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REPORT AND PROPOSAL INTERNATIONAL EN

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WORLDWIDE ACCESS TO TREATMENTS RELATED TO HIV/AIDS

SUMMARY

In response to the recommendations of the International Committee.

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INTRODUCTION

The task of the French National Aids Council, the CNS, an independent advisory body created in February 8, 1989 by decree of the President of the Republic, is to "give its opinion on the whole range of problems which AIDS poses for society, and to recommend courses of action to the Government". However, over the years it has become increasingly apparent that for it to fulfil its role in France, it must take into consideration the international dimension of the HIV/AIDS pandemic.

Firstly, the CNS has always sought to guarantee **absolute equality of access to screening and care for those infected by HIV in France** – whether rich or poor, men or women, adolescents or adults, of French or foreign nationality, free or imprisoned, and whether contaminated through sexual activity, blood transfusion or intravenous drugs. However, there can be no greater denial of the **fundamental moral imperative of equality** than what has been observed worldwide in the development of access to screening and, worse still, treatment itself.

The success of multi-therapies has widened the gap still further since 1996, a gap which, it should be borne in mind, has existed since the pandemic began. Most developed countries provide equalaccess to the treatments now available. However, only a tiny minority of patients in developing, less advanced or emerging countries have access to the therapeutic advances which have been developed since 1996. The HIV/AIDS mortality rate is continuing to rise in these countries, causing political, social and economic damage that is extremely worrying for the future of whole regions.

Secondly, no developed country – France included – can hope in the long run to control the effects of the HIV/AIDS pandemic alone. It is inconceivable for a developed country to isolate itself from the human, economic and political consequences of a pandemic currently raging in the rest of the planet. **In a globalised world, there can be only one pandemic!**

However, although there are examples outside the developed world of situations or countries where the prevailing HIV rate has decreased due to firm and targeted preventive policy, the lackof available treatment in very many countries has contributed to the general failure of such policy. In so far as there is no practical possibility of healthcare or ongoing therapy for the majority of sufferers, and therefore no incentive to seek to be screened, awareness of one's serological status can only be a source of despair and all too often a reason for discrimination and social exclusion. Therefore, the processes of empowerment founded on prevention, processes which have curbed the pandemic in the developed world, are ineffective.

After a report on Africa (*Vers une nouvelle solidarité. Pour un accès aux traitements antirétroviraux des personnes vivant avec le VIH en Afrique subsaharienne;* décembre 1998) (*Towards a new solidarity. Access to antiretroviral treatments for people living with HIV in Sub-Saharan Africa*; December 1998), the CNS set up its own International Committee in April 1999. Its task is to study the problemfurther against the background of unanimous international acknowledgment of the inequalities – which are intolerable from all points of view – in the healthcare provided to sufferers in different countries, awareness of the basic link to be made between prevention and the prospect of treatment if the spread of the epidemic is to be controlled, and also awareness of the economic issues involved – whether in terms of the appropriate legal intellectual property framework where medicinal drugs are concerned, or the role assigned to healthcare in development policy.

The report which follows is the outcome of an analysis of the issues by the members ofthe CNS International Committee, with input from discussions with representatives ofinternational bodies (WHO, UNAIDS, WTO, European Union) and evidence from representatives of non-governmental organizations (ITSF, MSF), the pharmaceutical industry (SNIP), and associations of individuals living with

HIV/AIDS (Act-Up Paris). A preliminary draft was published as a poster in the name of the International Committee at the XIII International AIDS Conference held in Durban (South Africa), in July 2000.

I THE GOAL OF ACCESS TO TREATMENT : LIMITS AND INADEQUACIES OF THE PROCESS FOR PLACING THIS ISSUE ON THE INTERNATIONAL AGENDA

1.1 PLACING THE ISSUE OF ACCESS TO HIV/AIDS TREATMENTS ON THE AGENDA

Since the autumn of 1999, the CNS has closely followed the changing positions of certain players in the global drug market – pharmaceutical firms, international organizations, national governments – on the issue of access to antiretroviral treatments. In making this goal a major international issue, such changes, which can be largely put down to unremitting pressure from a small number of non-governmental organizations and associations representing sufferers, has opened the door to a significant fall in the price of these treatments and to their more widespread availability in the countries hit hardest by the pandemic.

