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IMPACT OF IMPLEMENTING INTERNATIONAL REFERENCE PRICING ON PHARMACEUTICAL PRICES FOR UNITED STATES MEDICARE

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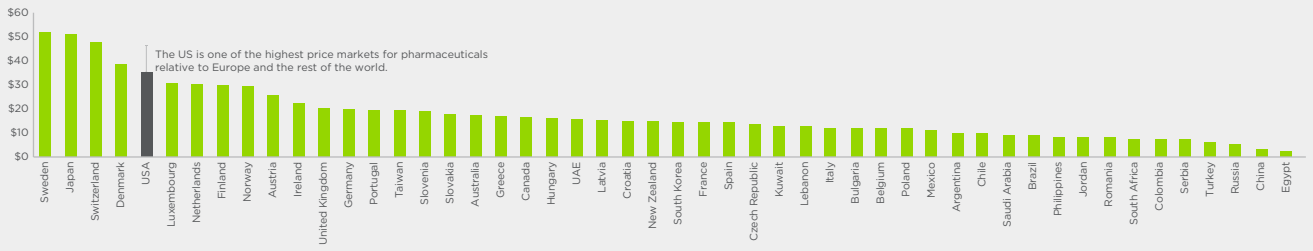
INTRODUCTION

- The ex-factory prices of pharmaceutical drug interventions in the United States are greater than those in Europe and the rest of world, with instances of U.S. price differences exceeding 200 – 250%.
- The majority of established pharmaceutical markets use pricing rules that reference products both across IRP (International Reference Pricing) and within TRP (Therapeutic Reference Pricing) country-lines, as effective measures to control the price of pharmaceutical products.
- The U.S. is the only developed market that does not employ the use of IRP to control pricing; moreover, the House of Representatives investigative panel is mounting continuous pressure on manufacturers to review the rising cost of prescription drugs and associated cost to patients.
- Given countries across Europe have been successful at employing IRP to control their prices, a similar approach may be useful for the USA, with a potential to limit parallel trade between neighboring markets.

METHODOLOGY

Prices by markets were obtained using aggregated sales and volume data across respiratory products using IMS MIDAS, applying a weighted average.

Weighted average PTW price by market at month 1

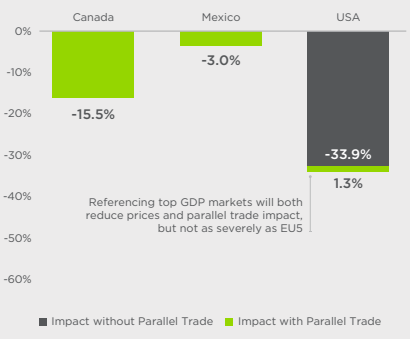


- Navigant's PROFILE model (Pricing and Revenue Optimization For International Launch Excellence) was used to simulate the impact of IRP, to quantitatively assess the impact of introduction of U.S. referencing with respect to other global markets.
- Respiratory products were analyzed as a class to prevent a biased analysis towards particular manufactures assessing impact of U.S. reference baskets including:
  1. Average of Top-5 Gross Domestic Product (GDP) ex U.S. (China, France, Germany, Japan, United Kingdom)
  2. Average of neighboring markets (Canada, Mexico)
  3. Average of EU5 (France, Germany, Italy, Spain and United Kingdom).
- Navigant's PROFILE model assessed relative changes in revenue due to IRP with and without parallel trade; volumes were aggregated by market and flat-lined across 10 years.
- In each scenario, the U.S. reference rule was assumed after 18 months of constant price (no price increases assumed), assuming re-referencing every 12 months.
- These scenarios did not test for the implications of TRP and generic entry.

RESULTS

SCENARIO 1 (FIGURE 1)

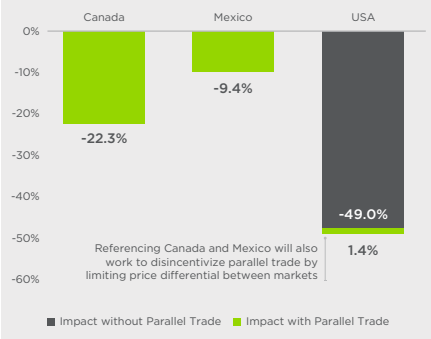
Relative percentage change in revenue vs. baseline due to referencing of top 5 GDP markets excluding USA (China, France, Germany, Japan and UK)



USA references high GDP markets consisting of higher-priced pharmaceutical markets. Scenario results in deflation of price at 39% at first referring time-point **(Figure A)**, with overall revenue decline of 34%, triggered by price development.

