



**National Consultative Ethics Committee for  
Health and Life Sciences**

**OPINION N° 119**

**Ethical Issues Raised by the Marketing of HIV Self-Screening  
Test Kits**

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# Summary

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## Key to Abbreviations:

<b>AIDS</b>	Acquired immunodeficiency syndrome
<b>ANRS</b>	<i>Agence nationale de recherches sur le sida et les hépatites virales</i> (National Agency for Research on AIDS and Viral Hepatitis)
<b>ANSMPS</b>	<i>Agence nationale de sécurité du médicament et des produits de santé</i> (National Agency for the Safety of Pharmaceutical and Health Products)
<b>CCNE</b>	<i>Comité consultatif national d'éthique pour les sciences de la vie et de la santé</i> (National Consultative Ethics Committee for Health and Life Sciences)
<b>CDAG</b>	<i>Centre de dépistage anonyme et gratuit</i> (Anonymous free of charge Screening Centre)
<b>CDC</b>	Centers for Disease Control and Prevention (United States)
<b>CNAM</b>	<i>Caisse nationale d'assurance maladie</i> (French National Health Insurance Fund)
<b>CNS</b>	<i>Conseil national du sida</i> (French National AIDS Council)
<b>DASRI</b>	<i>Déchets par activité de soin à risques infectieux</i> (infectious clinical waste)
<b>EC</b>	European Community
<b>ELISA</b>	Enzyme-Linked Immunosorbent Assay
<b>EU</b>	European Union
<b>FDA</b>	Food and Drug Administration
<b>HAS</b>	<i>Haute autorité de santé</i> (French National Authority for Health)
<b>HIV</b>	Human immunodeficiency virus
<b>INSEE</b>	<i>Institut national de la statistique et des études économiques</i> (National Institute of Statistics and Economic Studies)
<b>NGO</b>	Non Governmental Organization
<b>PACA</b>	Provence-Alpes-Côte d'Azur Region
<b>TDR</b>	<i>Test de diagnostic rapide</i> (Rapid Diagnostic Test - RDT)
<b>TROD</b>	Test rapide d'orientation diagnostique (rapid diagnostic test for referral)
<b>USA</b>	United States of America

## I Introduction

In a letter dated August 8th 2012, the Minister for Health and Social Affairs referred to the National Consultative Ethics Committee for Health and Life Sciences (CCNE) on “issues raised by the marketing of HIV self-screening test kits HIV<sup>1</sup>”.

This followed marketing approval given by the American Food and Drug Administration (FDA) on July 3rd, 2012, for a rapid diagnostic home-use test kit (Oraquick®, by sampling of oral fluid) designed for self-screening without medical supervision. Since October 2012, the kit has been available for over-the-counter sales in more than 30,000 outlets in the United States and also via the Internet. Would this form of marketing be likely to reduce the number of new infections in France? And what ethical issues could it give rise to?

Generally speaking, the principle underlying self-testing is giving anyone who so wishes, the possibility of performing and finding out for themselves the results of a Human Immunodeficiency Virus (HIV) screening test, without needing anyone’s assistance, using a readily available shop-bought kit. Currently, it is possible to run such a test using a finger-prick drop of blood or saliva as samples. The results can be interpreted by the person concerned after a short wait of 20 to 30 minutes.

**The subject of ethical issues raised by the sale of self-tests** for HIV infection screening is not by any means new: several documents have already been published on the availability of such self-screening kits, both by CCNE in its Opinion n° 86 (November 2004) and by the French National AIDS Council (CNS) in 1998 and again in 2004. The recommendations made by these Opinions are shown in the Annexes to this document. They all urged caution in the use of self-test kits<sup>2</sup>, mainly because of the lack of professional medical support if and when an HIV-positive verdict was returned and the solitude of those concerned in the face of a situation with serious implications for themselves and potentially for other people. Other reasons were that such tests were not totally reliable, that non professionals might well have difficulty in running the test and interpreting its results, that there was a risk of gaining a false impression of security in the event of a false negative, thereby encouraging risk-laden behaviours, and finally the possibility that various forms of pressure might be put on people to take the test and read the results, thus threatening their privacy and autonomy. However, the Minister’s letter of referral also mentions that *“in the meantime, the HIV screening context has evolved considerably both in France and in other countries.”* This is also true of the management of HIV infection, the progression of the disease and the way it is perceived.

## II Access to screening and serology: the current situation

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<sup>1</sup> See Annex N°1

<sup>2</sup> See Annex N°2

## 1- Techniques and Procedures

Diagnosing HIV infection by identifying antibodies to the virus in the serum is an essential step towards both the therapeutic management of the infected person and prevention against further propagation of the disease. Anyone who wishes to, may have access to screening, either provided free of charge by the French national health insurance system, or anonymously and at no expense in a CDAG. The presence of antibodies indicates HIV-positive status while their absence defines HIV-negative status. In France, current estimations are that some 150,000 people are infected by HIV (prevalence being 0.23%), approximately 120,000 of them (80%) being aware that they are HIV-positive. It would therefore appear that a significant proportion of seropositive people, around 20%, i.e. 30,000 individuals, do not know that they are infected or HIV-positive, despite the considerable number of serological tests carried out per year in France (5.2 million, excluding the 2 or 3 million tests for blood donors)<sup>3,4</sup>.

It is clear from the above that there is still a need for building up access to screening and for improving its strategy and that developing the means to do so remains a priority.

### Two different serological techniques are in use:

- a) - The standard reference technique, called the “Enzyme-Linked Immunosorbent Assay” (ELISA) which detects the presence of antibodies to HIV and possibly of a virus fraction (antigen p24) in the serum or the plasma from a venous blood sample. Its efficacy and reliability, regularly tested, are excellent. Results are available one or two days after sampling.
- b) - Rapid diagnostic tests (TDRs): they detect the presence of antibodies to HIV using kits providing results in less than 30 minutes. They may use serum, plasma or whole blood (a drop of blood collected from a fingerprick sample), or even saliva. Results are obtained by a subjective colorimetric reading by the person performing the test. Efficacy and reliability are acceptable for most of the tests that have been validated, but are not quite as good as serological assays with the reference technique ELISA.

### Procedures

In France, there are no circumstances in which an HIV screening test can be performed without explicit consent from the person concerned.

- a. **Medical laboratories**, hospital-based or privately owned, use the ELISA reference assay for screening, provided free of charge by the national insurance scheme<sup>5</sup>.
- b. **Anonymous free of charge screening centres** (CDAGs), set up in 1987 in each of the French administrative areas (*départements*) use the ELISA reference technique to test anyone requesting screening in one of these centres. The results are disclosed by specially trained medical counsellors, and only to the person who asked for the test

<sup>3</sup> Delfraissy JF. Éditorial. Bull Épidémiol Hebd. 201 ; 46-47: 523-524.

<sup>4</sup> Cazein F. *et al.* Prevalence and characteristics of individuals with undiagnosed HIV infection in France. Evidence from a survey on hepatitis B and C seroprevalence. J. Acquir Immune Defic Syndr 2012 ;60 : e114-e116.

<sup>5</sup> Cazein F. *et al.* Dépistage de l'infection par le VIH en France, (Screening for HIV in France) 2003-2011. Bull Épidémiol Hebd. 2012 ;46-47 : 529-532.

to be done. Out of the 5.2 million ELISA assays performed every year, CDAGs do approximately 300,000.