The main stages in the process of placing this issue on the international agenda during the first half of the year 2000 were: the meeting of the United Nations Security Council, which was entirely devoted to the HIV/AIDS pandemic (January 2000) ; the World Bank's undertaking, made in a statement by its President, to release "unlimited funds" to fight the epidemic (April 2000) ; the declarations of the Clinton Administration on the United States' strict compliance with certain clauses in international agreements on patent rights (May 2000) ; the promise made by five pharmaceutical majors, on the eve of the fifty-fifth World Health Assembly (May 2000), to make very significant cuts in the prices of their antiretroviral treatments (or treatments against certain opportunistic infections) for under-developed countries ; and the provision of details by some of the companies, in the run-up to, and during the 13th International AIDS Conference in Durban (July 2000), on the form (drug types, possible uses, size of price cut, countries concerned, etc.) that this reduction (amounting to an outright gift in some cases). Finally, all observers agree that this problem was the major issue at the International Conference in Durban.

1.2 THE LIMITATIONS OF THE AGENDA PROCESS

Nevertheless, several aspects of the process are still unsatisfactory :

- **The chosen procedures** are not totally **transparent**: they operate through a diplomatic or para-diplomatic framework, in which a combination of considerations, or even material interests - geopolitical, institutional, economic and health - are involved, with the concomitant risk of losing sight of the common goal.

- **They are dispersed and segmented** by company, drug, medical condition, country, etc. which is prejudicial to **coherence** and therefore the effectiveness of the support intended for the countries involved.

- **They are not based on any ongoing plan** capable of restructuring the world pharmaceutical market for greater effectiveness and equity in the battle against the HIV/AIDS epidemic, and more generally, in the war against the diseases that hit hardest, or even solely, developing, less advanced or emerging economies.

- They sidestep rather than address the real problems relating to intellectual property, especially the role to be assigned, or not, to generic drugs. Thus, in this framework, it hardly seems possible to tackle head on the difficulties arising from the implementation of the 1994 Agreement on the trade-related aspects of intellectual property rights (TRIPS)[1], in the area of health-related products (whether these relate to HIV/AIDS or any other disease).

- They create the **risk of failure to ensure the availability of treatment** in many countries,insofar as health systems would need to be restructured at the same time as it is proposed tomake access to treatment affordable. Public health policies – where they exist – are notredefined in this context to combat at one and the same time the HIV/AIDS epidemic and all the other health, sanitary and environmental problems causing the high mortality in these countries; similarly, the basic education issues are ignored in the agenda process.

- **They do not directly address the question of resistance developed by the infective agent of HIV/AIDS when using the available pharmacopoeia**. The experience of the developed world has shown that such resistance develops with an incidence and rapidity proportional to the inadequacy of medical and social welfare follow-up. Knowledge of this gathered over the last ten years, and especially since 1996, is likely to be useful to sufferers in developing, less advanced or emerging countries. The training of doctors and nurses, and circulating information to all concerned, must not be overlooked in this context.

If the planned measures are to be effective, the CNS considers that **two objectives** must be pursued simultaneously :

- Firstly, **reasoned and sustained interfacing of all the interests of those involved must be ensured ;**

[1] This multilateral agreement was signed in Marrakech at the end of the Uruguay Round trade negotiations, and is one of the agreements in the World Trade Organization system (WTO) created as a replacement for GATT.

- Secondly, an effort must be made to reconcile **internal** (specific to each country), and **external** (international) **aspects** in fighting the epidemic, by offering **treatment** (antiretrovirals or treatments for opportunistic infections) **suitable for each public health context**..

