Literature Review- Price Survey
Kirsten Myhr


Overview of issues, but not applied methodology

“Drug prices have become an important issue in the last few years as concerns about constrained healthcare have increased. Healthcare authorities in all industrialised countries are questioning whether their country is carrying a heavier burden than others in paying for drugs. In view of this discussion, several price comparison studies have been conducted. However, there is no generally accepted methodology on how to conduct price comparisons, and many methodological issues remain unresolved. The results of most published studies are affected by moderately serious methodological flaws, which are never properly addressed.

The purpose of this study is to discuss the methodological issue of international drug price comparison, in terms of 6 points that appear to this author to be necessary to conduct a methodologically sound study. A previous review of a large number of drug price comparisons revealed that they all fail to take into account some or all of these 6 basic methodological points. Studies that fulfil the methodological criteria outlined in this paper are therefore urgently needed before drug pricing studies can be fully utilised as a basis for important policy decisions in the healthcare arena”.

“In theory, an international price comparison between 2 countries entails the relatively simple question whether a consumer can buy a particular set of drugs for a lower price in one country than another (or vice versa).”

He identified 4 studies concentrating on the methodology of drug price comparisons. On the basis of these 4 studies and also a review of a larger number of drug price comparisons, he examines 6 methodological points that researchers and policy makers in this field ought to take into account:

1. Whether the countries compared are similar
2. How to select a representative sample of drugs
3. Which prices are to be used
4. How drugs are made comparable
5. Whether prices are weighted according to the importance of the drug
6. How prices are converted into a common currency

He discusses each point. Much to copy. Explains the indexes, PPPs

Most common flaws:
1. non-random samples of drugs (which implies that no conclusions can be drawn for the general price level of drugs)
2. arbitrarily standardised package sizes (the calculated price will differ according to standard package size chosen)
3. use of exchange rates to convert prices into a common currency (the results are vulnerable to fluctuating exchange rates and are not related to actual cost of living
4. failure to weight prices by sales (the researchers assume that all drugs have the same effect on the general price level.


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“This paper examines pricing of essential innovative medicines according to alternative strategies of firms:
- either a country-wise price of discrimination according to the revenues of the consumers of these countries, or
- a single world-wide price.

Two counter-strategies by countries’ governments are related to these strategies: parallel imports and compulsory licensing of patents. For each strategy, firms profits and affordability of such drugs are calculated with a simulation model. We show that the price discrimination maximise both indicators. Despite this result, some firms prefer to set a unique world-wide price, may be because they are afraid low priced medicines would find their way on to the black market and end up in the potentially higher price countries.”


Overview of issues, but not applied methodology

Editorial commenting on Danzon’s article.


Overview of issues, but not applied methodology

The article describes pricing strategies and regulations and describes the situation in EU, in France, UK, Australia, Canada and US.

Quote from 3, the challenge and evaluation of attempts to control prices

“It is troublesome to expect the price of an imported drug to be the same as the price in the country where the drug was manufactured, since the demand is higher in developed countries, and the economies of scale are significantly larger. Furthermore, drug prices are distorted by transfer pricing of multinational companies, which also complicates attempts at price control.”

A list of questions to help evaluate a country’s pharmaceutical pricing policies

Conclusion

“Pharmaceuticals are sure to play a significant role in the world’s future state of health, irrespective of their price, format or degree of regulation. Balancing the pros and cons of a free market with those of an administered market is nothing short of walking a policy tightrope. Is it fair that patients in some countries cannot afford drug therapy that is so easily afforded in others? We would be foolhardy, however, to execute a mere comparison of pharmaceutical prices around the world. While we are striving to increase the availability of effective agents, we do not want to become so extreme in our price controls that we stifle the very production of these essential elements of our healthcare system. Therefore, mechanisms enabling the most overall beneficial pharmaceutical pricing seem to involve drug utilization review, cost-effectiveness data, and outcomes research. These data allow us to determine the most suitable compromise between a free market and a controlled market philosophy. General health, patient outcomes and the associated overall expenditures must be at the focus of pharmaceutical pricing policies………..”
**Danzon P. Making sense of drug prices.** Regulation 2000; 23 (1): 56-63

“Critics of the US pharmaceutical industry allege that US consumers are subsidizing the rest of the world because US drug firms charge higher prices in the US than in other countries. A related allegation is that in the US there is cost shifting to cash-paying, retail customers – including many of the elderly – who pay excessive prices because of discounts to managed-care organizations and government purchasers. Then there is the general belief that drug prices are simply “too high” – that the pharmaceutical industry is making excessive profits. These bits of conventional wisdom may be conventional but they are not wisdom. Facts and logic will lead us to these conclusions:

Cross-national and domestic price differences are smaller than has been alleged.

Discounts to large buyers do not raise the prices paid by the elderly or other cash-paying retail customers.

Any form of price regulation, including the setting of uniform prices within the US or cross-nationally, would discourage innovation and competition.

The best way to make drugs more affordable for the elderly would be to allow them to choose among private-sector plans.”

**Very US**

**The health care implications of international price differences. IFPMA: 2000.**

**Overview of issues, but not applied methodology**

“Leading R&D-based pharmaceutical companies have proven enormously successful at supplying life-enhancing products to buyers all over the world. The fact that prices of any other company’s products frequently differ from one country to another has emerged as a central policy issue for governments, consumer advocates, international organizations, and other institutions with an interest in drug purchasing. All are asking the same question: why do different people pay different prices for the same products?

There are well-reasoned responses to this growing concern. While the global research-based pharmaceutical industry operates under a special mix of business conditions, international price differences for pharmaceuticals exist for many of the same reasons as for any other product or service. Prices reflect supply and demand in each distinct local economic environment as constrained by regulatory standards that arise from distinct political cultures. Additionally, as does any producer serving the health care sector, producers of pharmaceuticals encounter special conditions which affect prices in different global markets differently since medical practice patterns are shaped and reinforced by local cultural conditioning. Finally, in many markets, pharmaceutical prices are set for purposes of reimbursement by powerful bureaucracies who, pursuing a public interest objective, limit the manufacturer’s role to advice and consultation – if that.

Hence, the only reasonable conclusion for anyone taking a careful look at the issue to draw is that pharmaceutical companies’ business interests are but one of many elements that combine to determine prices.

This study showcases mounting evidence as to the folly of pursuing policies designed to force pharmaceutical companies to sell at uniform prices across countries. The accomplishment of this “single price” policy, industrial critics contend, would be to enhance access to medicines. In reality, the existence of price differences among countries results in broader access to medicines on a global basis. Uniform pricing, even if it were possible, would reduce access by discouraging manufacturers from selling in the widest spread of markets.

Indeed, if all markets had a uniform price, the biggest short-run losers would be those whose prices were previously lower than the average. Eventually, all buyers – rich and poor – would lose because fewer new products would be developed for sale at any single price.”
Five key facts about price variances
1. Price differences exist for pharmaceuticals and will continue to exist, as is the case for most other products.
2. The reasons for price differences are multiple and reflect different price and reimbursement systems, macro-economic differences and dynamics, national political priorities, the basics of organizing the market, and the specifics of local health care practices and markets. Commercial strategies of individual companies are only one factor in the mix.
3. Comparing prices across national boundaries in a meaningful way is methodologically challenging and must therefore be seen as a questionable tool for making public policy decisions on pharmaceuticals. There exists no single valid method for comparing prices and the results depend very much on the method used. Many published price comparisons are fundamentally misleading with regard to appropriate inferences about public policy.
4. There is a strong body of economic evidence showing that price variations increase access and use in situations where there are high fixed costs that cannot be allocated directly to the purchaser – as is the case with pharmaceuticals. Seeking to make prices uniform (and uniform presumably at a relatively low level) would have adverse consequences for patients, particularly in obtaining access to new medicines. In fact, the worst impact of a uniform pricing regime would fall on those buyers now able to buy at the lower end of the price distribution. This is because patients, or countries, previously supplied at lower than average rates would have to pay more for their drugs.
5. The real issue for policy-makers is not price but access – how best to supply quality drugs to developing countries while making more efficient the use of scarce health care resources in the industrialized world. Access to drugs is instead a broad issue covering many aspects besides pricing. Focusing solely on the removal of price differences will not solve the access problem. A solution depends on finding ways to address larger issues such as lack of national healthcare policies to address basic healthcare needs and the inadequacy of health care infrastructure in some developing countries.

Methods of price comparison at a glance
Comparisons can be made by looking at:
- prices of single products
- prices of a group of leading branded products
- prices of therapeutic groups, including generics, OTCs and prescription drugs
- prices of a sample of leading products in one country of comparison versus the same products in other countries
- prices of the full range offered in a country or the range covering 80% of a market versus the same products or a similar range of products of other markets

The comparison made be made on the basis of:
- a single product price
- average prices
- weighted average prices

The comparison may be made with reference to:
- the current exchange rate
- the exchange rates of a chosen period
- the exchange rates at the date on which the product was introduced in the different markets
- an exchange rate adjusted for economic differences (e.g. adjusted for purchasing power parity – PPP)

The comparison can be made in terms of:
- the ex-factory price level

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Developing a Methodology to Assess the Impact of TRIPs-plus Provisions Affecting Drug Prices

31 July to 1 August 2006

the level of the pharmacy selling price to the public
the reimbursed price level
the hospital purchasing level
the average unit sales figures (IMS)
prices with or without taxes (VAT)
the lowest or highest prices found in a country or just one sample without such a specification


“Pharmaceutical prices in the US are under evaluation as policy makers decide how to reduce health care expenditures and public subsidy of the pharmaceutical industry. Furthermore, evidence of higher drug prices in the US, compared with those in other countries, fuels the prescription drug debate. These issues are not new to the public forum and much can be learned from prior debates and policies. This paper begins by reviewing the pricing debate with the Kefauwer hearings on monopolies held during the late 1950s and early 1960s and continues with the current price debate. Government reports and academic studies are discussed, addressing the methodological differences and their implications to policymakers. Finally, the literature review includes foreign government prescription drug programs with their respective prescription drug expenditures. Evidence provided by academics about the pricing practices of the drug manufacturers indicates product quality and price information would force firms to compete on the price level, thus reducing pharmaceutical product pricing to the ‘true’ market price.”

This paper reviews federal policies associated with the price of prescription drugs.

PRIME index: a weighted average price change for the 200 top-selling drugs. Developed to track the change in manufacturers’ prices for the mix of drugs sold through traditional community pharmacies.

Cocks and Virts price index compared price and prescription size of selected products (top 8 products in terms of prescriptions written over a 10-year period) from 1 year to the base year.

Duncan Reekie price index compared the price of innovative and non-innovative products introduced in the market. Dividing the total sales per product by the respective number of prescriptions written. This price index compared the price of innovative products or NCEs with competing products.

A part on price control mechanisms.

Some relevance for methodology.


“This paper reports price indexes for drugs, at manufacturer price levels, for Canada, France, Germany, Italy, the UK, and the US for the period 1981-1992, using a comprehensive database and
consistent methods. These are compared to official producer price indexes for drugs, and to the price indexes reported by the OECD.

