Equity pricing as a strategy for improving the affordability of drugs in developing countries.

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I. Equity pricing: definition, issues and options

Introduction

The affordability of a drug for an individual or a household depends on several factors:

1) The cost of the drug, or more precisely, the cost of a full course of treatment.
2) The income of the individual or household in relation to its basic needs.
3) The existence of efficient insurance systems that allow the pooling of risks, making the healthy pay for the sick.
4) The existence of public or mandatory financing of the health expenditures or of the insurance schemes that ensures the coverage of the health care costs of those with lower incomes and higher needs that cannot be addresses by voluntary insurance.

Equity pricing can improve affordability of drugs in developing countries by addressing the first factor. The main candidate drugs for equity pricing are drugs that have a high proportion of fixed or of sunk costs. This is typically the case of on-patent drugs: the innovator is allowed to have a monopoly as an incentive for investing in R+D and bearing the risk. However, products with high fixed production costs are also suitable for equity pricing.

In an international comparison context, we might define prices as equitable if the price paid in each country is somehow related or proportional to the average wealth, income or to some other indicator of economic capacity, or to some composite indicator of economic capacity and need, which might be identified as the burden of disease. By extension, equity pricing can be defined as any policy or agreement leading to that structure. The term equity pricing seems preferable to differential pricing, tiered pricing or preferential pricing because by etymology and previous use the latter expressions are associated with price differences derived from market forces, with no concerns for need, equity or solidarity.

Types and justifications of price differences of drugs

The simple economic models of markets predict that a single price will prevail for a homogeneous product. This applies both to perfect competition and to monopolistic market structures. Economic analysis does not predict a single price when there are differences in quality or in the case of product differentiation, two common situations in the actual pharmaceutical markets. Product differentiation is said to occur when the differences among several brands of the same product sold by different suppliers are caused by advertising and do not reflect actual differences in the quality or in other intrinsic characteristics of the products. In practice, price differences might simultaneously reflect actual and perceived differences in quality.
When a new drug is developed, the innovator obtains a patent right that allows it to enjoy a temporary monopoly and charge a higher price. In a perfectly competitive market, the manufacturer would only be able to charge the average manufacturing cost plus a normal profit. In a monopolistic situation, the manufacturer is usually able to charge a higher cost and obtain an extraordinary profit.

If a patent-holding monopolist operates in a single market, it will be forced to sell at a single price; otherwise, arbitrage will level-off the prices. However, if the monopolist is able to segment consumers in several independent sub-markets, it might be able to charge different prices in each market. A similar behavior may be expected when the monopolistic power derives from product differentiation by brand name. In the absence of any government regulation and assuming market separability, economic theory would predict price differentials across markets that would follow the so-called discriminant monopolist or the Ramsey pricing models. The segmentation of the consumers may be set according to national borders or any other criterion, provided that consumers can be clustered and isolated from the other groups and that the resale of the good across segments can be prevented. The supplier will charge in each country “what the market can bear” in order to maximize its profits in each market and in the aggregate. Such a strategy might be superior not only in terms of the manufacturer’s profits, but also from a social welfare perspective, that is, taking into account the point of view of the consumers.

In fact, in spite of the increasing trend towards globalization, the world is far from being a single market in the sense of the economic theory. Therefore, there is some scope for differential pricing across countries. If this were possible, one would expect to observe the prices might be somehow proportional to the average economic capacity of the country: the prices of a given product would be lower the lower the average country income. Unfortunately, this might not necessarily be the likely outcome: in poor countries with large inequalities, the profit maximizing strategy of the discriminant monopolist might be to charge a higher price than that charged in richer countries, targeting only a small share of high income consumers with a small price elasticity of demand. This is a possible explanation offered by Scherer to the apparent paradox of higher prices often observed in poorer countries and the lack of an evident relation between drug prices and GDP per capita (see figure 1 in Annex).

Price differences across countries might be the result of suppliers’ strategies, but it can also be caused by other market factors, such as the negotiating capacity of collective health systems, or the result of the action of regulatory bodies. These factors that might bring prices down are more likely in medium and high-income countries. However, in high-income countries with a strong multinational industry, pharmaceutical policy may opt for accepting the burden of high prices on their consumers and taxpayers, in order to support the strength and dynamism of the national industry. Or they may mitigate that burden through some form of internal price differentiation obtained by regulatory or negotiating strategies. Two good examples of that situation are the USA and the UK. The USA government uses its negotiating power in order to obtain lower prices (discounts) for publicly funded insurance programs (such as Medicaid, or
the Veterans Administration). The UK uses the PPRS (pharmaceutical price regulation scheme) in order to indirectly force low prices for the drugs sold to the NHS (National Health Service), while leaving the prices charged in other markets free of control.

To sum up, price differences are potentially large in the case of goods for which a large part of the costs of production are **fixed costs** (equipment), **sunk costs** (R+D) or **overheads** (marketing), as it is the case in pharmaceuticals. Companies might be able so make some additional profit and hence be willing to sell some units of the product at a price much lower than the **average cost**, provided it is above the strict **direct cost** of manufacturing an additional pill (**the marginal cost**). Price differences are limited by the degree of **separability** or **segmentation** of the market. If two markets are totally independent large price differences might be maintained indefinitely. If the **barriers** between the two markets disappear, **parallel trade** and **arbitrage** will make the prices converge. Of course, price differences due to factors such as transport costs, volumes of sales, purchasers’ solvency and the like will prevail over time.

Equity pricing can be applied in theory to on-patent and to off-patent drugs, but it is probably more appropriate for the former. In the case of off-patent drugs, the possibility of charging different prices derives from the existence of large fixed costs and overheads. However, for on-patent drugs the justification and feasibility of equity pricing is more evident. On one hand, on-patent products often enjoy a monopolistic situation, which is usually justified by the incentive the patent provides to private firm for investing in R+D and for innovating. Drug innovation can be considered a public global or partial good. Granting exclusive market rights to the innovator is a way of allowing it to recover the investment on R+D, as the price charged might be well above the marginal cost that would prevail in a competitive market with no IPR. But even if one accepts the need for such a monopoly in order to secure adequate levels of R+D, this does not imply that all final consumers of the drug should pay the same price. Equity pricing can be seen as a mechanism for funding the public good “therapeutic innovation” in a more efficient and equitable way than by setting a single international price.