It is the view of the CNS that the creation of a permanent international body specifically dedicated to the issue of broadly-based access to treatments, is capable of ensuring that these objectives are achieved.

II OBSTACLES TO ENSURING WORLDWIDE ACCESS TO TREATMENT

Two types of obstacles must be removed if populations in developing, less advanced and emerging countries are to enjoy access to drugs guaranteeing their fundamental right to health and life :

- **the inability of the public and private health systems in** developing, less advanced and emerging countries to cope with the challenges of old and new infections ;

- **the lack of segmentation of the drug market** by pharmaceutical firms holding patents for new drugs or production processes.

2.1 THE INABILITY OF THE PUBLIC AND PRIVATE HEALTH SYSTEMS IN DEVELOPING COUNTRIES TO COPE WITH THE CHALLENGES OF OLD AND NEW INFECTIONS.

The rapid spread of the HIV epidemic did no more than highlight the inadequacy of the health systems in these countries, as pointed out in the previous CNS report, *Towards a new solidarity,* which dealt with Sub-Saharan Africa. This inadequacy not only concerns Africa, but is also apparent to varying degrees in most countries outside the developed world. Moreover, it isone of the basic arguments used to justify the absence of any concrete effort to make the treatments provided in developed countries available to sufferers in these countries.

The following points are raised in particular :

- The excessive cost of these new treatments in the light of the need to make efforts in other crucial areas of public health.

There is a risk of distortion due to the relatively small number of patients involved and the concentration of financial resources on purchasing these treatments, to the detriment of improvements in the health of the population as a whole. This argument obviously loses force insofar as, firstly, AIDS is increasingly among the main causes of death (even the single most important cause in a growing number of countries), making it the central public health issue and, secondly, the dynamic of the HIV epidemic is extremely strong in a number of countries, and that number is also growing.

- The inability of the health systems to make new medicines available under therapeutically satisfactory conditions.

It is alleged most notably that where HIV infection is concerned, recent antiretrovirals and antibiotics, especially if they are not used correctly, can cause resistant strains to appear while nevertheless failing to make any sustained improvement in the condition of sufferers. Notably, the use of antiretrovirals is said to be "unsustainable" over the long periods inevitably required by the treatment of HIV.

- A cultural gap in patients' willingness to observe prescribed courses of treatment between developed countries and developing countries, especially in Africa.

There is said to be a 'cultural bias' which makes people suffering or living under threat from AIDS incapable of following treatment programmes effectively, even if these are available at a reasonable cost. This argument supports the preceding one by spuriously backing it up on the basis of a cultural prejudice as to the ability to take responsibility for one's own health.

- An extremely profound and constant stigmatisation of individuals suffering from the condition and "groups at risk" (or groups perceived to be at risk).

Such stigmatisation relates in most cases to the status of sexuality in the countries involved, and discrimination against specific groups in each society (prostitutes, ndividuals with homosexual contacts, migrants, seasonal workers, intravenous drug users, ethnic minorities, etc.).

- **The specific status of women in each country**.

The degree of control which women have over their sexual relationships and their protection – insofar as the use of condoms is acceptable in financial and social terms – is crucial to the social and political control of the HIV epidemic.

- **A lack of political will on the part of national governments to tackle the issue of the HIV/AIDS epidemic head on** : The authorities in many countries are still reluctant to acknowledge that the epidemic is present on their territory, or they restrict recognition of its existence to a few socially stigmatised groups. It is far from being the case that all states have mobilised to combat the epidemic, even in those parts of the world that are hardest hit, or on the way to being so. Generally speaking, public health is far from being a priority everywhere in the world.

Taking these issues into account, the prevailing opinion in fighting the HIV pandemic is that the following is necessary :

1) **Concentration of financial resources on prevention** in all the meanings of that term (social, economic, environmental), emphasizing the importance of the use of condoms as a preventive measure for sexual behaviour placing the individual at risk.

