Vector Expedited Review Voucher (VERV)

A new incentive in the battle against mosquito-borne diseases

Malaria, Dengue fever, Zika virus, West Nile and Chikungunya are deadly and debilitating diseases. VERV incentivizes the development of new insecticides to control and prevent the spread of vector borne diseases.

Mosquito-borne global diseases pose a significant biosecurity and health security risk to the world. Malaria, Dengue fever, Zika virus, West Nile and Chikungunya affect people in poor and rich countries.

Malaria kills more than 600,000 people a year in sub-Saharan Africa; mostly children under the age of 5. Major vector-borne diseases account for about 17% of the global burden of communicable diseases. Eighty percent of the world's populations are at risk of one or more vector-borne diseases (mosquitoes, ticks, fleas and other insects are the "vectors" of certain infectious diseases) with over 700,000 deaths annually.

Medicines play a critical role in fighting these diseases, but a more efficacious and cost-effective approach is disease prevention using public health insecticides. Such insecticides play a critical role in limiting deaths and disability by controlling disease-carrying mosquitoes. Between 2000 and 2015, approximately 660 million clinical cases of malaria were averted due to vector control interventions like insecticide treated nets (ITNs) and Indoor Residual Spraying (IRS). However, the development of resistance to insecticides is a constant threat to their effectiveness. Our response must be to innovate novel public health insecticides faster than resistance to existing insecticides develops.

There are significant economic disincentives to developing new public health use insecticides. The development costs for a new, novel chemistry insecticide can range from $100 to $250 million. They can also require as long as twelve years to enter the market. Upon market entry there is a poor prospect of recouping the invested time and money.

In the past decade mosquitoes have become increasingly resistant to commonly used insecticides, particularly pyrethroids. During that period no new classes of insecticides have been developed specifically for public health.

The VERV, can mitigate the economic barriers to innovation. It encourages leading R&D focused agriculture companies to invest in novel insecticide development. Smaller companies and universities can also receive the incentive.

VERV rewards the registrant of a new public use insecticide with a voucher to receive an expedited review of a second, more profitable product.

There are two chemicals involved in VERV: the chemistry which controls disease-carrying vectors, and a second chemical (for any pesticidal use) which receives expedited review as a reward for discovery and development of the vector chemical. Getting to market faster is valuable and gives an innovator registrant an opportunity to generate a financial return to mitigate the development cost on a public health use insecticide. The awarded voucher can also be sold.

VERV is modeled after the Priority Review Voucher (PRV) program (Sec. 524 2007 FDA amendments Act) which is a proven incentive for sponsors registering new treatments for neglected tropical diseases, rare pediatric disorders or medical countermeasures. The FDA has awarded more than 50 (January 2022) PRVs over the 16 years since the program was enacted. (Read the history of the PRV program at: **www.priorityreviewvoucher.org**).

Further reading

- Ridley, Moe, and Hamon "A Voucher System to Speed Review Could Promote a New Generation of Insecticides to Fight Vector-Borne Diseases." Health Affairs. 2017. Describes the economic value of the voucher.
- Moe, Ayers & Hamon "VERV Policy Brief" IVCC 2020. Describes the eligibility criteria and proposed mechanisms for EPA to administer the new incentive.
- Moe "Vector Control Expert Opinions of the Vector Expedited Review Voucher" discusses the opinions of 19 vector control experts.
- Moe "How to Make the Most of a New Voucher Program, Encourage Pesticide Development, and Prevent Disease." Health Affairs. 2023.

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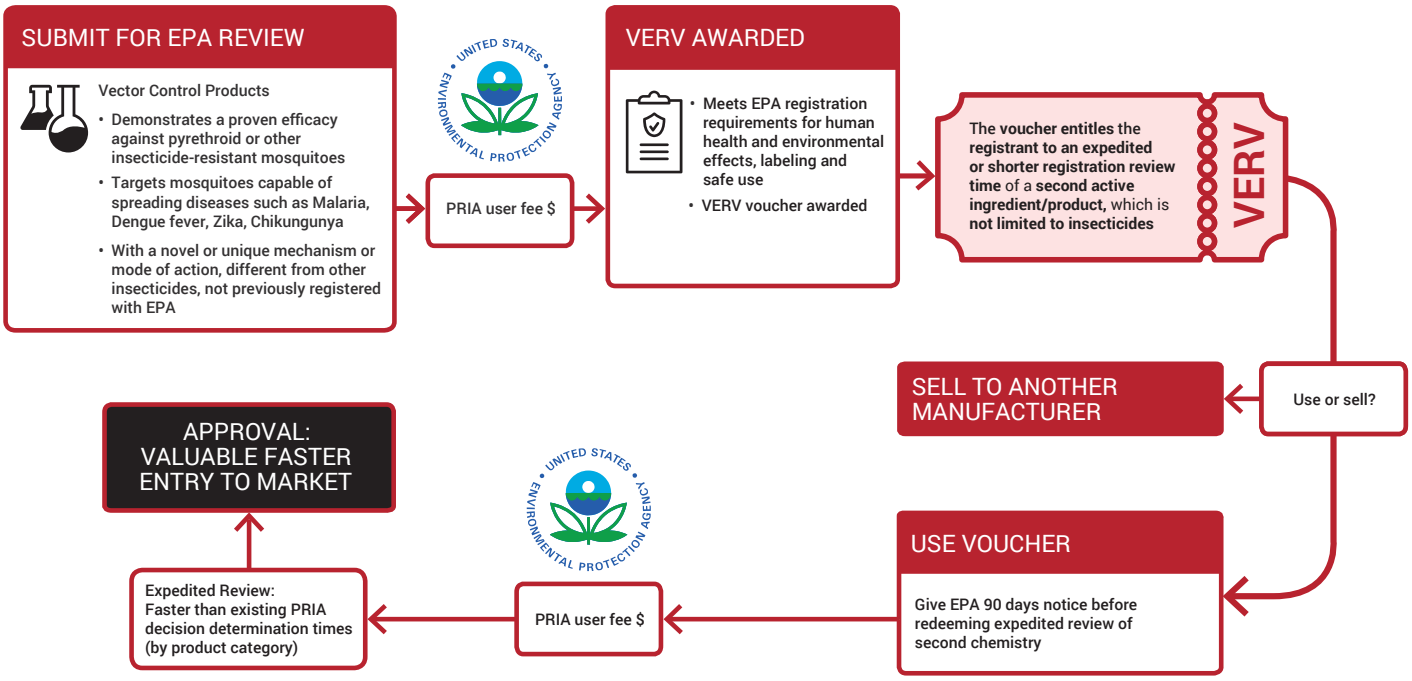
How Will the VERV Program Work?



Proposed VERV Eligibility Criteria

- A new insecticide effective against mosquitoes resistant to pyrethroids and other insecticides.
- Targets vectors of malaria, Dengue fever, Zika virus, West Nile, Chikungunya encephalitis and other mosquito-borne diseases.
- A novel active ingredient not previously registered with the U.S. EPA.
- Meets EPA registration requirements for human health and environmental effects, labeling and safe use.

VERV was originally proposed by Dr Nick Hamon (IVCC), Dr Jeffery Moe (Duke Global Health Institute) and Dr David Ridley (Duke University, Fuqua School of Business).

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Established in 2006, brings knowledge from every corner of Duke University to bear on the most important global health issues of our time. DGHI was established as a University-wide institute to coordinate, support, and implement Duke's interdisciplinary research, education, and service activities related to global health. DGHI is committed to developing and employing new models of education and research that engage international partners and find innovative solutions to global health challenges.

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