**Options in the design and implementation of an equity pricing scheme**

This section identifies the main options to be considered in designing and implementing an equity pricing system at international level.

**One price vs multiple prices**

First of all, international pricing can be arranged according to various models: a single international price for all countries or different prices. In the second option the price differentials may be the result of market forces or of a purposive arrangement lead by an equity criterion. The first case corresponds to the traditional discriminatory monopolist model or to a public monopoly applying Ramsey pricing. Both the discriminatory monopolist and Ramsey pricing might lead to equitable prices as defined in that report.
However, they can also lead to a price structure that would be defined as inequitable by most equity criteria.

**Institutional arrangements leading to equity pricing**

The arrangements that might lead to an equitable price structure are also manifold:

- Voluntary price discounts by patent-holders or manufacturers in general.
- Voluntary out-licensing.
- Provision by an international donor, e.g. the Global Fund.
- Compulsory licensing.

Any of these mechanisms might lead to similar equity price structure. But, of course, the existence of these arrangements does not guarantee in itself that equitable prices will prevail, they are just tools for policies and agreements aiming at equitable prices. Moreover, each mechanism would have a different performance in other aspects.

Voluntary discounts may be – or be perceived – by recipient countries as less reliable and hence less appropriate for basing a sustainable strategy. Moreover, developing countries may feel that this approach puts them in a weak position regarding their negotiating capacity on other issues. Voluntary discounts have also been criticized as a potential dumping strategy that would increase the productive capacity in a handful of countries and never allow a pharmaceutical industry to develop in developing countries.

A Global Fund buying the product at a single price and selling it to the individual countries at prices related to the countries’ economic capacity could also lead to an equity pricing outcome, by subsidizing the countries that cannot afford the market prices of a drug. It can also introduce a certain degree of cross subsidizing among beneficiary countries. The Global Fund option is likely to generate some of the concerns indicated for voluntary discounts, although they might be mitigated if the Fund is a multilateral agency.

Finally, the IPR approaches would be the more reliable and sustainable ones from the perspective of the developing countries and the most favorable to the industrial development of intermediate countries such as India, China or Brazil, but it does not guarantee in itself that products will be available at affordable prices. Companies enjoying IPR waivers or low royalties might take advantage of the lack of competition and sell at prices well above a competitive market price. There are examples of this behavior in South European countries before the EU rules forced them to join the common IPR system and endorse pharmaceutical product protection. In the pre-patent time, originator products and branded versions produced by local companies were sold at similar prices.
Criteria for defining the beneficiary populations

The concept of an international equity pricing scheme implies the identification of the beneficiary populations. The two most obvious options for defining beneficiary populations for access to drugs within an equity pricing scheme are countries and health systems. In the first case all citizens of a given country would be entitled to the benefit of lower prices. In the second option, the advantage would be restricted to the beneficiaries of certain health systems within a country.

An equity pricing scheme implies at least two categories of countries, one with a lower price the other with a higher price. There might, however, be schemes with three or more segments. At the extreme, one could consider the possibility of a perfect international market segmentation, each country potentially paying a different price for the same drug.

For the purposes of equity pricing, countries might be categorized and clustered according to several alternative criteria. Income or GDP per capita are two possible candidates, but one may want to consider other factors as well, such as, the burden of disease. The choice of criteria is essentially a value judgment and is likely to require some kind of negotiation process among countries. At the end, it would be convenient to end up with a simple, explicit and transparent indicator that reflects the agreed criteria and value judgments, but is easy and operational.

Setting the equitable price for each country

The same indicator discussed in the previous paragraph might be used for computing the price, royalty or compensation that a cluster of countries is assigned. One can think of many alternative formulae or algorithms to set up an equity price scheme:

1. The price assigned to a country (or cluster or countries) could be proportional to its income per capita (average income per capita, in case of clusters), or to the alternative indicator selected. The anchor (or baseline) price for determining the prices assigned to lower income countries should be an average price in developed countries. Explicit criteria should be established in order to compute and regularly update the anchor price.

2. The formula or procedure for computing the price for each country might also include the marginal cost of production. For instance, prices might be determined as the marginal cost plus a certain profit margin that could be proportional to the country’s per capita income. It might be also agreed that the price variation should not go below the marginal costs, because in that case the scheme would certainly not be a win-win solution for all parties: someone would have to bear the cost of subsidizing the difference between the price and the higher marginal cost: either the manufacturer, by selling at a price below the marginal cost, the richer countries of the cluster, by cross-subsidizing the poorer ones, or the donors supporting the scheme. The problem with including marginal costs is that it is a
very elusive concept - e.g. short-term marginal cost or long-term marginal cost? Are marketing cost included in the marginal cost? And so on – Moreover, effectively computing costs would be very time consuming and manufacturers are not likely to be pleased with the required transparency of internal economic data.

3. The relevant price in an equity pricing scheme is the manufacturers price in the country or the importing price fob. This would reflect the principle that equity pricing is justified by an equitable sharing among countries of the cost of innovation and of the fixed production costs. Differences in prices attributable to domestic factors – e.g. distribution costs – should therefore not be addresses by the equity pricing approach. If the justification of equity pricing is one of international solidarity, the cost of the drug to the consumer might be the relevant outcome variable to consider.

4. The equity price assigned to a country might be defined as either the effective price or as a maximum price. The second approach seems clearly preferable, as it would allow competition to work below the defined price, bringing it further down if suppliers want to do so in order to increase its market share.

5. If the equity pricing scheme is based on an out-licensing or a compulsory licensing approach, the focus will shift to the determination of a fair compensation for the patent-holder. A simple approach in a three cluster scenario might look like the following example:

   a. License fees freely agreed between the patent-holder and the licensee for developed countries
   b. 3%-5% royalty for emerging or middle-income countries
   c. A patent waver (no royalty) for least developed countries

Assuming the manufacturing might not necessarily take place in the country where the drug is used, the applicable royalties are those of the country where the product is used, not where it is manufactured. License fees might vary according to the nature of the drug. Higher fees might be foreseen for non-essential drugs.

