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MEMORANDUM EQUIVALENT TO OPINION

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INTERNATIONAL POLICY

EN

DEFEATING THE GLOBAL AIDS EPIDEMIC THROUGH INNOVATIVE FINANCING

ADOPTED BY THE NATIONAL AIDS COUNCIL (*CONSEIL NATIONAL DU SIDA*) ON 13TH OCTOBER 2011

This *Memorandum Equivalent to Opinion* was unanimously adopted by all members of the National AIDS Council present on 13th October 2011.

The document can be downloaded at www.sante.gouv.fr/IMG/pdf/2011-10-13_nva_en_politique_internationale

The French National AIDS Council (Conseil national du sida - CNS) is an independent, consultative French agency that was set up in 1989. It comprises 24 members: specialists working in the field of HIV/AIDS, representatives of civil society, and members of associations.

The CNS delivers opinions and recommendations on the full spectrum of issues that society faces as a result of HIV/AIDS. These papers are addressed to the French authorities and to all those involved in or concerned by the epidemic.

It is the intention of the CNS to participate in this manner in the development of public policy, within a framework that promotes respect for fundamental ethical principles and human rights.

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NATIONAL AIDS COUNCIL SUMMARY AND RECOMMENDATIONS

The French Presidency of the G20 summit has placed the issue of innovative financing on the international agenda, whilst high level discussions continue on the implementation of a financial transaction tax. This mechanism constitutes a **genuine opportunity for the international community to live up to their responsibilities** and **guarantee the universal access to antiretrovirals** promised for 2015.

Access to treatment and health care is not only in **the best interests of the direct beneficiaries** but also is in the collective interest as treating people infected significantly reduces the risk of HIV transmission, one of the conditions for ensuring a **substantial decrease in the number of new infections**.

THE NATIONAL AIDS COUNCIL OBSERVES

1. **The needs, notably in terms of access to treatment, are vast.** Today there are ten million people who do not receive the treatment for which they are eligible. The costs incurred remain extremely high and the financial resources required to ensure the provision of healthcare, need to increase over the coming years.
2. **Donor countries have not kept to the agreement** on official development assistance and seem unable to devote 0.7% of their gross national income to ODA by 2015, whilst the gap between the needs and the resources available has reached a critical threshold.
3. **The increase in levels of patent protection since 1994 has limited** competition in the pharmaceutical market and thereby **the expected reduction in the cost of treatments** which now constitute second-line products. The implementation of dispensation mechanisms open to low-income countries which allow them to bypass this increased protection has been insufficient.
4. **The global governance of HIV/AIDS control is ensured by a range of disparate organizations** with insufficient levels of coordination between them. Furthermore, there are very low levels of cooperation between stakeholders in the health sector and those involved in trade.

In order to tackle these issues, mainly related to the decisive question of universal access to treatment, the Council believes it is the right time **to implement a financial transaction tax** to provide significant additional resources for HIV/AIDS control. Furthermore, it recommends that further governmental action is taken **beyond the scope of this mechanism alone**.

THE NATIONAL AIDS COUNCIL RECOMMENDS

1. **The programming of multiannual financing of tens of billions of dollars per year**, in order to increase efficiency and bring down both the incidence of the epidemic, as well as the future levels of spending.
2. **The mobilization of complementary and combined financial resources**: official development assistance, diversified innovative financing (taxes, public/private partnerships) and a high yield financial mechanism (financial transactions tax).
3. **A reduction in the cost of treatments**, made possible by the implementation of the dispensations to intellectual property rules available to low-income countries.
4. **A new global governance** based on the effective coordination of the fight against HIV/AIDS under the aegis of UNAIDS, and reinforced cooperation between the World Health Organization and the World Trade Organization.

