
MARKET SEGMENTATION AND INTERNATIONAL PRICE REFERENCING

1. WHAT IS THE ISSUE

Can pharmaceutical companies charge vastly different prices for the same product in different countries, taking into account differences in ability to pay?

To answer this question, we need to address the following challenges:

- How can we secure continued incentives for risky and expensive investments to develop new drugs for challenging diseases, such as AIDS, while enabling broad access to state of the art treatment (including drugs).
- Will governments allow for price differentiation without engaging in new opportunities for drug budget cuts through price referencing or parallel trade?
- Will authorities be willing and able to control an emerging black market for pharmaceuticals
- When allowing for tiered pricing, how to define the tiers? How to modify tiers over time?

2. WHY IS THIS AN ISSUE FOR PHARMACEUTICALS

What is the cost of an airplane in an African country vs. the cost in Germany or Spain? What is the cost of advanced medical equipment in Thailand vs. its cost in the United States? For most products, global price differences are not likely to be huge, particularly when they are developed and manufactured on a global scale. For these products it is generally accepted that companies would have to incur financial losses if they would have to sell the product at half price in developing countries. Why is this different for pharmaceuticals?

The pharmaceutical industry has an unusual cost structure:

- Extremely high upfront investment (at least M\$500 for a new product)
- Very high product failure rate
- High product liability
- Relatively low variable cost of production within capacity for most non-biotech products

- Require long payback period (dependent on patents)

From a financial perspective, it would make sense for pharmaceutical companies to take local affordability into account in setting price levels for each country. Less affluent countries would in this case pay a somewhat lower price than the United States, Europe or Japan, but would still modestly contribute to the funding of important new research and development.

So why have pharmaceutical companies been hesitant in engaging in tiered pricing? Actually this all has to do with the fact that in most countries there is no free market for pharmaceuticals.

3. PROBLEMS OF DIFFERENTIAL PRICING; A HISTORY LESSON

The industry's perspective on differential pricing is actually best described with a well-known quote from George Santayana:

“Those who do not remember the past are condemned to repeat it”

Pharmaceutical companies have gone through a rather difficult history on differential pricing in Europe. Most European countries have national price and/or reimbursement control systems for pharmaceuticals. These systems are exclusively designed to preserve national drug budgets, particularly in what used to be the less affluent Southern European countries. Global health care needs and funding of important health care innovations are not, and probably cannot be, a direct concern of most national health care authorities. As a result, many Southern European, Canadian and Australian governments have used their monopsony power to act as a free rider for many health care innovations, which as a result are primarily funded by US and Northern European citizens. Over the last few decades, pharmaceutical companies have been forced, under global competitive pressures and due to lack of intellectual property protection (in Southern Europe and Canada), to accept lower prices in these controlled markets. Alternatively, they would have been blocked out entirely and hence foregoing any contribution towards the high fixed expenses. This dynamic, together with currency exchange rate fluctuations, has caused substantial price differences for pharmaceuticals within Europe. Since then, European countries have strongly encouraged international price referencing and parallel trade to take advantage of prices in weak currency price controlled markets, thus bringing down the overall European price level for pharmaceuticals. Interestingly, the Southern European economies have strengthened sufficiently to allow them to enter the European

Monetary Union. However the price levels of pharmaceuticals have not seen the benefits of economic growth.

4. CURRENT SITUATION

The global environment for pharmaceuticals is extremely complex due to the large degree and variability in government interference on pricing and reimbursement. Pricing and reimbursement control systems, although vastly different from country to country, usually contain a number of the following elements:

- Generic referencing or substitution
- Therapeutic referencing i.e. A-II's versus Cozaar
- Profit controls i.e. PPRS in UK, margin controls in Turkey, Pakistan
- International Referencing

