

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.

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

The goal for FDA *Standard Review* is **ten months**, and 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 important edge in a very competitive field when a company’s product can reach the market before its competitors, or “first-mover advantage.” 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 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.

¹ Neglected tropical diseases include tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue, guineaworm 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.

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:

1. ...for approval of a human drug or biologic
2. ...for the prevention or treatment of a neglected tropical disease¹
3. ...approved after the date of enactment (September 27, 2007)
4. ...deemed eligible itself for priority review by the FDA
5. ...for a new chemical or biological entity

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.

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 not yet set an amount, but 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. The FDA will calculate and publish this fee each year in the *Federal Register*. Estimates speculate the fee to be approximately \$1.5M.

If these criteria are met, 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. That said, the PRV user fees have yet to be set by the FDA.

In April 2009, Novartis AG was awarded the first priority review voucher for the anti-malarial drug Coartem® (artemether-lumefantrine). Novartis has not yet used, traded, or sold the voucher.

BIO Ventures for Global Health, is a non-profit organization whose mission is to save lives by accelerating the development of novel biotechnology-based drugs, vaccines, and diagnostics to address the unmet medical needs of the developing world. We spur biotech industry involvement in global health product development through synthesis and dissemination of critical information and quantitative analysis, timely collaboration with global health experts, and compelling market-based incentives.

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