

PRIORITY REVIEW VOUCHERS (PRVs)

Fact Sheet



The Priority Review Voucher Program

The Priority Review Voucher (PRV) Program is an important market-based incentive for investment in new drugs and vaccines to prevent and treat neglected tropical diseases, such as malaria, tuberculosis, and intestinal worms¹. It was enacted in September 2007 as part of the Food and Drug Administration Amendments Act of 2007 (FDAAA). **Administered by the FDA, this program awards a PRV to the sponsor of a newly-approved drug or biologic that targets a neglected tropical disease.** The PRV, which is transferable and can be sold, entitles the bearer to priority review for any future new drug application – potentially shaving four to 12 months off the standard FDA review.

Priority Review applies to drugs or vaccines that offer major advances in treatment or provide a treatment where no adequate therapy exists. The FDA's goal for completing a *Priority Review* is **six months**.

The goal for FDA *Standard Review* is **ten months**; actual FDA review timelines often exceed this target, especially for new products.

Designation as “priority” does not alter the scientific/medical standard for approval.

The world needs new medicines to tackle these devastating diseases. Biopharmaceutical companies have revolutionized health care for developed nations. In order to extend those benefits to developing countries, free market-based incentives like the PRV program are necessary.

Valuing the Voucher

The estimated value of a PRV is based on saving time in the FDA approval process. It is calculated with the assumption that the PRV will be used for a blockbuster drug that would not normally qualify for priority review. Saving time in the approval process allows for accelerated profits and the potential for “first-mover advantage” by helping a company bring its product to market before its competitors in a very competitive field. Value estimates based on these criteria range between \$50 million and \$500 million – amounts that could offset the substantial risk and investment required for discovery and development of a new neglected tropical disease product. The market value of a voucher is increased by its transferability – a voucher awarded by the FDA may be applied to another product of the bearer's choosing, or it may be traded or sold.

Companies and investors have reacted positively to the program. Ultimately, investors could establish a market for the purchase and sale of PRVs based on their perceived future value.

Products Eligible for a Voucher

Sponsors that obtain FDA approval for a product that treats or prevents a neglected tropical disease may earn a PRV. To be eligible to earn a PRV, an application must:

- ... be for one of the sixteen listed tropical infectious diseases¹
- ... be for a novel human drug or biologic product
- ... be for a product that does not contain an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any other application
- ... be submitted for FDA review after the enactment of FDAAA (September 27, 2007)
- ... qualify for a priority review on its own merits

¹ Tropical diseases include tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue, dracunculiasis (guinea worm disease), fascioliasis, Human African trypanosomiasis (African sleeping sickness), leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis, and yaws. The list of diseases can be expanded by the FDA through regulation.

The program applies to a range of drugs and vaccines critical to improving health in poor countries, yet certain products are not covered to maintain an emphasis on truly novel drugs and vaccines. Combination products containing a product previously approved by the FDA, pediatric formulations of existing products, and diagnostics are excluded and ineligible for a PRV. Notably, Chagas disease is not currently on the list of eligible diseases.

Putting the Voucher to Use

The holder of a PRV must notify the FDA of its intent to use the voucher and request a priority review 365 days in advance of filing an application. The sponsor applying the voucher must also pay the FDA an additional user fee to defray the costs of the expedited review. The FDA has indicated that user fees will be determined each fiscal year (FY) and will be based on the average cost of a priority review for new drugs or biologics in the previous FY. In September 2010, the FDA announced the PRV user fee to be \$4,582,000 for FY 2011.

If these criteria are met, the FDA must then grant that application a priority review – aiming to complete its review of the application within six months.

Current Status of the Program

- The program went into effect on September 27, 2007. A PRV can be used as of September 27, 2008.
- In October 2008, the FDA issued a draft guidance for industry. The public submitted comments through December 2008. The program is largely self-implementing – no supplemental regulations are needed for the program to operate.
- In April 2009, Novartis AG was awarded the first PRV for the anti-malarial drug Coartem® (artemether-lumefantrine). Novartis has not yet used, traded, or sold the voucher.
- In September 2010, the FDA announced the PRV user fee to be \$4,582,000 for FY 2011.
- In March 2011, Senator Robert Casey (D-PA) introduced the Creating Hope Act of 2011 (S. 606) to the U.S. Senate Committee on Health, Education, Labor, and Pensions. If passed, the legislation will, among other amendments, expand PRVs to include treatments for rare pediatric diseases, close a loophole in current law to prevent companies from receiving a voucher for products that are already marketed in other countries, offer unlimited transferability of vouchers, and provide greater certainty to sponsors by permitting them to seek a designation from the FDA before they submit their new drug application that the drug, if approved, will qualify for a voucher.

BIO Ventures for Global Health (BVGH) is a non-profit organization whose mission is to save lives by accelerating the development of novel drugs, vaccines, and diagnostics coming from the biotechnology industry that address the unmet medical needs of the developing world. BVGH works at the crossroads of biotechnology and global health to find the common ground between the goals of the global health community and the pragmatic needs of companies.

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