

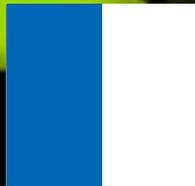


Southern African AIDS Trust

**REPORT**

**REGIONAL**

**2014**



**REVIEW –FRANCE**

**HIV SELF-TESTING  
REGULATION AND POLICY**



# FOREWORD

While the focus of much of the global community may be moving on from HIV and AIDS to other issues, it cannot yet be said to be “the end of AIDS” in Africa. HIV & AIDS will continue to impact communities and public health systems in eastern and southern Africa for decades to come and both morbidity and mortality in the region will be significantly increased as HIV & AIDS influences health issues such as TB, maternal mortality, and sexual and reproductive health more broadly.

One of the key critical success factors in fulfilling the UNAIDS and global goal of zero new infections, zero deaths and zero discrimination is people knowing their own HIV sero-status and having the ability to act on the knowledge. Yet in eastern and southern Africa, despite decades of investment in HIV testing and counselling, many people still do not know their status.

Across the region there remain wide variations in data regarding the proportion of the general population who have accessed HTC. Figures for 2011<sup>1</sup> show Botswana at over 60% (2011), Malawi at 34%, and Zambia 15%. **Presently less than half of all Africans know their HIV status, and only 25% received an HIV test in 2012<sup>1</sup>.** Uptake and access to HIV testing is lower among members of key population communities who, while facing a higher HIV burden, also face issues of stigma, discrimination and other barriers to access.

It is in this context that SAT believes in thinking out-of-the-box. After decades of investment more of the same is unlikely to be a game changer with regard to increasing the number of people empowered by knowledge of their own status to take action.

HIV self-testing may be just such an ‘out-of-the-box’ solution. Defined as, ‘when a test is collected, performed and interpreted in private by the individual who wants to know their HIV status’, self-testing, in combination with other new thinking on HTC opens new possibilities for reach and engagement.

To explore this possibility, SAT commissioned a multi-country legal review of national policies and legislation that frame and provide the context for thinking about HIV self-testing.

With the generous coordination from the Thomson Reuters Foundation, SAT worked with a strong team of international and Southern African legal firms to conduct a review of the laws relevant to HIV self-testing (HIVST) in their respective jurisdictions, namely Botswana, Malawi, Mozambique, South Africa, Tanzania, Zambia and Zimbabwe as well as France, the UK (England) and the USA. All work conducted by the firms (see below) was done on a pro bono basis as a contribution to global development.

The review sought to answer key contextual questions that would frame any pilot or projects that countries might choose to take up to increase numbers of the population who know their HIV status. Included were questions such as, “Is HIV self-testing legal and, if so, under what conditions?”, “What

<sup>1</sup> UNAIDS 2013; WHO 2013

legislation governs the distribution of HIVST kits and what rules/conditions exist concerning this distribution?” and “What are the human rights issues surrounding HIVST?” The review looked across SAT’s countries of operating but also went broader to explore the situation in the USA, France and the UK – all of which have now legalised self-testing after thorough national debates and scientific input.

In the last stages of the review SAT and the University of Witwatersrand Reproductive Health Institute hosted a Consultative Workshop in March 2014 with participants from governments, National AIDS Councils, key population groups, community organisations, WHO, medical experts and researchers. The think tank worked with the emerging review as well as with evidence from two very successful research/pilot sites in the SADC region and explored what the possibilities and practicalities of implementing self-testing might be. The think tank report may also be accessed on the SAT website above.

The issue of self-testing is not uncontroversial, and it has been known to raise strong feelings both for and against. The think tank was useful and hearing from the research sites de-bunked many of the myths about self-testing such as “it is incompatible with referring people into the health system”, or “people will not understand how to use it or how to interpret the results”. Innovators in a number of places, not least in the SADC region, have worked hard and designed and tested solutions and in some cases products to overcome these challenges.

