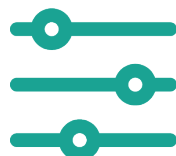
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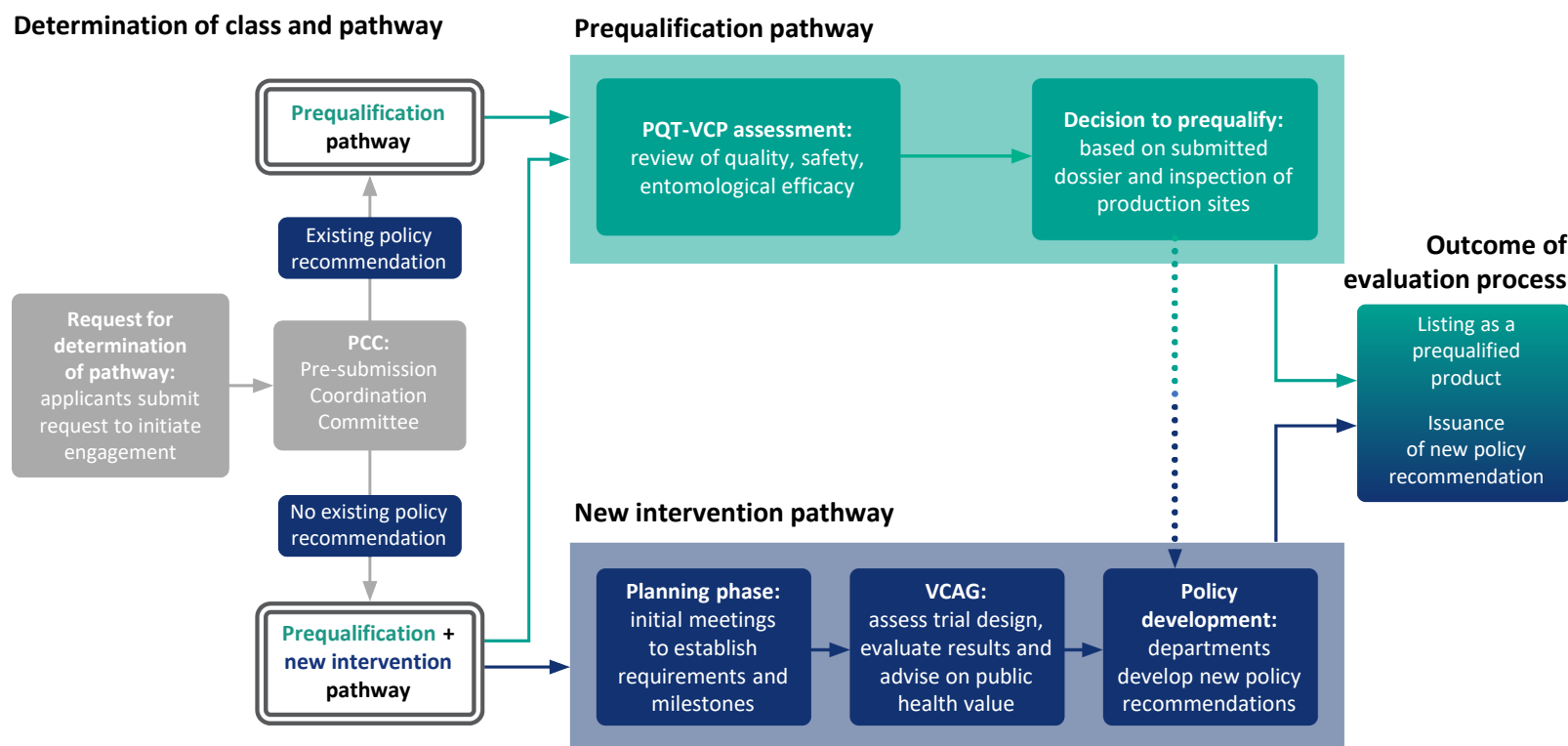
# **Managing the PQ/ Vector Control Products Programme during the past 2 years Impact of the Pandemic, Accomplishments and Priorities**

