure.
- Where there are no product developers engaged in areas of critical unmet need, the CSA approach is not appropriate; other means should be applied to **raise awareness and advocate** for funding and engagement in an area of unmet need.

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**Box 1. Revised WHO process for optimization of R&D and health product assessment**

1. **Better anticipate** to trigger the policy development process, including horizon scanning and developing or endorsing preferred product characteristics (PPCs)/target product profiles (TPPs), in order to stimulate innovation, guide product development and provide predictability to manufacturers with respect to the evaluation process anticipated for these new tools.
2. **Develop WHO policy recommendations** based on the generation of evidence by manufacturers and/or research groups to demonstrate that an intervention has public health value.
3. **Ensure timely prequalification assessment outcomes** through appropriate generation of evidence needed to fulfil prequalification requirements.
4. **Optimize uptake:** Policy guidance is disseminated and its use supported and monitored.

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**2. Scope of the CSA procedure**

The scope of the CSA procedure is based on a series of key principles that are outlined below.

The scope of the WHO Coordinated Scientific Advice procedure is to provide advice to product developers on the generation of robust data for future evaluation towards WHO policy recommendation and product prequalification in areas of unmet public health needs.

This includes discussion on pros and cons of various clinical development methods and trial options so as to maximize the relevance of trial outputs. In turn, it is expected that the CSA procedure will allow product developers to understand better the WHO perspective.

On this basis, advice will be provided on product development questions concerning the following aspects of new products or updated forms of known products:

- quality
- non-clinical aspects
- clinical/epidemiological aspects.

Throughout this document, it is important to bear in mind that the procedure is not a route for WHO to endorse any particular product or service.
• WHO must at all times maintain independence, competitive neutrality and impartiality with respect to manufacturers and other stakeholders and in accordance with WHO’s Framework of engagement with non-State actors\(^3\).

• WHO should be accountable for advice that it provides; hence the importance of clearance and documentation to ensure advice is on behalf of the organization rather than on behalf of individual staff members.

• The CSA procedure is distinct from WHO’s guidelines and PQ procedures.

• Transparency principles imply that the procedure itself should be publicly available and open to all product developers meeting eligibility criteria.

• All information shared by a product developer seeking scientific advice and the specific advice provided will remain confidential.

The CSA will be prospective in nature, since it will allow input on product development, so that product development plans can be amended based on the advice provided.

Importantly, while scientific advice will focus on development strategies, it will NOT be a pre-evaluation of the product and will not itself confer any WHO endorsement or unfair competitive advantage. Further, the scientific advice will not be binding on product developers and will not guarantee positive outcomes from the PQ assessment or policy recommendation, as those assessments will always be based on data not yet available at the time of the scientific advice.

3. Objectives
   3.1. Primary objectives
   1. To provide advice to developers seeking to develop a health product in line with WHO’s expressed unmet public health needs in a given disease/condition area.
   2. To ensure good understanding of WHO policy and PQ data needs and processes by developers as well as to provide feedback on specific areas of content for manufacturer’s development plans.
   3. To accelerate timelines from clinical trial start to the provision of data that would satisfy both policy and PQ requirements (depending on quality, safety and efficacy/performance data generated as well as any other relevant factors) and improve the quality of submissions received for PQ assessment and available for guideline development.

3.2. Secondary objectives
   1. To help identify promising products in the pipeline whose developers are including a focus on global/LMIC markets.
   2. To incentivize product developers to invest in an area of unmet needs and consider global public health aspects from the start.
   3. To formalize WHO evidence generation standards for policy recommendation related to TPP/PCC specifications.

4. Description of the Procedure

4.1. Description of the Procedure

The CSA will take place based on a request from a product developer submitted to WHO. The request may be initiated independently by the developer or may be solicited by WHO, in agreement with the product developer, where this is in the public health interest. It will follow a submission process with a clearly defined single entry point that is the Science Division /Research for Health Department (SCI/RFH) at WHO. WHO’s advice to the product developer will be joint between the relevant TD(s) and PQT, through a formal and harmonized process.

The optimal time for initiating CSA contact will vary for the different product streams but in general, it will be after clinical development has started and before the pivotal trial(s) design is/are finalized in the case of therapeutics and vaccines, or before the start of clinical validation studies for IVDs. Under certain circumstances CSA would be considered at even earlier stages, such as at the discovery to development interface, as in the case of vector control products where one of the driving forces for this process is the need to support innovation. Other circumstances may include when the novelty of the product class means that there are little to no established pathways for clinical evaluation. Ultimately, the timing for CSA requests will be determined by the product developers’ needs based on the products under development and should be discussed with WHO.