- c. **TDRs** are sometimes used in healthcare settings to serve as an emergency procedure during the 24 to 48 hours required before the results of the standard ELISA test performed simultaneously become available.
- d. **TRODs:** TDRs may be used by doctors in private practice, nurses, midwives, members of approved associations who have been given appropriate training (decree dated November 17th, 2010). In that event, they are referred to in the French system as “*tests rapides d’orientation diagnostique*” (TROD) meaning a rapid diagnostic kit for the purpose of referral or guidance; they may be based on samples of whole blood, plasma and serum, but excluding saliva. The aim is to develop a kind of “non institutional” more user-friendly testing procedure, away from laboratories and healthcare institutions and therefore closer to people and places where a risk of contamination exists. The follow-on is that people are encouraged as a next step to get confirmation of test results through the standard reference ELISA assay.
- e. **Self-test kits.** The test procedures are TDRs and TRODs, but the test itself and interpretation of the results are performed by the person concerned, without any external help. Currently, reliability varies, in particular as regards sensitivity<sup>6</sup>, depending on whether the sample is whole blood or saliva and whether the tests are run in the presence of medical professionals or in truly self-testing situations by non professional, inexperienced people, acting on their own<sup>7</sup>. These important differences raise the issue of missed opportunity to obtain psychological and therapeutic care since there is no one present to provide counselling and because the tests themselves are less reliable in the hands of untrained people. However, at least in theory, such missed opportunity would be offset by a gain in autonomy.

## 2- Self-test kits

For such *in vitro* diagnosis medical equipment, classified as a “health product”, a European Community (EC) conformity marking is required before it can be marketed in Europe, and therefore in France, without the National Agency for the Safety of Pharmaceutical and Health Products (ANSMP) needing to take any direct action. Marking may be in the hands of industry itself or, as is the case for self-test kits, once a European Certificate of Conformity has been issued by a Notified European Body according to European Union (EU) regulations, from any country. However, a country’s national regulatory authorities may intervene to stop marketing if the product’s quality is found wanting. For example, the Oraquick® test, which can be used with whole blood, plasma, serum or saliva, has had EC marking (except for saliva-based testing) since 2007 but solely for professional medical use and therefore not for self-testing purposes. It cannot be legally marketed and sold to non professionals in Europe for use with any kind whatsoever of sample (blood or saliva).

The 9th November 2010 decree stipulates that French healthcare professionals can only use a TROD for screening using serum, plasma and whole blood samples, but not saliva. In

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<sup>6</sup> See annex N°3

<sup>7</sup> See annex N°3

contrast, the Oraquick® saliva test, which the FDA authorised for availability to the public at large in July 2012, has been authorised since 1994 for use in the USA as a TDR by professionals. Like any of the other existing self-test methods, it does have one drawback: results are not as reliable (a greater number of false negatives) as when the kit is used by a professional healthcarer. Currently none of the HIV self-test kits are entitled to an EC marking, and therefore they are not authorised in Europe.

Trading practices for these self-test kits are obscure, with aggressive marketing techniques prevailing, particularly on the Internet. Quality control of TDRs are limited to Europe and the USA. There is some confusion regarding industrial manufacturers, mainly based in Asia, with agents mostly active in Europe and the USA, while distributors operate in various countries. Furthermore, most of the major pharmaceutical companies have withdrawn from this market because they consider that the products are of less good quality than standard tests. This is all the more true of saliva-based tests in which the antibody count is lower.

Finally, these self-test kits are not suited to the detection of primary HIV infection. The negative **“window period”**, during which antibodies are not yet detectable, which lasts **10 or 12 days with the latest up-to-date ELISA tests, can be as long as several weeks and even as much as three months with the saliva-based self-test kits**. However, their speed and relative ease of handling by subjects on their own, and also the possibility of anonymous screening in a place of a person’s own choosing are undeniable assets.

### III - The epidemic and the disease, their perception; screening and self-testing

#### 1 - Development of the epidemic and of the disease

The development and availability as of 1996 of very active treatment against HIV infection have considerably modified the course of the disease by reducing the main complications, diminishing morbidity and mortality and achieving a life expectancy close to that of disease-free individuals. For this to happen, treatment must start sufficient early, conform to required prescriptions and be well tolerated by the patient. Such therapy reduces considerably the quantity of virus present in the body (viral load), including in mucosal secretions, thereby contributing significantly to reducing HIV contamination and, as a result, limiting the spread of the epidemic.

In France, some 80% of people who know that they are HIV-positive are under active and effective patient management, so that they can enjoy a quality of life that compares well with that of people suffering from an adequately controlled chronic disease. The psychological, emotional and social consequences, however, are still considerable and the root of possible discrimination.

Reliable annual epidemiological statistics have become available since 2003 with the introduction of anonymous mandatory notification of diagnosed HIV-positive cases, so that there are now instruments for evaluating the number of new contaminations annually, i.e. the incidence, which stands at approximately 6,000 to 7,000 per year<sup>8</sup>.

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<sup>8</sup> Of which, for 2011, 40 % involved men engaging in sexual activity with men and 40% migrant populations, two thirds of whom come from sub-Saharan Africa where prevalence of the disease is high. This data has remained fairly steady since 2003 with, however, a slight drop in the total number of new contaminations, including a relatively clear drop in new



## 2- Marketing authorisation for a saliva-based test in the USA was motivated by public health concerns.

We should first remember that public, collective health relates to health concerns involving or that could involve all or part of the population in a given area. It provides an essential complement to the medical care given to individuals and, more generally, to each person's chances of enjoying the best possible health. It is mainly focused on evaluation, prevention, prognosis and epidemiology with the aim of gaining insight on major trends in the health status of the population and of taking appropriate decisions in the event of a collective threat such as an epidemic. This task of protecting the health of its citizens is one of the constitutional obligations of the State and a citizen right that the Constitution guarantees.<sup>9</sup>

The prevalence of HIV infection in the USA (0.38% of its inhabitants) is more than one and a half times higher than in France (0.23%). The FDA's recent consent to making Oraquick® (a saliva-based self-test) available to the public was essentially based on public health considerations: it is estimated that 20% of HIV carriers in the USA (1.2 million people) are not aware that they are infected. They do not undergo treatment and are thought to be the cause of 70% of new infections. Based on a mathematical model<sup>10</sup>, the FDA evaluated the number of secondary contaminations that could be avoided according to the percentage of people — among those unaware of their HIV-positive status — who would avail themselves of the Oraquick® self-test kit.

### What is the situation in France? Would this line of reasoning apply here?

The organisation of access to screening is broader and more structured in France than in the USA, this for three reasons:

- a) Serology using the reference technique ELISA, either in a hospital or in a private test laboratory, is provided free of cost by the national health insurance system.
- b) The Anonymous free of charge Screening Centres (CDAG) have been using the same standard ELISA test since 1987, and
- c) TRODs have been in use since November 2010, in particular by non medical operators with appropriate training in the use of the technique, and also by members of associations. Evaluations of the system have demonstrated that it is effective and easy to implement. It provides rapid, assisted screening, in a non-institutional environment, in places or at times when people at high risk of contamination are

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seropositive cases diagnosed among migrants from sub-Saharan Africa. There are large regional disparities so that for instance in 2011, there was a great deal more screening and higher incidence in French Guiana, Guadeloupe, the greater Paris area (Ile de France) and the PACA (Provence Côte d'Azur) region than elsewhere. Epidemiological data on HIV infection and STIs. 30/11/2012. *Institut de veille sanitaire* (French Institute for Public Health Surveillance). [www.invs.sante.fr](http://www.invs.sante.fr)

<sup>9</sup> "Preamble to the (French) Constitution dated October 27th, 1946. Article 11. The Nation guarantees all its citizens, in particular children, mothers and elderly workers, **protection of their health**, physical security, rest and leisure. All those unable to work, because of their age, their physical or mental condition, or economic circumstances, are entitled to adequate support from the community."