2) **Implementation of actions to remove the stigma attaching both to so-called groups at risk and individuals living with HIV** ; elimination of discrimination highlighted by development of the epidemic; use of social and political language appropriate to the promotion of prevention in discussing sexuality.

3) **Changes to the status of women**, and especially women's control over their own sexuality.

4) **Utilisation of the pharmacopoeia for prevention only when the cost/benefit ratio for public health is established and sustainable over the long term** : where antiretrovirals are concerned, only drug-based prevention of vertical transmission (mother to child transmission) is considered feasible on the large scale, especially given the appearance of treatments effective in single doses ; the use of antibiotics, particularly against sexually transmitted diseases or to prevent certain opportunistic diseases, may also be envisaged due to their lower cost and administration over short periods.

5) **Concentration and intensification of research efforts to develop new vaccines which** are curative and/or preventive and adapted to the various HIV types.

6) **Efforts to obtain the active agreement of all concerned governments to the above policies** which, in most cases, can have no profound or lasting impact without their involvement.

The above practical objectives are legitimate and not mutually exclusive. But are they enough ?

In addition, numerous actions, privately or publicly initiated and often in partnership, are being conducted in developing, less advanced or emerging countries. They aim to demonstrate that **access to antiretroviral treatment is both feasible and sustainable everywhere**, as long as certain prerequisites are present (therapeutic, economic, social, organizational, etc.). The International Therapeutic Solidarity Fund (ITSF), launched at the initiative of France at the 1998 Congress in Abidjan, reflects just such an ambition. UNAIDS, which is itself leading certain programs, is currently compiling a list of the various actions in progress. Nevertheless, no demonstration of the feasibility of access to antiretrovirals, despite its desirability, with the gathering of information on general experience that such a demonstration would involve, should lead to what would be a *de facto* moratorium on the generalisation of such access.

2.2 THE LACK OF SEGMENTATION OF THE MEDICINE MARKET BY PHARMACEUTICAL COMPANIES HOLDING PATENTS ON NEW DRUGS OR PRODUCTION PROCESSES.

To date, **pharmaceutical companies in developed countries have not had a commercial policy of market segmentation** : they do not try to sell by systematically using differential pricing to reflect the level of economic development of individual countries, so much so that it is not unusual to encounter cases in which prices paid by the final consumer for new drugs are higher in the "South" than in developed countries, because the costs entailed in distributing in the "South" are added to the price applied in the "North". However, companies sometimes give buyers (public-sector or charitable bodies) discounts on the prices for drugs – where they exist. Certain firms even seem to prefer to make selected outright gifts rather than sell at prices appropriate to the financial capacity of the end consumers of their products.

Additionally, pharmaceutical companies seem to be encouraging governments in developed countries to **apply bilateral trade pressures**, or to **bring proceedings before the World Trade Organization (WTO)**, in order to prevent countries with appropriate industrial capacities making available to their populations "generic" versions of drugs for which these companies hold patents. They insist that the 1994 TRIPS Agreement should be interpreted as strictly as possible in new legislation in the countries

of the South. In particular, they challenge the inclusion in national legislation of legal standards authorising "compulsory licensing" and "parallel imports", despite the fact that such measures are provided for in the TRIPS Agreement.

If such standards are already in force, they do not hesitate to challenge their implementation.

"Parallel imports" are among the exceptions to the exclusive rights enjoyed by patent holders : they involve importing products from other countries where they are patented. However, such exceptions should not only be "limited" and "justified", but in addition they should not "unreasonably prejudice the legitimate interests of the patent owner" (article 30). A balance must therefore be found between the patent-holder's interest and the interest of the country involved.

