



Improving development time and speed to market of new and innovative Vector Control products

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The view of the private sector

- Authors:
CropLife Vector Control Group
- Member companies:
 - BASF
 - BAYER CropScience
 - Bestnet
 - Clarke Mosquito Control
 - Sumitomo Chemical/Valent Biosciences
 - Syngenta
 - Vestergaard-Frandsen



Good regulation:

The foundation for environmentally-sustainable, economically-feasible and socially-responsible action



Industry facing many challenges to bring new innovative Public Health Products

- Limited market size
 - Difficulty to re-purposed agrochemical products
 - Higher regulatory costs
 - Longer and complex registration process
- ⇒ Industry focus on agricultural markets
- ⇒ Lack of incentives to invest in specific new chemistries for Public Health products



Five key founding principles for improvement of current processes

- Encourage public/private partnerships for new product development
- Establish a harmonized set of public health product registration requirements
- Review new actives and end use products with relevant risk/benefit assessments for human safety, disease control and lives potentially saved
- Establish one universal dossier package assessed by work-share review by relevant expert from global regulatory bodies and stakeholder countries
- Following the work-share data review, registration and re-registration decisions to be fast-tracked in countries to improve speed and consistency of public health product registration



Registration of Vector Control Products for the disease endemic countries – Role of WHOPEs

- Pivotal role played by WHOPEs as an international recommendation scheme for Vector Control products
 - International technical guidelines for product testing
 - Product recommendations for Vector Control programmes.
 - Product specifications.
- WHOPEs recommendations:
 - Used as a *de facto* registration for countries lacking proper capacity for data review
 - Necessary for participation to international tenders
- The industry group recommends to build on the existing scheme for Vector Control.



Proposals for an improved scheme

An extended data review team

- WHOPEP establishes work-share arrangements with global regulatory bodies such as USEPA, EU, JMAFF, Australia, and key stakeholder countries or other qualified bodies with expertise in toxicology, risk assessments, labeling and safety for product dossier review.
 - ⇒ International Data Review Team (**IDRT**)
- WHOPEP to be an active member of the IDRT.
- Decisions of the IDRT ultimately recognized and accepted by the relevant regulatory authorities and WHOPEP.
- The WHOPEP Working Group continues to issue technical recommendations on vector control product efficacy and definition of the product standards.
- The industry group strongly recommends that stakeholder countries be participants or observers in the IDRT and be informed regularly about the critical findings in the review work.
- Stakeholder countries will promptly after the IDRT review, make decisions necessary for local registrations.



Proposals for an improved scheme

For more transparent and consistent efficacy testing guidelines

- All recommendations based on established WHOPEs guidelines.
- New guidelines:
 - Old Products to be re-evaluated under new protocols
 - Every ten years all products to be re-assessed incl. safety.
- Testing guidelines for innovative products:
 - Open dialogue between scientific experts, WHOPEs and the developing company.
- Guidelines to qualify institution to execute WHOPEs-compatible efficacy studies to be developed.
- Secondary or me-too products:
 - Data that prove equivalence of product.
- WHOPEs provide guidance to countries to establish eco-geographic areas or zones for efficacy trials.



Proposals for an improved scheme

The WHOPEs Working Group

- The WHOPEs WG to meet at least 2 times per year
- Expertise expanded to include members with previous commercial and practical expertise.
- Decisions based on the product review and risk assessments performed by the IDRT.
- Distinct responsibilities:
 - Product testing
 - Evaluation of product efficacy
- Applicants given the opportunity to review or comment on the draft reports of their product.
- Re-examination system to be allowed.



Proposals for an improved scheme Registration in countries

- Developed and developing countries participate in IDRT on product dossiers reviews.
- Developed and developing countries recognize and accept reviews and risk assessments from the IDRT for local registration decisions.
- WHOPEs product recommendations as interim or preliminary registration in accordance with national law.
- Local data if necessary to be generated complementary to reviewed data.
 - Clear and transparent guidelines
 - Consistency for products from national and international companies.
 - Best labs for testing within the region for work share.
- Mutual recognition of registrations within a particular eco-geographic region or sub-regional level.



A final word

- Transparency**
- Consistency**
- Speed**
- Universal acceptance**