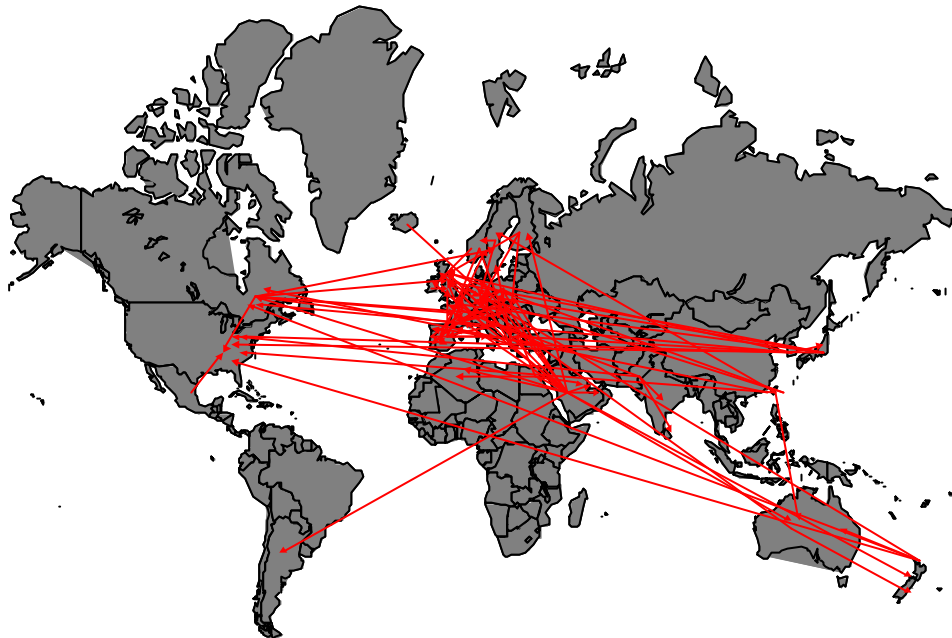
For the purpose of this discussion, I will only focus on various forms of International Referencing and both government encouraged and illegal parallel trade.

4.1 Formal Price Referencing

In many countries, price comparisons with a number of other countries are performed as part of the price approval process. For example in Canada, the price of any new product cannot exceed the median of the prices for the US, France, Germany, Italy, Sweden, Switzerland and the UK. When a company sets a higher price, it is forced through public hearings to adjust its price. In Denmark and Italy, prices cannot exceed the European average price. Countries such as Spain and Greece simply demand the lowest price in Europe. In Saudi Arabia, price is referenced to a list of 40 countries all over the world. Taiwan has a similar rule for 10 countries. A large number of countries are also limiting price at the level of the country of product origin. For the purpose of this discussion, I will only focus on International Referencing, which is taking place in various forms.

The chart below provides a graphic overview of the formal international referencing rules. Each line represents a comparison from one country to another for price control purposes. As you can see there are an overwhelming number of these, a factor that cannot be ignored by the pharmaceutical companies when making local pricing decisions. It is of particular importance to note that most of these referencing laws were instated in the last 5 years; also they are increasingly global in nature and not restricted to Europe.

Formal International Price Referencing in 2001



4.2 Informal Price Referencing

In a large number of countries, price is set in a process of negotiation. Whether international price referencing is a formal part of the process or not, it certainly plays an informal role in the negotiations. Ministries of health generally have easy access to pricing information in other countries and are naturally prepared to use it to their advantage. Differences in affluence of the comparator country are not always accepted as an argument during these discussions, particularly since officials assume that companies can still make a profit at these price levels.

4.3 Parallel Trade

Parallel trade or parallel importation is an arbitrage activity that is engaged in very actively by distributor companies. In the European Union, many health care systems encourage companies to take advantage of international price differences by providing easy approvals and financial incentives. Recently, parallel trade has been authorized in countries outside Europe. Israel has approved and implemented legislation to allow for parallel import from all European countries, the US, Canada, Japan and Australia. Parallel trade is now legal in other Middle Eastern countries and South Africa.

In 2000, legislation was approved in the United States, to allow parallel trade from countries with a regulatory system that is similar to the United States. The list of

countries includes countries, such as Australia, New Zealand, South Africa and Israel. Some hurdles around patient safety concerns will hamper implementation of this legislation, which was approved with a large majority with support from both democrat and republican parties. The inclusion of South Africa on this list of source countries creates direct concern over the feasibility of “public aid drug pricing” for that country.

4.4 Black Market

Beside authorized legal parallel trade, the existence of illegal cross border trade (i.e. black market trade) is of increasing concern. Currently, black market activity for drugs mainly takes place on relatively small scale in Asia and Latin America. However the emergence of tiered pricing for pharmaceuticals will greatly increase incentives for black market activities. Beside economic concerns, there are important safety concerns with black market trade of drugs, both with respect to product deterioration due to inappropriate storage conditions and the emergence of counterfeit products.

