MAN_02 - Development of a market projection methodology, based on clinical data, for decision making on investments in biosimilars

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Introduction: Biotherapeutic products has revolutionized the treatment of many chronic and life-threatening diseases, as cancer. The expiration of this patents allowed the development of biosimilar products, that are similar and cheaper than original products. Pembrolizumab, an anti-PD-1 monoclonal antibody, has been approved by ANVISA for 8 different types of cancer, but only one of them is recommended through the SUS. The present study shows a methodology to help decision-making public managers.

Objective: Perform a demand and price projection study, through the pembrolizumab case, in order to establish a methodology for decision-making in the area of biosimilar development.

Methodology: Retrospective cross-sectional study using publicly available Brazilian data from 2010 to 2019. It was calculated the potential number of Pembrolizumab prescribed patients from each of the indications approved by ANVISA, using INCA data. [HGTD1] This data was used to calculate the estimated percentage of users (target-group), considering 6 months of treatment, the overall survival and the percentage of beneficiaries. From these data, a trend of annual increase in the number of pembrolizumab vials was projected aiming at 3 different scenarios of possible incorporation into the SUS. Afterwards, a set of price premises were established, based on and Bio-Manguinhos experience in the biotherapeutic market, in order to estimate the gross revenue potential of this therapy after patent drop (2028).

Results: The study showed that in 2019, 64,683 patients would be eligible for Pembrolizumab in Brazil. In the projections there is a repressed demand when compared with the purchase historic in both markets (public and private). For the 3 scenarios of indications approval were applied a price projection based on CMED table and the following factors applied: entrance of competitors, decrease trend of price along the years, projections of price's discounts and the disease incidence projection. The study pointed out a potential demand of vials varying from 932.405,97 to 39.236,85, what represents a gross revenue of R$ 5 bi and R$ 210 mi by 2029, respectively, depending on the scenario analyzed.

Conclusion: The incorporation of Pembrolizumab biosimilar in the Bio-Manguinhos project portfolio represent a feasible economic choice for R&D development, which may contribute to the drug price reduction and expansion of access to this treatment by SUS cancer patients. The methodology developed for this study showed that real-life clinical data could represent a benchmark for the decision-making of including other biosimilars in the R&D portfolio.

Keywords: Real world data; Medicine access; Biosimilars