Different regulatory systems lead to different pricing patterns and competitive strategies. Regulation generally depresses real prices over the life cycle of a drug. After adjusting for GDP inflation, all of the European countries and Japan have negative real price growth for individual products. Only Canada and the US have positive real growth. Using our “best” indexes based on price per gram for the molecule, we find that cross-country differences are less than appears from the OECD price indexes, which tend to underestimate true drug price inflation in countries with regulatory systems.

The use of fixed weight (Laspeyres) indexes, which delay the incorporation of new products, rather than chained weight (Divisia) indexes, leads to quite different biases in different countries. For some countries price per standard unit (dose) has increased more rapidly than price per gram. This is consistent with the hypothesis that in countries with strict price regulation, increasing the average strength per dose is one means of achieving a higher price per gram.

We report indexes for products and for molecules, to show the effect of treating generics and line extensions as new products rather than as modifications of old molecules. For the US, we find that treating new forms as new products leads to upward biased estimates of price inflation. A similar but smaller bias in found in Canada, Germany and the UK, the other three countries with significant generic penetration. However, the opposite effect is found in countries with heavy price regulation. In France, Italy and Japan, molecule price indexes exceed product price indexes, plausibly because the main form of molecule modification is line extensions that are launched to obtain a new, higher price, to offset the downward regulatory pressure on real prices for existing product forms.

The official PPI indexes for drugs systematically overestimate “true” price inflation, as measured by our Divisia molecule indexes for price per gram. For most countries the main source of upward bias in the official indexes is the treatment of generics and line extensions as new products rather than as modifications of old molecules, and the focus on a single pack for each drug, which omits upgrades in presentation form, strength and packsize. The OECD indexes generally exceed the official PPI indexes and are therefore even more upward biased compared to the preferred Divisia molecule indexes.”

The objectives are to
1) report consistent indexes of manufacturer prices for drugs for seven major OECD countries, using a comprehensive database and consistent methods
2) test whether the biases observed in the US drug price indexes, due to use of fixed weights and treatment of generics as new products are present in other countries
3) compare their price indexes to the official PPI indexes for drugs for these countries, and to the price indexes reported by the OECD.

One reason for doing this exercise was that the official pharmaceutical price indexes submitted to the OECD are not based on consistent methods of sampling and weighting. It should also be noted that these indexes are intended to reflect prices for final private consumption, and thus are not strictly comparable to the official PPIs and the indexes used by Danzon.

The indexes are used on IMS data, ex-factory prices, from Canada, France, Germany, Italy, Japan, the UK and the US for the period 1981-1992. She uses indexes for products and molecules, fixed weight (Laspeyres) indexes and chained weight (Divisia) indexes. No combination products included – their share of the market is said to be less than 10 %, it is not clear whether this is in the US or in all countries.

The fixed weight index delays the introduction of new products. Divisia indexes include new products in their second year on the market. The price of the molecule is defined as the volume-weighted...
average of the price for all products in that molecule, regardless of brand or generic status. This implicitly treats generics and line extensions as perfect substitutes for originator drugs and for each other. The product indexes treat each generic and each modification of an old drug that is marketed under a new name as a new product. The difference between the two indexes depends on the relative mix of quality enhancing vs. pure imitator new products in old molecules and their relative prices. If most new products are generic imitators and sell at lower prices, then PIs should exceed MIs and price indexes based on products overstate the true quality-adjusted rate of inflation. On the other hand, if most new products within existing molecules are improved forms and sell at higher prices, then the MIs should exceed the PIs and the MIs overstate the quality-adjusted rate of price increase.

One conclusion is that the use of fixed weights rather than chained weights which affects the lag in incorporating new products into the index, leads to quite different biases in different countries.


The author describes the WHO/ATC classification system and different units for “measurement of pharmaceuticals”. She goes on to describe basic principles for measuring health inputs, discusses application of these principles to the ATC/DDD system and ends up with a proposal for implementing an outcome-based ATC/DDD system. Her system has many positive features, but is very unrealistic and in my opinion impossible to implement. E.g. it needs specific indications, that indication is known for all use (i.e. put on prescriptions) and that duration of treatments are known for all indications. Drugs should be classified in groups of therapeutically interchangeable products and with a sort of ranging starting with best value for money. It also presupposes that drugs should be priced according to value, not e.g. price of raw, development etc. This means that if a drug may prevent an operation, it should be priced according to what cost is then saved.

The main purpose of this exercise is to show that the ATC/DDD system is not suitable for fixing prices for reimbursement. However, this has never been the intention either and is clearly discouraged. That some countries still do so cannot be blamed on the system.


“Bilateral drug price and quantity indexes, based on comprehensive data for seven countries (US, Canada, France, Germany, Italy, Japan and the UK), refute the conventional wisdom that US drug prices are much higher than elsewhere, for Laspeyres’ (US-weighted) indexes. Previous drug-price comparisons are biased by unrepresentative samples and unweighted indexes. Quasi-hedonic regression shows that cross-national price differences reflect differences in product characteristics and in their implicit prices, which reflect the regulatory regime. Strict price regulation systematically lowers prices for older molecules and globally diffused molecules. Generic competition lowers prices in less-regulated regimes, which also have more price-elastic demand.”

IMS sale through retail pharmacies between October 91 and September 92. Canada, France, Germany, Italy, Japan, UK, US. Compared US with the others.
Sample 1: all molecules available in both US and the comparison country, brands and generics.
Sample 2: all molecules available in all seven countries (problem: excludes >40% of drugs in Germany, France)
Price for each molecule defined as weighted average price based on all products in the molecule.
Prices at manufacturer’s level, no discounts. Price/gram and price/IMS SU.

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Danzon does not understand WHO DDDs! see page 164.

Points from article:
Methods used for previous cross-national drug price comparisons
PPPs and what they are based on

3 purposes of the paper:
- report indexes of manufacturer-level drug prices of six countries
- examine factors inherent in these index measures that contribute to the different estimates
- analyse the determinants of the variation in price relatives across molecules for each country relative to the US.

See 177 on quality. Some weird comments on e.g. strength and price, and competition (‘generics are closer substitutes’)

Conclusion quote:
“The main conclusion from this analysis is that any generalization about relative prices for drugs in different countries are tentative at best, because of the diversity of products, prices, and volumes, which makes conclusions very sensitive to the sample and methods. The safe conclusion is that results will be systematically biased if the comparison is based on a sample that is unrepresentative with respect to either age of molecules, extent of globalization or generic share.”

Have attempted to replicate the GAO-92 results using IMS data for the subsample of drugs they could match.

Compares also with BEUC 1989 (no generics)


Both study and methodology

“Cross-national price comparisons for pharmaceuticals are commonly used for two purposes. Comparisons based on a sample of products are used to draw conclusions about differences in average price levels. Cross-national comparisons applied to individual products are also used by governments to set domestic prices.

The paper examines the major methodological issues raised by international price comparisons, focusing on measurement of differences in average price levels and the validity of policy conclusions drawn from such price comparison studies. It argues that valid measures of average price levels can only be obtained from comparisons based on a comprehensive or representative sample of products, appropriately weighted, following standard index number methods. Comparisons of individual product prices should take into account the manufacturer’s entire portfolio over time rather than focus narrowly on a single product at a point in time.

Because of the great variation across countries in both the range of drug compounds available and the dosage forms, strengths and pack sizes for each compound, obtaining a broadly comprehensive or representative sample is problematical. If products are required to match on all dimensions, including molecule, manufacturer, strength and pack, as is common in most international price comparisons, then only a very small and unrepresentative sample of the drugs available in each country can be included in the analysis. A trade-off between the desire to compare only identical products and the need to compare a truly representative sample of a country’s pharmaceutical market is therefore

DRAFT NOT FOR CIRCULATION Compiled by Kirsten Myhr in 2000 as background to the development of 8 the WHO/HAI methodology for measuring medicine prices
necessary. A valid comparison of average drug prices should include generics and over-the-counter products that are good substitutes for branded prescription drugs, with all forms, strengths and packs. To achieve this broad representation, however, the requirements of same manufacturer, same brand, dosage form, strength and pack size must be dropped.

When such an approach is taken to the comparison of international drug prices, quite different results from those obtained from less comprehensive comparisons may be obtained. Indeed, a major conclusion of this analysis is that international drug price comparisons are extremely sensitive to choices made about certain key methodological issues, such as sample selection, unit of measurement for price and volume, the relative weight given to consumption patterns in the countries being compared, and the use of exchange rates or purchasing power parities for currency conversion. In particular, the results of this analysis indicate that recent reports suggesting that manufacturer prices in the US are 32% higher than in Canada and 60% higher than in the UK are in fact overstatements which arise from limitations of the sample and methods used to calculate these price differentials.”

The author seems not to have a full grip on pharmaceutical terms: Generics and OTC being “important substitutes for branded Rx drugs”, (domestic products not exported cannot be included,) why drugs are unavailable in particular countries, generics being close substitutes for the originator brand, DDDs being the number of grams for either a normal dose or a recommended dose.

International price comparisons
She illustrates some of the issues using IMS data from 9 countries on cardiovascular drugs
Main conclusions about broad comparisons of average price levels are based on standard index number theory.

“The main conclusion from this analysis is that there is no single right measure of international price differences for drugs. For the purpose of drawing policy conclusions, price comparisons raise more questions than they answer. Price indexes are designed to measure average price differences, not to identify the causes of those price differences. At most, a comparison across different indexes can suggest the effects of certain factors, such as consumption patterns (weights), average strength per dose, mix of dosage forms, strengths and pack sizes.”

**Senior I. International medicine prices – is a new index needed?** Scrip Magazine 1996; no. 49 (September): 12-4.

The author discusses the ABDA and the OECD indices and discusses international comparisons and variations in general.

“Although a given medicine is in many ways a homogenous product internationally, there are huge variations in the prices of medicines which cannot be explained by the principle of comparative advantage.

There is very little variation in the prices of the fine chemicals which produce the active ingredients. Labour costs have only a small part to play in determining the final price of a medicine.

Medicines have a high ratio of value to weight and volume, and they are cheap and easy to transport.

To produce a comparative index, there must be a standard basket or sample of medicines. The basket must include only those that are sold in all or most (say 90%) of the countries to be compared. Most importantly, the price of each medicine must be weighted by its share in the value of the total sales of the basket in the country concerned.

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In addition, a consistent and transparent approach must be adopted on the prices used in the index:

- All prices must be the same level, normally ex-manufacturer or retail.
- Statutory discounts must be uniformly and expressly included or excluded.
- VAT or other sales taxes imposed on medicines in some countries and not in others must be eliminated.
- An appropriate exchange rate must be used.

PPP are the currency conversion rates required to eliminate the differences in price levels (and so equalise the currency purchasing power) between countries. This means that a given sum of money, when converted into different currencies at the PPP rates, will buy the same basket of goods and services in all countries. It would not be appropriate, however, to use PPPs in the context of an international pharmaceutical price index. The purpose of estimating PPPs is to enable comparisons between countries which expressed as value data to reflect differences in the volume of goods and services. Medicines are an international commodity and the purpose of a price index is to compare different price levels across countries rather than the different volumes of medicines consumed.”