**Criteria and procedures for the inclusion of drugs in the scheme**

An equity pricing scheme should also define the list of products included. Essential on-patent drugs are the main candidates, because they are likely to have the largest margin for price differentiation, from the marginal cost of production to the highest price the market can bear in the higher income countries. However, the existence of large fixed costs of production may allow equity pricing to be an appropriate option for some off-patent drugs. In the case of vaccines, price differentiation has mainly been possible due to the relatively large fixed production costs, as most traditional vaccines are off-patent.
Essentiality is a difficult concept to define in operational terms. It might be interpreted as referring to the WHO essential drug list. But in fact, even WHO agrees that the WHO core list is only a reference that might be adapted to each country’s circumstances.

An additional issue is whether either specific drugs, diseases, or drugs only when used for certain diseases should be defined as the object of equity pricing. Specifying drugs apparently is the option less subject to alternative interpretations and disputes. At the end, the price must be assigned to a drug, not to a disease. However, in order to account for innovations and allow a quick process of updating, it would be important to agree as well on a disease criterion. The disease criterion is essential in order to maximize sustainability. Imagine a country that made a great investment in order to scale up ARV treatment on the basis of a current price of, say, $300 per year. If a new drug were to appear that doubled the effectiveness of the existing ones but was offered at $3,000 the country would be faced with the dilemma of either maintaining the old, relatively ineffective treatment or supporting a dramatic increase of the treatment costs. Such a possibility cannot be totally ruled out, but can at least be minimized if the equity pricing scheme applied to any ARV drugs, as the new drug would automatically fall under the scheme.

In fact, if the equity pricing scheme was (and was perceived as) a win-win solution for all parties concerned, there would not be any reason for some stakeholders trying to restricting the scope of drugs to be included in a equity pricing scheme to a defined set, e.g. to infectious or developing-countries-specific diseases. But equity pricing is probably not always the best option for all parties or is not perceived to be it. Patent-holders may prefer the option of a single international price or of differential prices according to what each market can bear, as more profitable options for them, and might therefore insist in restricting equity pricing to products where the humanitarian concerns and public opinion might produce reputational and image costs in case that company does not collaborate to a generally acceptable solution.

**Duration of the scheme**

In relation to the duration of the equity pricing scheme, the options for which the low prices are maintained may range from a short period, say one year, to the whole life of the product. Another justifiable option would be the duration of market exclusivity: once market exclusivity has expired, competition could make its job in controlling the prices and the equity pricing scheme might become irrelevant. Needless to say that a short period puts the countries or systems in a very weak negotiating position: as in the example explained above, once the country has made a substantial investment in treatment capacity and has started scaling up treatment, it might be difficult to discontinue or scale down the program, and it is likely to be forced to accept increasing prices and a soaring drug bill or to face high social and political costs. On the other hand, patent-holders and manufacturers are likely to prefer short periods, at least until they are convinced that the scheme works as initially expected. There is an obvious conflict on
that issue, which might be minimized by starting the experience with products whose patents are going to expire relatively soon.

**Market segmentation**

Market segmentation is a necessary condition for any differential type of differential prices to be sustainable, unless the price differences are so low that they do not compensate the transportation and other costs of the arbitrage. The mechanisms for ensuring market segmentation are not exclusive options: any additional mechanism implemented will reinforce the independence and separation of the markets and reduce the likelihood of leakages or product diversion.

In a tiered price world there are strong incentives for entrepreneurial people to take advantage of price differences and make a profit out of arbitrage activities. International wholesalers are the obvious candidates for taking advantage of equity pricing by means of parallel trade. But consumers, health insurers, wholesalers, pharmacists and politicians in rich/high price countries may also see in parallel trade an opportunity for profits, savings or other types of benefits.

In the low income countries directly benefiting from equity pricing, there may also be other benefits from parallel exports besides improved accessibility, as parallel exports imply an increase in domestic production, and therefore in occupation, profits, taxes, etc. Of course, governments might understand that the short term production benefits from parallel trade are likely to lead to an end of the equity pricing and, hence, to higher, probably unaffordable drug prices in the future. But policy makers often have a short-term perspective and other incentives than serving the public interest of their people.

Market segmentation also runs counter to the honest or interested positions of those that believe in the intrinsic goodness of international free trade. The builders of the Single European Market were probably aware of the problems that could bring to industry in the short term and to the consumers in poorer countries in the long run the existence of parallel trade. They had, however, as their first priority the building of the Single European Market, and they did not want to compromise that goal by introducing exceptions for pharmaceuticals, which could later be claimed by other industrial sectors. It is however difficult to convincingly explain why the same faith in the Single Market did not lead was not able to remove the capacity of national regulators in controlling prices. The apparently coherent implication of building a single market would be the simple removal of national price controls or the establishment of a EU price control. The argument was that countries used price control as a cost-containment tool, and cost containment was an accepted national responsibility. But, of course, there are other ways to attain cost containment. And by removing market segmentation and allowing intra-EU parallel trade, price control lost its past effectiveness as a cost containment tool. When it comes to relevant therapeutic innovations, manufacturers charge approximately the same
price in all EU countries and faced with too demanding price reductions tend to adopt a “take it or leave it” approach.

Policy makers willing to implement an equity pricing scheme must not only accept market segmentation as a sound economic principle. Legislation has to allow it as well. Some multinationals companies (MNC) tried to avoid parallel trade in the EU. The intents of some MNC to sell at different prices according to the final destination of the product were declared an illegal practice by the EU. At some point of time, the Spanish government became aware of the problems of parallel trade – higher relative rate of increase of Spanish drug prices due to the loss of capacity of the regulators to negotiate lower prices in Spain for new drugs - out-weighted the benefits of an increased domestic production and tried to allow originators a double price, one for the national market and a second, higher one for exportation. But the EU ruled out such an option as contrary to the principles of the Single market. These strategies have a reasonable justification: price control was left to national regulators in Europe, because it was seen as a tool of health policy, a potential cost-containment measure. Following that justification, it made sense for the national authorities to retain the control of the prices of products consumed internally, but there is little justification for being able to control the prices of exported products.

Parallel trade of drugs from low price to high price countries usually takes place because the authorities in the richer, high price countries favor or at least tolerate them. Developed countries have many mechanisms at their disposal in order to halt or at least minimize parallel imports. The first one derives from their licensing capacity. By not licensing products aimed at low price markets, parallel trade would become an illegal activity. Which, on the other hand, would be relatively easy to control, given the fact that most of the products potentially object of parallel trade are delivered by a highly regulated and controlled distribution network.

