A conceptual modeling framework for manufacturers to navigate the Inflation Reduction Act and to negotiate a "fair maximum price"

HPR122

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Background

The Inflation Reduction Act (IRA)[1] became law in 2022 in the United States (US). It includes section 1194 (e), the Prescription Drug Pricing Reform (PDPR). In this PDPR, when a single-source drug with the largest total expenditures in Part B and D of Medicare is selected, the manufacturer must then negotiate a Maximum Fair Price (MFP) with the Centers for Medicare & Medicaid Services (CMS). A drug can be selected after being on the market for 9 years (small molecule drugs) or 13 years (biologics)[1]. A first selection of such drugs, done in Q3/2023, will see the result of price negotiations in 2026[2,3].

CMS defines nine input parameters that can influence the MFP. Potential inputs for each of those parameters and the relationship between them are also shown in **Figure 1**. Among those inputs, a few are worth mentioning, compared to a traditional modeling perspective used in Health Technology Assessment (HTA) countries:

- Comparative effectiveness could include the protection of vulnerable persons (e.g., elderly, disabled, or terminally ill individuals) and estimate other outcomes not associated with life extension. In doing so, CMS goes beyond the use of traditional outcomes such as quality-adjusted life years (QALYs) and may consider patient productivity and caregiver burden for comparative purpose.
- Relatively novel and innovative methodologies could be used to quantify health inequalities in the Distributional Cost-Effectiveness Analysis (DCEA) since this consideration is new and specific to the US[5].
- Single/multiple indication(s) and drug repurposing could also indirectly impact inputs such as Research and Development (R&D) costs.
- Federal financing is a US-specific input. CMS has not defined how it will impact the MFP, leaving the door open to interpretations.

This study aimed to develop a conceptual modeling framework to assess what an MFP offer from CMS might be and help manufacturers develop a counter-offer.