Vector Control Product Assessment Team  
World Health Organization

# Establishment of WHO VCP evaluation process



## New innovation and prequalification pathways



## Topics to be covered in the Session

- Impact of pandemic on the operations of PQT/VCP
- 2020-21 Commitments and Accomplishments
- Series of presentations on Key Priorities
  - New Communication Tools
  - Submission pipeline
  - JMPS
  - Product Review of Non pyrethroid only Nets
  - Prequalification of Insecticide Treated Nets (ITNs) Guideline
- Questions, Comments and Dialogue throughout the session

## Impact of the pandemic on PQT/VCP

- Focus of work was not impacted; however,
  - No face- to-face meetings
  - Workload impacted due to challenges faced by manufacturers to obtain information to support submissions
  - Operations for VCP of lower priority in comparison to Covid related streams
  - Testing studies delayed
  - Additional PQT/VCP technical expertise required to assist with issues impacting procurement/ deployment

# Commitments and Accomplishments 2021

## *Reported Commitments 2020 – 2021*

- Review and revise data requirements for different products.
- ✓ Revamp role of JMPS within PQT-VCP.
- Validate existing – and/or develop new – methodology.
- ✓ Continue to update evaluation process to accommodate new innovations.
- ✓ Update and develop guidance documents.
- ❑ Expand inspection activities to testing sites.
- ✓ Develop new and improved tools for information dissemination and communication.
- ✓ Develop new and modernized approach to electronic management of submissions.
- ✓ Collaborate with countries.
- ✓ Continue to engage best experts in the field.

## Specific Accomplishments 2021

- Submission workload and completed 2021
- Guidance documents and materials
- Infrastructure and Process Improvements
- Strengthening Evaluation Approaches
- Increasing knowledge base and expertise

## Commitments and Accomplishments 2021

### *Submission Workload and Decisions*

Determination of Pathway = 50 outcomes communicated

Pre-submissions meetings = 92

Application assessments completed

- study protocols = 9
- new products = 7

Prequalified: ReliefNet Reverte, 2GARD, Klypson 500 WG

- change submissions = 33

# Commitments and Accomplishments 2021

## *Guidance documents and materials*

***PQT/VCP develops programme specific guidance and also contributes to other WHO documents pertaining to the vector control sector.***

- PQT/VCP guidance documents
  - Overview document
  - Advice to Manufacturers Series
  - Generic Risk Assessments
  - and many others.....
- WHO guidance documents
  - WHO Evaluation of Vector Control Products (GMP lead)
  - Preferred Product Characteristics (PCC) documents (NTD and GMP)
  - Development of Targeted Product Profiles (GMP and NTD)
  - Position statement and guidance on GMM (TDR)
  - WHO Ethics and VBD Guidance



# Commitments and Accomplishments 2021

## *Infrastructure and Process improvements*



### ***Tools to strengthen infrastructure and support process improvements***

- Development of ePQS and migration of PQT/VCP submission information
  - ePQS data validation project
- Initiate a Quality Management System for PQT
- Publication of the PQT/VCP Overview Document
- Advancements in remote/virtual assessments
- Development of more templates
- Initiation of Executive Summaries
- Ability to access reports from ePQS to enhance tracking and monitoring of submissions

# Commitments and Accomplishments 2021

## Strengthening the WHO VCP evaluation process



### ***Establish enhanced / strengthened evaluation approaches and data to support product prequalification***

*Enhancements informed by the product review of specific ITNs, continued experience in evaluating PQ dossiers, literature and observations from the sector.*

PQT/VCP response,

- Requiring more baseline information on products
- Applying a weight of evidence approach to assessments
- Strengthening existing requirements for supporting data
- Introducing new requirements

