



Southern African AIDS Trust

REPORT

REGIONAL

2014



REVIEW-MOZAMBIQUE

**LEGAL ISSUES SURROUNDING
THE DISTRIBUTION OF
HIV SELF-TESTING KITS**



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 2011¹ 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 2012¹.** 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

¹ 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 Mozambique. This report is intended to inform SAT and all its strategic partners about the legal framework and human rights implications relevant to HIVST in Mozambique.

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,

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 Mozambique and across the region.

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

Jonathan Gunthorp



Executive Director - SAT

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SAT also wishes to thank civil society organisations and partners who attended the HIV Self-testing 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.

DISCLAIMER

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REVIEW



MOZAMBIQUE

MOZAMBIQUE

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CONTENT PAGE

1	INTRODUCTION/BACKGROUND	3
2	SUMMARY OF ADVICE	3
3	IS HIV SELF-TESTING LEGAL AND, IF SO, UNDER WHAT CONDITIONS?	4
4	WHAT LEGISLATION GOVERNS THE DISTRIBUTION OF HIVST KITS AND WHAT RULES/CONDITIONS EXIST CONCERNING THIS DISTRIBUTION?	4
5	WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?	5
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
7	FURTHER ISSUES CONCERNING HIV REGARDING CONSENT, COUNSELLING, DISCLOSURE AND CONFIDENTIALITY	10
8	WHAT ARE THE CRIMINAL IMPLICATIONS OF TRANSMITTING – OR BEING RECKLESS AS TO TRANSMISSION OF – HIV?	12
9	FURTHER INFORMATION	13
10	REFERENCES	13

1. INTRODUCTION/BACKGROUND

- 1.1 This memorandum was prepared for the sole benefit of the Southern African AIDS Trust (hereinafter “SAT”). It may not be relied upon by any person or entity without our express, prior written consent.
- 1.2 The purpose of this memorandum is to assist SAT in the understanding of the Mozambican legal framework relating to HIV self-testing.
- 1.3 The analysis and conclusions set out below are limited to the matters expressly stated herein, and no opinion may be inferred or implied beyond those expressly stated.
- 1.4 Mozambique is a republic with a semi-presidential constitutional democracy and multi-party system.
- 1.5 The domestic legal system is the Roman-German Civil Law or the Continental Law System, which was inherited by Mozambique from its former colonial power, Portugal. Most of the legislation in force in Mozambique (particularly the one that is codified) was also inherited from Portugal, although its interpretation is subject to the rules and principles set forth in the Mozambique’s Constitution.
- 1.6 After the official diagnosis of the first AIDS case in Mozambique, back in 1986, the Mozambican government engaged in an educational campaign on HIV/ AIDS through the Ministry of Health.
- 1.7 Between 1988 and 2009, the following programs/commissions were created/implemented:
 - 1988 – National AIDS Commission;
 - 1990 – HIV/ AIDS Epidemic Alert System;
 - 1994 – National Program for Contending STD/ AIDS, for the integration of the control of sexually transmitted diseases into the programs against HIV/ AIDS;
 - 1998 – Inter-Ministerial AIDS Commission and National Program to Contend AIDS;
 - 2000 – National Strategic Plan to Contend STDs/ HIV/ AIDS (PEN) (2000/2002);
 - 2000 – Action Plan to Contend HIV/ AIDS in Mozambique (Resource Requirements for 2001-2003);
 - 2001 – Action Plan for the Reduction of Absolute Poverty (2001-2005);
 - 2005 – Second National Strategic Plan (PEN II) (2005-2009).
- 1.8 Mozambique has also included some international rules regarding HIV/ AIDS in his domestic legislation.

2. SUMMARY OF ADVICE

- 2.1 As per the client’s request, we analysed several legislation and prepared this memo in order to provide the client with information on several matters relating to HIV self-testing, such as its legality and possible distribution of the relevant kits, liabilities regarding defective products, amongst others.
- 2.2 In summary, the legality of distributing and undergoing testing with HIV self-testing kits for use at home is uncertain in Mozambique as there is no law specifically dealing with this matter.
- 2.3 Although the Mozambican authorities are not aware of existing HIV self-testing kits in the country, HIV testing is only carried out at national hospitals and/or private clinics.
- 2.4 Thus, the possibility of allowing self-tests, which are not referred to in any legislation, needs to be assessed with the Ministry of Health (“MISAU”), as well as the authorization for use of the relevant kits, due to its associated ethical, legal and social implications.