DEFEATING THE GLOBAL AIDS EPIDEMIC THROUGH INNOVATIVE FINANCING

MEMORANDUM EQUIVALENT TO OPINION

The French G20 presidency has brought the issue of innovative financing to the forefront of the international agenda, whilst high level discussions continue on the implementation of a financial transaction tax (FTT). This mechanism for levying financial resources, promoted for several years by many stakeholders involved in HIV/AIDS control, constitutes **a genuine opportunity for the international community to live up to their responsibilities** and guarantee universal access to antiretrovirals (ARV) as promised in 2005 for 2010, and then in 2011 for 2015.

The United Nations Member States at their General Assembly last June, set extremely ambitious targets in their formation resolution[1], in order to respond to **the global emergency of an epidemic** which each day sees 7,000 people newly infected including 1,000 children: Reduction in the sexual transmission of HIV and transmission through the use of injected drugs by 50% by 2015, the eradication of mother-to-child HIV transmission, access to ARV for 15 million people by 2015.

It is now established that access to the widest possible range of treatments and healthcare is not only in the interests of the direct beneficiaries but also serves the collective interest as the treatment of people infected with HIV makes it possible to significantly reduce the risk of HIV transmission[2]. This reduction in risk represents an excellent opportunity for achieving **a substantial drop in the number of new infections over a relatively short period of time**. In order to obtain these results, public and private donors must today agree to an exceptional level of financial investment, which could then be progressively reduced over the next five years.

After an unprecedented increase in available revenue between 2000 and 2008, **investment in HIV/AIDS control** has dropped since 2009 and today **falls far short of the objectives set, and is largely insufficient in light of the spread of the epidemic**. Whilst the total available funds stood at 15.9 billion dollars in 2009, UNAIDS estimates that meeting the targets set for universal access by 2015 requires 28 to 50 billion dollars of investment each year[3]. Current contributions whether multilateral or bilateral, traditional or innovative, seem wholly inadequate, especially as the global economic crisis in donor countries is likely to reduce future perspectives for development.

In this context, it is vital to find new sources of revenue and promote innovative high yield financial mechanisms which solicit the international community as whole, including major emerging countries, in order to respond to HIV/AIDS control issues.

Based on this analysis, the National AIDS Council stresses the vital opportunity that the FTT project, supported by several European Union Member States, represents. The Council reiterates that this tax, whose allocation has not yet been discussed, **must be used to fund the Millennium Development Goals**. Moreover, the Council stresses that governments cannot consider the sole adoption of the FTT, without also implementing **a broader action plan** which addresses the crucial questions of funding, investment, price and governance. These objectives are intended to:

- Diversify and increase financial resources,
- Establish their allocation according to the investment requirements,
- Promote cost reductions, notably those related to the purchasing of ARV,
- Ensure reinforced coordination between stakeholders and organizations.

These conditions should make it possible to effectively and efficiently mobilize innovative financing, which is set to increase, in accordance with international commitments, the key HIV/AIDS control issues and the principles of development assistance.

THE NATIONAL AIDS COUNCIL OBSERVES

1. The needs, notably in terms of access to treatment, are vast, the costs incurred remain very high and the financial resources required to ensure the provision of healthcare, need to increase over the coming years.

Access to first-line ARV is still insufficient. The number of people living with HIV (PLHIV) under treatment was multiplied by 13 between 2004 and 2009, but **10 million people are still not receiving the treatment for which they are eligible**.[4] Access to second-line ARV, indispensable for those for whom first-line therapies are ineffective, is also extremely inadequate. It is estimated that 20% of PLHIV in Sub-Saharan Africa treated with ARV require a second-line therapy after 20 months[5]. However, only 2% of PLHIV in this region actually have access to such treatments[6].

Access to third-line ARV, despite their proven therapeutic value, remains extremely uncertain in the vast majority of low-income countries, not equipped with action plans.

It is also important to emphasize that access to ARV in low-income countries is based on the use of treatments with more frequent adverse effects and which are no longer used in countries in the north. This means 56% of treatment plans in low-income countries include Stavudine[7] despite the fact that long-term exposure to this drug can induce **potentially life-threatening toxicities**[8]. The alternative options (AZT and Tenofovir) are still more expensive, require more intensive biological monitoring and have to be discontinued more often.