HIV self-testing is not a magic bullet. In combination with other innovative thinking, however, it may hold the key to increasing reach of testing, opening new options for hard to reach communities, making life easier for serodiscordant couples and supporting both prevention and treatment.

We are pleased to present to you the HIVST Legal Report for France. This report is intended to inform SAT and all its strategic partners about the legal framework and human rights implications relevant to HIVST in France. The summary consolidated findings for all the above mentioned countries as well as individual country reports are available at SAT on request as well as on the website, [www.satregional.org](http://www.satregional.org).

It is our fervent hope that the findings will have a catalytic effect on dialogues on this subject and forge a way for HIV self-testing in France and across the region.

Welcome to the conversation. We look forward to your feedback.

Jonathan Gunthorp



Executive Director - SAT

## ACKNOWLEDGEMENTS

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Special thanks go to Dechert (Paris) LLP (France) who provided pro bono legal services to undertake the review on HIV Self-Testing in France and Arnold & Porter (UK), in particular to Catherine Young for coordinating the legal review in all the participating countries.

SAT also wishes to thank civil society organisations and partners who attended the HIV Selftesting Consultative Workshop in March 2014 to discuss the draft legal reports, including the merits, challenges and opportunities of integrating HIV self-testing into existing community level HIV and SRHR programmes.

SAT is grateful to Wits Reproductive Health Institute for all their technical support and input during the March 2014 HIV Self-Testing Consultative Workshop.

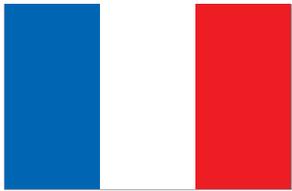
Last but not least, we would like to thank Thomson Reuters Foundation's global pro bono service, TrustLaw, who helped coordinate the project and brokered, free of charge, the relationships between SAT and the legal firms.

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REVIEW



**FRANCE**

**FRANCE**

**DECHERT (PARIS) LLP**

**(ANNE-LAURE MARCEROU,)**

Dechert  
LLP

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## 1. INTRODUCTION/BACKGROUND

- 1.1 For the purpose of this memorandum, “HIVST” refers to “expedited” HIV tests which are performed by the individual himself/herself and whose result can be read directly on the device itself after approximately 20 minutes (as opposed to laboratory blood tests which may only be performed in duly authorized medical labs).
- 1.2 For the time being, performance of expedited HIV tests is authorized in specific circumstances and under medical or social worker supervision. Expedited HIV tests performed under the conditions set forth in Section 2 below are referred to as “Tests Rapides d’Orientation Diagnostique” (decree dated 28 May, 2010 and decree dated 9 November, 2010).
- 1.3 The French Health Authority defines rapid diagnostic test as an unitary test with a subjective reading, of an easy use and conceived to give results in a short delay (generally 30 minutes). It may be performed with whole blood, saliva, plasma or serum according to the matrix claimed by the manufacturer for its product. The product enables to detect HIV-1/HIV-2 antibody.<sup>1</sup> Technically, an expedited HIV test (and later a HIVST) is defined as an in vitro diagnostic medical device which must comply with minimal technical specifications set out in the decision of the European Commission dated November 27<sup>th</sup>, 2009.
- 1.4 The French Health Minister, Marisol Touraine, recently announced that – subject to CE mark - in-home OTC tests will soon be available in French local pharmacies “for people who do not want to go to testing centers or hospitals (“unsupervised” self-testing).