Of course, it is easy to understand that governments in high price countries either dislike the idea of equity pricing: they have important constituencies – like the pensioners in the USA – for which access to drugs may become a hug problem. It is not easy to explain US pensioners that they must go into debt because the pay for some drugs several times what other people across the Mexican or the Canadian border pay. Of course, the US government could address the problem of accessibility of the elderly to drugs in different ways, for instance, by increasing redistribution by means of universal coverage of drugs, or by pressing down the prices of drugs in the US. The UK and other North European countries, on the other hand, try to maintain a basically free price environment that attracts MNC, R+D and industrial development in the country. But in order to control the impact of that policy they allows parallel trade coming mainly from Southern European countries. That is they do not apply price control, but through parallel trade they take advantage of the price control applied in Southern European countries. How can this policy mix be justified?

The segmentation of countries is complicated by two facts: 1) the internal personal income differences and 2) the differences among countries within free trade areas.
In many rich countries there are significant groups of poor or, at least, of relatively disadvantaged individuals. Similarly, in low-income countries, there are small elites enjoying higher income than most people in high-income countries. The poor or relatively disadvantaged in rich countries may hardly accept that their own country enters an agreement whereby other countries benefit from lower drug prices, especially if these prices also apply to the rich elites of the poor countries. They will probably find politicians to defend that they deserve low prices as well. The problem can be addressed by providing the disadvantaged in rich countries with an adequate financing of insurance coverage or by segmenting them as consumers and allowing them access at lower prices. The acceptability in rich countries of inter-country drug differences in drug prices would probably be higher if it is not perceived as a mechanisms that basically benefits the better-off; that is, that low priced drugs accessibility is restricted to the poor or that they are provided within a health system with a fair degree of internal cross-subsidizing, i.e., where the premiums are income related.

The segmentation of relatively poor countries that are members of trade areas, such as, NAFTA or the enlarged EU, may pose some additional problems, because trade areas try, by definition, to reduce or eliminate trade barriers among members and to create larger, unified trade areas.
II. Differential pricing: guidance from the economic literature

In this section, we approach differential pricing from a purely positive perspective. We first review the basic economic theory of why pharmaceutical firms might set different prices in different markets. We then ask to what extent discriminatory pricing in free market equilibrium is consistent with equity considerations and discuss a number of circumstances in which the theory of discriminatory pricing would fail in practice.

Basic economic theory: third-degree price discrimination

Economists have long analyzed the circumstances in which firms fix different prices in different markets. The economic literature refers to this practice as third-degree price discrimination and it relies on three distinct market conditions. First, firms must have pricing power. This is unquestionably the case for pharmaceutical products that are protected by the exclusive marketing rights conferred by invention patents. The extent of market power conferred by a patent depends on the existence of therapeutic substitute products that may offer patients an alternative medical treatment. Empirical evidence on the existence of pricing power is provided, for example, in studies that analyze the price-reduction effects of generic entry upon patent expiry (see, for example, Caves et al, 1991).

Second, demand conditions must vary across markets. This is likely to be the case for pharmaceutical demand—in particular, if one considers demand variation across countries at different stages of economic development. In particular, variations in the purchasing power of patients and the coverage with health insurance schemes is likely to contribute to varying demand elasticity faced by a pharmaceutical producer. Third, markets have to be segmented. If arbitrageurs can freely purchase drugs in a low price market and re-sell them in a high price market, a uniform pricing structure emerges in market equilibrium. As will be discussed further below, the ability of firms to segment markets depends on the legality and incidence of parallel trade.

If these conditions hold, a discriminatory pricing structure emerges. In the simple case of a monopoly producer, the price, \( p_i \), in market \( i \) is determined by the marginal cost of production, \( c \), and the elasticity of demand, \( \varepsilon_i \), in market \( i \):

\[
p_i = \left(1 - \frac{1}{\varepsilon_i}\right)^{-1} c
\]

In the parlance of economics, there are three types of price discrimination. First degree price discrimination refers to a situation in which a seller charges the highest price that buyers are willing and able to pay for each quantity of output sold. Second degree price discrimination occurs when a seller charges different prices for different quantities of a good. In the case of third degree price discrimination, a seller charges different prices to groups that are differentiated by an easily identifiable characteristic, such as location, age, or sex.

See Fink (2001) for a theoretical model and an application to pricing of pharmaceutical products in India.
If one allowed for competition from therapeutic substitute products, the price $p_i$ will additionally depend on the cross-elasticities of demand and the form of oligopolistic competition among pharmaceutical producers. However, for ease of presentation, we still stick to the monopoly assumption.

How does economic welfare in an equilibrium with price discrimination compare to welfare in an equilibrium with uniform pricing? The first point to note in this regard is that discriminatory pricing can be Pareto superior to uniform pricing. This possibility can be illustrated by the following hypothetical example. Suppose the world consists of two countries, one large high-income country and one small low-income country. If the pharmaceutical producer were forced to price uniformly across the world, patients in low-income countries would not be able to afford the drug. However, if the producer could segment markets and charge a lower price in the low-income country, patients in that market would be able to afford the drug. Patients in the rich country market would not be worse off, as they would face the same prices under either discriminatory or uniform pricing. The pharmaceutical producer would generate higher profits under discriminatory pricing, as the price in the low-income market would still exceed marginal cost. Hence, it is possible to “have the cake and eat it, too.”

Such an outcome is not guaranteed, however. If the pharmaceutical producer also serves some patients in the low-income country under uniform pricing, it is possible that patients in rich countries will face higher prices under segmented markets. The net welfare effect in high-income countries then depends on the size of the loss in consumer surplus relative to the increase in the pharmaceutical producer’s surplus. It is possible that some nations gain and others lose from discriminatory pricing. As for world welfare, Malueg and Schwartz (1994) show that uniform pricing by a monopolist can yield lower global welfare than discriminatory pricing if the dispersion of demand across countries is sufficiently large. Moreover, they show that global welfare can be maximized if one places countries into designated groups and allows discriminatory pricing between those groups, but uniform pricing within groups.

As a final note on the pricing theory, some authors have related pharmaceutical firms’ discriminatory pricing strategies to the concept of Ramsey pricing (see, for example, Danzon and Towse, 2003). This concept has its origins in efficiently regulating the prices of public utilities that need to recover fixed infrastructure costs. Regulated Ramsey prices have the same structure as discriminatory prices set by a monopolist, but they are lower in absolute terms. Some economists have argued that competition among therapeutic substitute drugs drives discriminatory prices down to their Ramsey levels, where firms, in the long run, do not make any profits in excess of what is needed to recover fixed R&D outlays. We feel that this is not a realistic assumption. In practice, pharmaceutical companies generate large profits from a few ‘blockbuster drugs,’ but may be unable to recover R&D costs for others. The argument also assumes that firms efficiently invest in R&D, which pre-supposes that the length of patent protection is fixed.