OECD index

“A basket of goods and services, found in all OECD countries, has been established which, in 1993, included around 700 pharmaceutical products. Also bandages, surgical items and consumables. Both patented and generic medicines, different strengths considered as different products. Updated every 3 years with new price data being collected by national statistics offices. Also inflation adjustments provided for the intervening years using data collected for their national consumer price indices. Medicine prices are not weighted according to their share in the total sales value of the basket.”

“An international price index of patented medicines would better inform policy makers whose actions are largely responsible for current price differences in the pharmaceutical industry. (…) What does seem clear is that the research-based industry as a whole would benefit by developing and maintaining a reliable international price index of in-patent medicines.”


“Cross-national comparisons in drug consumption are usually made in terms of dollars spent annually per person on pharmaceuticals. Expenditure reflects consumption, however, if measured in the same or very similar prices. When drug prices in different countries vary significantly, the expenditure comparisons may create a false image of consumption.

A comparative work has been undertaken in six countries: France, UK, Germany, Italy, Switzerland and USA. It appears that consumption of medicines has reached the highest level in France and Italy, while the highest spending occurs in Switzerland and Germany”.

Important for methodology. The author has compared prices from official price lists in Italy, France, UK, Switzerland, Germany, US. Chosen drugs that are common in all countries, only branded product, preferably the most popular and widely used, and with the same manufacturer in all countries, one presentation and dose, different pack sizes if needed. 1983 prices. Developed price coefficients as an arithmetical average of the price ratio from all drug prices compared. Part two only bestsellers. Part three 12 OTC drugs.

Did not quite understand how he measured consumption.
"The findings imply an astonishingly varying level of pharmaceutical prices in the different countries and give convincing support to the thesis that prices have a serious impact on the estimation of the consumption of drugs."

The price average for the bestsellers was found to be “very similar to that of all the medicines appearing in the study, which means that in absence of the weight technique, the arithmetical calculation of a price ration is also valuable.”

Finally, “the results suggest that prices of OTC drugs are also diversified, but less than ethical drug prices.”

Flaws/problems/limitations
His statement that “for international comparison of prices, the only suitable drugs are those which are present everywhere. They are relatively few in number but most important due to their predominance in both expenditure and consumption. Therefore, in order to elaborate the price coefficients, we do not have to worry about a sophisticated selection of samples of many thousands of drugs. Statistical techniques such as population average (parameter), the sample average (estimator), the sub-population (strata), the groups of samples (clusters), etc. are unnecessary. An unbiased selection is made automatically when the national price lists are compared.”

Assumes that prices are similar for all presentations and doses.
Some countries’ prices straight from price list, for others calculated based on manufacturer or wholesale price and routine mark-ups.
He uses the findings for calculating drug consumption as drug expenditure divided by the price coefficient, fixed at 1.00 for the UK with medium prices.

Controlling the prices of patented medicines in Canada. Annual report etc. PMPRB Canada.
http://www.pmprb-cepmb.gc.ca

PMPRB is the Patented Medicine Prices Review Board, an independent quasi-judicial tribunal created in 1987. Its role is to limit the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive.
In 1997, sales of patented drugs accounted for 52% of all drugs sold in Canada.

Factors affecting drug expenditures:
- prices of patented drugs
- prices of non-patented drugs
- prices of generic drugs
- retail and wholesale mark-ups
- dispensing fees
- changes in the total population, e.g. proportion of older persons
- changes in prescribing habits of physicians
- changes in the utilisation of drugs, i.e. number of drugs used per patient
- trends towards using newer drug therapy instead of other treatments

The document “Trends in drug prices and expenditures” analyses Canadian prices in comparison with USA and other countries and analyses trends over time

PMPI: Patented Medicine Price Index
CPI: Consumer Price Index
IPPI: Industrial Product Price Index
Canada requires manufacturers to report all publicly available ex-factory prices for patented drugs in seven foreign countries, listed in the Patented Medicines Regulations, in which the drug is sold.

“As in previous years, prices in the US appear to be higher than prices in Europe and in Canada. The pharmaceutical industry in the US has argued that the publicly available prices in that country do not reflect actual prices because of confidential discounts and rebates.”

“The quantities of patented drugs sold have consistently increased at a much faster rate than prices.”

“For review purposes, the PMPRB classifies all drugs sold in Canada according to the WHO’s ATC classification”


Study was requested by Waxman to examine the extent to which drug manufacturers charge more for the same products in the US than in Canada, and in particular when studying ex-factory prices to identify, to the extent possible, the causes of any documented price differentials.

Compares the manufacturers’ component of the prices paid by the typical retail consumer in both countries. 200 best-selling drugs in the US – 121 identical to both countries.
May 1991 prices from Medi-Span Master Drug Data Base-Select (wholesaler acquisition cost) and Ontario drug benefit plan.
US package size of 100, or extrapolated to 100.
Smaller differences when using PPPs.
Compared aggregate cost of the 121.

Canadian package sizes often units (larger)
No information on sales of these products in Canada, whether there were generics available, or other therapeutically interchangeable products available.

“Manufacturers’ prices to wholesalers for identical prescription drugs are typically higher in the US than in Canada. The price differences are largely attributable to actions taken by Canada’s federal and provincial governments to restrain drug prices, not to any differences in manufacturers’ costs between the two countries. The implications of adopting Canadian regulations in the US are in dispute. It is not clear how such regulations would affect manufacturers’ ability to develop innovative drug products.

The same manufacturer charges wholesale substantially more for identical prescription drugs sold in the US than in Canada. An entire basket of the 121 frequently dispensed drugs we studied would cost 32% more in the US than in Canada if common US prescription (such as 100 tablets) of each drug were purchased at factory prices in each country. A large majority of the 121 drugs studied (81%) was more expensive in the US. US-Canadian price differentials for specific products vary widely. On a per package basis, the US price to wholesalers ranged from being 44% lower to 967% higher than the Canadian price.

Major causes of drug price differentials
The major source of US-Canadian differences in drug prices is not variations in manufacturers’ costs. This holds true regardless of whether the cost differences relate to R&D, marketing, production, or distribution. Instead, government regulations and reimbursement practices contribute to lower average drug prices in Canada. …..”

“In this critique of the GAO report entitled Prescription drugs: Companies typically charge more in the United States than in Canada, we discuss possible misinterpretation of the GAO results, biases in the GAO results that overstate the differences between the US and Canadian pharmaceutical prices, and issues related to the statistical analysis performed by the GAO.”

A group of research-based pharmaceutical firms provided support for this project.

The GAO study started with 200 of the most frequently dispensed drugs in US drugstores and selected a commonly used dosage form, strength and package size for each product. 121 products were available in both countries. US prices are wholesale acquisition cost, Canada most from Ontario drug benefit formulary. Prices were also collected for some common consumer goods.

1. The Canadian prices are lower because Ontario is a large buyer. The author claims that ¾ of the difference in prices is due to failure by GAO to consider the effect of large buyers in the US.
2. More products not on the Ontario plan should have been included. And it is not obvious that ODB prices are representative of other provinces.
3. The impact of generic versions of brand-name products on pharmaceutical prices in either country is reflected.
4. The per unit ODB formulary BAP is almost always based on the largest package size of a given drug product sold in Canada. The US price is based on smaller (relatively more expensive on a per dose basis) package sizes.

“The larger penetration of generic products in the US mitigates the effect on consumers of higher prices for brand-name products in the US.”

“The GAO report confirms what is well known to people who work in the pharmaceutical industry on a daily basis; namely, pharmaceutical prices differ across countries. The GAO report, however, does not establish in a credible manner the reasons for the differences.

There are at least three possible problems for the pharmaceutical industry that could stem from the GAO report:
- Misinterpretation of the results by the general public; i.e., the public may erroneously conclude that, on average, US consumers pay 32% more for pharmaceuticals.
- Misuse of the results by politicians; i.e., politicians may use the GAO results to support the establishment of a PMPRB-type regulatory scheme in the US.
- Application of a statistically weak model to other countries; e.g., UK, Sweden, and Germany.”


“This study compares the prices of prescription drugs in Canada and the United States. The measure used is the replacement cost, at Canadian prices, of drugs consumed by the average American DRAFT NOT FOR CIRCULATION Compiled by Kirsten Myhr in 2000 as background to the development of the WHO/HAI methodology for measuring medicine prices
pharmacy or consumer. The sample was selected from the drugs consumed in the largest quantities in the United States. This ensures that the study captured non-patented as well as patented drugs. Other studies that compare drug prices across borders use price indices, which overwhelmingly reflect the prices of patented drugs.

The study finds that prescription drug prices are lower in Canada than in the United States. However, there is considerable variance among the price differences. A certain number of drugs are more expensive in Canada than in the United States. In all cases, these drugs are generic drugs. Indeed, if American consumers paid Canadian prices for generic drugs, they would pay higher prices than they do now.

As well, patented drugs have a smaller Canadian discount than branded, non-patented drugs. This is interesting because Canada has a price regulator, the Patented Medicine Prices Review Board, which controls patented drug prices but not non-patented drug prices. The fact that generic drug prices are often higher in Canada than the United States and that branded non-patented drugs have a greater Canadian discount than patented drugs invites a closer examination of the effects of Canada's drug-price control regime.


“The media often claim that pharmaceutical prices in Canada are low because of the Patented Medicine Prices Review Board (Arnold 2000; Evenson 2000; Trickey 2000). The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body that regulates introductory prices of new patented drugs and increases in the price of extant patented drugs in Canada. However, the PMPRB does not purchase drugs; rather, it determines the maximum prices that manufacturers can charge for patented drugs, thereby preventing market participants from negotiating a price among themselves.

The PMPRB was established in 1987 as part of the Bill C-22 amendments to the Patent Act, which were designed to allay American concerns about Canada's intellectual property policies on the eve of the approval of the Free Trade Agreement between Canada and the United States. In 1992, the PMPRB's mandate was expanded by Bill C-91, which brought Canada's intellectual-property laws up to the standard existing in developed countries at that time. The creation and expansion of the PMPRB was intended to mollify domestic fears that the legislative changes contained in C-22 might lead to higher drug prices. The mission of the PMPRB is to "contribute to Canadian health care by ensuring prices of patented medicines are not excessive" (PMPRB 2000: 6). The maximum price established by the PMPRB applies to all patented drugs sold in Canada. Hospitals, provincial drug-benefits plans, private insurers, and individual cash buyers are all affected by the PMPRB's price controls.

However, the PMPRB controls only the manufacturer's "gate price" (the price at which the manufacturer sells to the wholesaler) not the wholesale price, retail margin, pharmacist's dispensing fee, or any other distribution cost. The manufacturer must submit detailed price and sales reports for the first 30 days' sales and for every six months thereafter until the patent expires or the drug is removed from the market.

The pricing guidelines used by the PMPRB are decided behind closed doors with so-called stakeholders: provincial and territorial Ministers of Health, pharmaceutical and biotech companies, health associations, and self-styled consumers' advocacy groups such as the government-funded Consumers Association. The PMPRB classifies patented drugs into three categories. Category 1 ("line extension") usually contains drugs that are a new strength of an existing drug. Category 2 ("breakthrough") includes drugs that produce a substantial improvement over predecessors. Category 3 ("me-too") contains drugs that provide moderate, little, or no improvement over existing medicines. The basic pricing guidelines are as follows.

