World Market Strategies for Drugs to Fight Aids

Jérôme Dumoulin, Yves-Antoine Flori, Philippe Vinard, Thomas Borel

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Abstract

Faced with a situation where the market is unstable and the political context is crucial, we propose a three-part analysis. In the first part, an overview of the chronology of the main events shows that the evolution of the price of ARVs is interlinked with numerous issues of pharmaceutical patent rights. In the second part, we analyse the positions of stakeholders: how they behave in the market and influence market regulations. In the third part, we propose three scenarios which are both simplified interpretations of stakeholders’ strategies and options for the future. The first scenario is the status quo, where prices are high. The second scenario is driven by multinational companies who work to enlarge the markets by price differentiation and product diversification. The third scenario is driven by International Organisations which achieve a political consensus to enlarge access to ARV drugs through broader international financing and a systematic opening of the market to generics.

Résumé

Face à une situation de marché instable où le contexte politique est primordial, nous proposons une analyse en trois parties. Dans la première partie une esquisse de la chronologie des événements montre que l’évolution des prix des
Introduction

Since May 2000, the price of ARVs (antiretroviral drugs) has slumped dramatically [1]. This phenomenon is just one of the latest developments in the international ARV market to have received wide media coverage.

An increasing number of actions are being taken in this area, even though many of them are either on a limited scale or still in preparative phases. Market conditions are a paradox, with the theoretical needs being considered as huge, the existing demand already being strong, promises remaining cautious and actual achievements being nevertheless limited. Even if international debate often refers to “the ARV market” as if there were only one, the determinants of supply and demand and the regulatory conditions vary considerably from one country to the next. Can economic analysis give us an understanding of the mechanisms, particularly by looking at how markets are run and at the pertinence of the actions being taken? Should we introduce worldwide regulations to control the distribution of anti-retroviral drugs, or should we allow free competition by merely protecting innovation? These questions are at the heart of economic analysis of political transaction costs [2-4] and the institutional economics [5].

The concept of political transaction costs is used to improve and to deepen previous explanations of inefficient outcomes in economic policy-making. It focuses on political transaction costs such as failures of instrumental rationality in politics, the lack of adequate technology of commitment. Incentives to renege on agreements occur in many economic settings, but in such settings, repeated interactions often provide incentives for individuals to honour agreements in order to maintain a flow of benefits over time. Such reputational mechanisms of contract enforcement are however usually ineffective in a political setting.
Institutions behind the market are not considered only as constraints on the behaviour of pre-formed and unchanging individuals as they are in standard economics, but are considered also as shaping the individuals themselves. In order to understand the workings of the ARV market, we need to understand a wide range of institutions that affect and are affected by it. These institutions are, first, simply formal institutions like state, law and international regulation. Secondly, they include private-sector self-regulatory institutions (e.g. professional associations, producer associations) and informal institutions such as social conventions, although many of these institutions are supported by formal institutions (e.g. decisions by professional associations or social conventions are, when it comes to the crunch, enforceable through the legal system). With this approach, the institutions define who can hold what kinds of properties, who participate in what kind of exchanges, what are the legitimate objects to be exchanged, what are the acceptable conducts in the exchange process, and on what terms different types of agents may participate in which markets, and so on. In such an analysis, the market is a political construct. This approach is very useful for analysing the ARV market: the products are new and their market is under construction.

Using such a framework of analysis enables the working of the ARV market to be described, but does not allow us to build a formal testable model. So this chapter is complementary to the market analysis presented by Luchini et al. in this book [6].

Behind the announcement and the actual prices of ARVs, what conditions and what forces have led to that situation? Understanding the various stakeholder games will provide a framework for building similar scenarios. Given the number of non-homogenous stakeholders (governments, pharmaceutical industries, generic manufacturers, international organisations, NGOs), the situation is a complex one. What is publicly said by these actors does not always reflect their “true” objectives and strategies, and both of the latter change in accordance with events. Is it a question of explicitly designed and/or implicitly intended strategies, or rather a chaotic jumble of reactions to market shocks?

In order to analyse the future positions of the various actors, we will put forward scenarios, coherent alternatives, in line with a certain number of hypotheses (the conditions of which will have to be determined) essentially based upon the possible objectives of drug marketing. A return to economic theory would enable us to identify three types of approach (monopoly, competition and public property theories), each according a different role to ARVs and each enabling the different stakeholders to define more clearly differentiated strategies.
These scenarios represent extreme positions, whereas future change is likely to take an intermediary position. Nevertheless, this method illustrates the importance of the matter at stake. The evolution of the ARV market often appears to be the first step to future changes in other markets. Factors regarding the antiretroviral (ARV) market relate to vital questions in other domains: politics (the question of national sovereignty), economics (defence of a major industry), law (regulation of international trade). To what extent will debate and initiatives remain restricted to the ARV market? Or will they encompass other products? The answers to such questions might enable us to understand stakeholder positions and the level of tension in their relationships with one another, thus allowing us to use the scenarios to discuss likely evolutions which can then be compared with the desired goal of increasing access to appropriate HIV/AIDS care in developing countries.

The scenarios are fed by an analysis of the stakeholders’ positions and a short chronology of main events which shows the intertwining of strategies. This analysis and this chronology result from interviews carried out in private companies, international organisations and NGOs and from examining numerous papers, publications which cannot all be mentioned.

I

CHRONOLOGY OF THE MAIN EVENTS

The chronology comprises two series of interlinked events that mutually affect one another: the anti-retroviral market on the one hand, with its very sharp drop in prices, its donations and the creation of the Global Fund to Fight Aids, Tuberculosis and Malaria, and, on the other hand, international announcements and debates related to the World Trade Organisation’s (WTO) Trade Related Intellectual Property Agreement (TRIPS agreement). When the World Trade Organisation was created in 1994, little attention was paid to the risks of this agreement in terms of developing countries’ access to drugs. In 1996, the arrival of tritherapy treatments changed the nature of the problem, as all ARV drugs were patented in developed countries. The debate began in the late 90s – at the WHO [7] for example – and revolved around the situation in Brazil, which partially treats all HIV/AIDS sufferers with low-priced generic drugs, and in Thailand, which is trying to produce generic drugs. Developed countries, led by the USA, attempted to restrict the room for manoeuvre created under the TRIPS agreement (essentially with regard to compulsory licensing and parallel
importations). At the same time, initiatives were taken to treat HIV/AIDS patients living in sub-Saharan Africa, with donations from companies and from the French government, and with special prices negotiated within the UNAIDS framework. The year 2000 saw the irruption of Indian generic manufacturers who offer prices which are far lower than those of multinational companies. The debate was growing, because lower prices allow far wider distribution of treatments; the WTO’s regulation of patents thus became a major determinant in as much as it is able to forbid access to generic drugs. Most multinationals fell in line with these price drops whilst simultaneously increasing donations. In 2001, the question of AIDS and of access to ARV drugs became political: many countries took position, especially at the UN which suggested creating a Global Fund. In November 2001, members of the WTO approved the Doha declaration, which gave countries the right to compulsory licensing in cases of serious epidemics such as AIDS, malaria and tuberculosis (Doha Declaration on the TRIPS Agreement and Public Health art. 5 c) and to parallel imports (idem, art. 5 d). These members also promised to find a solution for compulsory licensing for parallel imports. The Global Fund to Fight AIDS, Tuberculosis and Malaria was created in 2002, when it granted its first funds. Through new funds, “the Global Fund will increase six-fold the number of people being treated with antiretrovirals (ARVs) in Africa with grants from its two initial proposal rounds, ensuring that 500,000 additional people receive these medicines in developing countries” [8]. The Fund agreed to finance the purchase of generic drugs. The WHO added ARV drugs to its list of essential pharmaceuticals and published two lists of pre-qualified suppliers. Yet in 2002 the members of the WTO were unable to agree upon import licences, with the USA attempting to restrict the diseases concerned to just a few epidemics, and developing countries trying to extend the scope to cover all public health problems.