It is expected that the product proposed by the product developer will be aligned with existing WHO Target Product Profiles (TPP)¹ or Preferred Product Characteristics (PPC) that provide guidance on unmet public health needs. In the case of no such TPP/PPCs, the TD(s) will indicate whether the submitted product aligns with a recognized unmet public health need.

The CSA procedure will apply for new products, or new/additional data on existing products with the view to assess their potential significant public health value.

4.2. Respective roles

SCI/RFH, as Secretariat for the CSA procedure, will:

✓ act as point of entry for product developers
✓ verify the submission by the product developer and request for clarification as needed
✓ share the submission with the respective focal points in the WHO TD(s) and PQT
✓ organize the CSA face-to-face/virtual meeting
✓ take, finalize and record the meeting minutes, and
✓ communicate meetings outputs to product developers.

The TD(s) and PQT review the submission and verify data requirements.

The TD(s) will:

✓ review the submission and assess alignment with TPP/PPCs or recognized unmet public health need;
✓ evaluate the potential public health value and the capacity to support potential formulation of a WHO policy recommendation on the product, if appropriate; and

✓ assess the development plan, proposed study design, protocol(s) and expected data against guidelines requirements.

PQT will:
✓ review the submission and check intentions against requirements for data generation on efficacy/performance, safety and quality that will apply at the time of PQ submission and manufacturing standards.

Together, WHO experts from the TD(s) and PQT, with assistance from RFH if needed, will provide guidance to applicants on the suitability of the development plan and study designs for the generation of relevant data to ensure that the resulting evidence meets WHO’s standards for determining public health value.

Note: It is not the role of the CSA process to substitute the industry's responsibility in the development of their products.

4.3. The CSA procedure
The CSA procedure takes place in four successive steps.

Step 1: Request for CSA and determination of Eligibility
A developer who is willing to develop or is developing a product responding to a WHO recognized public health unmet need contacts WHO for scientific advice on product development. At WHO, the point of entry is the SCI/RFH division who receives the request, checks the elements of the request application and shares it with the relevant TDs and PQT. The TDs and PQT assess the eligibility of the product (see section 4.4.1. for eligibility criteria) and revert to SCI/RFH who informs the Developer on the eligibility (or not) of their request for CSA. If the product is considered eligible, then the developer is invited to provide the full Submission Package.

Step 2: Formal application
The developer provides the full Submission Package (see 4.4.2) to SCI/RFH who checks its admissibility and shares it with the relevant TD(s) and PQT for evaluation. If needed, SCI/RFH requests potential clarifications. The product development plan submitted by the developer at this step is the most important element in the request for WHO CSA. The provision by WHO of scientific advice will primarily be based on the questions and the position of the developer presented within this document. When everything is clear on the full Submission Package, SCI/RFH proposes a meeting date to the developer and organizes the meeting.

Step 3: Face-to-face meeting or virtual meeting
A joint face-to-face meeting takes place where the developer meets the respective focal points from the TD(s) and PQT for scientific advice. The meeting is chaired by SCI/RFH who also takes and finalizes the minutes of the meeting.

Step 4: CSA output
Based on the minutes, and after consultation with TD(s) and PQ, SCI/RFH provides the developer with a written report that presents the key elements and outputs of the CSA.
4.4. The application
The application process is divided in two steps: 1. Determination of eligibility and 2. Formal application.

4.4.1. Determination of Eligibility (Step 1)
Developers interested in gaining WHO CSA for products intended for use in an area with recognized unmet public health needs should contact WHO through a single point of entry located at SCI/RFH (ScientificAdvice@who.int).
The application will include:

- a summary of the product’s characteristics;
- a written justification for the product meeting an unmet public health need. This includes due reference/compliance with established WHO TPP/PCC if available;
- a brief presentation of the Product Development Plan with indication on the steps and studies already achieved and key results and the plans for future studies and development steps;
- a description of the questions to be addressed to WHO and the developer’s position on each of the issues raised.

Note: Requests for CSA must be submitted using form CSA_002, available [here](#).