SCENARIO 2 (FIGURE 2)

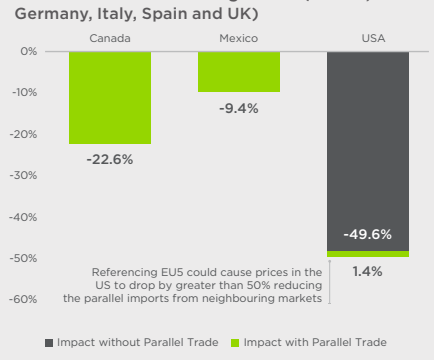
Relative percentage change in revenue vs. baseline due to referencing of neighboring markets (Canada and Mexico)



Referencing Canada and Mexico has the greatest immediate impact on price (61%; **Figure A**). This will help disincentivize parallel trade as illustrated by percent revenue decline in Canada and Mexico between baseline and modelled scenario (22.3% and 9.4% revenue decline in Canada and Mexico).

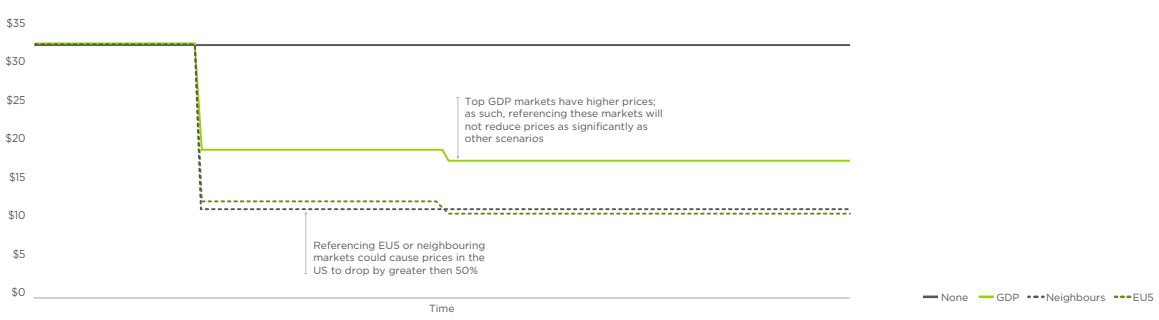
SCENARIO 3 (FIGURE 3)

Relative percentage change in revenue vs. baseline due to referencing of EU5 (France, Germany, Italy, Spain and UK)



Referencing EU5 will drive the largest price decline over a 10 year period (maximum percentage difference of 62%), due to inclusion of low-priced markets (e.g. Spain) whose price is influenced by price evolution throughout the EU. Additional price decline further limits parallel trade revenue in Canada and Mexico vs. Scenario 2.

Figure A: Aggregated 10 year PTW price evolution by IRP referencing scenario



CONCLUSIONS

- The U.S. price evolutions follows a unique trend vs. other markets, as it allows for price increases on a semi-annual/annual basis.
- Navigant utilized its PROFILE Model that can be used to employ varying IRP and TRP rules that can assist manufacturers in developing a comprehensive pricing strategy capable of evolving over time; PROFILE was used to assess the implications of reference pricing in the U.S.
- Inclusion of IRP into pricing decisions will have a significant impact in driving pharmaceutical price decline in the U.S. and in reducing price differential between North American neighboring markets.
- Parallel trade import – particularly from Canada – may be reduced following inclusion of price control mechanisms such as those employed across Europe.
- In general, studies suggest reference pricing can serve an ideal role in supporting the Affordable Care Act (ACA) by controlling pharmaceutical costs, reducing the gap between federal budget and cost of insuring all U.S. citizens[1]; however, previous studies have suggested the significant challenges of employing such mechanisms within the U.S. market[2].

Sources: [1]Marie Salter, 35 Nw. J. Int'l L. & Bus. 413 (2015);
[2]Panos & Reinhardt, Health Affairs 22, no.3 (2003):16 – 30

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