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Priority review vouchers: A shortcut in a drug's race to market

Drug development is expensive and difficult, and companies have traditionally spent little to develop drugs for diseases with unlikely returns on investment. But two regulatory programs for rare and neglected diseases allow companies to earn special vouchers that can be used to accelerate the regulatory review of any drug by several months or sold for profit.

A priority review voucher is a regulatory option contract that gives its holder the right to have one of its products reviewed by the FDA as a "priority" drug in eight months instead of the standard 12 months. Vouchers are earned by getting drugs approved for rare pediatric diseases (affecting fewer than 200,000 people, of which more than half are under the age of 18) like neuroblastoma or any one of 21 FDA-defined tropical diseases such as Ebola or cholera. To be eligible for a voucher, a drug must qualify for priority review and cannot have been approved in the US previously.

Vouchers may be used by the original company or sold to another company. Use of the vouchers is not without risk. Each voucher can only be used once, and there is no guarantee of the product being approved or even reviewed on time. There also is a $2.7 million fee to redeem a voucher in addition to the standard new drug filing fee of $2.4 million. A pediatric voucher may be taken away if the company fails to market the approved drug within one year. Some new fixed-dose combination drugs also are ineligible for vouchers despite being eligible for new drug exclusivity.

To date, nine vouchers have been awarded: three tropical and six pediatric. Four have been redeemed; five have not. Five have been sold or transferred to other companies. All vouchers have been used by or are owned by companies with market caps over $35 billion.

The rare pediatric disease priority review voucher program is scheduled to end in September 2016 unless its authorization is extended by Congress. Existing vouchers would not be affected.

Industry implications

Voucher benefits depend on the context of use. A company using a voucher can benefit from reaching the market four months faster than usual. This time advantage can help a company establish a market lead over competitors, set its preferred price for its drug and nurture familiarity with patients. Faster review allows a company to profit from its drug more quickly and benefit more from its patent life. For an early-stage company, a voucher-eligible product may help boost its valuation and attract investment, aiding development.

Not all products will benefit from a voucher. Companies that have earned or purchased a voucher are likely to benefit most when using the option on a product intended for large numbers of patients. A large patient population allows a company to recoup its cost to obtain a voucher. Some companies may find it makes more sense to sell a voucher than to use it. However, record numbers of new vouchers—five were awarded in 2015—may drive down their prices in the near future.

Voucher benefits still uncertain. In 2015, the first drug was successfully approved using a voucher. The drug was approved a month before a competitor's product with the help of a purchased voucher. Another voucher was used to accelerate the review of another drug in 2011, but the FDA did not approve it at the time. An unsuccessful attempt at using a voucher will mean an even higher cost of drug failure, even if the product is later approved. Even when used successfully, increasing insurer power may decrease the benefit of early market access. Due to the faster review, companies may have to comply with additional post-approval trials or a less favorable label due to the potential uncertainty of regulators.

At a glance

Priority review vouchers are an FDA incentive used to promote development of drugs for rare pediatric and tropical diseases.

The Tropical Disease Priority Review Voucher and Rare Pediatric Disease Priority Review Voucher are highly similar programs created by Congress in 2007 and 2012.

Vouchers may be used to review a new drug four months more quickly than normal.

Vouchers also may be sold. In 2015, the sale of a voucher for $350 million set a new record.

Nine vouchers have been issued to companies to date, of which five were issued in 2015.

Use of a voucher can help companies gain back patent protection otherwise lost to the FDA review cycle.

The pediatric voucher program is scheduled to end in September 2016 unless it is reauthorized by Congress.

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