SCI/RFH will confirm receipt of the request for CSA, check its content and ask for clarification in case of any outstanding issues. SCI/RFH will inform the relevant TD(s) and PQT and share the application for evaluation of the request’s eligibility. Based on feedback from the TD(s) and PQT on the validity of the request, SCI/RFH will inform the applicant whether or not the product is eligible for WHO CSA. If positive, SCI/RFH will request the Developer to formally apply and deliver a full Submission Package.

### Eligibility criteria for CSA:

- Requests must be submitted using the relevant standard form. Only complete forms will be accepted.
- Requests will be considered for innovative products (or combinations of products) under development, not yet commercially available. Commercially available products under development for additional indications/uses will also be eligible for CSA (see optimal time for CSA requests in Section 4.1).
- Requests will be considered for products under development that fall within the scope of PQ.
- Under certain circumstances and in agreement with relevant TD(s) and PQT, a request for a product that is not currently within the scope of PQ may be considered.

**Box 2. Eligibility criteria for CSA**

#### 4.4.2. Formal application (Step 2)

The full CSA Submission Package will provide a comprehensive scientific overview of the product and its development plan. The level of detail in the application depends on the questions raised by the applicant and may include but may not be limited to:

- Background information on the disease/condition to be considered and related unmet need;
- Detailed background information on the product (mode of action/assay format, chemical structure/method and pharmacological classification, intended indication/use);
- Quality background information;
- Non-clinical background information. This includes a tabulated overview of all non-clinical studies (completed, ongoing and planned);
Clinical background information: including a tabulated overview of all clinical studies (completed, ongoing and planned);

Rationale for seeking advice, with a clear, concise and unambiguous description of the question(s). Questions should be specific and clearly labelled according to the expertise required for the assessment and numbered sequentially. It is not the role of WHO to enter into a “co-development” process with product developers. Questions should focus on data needs for policy development and PQ processes, e.g. review of proposed choice and number of endpoints, case definition, target population and intended use setting, formulation, presentation, stability, dosing, schedule, route;

List of references: any relevant publications included in the list of references should be annexed (in .pdf format), preferably collated as a single document or compiled in one or more compressed files;

List of Annexes: Annexes should include any information potentially relevant to the questions, e.g.:
- investigators’ brochure
- study protocols (final, draft or outline/synopsis)
- study reports (final/draft/synopsis)
- any previous scientific advice received (e.g. EMA/CHMP Scientific advice, US FDA, other national regulatory authorities)
- any published data.

Note: Detailed information on the contents of a Submission Package are specified in documents CSA_003 for medicines, CSA_004 for vaccines, CSA_005 for IVDs and CSA_006 for vector control products.

Full processing of the application at WHO is determined by SCI/RFH in collaboration with relevant TD(s) and PQT.

4.5. The Evaluation

In the evaluation, TD(s) and PQT technical staff will assess the potential public health value of the product under consideration, its capacity to support potential formulation of a WHO policy recommendation and PQ listing, and the appropriateness of the development plan to deliver data that are deemed necessary for a potential policy recommendation and PQ listing.

The following aspects will be considered:
- Product type, description, indication, intended use, intended use setting and user;
- Non-clinical and clinical data available on efficacy/performance, safety, quality and manufacturing standards;
- Types of ongoing studies and trials;
- Projected trial and study protocols including objectives, methods, sample size calculation and statistical analysis plan (with a clear indication of the a priori hypothesis, target effect sizes and levels of significance, justified by appropriate power calculations), age groups and populations included, characteristics of study settings;
- Indication of factors that might influence the long-term efficacy of the product;
• Any identified challenge.

If required, as part of the evaluation, a meeting between TD(s) and PQT will take place to discuss relevant elements of the submission package. Written feedback on any issues identified during the evaluation may be shared with the product developer ahead of the face to face/virtual meeting to allow product developers to prepare.

4.6. The Meeting (Step 3)
The purpose of the face-to-face/virtual meeting is to obtain clarification on the application and address any additional questions to allow WHO TD(s)/PQT to provide thorough responses in the report.

– The Applicant will present a brief review of the relevant information on the new product (type, characteristics, indication, objectives, etc.) and its full development plan, including a review of available data and future prospects.

– TD(s) and PQ will present their observations and comments on the application. This includes comments on the protocols as well as on associated documents including (but not limited to) statistical analysis plans, study design, methodology, quality assessment.

– The discussion will take place on the presented product characteristics and R&D aspects, in view of determining the product’s potential public health value and its potential to comply with a possible policy recommendation and PQ listing.