II
THE POSITION OF THE STAKEHOLDERS

The market of ARV is not just an equilibrium between supply and demand. Market regulation is not yet stabilized, so suppliers (manufacturers) and demanders (southern hemisphere countries) exert an influence to curb these rules in favour of their own interests. Rules are laid down in International Organisations by agreement between countries. NGOs engaged in health care programmes act as buyers, but mostly as lobbyists representing patients. All stakeholders play
different roles which can be analysed. The position of different stakeholders can be represented simply by the following figure:

Figure 1: Position of the stakeholders

Pharmaceutical companies

Very few companies produce ARV drugs: 6 multinational firms in the northern hemisphere (including some of the biggest pharmaceutical laboratories) and a dozen or so generic manufacturers, mainly from the southern hemisphere.  

1. If there is a problem about how to name the different types of pharmaceutical companies for the ARV market, in reality it is simple: on one hand, there are multinational companies based in the northern hemisphere who market ARVs as innovators, and on the other hand, there are southern hemisphere companies who market copies of ARVs (sometimes with improvements). So we have chosen to call them “multinational companies” and “generic manufacturers”.
Multinational firms

Although they always describe themselves as R&D companies, they have not always been the creators of these products, some of which stem from public research (this point is developed in [9] in this book). How much they have really spent on R&D for ARV drugs is a well-guarded secret. These companies have a monopolistic strategy based upon intellectual property: patents and brand names. The main markets are in developed countries, which has led companies to set their prices to suit, e.g. approximately US$10,000 for annual treatment, a price which is totally beyond the means of patients in the southern hemisphere. To defend their monopolistic position, these companies have basically implemented two strategies in recent years: lobbying and pricing or donation policies.

Lobbying is mainly organised through the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and national associations which greatly influence debates and national authorities (e.g. PhRMA in the USA, LEEM – formerly SNIP – in France). It was pressure from the IFPMA that led developed countries to introduce measures to protect the patents included in the WTO’s TRIPS agreement. The PhMRA works closely with the USTR (US Trade Representative) who is the American government’s official on international trade policy and who has his own lists of countries under surveillance. The other northern hemisphere countries support most of the IFPMA’s positions, as they have thriving pharmaceutical industries (especially in the United Kingdom, Germany and Switzerland).

The purpose of the donation policies is to protect the image of pharmaceutical companies, who thus come across as being concerned about public health [10]. Above all, they are designed to counter the low prices offered by producers of generic drugs. Most multinational companies have developed donation programmes, but in most cases it is not just a question of donating pharmaceuticals. Such programmes can also be a way of demonstrating that the price of drugs is not the only question. It is sometimes a means of beginning treatments with international funding in accordance with the old saying that “to know it is to love it”.

Whilst pricing policies are sometimes put forward as having a humanitarian purpose, they in fact exist solely to protect commercial positions. The discounts offered by multinationals always lead to price cuts by generic manufacturers and never take place if no copies are on offer from generic manufacturers (cf. Efavirenz and Efinavir). These price-cutting policies are related to compulsory licensing in two ways: firstly in countering compulsory licensing policies, by
showing them to be of no future utility; secondly as a result of the threat of compulsory licensing made by Brazil [11]. The problem is that these differentiated prices lack transparency and are subject to conditions which are often unclear [12]. The objective is to make each buyer believe that he is getting a better deal than anyone else. How much multinational companies are in favour of lower prices is an indication of how much importance they attach to markets in the southern hemisphere.

Generic manufacturers

Producers of generic pharmaceuticals sell copies of original drugs. Their objectives will be different, depending on whether they are public companies or private companies.

There are currently two public generic manufacturers producing ARV drugs: Far-manguinhos in Brazil and GPO in Thailand. A Chinese company is soon to begin production. Compared to multinationals, these are small companies whose prime objective is to supply their domestic markets at lower prices. Their entry into international markets is due less to the sales or transfers of technology (licences) that they announced, than to their participation in the debates on compulsory licensing and prices: they demonstrate that it is possible to negotiate [11, 14]. Generally speaking they do not offer prices as low as those of private generic manufacturers, as they are probably less efficient economically, searching to satisfy domestic needs in both quantity and quality rather than offering aggressive prices at international level.

The private manufacturers of ARV drugs are mainly Indian [5]: these companies sell many other generic drugs and have a large share of the world market in this domain (including in the USA). By offering very low prices to the international markets they triggered a price war. They also produce active substances for public Thai and Brazilian companies. Indian pharmaceutical companies benefit from their country’s pharmaceutical policy, which for the last twenty years has been to favour local production. After conquering the domestic marketplace, they attacked the international market. Their low prices for ARV drugs (less than US$300 per annum for a tritherapy) gave them a potential huge customer base. We do not yet have detailed information, but their effective sales of ARV drugs in Africa remain limited. They have yet to make any major penetration

2. In Brazil, other private and public manufacturers operate on a much smaller scale than Far-manguinhos, and most are abandoning ARV production [11, 13].
into African markets for other products. They are not yet properly prepared for public offers to tender, or for meeting the requirements of public financing. They are nevertheless beginning to carry out promotional operations in several African countries, using the notoriety they acquired in the ARV drug campaign.

Countries

The “southern” hemisphere

We will distinguish between countries with and countries without a pharmaceutical industry, the former being both producers and consumers, the latter merely being consumers.