Despite the considerable drop in the cost of first-line treatments which today cost around one hundred dollars per year and per patient in low-income countries[9], the international community is not in a position to mobilize the resources required to ensure universal access for those eligible. **The cost of second-line treatments, which remains high** due to their limited availability as generics, constitutes a further difficulty. This cost is approximately 3 to 6 times greater than for first-line treatments in low-income countries and 3 to 22 times higher than in middle-high income countries which themselves face specific problems in terms of access[10]. The price of third-line treatments means they cannot be supplied to the vast majority of low-income countries.

In addition to access to medication, it would seem that care management for PLHIV, which remains costly at around 400 dollars per year, per patient, i.e. **four times higher than for first-line treatment**, is often both incomplete and inadequate. Access to specific prevention programs (promoting the use of condoms, adapted behavior, male circumcision, mother-to-child transmission prevention, campaigns adapted to the most at-risk groups) is also insufficient, despite some progress being made.

The fight against HIV/AIDS will **require even more resources in the years to come**. This prediction is based on a number of factors: The regular increase in the number of PLHIV being treated for life with first and second-line treatments, the increase in the life expectancy of PLHIV with a gain of 14.4 million years of life since 1996, thanks to the use of ARV[11], the decrease in the number of deaths per year due to AIDS, the increase in the number of people eligible for treatment following changes in international recommendations on treatment initiation[12]. Furthermore, the decrease in the incidence of HIV/AIDS is not substantial enough to contradict these predictions. The epidemic continues to progress at an astonishing rate with an estimated 2.6 billion new infections for 2009.[13]

2. The donor countries have not kept their commitments in terms of development assistance and universal access to treatment, whilst the gap between the needs and the available resources has reached a critical threshold.

At the 2005 G8 and United Nations summits, world States agreed to devote **0.7% of gross national income (GNI)[14] to official development assistance (ODA)** by 2015. However, six years off the deadline, France's ODA/GNI ratio was 0.46% in 2009[15], well below the objective set for 2009 to ensure the country is on track to reach 0.7% in 2015. Other European countries such as Sweden, Denmark, the Netherlands, Belgium and the United Kingdom have reached or even exceeded target levels.[16]

In terms of contributions to HIV/AIDS control funding, France ranks fifth in the world, behind the United States (58%), the United Kingdom (10.2%), Germany (5.2%) and the Netherlands (5%) with a financial contribution in 2009 which represented 4.4% of total contributions from all donor countries. **Highly committed to multilateral action**, France devotes 80% of the funds allocated to HIV control to funding two international organizations. It is the biggest donor to the Global Fund to fight Aids, Tuberculosis and Malaria having pledged to donate 1.4 billion dollars over the next three years. Furthermore, France also makes a significant contribution to the airline ticket tax system used to fund UNITAID, with a total contribution to HIV/AIDS control of 78.6 million dollars in 2009[17] and 107.5 million dollars in 2010[18].

Despite this, France has not been able to **create a dynamic within the donor States towards multilateral aid and innovative financing solutions**, such as the airline ticket tax, which they were instrumental in developing. This means that despite the increase in the number of partner countries, over half of UNITAID's budget is still funded by France i.e. 58.5% in 2010. **France's contributions to global financing of the fight against HIV/AIDS are not proportional to its gross national income**. With a 4.6% share of global GNI, in 2009 France committed 2.1% of funds made available for HIV/AIDS control. By way of comparison, with a share in global GNI of 24.6% and 3.8% respectively the United States and the United Kingdom contribute 27% and 4.7% of available funds.[19]

In light of its gross national income and its pioneering role in the fight against HIV/AIDS, France could certainly make a more significant contribution, especially as the needs for which there is no financial cover remain substantial. The significant gap between the needs as estimated by UNAIDS, and the available funds allocated to the fight against HIV/AIDS increased in 2009, and the trend seems set to continue for 2010 and 2011.

3. Increased patent protection has limited both competition in the pharmaceutical market and the expected decrease in the cost of antiretrovirals.