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3 This argument is formally illustrated by Hausmann and MacKie-Mason (1988).
at the social optimum—which is unlikely to hold in practice.\footnote{See Scherer (2001) for a more detailed review of the Ramsey pricing argument.} [insert reference to Scherer]

**Is unconstrained discriminatory pricing consistent with equity objectives?**

At first sight, the simple model of a large high-income region and a small low-income region alluded to above may not seem an inappropriate description of the global pharmaceutical market. It is possible that unconstrained discriminatory pricing will lead to low prices in developing countries, while not affecting drug prices in the rich world. From this view, discriminatory pricing would be in line with equity objectives.

But there are two important caveats to this argument. First, there is no guarantee that demand elasticities necessarily correlate (negatively) with countries’ per capita income. Such a correlation may hold for some demand functions, but not for others.\footnote{For example, a demand function that generates a positive correlation between market size and demand elasticity is the linear demand system assumed by Malueg and Schwartz (1994), whereby the size of the market determines the demand curve’s intercept.} In particular, it could be that it is most profitable for companies to focus on the rich population segment in a low-income country, which may exhibit the same or even a higher demand elasticity than the one observed in a rich country [quote study by Keith’s student]. Similarly, while there are good reasons to believe that demand is more elastic in poorer countries with a smaller health insurance coverage, it is not clear that health insurance coverage always varies with per-capita income. Unfortunately, there are no empirical estimates on the structure of demand for pharmaceutical products in developing countries that would help shed light on this question.

Second, under unconstrained discriminatory pricing, prices in poor countries are still above marginal production costs. In general one would expect the demand for pharmaceutical products—especially lifesaving drugs—to be inelastic, such that markups over marginal costs can still be significant. If equity considerations call for the lowest prices in poorest countries, discriminatory pricing may be insufficient.

**Why the pure discriminatory pricing model may not hold in practice**

There are a number of reasons why the ‘simple’ theory of discriminatory pricing may not hold in practice. First, firms may not set prices to the profit-maximizing level determined by equation (1). On the one hand, they may set prices closer to or at marginal cost in poor countries. Charity may be one motivation; pressure from NGOs, health activists and the media another. The latter motivation is likely to play a role for epidemics that are in the public spotlight, such as HIV/AIDS, but it may be less influential for other diseases. On the other hand, pharmaceutical companies may opt for a more uniform pricing structure, even though markets are perfectly segmented. The fear may not be the ‘physical’ leakage of products to high price markets, but the political pressure to lower
prices in high price markets that may be created by the revelation of low prices in some countries. Politicians and patients in high price markets may show little understanding for the idea of Pareto improving price discrimination and (wrongly) feel they subsidize patients in other countries.

Second, pharmaceutical prices are often not set by market forces, but regulated by governments. Price regulations can take two basic forms. One is to estimate production costs, possibly make an allowance for the recovery of R&D costs, and add a reasonable profit margin. The other is to base prices on prices of therapeutically similar drugs on the market or, alternatively, the price of the same drug in foreign markets. Such reference-based price controls can undermine discriminatory pricing structures. A firm that faces a reference-based control in a large high price market may choose to price uniformly across countries to avoid cheap price references. Indeed, as argued above, the revelation of low prices in one market may lead a government in another market to introduce reference-based price regulations.

Third, we implicitly assumed that drugs are purchased by individual patients on the open market. In practice, large buyers, such as governments and hospitals, may possess monopsony power that may allow them to negotiated lower prices from a monopolistic or oligopolistic seller. It is possible that monopsony power correlates positively with per-capita income, which would favor lower prices in richer countries—offsetting the discriminatory pricing structure outlined in the simple theory.

Differential pricing and dilution of patent rights

So far, we have considered the circumstances in which a patent holder may price differentiate across markets, assuming that patents are perfectly protected in developing countries. This scenario is of increasing relevance, as most developing countries are members of the World Trade Organization (WTO) and have to comply with the provisions of the Agreement on Trade-Related Intellectual Property Rights (TRIPS), which mandates 20-year patent protection for pharmaceutical products and processes.\(^6\)

Nonetheless, there are two possible circumstances, under which competitive provision can still emerge. First, a patent holder may not seek out a patent in a certain market or grant a voluntary patent license to generic producers. Obviously, if licenses are granted on an exclusive basis the monopoly conferred by the patent remains in place. Unless the generic licensee produces and sells the drug on a not-for-profit basis, pricing decisions should be the same as in the one firm differentiated pricing model outlined above. However, if several generic producers are allowed to compete in the provision of the pharmaceutical products, prices would—in a perfect world—fall toward marginal cost. Thus a differentiated pricing structure would emerge, with the lowest prices in countries where the patent holder does not seek out patents or grants voluntary licenses to generic

\(^6\) Under the provisions of the TRIPS Agreement, developing countries can delay the introduction of pharmaceutical patent protection to the beginning of 2005 and least developed countries are entitled to a transition period ending in 2016 (with the possibility of a further extension).
producers. This implicitly assumes, of course, that there is generic production capability in markets for which patents are not sought out and that royalties in licensing agreements are sufficiently low for generic producers to enter the market.

More fundamentally, it is unclear why a profit-seeking patent holder would want to undermine her exclusive rights and encourage competition. As above, charity and public pressure from NGOs may be one motivation. A second, probably more relevant circumstance, in which competitive provision may emerge, is for a government to grant a compulsory license to a generic producer. The TRIPS Agreement explicitly allows the use of compulsory licenses and, in cases of ‘national emergency or other circumstances of extreme urgency,’ does not even require a government to make efforts to obtain a voluntary license from the patent holder. However, TRIPS requires that the patent holder be paid ‘adequate remuneration’ (though the term ‘adequate’ remains undefined). As above, if compulsory licenses are non-exclusive and royalties sufficiently low, competition would—in a perfect world—lead prices to fall close to marginal cost.

