

“ADVANTAGES AND RISKS OF DIFFERENTIAL PRICING FOR PRESCRIPTION DRUGS”

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Differential pricing of prescription drugs is not a new phenomenon. International comparisons have always shown price differences for a particular drug in various countries. Sometimes, these differentials have been wide – so wide, in fact, that much of the last decade has been spent in trying to bring about more uniform pricing in, for example, the European Union.

What is new, is the sheer magnitude of the price differential that is required if access for poorer countries is to be greatly improved. Here, need is paramount and access is clearly inadequate.

QUESTION: *Is differential pricing the answer, or part of the answer, or no answer?*

I have been asked to discuss concepts, not conflicts; longer-term principles, not knee-jerk reactions: the way to agree, not the impulse to fight. If you believe that concepts belong to the ivory tower, then I can only plead that I hope to keep both feet firmly on the ground floor.

Differential pricing is a task for the pharmaceutical industry. There are two sides to it: it affects not only the recipient of drugs but also has repercussions for the industry. I suggest, therefore, that we consider its impact on both.

Differential pricing can be adopted in three separate contexts:

Firstly, as part of normal commercial practice in free markets. Differentials can take the form of quantity rebates, discounts to key purchasers, concessions for long-term contracts, and so on. It is applicable both to patented drugs and to generics.

Secondly, in international trade between countries with different degrees of pricing freedom or price regulation for drugs. Regulated prices will be more or less uniform for single-source drugs within a particular country, but parallel trade will arise from price differentials in a free trade area or economic union. Severe price controls in some countries will open up tradable price differentials for re-exports to the country of origin if much higher prices prevail there. The European Union is an example of fairly prolific parallel trade for that reason.

The *third* type of differential pricing – and the one of most direct interest to this Workshop – is based on the relationship between price and affordability.

Should drug prices be adjusted to reflect what different patient populations can afford?

That sounds fair. But is it practicable? And if so, under what conditions and limitations?

Past experience suggests that it can certainly be applied in the form of assistance programmes, donations, or special prices to limited patient groups where it is feasible to insulate these from normal markets.

Whether it would also work under existing trade rules and systems when applied to whole nations or regions needs to be explored. It cannot be taken for granted. 'Leakage' or re-exportation of such drugs into markets with much higher prices may be unpreventable and unpredictable.

Securing better access to adequate drug supplies in poverty-stricken countries is desirable and may appear simple, but is in fact complex. Expensive drugs are part of the problem but not the problem. Countries differ one from the other, but poverty, weak medical infrastructures, or defective distribution to rural areas all play their part in preventing or obstructing access.

Cheaper medicines would certainly help; but they must be seen with a sense of proportion of what can and what cannot reasonably be expected from differential pricing of patented and generic drugs.

I mention both, because single-source drugs and generics are both involved in the issue of access. The World Health Organisation's Model List of Essential Drugs¹ consists largely of patent-expired *generic* drugs. In resolving the access problem, generics are the dominant source of drugs in terms of volume, and they are far from therapeutically obsolete. In fact, many of them continue to form the backbone of prescribing in the industrialised world.

As an example, here are five generic drugs – all of them on WHO's Essential Drug List of 1998, and all first launched between 1969 and 1976 – that are still ranked among the Top-20 brands and generics in the USA in 1999. Measured not in dollars but by the volume of units prescribed of the Top-200 brands and Top-200 generic drugs, they are:

generic atenolol, beta-blocker, ranked 5th among the 400 listed brands and generics
generic furosemide, diuretic, ranked 6th
generic amoxicillin, antibiotic, ranked 8th
generic salbutamol, for asthma, ranked 9th
and generic ibuprofen, for arthritis, ranked 17th

(Source: extracted from Scott-Levin's Source Prescription Audit, tabulated in Drug Topics "Special Report", March 6, 2000, 69-70)

Among Essential Drugs, the part played by *patented* products is much smaller in volume but more serious in terms of price.