## 2. SUMMARY OF ADVICE

- 2.1 HIV tests are performed in France mainly by a full biological test in a medical lab. The French legislation authorizes as an exception the use of expedited HIV tests in certain circumstances but always under medical and/or trained social workers supervision. In consequence, for the time being, HIVST kits cannot to be sold to the general public. However, French Health Minister, Marisol Touraine, recently announced that in-home OTC test will soon be available in French local pharmacies for “people who do not want to go to testing centers or hospitals” and it is likely that some changes in national legislation will be implemented in the coming months.
- 2.2 In France, performance of HIV tests, including expedited HIV-testing, cannot be imposed on individuals, except in very specific situations and healthcare professionals supervising the test must obtain specific and informed consent from the tested individual and keep absolute medical confidentiality. It should be noted that the disclosure of the HIV test result – even if it is positive – is solely the responsibility of each individual and, in any event, discrimination against HIV-positive individuals is unlawful.

## 3. IS HIV SELF-TESTING LEGAL AND, IF SO, UNDER WHAT CONDITIONS?

- 1.1 HIV self-testing kits for use by the patient without medical supervision cannot currently be sold in France. The French Health Minister, Marisol Touraine, recently announced that – subject to CE mark - in-home OTC tests will soon be available in French local pharmacies “for people who do not want to go to testing centres or hospitals (“unsupervised” self-testing). The details of the planned changes to the law are not known. For the time being, performance of expedited HIV tests is authorized in specific circumstances and under medical or social worker supervision. The French National Agency for Medicines and Health Products Safety (ANSM) in a recent press release (12 February, 2013) indicated that, according to them, in Europe, the HIVST kits that can be purchased directly by patients do not satisfy applicable regulatory requirements in the European Union. The Agency noted that the assessment of HIVST kits by manufacturers is still on-going to ensure that before their commercialization the HIVST kits won’t compromise the clinical condition or the safety of patients and achieve the performances intended by the manufacturer.

<sup>1</sup> HAS, Recommandations en santé publique, Dépistage de l’infection par le VIH en France” October 2009, p.4

- 3.1 Performance of expedited HIV tests in certain urgent situations (when it is impossible to perform a full biological test in a medical lab) has been first authorized by a French Decree dated 28 May, 2010. This decree has authorized expedited HIV-testing (using capillary blood sample<sup>2</sup> – not saliva) under medical supervision and in the following circumstances:
- blood exposure incident (the person who is the “source” of the blood is the one to be tested)
  - sexual exposure incident
  - birth delivery (the test is proposed to the pregnant woman if her serological status is unknown or if she has been potentially exposed to the virus since her last test)
  - the test is urgently required to diagnose an acute pathology, which is symptomatic of AIDS.
- 3.2 The test can be performed under supervision by the following professionals:
- a physician in private practice, a physician or a biologist practicing in a hospital or a health service (*service de santé*)
  - a mid-wife practicing in a hospital or a health service
  - a nurse or a medical lab technician practicing in an hospital or a health service, under the responsibility of a physician or a biologist
- 3.3 The professional who supervises the test must ensure that the patient has consented freely to such test. The result of the test is communicated to the patient during an individual medical consultation.
- 3.4 Regardless of whether the result of an expedited HIV-test is negative or positive, it must be confirmed by a full blood test performed in a medical lab.
- 3.5 Another decree dated 9 November, 2010 authorized the performance of expedited HIV tests (on capillary blood) under medical supervision and/or the supervision of trained social workers in non-urgent situations. It should be noted that the decree of 9 November 2010 extends the scope of expedited HIV-testing and provides that it may be performed even when there is no urgency, provided it is done under the supervision of a healthcare professional or an authorized social worker.
- 3.6 This new decree has authorized performance of expedited HIV tests, in the interest and for the sole benefit of the patient, under supervision of:
- 3.7 The above professionals/persons<sup>3</sup> have a duty to keep medical confidentiality (breach of medical confidentiality is criminally sanctioned – up to one year imprisonment and fine up to 1,500 euros – Article 226-13 of French Criminal Code).
- 3.8 The individual tested must receive adequate information and must specifically consent to the test. The testing device can only be used if it has received the CE mark in compliance with EU regulations (article 1 of decree dated 28 May 2010). After the expedited HIV-test has been performed, he or she is systematically invited to confirm the result by performing a full blood test in a medical lab.
- 3.9 It should also be noted that the *Conseil National du Sida*<sup>4</sup> issued in March 2013 a positive opinion in favour of broadening the use of saliva HIVST kits. The French Minister of Health indicated that, subject to their obtaining of the CE mark, those kits should be available for sale to patients in local pharmacies within a few months. It is intended that those tests be authorized for use without medical supervision. To our knowledge, for the moment, no legislation has been passed concerning the sale of HIVST devices to the general public (only general declarations have been made in this respect by the French Minister of Health).

