Drug Price Negotiation Outside the U.S.

Recent Examples from Trade Press

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INTRODUCTION

This resource provides information from trade press on pharmaceutical price negotiations in different countries where pharmaceutical prices or spending are regulated at the national level. Even in the context of government regulation, the process is considered a negotiation. It is a negotiation, but governments have a price point in mind which seems to be the upper bound for the result of a negotiation. This is roughly similar to the new process of Medicare negotiation which arrives at a Medicare Maximum Fair Price (MFP). The ex-U.S. processes are also similar to how state all payer, all purchaser upper payment limits on certain high-cost pharmaceuticals would work.

In Europe and elsewhere, companies can choose to exit the market, but very few do so.¹ Examples of companies that exited the market are included in this resource.

It is interesting to note that negotiations occur on drugs that enter an ex-US market at prices considerably lower than the US price and those lower prices are considered too high, so negotiations start from that lower in-country price.

There has been a good amount of coverage of price negotiations in China since the process is newer than the process in other countries. And of course, something is newsworthy when there is a problem, or something is otherwise unusual. The sample of news articles in this document reflect that. There are links to all the articles.

The document also includes information price comparison charts from publicly available literature.

¹ It is <u>reported</u> that several pharma companies have pulled products out of the Turkish market. The issue is not a matter of price negotiation but an issue with the exchange rate in a country with very high inflation. US national news sources have periodically covered Turkish government management of the economy over the past several years. These pharma company actions seem to part of the larger swirl of country-wide economic problems.

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Drug Price Negotiation Outside the U.S.

I. DRUG COMPANIES NEGOTIATE RATHER THAN BOYCOTT

This section provides trade press headlines about drug price negotiations in other countries. It is not an exhaustive list of all the articles but provides a sample of the countries that negotiate and how the industry responds to difficult negotiations.

"<u>After</u> Pfizer offers discount, NICE gives thumbs up to breast cancer drug Talzenna"

By Kevin Dunleavy Jan 19, 2024. Fierce Pharma

Highlights: Pfizer agreed after six months of negotiation to "slash" the price of its cancer drug. *Before* UK negotiations, the launch price was \$6,300 (US)/30 days/1mg and \$2,100/30ays/.5mg. The US price is \$19,000 and \$6,300, respectively.

"<u>Gilead</u> prices hepatitis C giant Sovaldi in China at one-fifth the U.S. price: report"

By Arlene Weintraub Nov 28, 2017. Fierce Pharma

Highlights: Gilead agreed to drop the Sovaldi price in China to \$8,940 in 2017, which was still 80% less than the US price (which had also dropped to half its 2013 launch price of \$84000 for a 12-week regimen). *Note that China had previously negotiated prices and created a formulary* ~2009. *It did a major renegotiation prior to 2020.*

"<u>NICE</u> changes its tune on J&J's Zytiga"

By Emily Wasserman Mar 21, 2016. Fierce Pharma

Highlights: The prostate cancer drug Zytiga was too costly and was not going to be reimbursed in the National Health Service. Through negotiations, J&J lowered the price and agreed to cover the full cost of the drug after the first ten months of a patient's treatment.

"AbbVie, Novartis and more win national coverage in China even as Pfizer's Paxlovid gets left out"

By Angus Liu Jan 18, 2023. Fierce Pharma

Highlights: Brand drug manufacturers cut prices an average 60% off their in-market China prices to be on the Chinese national list. Pre-negotiation prices in China were already substantially lower than US market prices. Notable companies offering deep discounts include Biogen with Tecfidera for Multiple Sclerosis and gene therapy Spinraza. Roche cut the price of its gene therapy Evrysdi by 94% of its in-market China price.

"China wins major price cuts on patented drugs"

By EJ Lane May 22, 2016. Fierce Pharma

Highlights: Glaxo Smith Kline's Viread price dropped 67% of the in-market China price and Astra Zeneca dropped the price of Iressa by 53% of the already lower in-market China price.

"UK Landmark deal to boost nation's health and save NHS £14 billion"

Highlights:

- The pharma industry and the government negotiated a cost control plan that is voluntary for the industry to limit revenue growth to two percent each year 2024, 2025, and 2026.
- Companies in the voluntary program also agree to provide funding for drug development infrastructure: clinical trials, manufacturing, and health technology assessment. The Government will also provide new funding.
- A company can choose to limit itself to the annual revenue cap or participate in the rebate program (that predates the new annual revenue cap) where a percentage of revenues are returned to the government each year (22% 2024 rising to 27% by 2026).