Countries with a pharmaceutical industry (that has been developed to at least some extent) follow strategies which aim to improve their production capacities. Such countries favour the development of compulsory licensing in a broad range of cases and not only for AIDS, because they offer a means of developing this sector in order to satisfy local demand (cf. Brazil and Thailand) or to export (cf. India and China). AIDS is a strong lever for this point of view. Negotiations on patent rights fit into the framework of pressure or action aimed at lowering the barriers (price or otherwise) put into place by developed countries in all sectors of production.

Countries with no significant industry, such as most of the countries in sub-Saharan Africa, adopt strategies which aim to acquire ARV drugs at the lowest possible cost. In the short term, severe budgetary restrictions can force such countries to accept offers which allow them to treat a certain number of patients. They will therefore accept offers which include donations and purchase clauses that will link them to the producers for the long term. In this way, the poorest countries – especially African countries – can add their voices to those of the intermediate countries in order to gain several sources of supply and lower prices (by acquiring generic drugs). Yet because they need a flow of aid (be this in the form of donations or reductions of debts), and given their weak negotiating position, they have to accept the choices of the developed countries and deal with pressure in international negotiations. As representatives of such countries, NGOs put on the pressure in order to avoid their needs being ignored. Due to their administrative and legal weaknesses, most of the developing countries in the southern hemisphere also have difficulty in developing any dynamic AIDS policy, in as much as there is no strong domestic social demand, and in defining a position with regard to international questions that take health problems into account.
The “northern” hemisphere

The purpose of northern hemisphere policies is that of maintaining and developing a position on the international stage. The reason behind public aid is therefore twofold: to help southern hemisphere companies, and to preserve influence, be it economic or political.

Some countries, such as the USA, believe that it is trade not aid which facilitates growth, and that it is therefore necessary to permit development by reducing trade barriers and by creating a path towards growth. Under this hypothesis, aid and cooperation are restricted to whatever cannot be supplied by the market (public property and a safety net). Hence the rules of competition introduced within the framework of both the WTO and the OECD forbid aid to sectors which are open to competition. All that remains for governments is to finance unprofitable sectors (be they infrastructures, authorities or social sectors). This position separates trade policy from cooperation policy, and trade strategy sometimes tends to predominate – hence a position on trade agreements which essentially enables them to defend interests proper to northern hemisphere countries. The balance between trade policies and policies of cooperation nevertheless varies considerably from one country to another.

More and more countries are delegating a share of their external actions to international or infranational institutions (local authorities) or even to private organisations (NGOs). Thus trade policy and policy regarding aid from European countries are now to a large extent delegated to the European Union. In order to improve the technical (not political) effectiveness of aid, many countries transfer their actions to private organisations (both profit and non-profit making) or to international organisations, themselves remaining mere sleeping partners. This has contributed towards the rise in strength of NGOs and International Organisations with regard to technical health questions, especially AIDS-related, and to “social” questions being removed from trade policy.

International Organisations

Regarding the price of ARV drugs, there are three distinct groups of international organisations: The International Monetary Fund (IMF) and the World Bank; the institutions governing intellectual property rights; the United Nations.
The Bretton Woods system

For the International Monetary Fund, the World Bank and its group members, trade is considered to be one of the essential factors for development, in parallel with proper monetary policy and loans for long-term investments, such as infrastructures. Indeed, free exchange is supposed to benefit everyone, as long as the rules of “fair competition” are obeyed. Exceptions to this market rule have to be restricted. Defence of intellectual property would appear to be one condition for the development of long-term exchange.

The World Bank began investing in vast social programmes back in the 60s, but its top priorities were growth and the fight against poverty. Its interest in public health appeared somewhat later, in the early 90s [15]. The World Bank thus became the first international backer in the field of healthcare, especially with regard to the social aspects of structural adjustment programmes. Its interest in the fight against AIDS gradually increased, first with the publication of the results of the first studies on the economic consequences of AIDS and then with its participation in UNAIDS in 1994. As everyone became aware of the economic costs of AIDS, the World Bank wanted to become involved in the work and discussions on access to ARV drugs and in the Global Fund. Its position on access to ARV drugs remained cautious. Its opinion was mainly based upon cost effectiveness studies, with anti-retroviral treatment being deemed “costly, with uncertain results” [16]. This report states the concern not to create any special status for dealing with AIDS, as opposed to other diseases. Now the World Bank has agreed to finance ARV expenditures for treating patients.

However, the leading priority remained that of prevention (principally of sexual transmission, but also mother-to-child transmission). On the basis of the results of the work in Uganda – to which it had allocated considerable funds, the Bank decided that governments should concentrate on preventing and reducing transmission, and that anti-retroviral drugs should not be financed by governments but by private insurance schemes and by companies. So the question of producing generic drugs does not arise. The Bank feels that drugs to fight against opportunistic infections should be procured by invitation to tender.

Aside from its support for the World Trade Organization (WTO), the IMF - guarantor of macro-economic stability - takes no specific action within the ARV market. On the other hand, it is involved in the initiative to reduce the debts of over-indebted countries. As part of this programme, some scenarios allow a share of the funds to be allocated to the fight against AIDS.
Organisations dealing specifically with patents

Two relatively new organisations (in their current form) – the World International Property Organisation (WIPO), created in 1967, and the WTO, created in 1994 - have as their vocations to defend intellectual property and to develop trade. Developing countries (the least developed in particular) are poorly represented within these institutions and often do not have permanent representatives; this means that they have very little influence upon decision-making processes, despite the support they receive from departments within these organisations [4]. After the Uruguay Round, the WTO’s scope of action was enlarged. The result of the TRIPS agreement is that intellectual property rights are increasingly protected, and the stakes are higher than ever (new markets, new producers, greater investment in research) [17]. Although up until then the pharmaceutical sector in developing countries had evolved under less restrictive regulations, the pressure from developed countries – due to their influence within the Organisation – blocked the opportunity to build an innovative industry without any liberalising counterbalance in other sectors [18].

Whilst the regulations allow for exceptions, the specificity of healthcare product regulation is not explicitly mentioned. It was only during the Doha conference (2001) that the specific needs of public health began to be considered. Outside pressure from NGOs led to these exceptions being accepted, with international organisations playing more of a conciliatory role in order to preserve other decisions resulting from the negotiations. However, following the failure of the December 2002 negotiations on the application of the Doha decision, the scope of these exceptions remains limited.

The United Nations

Within the United Nations system, the consequences of HIV infection were initially examined by technical agencies, in particular those dealing with the health of populations and individuals. In 2001, the United Nations’ extraordinary session on AIDS marked the Organisation’s decision to take the global effects of the infection into account. The session led all agencies to examine the consequences of infection, and to the creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria (UNAIDS, UNDP, WHO, UNICEF, FAO, Security Council, UNRISD).