"Compulsory licensing" refers to licensing by court or official order, which is subject to formal conditions (article 31), but which can be used if necessary "to protect public health and nutrition" (article 8)[2]

Thailand, South Africa and India most notably have been attracting the attention of international public opinion to this problem in recent months. A recent MSF-WHO-UNAIDS survey emphasized that the 1999 review aimed at making the Bangui Agreements on patent right issues in the fifteen countries of the African Organization for Intellectual Property (AOIP)[3] consistent with the TRIPS agreements, makes no contribution to improving access for sufferers to the available pharmacopoeia[4].

Three reasons seem to explain the pharmaceutical industry's attitude.

1 The first is the fear of parallel imports from the South to the North in the context of market segmentation.

Pharmaceutical firms fear that, if they sell their new treatments directly or if they have them

produced under license in the Southern countries which are able to do so, at affordable prices for the end consumers in these countries (individuals, public or private health cover), they will be reimported or exported to the markets offering the best returns, to the sole benefit of intermediaries.

This fear appears to them to be confirmed by the following :

- "Trafficking" of this kind already exists.

- Manufacture of these drugs will be governed by the same safety standards as those applied in the aforementioned more profitable markets – differences in "packaging" and marketing aside, their therapeutic effects are identical.

- Some developed countries, including the United States, the companies' main market, are subject to a system of competitive pricing of treatments. The private managers of these countries' health systems would have everything to gain by using such reimports or exports to reduce their costs.

- The single European market provides an example, in that it authorises parallel imports in situations where differences in the financial capacities of the various public and private health systems are even greater, as well as differences in the political choices made by the various states, leading gradually to a situation in which it is impossible to differentiate pricing of drugs by national market, and this leads, from the point of view of pharmaceutical companies, to a loss of revenue, and is therefore prejudicial to their research efforts on new drugs.

2 The second is the fear of revealing their production costs in dealing with a competitive drug market or a public regulator through the cuts in their prices in countries of the South or emerging economies.

The production cost of a new medicine is basically made up of the initial fixed cost of Research and Development[5] - although, in many cases, including antiretrovirals, this cost is may be financed from the public purse – and the production cost, which varies according to quantities manufactured, and is often very low. Given the current differences in development throughout the world, the market segmentation of the prices for their treatments would inevitably result in the firms revealing their variable costs (assuming that they would sell nowhere at a loss). Their profitability, which is often reliant, even in the case of the leading companies in the

[2] See German Velasquez, Pascale Boulet, *Mondialisation et accès aux médicaments. Perspectives sur l'accord ADPIC de l'OMC,* Série " Economie de la Santé et Médicaments ", no. 7, Revised edition, WHO action programme on essential drugs, second edition., 1999.

[3] The member countries of the AOIP are Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Ivory Coast, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, and Togo. To date, only Cameroon, Gabon, and Senegal have ratified the Bangui Agreement of 1999.

[4] Pascale Boulet (MSF), Gilles-Bernard Forte (OMS/EDM), *Review of the pharmaceutical policy in Cameroon – Medicine patents in French-speaking Africa*, MSF-WHO-UNAIDS Cameroon joint mission, February 6-10 2000, MSF-WHO-UNAIDS, May 2000.

[5] The figure often put forward by the pharmaceutical industry in estimating its costs per new drug is USD 500 million, although there is no independent confirmation of this valuation.

market, on a small number of licensed drugs, would be severely prejudiced. This fear seems to be even more justified given that the cost of medicinal drugs is a matter of public debate in the United States, and that the managements of social security departments in Europe are continually searching for ways to curb budget overshoot in this area.

3 The third is the fear that strong competitive industries may eventually develop in the countries of the "South".

In their strategies for controlling the world drug market, the North's pharmaceutical firms carefully monitor the development of powerful competitors in the South and in the emerging economies, in terms of present industrial capacity and future research & development. India is often cited as a country where an independent pharmaceutical industry sprang up in the absence of any real protection for inventors' intellectual property rights. With this in mind, the manufacture of "generics" (whether authorised or not) of their most innovative products by firms in "copying" countries appears unacceptable to the dominant corporations, attempting as they are to streamline their own production through a process of concentration. This competitiveness, which is a source of positive effects on product price and access for sufferers in the South and developing countries, could eventually jeopardise the industries in the North.