1. For previously introduced and approved medicines in all categories, price increases are limited to changes in the Consumer Price Index (CPI). The excessive price test is based on a three-year cumulative change in the CPI. In addition, single year increases are limited to 1.5 times
the forecast change in the annual index. In periods of high inflation (over 10 percent), the limit to price increases is five percentage points more that the forecast change in the CPI.

2. For a new drug in Category 1, the introductory price will be judged to be excessive if it does not bear a "reasonable relationship" to the average price of the same medicine in the same or comparable dosage forms.

3. For a new drug in Category 2, the introductory price will be presumed to be excessive if it exceeds the higher of the cost of therapy with medicines in the same therapeutic class and the median of prices of the same drug in the United States, United Kingdom, Switzerland, Sweden, France, Germany, and Italy.

4. For a new drug in Category 3, the introductory price will be presumed to be excessive if the cost of therapy with the new drug is higher than the cost of therapy with existing comparable drug products in the same therapeutic class.

5. In addition, the price of a patented drug cannot exceed the highest price of the same medicine sold in the United States, United Kingdom, Switzerland, Sweden, France, Germany, and Italy. If the PMPRB considers that a price is excessive, it has the power to order a price reduction. Depending on the degree of harm that the PMPRB believes that the public has suffered, it can also order a rebate to customers, a payment to the Crown, a temporary greater reduction below the assessed fair price, or a temporary price reduction of another patented drug manufactured by the same company. In extreme cases, the company can be referred to the Attorney General for contempt of court.

During the five years from 1994 through 1998, 408 new patented human drugs were introduced, of which the Board classified 213 (52 percent) as Category 1 ("line extensions"), 171 (42 percent) as Category 3 ("me-toos"), and 24 (6 percent) as category 2 ("breakthroughs"). Given the pricing guidelines for different categories described above, 94 percent of new drugs were not able to enter the market at a higher price than their comparable predecessors.

On the face of it, these strict regulations appear to have served their purpose well. The Patented Medicine Prices Index (PMPI), which measures the manufacturer's gate price for patented drugs, has increased by less than the CPI for all years but one of the PMPRB's existence. Furthermore, the ratio of Canadian prices to international prices has decreased every year from 1991 to 1998, increasing marginally in 1999 (PMPRB 2000: 22). In 1999, the PMPRB's price indices showed that American prices for patented drugs were 62 percent higher than prices in Canada whereas, in 1987, the year in which the PMPRB was founded, the difference was 36 percent (PMPRB 1999: 21; 2000: 23).

Inspired by the apparent success of the PMPRB in keeping prices low in Canada and lists of drugs with large Canadian discounts, some American legislators are proposing similar price control agencies for their jurisdictions.

Maine, for example, has passed legislation to establish the Fair Drug Pricing Board in 2001. This Board will be broadly similar to the PMPRB. The two major differences are that the Maine Fair Drug Pricing Board will regulate wholesaling and retailing margins as well as the prices of non-patented drugs. Despite these differences, the impact of the Maine Fair Drug Pricing Board should resemble that of PMPRB. Firstly, in the United States, manufacturer's gate prices for cash buyers of pharmaceuticals (those who do not have insurance) make up 77 percent of retail prices (US Department of Health and Social Services 2000: 98), so this is where regulatory pressure is likely to focus. Secondly, since branded non-patent drugs generally (but not always) face generic competitors and generic drugs are unambiguously cheaper than patented drugs, it is unlikely that they will face real scrutiny by the Board.

Similar legislation is under way in other American jurisdictions. It is understandable that American observers, concerned about the costs of prescription drugs, are ready to adopt blunt instruments of price control fashioned after the PMPRB. After all, the circumstantial evidence seems to indicate that the PMPRB has kept Canadian drug prices low without serious negative consequences.

The history of legislated price controls, however, shows that they have results that are not immediately apparent and quite different from those intended by their creators (Walker 1976). This paper will examine the evidence for the differences between the prices that Canadians and Americans pay for prescription drugs, explore their actual causes, and assess all the effects of the PMPRB.

DRAFT NOT FOR CIRCULATION Compiled by Kirsten Myhr in 2000 as background to the development of the WHO/HAI methodology for measuring medicine prices
Conclusions

The average price of goods and services in the United States is 25 percent higher than in Canada. This situation has arisen because of the significant decline in incomes in Canada relative to the United States.

The types of products that drive this difference in prices are creations of intellectual property, which have low marginal production costs, so that manufacturers can earn marginal profits by charging low prices in those markets where consumers cannot pay prices high enough to cover the sunk costs of research and development.

Canada's low drug prices are exemplary of this type of product. They are chiefly the result of Canada's low standard of living relative to the United States and pharmaceutical companies' marketing response to our declining incomes. This gap in incomes and prices has increased over the past decade.

As well, higher legal liability costs in the United States account for about one-third to one-half of the difference in price of patented pharmaceuticals in Canada and the price in the United States.

The Patented Medicine Prices Review Board does not keep prices low; rather, it keeps prices high, because its guidelines discourage patented drug manufacturers from using price reductions as a competitive strategy.

This allows generic companies to charge prices significantly higher than they could in a free market and insulates them from any effects of price competition among brand-name competitors, which would lower the ceiling under which generic companies price their drugs.

High American drug prices result primarily from America's position as the world's most productive and wealthiest country. As long as the United States maintains this position, it is likely that its drug prices, along with prices of other goods and services, will be higher than they are in other countries.

American imitators of the PMPRB, such as the Maine Fair Drug Pricing Board, are unlikely to succeed in keeping prices low but will have unintended negative consequences, as has the Canadian PMPRB.”


The authors are from the Fraser Institute – a right-wing thinktank.

“Drugs that have low volume but high prices will have a large influence on the level of a classically constructed price index. However, such drugs may not impact the drug budgets of the average consumer. For example, epoietin alpha was the sixth largest selling drug (in dollar volume) in the US in 1998, but so few units are sold that the FDA classifies it as an orphan drug. The drug weights significantly in the national US-weighted drug basket, but clearly does not figure in the drug costs of the average American patient. (…) Furthermore, because regulatory approval is so slow in Canada, innovative and highly priced drugs may be included in the US price index before they are included in Canada’s. (…) Most importantly, these lists and indexes only contain patented drugs, not off-patent branded drugs or generic drugs. (…) In fact, most of the increased difference in drug prices is explained through a macroeconomic factor: the decline in the Canada-US exchange rate from purchasing power parities. (…) The litigious atmosphere in the marketplace contributes significantly to high American prices.”

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To litigation: “There was a consistent gap of about 15% in favour of Canada in the price of single source products, that is those without generic competition, going back as far as 1968, long before there were astronomical liability suits in the US”. (…)

From Scrip Mag.: “It would not be appropriate … to use PPPs in the context of an international pharmaceutical price index.

They ignore changes in the Canadian Industrial Product Price Index (IPPI (pharma)) and the US Product Price Index (PPI (pharma)).

While roughly 35-45% of drug units dispensed in either country are for generic drugs they account for a small minority of the total expenditures, about 8-9% in both countries.

These newer, more expensive drugs are the ones that are being prescribed to the elderly in the US and they are precisely the ones that have their prices regulated in the Canadian market by a combination of the actions of the PMPRB and the provincial governments.”

Berndt ER. Testimony of Ernst R. Berndt before the House subcommittee on health and the environment. 22 February, 1993

On why prices are lower 1) “I expect the costs of doing business in Canada are less than those in the US. In particular, given rather different legal systems, there is much lower exposure to liability in Canada than in the US. 2) Since buying power is more concentrated in Canada, I expect that distribution and marketing costs are lower as well”. 3) “With buying power more concentrated…I would expect that Canadian buyers are better able to exploit some of their buying power to obtain lower prices from drug manufacturers”. 4) “To the extent that effective patent lives are longer in Canada than in the US – and the extent of that is not entirely clear – it is possible that branded drugs in the US experience a shorter life span over which the fruits of their patent protection can be harvested”.

Further comments as in Rozek: price lists, purchasing package sizes, weighting versus market shares in Canada, lack of generics.


(available at www.house.gov/berry/prescriptiondrugs/studies.htm)

“The question of differential prices of prescription drugs across US, Canadian, and Mexican national borders is invariably raised in any discussion of public policy related to the regulation of the pharmaceutical industry, and, especially, the research-based pharmaceutical industry. The implication of the question is that the American consumer is being gouged by the drug manufacturer at the pharmacy.

The reality is that retail prescription drug prices in the US are higher than in neighbouring countries. While it is likely that the pharmaceutical companies price their products in these countries with a view to maximising profits, consistent with what the market will bear, it is also demonstrably clear that the structure of the markets in the three countries are very different, making it difficult, if not impossible for a single price to be charged in all three countries. In particular, government plays a significant role in the marketing of prescription drugs in both Canada and Mexico as compared with its role in the US.
Also, US government regulations preventing the importation of retail lots of prescription drugs may give rise to the unintended consequence of creating a barrier to price equalization across national borders.”

The paper refers the GAO US-Canada study (1992). This study selected the most frequently dispensed drugs in their most commonly used dosages and package sizes by US drugstores. 121 products. Prices were obtained from private US databases, and are wholesale acquisition costs paid by the drugstores. Canadian prices were the Canadian factory prices listed by Ontario Drug Benefit Formulary. It indicates the maximum amount of reimbursement to the druggist for each prescription drug.

Mexican price data are not available in the same detail. PhRMA has argued that reasons for lower prices in Mexico are international income inequality and the lower value of the peso. PhRMA ignores business decision criteria on the supply side of the market. “In an idealized free market, the proposition that people with low incomes may not demand large quantities of a product at any given price as compared with persons with high incomes does not mean that suppliers would simply make the same product available to the former group at lower prices. The suppliers in such a market are thought to be motivated by considerations of profit, if not maximum profit. As a result, unless the supplier can cover all costs of production – including embedded costs of research, development, and testing, they are not likely to enter a given marketplace.”

“The question can be raised: if the manufacturer can realize profits in countries with price controls and/or government purchasing plans, why do they charge higher prices elsewhere? In a pure market economy, the objective of any firm is to maximize profits. When markets can be segregated so that consumers in one area cannot buy in another, the seller may be able to increase its profits by engaging in what economists call price discrimination.


Study was requested by Waxman to examine the extent to which drug manufacturers charge more for the same products in the US than abroad, and in particular when studying ex-factory prices to identify, to the extent possible, the causes of any documented price differentials.

“Our study focuses on factory prices, brand-name drugs, and the market segment in which retail pharmacies generally do not receive manufacturers’ discounts. Given this focus, we examined the top 200 prescription drug products most frequently dispensed in 1991 in the US. These 200 drugs accounted for the majority (54.9 %) of all prescriptions dispensed in the US. We succeeded in matching 77 of these popular products with the identical drugs sold in the UK. Our study included only products for which the same manufacturer sold or licensed the identical product in both countries in the same form and dosage strength.”