Some legal uncertainty exists under the TRIPS Agreement exists whether countries with insufficient manufacturing capabilities are allowed to import generic drugs under a compulsory license. Members of the WTO recognized this problem and, in 2001, agreed to find an ‘expeditious’ solution to it. However, despite intensive negotiations, no agreement could so far been reached at the WTO.

Compulsory licenses do not necessarily have to be granted for them to have an effect on prices. The implicit or explicit threat of granting such a license may lead patent holders to supply drugs more cheaply or license drugs voluntarily. As will be further discussed in Section IV, compulsory licensing regulations and practices may therefore play an important role in promoting differential pricing structures that seek to be in line with equity objectives.

### III. Empirical Evidence

The previous section conceptually identified the circumstances in which differentiated pricing may or may not emerge. This section tries to confront the various theoretical arguments with available evidence. Specifically, we review empirical evidence on the following four questions:

- Do companies actually price differentiate?

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7 Responding to concerns that the TRIPS patent rules could undermine access to medicines in poor countries, members of the WTO issued a Declaration at the Ministerial Meeting in Doha, Qatar in 2001, which reaffirms the right governments to use compulsory licenses. Specifically, the Doha Declaration recognized that “each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” Moreover, it recognized that “Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”
• How do parallel imports affect prices when they are legally permitted? And can parallel imports be effectively constrained?
• Are there ‘informational’ price spillovers?
• Is compulsory licensing an effective way to reduce prices?

Do companies actually price differentiate?

While this would seem the most obvious question to ask, empirical evidence to answer it is scant. Scherer and Watal (2001) analyze the correlation between national wholesale prices for 15 anti-retroviral (ARVs) drugs and countries’ per-capita income between 1995 and 1999 (See figure 1 in Annex). While there are notable price variations across countries, they do not find a correlation between these two variables. This finding does not provide evidence against the hypothesis that countries price discriminate. But it would seem to question the hypothesis that demand elasticities correlate negatively with per-capita incomes or patients’ purchasing power or, at least, it suggests that other influences (e.g., monopsony power, price controls) outweigh the influence of cross-country differences in demand elasticities. In any case, Scherer and Watal’s result suggests that markets, left alone, do not provide for a pricing structure consistent with equity considerations.

A somewhat more optimistic picture emerges from an analysis of price offers of ARVs to developing country governments, not-for-profit organization and international aid agencies (see the pricing guide published by Médicines sans Frontières, 2002). While no systematic analysis is available, pharmaceutical patent holders—also referred to as originator companies—offer special discounts to these buyers that seem significantly below the prices charged in developed countries. At the same time, these special discounts seem to be at least in part brought about by competition from generic producers of ARVs (which, for the most part, are still free of patents in the key developing country producer nations). Moreover, in some cases generic producers offer substantially lower prices, suggesting that originator drugs are still priced in excess of marginal cost (or, alternatively, originator companies exhibit significantly higher production costs). 8

What may explain the unwillingness of patent holders to not offer drugs more cheaply in the open wholesale market in developing countries, but to offer substantial discounts for the same drugs to government purchasers and the not-for-profit sectors? A variety of explanations are possible. Public pressure to lower prices may be stronger and can be exercised more directly in the case of public procurement. Monopsony power may also play a role, although many governments in developing countries are still relatively small

8 Comparing prices of originator and generic drugs is a tricky business. For example, the pricing guide published by Médicins Sans Frontières shows that originator drugs are the cheapest for the majority of ARVs among producers pre-qualified by the WHO as meeting standards of quality and compliance with Good Manufacturing Practices. In many cases, however, generic producers not pre-qualified by the WHO offer the cheaper prices. These generic drugs are not necessarily sub-quality products, as exclusion from the WHO list does not mean that a drug has not been approved by one or more national drug regulatory authorities. Different price quotation practices with regard to transportation and distribution costs as well as currency fluctuations often further complicate price comparisons.
buyers. Another important consideration is that parallel trade may be significantly more
difficult to control, once products have been placed on the open market. Purchasing
contracts with governments or not-for-profit organizations can include provisions against
reselling the drugs and, indeed, these purchasers typically have an interest to make sure
that the medicines reach the patients in need.

In order to assess how the apparent difference in pricing patterns between the retail
market and the government/not-for-profit market affects patients’ access to medicines, it
would be important to examine the share of ARVs in developing countries that are
purchased out-of-pocket. [is such data available?]

Unfortunately, no evidence on the extent of price differentiation is available for drugs
other than ARVs—which are important for combating, for example, malaria,
tuberculosis, diarrhea, or cancer. As discussed above, these diseases command relatively
less attention in the media and the public pressure on companies to lower prices may
therefore be smaller.

Although there is an increasing number of sources of price information aimed at making
the market more transparent and assisting procurement agencies in their purchasing
activities (for a summary of sources see Essential Drugs Monitor, Issue N0 31, 2002,
WHO fact sheet on drug price information services), the price information provided is not
appropriate for the type of country comparisons required by an analysis of differential
pricing. The information refers often to catalogue prices, rather than to the prices
effectively paid. The different prices correspond to different manufacturers or
wholesalers rather than to the prices effectively paid by the countries. The country
specific information covers several countries: Australia, Brazil, Denmark, India, Latvia,
Malaysia, New Zeland, Sweden, the United Kingdom, and the US Veterans
Administration. But these prices are provided by the countries without any systematic set
of definition and methodology.

A recent project by WHO and HAI has tried to improve the situation by developing and
testing in eight low and middle-income countries ("Medicines Prices: a new approach to
The first results of this project were launched recently, during last World Health
Assembly. The nine countries included in the field test of the study (Armenia, Brazil,
Cameroon, Ghana, Kenya, Peru, Philippines, South Africa and Sri Lanka) are probably
not enough in order to test any hypothesis on international price formation, but the
initiative is expecting to collect data from additional countries that would make a
sufficiently large sample.

This initiative is highly relevant as it provides the basis for an increased knowledge on
comparable drug prices in developing countries. So far the only regular international
source of drug prices is the market studies by IMS, a private company that collects and
supplies pharmaceutical market data aimed at the industry marketing departments at
prices seldom affordable for independent researchers. The confidentiality of IMS data
questions the scientific validity of any analysis based on them. The sampling and
statistical methodology cannot be checked and hence the validity of the data cannot be verified. Similarly, the validity and soundness of the results based on these data are difficult to verify, as the original data are only available at a high cost.
IV. A review of equity pricing schemes

In recent years, equity pricing has been increasingly discussed as one of the mechanisms for improving affordability to drugs in developing countries.