With the present emphasis on sustainable human development, the United Nations Development Programme (UNDP), with fewer resources than the Bretton Woods institutions, stressed the importance of social sectors, and health within
Since 1999, the UNDP has been analysing AIDS as a factor of poverty. But given the search for consensus between member countries and between experts, the formulation of recommendations has sometimes remained hazy and has led to only a limited number of projects.

As from 1987 the WHO, along with the Global Programme on Aids, played a precursory role regarding AIDS, followed by a more cautious attitude, and then a partial move away with the creation of UNAIDS. Since 2001, the WHO has once again been playing an active role in two areas: the therapeutic treatment of AIDS, with the creation of a specialised division, and with its participation in debates on access to pharmaceuticals. With the former, it has returned to its role of technical expertise and has invested in the assessment of treatment experiments. It has thus become involved in the quality requirements of available products (pre-selection of manufacturers, monitoring resistance). Putting the accent on the prior conditions for the different experiments is sometimes criticised as being an excuse for non-decision, or as a factor which slows everything down. Progress has been faster in the area of drug policy. After an extremely cautious attitude which had a great deal to do with strong pressure from the pharmaceutical lobby, the WHO began to make decisions on trade exceptions which benefited generic manufacturers (qualification, decisions regarding differential prices). It wanted in this way to participate in rallying civil society, which, whilst often criticising the Organisation’s overcautious attitude, was also asking it to play a greater role in international discussions. Yet the WHO still does not take part in certain international trade negotiations despite the fact that they involve the drugs market (November 2002 in Sydney for example).

UNICEF has evolved in parallel to the WHO and the UNDP. It now plays a major role in the field of mother-to-child prevention. After initially adopting a highly cautious attitude – largely due to its traditional campaigns in favour of breast-feeding – it began to insist upon prior conditions for experiments. Following the prescription of Nevirapine, UNICEF started to invest in programmes on a vast scale, and to negotiate with manufacturers. Like the World Bank, it remains very cautious with regard to tritherapy. It favours prevention (especially among the young) and social action to help AIDS orphans.

At first, UNAIDS adopted a very low-key position on tritherapy, and its branches, which mainly comprised people from civil society, essentially opted for actions of prevention and sensitisation. There was a lack of technical expertise on therapeutic treatment. In response to the pressure of demand, the “Access” programme was launched in 1998. Limited experiments were gradually started.
UNAIDS often follows the position of civil society (for example, regarding the free treatments in Ouagadougou in 2001), but then adopts a more cautious attitude due to a desire to achieve consensus. Since 2000, its actions have been reoriented towards preventive aspects, with curative actions once again falling under the umbrella of the WHO (with a new transfer of experts). This trivialisation of AIDS compared to other diseases does not help towards specific regulations for ARV drugs. Following this restructuring and the creation of the Global Fund to fight AIDS, tuberculosis and malaria, UNAIDS has had some trouble defining its role.

In some ways, the installation of the Global Fund in Geneva has strengthened the positions of the WHO and UNAIDS, due to the existing links between experts [19]. With the participation of NGOs, companies and governments, the Fund has become a new style of international organisation. It can be a platform for dialogue between the different stakeholders. But it is greatly influenced by financial backers, who are able to considerably reduce its actions. As a new institution, it can take an offensive stance in order to bestow particular status upon the ARV market. As a major financial backer, it can become a negotiating platform for the purchase of ARV drugs on a larger scale. For the time being, the Fund has authorised the purchase of ARV drugs (pre-qualified by the WHO [20]) for backed projects. US$ 1.8 billion have been allocated, although actual needs were assessed at five times that figure.

Non-Governmental Organisations (NGOs)

Unlike manufacturers, there are a huge number of NGOs. Whilst clusters of NGOs have joined together on many occasions to demand changes which would allow lower prices for ARV drugs, only a small group of forerunners have intervened on an active basis. Many NGOs from the southern hemisphere (with the notable exceptions of South Africa and Thailand) have chosen not to take concrete action, or are content simply to echo the opinions of the northern NGOs. They do not have sufficient resources, are mainly involved in prevention, and are highly dependent on backers (often International Organisations, government cooperation and sometimes even pharmaceutical companies) [21].

The Médecins sans Frontières (MSF) campaign is a good example of action being taken by NGOs from the northern hemisphere. This campaign for access to drugs did not immediately concentrate on AIDS treatment, access to ARV drugs only being mentioned as one example among many [22]. Similarly, the question of the TRIPS agreement was initially only a subsidiary one. The growing
importance of HIV/AIDS treatment within the campaign was powered by field projects, especially in Thailand and Africa. Legal aspects became very important due to a fairly remarkable convergence of events [22]. WTO deadlines and the international activity surrounding globalisation gave a considerable media boost to the campaign. It might be said that the latter successfully influenced many international organisations (the WHO in particular), governments (especially the French) and even (though gradually) the European Commission. Yet the lobby for African countries and trade organisations did not yield such good results [23], despite all the efforts that were made (ministerial meetings in Africa, participation in WIPO conferences).

The main objective of northern and southern hemisphere NGOs which are active in this field is to broaden access to ARV drugs in the name of human rights. Above and beyond the “humanitarian” aspect, their legitimacy resides in the proximity of sufferers, either as NGOs providing care (e.g. Médecins sans Frontières) or as associations for sufferers (like Act Up in France and the USA, Treatment Access Campaign in South Africa). These NGOs see themselves as representatives of sufferers’ true interests, and as a counterweight, even if they do not possess the legitimacy of governments or the economic power of purchasers. One major aspect of their legitimacy stems from their technical competency, due to the fact that they remain very much au fait with all the medical and scientific details of AIDS. Legitimacy may also come from working on information on specific points – economic and legal for example (with Health Action International, Oxfam, Consumer Project Technology). The work covers both legal (patents) and price aspects. Networking enables them to rapidly share information and coordinate their actions, thus giving them considerable strategic power in an ever-changing situation.

Yet the power of NGOs must not be over-estimated. Their pioneering role and their work on the fringe are particularly useful when their ideas end up being adopted by other partners (international organisations for example) which then take over. They supply technical information to southern hemisphere countries, which whilst it makes them stronger, does not fundamentally change the influence of such countries in international negotiations. The effect of their actions depends upon the political context of the moment. Finally, they do not have sufficient financial resources to make them major purchasers. The NGO campaign is run by a limited and flexible structure which has a lobbying role but which is not directly involved in managing NGO projects. In practice, NGO field managers have a far more pragmatic attitude, which can also tend to slow down NGO lobbying action.
Theoretical framework

Standard microeconomic theory allows us to analyse drug market(s) by using the theoretical results obtained via hypotheses on the way a pharmaceutical company works, the product(s) manufactured, or the nature of the production. In order to study the way in which a drug market works, and the possible types of regulation, we need to differentiate between several configurations or approaches in answer to the following questions:

What objective is the company maximising: profit from the sale of one product, or profit from a portfolio of several different products?