Compiled a price index to account for differences in quantities of each drug sold in the US. Interviewed UK government officials, industry representatives and academic experts in both countries about likely causes.
To provide perspective on our central findings, we conducted additional price comparisons. First, to permit us to contrast the typical consumer’s perspective on factory prices of drugs with the manufacturer’s perspective, we also estimated US-UK price differentials using an average US price measure that includes discounts and rebates provided to certain non-federal institutional buyers. The average US price does not address our central question - how factory prices differ between the market segments frequented by typical consumers in the US and the UK. Nonetheless, the average US price does help shed light on a related question that is vital to manufacturers - how the amount of revenue per package received by the manufacturers differs between the US and the UK. Second, because lower priced generic drugs are available as alternatives to some higher priced brand-name drugs, we also estimated the price differential that would occur if American consumers always substituted generic drugs, if available, for the brand-name drugs in our sample.

We found significant differences in the prices that manufacturers charge wholesalers for identical, frequently dispensed prescription drugs sold in retail pharmacies in the US and the UK. A market basket of 77 frequently dispensed drugs that we analysed would cost wholesalers 60% more in the US than in the UK. A total of 66 drugs (86%) were priced higher in the US than the UK, and 47 (61%) were priced more than twice as high in the US as in the UK. US-UK price differentials varied substantially among individual products. US prices ranged from 62% lower to 1712% higher than the UK prices.

May 1, 1992 prices
Price to wholesalers
Drugs identical in US and UK, selected from a list of the 200 most frequently dispensed by US drug stores (54.9% of all prescriptions dispensed during 1991).
Single, commonly used US dosage form, dosage strength and package size for each specific drug product
Manufacturers’ ex factory prices
Brand name drugs, same manufacturer
Compared unit prices
UK prices from Chemist & Druggist Monthly Price List, this is wholesale prices, 12.5% discounting deducted.
The segment of the market populated by the typical consumer who, in both US and UK, buys prescription drugs at retail pharmacies “Although these consumers account for at least 55% of all outpatient prescriptions in 1992, they generally do not benefit from discounts that certain purchasers such as hospitals, mail order pharmacies, and certain HMOs may obtain from manufacturers.” (undiscounted market segment).

Weighting: “Summarized the spectrum of price differentials by comparing the cost of purchasing, at factory prices, a weighted market basket of all 77 drugs in the US to the cost of purchasing the same market basket at factory prices in the UK. This market basket is, in effect, an index that weights each individual drug price by the quantity of the product sold in the US.(these weights are from the IMS America US Drugstore database). This comparison of aggregate cost captures the difference between US and UK prescription drug prices in a more meaningful way than, for example, the mean or the median of the individual differences in unit prices.”

To contrast the typical consumer’s perspective on factory prices of drugs with the manufacturer’s perspective:
“Estimated US-UK price differentials using an average US price measure that includes discounts and rebates provided to certain nonfederal institutional buyers. (discounted and undiscounted market segments). We compared this alternative measure of US prices (for the same market basket of frequently dispensed drugs in the US) to the factory prices charged for the same drugs in the UK. The average US price does not address our central question – how factory prices differ between the market segments frequented by typical consumers in the US and the UK. Nonetheless, the average US price

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does help shed light on a related question that is vital to manufacturers – how the amount of revenue per package received by the manufacturers differs between the US and the UK. Second, because lower priced generic drugs are available as alternatives to some higher priced brand-name drugs, we also estimated the price differential that would occur if American consumers always substituted generic drugs, if available, for the brand-name drugs in our sample.”

77 drugs in the basket. (included 27 of the 50 most commonly prescribed drugs). Would cost wholesalers 60% more in US. Variation from 62% lower to 1712% higher. Dramatically smaller for more recently introduced drugs. Price differentials tended to be smaller for single source brand name drugs than for brand name drugs that have generic substitutes. Consistent with findings from other studies that, in the US market, manufacturers respond to competition from lowered priced generic drugs by increasing – rather than decreasing – the prices of brand name products.

Result largely unaffected by the methodological decisions made.

21 of the 77 had generic substitutes. The researchers found that if US consumers purchased lower priced generic substitutes when available, and UK consumers did not, US consumers would still pay substantially more for the basket. (50%)

Using price conversion versus PPPs. Still substantial drug price differentials. Main cause of the difference attributed to price regulation in UK.

GAO-94 discusses in Appendix III methodological issues for international drug price comparisons. It states that methodological controversies in drug price comparisons centre around three basic questions:

- What price concept is being measured?
- For what sample of drugs are these prices measured?
- How are the results of this price comparison summarised and presented?

The purpose of the study will influence the price concept measured, e.g. whether to choose a segment of the market or the entire market. From a manufacturer’s point if view, each price in each segment of its market is relevant to the total picture. However, from the consumer’s point of view, the prices paid by buyers in other markets are irrelevant – the relevant price is the price paid in that consumer’s particular submarket. Another point to consider is whether to focus on the manufacturer’s role in determining price or the retailer’s role. A decision also has to be made on whether to compare only manufactured or licensed by the same firm in each country. This practically excludes generics.

The purpose of the study suggests criteria for sampling decisions. Which country should be the reference is one aspect to consider, another is whether to compare only identical products. As many products as possible should be matched to enhance the reliability of the results, and in choosing among methodological options, GAO preferred to underestimate price differentials. These might be conflicting goals.


98 randomly selected pharmacies in Pennsylvania. 10 most widely prescribed drugs for older adults and people with disabilities. Retail price compared to the best federal price. (eq. to the price the manufacturer charge their most favoured customers.)

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Part One: Pennsylvania State Drug Price Survey

Thousands of Pennsylvania senior citizens and persons with disabilities without prescription drug coverage face price discrimination by pharmaceutical manufacturers. A price survey of ninety-eight randomly selected pharmacies in Pennsylvania, conducted by the national consumer group Public Citizen and Citizens for Consumer Justice shows seniors are being charged retail prices that are more than double the prices charged by prescription drug makers to their most favored customers.

Senior volunteers surveyed the prices of ten of the most widely prescribed drugs for older adults and people with disabilities at randomly selected pharmacies in the state of Pennsylvania. The retail price was compared to the best federal price, which according to the U.S. General Accounting Office is equivalent to the price pharmaceutical manufacturers charge their most favored customers. Prices charged to local seniors were more than double - about 113% more - than the most favored customer price.

For the top ten drugs used by seniors to treat a variety of illnesses, those in Pennsylvania paid between 48% and 231% more than drug companies’ most favored customers:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Condition Treated</th>
<th>Price Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosamax</td>
<td>osteoporosis</td>
<td>101% more</td>
</tr>
<tr>
<td>Lipitor</td>
<td>cholesterol</td>
<td>64% more</td>
</tr>
<tr>
<td>Norvasc</td>
<td>blood pressure</td>
<td>90% more</td>
</tr>
<tr>
<td>Pepcid</td>
<td>ulcer</td>
<td>48% more</td>
</tr>
<tr>
<td>Prevacid</td>
<td>ulcer</td>
<td>171% more</td>
</tr>
<tr>
<td>Prilosec</td>
<td>ulcer</td>
<td>96% more</td>
</tr>
<tr>
<td>Rezulin</td>
<td>diabetes</td>
<td>96% more</td>
</tr>
<tr>
<td>Tegretol</td>
<td>epilepsy</td>
<td>64% more</td>
</tr>
<tr>
<td>Ticlid</td>
<td>stroke</td>
<td>147% more</td>
</tr>
<tr>
<td>Zocor</td>
<td>cholesterol</td>
<td>231% more</td>
</tr>
<tr>
<td>Zoloft</td>
<td>depression</td>
<td>102% more</td>
</tr>
</tbody>
</table>

Part Two: Medicare Beneficiaries’ Drug Coverage and Pharmaceutical Industry Price Discrimination and Profits

Instead of offering most favored prices to Medicare beneficiaries because of their huge collective buying power, pharmaceutical makers practice price discrimination against seniors and people with disabilities by charging them their highest retail prices. One out of three Medicare beneficiaries - 14 million older adults and people with disabilities - have no prescription drug coverage. They constitute a far larger purchasing block than any current customer receiving best price treatment from pharmaceutical manufacturers.

Millions of American seniors are suffering under this discriminatory pricing since Medicare does not cover outpatient prescription drugs. In addition to the 14 million beneficiaries who have no coverage for prescription drugs and therefore pay high retail prices totally out-of-pocket, many more older adults have inadequate or insecure insurance coverage with high deductibles and co-payments and low annual caps for coverage. Moreover, Medicare HMOs and employer plans are reducing drug coverage or raising costs for retirees.

The pharmaceutical industry profits handsomely from price discrimination. For decades, brand name prescription drug makers have consistently been among the most profitable industries in America. In
1998, pharmaceutical companies ranked first among all industries in rates of return on equity, assets, and revenues. Despite these high profits, the prescription drug industry pays much less in federal taxes than other major industries, according to a new study by the Congressional Research Service. Moreover, CEOs of the top ten pharmaceutical companies last year averaged $20 million in annual compensation, including stock options, and now hold nearly $1 billion in stock options.

The drug industry claims that high U.S. prescription drug prices are necessary to fund research and development. But R&D is a lower priority than profits for the manufacturers. In 1998, the top ten firms put one-and-a-half times as much money into profits as into research and development. Moreover, not everyone pays such high prices. Foreign consumers get U.S.-made drugs at a fraction of the price paid by American senior citizens because their governments negotiate fair prices with prescription drug makers.

Congress is currently considering legislation to prohibit price discrimination against seniors and people with disabilities in the Medicare program and to add a comprehensive prescription drug benefit to Medicare:

"The Prescription Drug Fairness for Seniors Act" (H.R.664/S.731) would harness the buying power of 39 million Medicare beneficiaries to allow seniors and the disabled access to the same low prices as drug companies’ most favored customers. Pharmacies would purchase prescription drugs for Medicare beneficiaries from the manufacturer at the same low prices charged favored customers such as the Departments of Defense and Veterans Affairs and other large purchasers. Since these prices are nearly half the retail prices paid by Medicare beneficiaries without prescription drug coverage, seniors will benefit from large cost savings even after fair pharmacy dispensing fees are included. H.R. 664/S. 731 have more support than any other prescription drug reform legislation in Congress - 151 House co-sponsors and 12 Senate co-sponsors as of April 12, 2000.

President Clinton and Congressional leaders have proposed that a comprehensive prescription drug benefit be added to Medicare. To be cost effective, such a benefit must use the bargaining power of the federal government and Medicare beneficiaries to negotiate significantly lower drug prices - similar to the savings that could be achieved under the "Prescription Drug Fairness for Seniors Act." Negotiating fair prices is the first step in constructing an affordable benefit plan - with low premiums, low or no co-payments, and good coverage for those with high as well as low or moderate drug expenditures.


**ABSTRACT**

*Background:* Recently introduced antipsychotic and antidepressant drugs may have advantages over older drugs but their high cost may be a major limitation to their availability. Anecdotal reports have described large differences between costs for these drugs in the US and other countries.

*Methods:* Physicians and pharmacists from 17 countries in North America and Europe provided information on the acquisition cost to the pharmacist of an average 30-day supply for three newer antipsychotics (clozapine, olanzapine, and risperidone) and five newer antidepressants (fluoxetine, fluvoxamine, paroxetine, sertraline, and nefazodone).

*Findings:* For each of the eight drugs studied, the acquisition cost in the US was higher than in any other country, varying from 1.7 times to 2.9 times higher that the average acquisition cost in all other countries studied. For example, clozapine's acquisition cost was $317 in the US for a one month’s supply compared to an average acquisition cost of $111 in the other countries. In 1996, $2.1 billion would have saved if people in the US could have purchased the eight drugs for the average acquisition costs in the other countries.