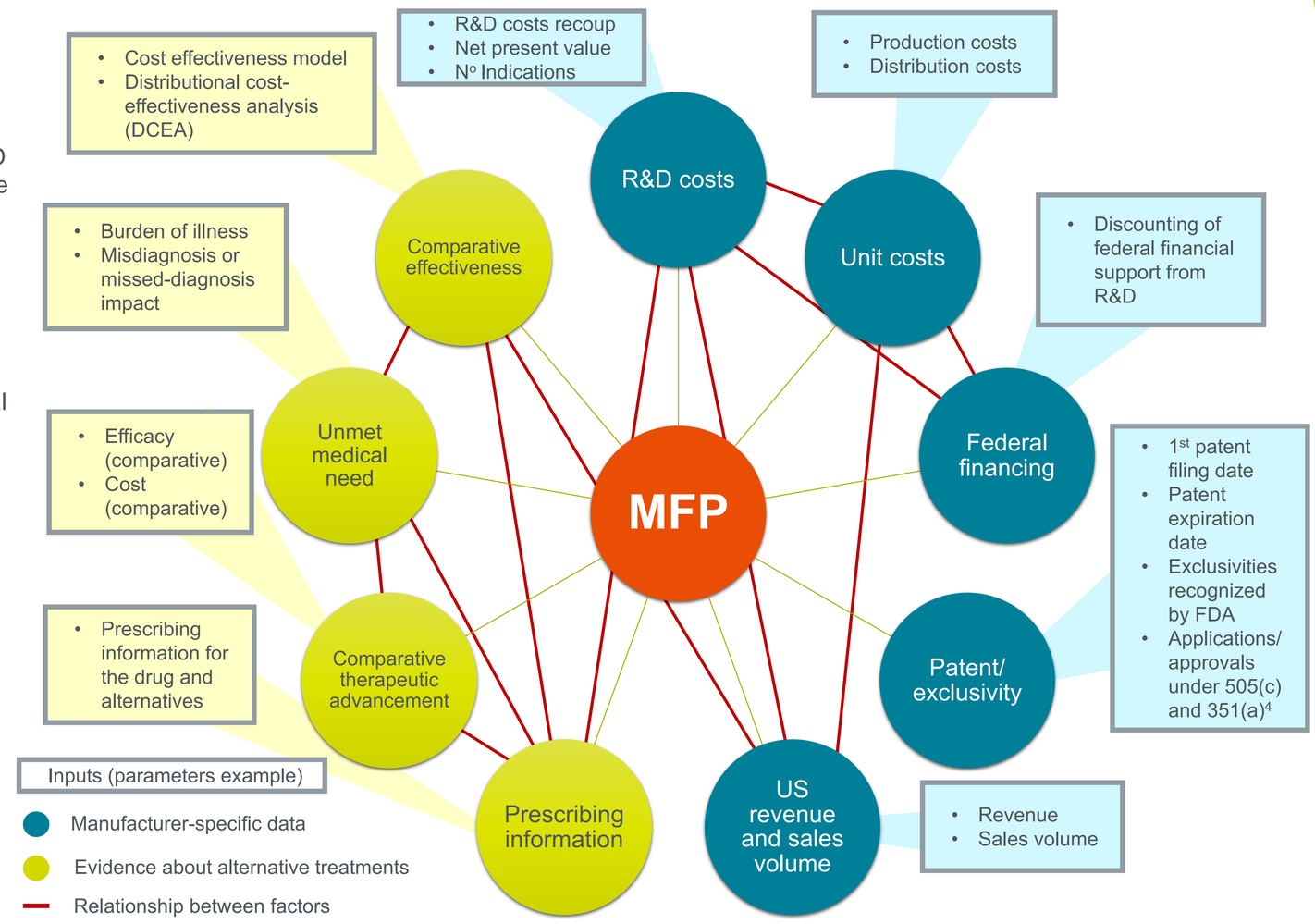


Figure 1. Maximum fair price inputs and parameters

Methods

We first extracted and prioritized the various elements MFP. These elements were then classified in a sequence of a discrete number of steps. Put together, the aim of our framework is to allow for a simple, progressive calculation and an independent analysis of the MFP (augmented by scenario analyses, if needed). Finally, we briefly compared pricing re-negotiation frameworks in HTA markets (European countries and Canada, for instance) to inform of potential impact of IRA on how methodologies for pricing re-negotiations might evolve in the HTA markets.

Results

Our MFP framework (**Figure 1**) classifies the nine input PDPR parameters into two broad categories: Comparative Adjustment Factors and Negotiation Adjustment Factors.

Based on the US FDA prescribing information of the selected drug (e.g., indication, and dosage forms and strengths) our starting point price is the Part D net price or the Part B Average Sales Price(s) (ASP). Comparative Adjustment Factors (regrouping unmet needs, comparative effectiveness, and comparative therapeutic advancement) allow us to define a Preliminary Price in a second step. Afterward, Negotiation Adjustment Factors (including unit and R&D costs, federal financing, patent and exclusivity elements, and revenue / sales volume) ends up with a new cost, targeting the highest MFP possible (not exceeding, however, the ceiling price defined by CMS)[2,3].

All these factors, their interconnection, and the proposed inputs for each of them enable the manufacturer to estimate a plausible MFP based on negotiation. Depending on the inputs provided and their relationship (e.g., unit cost and R&D), the manufacturer can evaluate the consequences of adjusting the preliminary price upward or downwards or the application of no adjustment.