<sup>10</sup> Audition of Dr. S. Le Vu

present, such as social gatherings, leisure settings, while they are on holiday and at recreational locations.

CCNE notes that the organisation and conditions of access to screening are attributable to national solidarity, in so far as they are entirely financed by the national health insurance system, are available throughout the country and by reason of the support provided by the presence of a professional healthcare worker or a properly trained member of an association, able to help and guide the person concerned to gain access to treatment in the event of a positive HIV serology test result. As noted by CCNE, the principles of justice, solidarity and equity are effectively served in the way access to screening is organised. Furthermore, due regard is given to personal autonomy since the decision to be screened is in the hands of the person concerned who must give prior consent, who enjoys the benefit of guaranteed confidentiality and, if he or she so wishes, may remain anonymous, as is the case in CDAGs.

The importance of not being left to one's own devices in such circumstances is fully understood and clearly expressed in the results of the webtest on the acceptability of self-testing procedures. Nearly 50% of people who, replying to the enquiry, say that they do not care to use a self-testing kit, give as their reason for this position that they would not wish to be alone if they discovered they were HIV-positive<sup>11,12</sup>.

There is no denying, however, that the percentage of contaminated people who are unaware of their positive serology in France is about the same as in the United States, since out of 150,000 people thought to be infected, 30,000 or 20% of them are not aware that this is the case. Furthermore, the frequency of infection discovered at a late stage, when patients are already symptomatic or even after the onset of the acquired immunodeficiency syndrome (AIDS), is still high, around 30%.<sup>13</sup> The French National Authority for Health (HAS) therefore recommends that screening should be offered at least once to all of the adult population and furthermore, a regular, repeated, targeted screening offer should be proposed to people who are specially exposed to a high risk of infection.

**In the circumstances, CCNE wonders whether there would be any residual advantage, in public health terms, in making self-testing kits available for sale.** As is the case for any public health action, an evaluation of the impact of the actual extent of their use will need to be done, based on epidemiological data. **CCNE notes the presence of a significant difficulty as regards public health:** HIV seropositivity detected by self-testing kits would not be the subject of mandatory anonymous notification, which would make it very difficult, or even impossible, to evaluate their possible contribution to the prevention and treatment of HIV infection. It is of course reasonable to suppose that a number of people discovering that they are HIV-positive would seek confirmation from a laboratory test, in which case their seropositive status would be subject to mandatory notification, thus limiting the decreased volume of epidemiological data collection.

However, CCNE continues to believe that apart from this evaluation issue, the absence of personal support when using self-testing kits is one of the main ethical problems that have already been highlighted in each of the Committee's previous negative Opinions on this

<sup>11</sup> Greacen T *et al.* Access to and use of unauthorized online HIV self-tests by Internet-using French-speaking men who have sex with men. *Sexually transmitted infections*. 2012 ;88 : 368-374.

<sup>12</sup> JFGreacen T *et al.* Internet-using men who have sex with men would be interested in accessing authorized online HIV self-tests. *Aids Care*. 2013 ; 25 : 49-54.

<sup>13</sup> Delfraissy JF. *Ibidem*, p.3

same subject<sup>14</sup>. This is all the more true because discovering a seropositive status is the cause of highly charged emotional reactions which can upset the fragile psychological balance of lonely and vulnerable people. It is also worth remembering that the FDA hesitated to authorise HIV self-screening tests in 1994 because it was feared that people discovering they were seropositive while they were on their own might decide to commit suicide.

Since the arrival on the scene of anti HIV treatment in 1996, however, HIV infection has become a chronic disease, although it is true that patients have to contend with therapeutic constraints, clinical monitoring and also some complications still. But the threat of early death due to AIDS is no longer nearly as ominous. Moreover, in France, no matter which screening method is used, discovering seropositivity would not be in itself a trigger for suicide attempts in view of the fact that screening has never so far been a solitary experience.

In fact, the impact on people's social, emotional, sexual prospects and on any child-bearing plans they might have, as well as the possibility of discrimination and the taboos encumbering the disease and its social representations, are the repercussions which are most feared by those concerned; in this respect, there has been little or no change over time. The intense reactions that an ordeal of this nature may precipitate could be significantly more difficult to bear by an isolated person.

### 3 – Who might be concerned by self-testing?<sup>15</sup>

Various enquiries to evaluate how acceptable self-test kits might be and what advantages could be perceived by people who already use them or who are possibly planning to use them. Mostly, these enquiries addressed men having sex with men, some of whom were already using self-testing kits accessible via the Internet. Most of them were interested in having kits available and considered that rapidity, confidentiality, sexual orientation not being disclosed, anonymity and availability from one's own home, were all clear advantages. In order, however, to avoid mistakes in handling and interpretation, some of the responders would have preferred to have some access to assistance with the self-testing procedure, either purely technical advice or counselling to refer to a more efficient screening structure<sup>16</sup>.

We should remember that the saliva-based Oraquick® self-test kit was authorised in the USA with the purpose of fighting the hidden epidemic which included people who were infected but did not know that, either because they were reluctant to access assisted screening procedures or because they did not know they were at risk of being infected. Studies have revealed that the 30,000 (20%) HIV-positive people who are unaware of their serostatus in France, are also in many cases people who are particularly exposed to the risk of HIV infection<sup>17</sup>.

Other enquiries showing the prevalence and incidence of HIV infection in men who have sex with men are evidence of the failure of screening and prevention policies<sup>18</sup>. There is,

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<sup>14</sup> See annex N°2

<sup>15</sup> See Annex N°4

<sup>16</sup> Greacen T. *Ibidem*, p.8

<sup>17</sup> See Annex N°4

<sup>18</sup> Le Vu S *et al.* *Incidence de l'infection par le VIH dans un échantillon d'hommes ayant des relations sexuelles avec des hommes à Paris.* (Incidence of HIV infection in a sample of men who have sex with men in Paris) Enquête Prévagay 2009 ANRS-InVS. Bull Épidém Hebd. 2012 ; 46-47: 537-540.

therefore, reason to believe that making available for sale self-testing HIV screening kits, suitably regulated by the authorities, could be a complement to the range of screening options for their use so that, however tenuous, no possibility is ignored in the fight against this failure to achieve results for people who are at high risk of HIV contamination.

If these self-testing kits were to be put on the market, they should be made accessible by appropriate methods to migrants who are also vulnerable to HIV infection, as well as to the population as a whole. The authorities would need to circulate easily comprehensible instructions for their use. Family doctors and general practitioners could help spread the information, encouraging those in their care to take the tests and even, in some cases of reluctance or personal preference, provide their patients with appropriate self-testing kits. Similarly, some relevant associations, those for instance specialising in fighting HIV and AIDS, or in assistance and support to migrants, could also be supplied with self-testing kits for distribution to people whose special circumstances warrant it. Associations providing assistance to people in precarious social and economic circumstances could also help out in the same way. It is a known fact that people in the lower income brackets are 1.7 times more likely to have never been screened for HIV than their counterparts of the same gender and age-group<sup>19</sup>.

It is, however, probable that use of these self-test kits would be rather limited in population groups less exposed to risk, in view of the already existing availability of screening facilities and the number of standard testing procedures currently available to the public in test laboratories, even though 85% of the population says it approves of self-testing<sup>20</sup>.