– Minutes of the meeting will be taken by RFH to serve as a basis for the formal WHO CSA report.

4.7. The Output (Step 4)
Formal written feedback on the outcome of the CSA procedure will be provided to the Applicant.

Based on the face-to-face/virtual meeting minutes, and after consultation with the concerned TD(s) and PQT, RFH will provide the developer with a written report that presents the key elements and outputs of the CSA, including guidance on the generation of suitable data for the product to be considered for WHO policy recommendation and PQ listing.
Annex: WHO Prequalification and policy recommendation procedures and websites

WHO Prequalification: [https://extranet.who.int/pqweb/](https://extranet.who.int/pqweb/)

WHO Prequalification aims to ensure that key health products (IVDs, medicines, vector control products and vaccines and immunization-related equipment and devices) for high burden diseases meet global standards of quality, safety and efficacy, in order to optimize use of health resources and improve health outcomes. The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, product testing or performance evaluation, and inspection of manufacturing sites. This information, in conjunction with other procurement criteria, is used by UN and other procurement agencies to make purchasing decisions regarding IVDs, medicines, vector control products and/or vaccines.

**Vaccines** prequalification aims to ensure that a sufficient supply of safe, effective vaccines is available for immunization programmes, including in emergency situations and in response to novel disease outbreaks. It assesses vaccines via a rigorous process of evaluation and applies WHO-established standards and norms of acceptable quality, safety and efficacy. These cover vaccine standards that address the manufacturing, licensing, quality control, labelling, transportation and storage of vaccines. Vaccines prequalification covers all vaccines required for routine immunization against 24 priority diseases, while prequalification of immunization devices covers all equipment needed for an effective national vaccine programme.

Policy development for vaccines at WHO is currently supported by several active bodies with different roles from facilitating the development of novel vaccines to issuing global recommendations and ensuring access to quality assured prequalified products.

1. **Supporting and facilitating product development:** assessment of unmet public health need, development of TPPs, PPCs done by Product Development for Vaccines Advisory Committee (PDVAC). In some cases, and under the recommendation of PDVAC, product specific advice has been provided by WHO in collaboration with specifically convened expert groups to guide the evaluation of vaccines in pivotal trials, including advice on aspects of trial design and data generation in view of policy recommendations by the Strategic Advisory Group of Experts (SAGE) on Immunization.

2. **Evidence reviews and global policy recommendations:** Evidence reviews including burden of disease, clinical characteristics of the targeted vaccine, other options for disease control and prevention, vaccine and immunization characteristics, economic considerations, health system considerations, social impacts, legal considerations, and ethical considerations and issuance of evidence-based recommendations is a process that is overseen through the SAGE committee and its associated Working Groups who provide evidence-based recommendations to WHO. As is the case for evidence-based recommendations issued for other health products, the review process includes systematic reviews of the evidence, GRADing of the certainty of the evidence, and a reflection of benefits and harms, values and preferences, resource use, equity, acceptability and feasibility considerations of the intervention within evidence-to-recommendation tables. Based on SAGE recommendations, WHO issues non product-specific global policy through vaccine position papers, published with open access in the Weekly Epidemiological Record.

For additional details on vaccine policy development see: [https://www.who.int/immunization/policy/WHO_vaccine_development_policy.pdf](https://www.who.int/immunization/policy/WHO_vaccine_development_policy.pdf)
**Medicines** prequalification ensures that active pharmaceutical ingredients (APIs) and finished pharmaceutical products (FPPs) are safe, appropriate and meet stringent quality standards. The principal medicines prequalification activities are: assessment of product dossiers (for FPPs) or master files (for APIs); inspection of manufacturing and clinical sites; and organization of quality control testing of products. These activities form part of WHO’s broad access agenda which seeks to expand access to quality-assured medicines. Medicines prequalification currently covers HIV/AIDS, malaria, tuberculosis, reproductive health, hepatitis B & C, influenza, diarrhoeal diseases and selected neglected tropical diseases, as well as infections in newborns and young infants and childhood pneumonia. It recently initiated prequalification of biotherapeutic products: selected products to treat certain types of cancer, and human insulin for diabetes.

The process for policy recommendations for medicines varies depending on the disease/condition area of the class of products and is generally undertaken by WHO technical departments. It includes systematic reviews of evidence and GRADing of the certainty of the evidence. It also considers benefits and harms, values and preferences, equity, acceptability and feasibility considerations. Policy recommendations are generally framed within WHO guidelines, and all WHO guidelines are reviewed and approved by the WHO guidelines review committee to ensure key requirements for guideline development are met.