4.5 Political Referencing

Politicians in the United States and in Europe have become upset when noticing price differences for pharmaceuticals, for example between the United States and one of the Caribbean Islands, Canada or Mexico. Politicians and the public in the United States are clearly not ready to accept lower prices for drugs in less affluent Mexico or the Caribbean as further evidenced by publicity around border traffic for drugs.

In 1994 this issue became clear to some American vaccine manufacturers, when they were heavily criticized by the democrats under leadership of Hillary Clinton over supplying vaccines to developing countries at prices below the CDC contract price.

Politicians have frequently used the complexity of global drug pricing as a platform for their political campaigns. The cost structure of pharmaceutical companies and the resulting complexity of global competition and pricing practices are very difficult to explain to the public. Pharmaceutical companies have long struggled with this issue.

5. IMPLICATIONS

The pharmaceutical industry is caught between the need to provide support to urgent medical needs in developing countries and its justified historically based concern that this will threaten its ability to continue new drug development and hence its existence.

Pharmaceutical companies make investment decisions for the exploration and development of new drug treatments on the basis of its scientific probability of success

and its ability to recoup its investment and make a reasonable profit. The ability to recoup its investment is heavily driven by its confidence that a reasonable price can be charged. It is therefore critical that a workable solution is found that addresses both urgent need for affordable treatment (including drugs) while addressing legitimate industry concerns on price referencing.

Sadly, it is the pressure to provide access to new AIDS drugs at low prices, together with the tremendous complex of national price control mechanisms, that may very well shy companies away from developing much needed new drugs in the battle against a highly complex and combative virus that is closely affecting the lives of many among us. I assume that consumer groups are considering the impact that any short-term wins may have on the long-term ability to battle diseases that threaten human lives.

6. REACHING RESOLUTION

The challenge is to find a resolution for urgent global health care needs, while continuing to stimulate new costly and risky investments for innovative drugs for the prevention and treatment of diseases such as AIDS. The pharmaceutical industry is unlikely to have major objections to a policy that makes drugs available at relatively low cost to developing countries, provided that a number of concerns are addressed.

1. The industry needs to be comfortable that countries will not use “public aid pricing” for referencing purposes. Many western countries accept this concept, but for example the most recent parallel trade (“re-importation”) legislation in the United States includes South Africa as an approved source.
2. Legislation will have to be enacted and enforced to prevent public aid goods to flow back into other countries. Making this work may require special distribution arrangements for public aid drugs.
3. Most difficult to address, but important, is the need to control political referencing. The justification for tiered pricing is difficult to comprehend and accept for the public and has been proven to be an easy platform for politicians who wish to use it for furthering their political aims.

Addressing these concerns will require strong support from organizations such as the WHO and WTO, as well as active endorsement from major western governments. Hopefully we can reach a practical solution that enables us to focus on the urgent need for patient access to effective treatment, education and prevention programs and the continued search for newer and better drugs.

PERSONAL PROFILE

Ed Schoonveld, Executive Vice President Cambridge Pharma Consultancy

Ed Schoonveld, Executive Vice President of Cambridge Pharma Consultancy's New York office is responsible for the US-based pricing, reimbursement and managed care practices, as well as the firm's Japan consulting practice.

Ed has gained extensive experience in the pharmaceutical industry through various sales, marketing and general management positions with Lederle, Wyeth and Eli Lilly in the United States and Europe. He has gained deep expertise in global pricing and reimbursement, both on an affiliate level as a general manager of a European affiliate, and at corporate level as the leader for global pricing groups in Wyeth and Eli Lilly.

In his most recent position at Eli Lilly, he established a new strategic pricing group and integrated the group with the R&D-based health outcomes group. He led a team that designed and implemented new pricing and value support processes and optimised favourable pricing and reimbursement approvals by payers worldwide, helping to ensure rapid market uptake in the United States.

Ed holds an MS in engineering from the Delft University of Technology in The Netherlands and a Masters in Business Administration in Finance and International Business from the University of California in Los Angeles.

<u>Contact</u>	<u>Information:</u>
Cambridge	Pharma
300 Park Avenue	17 th Floor
New York, NY	10022-7402
Tel:	(212) 572-6289
Fax: (212) 572-6444	