

PRIORITY REVIEW VOUCHERS (PRVs)

Fact Sheet



The Priority Review Voucher Program

In 2007 Congress enacted an important market-based incentive for investment in new drugs and vaccines to prevent and treat neglected tropical diseases such as malaria, tuberculosis and sleeping sickness. **This program, to be administered by the FDA, awards a *priority review voucher (PRV)* to the sponsor of a newly approved drug or biologic that targets a neglected tropical disease.** The voucher, which is transferable and can be sold, will entitle the bearer to a priority review for any future new drug application – potentially shaving from four months to as many as 12 months from the standard FDA review.

The world needs new medicines to tackle these devastating diseases. Incentive mechanisms that leverage free markets are essential to harness the biopharmaceutical technologies that have revolutionized health care for developed nations and extend those benefits to resource-poor countries.

Valuing the voucher

The market value of a PRV will reflect the perceived approval time saved and the accelerated revenues of a new blockbuster product. 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 awardee's choosing, or it may be traded or sold.

An intangible benefit of the voucher is the value created for a company if the faster review provides them "first mover advantage," allowing the voucher-holder's product to be introduced ahead of a similar, competing product.

Over the year since passage, companies and investors have reacted positively to the program. One product for malaria has already been submitted for priority review, and could potentially be eligible for a voucher. Ultimately, investors could establish a market for 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, including (but not limited to) tuberculosis, malaria, and leishmaniasis, 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

While the program will apply to a range of drugs and vaccines critical to improving health in developing countries, certain products are not covered to maintain an emphasis on truly novel drugs and vaccines.

Definition of Priority Review

Under current Prescription Drug User Fee Act (PDUFA) targets, FDA aims to complete "priority" reviews of new drugs within six months instead of the standard ten month review period. Actual FDA review timelines, however, can be longer than the target PDUFA review periods, particularly for new products that haven't previously been approved.

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

Products excluded include combination products containing a product previously approved by the FDA, pediatric formulations of existing products, and diagnostics.

Putting the voucher to use

To use a PRV, the holder of the voucher must notify the FDA of its intent to request a priority review 365 days in advance of filing an application. At the time of notification, the sponsor applying the voucher must also pay the FDA an additional user fee to defray the costs of the expedited review. The user fees for the PRV program have not yet been set by the FDA, but should be a fixed fee for all applications and may be adjusted annually.

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

Current status of the program

The program went into effect on September 27, 2007 upon enactment. FDA will award a voucher for any eligible products approved after this date. As of September 27, 2008, following a one-year delay set by Congress, companies that obtain a voucher can now apply them to a future new drug application.

The program is largely self-implementing – no supplemental regulations are needed for the program to operate. FDA is currently accepting comments on its Draft Guidance for priority review vouchers. Comments are due December 19, 2008.

BIO Ventures for Global Health (BVGH), a non-profit organization, is harnessing the resources of the biotechnology industry to create new medicines for neglected diseases of the developing world. Our mission is to break down barriers that hinder industry involvement in global health product development and to catalyze new industry investment.

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