The WHO Expert Committee on Selection and Use of Essential Medicines also issues recommendations and meets every two years to review the latest scientific evidence on the efficacy, safety and cost effectiveness of medicines in order to revise and update the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc). In some non-communicable disease areas WHO has few guidelines and relies on EML for policy recommendations. EML also plays a role in prioritizing amongst medicines, those of greatest public health value.

In order for a medicine to be eligible for prequalification, it must either be listed in the EML or be part of a WHO policy recommendation.

**In vitro diagnostics** (IVDs) prequalification aims to promote and facilitate access to safe, appropriate and affordable IVDs of good quality in an equitable manner. The focus is on IVDs for priority diseases that are appropriate for use in resource-limited settings. WHO IVD prequalification incorporates comprehensive assessment of individual IVDs through a standardized procedure, to determine whether the product meets WHO prequalification requirements. The assessment has three components: review of a product dossier; laboratory evaluation of performance and operational characteristics; and manufacturing site(s) inspection(s). IVD prequalification covers a wide array of diagnostics for both endemic and epidemic diseases in LMIC: HIV/AIDS, hepatitis B & C, Human Papillomavirus (HPV), malaria, cholera and syphilis and certain conditions such as glucose-6-phosphate dehydrogenase (G6PD) deficiency. In 2019, this list was expanded to include IVDs for the following analytes and diseases: haemoglobin (point of care), glucose meters and test strips, tuberculosis, yellow fever, dengue fever, gonorrhoea, chlamydia, measles, rubella, leishmaniasis, schistosomiasis, mycoplasma genitalium, onchocerciasis.

Similarly to the medicines process for policy recommendations, IVDs are currently considered by technical departments based on programmatic needs through an evidence-based approach overseen by the WHO guidelines review committee.

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5 https://cms.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines accessed 29 April 2021
In addition, the Strategic Advisory Group of Experts on IVDs\(^6\) issues yearly recommendations to WHO on IVDs that should be made available at different levels of the healthcare system based on their complexity, need for infrastructure and intended use.

**Vector control** prequalification focuses on assessment of new products used for the prevention of vector-borne disease – i.e. bed nets, sprays and larvicides. Prequalification assesses vector control products and public health pesticide active ingredients to determine if they are manufactured to a high-quality standard and can be used safely and effectively. This is done by assessing product dossiers, inspecting manufacturing sites and supporting quality-control testing of products. Products that meet prequalification requirements are added to the WHO list of vector control products. WHO prequalification of vector control products primarily benefits populations most affected by major vector-borne (often also neglected tropical) diseases such as malaria, dengue fever and other arboviral diseases (Chikungunya, Zika virus), Chagas disease, lymphatic filariasis, visceral leishmaniasis, and human African trypanosomiasis.

Policy development for vector control products is managed by the Malaria Policy Advisory Group\(^7\) (MPAG) and the Strategic and Technical Advisory Group on Neglected Tropical Diseases\(^8\) (STAG). These groups provide independent, strategic advice to WHO on all policy areas relating to malaria and NTD control. MPAG is supported by the Global Malaria Programme Guidelines Development Group and ad hoc Evidence Review Groups which support the policy making process.

In addition, the Vector Control Advisory Group (VACG), jointly managed by the Global Malaria Programme, the Department of Control of Neglected Tropical Diseases, and the WHO Prequalification Team for vector control products provides guidance to product developers on the generation of epidemiological data and study designs to enable assessment of the public health value of new vector control interventions. It also provides advice to WHO, for submission to MPAG and the STAG on the public health value of new interventions.

A series of paths have been established by each of the above PQ product streams to encourage early contact with manufacturers:

**Advice to manufacturers:**

The Prequalification Team medicines (PQTm) is available to provide prompt advice on quality and bioequivalence (BE) aspects of generic products dossiers.