III THE NEED FOR SWIFT ACTION

There are five major dangers, most of which are already present, if the international community does not coordinate its action to remove these obstacles :

1 Rapidly rising HIV-related mortality rates in many developing countries, especially in Africa, but also in Asia.

AIDS is now the fourth most important cause of death in the world, and second most important in Africa.

2 A widening gap between the outcomes in the North to the South for those affected by the epidemic.

This gap represents a new challenge to ethics, to the principle of the right to health as a fundamental human right and to the belief that scientific and medical progress is part of humanity's common heritage.

3 A general failure of prevention in the South, capable of spreading rapidly to certain of the emerging economies.

Such a general failure is due in large measure to the fact that the individuals concerned have no personal incentive for knowing their HIV serological status as there is no treatment available for them. The emphasis which national and international public policies, when they exist, give to prevention alone (usually perceived as different forms of communication aimed at modifying "high-risk" sexual behaviour) will be partially ineffective whilst there is no reasonable hope of follow-up treatment for those infected.

4 A mortality rate which undermines development.

The demographic profile of the victims of the HIV epidemic, direct (young people of working age) or indirect (the millions of orphans it creates), means that it has now become very much a barrier to economic development. The epidemic, especially in Africa, seems to have entered a cycle where the very high level of mortality, which targets young working people and certainly does not spare the most educated among them (the case of teachers is often cited) exacerbates the underdevelopment which is one of its major causes. On this the World Bank and the United Nations Development Programme(UNDP) are agreed.

5 A growing risk – due to the knock-on effects – that control will be lost of the epidemic to the North.

This risk may lead to a questioning of health policies based on freedom and individual empowerment – policies which have been pursued for more than fifteen years, particularly in European Union countries. The AIDS epidemic is the first to be fought without using procedures which infringe the rights of sufferers, but by encouraging voluntary screening. However, in a world with major population flows between developing and developed countries, there is a risk that if the HIV/AIDS epidemic continues uncontrolled in the South and in some of the emerging economies, there will be strong pressure in the North to go back on this choice.

Given these grave dangers, it is manifest that prolonged inaction on the part of the International Community would be criminal.

IV PROPOSITIONS FROM THE NATIONAL AIDS COUNCIL

An overriding truth emerges from the facts as they are observed : an immediate commitment is essential to cope with what is an extremely grave situation. The time for experimentation is now long gone – it is now time for policy choices. The players in the fight against AIDS throughout the world must shoulder their responsibilities.

In the time since an earlier version of this report was presented at the Durban Conference, the CNS has noted with satisfaction that the French Government and the European Union have set in train two promising initiatives. The organisation by the French Government of an International Conference on access to care, planned for the end of the year 2001, in collaboration with multilateral bodies, should help improve health systems in a certain number of States, which is the basic prerequisite for providing generalised access to treatment for individuals infected by HIV/AIDS. The European Commission's recent communication favouring "accelerated action targeted at major communicable diseases (HIV/AIDS-Malaria-TB) within the context of poverty reduction" (September 20, 2000), seems to herald a major change of direction for European Union policy, in so far as it defines as the main thrust of its action "making essential medicines more affordable by an overall approach" taking into account price differentiation and the application of measures provided in the Agreement on TRIPS (compulsory licensing). The CNS notes with satisfaction that this new policy was clearly presented at the Round Table on accelerated action targeted at major communicable diseases (HIV/AIDS-Malaria-TB) within the context of poverty reduction, organised on September 28, 2000 by the Directorate-General for Development. Indeed, the very fact of holding a Round Table with representatives of the Northern and Southern countries, drug firms, international institutions, nongovernmental organisations, and others, seems to echo the idea of an international forum proposed at the Durban Conference by the CNS through its international committee.

The CNS is using the present report to make a series of proposals to the French Government and to the international community.

