Introduction

The Priority Review Voucher (PRV) programme was developed in 2007 as an incentive to manufacturers to invest resources towards developing treatments for rare tropical and pediatric diseases. The programme was initiated to encourage companies to develop treatments for diseases that are traditionally neglected in favor of more common, more profitable conditions. The programme recognizes the unique challenges associated with drug development for these diseases, and provides manufacturers with a priority review for a new drug application that has been approved by the US Food and Drug Administration (FDA). The programme is designed to incentivize companies to develop treatments for diseases that do not have adequate treatment options, by providing a shortcut to regulatory approval.

Objective

The objective of this analysis was to understand the commercial and evidence quality implications of the PRV acquisition and eventual redemption to shorten the pre-approval timeline.

Methods

The study employed a descriptive literature review, including public company share price analysis, academic journal articles, pharmaceutical industry news sources, and FDA data to assess the use and transfer of PRVs, as well as their impact on bringing market authorization and subsequent evidence assessment.

Results

As of May 2017, 14 PRVs have been granted for a variety of rare tropical and pediatric disease treatments. Of these, 10 have been transferred to other manufacturers, but only two of these transferred vouchers have been used to date. The remaining vouchers clear to the public.

- PRVs have been used sparingly due to factors such as high upfront cost, the need for additional manufacturing capacity, and the long timeline required to bring the new drug to market.
- Manufacturers must pay an additional ‘user fee’ to the FDA for the acquisition and eventual redemption to shorten the pre-approval timeline.
- The acquisition of a PRV could become a critical tool to support competitive differentiation, as well as an attractive formulary position, and the opportunity to initiate the collection of real-world evidence earlier than competitors.

Conclusions

While PRV acquisition and subsequent employment may provide a product with some enhancement of its long-term position, the late-stage time gap and lack of technology alignment may counteract other benefits. The absence of benefits using a voucher route as earlier stated promises a less significant promotion. Near-term attractiveness for regulations of promotion are and the opportunity to improve on a mix of reduced evidence earlier than company. Sleeping scheduling and focusing on the opportunity to demonstrate clinical and economic attributes of the two PRVs, as well as willingness to adjust their approach to not only meet FDA requirements but also industry standards when reviewing new applications, which has been received with mixed reviews. The prevalence of PRV could descend a critical tool in supporting differentiation, as well as an attractive formulary position, and the opportunity to initiate the collection of real-world evidence, particularly when considering comparisons across approval rates of PRVs and over greater clinical and economic value assessment once approved by the FDA.

References

3. Carroll J. FierceBiotech: AbbVie hands United a record $350 M payoff for a speedy FDA review voucher, August 2015
4. Sanofi . Sanofi Receives FDA Approval of SOLIQUATM 100/33 for the Treatment of Adults with Type 2 Diabetes, November 2016
5. AMGEN. AMGEN Reports Fourth Quarter and Full Year 2016 Financial Results, February 2017
6. Tropical Disease Priority Review Vouchers: Guidance for Industry
7. TOBI PRP-COMPARE: A Randomized Clinical Trial Comparing PRP and tobramycin in Chronic Suppurative Lung Disease
8. Comparison of the therapeutic effectiveness of topical STREP A and ERYTHROMYCIN for the treatment of bacterial conjunctivitis
9. AMGEN. AMGEN's ERASURE(TM) (nibotinum mepetabole) Receives FDA Approval for the Treatment of Chronic Wound Care
10. BaxTER. Baxter Receives FDA Approval for NECTAVEN(TM) for the Treatment of Hepatitis C in Patients Who Have Not Responded to or Tolerated Previous Direct-Acting Antiviral Therapy
11. Genentech. Genentech Reports Positive Results from the Phase 3b Trial of GENETIX(TM) in Patients with Advanced Head and Neck Cancer
12. Sanofi . Sanofi Receives FDA Approval of SOLIQUATM 100/33 for the Treatment of Adults with Type 2 Diabetes, November 2016
13. PWC. Regulatory Spotlight – Priority Review Vouchers: A shortcut in a drug’s race to market
15. GOH. Cost of Care for Patients with Adult-onset Still Disease
16. Gilead Sciences. Gilead Sciences Receives FDA Approval for ODEFSEY(TM) for the Treatment of Adults with Chronic Hepatitis B
17. CPCOR. CPCOR Envisioned Solutions for the Pediatric Patient: Understanding the Needs
18. GLP1 combination), cholesterol (PCSK9), and HIV (single-tablet combination).
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