Declaration of Labelling to Support the Prequalification of Vector Control Products

Background

The Vector Control Group of the Prequalification Team (PQT-VC) is responsible for the assessment of Safety, Quality, and Efficacy of vector control products (VCP) submitted to the World Health Organization (WHO). The labelling of vector control products is critical documentation which conveys the identity of the product, its intended effect, directions for use, and potential hazards and risks of the product. In order to assess a vector control product, the labelling must be reviewed in order to understand the product and thereby assess the safety, quality and efficacy of the product.

In many countries, labels for VCPs (or pesticides in general) are legal documents which are specified and regulated through country and/or local legislation. For National Regulatory Authorities (NRA), the approval or acceptance of a label is typically part of registration of the product, or granting of a marketing authorization for legal sale and distribution of the product. This means that in most cases, product labels are enforceable legal documents which direct the authorized uses of the product.

In contrast to the role of a national regulatory authority, the purpose of the WHO Prequalification of VCPs is to assess the safety, quality and efficacy of submitted VCPs for the purpose of providing guidance to interested United Nations (UN) agencies, WHO Member States and other stakeholders in their procurement decisions. The prequalification of a VCP is neither a registration nor marketing authorization. As such, the necessary labelling content and review process for the purpose of prequalification is different than that of an NRA.

For the purpose of WHO Prequalification of vector control products, labelling refers to:

Label – the written, printed or graphic matter on, or attached to, the pesticide or the immediate container thereof and also to the outside container or wrapper of the retail package of the pesticide.

Leaflet – a part of the product label that is supplied in the form of a detachable or separate leaflet(s), booklet(s) or similar, rather than attached permanently to the container.

Marketing Materials – advertising language to be used in brochures, flyers, or through online distribution which describes the product, its benefits, and/or claims.

Purpose

The purpose of this document is to guide manufacturers/applicants of VCPs in the development and formatting of labelling to be submitted as part of an application for prequalification. Additional guidance on good labelling practices can be found in the “International Code of Conduct on Pesticide Management: Guidelines on Good Labelling Practice for Pesticides (revised).”

Declaration of Labelling (DOL)

The labelling information submitted to WHO in support of the evaluation of a product is referred to as the Declaration of Labelling (DOL). Applicants should use this guidance document to adhere to the recommended standard formatting of the DOL submitted as part of the dossier for WHO evaluation. The DOL is a required element of the product dossier and should be submitted in .pdf format. If the labelling appears in multiple forms/locations (e.g. LLIN - printed on the bag and on a sewn tag) the content of all labelling should appear in the submitted DOL and identified in separate chapters. In some cases, not all sections of the standard format will be applicable. If there is no relevant content for the identified section, maintain the section heading and indicate "Not applicable".

Final labels (ie those in the form as printed on the final product) may be submitted in addition to the DOL, but are not required. For prequalified products the DOL will be published on the prequalified product page. Final labels will not be published.

It is the applicant's responsibility to propose the necessary information for each section. The DOL will be reviewed as part of the assessment to ensure that the labelling content is consistent with and supported by the dossier. PQT-VC may provide recommended changes to the labelling content to improve clarity and accuracy.

Product Labelling for National Regulatory Authorities

The DOL is not intended to replace or supersede labels required by National Regulatory Authorities. Country or region specific labelling requirements may lead to differences in the label content between an NRA label and the DOL.

Standard Format

1. Product Identification
2. Ingredient Statement
3. Safety
4. Directions for Use
5. Product Claims

Description of DOL Sections

This section provides guidance on the content which should appear in each section of the DOL. The bullets under each section are intended to provide guidance on the expected content to appear in each section.

1. Product Identification
   - Identify the Product name and all other brand or trade names under which the product is distributed.
   - Product Type (state clearly if intended for IRS, Larviciding, ITN Kit, LLIN, Space Spray, Skin Applied Repellent, …)
   - Specify the Formulation Type[1]
   - Manufacture information and contact

[1] Manual on development and use of FAO and WHO specifications for pesticides: Appendix E

- Lot Number – Include a placeholder which indicates how lot/batch information is identified on the label
- Package Size – Include a placeholder which indicates how package size (e.g. net contents, weight or volume) information is identified on the label
- Expiry date (if applicable)

2. Ingredient Statement - Identify the active ingredient(s) and the concentration(s) either as a w/w percentage or as a mass/volume ratio. Ensure that the units are identified. Synergists should also be identified here.
   - For LLINs, indicate the ingredient as a function of denier. If panels/roof or fibers differ in content/denier, identify this as necessary.