Where there are one or several separate markets, is it possible to have different prices? In other words, can there be price discrimination, be it in a situation of questionable monopoly or not?

Is a drug a final product or a component in the production of public welfare?

Portfolio maximisation strategy

Any company producing an original drug wants to maximise profitability, and the latter must cover Research and Development (R&D) costs over a limited period. This limited period is the duration of the patent, which gives the company a monopoly. The length of time during which the drug is marketed under a monopoly is shorter than the duration of the protection under patent, and given that research is taking longer and longer, the marketing period is reduced.

But pharmaceutical companies do not produce one single product; they produce several products with markets that are to some extent identical in as much as several diseases can often occur within the same territory. In such a case, the company’s strategy can be either to maximise profit for each individual drug, or to maximise profit for the entire drug portfolio as a whole. Another option is to maximise overall profit by taking into account any interactions between individual drugs. Like any business, pharmaceutical companies maximise their product portfolios (in this case, molecules). This hypothesis is even more realistic in as much as the costs of research are joint costs and laboratories try to finance new research with the profits made on molecules which have passed the break-even stage.
In such cases, the company can accept prices which are lower than the monopoly price as long as there is a positive correlation between the purchase of the drug in question and the purchase of other drugs which are already profitable. One supports the other. By offering several different pharmaceuticals, the company reduces some of these transaction costs, thus achieving economies of scale which can be shared between the manufacturer and the purchaser. Finally, this can create barriers to entry of newcomers to the local market, because the firm became a local leader and created prescription habits in favour of its own products.

This approach will lead companies to adopt strategies designed to preserve their monopolistic positions and to maintain the current status quo as firmly as possible (scenario 1). To achieve this, they will defend a single world market and absolute respect for patent rights.

One product, many different prices

To make the most of a new product during the limited time available, a company can either impose a single worldwide price, or decide to differentiate in accordance with demand, e.g. using third degree differentiation, because individual demand and reservation prices cannot be directly observed. Discrimination makes a product available to more people. In principle, collective well-being increases, due to the increase in satisfied demand. If prices are set in accordance with the opposite of elasticity (Ramsey’s principle), as Danzon [24] has pointed out this will allow the most to be made of sunk research costs. Ramsey’s price, linked to the opposite of elasticity, enables a company to cover the costs of monopoly under the constraint of a set profit. Some people therefore recommend pricing pharmaceuticals using Ramsey’s system in order to satisfy world demand. Ramsey’s price lies between the monopoly price and the marginal cost. In order for it to be applicable, and given both the high elasticity of developing countries and their low income, this would almost certainly involve financing via international aid. Price differentiation means that prices in developed countries will be both higher than those in developing countries and higher than the price they would have obtained if they were the sole purchasers.

Discrimination is only possible under certain conditions [25]. The first risk is that both markets – that of the developing countries and that of the developed countries – must be properly separated in order to prohibit parallel imports. This means that distribution must be controlled, and that the products must be differentiated (packaging, etc.). The second risk is that of “outside reference” where a purchaser uses the low price of a different market as its reference point for price regulation. Buyers in developed countries might therefore ask pharmaceutical companies to let them...
benefit from the prices in developing countries. Finally, two further conditions restrict the opportunities for price differentiation. The first is that the application of differentiated prices leads to higher prices in countries with higher payment capacities. This can be taken to be an implicit transfer which can be refused. The second is that in developing countries the price cannot be lower than the marginal cost of production. However, a given country’s capacity to pay for a drug may be lower than the marginal cost, in which case the solution has to include a subsidy, and is thus no longer a discriminatory monopoly regulated solely by the market.

A pharmaceutical company may therefore defend or enlarge its market through price differentiation as long as the products are differentiated and the markets separated; this will be examined in scenario 2.

Treatment of HIV infection and global public goods

A “public good” has two essential characteristics: there is no consumption rivalry, and the marginal cost is zero for any additional person, so each individual may enjoy the benefits of the said good (non-exclusion). These characteristics imply that it cannot be socially desirable to prevent a person from benefiting from the said good because the efficiency principle suggests that the price of the good is zero. Furthermore, non-rivalry implies that private manufacturers may not sell this good (though they may participate in its production), in as much as companies cannot make direct profits. The supply of public goods thus requires some form of public intervention. The concept of public goods was initially analysed within the framework of governments, and was used as a basis for numerous public policies, namely in the fields of information and health.

A global nature is applied to public goods under the following conditions [26]:
– the beneficiaries must reside in more than one “country group” (developing, developed, etc.);
– the benefits must reach a large part of the world’s population, both rich and poor, whatever the zone;
– “beneficiaries” may include future generations.

On the basis of this definition, no pure global public good exists, but there are goods which, to a greater or lesser extent, include a public aspect. As stated by Tubiana and Séverino [27], the assessment of a good having a public nature is a joint decision and leads to questions on its use and financing. Given that the utility of the good may vary from one zone to another, consensus is required on the utility of that good, a matter which is especially complex at an international level. Furthermore, there is the problem of identifying the beneficiaries and of the effective distribution of production to those who really need it the most.
As far as pharmaceuticals are concerned, we need to consider two public goods. The first is knowledge and information, the second is public health care. Scientific knowledge has long been considered to be a public good [28]. Drugs are thus produced by a public good (scientific knowledge) which is itself an input for healthcare production. Hence the question of public regulation is raised for patents, as patents lead to restrictions on the use of information and on access to drugs. The medical knowledge which enables production of anti-retroviral drugs is a global public good because it enables sufferers from several different zones to be treated. Yet this knowledge is partly financed by governments, through partnership between public research centres and private companies, or via subsidies. This implies that the patent rights belong in part to governments, which can choose between two strategies:

1) to let the patent rights to private companies for some royalties without restraint on pricing;

2) to act as full patent holder and to let the patent rights to the world community at lower prices.

Finally, both the prevention and treatment of HIV may be considered as not only national but also global public goods, due to the risks of infectious disease spreading, and due to the impact of the AIDS epidemic on individual economies [29]. Trade regulation is insufficient for such public goods, and price differentiation is ineffective; international intervention is required – what Tubiana and Séverino call special governance. This can take two forms, depending on the type of product. The first aims to favour research into specific drugs, which involves financing research funds, as was the case for the vaccination initiative. This type of global governance is different from that of market governance alone, in as much as it encourages research and the creation of specific types of distribution. The second covers pharmaceuticals available in developed countries. If we want drugs to reach those who most need them, with no exclusion, then international negotiation must indicate both the most appropriate treatments and the means of funding. We must determine what we wish to treat, and thus exclude (at least temporarily) any totally commercial regulations and all standard rules (this is the role of the TRIPS agreement), and then agree on how to divide the cost between the various parties present3. We examine such a policy in scenario 3.