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

- 3.1 There is only one regulation that expressly deals with HIV testing: the Regulation on HIV Counselling and Testing for the users of the National Health Service (Ministerial Order No. 201/ 2009, of 10 August 2009, hereinafter “**Regulation**”).
- 3.2 The Regulation does not contain any provisions or legal definition on HIV self-testing. Moreover, it is worth mentioning that according to the information gathered (on a non-name basis) from the Ministry of Health and some pharmacies and private clinics, self-testing kits (*disposable or home testing*) are not available in Mozambique.
- 3.3 Currently, there are mainly two types of HIV related tests available in Mozambique: (i) blood testing and (i) the so called “*rapid testing*”. Blood testing is performed free of charge before the National Health Service (state hospital) or, at a cost, before private clinics, hospitals and laboratories. The “*rapid testing*” is exclusively used by the National Health Service and involves the taking of a blood sample from a patient’s finger and dropping it into a solution that provides immediate results.
- 3.4 Do note that aside from the above, the National Health Service has also available another type of tests, which, despite being more comprehensive, is not commonly used as it is far more expensive than the two name above: the DNAPCR, normally used in children of HIV patients or in more sensitive cases.
- 3.5 Pursuant to the Law on the Rights and Duties of the Persons Living with HIV and AIDS, all laboratories and blood banks that perform HIV tests are required to be registered with the Ministry of Health and to maintain an updated system of registration and information available to the Sanitary Authorities.
- 3.6 Although the law is silent with regard to the legality of HIV ST, there is also no law prohibiting it. Thus, the actions referred to in section 4 should be taken into consideration when distributing HIVST. What legislation governs the distribution of HIVST kits & what rules/conditions exist concerning this distribution?

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

- 4.1 In order to trade and/or distribute products in Mozambique, one is required to obtain a business license from the Ministry of Trade and Industry (“MIC”) or a specific license issued by the Ministry responsible for the sector of activity in which such product is included, otherwise said trading and/or distribution shall be deemed as illegal.
- 4.2 Although there is no specific law on medical devices, same can be traded, distributed, imported and exported under a business license issued by MIC, provided that same are previously registered with MISAU.
- 4.3 Aside from the aforesaid business license, one needs to obtain MISAU’s prior authorization for importation and trade of the HIV ST kits. The HIV testing kit and/or self – testing kit is considered as a medicine pursuant to the Medicine Law. The definition in article 1(a) states that, amongst others, substances or compositions capable of establishing a medical diagnosis are also deemed as medicines. The Medicine Law states that all medicines and pharmaceutical products can only be imported and placed on the market in Mozambique if the same are registered with the MISAU.
- 4.4 Pursuant to article 18, of Decree no. 22/99 of 4 May, 1999, the interested party (which needs to be a company duly incorporated and registered in accordance with the Mozambican laws) needs to complete the relevant form, which should be submitted alongside with:
 - i) Technical-dossier of the pharmaceutical product;
 - ii) Certificate of registration and trading license from the country of origin, under the terms established by W.H.O, as per the Quality Certification System for Pharmaceutical Products in International Markets; and
 - (i) Samples of the finished product in packages used in the country of origin;
 - (ii) Proof of payment of due fee.
- 4.5 If deemed necessary, MISAU may request additional documents providing sufficient evidence of trials, studies and control, in order to obtain the necessary guarantees relating to the safety, effectiveness and quality of products submitted for registration.
- 4.6 MISAU will issue a license authorizing the entrance of said products in the Mozambican market and afterwards it will update the list of authorised products (according to the information gathered from MISAU, the list is usually updated quarterly). Said license is valid for a period of 5 years, which shall be renewed at least 180 days prior to its expiry date. One can obtain a copy of the medicines and pharmaceutical products authorized, provided that an application is submitted for said purposes, alongside with a blank CD.
- 4.7 Should the purpose consist in supplying ST Kits with no monetary consideration, the aforesaid registration with MISAU is still required and such supply could be achieved through agreements with MISAU and/ or with existing local or foreign NGOS. Alternatively, the interested party may request its registration as a foreign NGO, at the Ministry of Foreign Affairs and Cooperation (“MINEC”), and supply the ST Kits itself.