This section revises a set of proposed and actual schemes aimed at producing equity prices:

1. **EU PROPOSAL**: Proposal for a COUNCIL REGULATION to avoid trade diversion into the EU of certain key medicines.

2. **THE UK WORKING GROUP ON INCREASING ACCESS TO ESSENTIAL MEDICINES IN THE DEVELOPING WORLD. POLICY RECOMMENDATIONS AND STRATEGY.** Claire Short, Secretary of State for International Development, 28 November 2002.


4. Developing and Distributing Essential Medicines to Poor Countries: The **DEFEND Proposal.** Mattias Ganslandt, Keith E. Maskus and Eina V. Wong


6. **CONFIDENTIAL DIFFERENTIAL PRICING** Adrian Towse, Patricia Danzon


Most schemes are general proposals not aimed at an immediate implementation. The two main exceptions are the AAI and the EU proposal.

The EU initiative is aimed at ensuring market segmentation between developing countries and the EU market. Still the leading role for setting low equity prices depends on the patent-holder perceptions of the risks and benefits involved and on their willingness to take these risks.

The AAI proposal is the only operational initiative. However, its achievements are considered by some critics to fall short of initial expectations and to be hardly significant.
in relation to the total needs. On the other hand, in spite of looking as a collective initiative, in fact it is mostly based on country-by-country negotiations of single firms.

The core mechanism for attaining equity prices considers one or more of the following options. The two former schemes are based on voluntary price discounts, but among the proposed schemes all other options are considered: voluntary licensing, compulsory licensing (and parallel trade) and donations.

The leading organizations in most of the proposals are the patent-holders firms, except in the CIPR proposal, based on compulsory licensing and parallel imports. In fact, in spite of the claims of some supporters of compulsory licensing, this approach alone is not necessarily going to lead to equity pricing as defined in this paper. The use of compulsory licensing is likely to result in lower prices than otherwise might prevail, but there might be regulations, market imperfections and monopolistic structures independent from IPR, that can lead to higher prices than in countries without CL. CL is a necessary, but not a sufficient condition for attaining lower prices. Moreover, the price reduction obtained through CL may not bear any relationship with the countries income, wealth or need. The same can be said of parallel imports. In the past it might have been a valid option for developing countries where prices were relatively high. However, at present parallel trade is more likely to benefit high-income countries that take advantage of the lower prices in low-income countries. In fact, parallel trade from low income to high-income countries is an obstacle to equity pricing, as it removes the incentives for patent-holders to charge lower prices in low-income countries.

The main supporting organizations in the proposals are the country authorities, which are expected to ensure market segmentation.

There are also broad differences in the criteria for defining eligible countries or organizations. All proposals either name or would probably include the least developed and the Sub-Saharan African countries, but there seems to be less consensus in relation of developing countries in the higher income brackets, such as Brazil, India, China, etc.

The majority of proposals explicitly or implicitly consider only two segments or clusters: the developed-high price countries and the developing-low price countries. The Out licensing proposal acknowledges the existence of countries where an intermediate price might apply. The AAI scheme considers three segments. But only the prices for the African countries are known and can therefore be said to be substantially lower than those in developed countries. The lack of transparency regarding the prices charged in intermediate countries does not allow drawing any firm conclusion. A two-segment model has the advantage of its simplicity, however, it is not easy to draw the line between the two segments and any decision is likely to be seen as unfair by the countries with the lowest income that are excluded from the low price segment. Multiple prices – somehow proportional to an indicator of income and needs - would allow a smoother adjustment to an equity principle prescribing a relationship between the countries price levels and the countries’ conditions. However, the larger the number of segments, the more difficult would be to isolate the markets. In the extreme, if each country was assigned a different
price, each country should become a segmented market. Physical differentiation of
products would be unfeasible and there would be no scope for competition. A continuum
of effective prices according to income and need would probably require very particular
arrangements, such as a posteriori rebates based on the amounts actually used within a
country or health care organization.

Most proposals ignore the issue of possible segments within countries; others address it
by assuming that the high income in developing groups should or would not benefit from
the low prices. In countries with a universal mandatory system this would not pose a
problem: the country would be allocated a price according to the average income, and
high income individuals could be assumed to make a larger contribute to drugs, provided
contributions or taxes are directly related to income. But in most developing countries
there are several subsystems, which seldom cover drugs and large income inequalities.
Allowing the country a price related to the average income might mean that an affluent
minority will enjoy unfairly low prices while the majority of the population is likely to
experience no significant change in affordability. This scenario would not be equitable by
most definitions of equity, nor would it be acceptable by people in rich countries that
experience affordability problems, e.g. the pensioners and elderly in the USA.

Products or diseases included in the scheme include in all instances HIV/AIDS, malaria
and TB drugs, but there are broad differences beyond that set. While most people might
agree that equity pricing – and other mechanisms to ensure accessibility – should include
essential medicines, there is no clear criterion to make this concept operational. On the
other hand, the products which are a priori more appropriate fore an equity pricing
approach are on-patent drugs, as the difference between the market price in high income
countries and the manufacturing cost, which sets the limit to supply without a theoretical
loss, is likely to be larger than in off-patent drugs. But few proposals address that issue.

Most proposals - with the exception of the EU and the out-sourcing one - do not indicate
figures or precise methods for setting the prices, and no one addresses the issue of how
updating them or what should be the period for which the price agreements should last.
The AAI scheme seems to favor one-year agreements. It is certainly surprising that this
key sustainability issue seems to have been ignored in most proposals.

Most proposals assume that developed countries, the potential importers of low price
drugs aimed at developing countries, should and could control the diversion of equity
priced products and ensure market segmentation. Low-income countries are expected to
do the best they can to contributing to market segmentation, but they are assumed to play
a secondary role.

Finally, most proposals ignore the more operational issues of monitoring and controlling
the scheme. Even the two schemes that can be considered operational – AAI and EU –
have very loosely defined mechanisms for that purpose.
V. The Global Store proposal

A scheme is proposed that mostly reflects features of the revised schemes as well as ideas and features that were not made as part of a comprehensive equity-pricing scheme. The present scheme could coexist with other existing and proposed schemes. The basic characteristics of the scheme are presented below:

Core mechanism for attaining equity prices: An international or regional agency that we call Global Store will operate on the basis of pooled purchasing and distribution of the products included in the scheme. It will also negotiate voluntary licensing on behalf of its members and coordinate if required compulsory licensing by its member countries. The first option is certainly preferable if satisfactory royalties can be agreed, especially if the licensing agreements include some element of know how or technology transfer.