*Interpretation:* All countries studied except the US have national health insurance that may allow them to negotiate lower prices with pharmaceutical companies. Even with negotiated prices, the companies
make a reasonable profit, e.g. 20% for all drugs in the UK. By contrast, the profit margin for these same eight drugs in US is estimated to be 42%. Annual 1996 net profits for the six companies about which such information was available were $12.3 billion. This profit margin and the concomitant high prices for these drugs in the US may deny many individuals with severe psychiatric disorders access to the drugs in the study.

17 countries comprising EU, Canada, Mexico, USA. One local community pharmacy in each. Interviewed by pharmacist or physician. Acquisition cost. Relatively new drugs. (probably patented). An average 30-day supply of 8 drugs, if suitable pack size not available, quantities and costs converted to 30 days. Converted to USD using exchange rate on day of collection.

Large price differences and even EU drugs more expensive in US. Average American price twice as high as the average of the other countries. Up to 6x higher

“A major limitation of this study was obtaining acquisition costs that were representative of a national average and clearly one pharmacy in each of the 17 countries may not represent a reliable national estimate. In some countries as many as four pharmacies were contacted before a pharmacist was found who was willing to disclose the acquisition costs of the study drugs. Nevertheless, the important consideration is the magnitude of the differences in reported acquisition costs between the US and other countries.”

Bedsted T, Jørgensen K. Sammenlignende undersøgelse af medisinpriser i 1999 (Comparative study of drug prices in 1999). I. Center for forskning og udvikling på ældreområdet (Centre for research and development in the elderly), University of Copenhagen 28 January 2000. (In Danish)

“This comparison of Danish and foreign drug prices is based on price material collected by the Association of pharmaceutical manufacturers in connection with an agreement between the industry and the Ministry of Health, and it gives opportunities for comparing prices of individual products in Denmark and abroad.

In the study a price index has been developed for AIP as well as AUP, the latter with and without VAT.

The study shows that the Danish price level (for AIP) in 1999 is not high compared to other countries as the number of countries Denmark is compared to having higher prices than Denmark is higher than the number having lower prices. Even if method of calculation differed for a similar study in 1996, the result seems to confirm that the Danish price level relative to foreign countries declined somewhat in this period.

The results for AUP shows that when the VAT is included, the Danish prices will be close to the top, but if VAT is removed from all prices, the picture changes substantially and is much more in agreement with the result for AUP. The relatively high Danish VAT thus stands out as an important part of the explanation for the high retail prices.”

Calculation of price index for AIP (price to pharmacy) in Denmark and other European countries. An AUP (pharmacy sales price) price index has been constructed based on information on profit margins in pharmacy and VAT in the countries surveyed.

Choice of drugs in general:

DRAFT NOT FOR CIRCULATION Compiled by Kirsten Myhr in 2000 as background to the development of the WHO/HAI methodology for measuring medicine prices
Developing a Methodology to Assess the Impact of TRIPs-plus Provisions Affecting Drug Prices
31 July to 1 August 2006

- reasonable assortment
- each product weight must be related to its importance in the Danish consumption
- then calculate what the Danish consumer would have to pay in each of the countries surveyed for a basket which in Denmark would cost 100 DAK.

for this survey:
- chose a reasonable number, sufficient to obtain an acceptable coverage, in terms of money, of the consumption.

if not available in any of the other countries at all or in the form surveyed:
- used the regulation of conversion which has been agreed between the government and the manufacturers (the industry's documentation)

other problems
- the value of the price index is to be seen in connection with the price level in the country. This is not always reflected in the calculation of an index where foreign prices, as in this survey, is calculated using current exchange rates.

Used the price information collected by the manufacturers as part of the agreement with the Danish government of 1998, and from the assortment covered by the agreement. In addition, supplementary material, mainly from the manufacturers. If products not identical, used calculations agreed upon in the contract of 1998. The general problem of matching is there.

Data collected for another purpose and therefore not collected for this study. 1 April 1999.

Assortment: (cf. 1996) the most sold drugs:
- drugs with the largest sale (assortment I): 125 item codes
- the largest drug within each generic area (ATC 5.) with largest sale (assortment II): 100 item codes

Laspeyres’ price index, weight Danish sales data.

Not so many products matched, when looking at pack size even fewer (down to 5/100!)

Each product weighted relative to its importance in the consumption of drugs in Denmark.

A basket which in Denmark costs 100 DAK - what would a Danish medicines user have to pay in other countries?


22 commonly used oral drugs in units of 100 in 29 countries. Questionnaire mailed to colleagues.
Retail prices from pharmacies. UK prices from BNF
Also prices of four common food items. Economic indicators were PPPs and minimum daily wage of unskilled worker. Converted to USD by collector.

Some findings:
The average price of a basket of six commonly used drugs is about five to seven times more expensive in the Philippines and Indonesia respectively than in India or Nepal.

What is most alarming is the finding that the prices which consumers with low purchasing power in developing countries pay for some commonly used drugs are much higher than the prices rich consumers in developed countries pay for the same drugs.

Bala K, Lanza O, Kaur SL. Retail drug prices: The law of the jungle. Hainews 1998; no 100 April: 2-4, 13-16 and inserted table.
21 commonly used drugs in units of 100, oral, in 39 countries. Questionnaire mailed to colleagues. Retail prices from pharmacies. Also price of four common food items. Economic indicators were PPPs and minimum daily wage of unskilled worker.

Some findings:
Higher retail prices for some drugs, particularly the more expensive ones, in low income developing countries compared to the much more affluent OECD countries.

The average retail price of each of 20 commonly used drugs in 10 developing countries of Central and South America are all higher than the average retail prices of these in 12 OECD countries.

Bala also 1992. (Scrip 1785 12 January 1993 page 19, Hainews no 68, December 1992)

12 drugs in 11 countries.


This is the 4th international survey by Bala. (1992, 1995, 1998, 1999)
Retail prices. 16 drugs, 36 countries. How the 16 drugs were identified is described. Grouped in 3 categories according to patent status

Collected by colleagues in different countries on a voluntary basis. I.e. countries may differ. Each colleague asked to record from leading pharmacy in the capital city the price of the brand and two top-selling generics of the drugs listed. (Top-selling would probably be what the pharmacy thought was selling best). Total number available of each. Record pack size. Convert to US dollars. Converted by Bala to units of 100.

HAI partners and CI members were requested to select a leading retail pharmacy in the capital cities of the respective countries, and discuss with the pharmacy the following:
· Ask for the availability and retail prices of the proprietary or brand name product of each drug listed.
· Find out the total number of products which include the originators’ brand, branded generics and generics of each of the 16 drugs available in the pharmacy.
· Record the retail prices of the originators’ brand and the package size
· In cases where there are several products of drug available, record the prices of the next two best selling products in addition to the proprietary brand or top-selling brand.
· Record the prices of each package size in the national currency and convert it to US dollars

See also IFPMA comments.

Conclusions & Recommendations
The most striking feature in this survey are the following:
· The higher prices of proprietary drugs in some of the developing countries of Africa, Asia and Latin America compared to prices in the 10 OECD countries. The retail prices of 15 out of the 18 dosage forms of eleven drugs for which comparable data are available are all higher in some of the developing countries than in the OECD countries.

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Proprietary brand forms of several of the multi-source drugs surveyed are the only products available in many of the African countries enjoying a monopoly market, although low priced generic equivalents, are available in the world market. These countries do not offer patent protection to drugs.

There is a very wide variation of retail prices in the countries surveyed:

(i) The variation in the retail prices of proprietary drugs are much wider (range: 1:16-1:59), than the variation in prices of generic equivalents (range 1:7-1:18).

(ii) The variation in the retail prices of multi-source drugs in developing countries (range 1:1.7-1:59) are much wider than the variations in OECD countries (range 1:2-1:11.5)

It is assumed that market forces promote competition. It should therefore follow that in a free market, competition will result in lowering and more importantly, leveling of the prices. This appears to be so, in the OECD countries and to a certain extent in the generic drugs market in the developing countries but not in the proprietary drug market in developing countries.

The smaller variation in retail drug prices in OECD may be due, as stated earlier, among others, to the following:

- Co-marketing arrangement by manufacturers;
- Parallel importing;
- Reference pricing; and
- Drug pricing policies.

The wide variation in prices of proprietary drugs in the developing countries suggests that the guiding principle which the drug industry seems to adopt in fixing prices is to set the limits according to what the market can bear. Profit maximisation seems to be the only objective.

There is evidence that competition is possible in the pharmaceutical market and this will bring prices down. Data from India proves this. When competitors introduce their products, the originators will lower their prices and compete with the national firms. They will not withdraw from the market. Thus, it is important to introduce generic competitors as early as possible to prevent the originators having time to secure brand loyalty to their products by skillful promotion.

There is a time lag between the introduction of a drug in the world market and a competitor to get its product into the home market. It takes further time to capture adequate market share so as to increase production, lower costs and compete with the originator. The Indian data on retail prices of three drugs recently introduced and four others which were introduced much earlier, illustrate this phenomenon and underscores the need for national policies on intellectual property system with provisions to enable national firms to initiate production of new drugs as early as possible. Indian firms were able to do this by a process of reverse engineering. This was possible because the Indian national legislation on patents did not provide patent protection for products.

However with TRIPs Agreement taking effect, all member states of the WTO should provide patent protection for products and processes for 20 years. The only way national firms can initiate production is by compulsory licensing which is allowed in the TRIPs Agreement. Nevertheless, only a few of the advanced developing countries can use compulsory licensing to manufacture new drugs. A vast majority of developing countries do not have any facilities for production of pharmaceuticals.

These countries depend on imports of raw materials and finished products. They can have access to lower priced drugs produced in the more advanced developing countries or by generic manufacturers in some developed countries only by parallel importing. This is also allowed in the TRIPs Agreement.

Analysis of empirical data provided in this paper supports the position that compulsory licensing and parallel imports are two provisions which should be in all national legislations on intellectual property rights. TRIPs Agreement allows these provisions to be included in the national legislation on prices. This will enable developing countries regular access to good quality essential drugs at affordable prices.

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25 drugs in 51 brands from multinational companies to ensure they were widely available, i.e. same brand names in all countries. As I interpret it, brands compares innovator’s brand and branded generics (otherwise you would not have more than 25 products). 5 ‘levels’ with one pharmacy from each. Philippines, Thailand, Malaysia, Singapore, Indonesia.


Prices found averaged for each substance in each country. Price ratio = Philippines: country of comparison.

Also a comparison between sectors. E.g. calculated mark-up in Philippine private hospitals to be 18.5%.

Very few matches especially in finding pharmacies from same sector. Malaysia no specified sector, Indonesia only one pharmacy, Thailand 2. 12 generics checked. No information on the generics, if there were one of each substance, if it was the same in each country etc.

Descriptive study. Main findings that Philippine drug prices for branded products are 40-70% higher than in Thailand, Malaysia and Indonesia. Singapore has higher prices, but also a higher per capita income.