#### IV – Medical devices for diagnosis *in vitro*:

##### 1- The commercial dimension of health products

Self-testing kits are sold by private industry directly to the general public. This being so, sales are governed by freedom of trade regulations and their purchase for payment is the consumer's decision. And yet, medications are considered to be a special kind of commercial product since they aim at saving human life and health<sup>21</sup>. One might have thought that medical devices for the diagnosis *in vitro* of a serious threat to human health, in the form of a transmissible disease, would also be seen as belonging to a special category of commercial product. Such considerations could have consequences on the quality demanded of them, and on the information and support, even at a distance, supplied with them and paid for by the manufacturer. *"As regards tests, regulation is justified, on the one hand to protect the consumer and, on the other, to ensure an equitable distribution of publicly funded goods and services."*<sup>22</sup>

<sup>19</sup> Insee. 2003 health survey.

<sup>20</sup> *Ibidem*, p. 6

<sup>21</sup> The so-called Doha Agreements at the time of the World Trade Organization conference in November 2001, concerning medications active against HIV, recognised that in certain health emergency circumstances, countries could ask for and obtain a "compulsory licence" with which they would be allowed to manufacture the pharmaceutical in generic form, without fees, before the patent has expired.

<sup>22</sup> Aymé S. Cahiers du CCNE 2005: n° 41.

## 2 - Checking efficacy and safety

Efficacy and safety checks are not as demanding for medical devices as they are for pharmaceuticals, either before marketing approval or in subsequent monitoring procedures once they are in use by consumers. Self-test kits are approved for marketing on the basis of being granted EC marking according to complex rules, as we have noted above. The quality of HIV infection detection by self-test kits varies, in particular depending on whether they are used by medical professionals, by non professionals or again by people with no previous experience. Marketing of an EC marked product may be denied or suspended by national health authorities if these authorities consider that their quality requirements are not met.

Since such devices are already distributed and accessible via the Internet, the matter requires deserves special consideration in view of the large number of sites selling kits which have not undergone any form of quality control. To keep members of the public out of harm's way, health authorities should issue general information and a warning against the unverified and sometimes mediocre reliability of these self-test kits.

ANSMPS is already checking on some French structures as regards the efficacy and safety of the self-test kits they are selling *via* the Internet. These procedures can lead to closing a website if the product for sale does not conform to European regulations and ANSMPS contacts consumers to warn them of danger. Although checks of this kind are difficult to implement and have their limitations, ANSMPS should be strongly encouraged to expand this activity.

## 3 - Economic considerations and conditions of purchase

If self-test HIV infection screening kits were to be marketed in France, since they are medical devices CCNE considers that their availability and sale should be restricted to pharmacies whose prerogative it is to market such items. Pharmacists have the necessary training and expertise to provide pertinent information on medical products and they should be given more opportunity for involvement in information campaigns about HIV self-testing kits. They could, moreover, give advice on how to go about obtaining screening plus counselling, CDAGs in particular, and on the need to confirm the results of self-testing.

When the Internet is used by various organisations, commercial websites and manufacturers, for the purpose of trading without the involvement of pharmaceutical professionals, the issues of potential harm, pertinence and benevolence are so far left unaddressed. Many self-test devices are offered for sale in this way although their validity and safety are either unknown or uncertain and may be based on information which is either erroneous or of dubious quality.

If self-test kits made available by pharmacies were thought to make a useful contribution to screening for HIV infection, thereby playing a role in matters of public health, equity and solidarity would require that they be provided free of charge to vulnerable people in precarious circumstances who would have difficulty in accessing health care facilities. In which case, self-test kits on sale which have been recognised as reliable and certified by the health authorities should also be handed over free of charge by certain structures or people to potential users, such as doctors in secondary schools and universities, private bodies including associations fighting AIDS or providing assistance to migrants or to other categories of people in precarious circumstances.

Some general practitioners with experience on the subject of screening could also have kits made available to them, so that they could, as they are legally entitled to do, test their patients in their own surgeries. Alternatively, they could hand the kits over to those of their patients they consider are at risk of being contaminated but who are reluctant to be tested on the doctor's premises or in a test laboratory in the usual way<sup>23</sup>. Such an extension of procedures so that they are more readily available to users, would be a move in the direction of broadening access to screening, as was previously pointed out in CCNE's Opinion N° 86.

However such self-tests were made accessible to users, the information supplied with them would need to be appropriately drafted and controlled by the health authorities. It should necessarily include a description of the various screening facilities already in existence. Self-screening must not be allowed to supersede traditional screening methods using the ELISA reference technique, including tests performed in CDAGs. Another essential requirement would be that users are given access to a permanent hotline providing telephone contact, if needs be, with someone who has professional training in answering questions on the subject, in giving advice on how to use the self-test kit, as well as, if so requested, advice on where to go to obtain professional medical management of the condition.

## V- Ethical issues

On this subject, two types of ethical issues, sometimes defined as guiding principles, seem to be in contradiction. Personal autonomy is often opposed to benevolence involving in particular solidarity and the duty to afford protection to those who are most vulnerable.

### 1- Autonomy and solidarity

a) Self-testing would appear to give additional freedom and autonomy to users: deciding for themselves that they will be the first, and even the only ones to know of their HIV-serological status, feeling their anonymity is better safeguarded, avoiding other people learning that they are at risk of becoming infected and escaping from what they may feel, rightly or wrongly, as the empowerment of a third party (medical professionals, associations, public institutions, etc.). Another important point is that they are free to decide in all conscience, without outside interference, on the conduct they will henceforth be adopting. The wish to have self-test devices available to them, perceptible in public enquiries, that some people are expressing is a sign among others of their growing widespread inclination to avail themselves (*via* the Internet or otherwise) of information, services, medical products, etc. to which they previously did not have access, in fact or in law<sup>24</sup>. This does indeed reveal a fundamental trend, the demand for the marketing of self-testing devices being only one sign among many. However, this strong current of opinion runs in parallel with another apparently contradictory trend, that of a demand for increased official regulation and protection, with reference to the precautionary principle. This swiftly changing context is in

<sup>23</sup> Gauthier R *et al.* Feasibility and acceptability of rapid HIV test screening (DEPIVIH) by French family physicians. *Méd Mal Infect.* 2012 ;42 :553-560.

<sup>24</sup> Frith L. HIV self-testing : a time to revise current policy. *Lancet* 2007 ;369 : 243-245



fact what has most marked a change since the previous Opinions published by CCNE and CNS on the same subject. This would mean that, although they are still just as pertinent, they need to be refreshed.

For certain members of CCNE, any measure which would seem *a priori* to increase individual freedom and autonomy should be welcomed. Is that reason enough to accept the marketing of self-test kits without any limitation, precaution or cautionary information? Surely not: as most probably is the case for any freedom, that of using self-tests should go together with limits so as to prevent practices which are clearly dangerous not only to the individuals directly involved, but also and above all to the health of others and therefore to public health itself.