The introduction of low-cost generic drugs, copies of the first expensive brand-name products, has made it possible to increase access to ARV. Over 60 low-income countries have benefited from generic versions of antiretrovirals[20] and today **95% of the treatments funded by the global fund are generics**[21]. All the first and second-line treatments recommended by the WHO[22] are available as generics[23], **but not all regions are guaranteed access to them**. The increased patent protection accorded by the 1994 trade agreements[24], has complicated competition in the pharmaceutical market and limited the decrease in the price of ARV, notably for second-line treatments. The dispensations for low-income countries to the patent rules established by these agreements, the necessity of which was reiterated in 2001 in the Doha Declaration[25], has not lead to a sufficient reduction in the price of second and third-line treatments.

However, **thanks to these dispensations and the mobilization of several states to promote their implementation**[26], Thailand[27] and Brazil[28] in particular were able, in the second half of the 2000s, to produce a limited number of generic drugs for which they do not hold the patent by obtaining a compulsory license and thereby producing vital treatments at a low cost[29]. Furthermore, more than ten countries have used the mere **threat of resorting to compulsory licenses** as a tool for negotiating with pharmaceutical companies[30] and have directly obtained a voluntary license, granted against the payment of royalties, to allow them to benefit from generic drugs[31]. Finally, around one hundred low-income countries have recently obtained authorizations to benefit from low cost copies of the ARV produced by the firm Gilead Science, some of which are still in clinical development.[32] This agreement was reached as part of the Patent Pool, proposed in 2006 by UNITAID, then defended by the Medecines Patent Pool (MPP)[33] and recently supported by the G8 under the French presidency[34].

The initiatives promoted by the pharmaceutical firms, sometimes in partnership with international organizations **have their limitations**. The licenses granted bilaterally by pharmaceutical companies to States often have specific conditions built in which are unfavorable to the licensee, and allow the companies which produce brand-name drugs to control competition and keep their grip on the market. Furthermore, the agreements signed under the Patent Pool framework exclude middle-income countries and are difficult to transpose to pharmaceutical firms who do not adopt the same economic model as Gilead. Indeed, the company compensates for its limited implantation in low-income countries through grouped patent assignment. Finally, agreements which make provision for the not-for-profit sale of brand-name ARV, as is the case under the Accelerating Access Initiative (ACCESS) promoted by international organizations[35] and companies[36], have lead to a reduction in the price of certain ARV of between 80% and 95%[37], but these agreements are rather opaque[38] and of limited scope, as the price set can be higher than the price of the generic drug[39].

Today one of the main difficulties in terms of access to low-cost generic drugs is **the signature of bilateral agreements which bypass the dispensations in place**.[40] Certain countries, notably the United States have introduced more stringent standards than those set out in traditional agreements, such as those in force in Thailand[41], Jordan[42], Morocco[43] and Singapore[44]. Today, it is India who is being encouraged by the European Union, in exchange for less stringent conditions on its agricultural imports, to adopt additional protective measure for brand-name drugs, which may well compromise the production of generic drugs. Moreover, the Anti-Counterfeiting Trade Agreement (ACTA), an international multilateral treaty which aims to ensure the optimal quality of goods and which notably makes provision for increasing the inspections of goods not approved by the competent authority[45], could also complicate international trade in generic drugs.

4. The global governance of HIV/AIDS control appears to lack coordination and levels of cooperation between stakeholders in health and those in trade are insufficient.

The global management of the fight against HIV/AIDS **is ensured by a disparate range of organizations**: Beneficiary and donor countries, free to engage in multilateral or bilateral actions, in some cases carried out by *ad hoc* bodies such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the United Nations agencies, notably the World Health Organization (WHO) which coordinates global public health initiatives, the Joint United Nations Programmes on HIV/AIDS (UNAIDS) responsible for partnerships between different agencies, fundraising bodies such as the Global Fund and UNITAID, private foundations, and public-private partnerships which involve a growing number of businesses and non-governmental organizations (NGOs) which in recent years have reinforced the role they have carved out for themselves in global governance.