Published 20 November 2023

II. COMPANIES THAT FOUGHT NEGOTIATIONS OR BOYCOTTED

This section details the few notable times a pharma company essentially boycotted a country because it would not accept a country's financial evaluation of its product and would not negotiate based on that evaluation. Vertex pulled this off but suffered reputational damage among patients. BlueBird Bio held a monopoly position (similar to Vertex) but suffered shareholder blowback from its full-on EU boycott. Importantly, the EU and English launch prices found to be excessive were fully 50 or 60 percent less than the list prices in the US.

Vertex

"Vertex opens up \$500M in sales with landmark CF deal in England"

By Eric Sagonowsky_Oct 24, 2019

"Cystic fibrosis: The miracle drugs priced out of reach"

By Catherine Snowdon 14 December 2023 BBC News.

Highlights of both articles: Vertex cystic fibrosis products were found to be excessively priced in the UK. There were four years of negotiations over Orkambi, Symkevi, and Kalydeco from 2015 to 2019. Patients already on treatment with one of the products remained on treatment but new patients not on treatment had to import from India, Ukraine, Brazil, and Argentina. The 2019 deal was expected to generate \$500M in new sales. The newest product, Trikafta was also found to be excessively priced by the UK's NICE. Price negotiations began in

November 2023 and are ongoing. Patients already on Trikafta treatment continue to have access. Others will have to import. **Trikafta's annual US wholesale price is \$320,000. The UK market price that is considered excessive, is US \$127,200.** UK academics have estimated the average cost of Trikafta production is \$7,634. The average cost of cystic fibrosis illness relative to other illnesses is estimated to be \$8272/year more than other illnesses.

BlueBird Bio

"<u>Bluebird</u> bio cuts 30% of its workforce as gene therapy dreams dashed in Europe, delayed in US" By Angus Liu_Apr 5, 2022. FiercePharma

"<u>Bluebird</u> Bio Has Serious Cash Flow Concerns; Inability To Strike Reimbursement Deals In Europe Partly To Blame" Joshua Cohen, April 3, 2022. Forbes

"<u>UPDATED</u>: Bluebird bio's \$2.8M gene therapy Zynteglo wins FDA backing. Will its US launch take flight?"

By Fraiser Kansteiner Aug 17, 2022. 1:55pm. FiercePharma

Highlights of all three articles: BlueBird Bio withdrew its blood disorder treatment Zynteglo from Germany in early 2021 after failing to negotiate a satisfactory reimbursement agreement. It then decided to pull the drug from the entire EU market at the end of 2021 and pulled out Skysona, a neurodegenerative disease treatment, from the entire market at the same time – which was only 5 months after Skysona was approved. In an SEC filing, the company said its EU action was due to "challenges to achieving appropriate value recognition" for its products. Zyteglo was approved in the US in mid-2022 with a price of \$2.8M. The price that was rejected in the EU was almost half that, \$1.8M. Skysona was FDA approved in the fall of 2022 with a record-breaking launch price of \$3M/treatment. These are both orphan disease products.

II. EVIDENCE OF SIGNIFICANTLY LOWER PRICES OUTSIDE US MARKETS

This information further reinforces the growing drum beat that prices in other countries are so much lower than in the United States.

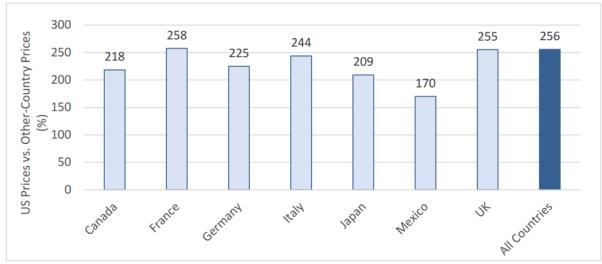
"Price of Ten Medicare Negotiated Drugs Compared to Ex-US"

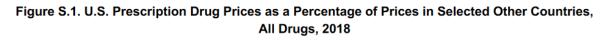
Highlights: For the first ten drugs subject to Medicare negotiation, the report shows US price compared to the price in comparable countries. The report also compares adjusted prices of US prices (net of rebates) compared to the prices in comparable countries. This is the <u>link to the power point chartpack</u> with graphs that can be cut and pasted.