Uncertainties with the MFP framework

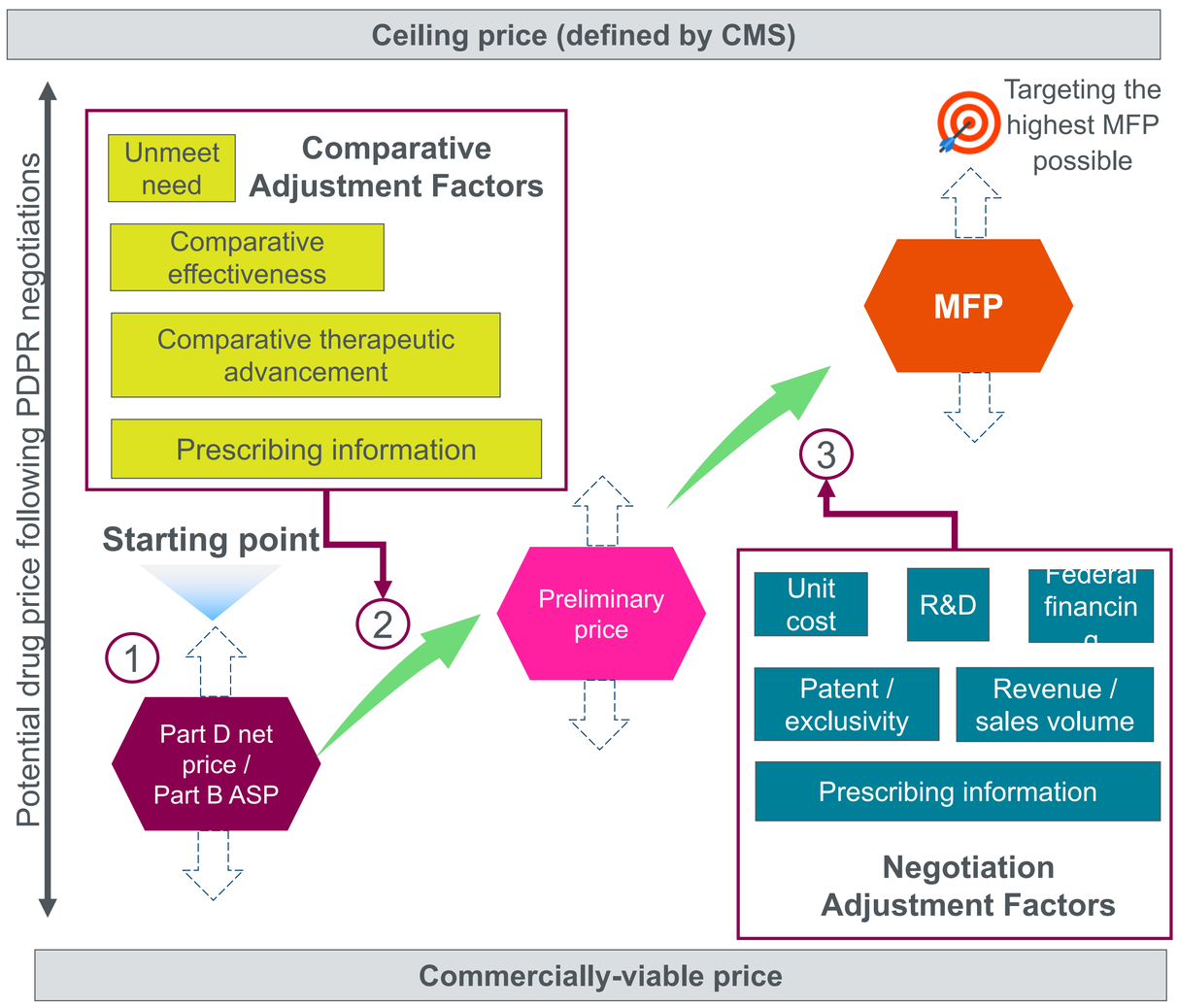
Although guidelines have been provided by CMS, the specific methodology employed by CMS to derive the MFP remains unknown and is expected to evolve throughout the process.

Key uncertainty is around how CMS will choose a comparator for baselining MFP. Second, it is unclear how Federal financial support will be integrated, considering that many drugs have received some form of financial support during their R&D process. Further discussion is also needed on what methods will be utilized to establish price thresholds in the absence of QALYs. These uncertainties are tackled in our framework with scenario analyses.

Comparison outside of the US

The timing of the PDPR negotiation in a drug life cycle is similar to price revisions in HTA countries. Besides catching up on most major parameters that were not evaluated when a drug was launched, the PDPR also introduces factors that are partially used or could be introduced in HTA countries in the future, such as the number of indications and health inequalities (in the DCEA). Our framework can inform HTA markets of the potential spillover effect of the PDPR when these factors would be introduced.

Figure 2. Conceptual framework - maximum fair price calculation sequence



Conclusions

- The Inflation Reduction Act in the US provides a broad summary of the factors that will be used to assess a calculated maximum fair price as the basis for determining the offers and counteroffers.
  - By leveraging all factors in three steps, our modeling framework allows for a simple, progressive calculation and an independent analysis of the MFP.
  - Anticipating the PDPR implementation, our modeling framework allows manufacturers to develop optimal strategies and pre- / post-launch activities in preparation for potential negotiations with the Centers for Medicare & Medicaid Services.

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