<sup>2</sup> i.e., blood obtained, for instance, from a fingertip

<sup>3</sup> Performance of expedited HIV tests by any individual other than the above professionals is prohibited and may result in a claim for damages from the patient.

<sup>4</sup> The Conseil National du Sida is an advisory body whose composition shall be such to allow for a comprehensive understanding of the problems posed by HIV and which shall be consulted for any information, or harm-reduction and education for health programs set up by the Government and public bodies and more generally may give opinions on the issues posed by HIV and make any proposals to the government.

## 4. WHAT LEGISLATION GOVERNS THE DISTRIBUTION OF HIVST KITS AND WHAT RULES/CONDITIONS EXIST CONCERNING THIS DISTRIBUTION?

- 4.1 For the time being, it is legal to sell/distribute expedited HIV-testing devices for use by healthcare professionals and/or trained social workers listed in decree dated 28 May 2010 and decree dated 9 November 2010. Several companies (e.g., Inverness, Servibio, Biomérieux) currently sell expedited HIV-testing devices (using capillary blood) for use by French healthcare professionals.
- 4.2 To be placed on the French market, the device must be CE-marked (Article 2 of decree dated 28 May 2010). However, said devices may only be used under the conditions set forth in French decrees dated 28 May 2010 and 9 November 2010, which are detailed in Section 2 above.
- 4.3 It is anticipated that, in the coming months, saliva HIVST kits are to be sold in local pharmacies for use by patients (without specific medical supervision). To our knowledge, for the moment, no legislation has been passed concerning distribution of HIVST in local pharmacies (only a general declaration has been made by the French Health Minister).

## 5. WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?

- 5.1 Human rights issues related to HIVST which have been identified by French authorities and consulting bodies (such as *Conseil National du Sida* and *Conseil National d’Ethique*) mainly concern freedom to consent to the test and confidentiality of the results. The ECHR and the Charter of Fundamental Rights apply to France.
- 5.2 It is a general principle under French law that individuals must specifically consent to any medical act/diagnostic (Article L. 1111-4 of the French Public Health Code - subject to limited exceptions – see below for HIV test).
- 5.3 In France, performance of HIV tests (either expedited HIV tests or tests performed in a duly authorized medical lab) cannot be imposed on the individual, except in very specific situations (donation of blood, organs, gametes, maternal blood) or if the concerned individual has a professional occupation where safety is critical (e.g., aircraft pilot).
- 5.4 The obligation to obtain specific and informed consent for expedited HIV-testing is set forth in Article 3 of decree dated 28 May 2010 and Article 1 of decree dated 9 November 2010.
- 5.5 The expedited HIV-test must be performed in a setting which guarantees confidentiality and privacy (decree dated 9 November 2010 – Annex I, Article 1.5). The healthcare professionals supervising the test must keep medical confidentiality (Article 3 of decree dated 9 November 2010 and Article 226-13 of French Criminal Code).

### 5.6 Does every person have a right to be tested?

- 5.6.1 In France, any individual has access to free and anonymous HIV testing. In particular, French law dated 30 July 1987 and implementation decree dated January 18, 1988 authorize performance of anonymous and free medical labs tests at the patient’s request. Those tests are performed in dedicated free and anonymous testing centers – “*centres de dépistage anonymes et gratuits*”).
- 5.6.2 Also, any individual can access expedited HIV-testing provided the conditions detailed in Section 2 are met.