His paper has the following sections:

1. High drug prices in the Philippines which is an introduction as to why this issue is raised (reason to believe prices in the Philippines are high, with references e.g. to HAI-survey).
2. Analysing trends in prices of ten essential drugs where prices in the Philippines are compared with UNICEF prices for second half of 1994 to second half of 1995. Philippine prices have been averaged for brands and generics (I suppose this means innovator and branded generics in one group).
3. Demand elasticity and differential price behaviour among drugs.
4. Price differentials and competition between brand-named drugs and generic drugs, addressing e.g. the fact that drugs such as nifedipine with less competition has a higher price relative to the UNICEF price.
5. Inflation rates of drug prices. Shown together with the general CPI inflation as well as the inflation of prices quoted by UNICEF.

After these chapters he concludes:

Drug prices in the Philippines are much higher than in other countries and in comparison to UNICEF’s suggested prices for essential drugs.

Brand-named drugs are also much higher in prices than their generic counterparts by an average ratio of around 2 to 1.

Cost reductions in drug production abroad have not fully benefited the Philippines since most of these cost reductions have not been fully absorbed locally. This, however, has allowed inflation in drug prices to be below general price inflation in the Philippines, but has maintained (and perhaps aggravated) the disparity of Philippine drug prices with those abroad.

The differential performances of various drugs in terms of prices and mark-ups over foreign prices may be due partly to the nature of the drug, particularly demand elasticities of the drugs.

The amount of competition of branded and generic names for each type of drug has some correlation with the mark-up over foreign costs of that particular drug.

6. Structure of costs of production (production, tariffs and costs of imported inputs, labour costs, marketing, promotion and distribution, other)

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7. Monopolistic competition in the drugs industry.

Finally the paper gives recommendations – also for further studies.

Flaws/problems/limitations
The paper (unknown status) has no chapter discussing methodology.

Philippine prices seems to be retail, but not clearly stated. Prices are said to come from the monitoring data of the Philippine National Drugs Policy. UNICEF prices are fob Copenhagen.

NB Most of the Philippine products are combinations which are then compared to single component UNICEF products.

The explanation given on why prices of TB drugs are closer to UNICEF prices than prices of other drugs seems strange. He seems to be over-stating the importance of price elasticity.


The paper, which has been supported by the research-based industry, considers the following issues relating to the Philippines:

i) international price comparisons
ii) market structure – manufacturing and distribution
iii) market structure – retailing
iv) government encouragement of generic supply
v) the state’s concern with generic demand

The two papers by Lim and Wong are commented upon. He calls UNICEF prices “charity” or “give away” prices.

Retail mark-ups are low (8 %) by international standards.

The paper recommends some actions to be taken to reduce cost, including centralised procurement, careful encouragement of generic demand.

His final comment is:
“Government should not try artificially to restrain prices in those sectors where prices are already market based and competitively determined. Rather is should concentrate its efforts on procuring and supplying medicines for the poor and underserved.”

Not relevant


Overview of a WHO drug pricing project. Prices collected in European countries.

Prices collected over a 2-months period summer 20000. 29 countries, 25 innovative drugs in 61 drug presentations, covering 14 therapeutic areas.

Information:
Consumer drug prices in local currency (and converted to USD and Euro)
Reimbursement prices

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MA decision date
Reimbursement decision date
Restrictions on distribution and prescription

Drug selection:
25 innovative drugs by brand name (HIV/AIDS 8/25)
Approved by EMEA
With <= 4 presentations, all included

Country participation:
12/15 EU countries
11/15 CEE countries

Currency conversion:
To USD using UN conversion rates as of August 2000
To Euros using EU Commission conversion rates as of August 2000
As PPPs were not available for year 2000, this was not used.

No averaging of price per country
No volume adjustment
No generics

Andrew concludes:
Apropos the EURO study, the main lessons in terms of our work seem to me to be:

- Don't even consider an index of prices; keep the information as disaggregated as possible. You will see that EURO present their results in rank order of consumer price by country, for each drug, for all 27 drugs. The resulting rankings are still informative.
- Be clear about what prices we are comparing. I think this is price to the consumer (in different settings) - markups, taxes etc we want to analyse subsequently in examining the composition of consumer prices.
- Take advice about each country's context before identifying the sub-markets from which to elicit price information. The EURO study made the mistake of assuming that there was just one price for each country (except the UK), thus failed to recognise differences within countries.
- Reflect critically on EURO's method of standardising drugs for comparison. I know you are keen to use DDDs - Euro compared only brand name drugs in up to four presentations, but this obviously won't be appropriate when we are comparing drugs with differing presentations.
- Take great care in checking the reliability of data before going public with it. The Euro decision was to make their data available only on request, as there are many reservations about it.


Discusses TB drug treatment, choice of drugs and FDCs. Prices are compared from a range of countries:
US private sector: 1999 and over time from Red Book
US public sector: Actual prices paid by Mass PH Dep and NY PH Dep averaged for current pricing
International: MSH price indicator
Japan: Research Institute for TB, Kiyose, Japan
Africa: Tender prices from Afro Essential Drugs price indicator

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India: Mumbai city market and Mumbai municipal corp. tender prices
South Africa: public tender 1999
Singapore, Pakistan, Russia, Kazakhstan: colleagues in those countries

Prices varied dramatically. For all drugs except INH, the US prices are the highest. Japan has highest INH prices.


Prices collected for a lecture in Durban, electronically from colleagues. Available as powerpoint presentation.

2000 prices from retail and public tenders. 18 countries - 11 by E-mail, 3 from publications. US prices from private and public sector. Developed and developing countries. 9 drugs, 1 dosage form of each.

Result: Prices varied dramatically. US highest.


**ABSTRACT**

**Objective:** The overall objective of the study was to compare drug prices and availability of a selected number of essential drugs in different sectors of the health care system in four East African countries, Ethiopia, Kenya, Tanzania, and Uganda and to compare with international figures.

**Method:** A basket of 15 different essential drugs, each in one strength and one package size were selected. The selection was made on the basis of essentiality for tropical diseases and HIV/AIDS/opportunistic infectious diseases, and patent status. Prices were collected from different sectors and rural and urban areas in each country. Information on official duties, taxes and mark-ups was also collected. The data collection was done in random facilities during 1-2 weeks in mid May 2000. International data were taken from the Norwegian official price list, as representative of average European prices and from previous international surveys.

**Results:** Ethiopia and Tanzania had low or non availability of many of the tracer drugs, Kenya had high availability. The lowest availability was generally found in the public sector. In the private non-profit sector the availability was almost the same as in the private sector. Private hospitals in Ethiopia and Tanzania were poorly stocked with the basket drugs.

Looking at the range, and the difference between patented drugs and generics, in general generics were found to be significantly cheaper than the originator’s brands. It was also observed that the more generics were available, the larger the spread and the range between cheapest generic and originator’s brand. Examples are given of azithromycin (under patent in Kenya and with only one generic in Tanzania and Uganda), and aciclovir (no longer patented and with 12 different generics identified). Ciprofloxacin was found to be almost twice as expensive in Uganda as in Norway and mefloquine 77 % more expensive in Tanzania than in Norway when brands were compared. Worth noticing is also

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the large regional differences with 29 to 124% difference between lowest and highest price for the same brand. When comparing the unit prices of originators’ brands of antivirals (aciclovir) and antiretrovirals, there were some striking figures with e.g. aciclovir and nevirapine found to be twice as expensive in Kenya as in Norway, and zidovudine 35% more expensive in Tanzania than in Norway. Regional differences between lowest and highest price of the same drug were between 35 and 100%. When comparing with international prices from previous studies, except for lamivudine and zidovudine prices in the region and in South Africa tend to be higher than in high income countries in Europe and Canada.

Conclusions: Our data confirm earlier findings that pharmaceutical pricing is about the law of the jungle where might is right and drugs are very far from being equity priced. The wide variation in prices of proprietary drugs in developing countries suggests that the guiding principle that the drug industry seems to adopt in fixing prices is to set the upper limits according to what the market can bear. The results further confirms the high retail prices in developing countries of originators’ brands which are often twice as high as in European countries even in absolute terms, the impact of generic competition on prices with generics often less than one tenth of the price of the originator’s brand, and the large differences in price between the four countries surveyed.


Compared to Bala’s results


ABSTRACT

Background: Ninety five percent of people with HIV/AIDS live in developing countries, and the vast majority of them do not have access to medicines that are prolonging and improving the lives of people with HIV/AIDS in industrialized countries.

Methods: This report compares institutional prices of 10 essential drugs for HIV/AIDS in 8 countries and examines the effect on prices of generic availability and patent status. Justifications for high prices of originator branded products including the role of government in R&D, and time-to-approval, are also explored.

Results: According to analysed data, the minimum price for AIDS drugs in the countries studied is, on average 82% less than the US price (in update 85%, without efavirenz 90%). Price differences have significant repercussions. For example, the report points out that it costs the Brazilian public health system the same amount to treat 1,000 people living with HIV/AIDS per month as it does the Ugandan government to treat 228 individuals (update compares Brazil with 350 Thai patients).

Discussion: The widely divergent prices found, puts into question current drug pricing and highlights the lack of transparency with regard to the relationship between production costs and prices. On the other hand, it is clear that competition from the generic industry, and international institutions’ involvement, leads to dramatic reductions in prices.

Recommendations: There are several mechanisms to improve access to more affordable drugs, even if the country in need is already compliant with the TRIPS agreement. Available information suggests that it is feasible to bring yearly treatment cost with ARVs down to US$200 per patient, per year, in developing countries. The conclusion to the report is that the means to dramatically reduce prices are within reach, but what is needed is the political will to mobilise resources on a global scale.
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NB. The price information presented in this report is not exhaustive and should only be considered as an indication of the variation in prices between countries for given drugs.

Sources differ, but are listed. Countries: Brazil, Colombia, Guatemala, India, RSA, Thailand, Uganda, USA.

Used companies approved by regulatory authorities.

Rozek RP, Berkowitz R. The effects of patent protection on the prices of pharmaceutical products. Is intellectual property protection raising the drug bill in developing countries? NERA, 1998; 179-243. (Financial support from PhRMA)

“Policymakers in developing countries are concerned that protecting intellectual property will raise the country’s health care costs due to rising prices of pharmaceuticals. We studied prices of pharmaceutical products in nine developing countries with and without patent protection over a period of eleven years to determine whether enacting intellectual property laws increases the prices of drugs. We found that price movements of branded pharmaceutical products are generally not affected by changes in patent laws due to four factors: patent protection does not apply retroactively to drugs already marketed in a country, therapeutic competition exists in each country, monopsony buyers constrain prices for pharmaceuticals, and the regulatory environment in a country dictates drug prices.”

IMS ex factory prices
6 therapeutic categories: antiulcerants, antidepressants, calcium antagonists, non-narcotic analgesics, broad-spectrum penicillins, ACE-inhibitors
9 countries: South Korea, Mexico, Taiwan, Hungary, Brazil, Argentina, Egypt, Jordan, Turkey. First 5 with IPP. Egypt and Taiwan low-income, the others middle-income
1985 – 1996 (= 11 years)
3 sets of products:
- branded products sold in all countries with IPP
- original brands available in a country before IPP
- all products included in the data set
Total number between 105 and 424 per country

Description of each country.

