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# KEI Comments to the Priority Review Voucher Mechanism

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Knowledge Ecology International (KEI) is a non-profit organization with offices in Washington, DC and Geneva, Switzerland, that searches for better outcomes, including new solutions, to the management of knowledge resources. The following are our comments on the FDA Priority Review Voucher Mechanism.

## Background

The new section 524 of the Federal Food, Drug, and Cosmetic Act requires the Secretary to award transferable priority review vouchers to developers of certain tropical disease products. The priority review voucher (PRV) has been created to induce innovation and investment on new medicines. The PRV holder can use or sell the right to accelerated evaluation and market approval for unrelated products.

The PRV is valuable for products that do not otherwise meet the FDA's requirements for priority reviews. The value of a PRV is unknown, but has been estimated to have a market value of $50 to $600 million.

The PRV program exists in combination with other incentive programs. For example, an innovator could qualify both for the PRV and for benefits under the Orphan Drug Act that allow a company to receive extended U.S. market exclusivity, and tax credits equal to as much as 50 percent of the cost of clinical trials.

## Comments on the PRV

KEI welcomes the initiative of Senators Brownback and Brown to stimulate investment in new drugs and biologics for diseases "for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations."Our comments are designed to address areas where the PRV could be strengthened.

### Scope of diseases.

Section 524 lists 16 diseases that qualify for the PRV, plus a general criteria for other infectious diseases that could be added by regulation. Chagas Disease should be added as a qualifying disease.

### Transferability of voucher

The transferability of the voucher is essential, as it extends the benefits of the initiative to the broadest range of actors, including smaller firms or non-profit product development partnerships that are not likely to have an internal use for the voucher.

### Affordability of end products

The PRV as currently designed has the capacity to reduce the innovation gap for neglected diseases, but

without assurances that products will be affordable. As currently implemented, the PRV is a "complementary" incentive scheme that allows the innovator to maintain its intellectual property rights and has no mechanisms attached to address the pricing of resulting products.

To the extent permitted by the statute, or allowed by a future amendment to the statute, the benefits of the PRV should be linked to measures to address access by poor persons. These should include an obligation to price products at affordable prices, and to license patents and other intellectual property rights to generic suppliers. The licenses to generic suppliers could be limited to a specific field of use (the neglected disease for which the PRV was based), and to countries not designated as high income by the World Bank. Alternatively, a beneficiary of a PRV could agree to license the product through the UNITAID patent pool for medicines.

## Transparency

Policy in this area was based upon a theory of how the PRV would work. Over time it will be important to have evidence of how the PRV actually works in practice. Given the enormous value of the PRV, and the public interest in evidence based policy making, there should be obligations for disclosing certain data. The transparency that would be most useful would include the following items:

1. How much money was spend on the clinical trails used to register the PRV product?
2. To what extend did the product benefit public sector grants, tax credits and other subsidies and incentive mechanisms?
3. How much money was the PRV worth when traded in the market?
4. How was the product priced?
5. Where has the product been registered for use?
6. How many people have access to the product?

## Extensions to cases where active ingredient was previously approved

The current design of the mechanism excludes its applications to products whose active ingredient (including any ester or salt of the active ingredient) has been approved in any other application. The discovery of new uses of existing products, including the development of new combination therapies, will not be rewarded.

This limitation is not necessarily a defect in the current formulation of the PRV, where only a registration of the product is necessary to trigger the benefit. However, in some proposals to modify the PRV, it would be appropriate to revisit this limitation.

## Unintended Consequences of the PRV

By design, the PRV provides for an accelerated review for unrelated products that have otherwise failed to achieve priority review status. There is some concern that an accelerated review may increase the risks to patients.

Another concern regarding the PRV is that it may decrease the willingness of persons to share

knowledge, data, materials and technology, without prior payment or agreements to share in the benefits of the PRV.

### Abuses of the PRV involving old products not yet registered in US

According to news reports, Novartis is attempting to claim the PRV for a U.S. Registration of Coartem for malaria. While Coartem had not been registered in the U.S., the product had been used for years in developing countries, often subsidized by the PEPFAR or Global Fund programs. This is an abuse of the PRV. No PRV should be granted for products that have already been developed, marketed and used in developing countries prior to the enactment of the PRV program.

## Future Reform of the PRV

The FDA and the Congress should consider further reforms of the PRV. In particular, if the PRV is to be the instrument for funding R&D incentives, consideration should be given to auctioning off a fixed number of PRVs per year, and using the proceeds for a prize fund for neglected diseases. The prize fund should be used to reward developers of new medicines, diagnostics and biologics for neglected diseases. The fund should be a proportional reward system, with larger proportional rewards being given to products that have greater incremental health benefits, and that are used by more patients. The payments could be made over a ten year period of time, based upon evidence of utilization and efficiency in each year, for all qualifying products.

If a prize fund with proportional rewards is used, the qualifying products could be extended to new uses of older medicines, to the extent that the new use was rewarded for its impact on health outcomes in developing countries, in the specific field of use that qualifies for the PRV. This could be further limited to the impacts in countries not defined as high income by the World Bank.

As noted above, the benefits of the prize fund could be linked to requirements for reasonable pricing and open licensing of inventions.

The prize fund could also include an "open source or access to knowledge dividend." This would be the sharing of a a fixed proportion of the reward generated for a product to persons or organizations that provided non-remunerated and non-discriminatory access to knowledge, data, know-how, and technology. For a qualifying product, the open source dividend could be decided by a time limited jury, evaluating competing claims.

## For more Information

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