### 5.7 Can a person be compelled to make any disclosures concerning a positive diagnosis and, if so, in what circumstances?

- 5.7.1 Under French law, individuals tested cannot be compelled to disclose the diagnosis and the healthcare professionals supervising the test must keep medical confidentiality (Article 3 of decree dated 9 November 2010 and Article 226-13 of French Criminal Code).

### 5.8 Can a person be forced to take a test or compelled to have a child tested?

- 5.8.1 No, the individual tested (or his/her legal representative in the case of a child) must specifically and freely consent to the test (after having received adequate information - Article 3 of decree dated 28 May 2010 and Article 1 of decree dated 9 November 2010).

### 5.9 What is the law regarding discrimination based on a person’s diagnosis with HIV?

- 5.9.1 In France, pursuant to article 225-1 of French Criminal Code<sup>5</sup>, it is unlawful – in particular, for employers – to discriminate individuals on the basis of their serological status.
- 5.9.2 However, insurers never have the obligation to provide insurance coverage and they can make their own assessment on the basis of the information provided (on a voluntary basis) by the concerned individual.

<sup>5</sup> Discrimination is punishable before French criminal courts and may entail up to three years’ imprisonment and a fine of 45 000 € (article 225-2 of the French Criminal Code).

## **6. WHAT IS THE LIABILITY, TO THE PATIENT AND/OR THIRD PARTIES, OF A SUPPLIER IF A KIT IS FAULTY/GIVES AN INACCURATE DIAGNOSIS? IS THE ANSWER DIFFERENT IF A KIT IS SOLD RATHER THAN SUPPLIED FREE OF CHARGE?**

- 6.1 The manufacturer/distributor would be liable to the patient and/or to third parties if the product is defective and/or if a fault in the manufacturing/distribution of the device can be evidenced. The main grounds establishing the manufacturer/distributor's liability would be Articles 1386-1 et seq. of the French Civil Code (implementing Directive 85/374/CEE under French law) or Article 1382 of the French Civil Code (tort liability, fault-based regime), it being specified that those grounds are not specific to HIVST. The manufacturer/distributor may also be held liable if the device has been provided free of charge.
- 6.2 Health authorities may also decide to prohibit and/or suspend commercialisation of the test.

## **7. FURTHER ISSUES CONCERNING HIV REGARDING CONSENT, COUNSELLING, DISCLOSURE AND CONFIDENTIALITY**

- 7.1 Before the test is performed, the patient is to be informed that the test is just an indication of the diagnosis and that it will, in any case, need to be confirmed by a full blood test (performed in a medical lab).
- 7.2 Must a person consent to testing (is written consent required)?**
- 7.2.1 As indicated at paragraph 5, the individual tested must specifically consent to the test but written consent is not required (Article 3 of decree dated 9 November 2010).
- 7.2.2 Failure by any of the professionals listed in points 3.3 and 3.7. to obtain the patient's prior consent may result in a claim for damages from the patient under tort. It may also constitute for health professionals a disciplinary offence<sup>6</sup>. In the case of a lay person who uses an HIV self-testing kit on someone without obtaining their consent, they would be liable to the individual for damages under tort and, if violence was used, they might also be criminally liable.
- 7.3 What is the legal age to give consent and what powers do parents/guardians hold in relation to consent process?**
- 7.3.1 The legal age to give consent is 18. Parents/guardians have the authority to decide for their children who are under 18 (healthcare professionals are supposed to consult individuals under 18 even though it is their legal representatives who can make the final decision – Article L. 1111-4 of the French Public Health Code).
- 7.4 What are the rules/norms concerning the provision of counselling to those with a positive diagnosis?**
- 7.4.1 The results of the test are communicated to the patient during an individual medical consultation. During this consultation, the professional supervising the test must explain the limits of expedited HIV-testing in terms of reliability (Article 2 of decree dated 28 May 2010).
- 7.5 Confidentiality of test results**
- 7.5.1 Test results are confidential and the healthcare professionals supervising such test are subject to medical confidentiality duties (Article 3 of decree dated 9 November 2010 – Article 226-13 of French Criminal Code).
- 7.6 Duties of disclosure to partner/employer/insurer**
- 7.6.1 The law does not provide for any general duty to disclose to partner/employer/insurer (subject however to potential criminal liability in cases of HIV transmission to a partner).
- 7.6.2 Insurers can request information from the patient himself / herself but cannot obtain medical information directly from healthcare professionals (who are bound by medical confidentiality). If it can be evidenced that the patient has provided false information to the insurer, then the latter can consider that the insurance contract is not valid (Article L.113-8 of French Insurance Code).

