

PRIORITY REVIEW VOUCHER PROGRAMS

Priority review vouchers (PRVs) provide a powerful incentive to stimulate drug development for underserved diseases or conditions. These conditions often lack the market opportunity to attract substantial investment or may present other significant development obstacles and costs that may deter investment from biopharmaceutical companies. The programs work by granting a priority review voucher to a drug developer who develops and gains approval for a therapy that treats a (1) **neglected tropical diseases**, (2) **rare pediatric diseases**, or that is a (3) **medical countermeasure**. A priority review voucher allows a drug developer to speed the review of another therapy from 10 months to 6 months, while still meeting the regulatory standards of safety and efficacy. The opportunity for priority review incentivizes R&D and the speed by which therapies are delivered to patients.

When a sponsor presents a voucher to FDA for priority review, the Agency aims to review the application within **6 months**, versus **10 months** for a standard review.



Neglected Tropical Diseases

The priority review voucher program was originally established in 2007 in order to encourage the development of therapies to treat neglected tropical diseases. Diseases that are considered neglected tropical diseases include [malaria](#), [tuberculosis](#), [dengue](#), [zika](#), and [Ebola](#), among others.

This program has been made permanent and does not have a sunset date.

Rare Pediatric Diseases

In 2012, through the Advancing Hope Act, and in 2016 through subsequent reauthorization in the 21st Century Cures Act, drugs approved for the treatment of a rare pediatric disease are granted a priority review voucher. Some examples of diseases where a therapy has been developed and a voucher has been issued, include: [cystic fibrosis](#), [Duchenne muscular dystrophy](#), [certain types of leukemia](#), [lysosomal storage disorders](#), and [spinal muscular atrophy](#).

FDA may not award any rare pediatric disease priority review vouchers after September 2020, unless the drug is designated as a drug for a rare pediatric disease and receives marketing approval by September 2022.

Medical Countermeasures

In 2016, through the 21st Century Cures Act, drugs approved as a medical countermeasure also become eligible to earn a priority review voucher. Medical countermeasures are drugs to prevent or treat harm from a [biological](#), [chemical](#), [radiological](#), or [nuclear agent](#) identified as a material threat.

Currently this voucher program is not permanent and will expire in September 2023.