- 4.8 Exceptionally, in very specific situations, the MISAU may authorize the importation of products not previously listed on the list of medicines and pharmaceutical products registered with MISAU (a copy of the list may be obtained from MISAU). The documents required to obtain this authorization are less in number and in complexity¹ and although MISAU did not provide us with any specification on its timeframe, we were informed that the process to obtain an exceptional authorization is less time consuming than the normal process, which can take up to a year to be finalized. Even if an exceptional authorization is granted, the product is not automatically registered at MISAU. The importer shall have to subsequently request the registration of said product at MISAU and the relevant procedures and documents do not differ from those requested for the issuance of a normal authorization.

With reference to the specific situations, the Law only states that non-registered products can be authorised on an exceptional basis in two circumstances: (i) whenever a product is deemed essential to a treatment or the diagnosis of certain pathologies i.e. public health is at stake, and provided that the practitioner provides MISAU with detailed information on the reasons for requested such product; and (ii) whenever the product is to be exclusively used in research and clinical trials, provided that MISAU has previously approved the intended research protocol. Unfortunately, we cannot confirm whether MISAU would need to make an exception for HIV self-testing kits as MISAU's position can only be confirmed following the submission of the documents required for the registration of the ST kits. However, in light of the above, please bear in mind that it is our understanding that the importation of the HIV self-testing kits does not seem to be included among the grounds for an exceptional authorization.

- 4.9 Devices used by public hospitals are purchased in accordance with the provisions set forth in Law no. 15/2010, of 24 May 2010 (which approves the Regulation on Procurement of Public Works and Supply of Goods and Services to the State). Pursuant to this law, the general rule of procurement of goods for Governmental Institutions is by public tender and the assessment criterion is based on the lowest price. This law is only applicable to government's purchases, thus, it does not have any relation nor can be used in matters connected w/ HIV ST Kits purchased by private bodies or individuals.
- 4.10 According to the information gathered (on a non-name basis) from MISAU, when the national health service purchases medical devices, the main criteria consists in ensuring that such products are W.H.O accredited.
- 4.11 The question of legislative change can only be taken into consideration after MISAU's (eventual) refusal to authorize the distribution of ST Kits, whether for free or not. In such case, one could try to discuss the grounds for the refusal with MISAU in hope of a change of opinion.
- 4.12 Laws, decree-laws, decree, resolutions and ministerial orders can, at any time, be created/ amended through the appropriate channels, in order to accommodate matters that despite being important are not contemplated in any legislation. The procedures, timing and complexity shall depend on the entity with powers for said creation or amendment.
- 4.13 Since the distribution of ST Kits falls under MISAU's umbrella, should it be necessary to include matters in existing legislation and/or create specific ones, one could expect MISAU to propose the issuance of a law, decree-law or decree, to the Parliament or to the Council of Ministers.

5. WHAT ARE THE HUMAN RIGHTS ISSUES SURROUNDING HIVST?

5.1 Does every person have a right to be tested?

- 5.1.1 The Mozambican Constitution establishes the general right to health, comprised by the right to medical and sanitary assistance. This is an absolute right. Under the Mozambican Constitution, the State is responsible for providing medical and sanitary assistance to its citizens through a national health system. Thus, MISAU, through its National Medical Assistance Directorate, is responsible for the management of the national health system.
- 5.1.2 Moreover, it is worth mentioning that medical and pharmaceutical assistance to HIV patients is free of charge in this system.
- 5.1.3 Please note that we are unable to ascertain whether this right has been infringed.

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

- 1.1.1 The Law on the Rights and Duties of the Persons Living with HIV and AIDS expressly forbids practitioners or any health official to disclose HIV tests results to non-authorized third parties. The results can only be disclosed to the person taking the HIV test or to his/her parents in case such person is a minor.
- 1.1.2 The General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/ AIDS, also expressly forbid HIV/ AIDS testing on employees or candidates when requested by the employer without their prior consent.