For other members of CCNE, the question arises of whether this new freedom of action is as favourable to personal autonomy as the above analysis might make it appear. Is individual freedom to be equated with true individual autonomy? The answer to that question must be subject to the following qualifications.

b) *“Autonomy develops upon entry into the healthcare system”*, notes *Aides*, the French Association against HIV/AIDS and viral hepatitis; autonomy being facilitated by screening methods in the presence of attendant carers. There is some analogy with the concept of relational autonomy developing within an actual health caring system, not in opposition to carers but in partnership with them. Such support for access to screening, as it is organised in France, may be seen by some as intrusion into their private affairs, or as empowerment of health carers, of doctors and also of associations, powers encroaching on an individual’s freedom of choice. *“Is it not true to say that ethical deliberations on the marketing of self-testing devices acts as a mask for the issue of the decline in the power of doctors in a market-ridden society where economic values have pride of place over everything else?”*<sup>25</sup>

c) Those concerned now need to become aware of such limits. The consequence of freedom of choice by one and all as regards matters of public health means that every one must have the knowledge required to clarify — and therefore make — decisions. This is well established in the relationship between doctors and patients with the concept of free and informed consent. But as regards public health, such knowledge is a complex matter. It is up to health institutions to organise the imparting of knowledge in such a way that everyone may exercise freedom of choice without hindrance. It is also their task to make sure that such knowledge is heard and understood, in the same way as it is the task of a doctor to do as much for a patient.

## 2- Autonomy, confidentiality and the risk of pressure

- The confidentiality and anonymity provided by self-testing devices are important points, clearly expressed by users, as a wish to be able to ensure their autonomy and their liberty to buy such devices and use them. However, in certain circumstances<sup>26</sup>, self-testing is not as totally discreet as one might believe. Furthermore, the impression of anonymity when making the purchase in a pharmacy or on the Internet may be no more than an illusion. The

<sup>25</sup>Di Volgo M-J. Cahiers du CCNE 2005; n° 43, 2005.

<sup>26</sup> See annex N°4.

ease and speed with which purchases are made may even be a factor in making them less anonymous than are current forms of screening in which confidentiality is preserved by the attendant carer. **Features such as unrestricted availability to all and sundry, as well as the simplicity and speed of the self-screening procedure, could make it easier for a spouse or a close relative to exert pressure, or else, within the family or at work, coercion to force someone into screening and obtain immediate test results.** The apparent autonomy supposedly inherent to self-screening would in such cases be completely distorted or even supplanted by increased risks of loss of freedom, autonomy, confidentiality and anonymity which could lead to discrimination or even blackmail. This danger was very extensively addressed in previous Opinions by CCNE and CNS and was added fuel to misgivings listed in these documents, which may, by the same token, be considered as still justified today<sup>27</sup>.

### 3 - Autonomy, confidentiality and the Internet.

Personal autonomy may well be further restricted by the current availability and sale *via* the Internet of self-test kits whose quality is frequently unverified. On many websites, the security of advertised confidentiality is probably unverifiable and could well be less reliable than the anonymity guaranteed in CDAGs. Is it realistic to consider that really determined efforts to draw up lists of people interested in self-test kits — in doing so, violating their privacy — could be thwarted?

### 4 - Liberty, knowledge and choice.

Clearly, in democratic societies, the right to know and to choose has gained strength. It is part of our essential liberties. The right to **free and informed choice** has been one of the basic principles of biomedical ethics for nearly seventy years and is currently one of the cardinal principles governing our healthcare system. One example is to be found in the Law dated March 4, 2002 (the Kouchner Law) on patient rights and the quality of healthcare. It was reinforced by the Law dated April 22, 2005 (the Léonetti Law) on patient rights and the end of life. **It should however be emphasised that this right to free and informed choice is currently embedded in the circumstances of access to counselling and to treatment within the healthcare system.**

The possibility of knowing and choosing is apparently facilitated by the development of access to unbridled transactions on the Internet in our highly consumerist societies. But it should be underlined that as long as the quality of what is on offer remains unverified, as is the validity of the information available, being able to choose may be no more than an illusion, or even a denial of truly free and informed choice.

Another aspect of autonomy as developed by the availability of self-test kits is that, for some people, it may express a desire for empowerment. By using this facility, they could be stating that they are accountable for their own health and that of their partner (or partners): this could in particular be the case of people who know that they have been exposed to a possible risk of contamination. In the event that seropositive status was confirmed, a responsible person may wish to seek support, advice and/or counselling as a prelude to

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<sup>27</sup> CCNE. Opinion N° 86 *"Nor should the possible risk of abuse be neglected, for example pressure or coercion by a partner, a family, an employer, an insurer or the police."*



starting treatment and taking steps to avoid transmitting the infection to others. But increased autonomy and empowerment could also, in the absence of counselling, lead to increased fear of rejection and discrimination, thus delaying recourse to medical assistance and treatment. A concern for public health and awareness that a person's personal state of health could represent a danger for other people are sentiments which are probably keener and more manifest in other societies, the Anglo-Saxon<sup>28</sup> social model in particular, although in fact the existence of the same percentage of people apparently unaware of their HIV-infected status in both the USA and in France, seems to be an indication that this is not so.

## 5 - Autonomy, solidarity and responsibility

From an ethical standpoint, public health policies imply a dual responsibility: on the one hand, the community's responsibility to protect and preserve the health of its citizens; on the other, the responsibility of individuals who are infected or at risk of becoming infected towards others they could contaminate<sup>29</sup>.

Manufacturers of self-test kits and health authorities who authorise and make them available to the public could also be concerned by the ethical issue of responsibility. This would be the case, since they may have an effect on public health, if they were potentially hazardous to users because of inadequate reliability and sensitivity. Accountability would be aggravated if people were to use a self-test kit and, believing themselves to be free of infection although they were in fact contaminated, put other people in harm's way or even contaminated them.

## 6 - What services could be expected of self-screening HIV-test kits?

### a) As regards public health

As stated above, the FDA in the USA authorised the marketing of saliva-based Oraquick® to the general public for two reasons: on the one hand, because the test had already been authorised for use as a TDR (rapid diagnosis test) by health carers; and on the other hand for reasons of public health, in an effort to reduce the number of infected persons unaware of their HIV status who are the source of the greater number of new instances of

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<sup>28</sup> In these societies, there is in addition a high degree of autonomy as regards an individual's own health status, together with empowerment provided by health education at various times in a person's life (e-learning, video information), all of which contributes to more accountability for oneself and for others.

<sup>29</sup> Legally speaking, it should be noted that if a person, knowing that he or she is infected, has unprotected sexual intercourse thus contaminating his or her partner, this qualifies as an offence against the law, i.e. administering a harmful substance impairing someone's physical or mental health, this offence being recognised and punishable by Article 222-15 of the *Code Pénal*. In this context, the situation would be identical for someone who has learnt of his or her HIV-positive status through the use of a self-test kit, or, as may be the case currently, through an anonymous screening procedure in a CDAG.

contamination.

**CCNE draws particular attention to how difficult it might be to ask people using the self-test procedure because they wish to stay out of the current counselled screening system, to proceed after self-screening — regardless of whether the results were positive or negative — to obtain confirmation with an ELISA test in the framework of the very screening system they wished to keep clear of.**

As we have seen, in France, many such people are exposed and at high risk of transmission: they were at some point, and sometimes they still are, knowingly engaged in high-risk behaviours. They might therefore be ready to use a self-test if one was available, thereby making a positive contribution to public health.

It would therefore seem possible that if HIV self-test kits were made available in France, the incidence of contamination might be lessened among people who are most vulnerable to HIV contamination, such as men having sexual intercourse with men, a population in which the epidemic remains largely out of control. The associations making intensive use of TRODs and in closest contact with some particularly high risk groups of people, point out that HIV self-test kits could be extremely useful to those who are well aware of the risks and of their responsibilities, as they could be used to do some “intermediate screening” between two visits to a test laboratory or to a CDAG.

Predicting the use that would be made of them and their effect on other groups less at risk of contamination, is not an easy task. In any case, should this method of screening be made available, it would be quite essential to use it only as a complement to, and not as a substitute for the screening with counselling method now in use throughout the country.

#### **b) For individuals.**

Results of self-testing indicating HIV-positive status, despite the psychological repercussions of such a discovery, or perhaps because of those repercussions, might reasonably incite the person concerned to seek confirmation from a doctor or by going to a CDAG. As a result, medical management and treatment of the case, as well as preventive measures to avoid transmission, could be a logical follow-up.

**When the results of self-testing are negative for HIV contamination, which is the most frequent case, the risk for the persons concerned is false reassurance by the negative result of a test done entirely without assistance, so that they might not seek confirmation, all the more so since they were likely to have used a self-screening procedure because they were reluctant to enter into a supervised system in the first place.** For this reason, users need to be particularly well briefed beforehand on the limitations of the test results, on the shortcomings of the self-test kit’s sensitivity and on the fact that primary infection cannot possibly be detected before quite a long time has elapsed, which may be as much as three months after contamination. They should also be made aware that for the test to produce results as close as possible to its maximum reliability potential, the instructions for use, handling and interpretation of results must be followed to the letter.

Excessive reliance on the self-test’s quality and failure to understand its limitations can be extremely prejudicial. As we have already noted, it is less sensitive when it is used for unaccompanied self-screening than it is if professionals are involved. This should be clearly stated by the manufacturer in the information supplied with the product for sale, and health authorities must take whatever steps are necessary to ensure that this is the case.

When the self-test results are negative for HIV contamination, as we have noted above, the most probable consequence would be failure to seek support and counselling; but another possibility, for example, might be outrage on the part of someone contaminated by a partner who was lulled into thinking he or she was free of contamination by a false negative provided by a self-test. In such a situation, those concerned could also vent their anger at the manufacturers of these devices or even at health authorities who allowed unsafe medical devices to be made available for sale to members of the public.

The ethical issue of responsibility arises therefore for the person whose test results were negative and who should have arranged for confirmation with an ELISA test in a screening centre, on the one hand, and on the other, for the community whose responsibility it was to make it absolutely clear to anyone using a self-test that the results should be confirmed by re-testing in a supervised screening centre.

CCNE wishes to emphasise that health authorities would probably have some difficulty in making self-test users understand that their test results must be confirmed, be they positive or negative, the latter paradoxical case being even more unacceptable.

### **7- Equilibrium and choice between autonomy and solidarity vs reliability, efficacy and responsibility.**

This issue could arise if two versions of the same test (one based on whole blood and the other on saliva), Oraquick<sup>®</sup> for instance, were to obtain EC marking and were authorised for sale to the public in Europe. With the first of these versions, results are close (sensitivity 98.5%) to those provided by the ELISA reference test, but they are more difficult to come by (since the basis is a drop of blood from a finger prick, and all the components must be subsequently disposed of in compliance with the prescribed infectious clinical waste DASRI procedure). The saliva-based test is easier to deal with, but results are less reliable (sensitivity 93%) with on average 7% false negatives. The choice would be between a reliable but difficult test and one that is simpler to implement but involves a significant degree of potential harm because it is notably less reliable.

If choosing between the two alternatives became necessary, CCNE considers that quality and efficacy should be the preferable option in order to limit to the fullest extent possible the harmful consequences of false negatives. It would also be advisable to send out a reminder that screening tests currently organised in France using the ELISA technique are of quality. In any event, self-test performance in a non professional environment should be the subject of evaluation before considering the possibility of granting EC marking approval for use by the public.

## **VI- Conclusion. Ethical issues and precautionary measures to be taken were marketing allowed.**

**1. The ethical issues raised by the possible marketing of self-screening tests** for HIV contamination are, for a large part, those that CCNE had already indicated in its 2004 Opinion. The need for self-screening to be “assisted”, evidencing solidarity, was particularly highlighted, as were the technical flaws of self-test kits: failure to detect antibodies in the three months following primary infection, the potential risks of faulty interpretation when

they are used by non-professionals and possible false negatives, all of which can be seriously detrimental for those taking the test and for their sexual partners. Such assistance is still most evidently desirable and, despite all the difficulties inherent to the process, is carried out successfully under the present screening arrangements currently in use in France. To the risk — due to the absence of any assistance when running the test — of losing an opportunity of obtaining support and patient management when self-test kits are marketed, is added a further risk: losing an opportunity of obtaining information and of taking certain precautions due to the flawed quality of the kits.

Nevertheless, the current perception of the advantages of these self-screening kits for HIV infection differs from the one discussed in previous Opinions. HIV infection and its representation, both individually and collectively, have in fact evolved considerably over the last ten years, even though psychological, social and emotional negative repercussions are still largely present, as is the risk of discrimination. Although free screening facilities are now widely available, they are still not being used by a sufficient number of people at high risk of contamination. It is this essential fact that prevents the epidemic from significantly abating. Reliable self-screening kits for HIV infection could help to overcome this failure and respond to the demands of public health.

Furthermore, generally speaking, people attach more importance nowadays to individual freedom and autonomy in the conduct of their health-related affairs. Finally, the advent of marketing in Europe of a self-screening test for HIV infection can reasonably be considered at this point as a probability; there is therefore a need to plan ahead and to have ready without further delay, an analysis of the various ways in which it could be used and possibly fitted in to the existing screening system.

Finally, a number of important considerations still need to be reviewed, among which the merits of using these self-test kits in terms of public health, an evaluation of their reliability, the possibility of measuring their effect on the number of contaminations and the risks of compromising confidentiality and of people being subjected to pressures which their use could cause. There is therefore a case for a full evaluation of the expected benefits as regards public health to be measured against both the benefits of course, but also the possibility of prejudice, to individuals. There also remain two important challenges of a more general nature: on the one hand, the conditions required for obtaining EC marking authorising the sale of medical devices are in need of improvement; on the other hand, setting up a system of quality control for the devices which are on offer and accessible *via* the Internet and warning the public of the risk that products of uncertain quality may represent, and also of possible breaches of confidentiality .

2. In view of the current situation, as we have seen, no longer identical to the situation when previous Opinions were published, there are compelling ethical reasons why health authorities should take certain precautions if the possibility existed that HIV self-test kits were to be marketed. Such precautions bear on the following essential areas in biomedical ethics: pertinence, individual benefit and autonomy, collective benefit and solidarity.

### ***Pertinence:***

- 1- **Make sure that the detection efficacy** of anti-HIV antibodies by the self-test kits is on a par with the standard of tests currently approved for use with assisted screening.

Set up mandatory verification procedures to be carried out by independent laboratories to check on the quality, performance and efficacy of self-test kits as regards their compliance with currently applied criteria. Of particular concern would be the test's sensitivity in the hands of inexperienced users with a risk of false negatives and therefore of potential prejudice to those concerned.

- 2- **Organise sales of the kits in pharmacies, or even on the pharmacies' internet sites**, in complete safety as regards confidentiality, at reasonable prices, but not covered by the public sickness insurance system.

***Individual benefit and autonomy:***

- 3- **Require information to be provided by the manufacturer** at the time of purchase of the self-test kit, that this information be reviewed by the health authorities and ensure that it includes a description of screening for HIV as it is currently organised in France, in particular by CDAGs. The information must also be entirely clear on the limitations of self-screening techniques — saliva-based in particular — and the overriding need to comply fully with instructions for use. The accompanying leaflet must provide precise data on the time that elapses after contamination before it can be detected. It must also provide full details on the risk that the test could return a false negative because of its loss of sensitivity in the hands of a non professional inexperienced person. All this information must be drafted in clear and simple terms readily understood by vulnerable members of the public.
- 4- **Ensure the provision** of a continuously accessible telephone line to respond to requests for advice, operating in such a way as to provide uninterrupted, multilingual and free service. This is particularly important for people who, rightly or wrongly, believe themselves to have tested positive and who are asking for more specific guidance, without delay, in a medical environment, possibly in a CDAG.
- 5- **Draw up** legal provisions to safeguard the autonomy and confidentiality of self-test use and to protect people from attempts to pressure or even force them to use a self-test in order to prove their HIV-negative status to third parties.
- 6- Finally, **understand** that since users are left to their own devices, the gain in autonomy provided by the self-test can be offset by a loss of opportunity to be provided with psychological and therapeutic guidance and by the further loss of confidence in the accuracy of results — particularly negative results — with self-testing kits because they are less reliable, particular in the hands of inexperienced users.

***Benefit to the community and solidarity:***

- 7- **Take care that** self-testing systems **do not replace** current national screening schemes for HIV infection since these are community driven, rely on assistance and solidarity provided by the presence of a trained counsellor and ensure anonymity when it is wanted.

- 8- **Make further efforts to intensify preventive action**, in particular by reinforcing all the “assisted” screening schemes and offers, especially in CDAGs. This will involve doing everything possible to ensure that easy access to self-test kits does not bring in its wake a proliferation of high-risk behaviour because false negatives have generated illusions of safe protection.
  
- 9- **Organise the availability of self-test kits free of charge** by official networks and the national health insurance scheme, in public structures such as medical facilities in secondary and higher education institutions. These should also be provided through motivated family doctors or general practitioners, not necessarily the patient’s own registered physician, through NGOs (non-governmental organisations) providing medical care for vulnerable people, or associations committed to fighting AIDS, helping migrants and people in precarious circumstances, and generally speaking to any persons or structures able to serve as an appropriate source of guidance for referral to screening services using the standard ELISA technique.
  
- 10- **Using epidemiological evaluations on a regular basis, investigate the impact in terms of public health** of the availability of self-test kits on the number of new contaminations; **and take steps to reconsider the usefulness** of this availability if it was found that there was no positive impact on the number of new contaminations and on the number of people who are unaware of their HIV-positive status.

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The above are the precautions that would need to be taken in the event that self-screening HIV infection kits were to be approved for marketing.

CCNE states that this Opinion's aim is to consider ethical issues arising if self-screening HIV infection kits were to be marketed. Whether or not it would be appropriate to market such self-test kits in France is another matter which is not addressed here.

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In conclusion, CCNE considers that ethical issues arising out of the possible marketing of self-screening kits for HIV infection are part of a broader context: that of the possibility of marketing medical devices for *in vitro* diagnostic test procedures, including genetic tests, without the benefit of medical assistance. These ethical considerations as a whole will be reviewed in a forthcoming CCNE Opinion.

# Annexes

## **Annex 1: Letter of referral sent by the Minister for Health and Social Affairs on August 8th, 2012.**

### **The Minister for Social Affairs to the President of the National Consultative Ethics Committee for (CCNE)**

Subject: Self-screening HIV infection kits

Between 2004 and 2007, the ministerial departments in charge of health gave some thought to whether self-screening HIV infection kits should be approved for marketing. The National Consultative Ethics Committee (CCNE) and the National Aids Council (CNS) returned adverse Opinions.

The main supporting arguments were of an ethical and medical nature, addressing in particular the degree of reliability of the tests, the risks as a result of the absence of pre- and post-test counselling sessions providing an opportunity for information and advice regarding an adjustment of preventive strategies, the suppression of opportunity for giving immediate support and guidance for treatment in the event of a positive test. Furthermore, AFSSAPS (French Agency for the Safety of Health Products) had pointed out problems arising when non professionals were running the tests and interpreting the results.

Meanwhile, both in France and in other countries, the context of screening for HIV has evolved significantly.

In 2010, the terms of use in France of HIV rapid diagnostic tests for referral (TROD) were regulated: they may now be used either by medical professionals in a health care institution or by appropriately trained people in associations operating in a non medical environment.

On the 3rd of July 2012, the American Food and Drug Administration (FDA) approved the marketing of a TROD for HIV (Oraquick®) for use in non medically supervised self-testing. As of October 2012, the device will be available for sale over the counter in 30,000 outlets in the United States and it is more than likely that after that date it will become accessible on the Internet.

So far, no self-test kit complying with European regulations (EC marking) seems to have appeared on the market in France or in any of the other main European countries.



In this evolving situation, I would like to receive a new Opinion from your Committee on the subject of issues arising out of the marketing of self-screening HIV infection test kits.

I should add that I have also referred these issues to the National AIDS Council since I believe that working in cooperation would be valuable. A technical opinion from the National Agency for the Safety of Pharmaceutical and Health Products is also expected in September.

I would like to see CCNE's Opinion on this matter by the end of December 2012.

Marisol TOURAINE

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## Annex 2

### Summary and conclusions of previous Opinions on self-test kits

#### 1. National Consultative Ethics Committee – November 4, 2004.

##### Opinion n° 86

CCNE considers that the salient points on the subject of self-testing kits for the screening of HIV positive status contained in its Opinion n° 86 published in November 2004 should be reiterated as they are still entirely applicable in 2013:

“The prescription and interpretation of additional tests are based on medical considerations, so that a patient in isolation, without the required knowledge and information, cannot be the judge of whether the tests are appropriate. The results of biological tests are not equivalent to genuine medical information and have significance that exceeds the unprocessed results. The simplistic nature of results obtained without individualised counselling may cause distress, the delivery of socially destructive information and lead to irreversibly harmful consequences, such as thoughts of suicide.

A man or a woman's right to know when engaging in self-screening, must be exercised with due respect for the necessary protection of individuals, in particular those who are vulnerable.

Making HIV self-screening kits available on their own without assistance, would give those concerned the possibility of having access to information which is difficult to interpret without the help of professionals. Those using the test kits would be on their

own in coming to terms with the results without any possible recourse to a health carer whereas self-testing would only make sense if it were the point of entry for pluridisciplinary and coherent management of a medical condition.

HIV contamination involves relating to others in the context of possible transmission of the infection. Trivialising the test would lead to a simplistic view of screening and, paradoxically could contribute to encouraging risk-taking behaviour. In the case of recent contamination, the significance of a negative result returned by the self-test — at a time when the person is already infected and is a carrier of a considerable viral load — deserves explanation. Without help, interpretation of such results by a patient acting alone might well be falsely reassuring and thereby distinctly dangerous.”

### Conclusion

“Self-testing for HIV contamination and genetic data ignores three consequences:

A biological fact is not equivalent to genuine medical information and has significance that exceeds the unprocessed results.

The simplistic nature of results devoid of individualised counselling procedures may cause distress, the delivery of socially destructive information and irreversible harmful consequences.

The present demand for free access to information gives rise to irresponsible marketing inducing utopian delusions. Although this demand may appear to have obvious legitimacy, it in fact ignores the extreme complexity of the body of knowledge concerned...

The proposal to market self-test kits corresponds to this call for access to knowledge at all costs and whatever the consequences, which in itself reveals the consumers’ vulnerability. The market is very conscious of this and rushes to satisfy demand, never ceasing to promise truth or to deny the complexity of results. The paradoxical result, more often than not, is anxiety rather than serenity. For these reasons, the use of self-test kits should not just be regulated for ethical reasons; it should also inspire reflection on the myth such tests perpetuate.”

## **2. National AIDS Council – June 19, 1998.**

### **Report on the advisability of making home-tests for HIV-screening available on the French market.**

#### “3-1 Self-analysis

The symbolic value inherent to screening for a serious disease, which as far as we currently know, is still incurable, makes it quite unacceptable to entertain a situation

where a person aware of the risk he or she is facing is left alone in the company of a piece of coloured blotting paper, providing uncertain results that are not easily interpreted.

The easy access to a self-analysis test procedure, however sensitive and specific, opens up a possibility of it being used in a coercive situation. This would in effect be a case of forced analysis by a third party. Testing could be taking place with an adult exercising pressure on a child, of employers versus their employees, of insurers versus the insured, of policemen versus migrants, of men versus women or vice versa. This so-called 'self-analysis' represents a high risk of social and medical misuse and could place the principle of respect for the rights of individuals in danger of violation. For both of these reasons, the Council emphasises the serious risk of coercive and stigmatising misuse as a result of the marketing of self-analysis instruments.

### Conclusion

In conclusion of this enquiry and since home-tests are not in fact available for marketing, the National AIDS Council did not consider that a formal Opinion was required, but that it would suffice to outline the potential ethical and social impediments to the marketing of such test devices in this country.

These techniques are not very pertinent in the current social context and they are scientifically below par in comparison to new screening techniques. Furthermore, they raise ethical issues: the person concerned is left alone to face up to a diagnosis; they open the door to a breach in the principles of public health in so far as screening is neither supported nor financially covered and, finally, they could lead to practices contrary to the rights of individuals."

### **3. National AIDS Council. – December 9, 2004.**

#### **Memorandum of Opinion on Commercialisation of HIV Self-Tests**

"Unethical Use. When a test is easy to use, regardless of how reliable it may be, the risk of it being used coercively is increased. For instance, the test could be performed by employers as part of the hiring process, by insurers prior to signing a contract, by police officers during identity checks, etc. Another use – to be feared – is that prior to sexual interaction, to justify not using means of prevention, thereby heightening the current surge in sexually transmitted diseases.

The development of self-tests on the other side of the Atlantic is due in particular to the fear of breaching anonymity. In France, the law guarantees confidential access to screening and anonymised data processing, so that access to self-screening kits is less of an advantage.

### Conclusion

Self-testing, in addition to its low diagnostic value, cannot be integrated into a broader prevention policy. Moreover, it leaves individuals on their own when they are facing an HIV-positive result, so that they are not encouraged to seek out the medical and social care they need. It also creates a risk of inappropriate use contrary to individual rights. Above and

beyond HIV self-testing, these objections could also apply to other self-tests. For public health, medical, social and ethical reasons, the CNS is not favourable to the distribution of self-tests for HIV-infection screening.”

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## Annexe 3

### Oraquick®. Reliability; sensitivity – specificity

- **The sensitivity** of a diagnostic test is its capacity to provide a positive result if the disease is present. It accounts for false negative results with the test although the person concerned is infected. 98% sensitivity means two false negatives out of 100 infected persons.
- **The specificity** of a diagnostic test is its capacity to provide a negative result if the disease is not present. It accounts for false positive results with the test although the person concerned is not infected. 98% specificity means two false positives out of 100 non infected persons.

#### 1. Oraquick® sensitivity with a saliva sample

**FDA meeting May 15,2012<sup>30</sup>**

**Required sensitivity for a professional-use test: at least 98%.**

- **value obtained in the clinical trial: 98.4%**

In the hands of **lay-users**:

- **value obtained in the clinical trial: 93%**

(Lower bound of the 95% confidence interval = 86.6%).

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<sup>30</sup> Food and Drug Administration, 102nd Meeting of The Blood Product Advisory Committee, May 15, 2012, p. 123-135

**Prof. F. Simon's study<sup>31</sup>.** In professional-use:

- Saliva-based Oraquick® sensitivity: 86.5%,
- Whole-blood Oraquick® sensitivity:94.5%.

However, the Oraquick® test is negative for recently infected people (primary infection) and for patients receiving treatment with a very low viral load.

## **2. Oraquick® specificity**

According to the principal sources of information, specificity is 99%, i.e. 1% false positives.

## **3. Results of using the saliva-based Oraquick® self-test by 5600 non-professionals<sup>32</sup>.**

One hundred and fourteen subjects were HIV-positive, of which 106 reported a positive OraQuick® result and 8 false negatives, i.e. **sensitivity of 106/114 = 93%**

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## **Annex 4**

### **Self-test – prevention. “The hidden epidemic”.**

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<sup>31</sup> Pavie J. et al. *Sensitivity of five rapid HIV tests on oral fluid or finger-stick whole blood: a real –time comparison in a healthcare setting*. Plos ONE 2010 ; 5 ; e11581

<sup>32</sup> Food and Drug Administration, 102nd Meeting of the Blood Product Advisory Committee, May 15, 2012, p. 39-40

The “hidden” portion of HIV infection in France involves the 30,000 individuals who are thought to be HIV-infected but who are unaware of their positive status. A recent report provided more detailed data on how they were contaminated<sup>33</sup>: one third by homosexual intercourse between men, one third by heterosexual intercourse of migrants from regions with a high prevalence of HIV-infection and one third by heterosexual intercourse in the population at large. Prevalence (the ratio of frequency of HIV positives to the number of individuals concerned) is, however, different in each of these three thirds: 3/100 for men having sexual intercourse with men, 3/1000 for migrants from regions with high HIV infection prevalence and 3/10,000 in the population at large.

According to information collected from the hearings, the self-tests are generally acceptable to subjects. In the case of men having intercourse with men, self-testing facilities could be of use to those living in fairly small communities, whose sex preferences are discreet or even secret but above all to those who live in big cities leading a very active sex life with multiple and sometimes anonymous partners.

In the latter case, this is a group of people who are very largely HIV contaminated, lead a highly active sex life and whose recourse to condoms is average or low. In Paris, for this group of people, there is a very high prevalence of 18% and a person-year 3.8% incidence<sup>34</sup>.

This represents a failure of contamination prevention in anonymous and more often than not, unprotected sexual intercourse. *“We recognise that the situation in France is “out of control” as far as it concerns men having sexual intercourse with men and we further recognise that this situation only involves mainly high-risk groups of individuals<sup>35,36</sup>.”*

Self-tests are sometimes used by partners before sexual intercourse, to adjust their preventive options accordingly. There is, in such cases, a possibility that some form of pressure may be exercised.

In view of this acknowledged and factual failure of prevention in certain population groups, who are considered to be inaccessible by current prevention and screening schemes, self-tests could be of some use.

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<sup>33</sup> Information obtained from D. Costagliola (Inserm Unit U943 Director, and Université Pierre et Marie Curie, Paris), to whom we are deeply grateful for the work under his direction by V. Supervie: “Épidémie cachée : Combien ? Qui sont-ils ?” (The Hidden Epidemic : How many? Who are they?)

<sup>34</sup> Le Vu S et al. *Incidence de l’infection par le VIH dans un échantillon d’hommes ayant des relations sexuelles avec des hommes à Paris*. (Incidence of HIV infection in a sample of men having intercourse with men in Paris) Enquête Prévagay 2009 ANRS-InVS. Bull. Épidém. Hebd. 2012 ; n° 46-47: 537-540.

<sup>35</sup> Giami A. *La prévention biomédicale est une prévention comportementale*. [www.vih.org](http://www.vih.org) 13/10/2010. (Biomedical prevention is behavioural prevention).

<sup>36</sup> Lestrade D. *Quitter la lutte*. Journal du sida, 2013 ; n° 226: 50.