Leading organization(s): An international (regional) agency owned by or accountable to developing countries. It could be an existing agency or a new one created for that purpose. There might be more than one agency and countries would be free to join agencies or to create new ones. This is the most distinctive feature of the proposal: the organization and operation of the scheme is under the control of a group of developing countries.

Supporting organizations: Donors, such as the GFATM, should initially fund the agency (or agencies) and latter provide funds for subsidizing countries that cannot afford even marginal/manufacturing cost prices. International organizations such as the WHO, the World Bank, other UN and international organizations and NGOs, should provide expertise and political support, at least at the initial stages of the agency.

Eligible countries/organizations: In principle, all World Bank client countries might be eligible.

Number and characteristics of tiers/clusters with different prices: Three segments that correspond to the classification of countries for lending purposes by the WB. This classification might be adjusted in order to take into account burden of disease, production capacity, or other criteria.

Products or diseases included in the scheme: Essential drugs on patent. Off-patent drugs might however be included as long as there is a potential for substantial price reductions. The WHO Essential Drug List should be the minimum set, but the concept of essentiality might be broadened. A possible criterion could point to drugs reimbursed in a set of mandatory or publicly funded health systems or programs: UK NHS, Medicaid, etc. Although an operational specification should refer to products, rather than to diseases, it would be essential to include in the scheme a reference to disease in order to avoid the financially disruptive effects of a new drugs that made a substantial therapeutic improvement on current treatments if they were priced very highly.
The scheme could be implemented in a progressive way, starting with drugs for HIV-AIDS, malaria and TB.

**Criteria and procedures for setting and updating the prices or license fees:**
The purchasing price for the Global Store would be the competitive market price obtained through international competitive bidding. The agency would pay the patent holders an agreed royalty - defined as a percentage on the purchasing price by the Global Store - on all units purchased, irrespective of the supplying manufacturer or of the country of destination. That is, the scheme would in practice allow for a fair compensation to the patent-holder, but no for market exclusivity.

The Global Store would set selling prices according to an agreed rule, e.g. as a fraction of the average price in (a sample of) OECD countries for the developing countries.

If no international donations are available the price structure defined should allow the Global Store to be financially self-sufficient. As long as no countries are granted prices below the manufacturing costs, the higher income beneficiary countries are likely to benefit from participating in the scheme compared with the option of acting alone. If the lowest income countries had to receive the drugs for free or under manufacturing cost prices, a certain level of cross-subsidization would be necessary within the beneficiary countries. The relative rich countries may find it more profitable to act independently.

International donations to the Global Store – still better, a concerted action with the GFATM - would allow to further lower the prices charged to the poorer countries, without compromising the sustainability or the scheme.

**Duration of the scheme:** The agreement should cover the whole life of a product, or at least until patent and other market exclusivity rights have expired.

**Market segmentation mechanisms proposed or introduced by scheme:** The international market would be divided into three (or four) segments. Trade would be allowed from higher to lower price segments but not vice versa. Trade within segments would also be allowed. In fact, the role of the Global Store would reduce the interest of promoting competition at the final markets level. Competition would basically take place at the Global Store purchasing level, as manufacturers of all countries would be allowed to participate in the ICB of the Global Store.

**Rights and obligations of organizations participating in the scheme:** The authorities of high-price countries should explicitly agree in banning imports from lower-price countries and in setting administrative prices (if there is a price control mechanism in place) using the low prices applied to lower income countries as a reference. Countries benefiting from low prices should contribute in a reasonable way to avoid or reduce the likelihood of parallel exports. They could be asked, for instance, to keep adequate administrative records and make regular surveys of the distribution and utilization of the drugs under the scheme. Beneficiary countries should accept to have their information
systems and physical facilities open to audits and inspections from the Global Store of from other agreed auditing organizations.

**Mechanisms for monitoring and controlling the scheme:** By comparing the information from the Global Store with regular surveys, it would be possible to assess the existence of product diversions of a relevant magnitude.

**VI. Conclusions**

The present scheme is compatible with other approaches such as price discounts or equitable royalties by individual firms, cost containment policies by national countries. It would also be compatible with the scheme recently approved by the European Union. Like other schemes based on compulsory licensing, this approach assigns a leading role to the developing countries, but it assumes a certain degree of coordination and joint management. It also assumes some degree of equity and solidarity within developing countries: more affluent developing countries would make a larger contribution to R+D than the poorer ones. Some likely advantages over existing proposals are the lower transaction and administration costs of issuing CL. The scheme does not have the potential “dumping” effects of individual firm discounts: All manufacturers irrespective of the country of residence or of the level of vertical integration would be competing for the Global Store funds on a similar footing. Irrespective of which manufacturer gets the contract, royalties would be paid to the patent holder, which may have or have not participated on the ICB. The scheme therefore allows a trade-off between R+D incentives and affordability. If the current royalties do not seem high enough to provide an incentive to R+D in certain areas or diseases, countries could easily agree in rising the compensation for some diseases where there is a higher social need.

There are some issues not addressed in the proposal, such as how to deal with intra-country equity. Should the scheme be limited to programs for the poor in developing countries or to health systems that have a minimum degree of equity, e.g. universal coverage and funded by progressive taxation? If only high income groups in developing countries were to benefit from equity pricing, the justification for it would be far from clear.

The feasibility of the proposed scheme depends also on the behavior and attitudes from the parties involved. In theory a differential pricing scheme can be a win-win option. But this cannot be taken for granted. Patent-holders are likely to fare better under an equity pricing approach than under a single international price scenario. However, they may still prefer a Ramsey type approach that restricts accessibility to the more affluent minorities.

Anyways, in spite of the remaining difficulties for reaching a feasible option, it is encouraging to see that there are, at least, two equity-pricing schemes (AAI and EU) that have moved from the theoretical into the real world.


PRODUCT FLOWS IN THE PROPOSED MODEL OF MARKET SEGMENTATION

HIGH INCOME COUNTRIES

INTERMEDIATE INCOME COUNTRIES

LOW INCOME COUNTRIES