# Commitments and Accomplishments 2021

*Increasing the knowledge base and expertise in the area of vector control*

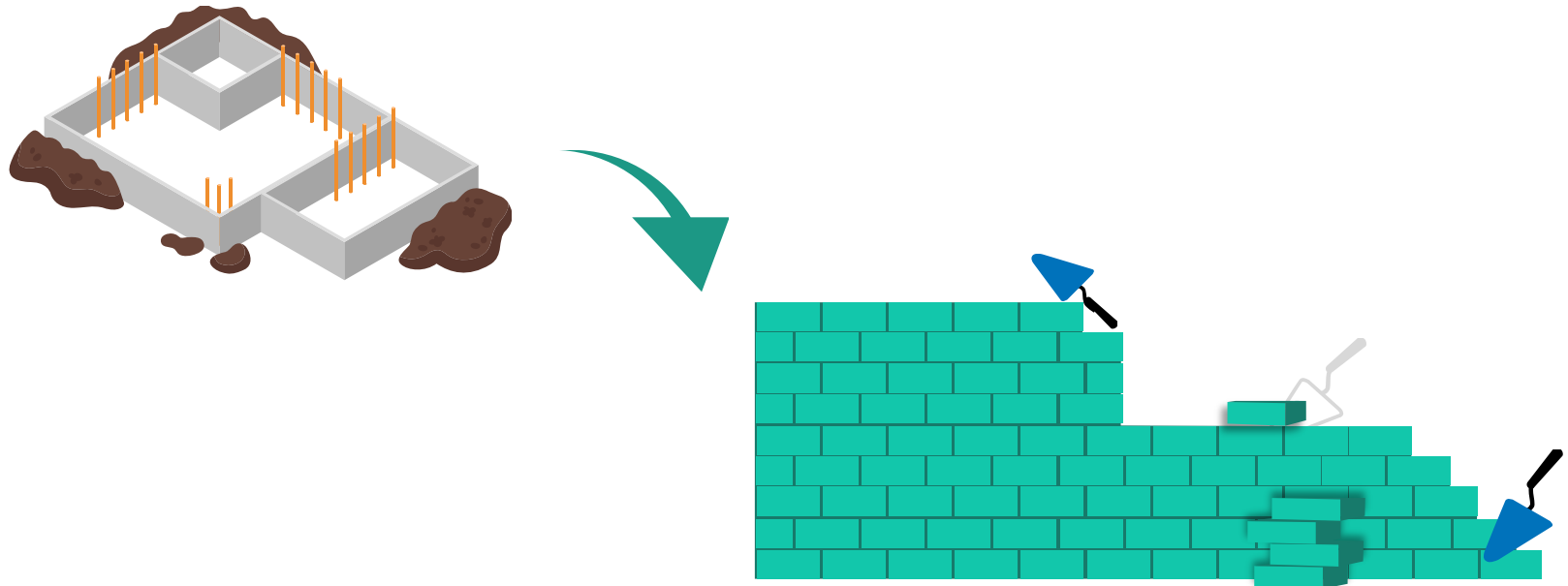


***Build knowledge and interest of partners and stakeholders***

WHO partners	External partners	Stakeholders
<ul style="list-style-type: none"> <li>• Other PQT product streams</li> <li>• GMP, NTD, TDR, Office of the Chief Scientist</li> <li>• PQT/VCP Assessors</li> </ul>	<ul style="list-style-type: none"> <li>• Member States</li> <li>• Procurement agencies</li> <li>• Innovation to Impact (i2i)</li> <li>• Academia (NIRI)</li> </ul>	<ul style="list-style-type: none"> <li>• Industry/IVCC</li> <li>• Research institutions</li> <li>• Academia</li> </ul>