1) Sought to select the same drugs in all countries
2) analysed price changes for existing original pharmaceuticals in all countries (Laspeyres indices)
3) analysed price movements for the comprehensive data set consisting of all existing products in the six therapeutic categories in each country (constructed PRIME indices)
4) conducted cross-country analysis comparing prices of the same drug across all countries (few drugs, even fewer sold in similar dosage forms and package sizes)
5) sought to determine whether IPP changes the mix of pharmaceuticals consumed in a country.

“Our results indicate that the shares of originator and copied products consumed are likely influenced more by consumer (payer, physician, pharmacist and patient) preferences and government regulation than by IP laws.”

“Our empirical analysis of pharmaceutical prices for products from six therapeutic categories in nine developing countries suggests that improving IPP does not have a measurable impact on real or nominal prices of existing drugs (those marketed before the implementation of IPP). Moreover, in our DRAFT NOT FOR CIRCULATION Compiled by Kirsten Myhr in 2000 as background to the development of the WHO/HAI methodology for measuring medicine prices
set of countries with price regulation, IPP had little, if any, impact on price changes of all drugs, including those introduced after the change in patent protection.”

“We found that IPP generally does not affect price changes for pharmaceutical products, yet firms still seek to implement IPP for at least two reasons. (……)"

**Hudson J. Pricing dynamics in the pharmaceutical industry.** Appl Econ 1992; 24: 103-12.

“Pricing behaviour has traditionally been approached from the concept of long-term static equilibrium. This paper argues that this approach is inappropriate, at least with respect to the pharmaceutical market, because new innovation, and patent expiry lead to a continually changing environment. A theoretical analysis argues that price change will depend on the age of the therapeutic class, the degree of brand loyalty, the extent to which it is sold ‘over the counter’ rather than on prescription, and measures of competition. The empirical results, based on analysis of the leading twenty-five therapeutic class of pharmaceuticals in the USA, the UK, West Germany and France over the period 1981-88, tends to support the theoretical conclusions. Although it would appear that government controls in the UK are distorting profit maximizing behaviour more than in the other three countries.”

“The literature on price determination within the general area of industrial economics has been somewhat confused. Much of it has concentrated on the impact of market power on prices or profitability. [snip] Much of the literature on price setting in the pharmaceutical industry has also concentrated on the impact of competition on price. [snip] “Statman introduced the important concept of brand loyalty. He found that only 4 of the 12 drugs in his sample showed substantial price declines on patent expiry.”

Data on the leading 25 therapeutic classes on 4 leading markets: USA, UK, West Germany, France. 1982-1988 = 175 observations. Laspeyres index number data. IMS.

Discusses age of therapeutic class a lot. The tc price is simply an average, weighted by market shares of the prices of the individual products which make up the tc.

“We have seen that markets characterized by low levels of brand loyalty will tend to observe slower price growth than markets with higher levels of brand loyalty. However, this position is reversed upon the introduction of new products.”

Attempts to answer several key questions:
- Is the general conclusion reached for earlier years that product prices have been declining still valid?
- Explore link between product competition and innovative price setting.
- Seek to expand on the concept of brand loyalty and its impact on price setting.
- Be concerned with the question as to whether the greater degree of government control on price setting has had any impact on firm behaviour.


**Boltuck RD, Riker DA: Estimating the cost to PhRMA member companies of inadequate intellectual property protection: A study of five priority countries and 20 drug markets.**

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Countries: Argentina, Brazil, Egypt, India, Israel.

Market data: sales value by producer, pharmaceutical molecule and country. IMS data
An economic simulation model for estimating the profit.

The 20 molecules selected by IMS from a list of 104 (products or compounds currently protected by US patents). The 20 are the ones that accounted for the largest sales for all producers - across all five priority countries
The 20 are:
4 fluoroquinolones
4 antidepressants
3 antiepileptics
4 antifungals
Levodopa (patent?)
Pseudo-ephedrine(!) (patent?)
Medroxyprogesterone
Midazolam
Pilocarpine (patent?)

Many wrong terms!

An example of bad industry research, using e.g. data collection methods which they criticise us for!


“The chief purpose of this study is to examine whether there are any economic advantages in allowing entry to markets at the manufacturer’s risk and at prices of their choosing. To examine the thesis that there are significant advantages, six countries were chosen for study because they do allow a degree of free access and (varying) degrees of pricing freedom (the USA, the UK, Denmark, Holland, Germany and South Africa), at least to the extent that new product prices are not directly controlled. In just about every other European market there is direct price control on new products used in the national health care system, which makes it impossible to examine the effect of innovative competition. Yet it is this innovative competition which Joseph Schumpeter claimed to be the “competition which counts”. Schumpeterian competition is seldom more evident than it is in the pharmaceutical industry. Innovative rivalry is a characteristic feature of the sector.

The key finding of the study is that, in markets where there is some semblance of pricing freedom, competition tends to keep down the price of medicines. Contrary to the claim made by some regulators, rival products serve a useful purpose in containing market prices.

Since innovative rivalry is a sine qua non in pharmaceutical markets, this price-depressing competitive influence should be allowed its full effect and not distorted or suppressed by regulation at the level of either the pharmaceutical manufacturer or the retail pharmacist. Rather, patients and prescribers should be empowered further to practice cost-conscious consumption by meaningfully exercising cost-effective demand for medicines. This can be facilitated by information provision, both by a greater reliance on price and by encouraging, not discouraging, sound disease management principles at prescriber, patient and patient-group levels.”

The author must be regarded as trying to put forward views favouring the industry’s interests.
Six countries, eighty therapeutic submarkets (ATC-groups, 2nd level) 1989 through to 1995. The objective was to work with submarkets where products would be truly regarded as competing both by prescribers and by manufacturers. That is, a high degree of demand cross-elasticity could be assumed to be present.

Prices of top five products in each submarket found and averaged. “Price” was defined as the price of the top-selling pack size per product. Generally only solid oral preparations were considered. Thus annual average sub-market prices were computed unaffected as normal index numbers are by weights relating to volume or values of sales. The aim was to look at prices not index numbers whose values either exaggerate (Laspeyre) or understate (Paasche) average price movements.

The ‘basket’ was assumed to be the actual top five products sold in the year in question irrespective of sales volumes in other years. The top five included generics when recorded. Each average price so computed was then expressed in constant money, adjusting by the inflation rate of the country concerned.

“The price data IMS present are average prices that pharmacies pay to wholesalers (or directly to manufacturers) for a given dosage, form and strength of a product. The average price is based on a survey of wholesalers, retailers and/or manufacturers’ price lists. Because of its data collection methodology, IMS is unable to include rebates, discounts and credits in its calculation price. The IMS data are, therefore, nor necessarily accurate estimates of actual transaction prices. This is not a problem if the ratio of the (unknown) actual transaction price to the (known) survey price is constant over time. But if rebates and discounts are increasing or decreasing over time, the IMS data would not capture these changes.”

The inflation-adjusted average price of the top five products in each submarket in each country was compared with the preceding year’s equivalent figure on a year-on-year basis.


Objective: To analyse the potential effect of generic drug competition on prices in Ontario to assess the costs and benefits associated with Bill C-22 (an act to amend the patent act)

Design: Comparison of the cost of the least and most expensive versions of all products sold by more than one manufacturer in 1991. The number of brand-name and generic drug companies marketing each of the products was recorded.

Results: Of 1599 products 437 (27.3%) were made by more than one company. Almost half (44.6%) of the 437 were sold by two companies. The more companies that sold a drug the greater the difference in price between the least and most expensive versions. Similarly, as the proportion of generic drug companies in competition increased, the greater the price difference. When competition was between generic drug companies only, the price spread was smaller than when it was between brand-name drug companies only.

Conclusions: Generic drug competition can result in savings to the Ontario Drug Benefit Plan. A more in-depth analysis of the potential savings is necessary to fully assess the costs and benefits associated with Bill C-22.

National study.


Comments to Lexchin’s article.

Lexchin’s article should be of interest for the methodology.
Parallel trade in pharmaceuticals has become a major European Union policy issue with several “solutions” being considered by the EC, Member State governments and the pharmaceutical industry in the “Bangemann Process”. This paper discusses the issues from an economic and public policy perspective - considering the economic cases for differential pricing and for “Euro-prices”, concluding that the economic case for parallel trade - to achieve convergence of prices - is not applicable to pharmaceuticals. It argues that health economic evaluation is not an appropriate tool to set “Euro-prices” because of differences in clinical practice and in resource use and cost across countries. Pricing rules should reflect local willingness to pay for innovation. It concludes, however, that in the absence of policy changes there is a strong likelihood of companies refusing to supply new innovative products at low prices to traditionally “low price” countries in order to avoid parallel trade undermining prices obtained elsewhere in Europe, with significant implications for the welfare of patients in those countries.


Conclusion. “After patent expiration, the originators’ prices continued to increase, while the price of multi-source drugs compete largely with other multi-source drugs in the price-sensitive sector, but indirectly with the originator in the price-insensitive sector. Originators have first-mover advantages, and therefore have a market that is less price sensitive after multi-source drugs enter. On the other hand, multiple-source drugs target the price-sensitive sector, using their lower-priced drugs. This trend may indicate that the off-patented market is imperfectly segmented between the price-sensitive and insensitive sector. Consumers as a whole can gain from the entry of multi-source drugs because the average price of the market continually declines after patent expiration.”

Interesting and different views / findings from PD. Much on markets and price elasticity. Confirms high prices of brands after generic competition. Confirms lower prices on generics as competition increases. “The average price of MSDs is a function of market concentration and the number of years since patent expiration”.

“One of the strengths of this study is the use of DDDs to combine quantities across a specific drug’s strengths and dosage forms.”


The article sets a framework for international price differentials then develops empirical approaches that yield evidence about the determinants of product-by-product price differentials.

How can prices for identical products differ between countries?
- Each country provides a separate market for each therapy = price set in each according to the characteristics of demand and the seller’s costs.
- When cost conditions in the two countries are the same, e.g. when the costs of supplying additional units of a drug do not vary across units or countries, seller may still charge different prices in different markets, or “price discriminate”. Two conditions allow this:

DRAFT NOT FOR CIRCULATION Compiled by Kirsten Myhr in 2000 as background to the development of the WHO/HAI methodology for measuring medicine prices
What factors lead prices in one country to exceed prices in another?

- In the absence of price controls, prices that a company sets in different countries depend, in part, on the average elasticity of demand, or price responsiveness, of consumers in the respective countries.
- International price differentials are also likely to depend on the nature and extent of organization among buyers.
- The average price of drugs in any country, and hence international price differentials, also depends on the extent and type of government regulation.

Drug-specific factors

- differences in the elasticity of demand between products or types of products and differences in the effects of regulation on drugs within the same country can lead to price differentials, as can differences in costs of supplying a product in one country vis-à-vis another.
- the presence of therapeutic substitutes can affect the relative elasticities of demand for different products:
- the emergence of a generic alternative to a brand-name drug can lead to an increase in the price of the brand-name drug - an effect that is counterintuitive
- a similar phenomenon may also occur with the entry of a new drug that is therapeutically similar to an existing drug (Tagamet/Zantac)

Some relevance for methodology

Not reviewed; not access to the reports:
