JOINT OPINION BY THE NATIONAL AIDS COUNCIL AND THE NATIONAL CONFERENCE ON HEALTH REGARDING THE DRAFT 2010-2014 NATIONAL PLAN FOR HIV/AIDS-STI.

ADOPTED BY THE FRENCH NATIONAL AIDS COUNCIL AND THE OFFICE OF THE NATIONAL CONFERENCE ON HEALTH ON JUNE 17, 2010.

This joint Opinion was adopted unanimously on June 17, 2010 by all the attending members of the National AIDS Council, and by all but one members of the Office of the National Conference on Health.

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LETTER OF MISSION

General Directorate for Health (*Direction générale de la santé)*
Division of Prevention of Infectious Risks
Office of Infections by HIV, STIs and Hepatitis

DGS/SDR12#224

To
M. Christian SAOUT,
President of the National Conference on Health

Prof Willy Rozenbaum
President of the National AIDS Council

Object: Consultation on the projected 2010-2014 National Plan to fight HIV and STIs
Attached: Strategy note, "HIV/AIDS-STI National Plan 2010-2014, *New Contexts, New Challenges*".

The preceding national program to fight HIV/AIDS and STI covered the 2005-2008 period.

A new strategic approach has been laid down for the construction of the fifth pluri-annual Plan to fight HIV and STIs, which has been conceived to cover the 2010-2014 period. In June 2009 the General Directorate for Health constituted a Pilot Committee (comprising the heads of central administrations of the Ministry of Health, other Ministries, health agencies, network-heading associations, knowledgeable groups and qualified persons), responsible for making proposals to the Minister for Health involving the construction of the future National Plan to fight HIV and STIs. This committee validated the principle of a segmented approach (Populations of overseas territories; Lesbians Gays Bisexuals Transsexuals (LGBT); Migrants; Persons in situations of vulnerability), and based its work on proposals issued by working groups for each population. Preparation of the Plan was founded on expertise that was pluridisciplinary and interministerial, associating all actors working in the field of HIV/STI in a collegial and participative construction that was further based on evaluation reports of the preceding plan; recommendations by the High Authority for Health; an expert report directed by Prof. Yeni; the Opinions of the National AIDS Council; a report by Mme. Lert and Mr. Pialoux on new methods for prevention; the recommendations of the report by the Court of Audit; and reports from professionals and associations in the field. This approach was announced by the Minister of Health in his press conference of November 27, 2009 on the question of World AIDS Day.

Subsequently, an inter-directional and interministerial phase of consultation about the primary orientations of the plan was directed by my services between December 2009 and January 2010. Following these consultations, the work of costing and writing the plan began.

In this context, it is my request that the National Conference on Health and the National AIDS Council should jointly pronounce on the strategic orientations of the future HIV-STI Plan, as well as on its methods of construction and governance.

The draft plan is in the process of being validated by the Office of the Minister responsible for Health. A presentation of the Plan will occur during the meeting of the Office of the National Conference on Health on May 18, to which the members of the National AIDS Council are invited. Prior to that, we are addressing you the strategy note "HIV/SIDA-STI National Plan 2010-2014 *New Contexts, New Challenges*".

Following the stage of validation, we plan to send you the entire Plan between June 7 and 14, in order that your two bodies, as proposed by the Office of the Minister, be able to issue a joint Opinion regarding the Plan. I would be grateful if the National Conference on Health and the National AIDS Council could deliver their Opinion on the Plan before the end of June. We wish to publish the Plan by mid-July, so it can be made available for the 18th International AIDS Conference which will take place in Vienna from July 18 to 23, 2010.

The services under my responsibility are available to you to deliver all the necessary help to assist in the organization of your shared work and in the production of an Opinion by the National Conference on Health and the National AIDS Council.

Yours faithfully,
The General Director of Health

Prof. Didier Houssin

PREFACE

In a letter dated May 14, 2010, the General Director of Health *(directeur général de la santé)* mandated the National Conference on Health (*Conférence nationale de santé, CNS)* and the National AIDS Council *(Conseil national du sida, CNS)* with a request that they rapidly come to a joint statement regarding the strategic orientations of the future 2010-2014 National Plan for HIV-STI, and the Plan's method of construction and governance. It further requested that this work be completed before the end of June, to permit its presentation during the International Conference on AIDS organized by the International Aids Society in Vienna, Austria, July 18 to 23, 2010.

In application of the Code of Public Health[1], the National Conference on Health and the National Council on AIDS must be consulted by the government during the process of drawing up the national plan for HIV-STI.

The two agencies firstly wish to note two observations regarding the conditions in which they have been consulted.

The National Conference on Health and the National Council on AIDS were given access to a strategy note for the National Plan, which was annexed to their mission letter of May 14. According to that letter, the completed Plan was to be sent to both agencies before June 15. To date, no such document has been received by the National Conference on Health or the National AIDS Council. These bodies can therefore only comment regarding a **strategy note** that provides no information regarding numerous decisive aspects of the Plan, most particularly programs targeted at specific populations and the section regarding sexually transmitted infections (STI).

The National Conference on Health and the National AIDS Council received this joint mission at an **extremely short notice**. In order to meet as a deliberative body they were able to jointly utilize the plenary session of the National Conference on Health on June 10, and the plenary session of the National AIDS Council on June 17

The partial communication of the Plan, and the short notice given by the authorities, did not permit these bodies to exercise their mandate fully. However, examination of the strategy note led to evaluations of its broad orientations which were so highly convergent that it appeared pertinent for the National Conference on Health and the National AIDS Council to deliver a joint Opinion on this basis alone. Nonetheless, both bodies reserve the possibility to add to these observations, jointly or separately, when the National Plan is presented or put into effect.

Furthermore, the National Conference on Health and the National Council on AIDS address this Opinion to the General Director of Health and, through him, more broadly, to the political authorities of France. Policy regarding the fight against HIV/AIDS and STI is effected by sectors in a number of different Ministries, in particular Health, Development Aid, the Interior and Immigration, Justice, the Budget and Overseas Territories, and it requires the highest possible degree of leadership and political mobilisation.

The assessment jointly reached by the National Conference on Health and the National AIDS Council in the present Opinion is severe. In its current condition, the **2010-2014 National Plan does not define an effective public policy, given the current challenges of the fight against HIV and STIs**. The responses to three essential challenges -- **screening policy** and early access to treatment; the necessary alignment of different public policies for **greater consistency;** and **France's international commitments** to the fight against the pandemic -- are deemed highly insufficient by both these bodies. Additionally, the mechanism of **governance** proposed for the effective implementation, follow-up and evaluation of the Plan raises a number of questions.

Approaching each of these four areas successively, the National Conference on Health and the National AIDS Council have been careful to match their observations with precise recommendations, in order to usefully contribute to **a profound revision of the projected National Plan,** which the two bodies both deem **indispensable**.

[1] Article L1411-3 for the National Conference on Health, article D3121-1 for the National AIDS Council.

I. SCREENING AND TREATMENT: A TIMID PLAN WITH NEITHER THE AMBITION NOR THE MEANS TO PUSH BACK THE EPIDEMIC

THE EPIDEMIC REMAINS DYNAMIC, WITH CONTINUING DELAYS IN SCREENING AND ONSET OF CARE

France's epidemiological situation is characterized by **an incidence of roughly 7000 to 8000 new infections every year**[2]**;** depending on the data utilized and the methodology for estimation, this appears to be roughly stable, or possibly in slight decline, over the past five years[3]. Prevalence was estimated at the end of 2008 as between **135,000 and 170,000 infected persons.**[4]

The most striking characteristic of the epidemic in France is its **concentration,** with certain high-risk population groups linked to extremely high levels of prevalence and incidence, indicating the epidemic's strong dynamic within these sectors. The population of men who have sex with men (MSM), which concentrates 40% to 50% of all new infections, registers an incidence level of 1% per year. In MSM who frequent gay recreational locations in Paris, the prevalence of infection is 17.7%, according to one 2009 study[5]. Incidence levels far higher than the average are also observed in migrants of sub-Saharan origin and injectable drug users (IDU)[6]. Finally, there are sharp differences between regions, with the French departments in the Americas and the area around Paris the worse affected by the epidemic. The department of Guyana, with a prevalence of over 1% in pregnant women, should be considered to be in a "generalized epidemic", according to international definitions.

The relative stability of the total number of new infections **in no way implies that the epidemic in France has stabilised**. The simple fact of maintaining a high level of transmissions of infection, associated with increased life expectancy of infected persons arising from effective treatment, leads to a **constant increase of the prevalence of HIV** in the population, as attested by various indicators.[7]

One of the essential factors involved in the dynamic of the epidemic is **the proportion of unscreened infected persons.** Given the number of new contaminations, -- estimated at between 7000 and 8000 per year -- screening for HIV led to about 6500 discoveries of seropositivity in 2007, as in 2008[8]; this suggests that the number of infected persons who do *not* know their serological status tends to be in constant increase. At the end of 2008 this number was estimated at about 50,000[9], ie between 30% and 40% of all persons infected.

This situation involves **delays in diagnosis and onset of medical treatment,** with damaging effects. The proportion of persons who discover their infection at the stage of AIDS and/or with a CD4 cell count lower than 200/mm^3 is in decline, but it nonetheless remains considerable[10]. Furthermore -- and notwithstanding these cases of very late onset of treatment -- the notion of delay in diagnosis is today perceived more widely, based on the current recommendations for onset of treatment. Currently, because of clearly demonstrated therapeutic benefit, it is recommended that treatment should be initiated for all patients whose CD4 count is lower than 350 CD4/mm^3. In 2008, roughly **50% of persons identified by screening as HIV positive** had a CD4 count below this level, and

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[2] *Medical care for persons infected with HIV - 2010 Experts Report*, to be published in July 2010

[3] INSERM estimates (back calculation method) / estimates by the Institute for Health Supervision (*Institut de Veille Sanitaire, InVS*) (direct method).

[4] *2010 Experts Report, op. cit.*

[5] Prévagay Study, InVS.

[6] InVS estimates of the level of incidence in 2008 :

Population group	Incidence (new infections per 100,000 persons per year)
Total Population	**17** /100,000/year
MSM	**1000** /100,000/year
Migrant of sub-Saharan origin	**240** /100,000/year
IDU	**91** /100,000/year

[7] Estimations based on the number of new infections, less the number of deaths; or based on the evolution of the number of patients accorded ALD 7 assistance (infection by HIV and AIDS).

[8] InVS data.

[9] Plausible interval between 32,000 and 68,000 persons. (Source : *2010 Experts Report, op. cit.*).

[10] FHDH-ANRS CO4 data. Between 2000 and 2008, the proportion of persons screened at the stage of AIDS or with a level of CD4 cells < 200/mm^3 fell from roughly 28% to roughly 22%.

could thus be considered to be **in a situation of delay in diagnosis and onset of treatment**[11], with consequent **considerable increases in morbidity and mortality**. We note that these recommendations are likely to evolve rapidly, towards even earlier onset of treatment -- given its demonstrated benefit -- and this evolution will continue to increase the already considerable proportion of persons whose access to treatment is tardy, and therefore non-optimal, because of delayed diagnosis.

This delay in diagnosis does not affect all population groups uniformly. Delays in screening are relatively less significant in MSM, and to a lesser extent in women, due to the effect of systematic proposals of screening during pregnancy. However it is particularly evident in **population groups that do not consider themselves at risk.** Thus, despite the concentrated character of the epidemic in continental France, the question of delays in screening and onset of treatment is particularly acute in communities that are more diffuse within the so-called "general" population than in those groups traditionally targeted by prevention and screening campaigns.

A PARADIGM SHIFT IS INDISPENSABLE TO CREATE A NEW ARTICULATION OF THE STRATEGY FOR FIGHTING THE EPIDEMIC THAT FOCUSES ON SCREENING AND TREATMENT

Delays in screening and access to treatment lead, for the individuals concerned, to a **considerable loss of therapeutic opportunity**. In collective terms, the benefit of early screening and treatment has been widely demonstrated: infected persons who know their serological status **are more likely to adopt prevention behaviour;** additionally, by reducing the quantity of virus in the blood, treatment **strongly reduces the risk of secondary transmission** of the virus.

Reducing the proportion of infected persons who are not aware of their status, in order to increase the proportion of persons treated in a timely fashion **("more and better screening to treat more people earlier")** should therefore be the **number one priority of the government in this field**, both in order to reduce morbidity and mortality (and thus improve the life-expectancy and quality of life of infected persons), and on a public health perspective, in terms of controlling the epidemic. Improving the timeliness of screening and access to treatment opens up the possibility of stabilising and **pushing back the epidemic, in France and in the world.** The effectiveness of current and future treatments, via their impact on secondary transmission, may lead to a reduction of incidence in proportions such that a reduction of prevalence may be envisaged. However, this effect will only be obtained if the proportion of infected persons who are diagnosed and treated increases sufficiently[12].

There is consensus about these objectives within the community of experts and actors, both internationally and in France. In a country such as France, where treatments are widely accessible and correctly compensated by the system of health insurance, efforts should principally be directed to **improving the performance of the screening system,** in order to diagnose more infected persons and insure a seamless hand-over from diagnosis to the system for medical care. Secondly, for the same reasons, the objectives of prevention messages should be redefined, in order to integrate and promote the notions that all persons can benefit from knowledge of their serological status, and that infected persons can thus benefit from early access to treatment.

France's screening policy and mechanisms have not significantly evolved since they were formulated in the late 1980s, although the epidemic and therapeutic contexts have been profoundly transformed. In this field, as the Court of Audit (*Cour des Comptes)* evaluation body recently demonstrated, **immobilism has predominated** for the past several years, **despite a number of converging evaluations** (ANAES 2000, CNS 2006 and 2009, National Report by the 2008 Expert Group, HAS 2009) and recommendations by various international institutions (WHO, UNAIDS).

Consequently, today there is a need for a **whole-scale redefinition** of screening policy and mechanisms, in order to create a **shift of scale** in terms of screening. Every additional year of delay in setting up a more effective screening system means new infections, increased complications during the evolution of the infection, and premature deaths that could have been avoided by more timely screening and treatment[13].

Following up the recommendations for screening that were formulated by the CNS in 2006[14], the High Authority for Health *(Haute Autorité de Santé,* HAS) began exhaustive work on the subject that was made public in October 2009,[15] and which involved very specific recommendations for improvement in this field. Although voluntary recourse

[11] Convergent estimates by InVS and INSERM.

[12] National AIDS Council, *Opinion and Recommendations Regarding The Potential For Treatment As An Innovative Tool For Fighting The HIV Epidemic*, April 9, 2009.

[13] Persons whose treatment begins at the stage of AIDS or when the CD4 count is lower than 200/mm^3 multiply by 14 their risk of dying within 6 months. After 4 years, 13,9% of them have died, compared with 3% of persons treated in a more timely fashion.

[14] National AIDS Council, *Report followed by Recommendations on the Evolution of Screening for HIV Infection in France,* November 16, 2006.

[15] Haute Autorité de Santé, *Dépistage de l'infection par le VIH en France. Stratégies et dispositifs de dépistage. Recommandations en santé publique*, October 2009.

to screening -- the basis of screening policy to date -- should continue to be encouraged and reinforced, the HAS particularly recommends **new strategies** aimed at systematically proposing the screening test both to the whole population, and also, at regular intervals, to targeted population groups. In particular, the HAS performed an economic evaluation that demonstrated a favourable relationship between the cost of the recommended measures and their efficacy.

THE DRAFT PLAN IS UNAMBITIOUS ON THE ESSENTIAL QUESTION OF SCREENING, AND ONLY PARTIALLY APPLIES RECOMMENDATIONS OF THE HAS

The National Conference on Health and the National Council on AIDS feel that the strategy note that they have received does not give sufficient **priority or visibility** to the goal of improving the efficacy of screening and timely onset of treatment. The policies that it envisages are, in several sectors, considerably less ambitious than those recommended by the HAS. They appear to be in continuity of current policies and mechanisms and are not of a nature likely to induce the whole-scale paradigm shift and change of scale that are needed.

Close reading of the strategy note leads to an impression that its authors aim merely for a very relative decrease in new infections in France, limited to certain population groups. The note is characterized by an **abusive interpretation of the available data**, to say the least, since they do not in any way permit the affirmation that incidence "has been declining for ten years", as a title in the strategy note declares.[16] The constant increase of prevalence is registered, but the document notes neither the goal of decreasing it nor the means to do so. The document also observes the sizeable proportion of undiagnosed infected persons, and delays in diagnosis, but here too it fails to recognize any priority for this major challenge to public health.

Strategic Orientation #3, which deals with these questions, signifies the modesty of its ambitions with its title: "Clarifying prevention and reinforcing screening policy" is a far cry from the *redefinition* of prevention and screening policy which experts have unanimously called for.

Rather than any such 'clarification', the note's considerations regarding prevention appear above all indecisive. It reaffirms both the maintenance of the classic conceptual framework of prevention (condoms remain the foundation of prevention) and the need to develop other approaches given the relative failure of this strategy. However it then enumerates a number of techniques -- treatment as a prevention tool; "positive prevention" and the reinforcement of screening as an additional tool -- and suggests that it could be sufficient to simply juxtapose these alongside existing strategy. It sidesteps the challenge of **reshaping the discourse of prevention**, which would aim at strongly articulating these new approaches with each other and with the various other tools available, which naturally include condoms. The document also gives insufficient emphasis to the question of **knowledge of one's serological status** and its inscription within a more global perspective on sexual health, together with the construction by every person of prevention strategies that are adapted to his or her situation, constraints and needs.

However, the most disappointing aspect of the document is its recommendations regarding screening. Of the two sectors recommended by the HAS – new strategies, and reinforcement of existing mechanisms -- the former is reduced to a shadow of itself.

An essential pillar of the HAS recommendations[17] is not picked up by this draft National Plan. The HAS recommended, in order to "improve timely detection of HIV infection and reduce screening delays", the "**proposal of screening tests** (…) **to the whole population aged between 15 and 70 … irrespective of notions of exposure to particular characteristics or risk of infection."** This measure, which was to rest on a vast mobilisation of multiple actors in the field of health (and particularly general practitioners), was further intended to "modify **attitudes to screening for HIV infection"** and to "promote the idea that improvement of knowledge of one's serological status to HIV can lead to significant benefits, both for the individual and on a collective level, for the wider community."

It is important to recall that government officials mandated the HAS mission with particular regard to the objective of basing their policy decisions regarding screening on evaluations of cost and efficacy. Abandonment of this recommendation appears all the more **incomprehensible** since its favourable cost/efficacy ratio was clearly established by the HAS study. The strategic document offers no explanation for abandoning the measure, which marks the refusal of the authorities to commit to a **deliberate strategy of a broader and less dramatic offer of screening,** which has for several years been recommended by all expert bodies in the field.

Regarding **targeted proposals of screening --** either for various population groups identified as particularly high risk, or in certain specific circumstances -- the strategy note only partially and minimally picks up the recommendations formulated by the HAS, while also restricting their impact or the scope of their field of application.

[16] There are no data for incidence regarding the past ten years that are comparable among themselves. Additionally, the 22% decrease in the number of new infections between 2003 and 2008 that is alleged in the strategy note cannot, for various methodological reasons, be considered statistically significant.

[17] Haute Autorité de Santé, *op. cit.*, synopsis, October 2009.

The principle of **annual proposals for screening** is retained for MSM and persons originating in sub-Saharan Africa and the Caribbean who have had more than one sexual partner during the preceding year, as well as for IDU. In addition, annual screening is to be systematically proposed, within the context of recourse to medical care, to the entire population of French Guyana, given the specific epidemiological situation of that Department. Indeed, the particular attention paid to French Guyana by the strategy note deserves to be highlighted. However, because of the absence of any information on the specific target programs for Overseas Departments and Territories, it is impossible to evaluate the mechanisms and budget that are proposed to attain this objective.

Meanwhile, **other target groups,** for whom the HAS also recommends the organisation of proposals for screening at regular (but unspecified) intervals, have been excluded. They include heterosexual persons with more than one sexual partner in the preceding 12 months, populations of the other French Departments in the Americas, persons in situation of prostitution, and persons whose sexual partners are infected with HIV. Moreover, the strategy note ignores the recommendation for **systematic proposal of the screening test in certain specific circumstances** (abortion, imprisonment, and suspicion or diagnosis of STI, hepatitis B or C or tuberculosis).

> The National Conference on Health and the National AIDS Council recommend that the National Plan should define and declare its priority to be **a significant decline of the number of new infections in all population groups.** To attain this goal the plan must:
>
> - aim for a **whole-scale paradigm shift and change of scale in terms of screening strategy** and a new articulation between screening, treatment and prevention of transmission.
> - use without restrictions **all the recommendations of the HAS**, and in particular those aimed at **a broader scope of screening, proposed to the entire population without regard to notions of exposure to a risk of transmission.**

II. ALIGNING PUBLIC POLICIES FOR GREATER CONSISTENCY WITH PUBLIC HEALTH IMPERATIVES: A CHALLENGE THAT IS UNDER-RECOGNIZED, LEADING TO SCANT PROPOSALS

PUBLIC POLICIES ARE CONTRADICTORY IN MANY WAYS, TO THE DETRIMENT OF THE MOST VULNERABLE POPULATIONS

Evaluation of the 2005-2008 National Plan, which was undertaken by the General Directorate of Health (*Direction générale de la santé*, DGS), as well as the body of expert advice produced by all actors engaged in the fight against HIV-AIDS in the past few years, strongly support the observation of **growing contradictions between the imperatives of public health and other public policies,** particularly those relating to questions of security and control of immigration. These contradictions strongly curtail the work of prevention, access to care and reduction of risks that are aimed at migrants and populations identified as vulnerable in the new Plan for 2010-2014: persons in detention; drugs users; and persons in situations of prostitution.

Migrants find it increasingly difficult to access the health-care system and welfare coverage, particularly if these persons are in an irregular situation with respect to immigration status, and even if their state of health does in principle justify their right to remain on French territory. The provisional authorisation to reside in France ("*autorisation provisoire de séjour*"), which is often issued in place of a temporary right to residence, does not permit access to sufficient health insurance coverage and involves no legal right to work. Foreigners who are not documented immigrants and who cannot document more than three months' residency in the country are not given access to State Medical Aid (*Aide médicale d'Etat,* AME). Furthermore, in practice there are a number of difficulties with the AME. Ignorance about the right to health coverage and the application process, as well as the slow pace of the administrative procedures involved, delay effective access to this mechanism, and many migrants who do benefit from access to the AME have been met with refusals of services by primary-care doctors[18]. These obstacles **cause delays in screening** and in access to treatment, with potentially serious consequences. They also accentuate poverty and insecurity, which is the most significant cause of poor observance of treatment among migrants.

Persons in detention do not benefit from satisfactory conditions, particularly persons living with HIV, and their access to authorized risk-reduction tools is **limited, varying widely** according to the penal institution concerned. Prevention of exposure to sexual risk is limited to the proposal of a screening test and access to condoms, which is not always optimal during detention. The sexuality of persons who are in the hands of the judicial system, and the sexual violence suffered by some detainees, are not sufficiently taken into account. Harm reduction in terms of drug use remains limited and highly variable across the territory of France[19], despite a high prevalence of HIV-AIDS and Hepatitis observed at entry to numerous penal institutions[20], as well as a significant proportion of injectable drug users in the prison population and demonstrable clandestine injection practices within certain detention centres. The establishment and generalisation of **mechanisms for harm reduction whose feasibility and efficacy have been proven --** such as the syringe-exchange programs that are freely accessible in the general community -- remains blocked.

Drug users who, outside the context of detention, practice sniffing, inhalation and injection, do not receive enough information and can benefit from **no structure to assist or supervise their usage,** despite the existence of groups involved in the field of risk reduction (CAARUD[21]) and care for addiction (CSAPA[22]). The absence of any drop in practices of heroin injection; new practices concerning cocaine injection; and increases in sharing of syringes, material for preparation, and poly-consumption -- particularly among young people less familiar with risk reduction[23] -- have led to fears of a disturbing incidence of Hepatitis C and HIV[24]. The risk of transmission remains high, confirming that despite unfavourable legislation, there is a need for powerful and innovative programs of information and assistance.

Persons in situations of prostitution have in the past ten years seen a very clear deterioration of the conditions in which they work, partly linked to legislation on soliciting. Increasingly tough regulations, which force prostituted persons into situations of clandestinity, increase their social exclusion, stigma and insecurity -- conditions that are

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[18] Boisguérin B., Haury B., "Les bénéficiaires de l'AME en contact avec le système de soins", *Etudes et résultats*, #645, DREES, July 2008.

[19] Ministère de la santé et des sports, *Plan d'actions stratégiques. Prise en charge des personnes détenues*, *in press*.

[20] Mouquet M.-C., "La santé des personnes entrées en prison en 2003", *Etudes et résultats*, # 386, DREES, March 2005.

[21] Centres d'Accueil et d'Accompagnement à la Réduction de risques pour Usagers de Drogues (Centers for the Accompaniment of Risk Reduction for Drug Users) created by law # 2004-806 of August 2, 2004.

[22] Centres de soins d'accompagnement et de prévention en addictologie (Care Centers for the Accompaniment and Prevention of Addictions) created by decree # 2007-877 of May 14 2007.

[23] OFDT, *Prévalence de l'usage problématique de drogues en France - estimations 2006*, June 2009.

[24] "Coquelicot" study *in* BEH # 33, September 5, 2006.

particularly acute among migrants involved in prostitution and among victims of human trafficking and exploitation. Current regulations complicate considerably the work of prevention, health-care access and risk reduction, and durably undermine the social context of populations[25] among whom the prevalence of HIV/AIDS is higher than in the general population: migrants of sub-Saharan origin in situations of prostitution; MSM; transsexual or transgender persons.

Concerning all the persons identified by the Plan, strategies for fighting the epidemic of HIV/AIDS, Hepatitis and STIs must, if they are to be effective, be based on **lifting the legal, regulatory and political obstacles** that may prevent access to prevention and care for the populations that are the most vulnerable and the most exposed to the risk of transmission.

A DRAFT PLAN THAT SIDE-STEPS CONTRADICTIONS AND FIXES NO CLEAR GOAL

The strategy note communicated by the General Director of Health **fails to focus on the need for consistency** between health policies and other public policy questions. A strategy note should lay out the context in which policies may be deployed, and **the difficulties encountered by the most vulnerable persons and the actors in the fight against HIV**. It should present a range of solutions in response to these constraints, in terms of actions and improved coordination. Regarding this last point, the Plan highlights a desire for coordination with other Ministries in its Orientation #4, but the text remains unclear regarding the prerogatives of the Ministry in charge of Health in piloting such coordination.

> The National Plan for HIV/AIDS-STIs should promote **an effective and universal right to health**, to sufficient health insurance, to conditions for life and lodging compatible with health, and to the range of existing mechanisms of prevention, risk reduction and assistance that are adapted to the various types of risk exposure, therapeutic follow-up and social context that are encountered, particularly by the most vulnerable persons.
>
> The National Conference on Health and the National AIDS Council recommend:
>
> - **alignment of public policy for greater consistency** between health policies and other types of public policy, notably in the fields of immigration, security, justice, housing and employment.
> - **greater concertation and collaboration** between Ministries and administrative bodies, in which the interests of public health should dominate.
> - **more effective response to impact studies** on the action of public policy, particularly to evaluations of difficulties encountered by actors in the fight against HIV/AIDS in the current legislative context.

[25] Guillemaut F. (dir.), *Etat des lieux des actions de prévention VIH auprès des personnes prostituées : étude préliminaire sur Toulouse, Lyon, Paris, Rennes*, December 2008.

III. FRANCE'S ACTION IN THE WORLD IS ABSENT FROM THE NATIONAL PLAN, CONFIRMING THE DECLINE OF FRENCH LEADERSHIP OF THE GLOBAL MOBILISATION AGAINST THE PANDEMIC

ACHIEVEMENT OF THE GOAL OF UNIVERSAL ACCESS TO TREATMENT IS UNLIKELY IN THIS CONTEXT

The number of persons living with HIV in the world is estimated at 33.4 million; this has tripled in the past twenty years. Roughly 2.7 million persons were infected in 2008, and the number of deaths attributed to illnesses linked to AIDS is estimated at 2 million in 2008[26]. Access to anti-retroviral treatments was multiplied tenfold between 2003 and 2008: 42% of the 9.5 million people living with HIV (PLHIV) who were eligible for treatment in countries with weak or medium level development were able to benefit from access to treatment in 2008, compared with 7% in 2003[27]. However, **the goal of universal access to treatments in 2010 has not been met,** and 5 million persons were deprived of treatment in 2008 in less developed countries, despite a very high degree of mobilisation.

In September 2000, the Millennium Development Goals (MDG) of the United Nations gave a central place to the fight against HIV-AIDS in the 21st century. Moreover, at the Gleneagles Summit in 2005, the G-8 member states committed to the goal of universal access to treatments in 2010. The following year, the member states of the United Nations, meeting within the framework of the UNGASS (United Nations General Assembly Special Session), adopted a political declaration that reinforced the MDG and specified their commitment to exceptional measures aimed at reaching universal access to prevention, treatment, care and support in the field of HIV in 2010. The financial contributions of the G-8 member states to various multilateral and bilateral programs were not, however, as significant as the goals these same countries had fixed. Additionally, **among the consequences of the financial crisis** there has been a decline in the bilateral aid of many donor states; dwindling national HIV/AIDS programs in many of the most affected less developed nations[28]; and stagnation of innovative financial instruments, particularly the solidarity levy on airline tickets.

However, the global plan's needs are considerable. Improvement of the scope of health care has contributed to an increase of the number of persons living with HIV, who require lifelong treatment. The goal of timely screening and access to treatment also leads to an increase in the number of persons eligible for treatment according to the new international guidelines.

The cost of first-line treatments is limited. However, the **cost of second- and third-line treatments,** for which no generic medications exist, **together with their delivery costs, remain very high,** and this partially explains their poor accessibility[29]. The cost of second-line therapy is, depending on the case, between 10 and 20 times higher than the cost of first-line therapy in a less developed country. Discussions on "patent pools", which began at the end of 2006, may lead to considerable declines in the cost of therapy by encouraging the production of generic medications in less developed and medium developed countries. However, there is difficulty in achieving agreements to this effect. Meanwhile, the cost of tests (screening, viremia measurement) -- which rarely include operational costs and salaries -- are steadily rising.

THE COLLAPSE OF FRENCH LEADERSHIP IS VISIBLE IN THE DRAFT NATIONAL PLAN

In this difficult international context, French mobilisation is vital. **France has historically been highly involved in this struggle, due to a series of pioneering initiatives** that significantly contributed to shaping the goals and instruments of international intervention from the mid-1990s to the middle of the first decade of this century: commitment as of 1997 to promoting access to antiretroviral treatments in the Third World (at a time when the concept was seen as unrealistic by most other nations); creation of the ESTHER network[30] in 2002 ; creation of the Global Fund in 2002; launch of innovative financial mechanisms and creation of UNITAID in 2006. These initiatives were backed with considerable financial commitments of an often exemplary nature, likely to create a follow-up effect within the international community.

In comparison with this period **the collapse of France's leadership is highly apparent today.** New initiatives are absent. Budgets remain considerable, but are significantly lower than France's international commitments. There is

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[26] UNAIDS, *AIDS Epidemic Update 2009*, December 2009.

[27] WHO, UNICEF and UNAIDS, *Towards universal access. Scaling up Priority HIV/AIDS interventions in the Health Sector, Situation Report*, 2009.

[28] According to a study by the World Bank, UNAIDS and WHO, on a sample of 69 countries including roughly 60% of the people benefiting from anti-retroviral treatment world-wide, close to one-third of countries plan budget restrictions on programs for access to treatment. The World Bank, *Averting a Human Crisis during the Global Downturn. Policy Options from the World Bank's Human Development Network*, April 2009.

[29] 2% of persons living with HIV benefit from second-line therapy in less developed and medium developed countries, according to WHO, UNICEF and UNAIDS, *op. cit.*

[30] *Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau,* a hospital-based network of solidarity.

no durable or consistent engagement in the bodies of international governance, an absence of follow-up of MDG that have not been met, and an absence of strong, mobilizing communication in debates about values -- whether defending human rights, promoting action to assist the most vulnerable populations, or clear statements regarding questions of intellectual property.

The 2010-2014 National Plan side-steps the question of France's international commitments. The strategy note communicated by the General Director of Health makes a number of general statements in its introduction regarding the broader challenges of development aid policy, producing a cloudlessly rosy vision of France's current action and financial efforts. However, the Plan itself develops no perspectives for future action, particularly in terms of access to treatments. Unlike this National Plan for 2010-2014, the previous Plan for fighting HIV/AIDS in 2001-2004 noted the major global objective of reducing inequalities in access to treatments between developing and industrial countries, and recommended that a network of solidarity regarding treatment be set up, alongside support for research in developing countries.

> France should **regain its leadership position** in the global fight against HIV/AIDS, in order to attain the Millennium Development Goals and to achieve, alongside all mobilized states, **universal access to screening and treatments,** particularly in less developed and medium developed countries.
>
> The National Conference on Health and the National AIDS Council recommend particularly:
>
> - Renewal of the strategic goals of the 2001-2004 National Plan for the fight against HIV/AIDS, at levels at least equivalent (in constant terms): **a network of solidarity regarding treatment** and **support for research in developing countries.**
> - The highest level of mobilisation regarding major international meetings, **particularly the Summit on the Millennium Development Goals and the G-20**[31].

[31] France will be taking on the role of President of the G-20 as of November 2010.

IV. DRAWING UP THE PLAN SHOULD BE A BETTER STRUCTURED PROCESS, AND CLEAR STATEMENTS ARE NEEDED REGARDING ITS ARCHITECTURE FOR GOVERNANCE AND FOLLOW-UP

THERE IS BROAD CONSULTATION OF ACTORS, BUT THE APPROACH IS TOO TECHNICAL AND INSUFFICIENTLY STRUCTURED, BLOCKING THE PARTICIPATION OF MANY GROUPS.

The process of drawing up the National Plan that was set up by the DGS was based on a broad consultation of the range of institutional, scientific and non-governmental actors, which took place between June and November, 2009. The National Conference on Health and the National AIDS Council **can only approve the principle of a broad consultation.** However the method for consulting these actors (particularly non-governmental organizations and associations) and the modalities for their work raise two reservations.

It is **neither intellectually coherent nor effective** to define a multiplicity of specific, highly separate fields for reflection and action, first laying out hundreds of action-briefs and subsequently reflecting about priorities. This method encourages specialized, technical discussions, to the detriment of debates on the overall strategic orientations of health policy, and it is doubtless one of the main causes of the Plan's lack of visibility and its **absence of powerful thematic directions**. The juxtaposition of hundreds of actions -- whatever the intrinsic pertinence of each action involved -- cannot contribute to the definition of a health policy. It would have been logical and preferable to **begin the consultation with discussion of the broad goals and priorities;** once these were clarified and the relevant decisions established, action-briefs could have been developed within this framework of structure.

Construction of the Plan involved contributions from numerous non-governmental associations, in the conceptual phase and during the establishment and editing of recommendations in the form of action briefs. These non-governmental associations were deeply implicated in the discussions and preparation of the Plan and its main goals. The authorities need to benefit from expertise that is plural, and which reflects the realities and diversity of the situations encountered in the field. However, **the scale of the contribution demanded from these non-governmental actors** in constructing the Plan (hundreds of hours of volunteer work, meetings, drafting and editing working documents) **may have discouraged certain among them from participating** in this background work, for fear of jeopardizing their budgets and pulling their workforces (whether volunteer or paid) away from their own work. The authorities should be attentive to the need to preserve a diverse range of non-governmental actors; the efficacy of major action programs on a national scale needs to be balanced with the specific characteristics of more modest programs. The Ministry of Health should be responsible for setting up mechanisms for governance, during both the conception and the follow-up of the Plan, which **insure a plurality of representation of non-governmental and associative actors.**

> The National Conference on Health and the National AIDS Council recommend that while the Plan is being drawn up, officials should:
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> - **Concentrate consultation of actors,** particularly non-governmental associations, **on the broad challenges of the fight against HIV and the main priorities of public action,** leaving more technical construction of programs to follow at a second stage.
> - Guarantee the non-governmental associations involved **sufficient means** for them to participate fully in this consultation and in the subsequent governance of the Plan, with the aim of **encouraging the expression of their diversity.**
> - Encourage the emergence of **forms of inter-association coordination and representation,** notably in the less structured sectors of the fight against HIV/AIDS: community health associations in French territories in the Americas; associations working with drug-users; community health associations working with persons in situations of prostitution; associations active in assisting with integration into employment and society.

ORGANISATION OF THE GOVERNANCE, FOLLOW-UP AND EVALUATION OF THE PLAN SHOULD BE CLARIFIED

The National Conference on Health and the National Council on AIDS are glad to observe the project's attention -- notably in Strategy Orientation #4 -- to **the Plan's governance, follow-up and evaluation.** This responds to lacunae that have been repeatedly noted in both the Plan's predecessors. However, the architecture and tools proposed in the strategy note raise several queries.

According to the proposed architecture, follow-up and steering of the Plan principally resides with two bodies to be created: a **Committee of National Follow-up** (*Comité de suivi national*, CSN), possibly to be presided by the Minister responsible for Health, and a **Compact Committee for National Steering** (*Comité de pilotage national resserré*, CPNR), under the aegis of the DGS Division for Prevention of Infectious Risks. Additionally, the regionalisation of responsibilities for health that followed creation of the Regional Health Agencies (*Agences Régionales de Santé,* ARS) confers on them a major role in the adaptation and practical aspects of the National Plan through Regional Health Plans (*Plans Régionaux de Santé,* PRS) -- thus giving, *de facto,* a major role to the **Regional Health Agencies National Committee for Steering** (*Comité national de pilotage des agences régionales de santé,* CNPARS), which becomes the Plan's third pillar of governance.

The National Conference on Health and the National AIDS Council wish to highlight, firstly, that the project proposes an architecture of governance specific to the National Plan for HIV/AIDS-STI, reversing the preference for unified governance of the diverse plans for public health.

Creation of the CSN and the CPNR, possibly inspired by the recent criticism of the Court of Audit regarding the organisation of public policy in the fight against HIV/AIDS, appears to respond to legitimate preoccupations -- to **insure the highest level of political follow-through and support** (CSN) and to set up an observatory for follow-up as well as a reactive and effective executive (CPNR).

However, **the rules of relationship between these two bodies is not clearly defined.** Although it appears that the CSN will be charged with the orientation and adjustments to the Plan while the Plan is in effect, its powers with respect to the CNPR and more generally, the Ministerial sectors concerned, are not specified, notably regarding a scenario in which the CPNR or various services would not follow through the orientations validated by the CSN. The articulation of the relationship between the CSN and CNPARS is subject to the same type of questions. Thus within the bi- or tri-partite architecture that is proposed, **the position of pilot is too unclear**.

Over and above the question of the link between CSN and CNPARS, the articulation between national governance of the Plan and the ARS should also be clarified. Given the logic of autonomous agencies and the CNPARS role as head of network, **it would seem coherent for the CNPARS to issue orders for the health agencies**. The CNPARS is responsible for:

- fixing quantified goals for the agencies;
- insuring that the agencies use the services of the COREVIH in elaborating the HIV sections of regional health plans;
- insuring that these agencies ' commissions for the coordination of prevention and medico-social commissions approach these challenges without ignoring their transversal character;
- participating in improving the structure of and support for prevention actors;
- recommending that responsibility for public debate of the regional health conferences, and their autonomy, allow better control of regional choices in this field.

Regarding the place of **Regional Coordinations for the Fight against HIV** (*Coordinations régionales de lutte contre le VIH*, COREVIH) within this mechanism, it would be appropriate for the strategy note to observe more explicitly that their triple mission (coordination of all actors, contribution to improvement of the quality of care and the harmonisation of practice, analysis of the medical and epidemiological data) should give them **a legitimate role as interlocutor and privileged partner of the ARS bodies** in the elaboration of the regional adaptations of the National Plan, as well as in its follow-up and evaluation.

> The National Conference on Health and the National AIDS Council **clear and precise definition of the role, the responsibilities and the respective prerogatives of the various bodies charged with setting up, following up and potentially revising the Plan**. In particular this should involve:
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> - Specifying the **prerogatives of the CSN** with respect to other bodies;
> - Clarifying the **articulation between national decision-making and the ARS agencies** responsible for effecting the National Plan on a regional level;
> - **Greater emphasis on the role of the COREVIH** in support of the ARS in the elaboration of the HIV sections of the regional health plans, which take into account both the specific characteristics of regions and the thrust of the National Plan.

CERTAIN PRIORITY INDICATORS FOR FOLLOW-UP AND EVALUATION SHOULD BE SPECIFIED

The strategy note is at present mute regarding **indicators for follow-up,** and gives responsibility for their definition particularly to the High Council of Public Health (*Haut Conseil de la Santé Publique,* HCSP), the body that is also responsible for the final evaluation of the Plan.

Given the priority that should be given to improving the efficacy of screening and early access to treatment, the National Conference on Health and the National AIDS Council deem that the strategy note, by virtue of its nature as a preamble laying out the major orientations of the Plan, must **explicitly enunciate the principle indicators of efficacy** regarding this essential objective.

> The National Conference on Health and the National AIDS Council recommend that the **effectiveness of the Plan** should be evaluated principally on the basis of the following markers:
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> - The goal of reducing delays in screening and improving the timeliness of health care should translate into **increased levels of CD4s** noted, respectively, **at the time of screening and at the onset of medical care**.[32]
> - The goal of reducing the proportion of undiagnosed infected persons should translate into **a number of discoveries of seropositivity that is durably and significantly higher than the number of new infections**.[33]
> - The two goals should translate into **a decrease in the number of cases of AIDS and the number of deaths,** figures that are currently stable.[34]

THE ROLE OF THE NATIONAL AIDS COUNCIL IN THE PROCESS OF FOLLOW-UPAND EVALUATION OF THE PLAN MUST BE SPECIFIED

Strategic Orientation #4, which lays out the modalities for follow-up and evaluation of the Plan, gives no indication of the **role assigned to the National AIDS Council.** As an independent consultative body, the mission of the CNS is not to participate directly in defining and setting up public action within the framework of the two bodies envisaged by the Plan. However, it should be consulted regarding programs for fighting HIV/AIDS, and consequently, regarding modifications that may be made to the Plan and to its programs by the two follow-up bodies. Responsibility for **calling on the CNS to deliver opinions** rests with the CSN, Committee for National Follow-Up. The CSN may also call the National AIDS Council to hearings, if it deems that this would be useful to clarify its work.

> Consequently, the National Conference on Health and the National AIDS Council hope that:
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> - the missions of the CNS regarding the mechanisms for steerage of the Plan can be specified;
> - the CNS can be **regularly kept informed of the work of the CSN, and the elements for follow-up and evaluation** that are in the hands of the CPNR.

[32] Data from the Obligatory Declaration of HIV to the Institut de Veille Sanitaire (OD-HIV-InVS) and DMI2/DOMEVIH data (INSERM).

[33] Data from OD-HIV-InVS and estimates of incidence (InVS and INSERM).

[34] Data from OD AIDS (InVS).

SUMMARY

The National AIDS Council and the National Conference on Health adopted a joint Opinion on June 17, 2010. Following examination of the strategy note that was submitted to them, the two bodies consider that the **draft National Plan for 2010-2014 does not respond adequately to the current challenges of the fight against HIV and STI**, and recommend a whole-scale revision of the project that takes into account their observations and recommendations in the following four areas:

SCREENING AND TREATMENT

The first objective and priority of the Plan should be clearly and explicitly stated to be **a significant decline in the number of new infections in all population groups**.

It is necessary to reduce the proportion of persons who do not know that they are infected by HIV. Currently, **one in two infected persons makes contact with the screening and health-care systems too late,** with serious consequences, both for the individual involved and for public health. This objective presupposes a **real shift of paradigm and scale in terms of screening strategy,** to permit earlier access to treatment, which will have significant impact on the prevention of transmission.

To achieve this, it is indispensible that the Plan should take up, without restrictions, **all the recommendations of the High Authority for Health**, particularly those aimed at **expanding proposals of screening to the general population, without regard to notions of exposure to a risk of transmission.**

MORE CONSISTENT PUBLIC POLICY

The Plan should contribute to guaranteeing **universal access to prevention and care,** particularly regarding the most vulnerable populations and those at highest risk of infection by HIV and STI. These include, specifically, **migrant persons,** notably undocumented immigrants; **persons in detention; drug users; and persons in situations of prostitution.**

Contradictions between health policies and other public policy, particular in the sectors of security and immigration, are obstacles to the work of prevention, risk reduction and access to care. Thus it appears necessary to **remove the contradictions between public policies** in the interests of the imperatives of public health.

Consultation and cooperation between the Ministries and the Heads of Administration should be significantly reinforced. **Impact studies,** particularly regarding the difficulties encountered by the actors of the fight against HIV **in the context of current legislation**, should be given greater weight.

FRANCE'S ACTION IN THE WORLD

The Plan should define areas for intervention within the development aid sector, and should contribute to responding to the goal of **universal access to anti-retroviral treatments** in less developed countries, which was defined in 2005 and intended to be met in 2010.

To make up for its delay, following **the collapse of its leadership** towards the end of the first decade of this century, France should reposition itself **at the head of initiatives** in favour of the global struggle against HIV/AIDS, particularly during the following international meetings: Summit on the Millennium Development Goals, and France's Presidency of the G-20.

This high level of mobilisation should be reflected in the Plan, which should reprise the strategic goals of the 2001-2004 National Plan for the fight against HIV/AIDS at levels at least equivalent (in constant terms): **a network of solidarity regarding treatment** and **support for research in developing countries.**

CONSTRUCTION, FOLLOW-UP, EVALUATION AND GOVERNANCE OF THE NATIONAL PLAN FOR HIV/AIDS-STI

Consultation of all the actors involved in the fight against HIV and STI should continue to be a feature of the Plan's construction, but it should be **focused on the broad goals and priorities of public action.** Officials should be attentive to the need to encourage **expression of the diversity of non-governmental and associative actors**.

Organisation of **the governance of the plan remains unclear**. The role, responsibilities and respective prerogatives of the various bodies involved in administering, following up and evaluating the Plan should be specified. The articulation between the national decision-making level and the **Regional Health Agencies** (ARS) should be clarified, and the **role of the COREVIH**, as priority partners of the ARS, should be further emphasized. The follow-up and continuous evaluation of the Plan should be based on **key indicators of efficacy,** particularly those that permit measurement of **improvement in the timeliness of screening and access to medical care**.