# Commitments and Accomplishments 2021

## *Excavating the foundation and laying bricks*



Thank you  
*Question, Comments, dialogue*

# Key Priorities 2022

## *Website and New communication Tools*

- Main communication tool is the new PQT Website
- Attendance and participation at meetings/ convenings/ conferences
- PQT/VCP targeted meetings and consultations, e.g., ITN manufacturers, procurement agencies
- Continuous improvement through a Questionnaire sent to stakeholders,
  - Quarterly Updates
  - Webinar Wednesdays
  - Video on the Evaluation process

# Key Priorities 2022

## *Submission Pipeline*

- Robust Pipeline established through,
  - Involvement at events/ meetings, e.g., IVCC ESAC etc.
  - Approached to PQT/VCP and referral to Determination of Pathway process
  - Applications to VCAG
  - Direct information to PQT/VC
- Pending submissions - (Under Screening/Under Assessment/Pending WHO recommendation)
  - New products - **20**
  - Change submissions - **47**
  - Protocol submissions - **2**
- Products involved in experimental studies
- New innovative product discussions, e.g., GMM, Wolbachia infected mosquitoes, medicines proposed for supplementary use as VCPs, housing modifications, etc.
- VCP includes, chemicals, biologicals/microbials, devices

# Key Priorities 2022

## *JMPS – implementing direction from WHO review of Advisory Groups and new QMS system for publication of documents*

- Governance
  - Update ToR
  - Determine Scope of responsibilities
- Operations
  - Consistent communication within the committee and with applicants
  - Consistent and timely processes to ensure a level playing field
  - Clear documentation and approval process for publication
- Procedures
  - Selection and appointment of members (roster)
  - Selection and appointment of Chair(s)
  - Term of Office
- Roles and responsibilities
  - Role of members, chairs and secretariat



# Key Priorities 2022

## *Updates to JMPS*

- Workplan development is now aligned with PQT/VCP submissions
- Evaluation documents edited by WHO editor following a final technical review by technical expert
- Process for communication with applicants streamlined through PQT/VCP case manager
- Specifications for ITN finished products moved to PQT/VCP responsibility
- WHO roster now includes additional members
- Revised FAO/WHO Manual to be published in coming weeks
- **Still need to address procedures for stakeholder engagement and consultation of new JMPS positions, policies or requirements.**

## Key Updates

### *Process for Establishing Specifications – JMPS*

- Applicable to WHO and FAO/WHO Joint submissions – FAO submissions may differ
  - Key Notes:
    - Assessors are not authorized to communicate directly with applicants – WHO Rule for advisory groups
    - Identified deficiencies will be communicated to applicants in a timely manner
1. Identification of intent to submit an application – as available
  2. Target submission of complete dossier to WHO – 31 October
  3. Screening – Target completion January
  4. Primary Review - Target completion March
  5. Secondary Review - Target completion April
  6. Meeting – June
  7. Finalization - Target completion September

# Key Updates

## *JMPS Submission Workload and Statistics*

- 39 WHO specifications published for relevant public health pesticide source materials
- 81 source material “products” (AI + Manufacturer combination)
- 30 different companies/applicants
- 20 source material “products” currently under screening/assessment

# Key Updates

## *JMPS Submission workload and statistics*

### Recent Updates of Published Specifications

Title	Year	Title	Year
Alpha-cypermethrin	2021	Diflubenzuron	2020
Alpha-cypermethrin Incorporated LN	2020	Flupyradifurone	2019
Alpha-cypermethrin+ Chlorfenapyr Coated LN	2019	Flupyradifurone + Transfuthrin	2019
Bifenthrin	2022	Imidacloprid	2019
Chlorfenapyr	2022	Imidacloprid + Prallethrin	2019
Clothianidin	2021	Lambda-cyhalothrin	2021
Clothianidin + Deltamethrin	2021	Malathion	2021
Deltamethrin + Piperonyl Butoxide Incorporated LN	2019	Permethrin (40 60 cis trans isomer ratio)	2019
Deltamethrin Coated LN	2019	Transfluthrin	2021

Thank you  
*Question, Comments, Dialogue*