

Priority Review Vouchers: How Much Are They Worth to Global Health

In September 2007, Congress enacted a new program granting a “priority review voucher” (PRV) to any “sponsor” that receives FDA approval of a product targeting a neglected tropical disease. This fully-tradable voucher entitles the holder to a priority review (a speedier review time) for a future product of their choosing. A group of panelists, including representatives from industry, venture capital, and the FDA joined Dr. Henry Grabowski, one of the Duke economists responsible for creating the mechanism, to discuss the value and potential effectiveness of this new market incentive to spur innovation for neglected diseases.

Companies have limited incentive to invest in medicines for the developing world because of the lack of a sufficient market opportunity for these products. New programs, such as PRVs and the Advance Market Commitment (AMC) pilot through the GAVI Alliance, have been created to enhance the market value for neglected tropical disease products and create incentives for industry to take the development risk.

Under PRVs, the voucher can shorten the review process by six to 12 months. If applied to a blockbuster product, Grabowski estimates the voucher could be worth up to \$300 million. If true, this sum enhances the value of an otherwise unattractive market and helps offset a risky investment.

Companies like Merck see the voucher as a great opportunity, according to Diana Lanchoney of Merck Vaccines and Infectious Diseases. “The impact of PRVs will be to pull forward products for tropical diseases.”

According to Grabowski, half of the blockbuster drugs approved in 1990s received standard reviews. “So the thinking was, if a company were expecting to enter a large market, a priority voucher could have large value.”

The actual value of the voucher, according to Leighton Read, a general partner at Alloy Ventures, depends on a number of factors including the product (including whether another company is in the race to be the first to market), the

anticipated sales of the product and the number of vouchers already in circulation.

PRVs, which are fully financed through user fees, play off of the competitive nature of the market. The promise that one company’s product can reach the market before a competitor’s gives the company an important edge in a very competitive field. Grabowski explained that this early-mover advantage is similar to a patent extension because, in financial terms, it achieves the same end.

How FDA chooses to implement the program has everything to do with the program’s success. One of the main tenets of the PRV is the transferability of the voucher. The panel agreed that full transferability, with no limits on the number of trades, is essential for the program to achieve its full impact.

In addition, panelists questioned whether FDA is prepared to review an NDA for a product not intended for use in the US. Tim Cote, director of Orphan Product Development, the office in charge of overseeing the new program, responded that the FDA “is blind to where the drugs will be used, but we’re committed to reviewing the applications.” How FDA will calculate the benefit/risk ratio for these products remains unclear.

Panelists called on FDA to provide players clear guidance as soon as possible. “In the case of drug development, the very long time frames between when capital has to be put at risk creates special conditions for portfolio management and economic behavior,” according to Read. “Having a point of view on how the FDA will act on something 2-4 years in the future is important.”

All agreed that the new program creates exciting new opportunities for global health. The ingenuity of the program, according to Diana Lanchoney of Merck Vaccines and Infectious Diseases, is that the voucher “leverages all the competitiveness for primary care in the developed world with primary care in the developing world.”

MODERATOR:

J. Leighton Read, MD
General Partner
Alloy Ventures, Inc.

PANELISTS:

Nancy L. Buc
Partner
Buc & Beardsley

Timothy R. Cote, MD, MPH
Director, Office of Orphan
Product Development
US Food and Drug
Administration

Henry G. Grabowski, PhD
Director, Program in
Pharmaceuticals and Health
Economics
Duke University Fuqua
School of Business

Diana M. Lanchoney, MD
Executive Director,
Developing World
Strategic Integration
Merck Vaccines and
Infectious Diseases