3. The application of the concept of global public goods to HIV/AIDS drugs needs to be discussed. Note that the concept is used here not for all pharmaceuticals, but for pharmaceuticals which address a typically severe pandemic.
Scenario methods

There are several reasons why it would appear difficult to analyse corporate strategies and validate them using data collected from the various stakeholders. The first reason is that the definition of corporate strategy and the calculation of R&D costs are industrial secrets. Our interviews with companies and their pressure groups revealed this culture of secrecy. The prices which can be obtained remain incomplete, and one rarely has much information on the conditions of the contracts (duration, etc.) or of the volumes involved. Finally, the creation of models containing several stakeholders of different sizes is still in its infancy. In order to demonstrate the effect of institutions such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, one would need to be able to model stakeholders which are of different sizes and which are simultaneously involved in several different marketplaces.

This said, it is possible to highlight strategies which fall into the above-mentioned framework by developing scenarios that take into account the objectives and constraints of the different stakeholders within the anti-retroviral market(s). Scenario-based analysis has been developed through war-craft and corporate management techniques in order to determine strategies when faced with uncertain environments [30]. Several alternatives and a large number of possible combinations are grouped together within a limited number of coherent scenarios. A scenario is a way of bringing numerous events and complex interactions together as manageable information [31]. A scenario-based approach allows one to develop a dialogue within a heterogeneous group that speaks the same language [32].

The logic behind a scenario is to simulate situations which are extreme yet coherent, so that real choices can be revealed. This way of clarifying arguments does not necessarily lead to realistic forecasts. In reality, evolution will often occur in an intermediate manner which involves aspects from various scenarios. Scenarios serve to highlight probable configurations and configurations which are desirable for all. Comparison of these two configurations allows one to see what needs to be done in order to get from a probable configuration to one that is desired. Theoretical analysis enabled us to offer three possible scenarios based upon the three approaches to ARV drugs set out above. The three scenarios are summarized in Table 1.
# Table 1: Outline of the scenarios

<table>
<thead>
<tr>
<th>Main Features</th>
<th>Scenario 1 Status Quo</th>
<th>Scenario 2 Market Extension</th>
<th>Scenario 3 ARV’s drugs as a global public good</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main Features</strong></td>
<td>Multinational companies succeed in convincing northern hemisphere countries that both interests match for highest global Intellectual Property Rights guaranteed by International Organisations. Prices remain high.</td>
<td>The power of the different stakeholders is balanced, but the multinational companies take the lead in organising the market. Prices are differentiated and generic manufacturers increase their market share.</td>
<td>Driving force: an international commitment to broad access to ARV drugs in developing countries. International organisations take the lead, and manufacturers adapt their strategy to statutory regulations.</td>
</tr>
<tr>
<td><strong>Stakeholders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Multinational Companies</strong></td>
<td>They will defend a single world market and absolute respect of patent rights. They are the leaders.</td>
<td>They develop their ARV sales through differentiation and diversification. They have an aggressive portfolio strategy.</td>
<td>Most of them withdraw from the market place.</td>
</tr>
<tr>
<td><strong>Generic manufacturers</strong></td>
<td>Only Brazil, India and China apply for Compulsory Licences and do not sell outside their countries.</td>
<td>Also have an aggressive strategy: ARVs are doorways to new markets.</td>
<td>Use new financing and new regulations to develop production dramatically.</td>
</tr>
<tr>
<td><strong>Northern Hemisphere Governments</strong></td>
<td>They defend their firms and distance themselves from the AIDS treatments issue.</td>
<td>Allow southern markets to open to generic drugs.</td>
<td>Support new financing and regulation by grants and donations.</td>
</tr>
<tr>
<td><strong>Sustainable Hemispheres Governments</strong></td>
<td>No initiative.</td>
<td>Use competition to reduce prices.</td>
<td>Abandon individual negotiations and accept joint solutions.</td>
</tr>
<tr>
<td><strong>International Organisations</strong></td>
<td>Reduced influence and a restrictive use of TRIPS room for manoeuvre.</td>
<td>Regulate the opening by allowing Compulsory Licensing and limited reference pricing in the Northern Hemisphere.</td>
<td>OI are the leaders. They achieve political consensus, and implement funds to buy drugs, to encourage research and to open southern hemisphere markets to generics industry.</td>
</tr>
<tr>
<td><strong>NGOs</strong></td>
<td>Have a delegation to treat AIDS/HIV patients only on a humanitarian basis.</td>
<td>Condemn multi-speed health care and have a reduced number of projects.</td>
<td>Help the funds and organize the treatment of patients.</td>
</tr>
<tr>
<td><strong>Sustainability</strong></td>
<td>Sustainable as long as the situation is under control and the epidemic growth only in Africa. All stakeholders are losers.</td>
<td>Very risky scenario, because it increases demand and inequalities which can spread to other pharmaceuticals.</td>
<td>Idealistic scenario which presumes political consensus, that could be achieved only if countries understand the dramatic consequences of AIDS.</td>
</tr>
</tbody>
</table>
Scenario 1: Maintaining the status quo

Multinational companies have succeeded in convincing northern hemisphere countries that both interest match for a highest global Intellectual Property Protection guaranteed by International Organisations.

The conditions for this scenario

In this scenario the monopolistic position of multinational companies is sustainable as long as patents bestow monopolistic power with poor possibilities for generic drugs. The room for manoeuvre created under the TRIPS agreement is hardly ever used. The fact that the patents come into play at the end of the product’s lifetime does not really make any difference, because resistance to the virus is developing and only the major companies are able to offer a continuous supply of new products to replace the old ones. Their monopoly grows.

The roles of the different stakeholders

Developed countries support stronger rights for patent holders to the detriment of access to ARV drugs. They fully support the most restrictive interpretation of the TRIPS agreement, by refusing any broader interpretation of the room for manoeuvre, by prohibiting third-parties from using them to even a small extent, and even by strengthening intellectual property rights under the agreement (in accordance with what is referred to as TRIPS – PLUS). Developed countries remove themselves from the problem of AIDS treatment on an international scale by concentrating exclusively on prevention and by delegating the treatment of sufferers to NGOs.

The international political influence of developing countries is reduced. The majority of developing countries have no influence on market organisation; they have neither the means nor the capacity. They are afraid of developed countries taking them before the WTO. The matter of treating HIV/AIDS sufferers becomes almost entirely a national responsibility: with the exception of sub-Saharan Africa, rates of infection are relatively low, and countries manage to control the epidemic with preventive measures. Sub-Saharan Africa is left to its own devices.