Patented drugs are critical for diseases where all effective drugs are still under patent. That is not the norm. It is an exceptional situation that has arisen with the range of new drugs for HIV. It is a crisis, because the new drugs have helped to keep the disease in check in the industrialised world while they have not been affordable in poor countries with high prevalence of AIDS.

To extrapolate this situation to a general condemnation of pharmaceutical patent protection is irrational, and to seek solutions by invalidating or circumventing intellectual property is, I believe, unnecessary and could be avoided by other means of resolving the evident clash of interests.

The purpose of pharmaceutical patent protection has always been to promote the development of innovative therapy. Although it is the *invention* that is covered by a patent, it is the long, costly and risky *development* process that is being protected by giving the inventor or its licensees an exclusive right to make and sell the invention for a limited period of time.

Most drug inventions originate in the pharmaceutical and biotech industries, and nearly all that do not are licensed to drug companies for development and marketing. Very few drugs have been *developed* by public sector agencies or academic institutions during the last fifty years. Earlier still, Alexander Fleming discovered penicillin and spent a number of years trying to find a way of turning it into a medicine before giving up. On a wider canvas, virtually no genuinely innovative drugs have emanated from countries without strong pharmaceutical product patents.

It is simply not worth the cost and risk to invent and embark upon the elaborate product development and clinical trial process without patent cover. Pharmaceutical patents were introduced in the 19th century, because piracy was depriving inventors of the rewards that are the incentive to *develop* inventions, making them marketable and – for pharmaceuticals – bringing them to the physician and the patient. To attack pharmaceutical patent protection because of its exclusivity is to remove those incentives. Eventually, that will turn the flow of new drugs that health care needs into a trickle.

Patented drugs can be priced differentially, given the will to do so and the basic safeguards that are needed to enable patentees still to benefit substantially from the development of their inventions. Weakening patent protection does nothing to solve the underlying problem of access: it merely throws out the baby with the bath water – the baby being the innovative drug of the future.

How can we best define and eventually resolve the problem of differential pricing with safeguards?

The aim is to find ways and means by which differential pricing can ease access to essential medicines in poor countries.

To make a real impact on access, differential prices have to be very substantially lower than normal market prices.

One of the main obstacles that needs to be overcome in order to make such differential prices workable, is 'reflux' trade: leakage and re-importation, especially of patented drugs, back into the full-price markets of North America, Europe, and Japan.

The first and main **advantage** of differential pricing as a contribution to problem solving is simply that more patients would gain access to essential medicines if they were cheaper. Affordability is not confined to those who can afford everything and those who can afford nothing at all, not even the lowest *differential* price. Affordability is graded. Differential pricing will bring access to more patients. The ultimate step is donations which have their advantages but are not generally welcome as the *sole* vehicle of the pharmaceutical industry's contribution.

The second advantage of differential pricing for the poorest countries is that the pharmaceutical industry is, if I may put it that way, losing business that it does not possess and never will, at full price. The financial sacrifice is limited, whereas the benefit to recipients can be life-saving. For this reason alone, differential pricing is, in principle, very desirable.

We now come to the **risks**.

Only an understanding of risk can turn the '*bottomless pit*' kind of gamble into a calculated and acceptable form of uncertainty. The critics of the pharmaceutical industry tend to underrate industrial risk, or ignore it altogether. It is, after all, not their risk or their industry.

The pharmaceutical industry, on the other hand, is excessively motivated by *fear* when it is being drawn into *non*-industrial societal problems. These fears can range from carefully reasoned anxieties to indeterminate states of obsessive alarm. Getting into a 'state' will always paralyse decision-making. As a result, the action that is taken tends to be "too little and too late", and eventually becomes a matter of day-by-day *ad hoc* decisions without regard for longer-term repercussions.