In this complex, multi-layered environment with close links between the private and public sector, several difficulties exist.[46] First of all, the different partners have not managed to equip themselves **with a powerful strategy and assessment tool** which would allow them to ensure the transparent monitoring of the contractual commitments made by States or other stakeholders, and the optimal use of resources in beneficiary countries. Furthermore, despite the creation of UNAIDS and the signature of memoranda of understanding between IGOs, public initiatives appear **to lack coordination** and the partners are not always capable of avoiding repetition and overlap between their programs for action.

Finally, the partners do not seem capable of taking action in other sectors **such as trade policy, which could have a significant impact on public health** and, in particular, access to medication. At international level, the WHO is not promoting any effective strategies likely to support low-income countries on the issue of access to treatment, nor is it trying to place public health issues on the World Trade Organization's (WTO) agenda, despite having observer status on a limited number of WTO bodies.[47] At national level, health ministers do not have the latitude required to represent health interests in trade negotiations between States which are solely conducted by finance and foreign trade ministers.

In order to face up to these issues, mainly related to the decisive question of universal access to ARV, the Council believes it is the right time to **implement a financial transaction tax** to provide significant additional resources for HIV/AIDS control, and recommends that **further official action is taken beyond the scope of this mechanisms alone**.

THE NATIONAL AIDS COUNCIL RECOMMENDS

1. The programming of multiannual investments of tens of billions of dollars per year, in order to increase efficiency and bring down the incidence of the epidemic as well as the future level of spending required.

It is today accepted that the rapid acceleration of access to antiretrovirals for HIV/AIDS infected populations can not only significantly reduce rates both of mortality[48] and morbidity[49] in those infected, but also the risk of transmission of the virus. Guaranteeing universal access to treatment is therefore a key means for permanently curbing the spread of the epidemic and reducing the levels of investment required in the future.[50] A theoretical strategy for universal access to voluntary annual screening and the early initiation of treatment, without taking into account the clinical stage nor the assessment of their immune system, with **the aim of providing 90% coverage of PLHIV by 2016**, could reduce the **incidence of HIV and mortality to less than 1 in 1,000**, and contain HIV prevalence at less than 1% in 50 years. It would also make it possible, as of 2032, to achieve a regular decrease in costs to below the level forecast for strategies currently being implemented.

Under another hypothesis, based on the most realistic objective in terms of universal access to treatment for the people currently eligible today according to international recommendations (with earlier treatment initiation, before the immune defenses are critically impacted)[51], the proposal is to significantly and regularly increase funding to several billions of dollars per year through to 2020 (with a peak in 2015)[52]. This additional funding, which could reach a total of 47 billion dollars over the next ten years, **would guarantee cover for 71% of the eligible PLHIV**, and **could prevent, by 2020 over 12 million new infections and 7 million AIDS-related deaths, including 1.9 million children**. This level of investment would then become cost-effective as it would correspond to 1060 dollars per year of life gained, i.e. less than the GNI per inhabitant in the world's poorest regions. This investment, offset by the direct and indirect financial benefits obtained through the reduction in the number of infected persons and therefore, of persons requiring treatment, would allow States to reduce their contributions as of 2016.

Whatever the treatment strategy chosen, the donors must increase funding with investment plans for several billions of dollars of additional funding per year, in order to have a significant impact on the spread of the epidemic and on future spending.

2. The mobilization of complementary and combined financial resources: Official development assistance, diversified innovative financing and a high yield financial mechanism.

Innovative financing should **not be used to replace official development assistance**, and the committed States, starting with France, are bound to keep their pledge to increase their contributions to ODA in order to meet the 2015 deadline for achieving a proportion of 0.7% of GNI devoted to ODA.