For multinational companies, the significant ARV market is the northern hemisphere: they act mainly to protect profits in this market and do not try to develop sales in southern hemisphere markets. For other treatment categories they can implement other strategies. They protect themselves against ARV parallel imports via a single global price policy (thus rendering such imports of no interest), or by restricting the quantity of drugs sold at differentiated prices,
and by very carefully controlling the destination of all products sold in this manner. The contractual conditions currently covering such sales are already of this nature, and are hence strengthened. The companies sign specific contracts with countries, restricting access to their products and binding them over the long term. Donations are simply used to get a market going.

Extremely strict limitations are made to any possibility of producing generic drugs, through the most restrictive interpretation of the ADPIC agreement and using all of the available legal arsenal. This means that only countries capable of producing the active substances themselves (only India, China and Brazil at the present time) would be able to apply for compulsory licences. In this scenario, generic manufacturers cannot sell outside their country of origin, and, even in such a case, their market access can be very greatly restricted by legislation.

The sustainability of this scenario

For every stakeholder, this scenario is easy to follow as nothing changes: no political will is needed nor is organisational innovation.

The sale by major companies of ARV drugs outside developed countries is highly restricted, with such sales contributing very little towards company profits. The prices are rarely discriminatory as there is little competition from generic drugs. The profits are partly reinvested in research on drugs for other diseases, the AIDS epidemic being contained at a low level in the northern hemisphere. Drug donations are of limited quantity and are distributed under restrictive conditions by NGOs which are subsidiaries of the pharmaceutical companies.

For various reasons, developing countries lack the political wherewithal to make themselves heard: they are divided by bilateral agreements made with northern hemisphere companies, and generic manufacturing countries are not interested in third-party countries, preferring to concentrate on their own markets – and their own needs. Furthermore, the deterioration of healthcare systems no longer allows proper administration of treatments, and is used by pharmaceutical companies as an excuse for limiting sales at reduced prices.

NGOs fall out over which strategy to adopt, and their popularity with the public is low: their cause is no longer taken up by the media, who are fascinated by the profits being made by the pharmaceutical industry and by the new drugs for typical health problems in the northern hemisphere: obesity, Alzheimer’s, etc. Public opinion is only interested in southern hemisphere health when it is a question of neglected diseases such as trypanosomiasis. In developing countries, NGOs are no more than service providers – drug distribution for example.
International organisations (WHO, WTO, UNAIDS) are immobilised by pressure from developed countries and by divisions between developing countries, and thus concentrate on technical matters. The Global Fund is unable to increase the level of available funds. It can only finance a limited number of projects and concentrates on countries which are closest to controlling the epidemic: the most developed, those with the lowest rates of infection, those with the best healthcare system... indeed, wherever the funds can be most effectively employed. Other countries receive only the crumbs. The scenario is sustainable as long as the situation does not spiral out of control.

Scenario 2: ARV drugs market extension

In this scenario, the power of the different stakeholders is balanced, but the multinational companies take the lead in organising the market.

The conditions for this scenario

ARV drugs are simply a part of a pharmaceutical company’s portfolio, with the company developing strategies for its drug portfolio as a whole. ARV drugs are therefore only important when new products are introduced and a share of the demand is made solvent. The increasing inequality within and between developing countries means that private services – with customers who are aware of the latest treatment techniques – can be developed. The arrival of resistant strains, the serious side effects of ARV drugs, and an increasingly varied and sophisticated demand forces companies into aggressive strategies whereby they must constantly reorganise production in order to cope with competitors. The ARV market can become the motor for the development of other markets (not only opportunistic diseases, but also new types of viral infection). At the same time, the scope of the AIDS epidemic, especially in new countries (China, Asia, Middle East, etc.) creates new markets and makes debate on access increasingly unavoidable.

The roles of the different stakeholders

For multinational companies, ARV markets are developed through price differentiation and product diversification (different formulation or packaging, etc.) and differentiation (through incremental innovation from less effective-cheaper molecules or combinations to more effective/more expensive molecules, price being by far the most important factor). In this way, companies can build a larger product portfolio including a range of ARV drugs from the bottom to the top of the market. Price differentiation and product diversification allow
multinational companies to market drugs according to market segmentation between countries and in some countries between people: the cheapest drugs for the poorest and the more expensive for the affluent. This compartmentalisation is presented as a concession to the poorest countries, allowing companies to make the most of launching new products whilst at the same time maintaining their former positions. Such differentiation enables a market to expand to another clientele, which may be either the privileged members of a poor society or persons treated under new international aid programmes; it also helps remove the threat of any generic drugs which are unable to be significantly less expensive and which depreciate in comparison to branded products. Countries with intermediate revenues (Asia in particular) can become major new marketplaces. These companies try to maintain the specific nature of ARV drugs, in order to avoid the scope of more flexible international regulations being extended to cover the entire range of pharmaceuticals.

Generic manufacturers have an aggressive pricing strategy, because ARV drugs are doorways into new marketplaces. Whilst such companies may benefit, exceptionally, from waivers to patent rights, in the long term these exceptions are not a viable solution: generic manufacturers can sell older ARV drugs whose patents have moved into the public domain, or else make alliances with the northern hemisphere industry, as is the case in South Africa. As they develop, their strategy becomes increasingly similar to that of multinational companies, with certain generic manufacturers becoming powerful enough to also want to have their own branded products and protected patents.

Northern hemisphere countries back international organisations to allow southern hemisphere countries to open up their markets to generic drugs to a certain extent. They guarantee market segmentation by preventing re-importation and refraining from reference pricing based on southern hemisphere prices for their domestic market.

Southern hemisphere governments are trying to use this competition to obtain the lowest possible prices. To achieve this, they opt for individual negotiations with manufacturers, whilst at the same time using the threat of generic drugs or compulsory licensing. A few of the poorest countries can nevertheless have access to ARV drugs through donations or by participating in new drug trials. The product cycle thus starts fairly rapidly and at a lower cost in developing countries, albeit in small quantities, and then, once the research has been amortised, continues over a relatively short period, at a high cost, but in larger quantities in developed countries. Developing countries feel that the sacrifices they make in order to become part of world trade are negligible.
Both northern and southern NGOs condemn such multi-speed healthcare, but are obliged to adopt the same attitude, with a multitude of small projects and several sources of supply.

The sustainability of this scenario

This scenario is quick to reveal its contradictions: the profit-making private sector is ineffective in its treatment of costly diseases, the total cost of treatment is very high (even for the wealthy), increased demand and inequalities, risk of not being able to maintain market segmentation, etc. One factor is therefore knowing if specific regulations for ARV patents are going to be introduced, or whether there is to be no differentiation with other pharmaceuticals.

Scenario 3: ARV drugs as a global public good

The driving force in an international commitment for a large access to ARV drugs in developing countries. International organisations take the lead, and manufacturers adapt their strategy to international regulations.