## **8. WHAT ARE THE CRIMINAL IMPLICATIONS OF TRANSMITTING – OR BEING RECKLESS AS TO TRANSMISSION OF – HIV?**

- 8.1 French courts have ruled that a person who has unprotected sex while he/she is aware of his/her serological status is guilty of intentional poisoning and is criminally liable (including through imprisonment) (CA Colmar – 4 January 2005, C. de Cassation – 10 January 2006). To our knowledge, there has been no court decision addressing specifically a situation where the defendant had discovered his/her HIV status through an expedited HIV-test but we can assume the same rule applies.

<sup>6</sup> Employees or voluntary members of an entity involved in disease prevention mentioned in point 3.7 must also comply with good practices guidelines (including obtaining of patient's prior consent) set forth in Annex III of decree dated 9 November, 2010.

## 9. FURTHER INFORMATION

9.1 As indicated above, OTC home tests should be available soon in French local pharmacies (but to our knowledge this is not the case yet). In her declaration, French Minister of Health has not detailed envisaged changes to French legislation. She only indicated that the relevant devices will have to obtain a CE-mark. In its opinion dated 22 March, 2013, the *Conseil National du Sida* suggested that HIVST devices be made available to the general public in community pharmacies (without medical prescription being required), para-pharmacies<sup>7</sup> as well as on the internet. These legislative changes can be followed on the Ministry of Health website ([www.sante.gouv.fr](http://www.sante.gouv.fr)) or on a specialized association website (<http://www.sida-info-service.org>).

## 10. REFERENCES

- 10.1 Arrêté du 28 mai 2010 fixant les conditions de réalisation du diagnostic biologique de l'infection à virus de l'immunodéficience humaine (VIH 1 et 2) et les conditions de réalisation du test rapide d'orientation diagnostique dans les situations d'urgence - <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022320859&dateTexte=&categorieLien=id>
- 10.2 Arrêté du 9 novembre 2010 fixant les conditions de réalisation des tests rapides d'orientation diagnostique de l'infection à virus de l'immunodéficience humaine (VIH 1 et 2) <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023093746&dateTexte=&categorieLien=id>
- 10.3 Conseil National du Sida – Rapport sur les autotests de dépistage de l'infection à VIH (22 mars 2013)
- 10.4 <http://www.cns.sante.fr/spip.php?article466>
- 10.5 ANSM – Mise en garde relative à la vente actuelle d'Autotests VIH sur Internet (22 février 2014)
- 10.6 <http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Mise-en-garde-relative-a-la-vente-actuelle-d-Autotests-VIH-sur-Internet-Point-d-Information/%28language%29/fre-FR>

Paris

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<sup>7</sup> A para-pharmacy is a company which can sell healthcare and hygiene products available without medical prescription (as cosmetics, some dietetic products) and with the exception of drugs.

# SOUTHERN AFRICAN AIDS TRUST

"COMMUNITY SYSTEMS FOR HIV AND  
SEXUAL & REPRODUCTIVE HEALTH &  
RIGHTS"



Southern African AIDS Trust

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Sexual & Reproductive Health & Rights

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