Background

International Pricing Index (IPI) model has been proposed in the United States (US) with the aim to reduce Medicare Part B medicines expenditures. IPI model may introduce the external references pricing (ERP) mechanism to the US market during 2020.

The proposed IPI model reference basket (RB) from October 2018 consists of 14 countries (AT, BE, CA, CZ, DK, DE, FR, GB, GR, IT, PT, NL, UK). The final price would be determined based on the ratio between spending under the US Average Sales Prices (ASP) and the average of medicines prices from the IPI basket.

IPI model countries frequently use ERP mechanism to regulate prices, i.e. referencing to other IPI or “non-IPI” countries and thus creating an interconnected ERP environment.

Objectives

To create a model of a new ERP environment with the following objectives:

- Analyze the average price ratio between the US and IPI model countries.
- Analyze the potential indirect impact of price drops in the non-IPI countries to the average price in the US via the IPI model.
- Describe the potential US price erosion mechanism.

NOTE: The criticism of the IPI model from the US conservative groups side.

Methodology

Price ratio

A sample of 25 active molecules was defined for the analysis based on the following rules:

- A model of medicine Plan B medicines with the highest sales price (March 2019).

Medication is administered in Europe (IE, Japan), and Canada.

Ex-factory package price levels were extracted in Cogvi Price Monitor in March 2019 (aggregated database covering EU publicly available sources of medicinal product prices – Member states and others). Subsequently, the ratio of US price to average unit price from the IPI basket was calculated. Analysis of prices was performed in EUR (Exchange rates – March 2019). This potential bias of biosimilarization/generificaton must be noted as the model should represent the potential real situation at the time of the IPI model implementation.

IPI ERP model

A model of the new ERP environment has been developed. The model encompasses:

- Countries
  - The US, also called the “master” country
  - Primary countries, i.e. IPI model basket countries
  - Secondary countries, i.e. all countries referenced by primary countries
- ERP Rules
  - IPI basket countries – an average of prices from the proposed IPI basket countries
  - Rules for IPI model countries – a systematic search for national regulations was performed in March 2019 and the model was created based on the results (i.e., the simplified model did not consider the differences in frequency of price revisions for each country)

Price drop simulation

This following simulation was performed using the created ERP model:

- An equal initial price was set for a virtual medicine in all countries included in the model
- Drops from 90% to 99% (with 10% increments) in ex-factory price of the medicine were simulated in each secondary country individually
- External price referencing was performed for all of the primary countries
- The US referenced the countries in its IPI reference basket
- The impact of price drops in countries was measured as a change in the original US price in percent

Results

Price ratio

25 active substances with 54 unique packages were included in the analysis. Figure 1 shows the price ratio between the US and average IPI basket package prices per active substance ranged from 1.0 (laptevotin and idarucizumab) to 4.6 (dolomirin) with average 3.3 for the US (i.e., 2.2 higher prices than in the IPI basket).

IPI ERP model

IPI basket countries (12 EU countries + Canada + Japan) are reference to a pool of 2 non-IPI countries (with 10% increments) in ex-factory price under the US Average Sales Prices (ASP).

The simulation showed that from the EU countries not included in the IPI proposal, Spain and Sweden had the greatest impact on the US price at all levels of price drops. Norway and Switzerland were omitted from the figure since they had less than 5% impact on the US price across all levels of price drops.

Discussion

Pharmaceutical companies may adjust their global pricing strategies to maximize revenues due to the interconnected ERP environment. Experience shows larger and economically stronger markets to be of higher priority for access.

As a consequence, traditional “low priority markets” in EU which are frequently referenced by the IPI model reference countries may experience additional delayed patient access to innovative medicines if they represent a potential “harm” to global revenues.

11 out of 14 IPI countries come from the top EU region countries ranked by GDP per capital in PPP (Int$), Sweden and Spain are the only two non-IPI countries from the top 10 EU countries by GDP per capita in PPP (Int$), not included in the proposed model. At the same time, Spain has the highest population size from non-IPI countries, which makes it less likely to experience an additional delay despite the findings of our analysis.

On the other hand, Sweden has the highest GDP PPP (Int$) from non-IPI countries, however, its population size is almost 5-times smaller than that of Spain.

Conclusions

The measured ratio of the US to the average IPI basket price on the selected sample showed medicines to be 2.3-4.6 times more expensive in the US - results are consistent with other available analyses. The IPI proposal intends to curb the ratio and alleviate the spending on expensive medicines in the US. This IPI model is designed to be rolled out in 5 years, each year increasing the reliance on the ERP calculated price.

Our model of the interconnected ERP environment and subsequent simulation proved and quantified the impact of non-IPI countries (three referenced by the proposed IPI model countries) to US prices. Spain (the 4th IPI country not listed in the IPI model) and Sweden have the biggest potential to indirectly impact the US in our simplified model. Other countries with potential impact are Portugal, Hungary, Slovakia, Lithuania, Poland, Latvia, and Slovenia (referred by IPI basket countries).

Pharmaceutical companies may adjust their global pricing strategies with a consequent delayed patient access to innovative medicines in both IPI and non-IPI countries.

References