The conditions for this scenario

ARV drugs are considered as a major component of a global public good-health. Their very characteristics, along with the political question of treating AIDS, gradually lead to special regulations. The international community takes the economic and social consequences of the epidemic on board (not only in Africa, but in all developing or emerging countries). Northern hemisphere countries thus directly or indirectly contribute towards the supply of anti-retroviral drugs, and also to the development of structures for treatment.

This process might be likened to that for vaccinations or products for treating tuberculosis. In 1994 UNICEF obtained an important agreement on vaccination supply which allowed a significant drop in prices. The Vaccination Independence Initiative has led to the release of public funds for financing and has enabled regional parity in West Africa.

The roles of the different stakeholders

International organisations have a major role in such a scenario. UN institutions in particular must work to achieve the political consensus which is required. As the concept of global public good can be implemented in different ways, different international organisations can take the lead. The first way (A) follows the line taken by the Global Fund: subsidizing ARV procurement by southern
hemisphere countries. With the second way (B), the Global Fund might become the main purchasing organisation to create pressure for lower drug prices and to encourage long-term research contracts in favour of pharmaceuticals to meet developing countries health needs. Its status would have to be defined to reconcile divergent interests and to ensure proper resource management. There would obviously be implications with regard to the way in which other international organisations were run. The third way (C) would be to open completely the southern hemisphere markets to ARV generic drugs. Developing countries would abandon Intellectual Property Rights. A new legal framework would be provided by WTO, restricting the scope of application to ARVs, in order to avoid it being extended to include other healthcare products.

In this scenario the majority of multinational companies withdraw from the marketplace. A small number nevertheless remain, adapting to make the most of not only having a single buyer and guaranteed long-term bulk purchases, but also of being able to split investment costs.

In the short term, AIDS drugs are produced by both multinational companies and generic manufacturers, and hence do not suit the strategy of the multinational companies which retain their specificities and their niches. The generic manufacturers use new financing and new regulations to develop production dramatically. This expansion, powered by public financing and free access to patents, must also lead to the production of new products, without which it will be difficult for the generic manufacturers to improve their reputation. Strong political support for generic drugs is therefore required.

In this scenario, southern hemisphere governments abandon individual negotiations and accept joint solutions. With solution A or B, they trade reduced autonomy for major financial advantages and for easier access to ARV drugs. On the other hand, in such a vital domain they might be wary of becoming too dependent upon the Global Fund, and may also be unhappy with international organisations and NGOs coming so much to the forefront. So, some could prefer open market solution (C) which also supposes that these developing countries undertake, in the long term, to finance a share of the treatments. Such financing might come from funds received under debt-reduction programmes.

It is highly likely that the NGOs will manage to increase their role within the Fund. They will use their projects to position themselves as one of the main potential beneficiaries for organising the treatment of patients. They will be able to use this experience to increase their role in healthcare systems within developing countries and to contribute towards the reform of healthcare funding. Such a situation raises important questions regarding the reliability, solidity
and legitimacy of NGOs. Yet the treatment of AIDS could become a shining example of healthcare management and even play a precursory role for a new type of international regulation.

The sustainability of this scenario

Many aspects of this scenario might seem idealistic. It supposes that political consensus can be achieved and that international organisations can play an important role in leadership. It also requires a certain structure for civil society which will nevertheless allow it to retain its dynamics. Management of an enlarged fund must not get bogged down in bureaucracy.

Finally, the exceptional situation of ARV drugs is likely to be increasingly difficult to justify. On the one hand there will be a strong temptation to extend this regulation to all healthcare products, with the subsequent risk of raising major economic questions. On the other hand, separation from the marketplace of rich countries cannot be watertight, especially with regard to the most wealthy people in the southern hemisphere countries who will demand the same healthcare as that available in the northern hemisphere. It will therefore be hard to avoid creating a “multi-level” system of treatment. There is the risk of an international black market being born, especially if the overly bureaucratic system is unable to meet demand.

If this system is not to discourage research, major public funding will be required in this area. The challenge is not just that of finding sufficient funds, but also of using them efficiently; to date, neither the world community nor companies have been able to do this.

Conclusion

Whilst we have attempted to demonstrate the positions of the different stakeholders, one might wonder whether they each have a real strategy with regard to the price of ARV drugs (e.g. objectives, and a decision to employ suitable resources). We have looked (essentially a posteriori) for the logic behind the sometimes erratic changes in reaction, and it is difficult to discern the medium and long-term strategies that lie behind what is said. It is not easy to develop such policies within an extremely uncertain context, where there are so many factors and where – despite what the media sometimes suggest – the ARV market is not always the real problem.

One might wonder whether, underneath the so-called victories or compromises voiced by the various stakeholders, lower prices do not in fact have negative
results for most stakeholders: it is estimated that in developing and East European countries only 5% of needs are covered (1% in sub-Saharan Africa) [33]. Certain increases (victoriously acclaimed) in the number of people treated are in fact based upon ridiculously small initial numbers and only affect small areas of the countries concerned [34]. Whilst major laboratories have had to agree to lower prices, as with generic manufacturers, such drops only relate to tiny quantities, and once again reveal the huge profits that the companies are making; this again calls the legitimacy of their pricing strategies into question. The UN’s efforts to create the Global Fund has not yet significantly changed the amount of money available in developing countries for the purchase of ARV drugs. The problem of the exorbitant costs of the drugs and the difficulties of treatment has become a stalling tactic for the main stakeholders. It is true that the healthcare systems in many countries are incapable of providing treatment, due to technical weaknesses, lack of financial resources and poor doctor-patient relationships in most hospitals and clinics. But it is also true that even with additional funding, prices have not fallen enough to make these drugs truly accessible to the majority of sufferers in developing countries.

The market will probably not evolve in line with any of the above scenarios, but rather in accordance with a mixture of one dominant scenario and aspects of the others. It is also possible that given the extent of uncertainty, a different solution will be born from those offered. In some ways, the case of ARV prices is proof of the problems caused by the emergence of a new method of world governance. Europe, and France in particular, is starting to change its position (or at least its arguments) in favour of a method of regulation that is specific to healthcare. One should note the increasing role of NGOs as go-betweens not just between governments and international organisations, but also between companies in both hemispheres. This evolution nevertheless remains limited. Whilst we may have felt Doha to be an NGO victory, post-Doha negotiations have pretty much been a failure for such organisations. Poor countries have achieved only minor concessions, and their right to freely use the inventions of wealthy countries has been almost totally denied. This has obviously refused them any major access to such technologies, despite the fact that many researchers from (and trained in) southern hemisphere countries are participating in the advance of science and technology in northern hemisphere countries.
REFERENCES


SECOND PART

Impacts of AIDS and Expansion of Effective Therapeutic Strategies