**Pre-submission meetings:**

This is required by PQT medicines (PQTm) for all new applicants submitting via the full assessment route – the goal is to help the applicant resolve critical issues before submission. This pre-submission meeting is an essential aspect of the medicines assessment process, that provides an opportunity for advice and guidance prior to submission of a dossier, as well as an opportunity for the applicant to meet the PQTm assessment team that will be involved with the assessment of their product. A pre-submission meeting allows the PQT medicines team to have an overview of the product and a)

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7. [https://www.who.int/groups/malaria-policy-advisory-group](https://www.who.int/groups/malaria-policy-advisory-group) accessed 29 April 2021

8. [https://www.who.int/groups/strategic-and-technical-advisory-group-for-neglected-tropical-diseases](https://www.who.int/groups/strategic-and-technical-advisory-group-for-neglected-tropical-diseases) accessed 29 April 2021
ensure that the applicant is on the right track, b) provide general guidance on how to proceed, and c) provide guidance on identified issues that should be dealt with prior to submission. At the same time, it is an opportunity for the applicant to: a) introduce and discuss the intended dossier, b) raise questions and gain valuable feedback and c) address issues prior to submission.
https://extranet.who.int/prequal/content/pre-submission-meetings

**Vaccines: Meetings with manufacturers**

If considered necessary or desirable by either party, a discussion may be held between the manufacturer, the responsible NRA (if willing to participate) and WHO before the actual evaluation process starts. This pre-evaluation meeting should be scheduled as early as possible, with a predefined agenda addressing questions sent to WHO in advance by the manufacturer. Such meetings are important for discussing programmatic suitability issues and can be scheduled when requested by the manufacturer. (TRS978 Annex6 – procedure for PQ of vaccines)

https://extranet.who.int/pqweb/vaccines/manufacturers

**Vector Control Products: early evaluation of public health value**

A Pre-Submission Coordination Committee (PCC) consisting of staff from PQT, the Global Malaria Programme (GMP) and the Department of Control of Neglected Tropical Diseases (NTD) conducts a review of a pre-submission package to determine whether: a) the product has potential for use in disease control programmes; and b) the product falls within an established product class.

Based on this review, the PCC will decide whether the product is eligible for WHO evaluation and, if so, which of the two evaluation pathways should be followed: either Prequalification assessment or a “new Intervention pathway” to validate whether the product has public health value and potentially resulting in a policy recommendation. The public health value is determined by an independent Vector Control Advisory Group (VCAG).

The applicant should then submit a full application to PQT or to the WHO secretariat of VCAG, as directed.

https://extranet.who.int/pqweb/vector-control-products.

**IVDs: pre-submission meetings and ad hoc meetings**

First time applicants must request a mandatory pre-submission meeting before submitting their first application for PQ assessment. Other applicants can schedule an ad hoc meeting at any time in the process to address specific questions.

**PQT websites**

**PQ medicines:**

- Website: [https://extranet.who.int/prequal/content/what-we-do](https://extranet.who.int/prequal/content/what-we-do)
- PQ list FPP: [https://extranet.who.int/prequal/content/prequalified-lists/medicines](https://extranet.who.int/prequal/content/prequalified-lists/medicines)
- PQ list API: [https://extranet.who.int/prequal/content/active-pharmaceutical-ingredients-0](https://extranet.who.int/prequal/content/active-pharmaceutical-ingredients-0)
PQ Vaccines:

- **Website:** [https://www.who.int/immunization_standards/vaccine_quality/vq_index/en/](https://www.who.int/immunization_standards/vaccine_quality/vq_index/en/)
- **PQ list:** [https://extranet.who.int/gavi/PQ_Web/](https://extranet.who.int/gavi/PQ_Web/)

PQ in vitro diagnostics:

- **Website:** [https://extranet.who.int/pqweb/in-vitro-diagnostics](https://extranet.who.int/pqweb/in-vitro-diagnostics)
- **PQ list:** [https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists](https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists)

PQ Vector control products:

- **Procedure:** [https://www.who.int/pq-vector-control/resources/170717pqvc_001_procedure1.pdf?ua=1](https://www.who.int/pq-vector-control/resources/170717pqvc_001_procedure1.pdf?ua=1)
- **Website:** [https://www.who.int/pq-vector-control/en/](https://www.who.int/pq-vector-control/en/)
- **PQ list:** [https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list](https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list)
For more information, please contact:
Research for Health Department
Emerging Technologies, Research Prioritisation and support Unit
World Health Organization
20, avenue Appia
1211 Geneva 27
Switzerland

Email: ScientificAdvice@who.int

Website: https://www.who.int/activities/optimizing-research-and-development-processes-for-accelerated-access-to-health-products/who-coordinated-scientific-advice-for-health-product-r-d