Opportunities for improved market entry & access to VC products in endemic countries

RBM VC WG meeting

Dr. Gerhard Hesse
What do we have?

Current state

**Current paradigms with reformulated AIs (e.g., LLINs, IRS)**

- Manufacturer develops product with currently used insecticides or repurposed formulation from agriculture
- WHOPES evaluates product safety and efficacy
- NRA reviews dossier, conducts local testing as needed, & registers product

**New public health AIs¹ (then formed into products)**

- Manufacturer develops new AI for public health, conducts safety tests
- Manufacturer formulates AI into a product (current paradigm)
- WHOPES evaluates product safety and efficacy
- NRA reviews dossier, conducts local testing as needed, & registers product

**New paradigms (e.g., spatial repellents)**

- Manufacturer develops new paradigm and conducts epid. trials
- VCAG³ assesses public health value of new paradigm
- MPAC⁴/STAG⁵ recommends policy for use of new paradigm
- WHOPES evaluates product safety and efficacy
- NRA reviews dossier, conducts local testing as needed, & registers product

Countries

Global procurers

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Bayer CropScience
National Regulatory Authorities

1. Stand alone national NRA

2. Regional NRA’s:
   - EU: BPR – Biocidal product Regulation
   - Africa:
     - CILLS
     - SADC
     - on the paper: East & Central
   - MEA:
     - GCC (Gulf Country Council) – on the paper only

that’s it !!!!!!!!!!!!!!!!!!!!!!
Stand alone national NRA

1. Dossier submission makes sense because of national peculiarities, e.g. language, format

2. Checking general dossiers (like tox, risk assessment, environmental fate etc) makes no sense (capacities, expertise, repetition)

3. Repeating efficacy studies can make sense if stratification / situation is unique

4. For vector control pragmatism is required (example for IRS / IRM in an important malaria hot spot in East Africa, oral tox of an LLIN etc)
Regional Regulatory Authorities

EU: BPR – Biocidal product Regulation

- can be a reference, but normally VC products

Africa:

CILLS

- agricultural scheme, suitability for PH or VC
- member countries with additional requests (IC)
- dossier in local format

SADC

- 14 member countries
- no harmonization in place
- seems to be more political / economical body

on the paper: East & Central
Best case scenario

- Vector control products

1. 1. WHO evaluation, recommendation and specification for the indication
2. (WHOPES, JMPS, JMPR, CIPAC et al) = basic dossier
3. 2. regionally harmonized acceptance of dossier and results based on “WHOPES”
4. 3. in case of unique situation (geographical, entomological, epidemiological strata) a local scheme for efficacy et al with acceptance of general data package (tox, environment etc) based on WHOPES / BPR / EPA et al
5. (reference)