US Health and Human Services: US: ex-US price comparisons. 2022

Graphic One

Figure S.1 includes brand and generic drugs. The columns show how much more expensive drugs are in the US than in other countries, *as a percentage of US prices*. The US generic prices are considerably lower than generic prices in other countries. Even though US generic prices are lower than other countries and generics are 85% of US drug sales and only 35% of sales in other countries, the data show that our prices are 256% higher despite the inclusion of generics.





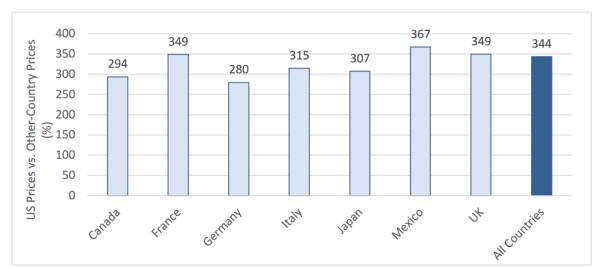
Source: US Assistant Secretary for Planning and Evaluation. July 2022. Research by RAND Corporation. Full report: <u>https://aspe.hhs.gov/reports/international-prescription-drug-price-comparisons</u>

Graphic Two

Figure S.2 excludes generics from the analysis. Without generics, the price differential between US prices and prices of other countries is *much* greater than the difference shown in Figure S.1. U.S. brand prices are 344% higher than the average prices of thirty-two other countries when generics of all countries are excluded from the analysis.

SOURCE: Author analysis of IQVIA MIDAS sales and volume data for calendar year 2018 (run date October 28, 2019). NOTE: "All Countries" refers to all 32 OECD comparison countries combined. Other-country prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

Figure S.2. U.S. Brand-Name Originator Drug Prices as a Percentage of Other-Country Prices, 2018



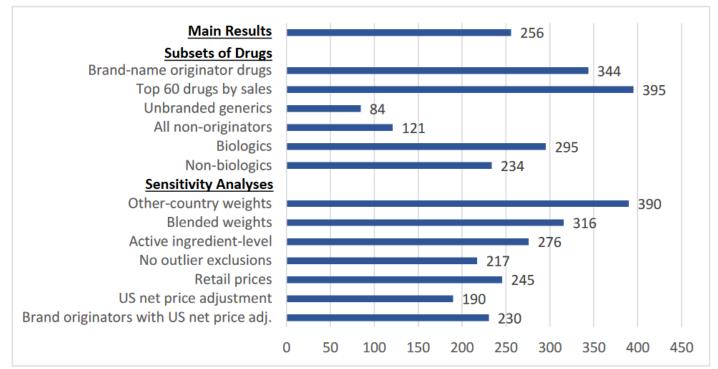


Source: US Assistant Secretary for Planning and Evaluation. July 2022. Research by RAND Corporation. Full report: <u>https://aspe.hhs.gov/reports/international-prescription-drug-price-</u>

Graphic Three

The important aspect of Figure S.4 (below) for policy purposes is the "Main Results/Subsets of Drugs" section that breaks down the price differentials *by type* of drugs. Brand name originator drugs are the first in class products, such as the first statin, or first long-acting insulin. Non-originator brands follow the innovator and treat the same aspect of a disease but may have a different mechanism of action or active ingredient; they are sufficiently different to obtain patents. Non-biologics are complex drugs that cannot be classified as either a biologic (large molecule, derived from living organisms) or a small molecule drug where the active ingredient is a chemical.

Figure S.4. Summary of Selected Results: U.S. Prices as a Percentage of Other-Country Prices, 2018



SOURCE: Author analysis of IQVIA MIDAS sales and volume data for calendar year 2018 (run date October 28, 2019). NOTE: "Other-Country Prices" refers to all 32 OECD comparison countries combined. For "Top 60," we compared prices for the top 60 drugs by U.S. sales at the active ingredient level, excluding combination products. "Adj." is adjustment. Only some presentations sold in each country contribute to bilateral comparisons.

Source: US Assistant Secretary for Planning and Evaluation. July 2022. Research by RAND Corporation. Full report: <u>https://aspe.hhs.gov/reports/international-prescription-drug-price-comparisons</u>