     Ex.

     Active Ingredient #1

     75D – **x** mg/m^2 which is equal to **y** g/kg

     100D – **x** mg/m^2 which is equal to **z** g/kg

     Synergist/Active Ingredient #2

     75D – **a** mg/m^2 which is equal to **b** g/kg

     100D – **a** mg/m^2 which is equal to **c** g/kg
   - Active Ingredient Mode of Action - Description of active ingredient mode of action and identification of the applicable IRAC Grouping.

3. Safety
   - Precautions of use (pre, during and post use) and storage (Temperature, relative humidity, etc)
   - Disposal procedures (e.g Disposal of waste and used containers must be done in accordance with applicable national, regional and local regulations.)
   - Warning messages (e.g. do not drink, do not smoke etc)
   - First Aid in case of any incidence or emergency (For example: If inhaled, If swallowed, If in eyes, If on skin…)
   - Caution cartoons to facilitate understanding of risks and danger by all (dos and don'ts)
   - Hazard color band as per WHO classification or instruction
   - Environmental protection measures

Decision Documents for prequalified products will include a summary of the product specific acute toxicity and relevant risk assessments intended to help inform regulatory authorities of the potential risks associated with the products and recommended mitigation. Precautionary Statements such as First Aid Information or Personal Protective Equipment need not be specified on the Declaration of Labelling to Support the Prequalification of Vector Control Products because the labelling requirements will differ by country.

4. Directions for Use
   - Provide all directions for each use/site. Clearly state the uses (e.g Intended for IRS). For each use:
     - Identify the target vector(s) of public health concern to be controlled.
     - Identify the application sites, application rates or dosages per site, expected duration of effect and other information necessary for a user to apply the product.
     - List any required application equipment and provide information on best practices for the equipment such as calibration considerations or operational use.
     - Preparation (Mixing/Dilution) instructions.

- Clear and detailed instructions for application of product (e.g instruction for how to spray an IRS product) and best practice for use and maintenance (e.g. washing or drying of net).
- Statement about compatibility of this product and others

Example Uses and Sites

Use	Example Use Sites	Considerations
Long Lasting Insecticidal Net	• Indoor	• Differences in use for nomadic populations, outdoor use, or use in humanitarian emergency situations • Precautionary statements against the use of the product for purposes other than intended, e.g. fishing, use as clothing, drying rack, …
Indoor Residual Spray	• Generic (applicable to all surfaces), or specific instructions per surface type (eg Mud, Wood, Cement, thatched roof and wall, or other surface types)	• Best practices for spray application (e.g. equipment/nozzle type and settings, target tank pressure, distance to spray from wall)
Larvicide	• Open water (flowing vs stagnant, degree of pollution/organic content) • Containerized water/water to be used for human/animal consumption	• Application restrictions for water to be used for human/animal consumption • Multiple Directions for Use sub-sections may be necessary dependent on application method
Space Spray	• Indoor • Outdoor	• Separation of cold vs thermal fogging application instructions • Best practices for calibration and settings of application equipment • Recommended timing of applications (e.g. early morning or late afternoon)
Skin/Clothing Applied Repellent	• Adult • Children	• Directions for application to bare skin vs clothing • Precautions for applying to face and hands

5. Product Claims
    - Provide a bulleted list of claims intended to be made regarding the safety, quality, and/or efficacy of the product.

Use of the WHO Name, Emblem and/or Units

The use of the WHO name and emblem, and any abbreviation thereof, is reserved for the official purposes of the Organization in accordance with a resolution adopted at the first World Health Assembly (resolution WHA1.133). Furthermore, the aforementioned resolution expressly prohibits the use of the WHO name and emblem in any manner without the prior authorization of the WHO Director-General.

Further, with respect to disclosures and public statements regarding review of a product by WHO, WHO does not allow manufacturers or suppliers of vector control products which have been reviewed or approved by WHO to use the name or emblem of WHO, or to refer to the fact of such review or approval, for commercial or promotional purposes.