Those proposals are based on the following principle : **all public, national and international policies must be retargeted according to the premise that more effective prevention for the greatest number of people is impossible without access to long-term healthcare for sufferers.**

1. The National AIDS Council requests that **declarations of intentions be replaced by genuine coordination of public policies**. With regard to this, the recent efforts of the French Government and the European Union should enable **pharmaceutical companies already committed to cutting the prices of their products to honour their undertakings and for other firms** holding patents for antiretrovirals and treatments for opportunistic infections **to join them in their action**.

2. The NAC requests that **the World Health Organization (WHO) publicly review the list of "essential drugs", within the framework of a debate in which all sides may participate, and that it take the developing, less advanced and emerging countries more fully into account**. The present list includes numerous inconsistencies and, despite the regular reviews, it is obvious that it does not address the challenge posed globally by the HIV infection. It is therefore important that this list be reviewed in the context of a debate in which all sides would be entitled to express their views, with direct participation, in a spirit of complete transparency, from the pharmaceutical companies, as the major players that they now are. This review should legitimise the steps taken by the developing and emerging economies, which want to have make use, within the context of their national legislation as adapted to the TRIPS agreements or their decisions regarding public health, to "compulsory licensing" or to "parallel imports" for drugs included in that list.

3. The NAC states that **synergy between all partners concerned by the issue of worldwide access to treatment in the fight against HIV/AIDS** (national governments, their diplomatic staff, international organisations, the pharmaceutical industries, NGOs, research bodies, etc.), **is absolutely essential, and that it must be sought through the establishment of permanent representative bodies** for generalised access to the treatments, as its International Committee proposed at the Durban Conference.

3.1 These bodies would be representative since they would bring the main participants in the world drug market together. They would be permanent in order to make possible not only decisions defined over time, but also rapid changes in policy to match developments in the world drug market and in the needs of sufferers in the countries concerned. The presence of international organisations (UNAIDS, WHO, WTO, World Bank, UNDP, etc.) should enable mediation of the various interests involved, to benefit those affected by the epidemic, wherever they may be.

3.2 Those same bodies would have as tightly interlocking aims the provision of a guaranteed effective and universally acceptable segmentation of the drug market and the encouragement of developing and emerging countries to improve their health systems. They could proceed by examining, case-by-case, projects for access to HIV/AIDS treatment submitted officially presented by national governments.

4. The NAC requests that **disputes laid before the WTO concerning pharmaceutical patents not only be settled on the basis of the legal validity of the arguments put forward, but also by taking into account, as a priority, the goals and issues of public health – especially their urgent character**.

ANNEX

The CNS wishes to express its gratitude to the following persons :

- **Ms de Cénival** et **Mr. Coudray**, Commission Nord-Sud, Act-Up Paris – evidence heard by the International Committee on 28 January 2000.

- **Mr. Chirac**, "Access to treatment" campaign, (Médecins Sans Frontières) – evidence heard by the International Committee on 28 January 2000.

- **Ms Coll-Seck**, Director, Department of Policy, Strategy and Research, UNAIDS –

discussion in Geneva on 22 March 2000 with a delegation from the International Committee (P. Hantzberg, F. Buton).

- **Mr. Lamy**, Trade Commissioner, Directorate-General for Trade, European Commission – discussion in Brussels, 14 April 2000 with a delegation from the International Committee (P. Hantzberg, C. Bouillaud).

- **Mr. Malkin**, Scientific Director, International Therapeutic Solidarity Fund – evidence heard by the International Committee on 28 January 2000.

- **Mr. Ravier**, Deputy Director-General, World Trade Organization – discussion in Geneva on 22 March 2000 with a delegation from the International Committee (P. Hantzberg, F. Buton).

- **Mr. Tarantola**, Senior Policy Advisor, Office of the Director-General, World Health Organization – discussion in Geneva on 29 March 2000 with a delegation from the International Committee (P. Hantzberg, F. Buton).