If that is happening now, it is not the first time. However, I am not an industrial psychiatrist, and will therefore confine my analysis to rational risks and fears, and to concepts that may help to evolve a longer-term policy on these matters..

For patented drugs with large price differentials, I want to address just one of many relevant questions:

Can differential pricing for the poorest countries be fenced in? or will artificially low-priced drugs migrate back into full-price commercial markets?

That is not a fanciful nightmare or a trivial risk. It begs the question of innovative research and development. Without fencing in the area of serious price differentials with binding agreements and modifying the existing rules of international trade, it is back to Square One: why go to the trouble of developing these drugs in the first place if it is actually easier to opt out?

So let me start from the other end. Supposing means were found to fence in differential pricing and to agree on eligibility and on the magnitude of price cuts in case-by-case talks: what then?

With adequate safeguards, the pharmaceutical industry must accept its share of societal responsibility. It will in future have to act before being forced to do so by external pressure and do what may not be profitable its own right and may fail to meet normal industrial criteria for investment - **provided** its intellectual property rights are not overthrown at the same time and its markets in the industrialised world are not destabilised.

Firstly, the industry could and should then grant voluntary licences with nationally or regionally limited rights under product patents, to make and sell cheap supplies without the need for patent infringement or compulsory licensing.

Secondly, with safeguards against parallel re-imports in place, the patent holder can export substantial quantities from its base in the industrialised world at steep price differentials without the fear of reflux trade into normal commercial markets.

Thirdly, donations and other professionally supervised assistance programmes should continue. In effect, a variety of methods based on differential pricing would widen the range of problem-solving initiatives for better access.

Action along these lines would need to focus on major disease problems in the poorest countries where all effective drugs are still protected by patents. For other drugs, brands and generic versions of Essential Drugs should provide the necessary price differentials competitively or unilaterally as their contribution to improved access. They, too, will need safeguards against reflux trade.

What needs to be *done*?

Firstly, fencing in areas of wide price differentials. This runs counter to the established principles of free trade, according to which all trade barriers are to be brought down. We already have the example of the European Union's interpretation of the Treaty of Rome which sets free trade above intellectual property rights. That may be good for trade. It is not good for advances in medicine.

It seems necessary to re-define the limits to free trade in special circumstances. Where the medical needs of the poorest countries, which we are discussing here, can be better served by differential pricing, special trade barriers would be preferable to the kind of free trade that undermines the foundations of pharmaceutical research and development on which progress in therapy is ultimately dependent. Stopping reflux trade into the industrialised markets does no harm to poorer countries who want and need better medical access for their own populations.

To fence in differential pricing would damage nothing except the dogmatic pursuit of free trade 'come-what-may'. Surely the circumstances that this Workshop is addressing are more critical and ought to carry more weight than the unalloyed purity of free trade. What is needed, in effect, is action that can fulfil desperate medical needs and at the same time provide the necessary industrial safeguards. That calls for a more pragmatic view of free trade than has been the established wisdom in recent decades.

Secondly, we need to encourage a more positive approach to original drug research into the diseases of poverty. For that to happen, adherence to strong intellectual property rights is essential.

The pharmaceutical industry has a moral, social and financial duty to make its contribution to solving the grave medical crisis of unaffordable access. It cannot stand apart and decorously avert its gaze. But it is an *industry*, not a charity. Demonising it for behaving like an industry will not get us very far in the long run. Measures that threaten industry's core interests will not help today's or tomorrow's need for advances in drug therapy.

Am I suggesting, then, that we should see both sides of the problem when many believe that one is right and the other is wrong? I am suggesting just that, because both are right and both are wrong. Setting up fantasy heroes and diabolical villains is easy. It is far more difficult to work our way through the complexities of give-and-take. Yet that is ultimately the only means of arriving at long-term solutions that are easy to announce but hard to achieve.

¹ "The Use of Essential Drugs", Eighth report of the WHO Expert Committee (including the revised Model List of Essential Drugs), WHO, Geneva 1998