Considering ODA in isolation, even if it were increased significantly, it would probably remain below the levels required to meet the vast needs in terms of HIV/AIDS control. States should therefore, as of today, **mobilize additional resources** which will make it possible to both increase available funds and diversify the means of action, so that all donor countries can implement actions according to their financial capacities and their economic model. It would seem vital to offer **a range of innovative financing**[53] both taxes and public/private partnerships (PPP). Under these partnerships, for example it would be possible to develop the Debt2Health scheme which allows a creditor to forgo their claim on part of the debt owed, on the condition that the beneficiary invests in the health sector over a designated period and within the framework of Global Fund approved programs[54]. In the same way advance market commitments (AMC), contractual partnerships between pharmaceutical companies and donor States, who commit to paying a pre-determined price for a product once it comes to market, should also be promoted. This mechanism is currently used for some vaccines and could be extended to ARV.

Due to their multiplicity, and the complexity of their financial circuits, it seems difficult to assess the impact of these innovative schemes on HIV/AIDS control[55]. It is however very likely that the financial yield will still fall short of the objectives set. It would seem necessary to promote **a broad based, high yield mechanism which would attract a large number of countries**. The FTT, supported by a number of countries and whose feasibility has already been established by various international agencies[56], would be paid by those buying and selling financial instruments, at a rate set according to the product, but which would not exceed 0.2%. Under these conditions, and despite the inherent limitations of such a system[57], the risk of avoidance would be minimized and revenues maximized. According to a recent study[58], the revenue generated by the tax is estimated at 265 billion Euros per year if it is implemented by all G20 members. Otherwise, a FTT applied solely in France could theoretically generate 12 billion Euros.

3. A reduction in the price of medical products, as made possible by the implementation of dispensations to intellectual property rules available to low-income countries.

A reduction in the price of ARV should today be obtained through the increase in demand and production volumes that the revenue generated by innovative finance will make possible, and by reinforcing competition between pharmaceutical companies, notably those producing generic drugs. The presence of a second competitor producing a given generic reduces the price to around 50% of that of the brand-name product[59]. It makes it possible to instigate a decrease in the price of medical products on the global markets[60].

Reinforcing competition between pharmaceutical firms depends notably on the dispensations offered to low-income countries to ensure they benefit from access to medical products. It would therefore seem crucial to **promote the opportunities available to these countries to obtain licenses for producing these drugs**, as well as the principles set out under **the Doha Declaration** i.e. the primacy of public health over the application of intellectual property rights for medical products. Furthermore, it is vital that the clauses included in certain bilateral agreements, which threaten countries' ability to avail themselves of these dispensations, are repealed

4. A new global governance based on the effective coordination of the fight against HIV/AIDS under the aegis of UNAIDS and reinforced cooperation between the WHO and the WTO.

It is vital that the monitoring of the objectives set by the States is encouraged, in order to respect the principles set out in the Paris Declaration on Aid Effectiveness[61] and the Accra Agenda for Action[62]: program harmonization and transparency, results-based management, mutual accountability of donors and beneficiaries, three to five year visibility on aid, freeing up aid by loosening the restrictions which prevent developing countries from purchasing the highest quality goods and services at the lowest possible price.

Responsibility for regulating, monitoring and assessing innovative financing dedicated to HIV/AIDS control must be exercised with **improved coordination in order to meet the objectives set**. In order to maximize the effectiveness of these innovative financing mechanisms, this coordination should ensure that donor countries meet their commitments and obligations, the beneficiary countries carry out structural reforms and define optimal HIV/AIDS control strategies, and that low-income countries are able to benefit from the dispensations available to them. UNAIDS does not have the competence required to take on responsibility for this coordination alone. Representatives of several organizations have the legitimacy and credibility to participate in this action, notably the WHO, which spearheads world health action and promotes political HIV/AIDS control objectives, and the World Trade Organization (WTO) which promotes free trade between States.

These last two organizations need to increase cooperation based on the principles laid out during the discussions on International Health Regulations opened in 2005[63]. The current objective is to ensure **the steering and evaluation of trade policy with a view to public health issues**, and to implement coordination between low-income countries in order to improve their access to ARV. In order to do this, both bodies need to meet specific challenges. WHO needs to reinforce its programs and expertise on the issues of access to ARV and intellectual property. The WTO needs to better integrate the WHO and low-income countries into its analysis and decision-making bodies.[64]

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