- **Mr. Teuliers**, Manager, International Contacts, Syndicat National de l'Industrie Pharmaceutique – evidence heard by the International Committee on 29 May 2000.

POSTER PRESENTED AT THE XIIITH AIDS INTERNATIONAL CONFERENCE IN DURBAN - JULY 2000.

TUPEE 3865 - FOR AN INTERNATIONAL FORUM TO ENSURE EFFECTIVE WORLDWIDE ACCESS TO ESSENTIAL DRUGS

Paul HANTZBERG, Claudine HERZLICH, Véronique NAHOUM-GRAPPE, Jean-Marie FAUCHER, Daniel LAURENT, François BUTON, Christophe BOUILLAUD, members of the International Commission of the French National Aids Council.

A) Why create an international Forum to facilitate access to essential drugs ?

- Current economic trends are a major cause, among other factors, of a widening gap between developed and developing countries in their access to effective treatments.

- The dominant pharmaceutical firms have not responded significantly to the urgent needs of developing and emerging countries for access to essential drugs.

- The pricing policies imposed by pharmaceutical firms are, first and foremost, based on a strategy of enhancing and protecting profits derived from sales in developed countries.

- National and International Institutions have failed so far to create mechanisms which would enable effective access to essential drugs.

- TRIPS agreements of 1994 allowed recourse to parallel imports and compulsory licences; but, under fierce bilateral pressure, most emerging countries have renounced implementation of such tools for giving their populations access to essential drugs .

- Actions taken thus far to lower prices for populations living in developing countries have only produced very limited results.

- An international forum, which would act as a body monitoring economic and health situations around the world, and would formulate coordinated policies to be implemented, is necessary to halt and reverse the crisis created by these factors.

B) What would be the functions of such an International Forum ?

- Such a forum could serve as a permanent body to reach consensual decisions among all parties concerned, especially pharmaceutical firms, the governments of emerging countries, NGO's and international institutions, including health institutions.

- Upon requests of countries interested in benefiting from a special pricing policy, the International Forum would lead deliberations and examine the merits of appropriate responses to be adopted for each particular case. All parties would be asked to share the economic costs of efforts to be made.

- As a consideration for their agreement to establish affordable prices for the average populations of developing countries, guarantees would be negotiated for pharmaceutical groups to prevent any erosion of their sources of revenue from developed countries.

- Such an International Forum could also serve as an advisory body to the worldwide health organizations and other relevant international institutions.

- In addition, it could provide advice to the World Trade Organization on all matters concerning intellectual property rights related to the production of medicine.

C) How should such an International Forum be structured ?

- This international Forum must be structured as a permanently organized institution in order to be able to provide a continuing effort in regard to such complex matters, and to ensure a seamless monitoring and control over the solutions agreed upon.

- It needs to be of a relatively small size in order to provide optimum focus and avoid diffused and fragmented actions.

- Financing would be provided through channels guaranteeing the independence of the forum, such as the World Bank and nongovernmental organizations that sponsor adequate fund-raising from the public.

- The president should be a distinguished person with a worldwide reputation for his or her ethical and humanitarian contributions.

- The board would be composed of a maximum of 10 Individuals with well established expertise in health economics. They would be designated by representative health institutions and nongovernmental organizations, which are involved internationally in health-related matters.

- The head office of this International Forum could be established in Geneva to ensure proximity to, and coordination with, the World Health Organization.

D) What benefits could be expected from such a forum ?

- Through its actions, this international forum would ensure appropriate distribution of essential drugs in all countries which submit justified cases for assistance.

- Distribution would be controlled so as to ensure effective access by all patients and avoidance of diversion and misappropriation of drugs.

- Coordination and consensus would ensure that pharmaceutical firms are not deprived of their current sources of revenue to fund research and development of new medicines.

- Self-regulation and negotiated terms would avoid recourse to publicly enforced new legislation which can always be subject to a risk of circumvention.