¹ One is only required to submit an application to MISAU, stating the following: the product's commercial and generic name; its dosage and pharmaceutical formula; the customs office, consignator and consignee; place of origin; and the required quantity.

- 1.1.3 The employee's confidentiality right is also stipulated therein, granting him/her the following rights:
- the right of non-disclosure of his/her condition to third parties in the place of work; and,
 - the right of non-disclosure of his/her condition to the employer without his/her consent.
 - The confidentiality right is also applicable to health officials that may be aware of the employees' condition.

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

- 5.3.1 Although there are no references to HIVST, Article 25(1) of the Law on the Rights and Duties of the Persons Living with HIV and AIDS establishes the prohibition of HIV testing without prior consent as well as the exceptions to such rule and the subsequent article stipulates that counselling and testing should be offered to pregnant women and/or same can request it as part of pre-natal care. Moreover, its article 28 refers that the State acknowledges and allows, among the several testing for HIV, the counselling and testing requested by users of the sanitary unit (ATIU).
- 5.3.2 The statute stipulates that HIV Tests can only be performed with the person's prior consent, except if:
- i) the practitioner deems HIV test necessary exclusively for the patient's health and treatment;
 - ii) related to blood or blood components, maternal milk, organs and human tissues donations²; or
 - iii) tests are required for criminal proceedings/investigations, provided that there is a prior judicial ruling in this regard.
- 5.3.3 The aforesaid statute also provides that HIV tests in minors can only be performed with their parents' prior authorization. However, said authorization is excluded in the situations referred to in paragraphs (i) to (iii), above. See section 7.2 for more information on minors.

5.4 What is the law regarding discrimination based on a person's diagnosis with HIV?

- 5.4.1 In Mozambique, the following internal legislation expressly forbids the discrimination based on a person's diagnosis with HIV:

- Constitution of the Republic of Mozambique – Principle of Universality and Equality;

Law on the Rights and Duties of the Persons Living with HIV and AIDS – forbids discrimination and mistreating of any person that lives with HIV;

Employment Law – establishes, among other principles, the principle of the right to work, of employment and job stability, and of non-discrimination on grounds of sexual orientation, race or HIV/AIDS;

General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/ AIDS – aims to ensure that all workers and job applicants are not discriminated in their workplaces or when applying for job positions for suspicion of being HIV/AIDS carriers.

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 Regulation is silent in this regard. However, the Mozambican (i) Consumer Defence Act (Law No. 22/2009, of 28 September 2009) and (ii) Civil Code, contains general provisions on liability due to faulty goods and/ or inaccurate information.
- 6.2 The information below on the Consumer Defence Act, which is only applicable in cases of sale of goods, relates to the consumer right to be compensated from damages arising from defective goods, whether such consumer is the immediate purchaser of the product or not. The Civil Code's specific provisions on Sale and Purchase Agreements do not contain any references of the extension of said rights to third parties. However, said code has general provisions on non-contractual liability and the provisions therein may also apply to third parties who are affected by an inaccurate diagnosis.

² Since article 13(2) of the Law on the Rights and Duties of the Persons Living with HIV and AIDS stipulates that such persons are proscribed from donating their blood or blood components, breast milk, organs and human tissue, except if for scientific investigation purposes, the HIV test can be made in this circumstances without their prior consent. This exception is indicated in paragraph b, of its article 25(1).

Third Parties

- 6.3 The Civil Code contains a general principle, whereby anyone who intentionally or recklessly (carelessness and negligence) violates a third party right or any legal provision that protects third party rights has to compensate the injured party for the damages arising from the infringement. Based on this general principle (and provided that sufficient evidence is presented), the affected party will be able to seek moral and/or monetary compensations. The following scenario is an example of a situation where an inaccurate diagnosis could lead to a claim by a third party against the supplier:

A and B have recently married and are thinking of expanding the family. A already tested for HIV at a public facility and his results were negative. Since B was not comfortable with going to a private and/or public facility in order to do the test, she purchases an HIVST Kit on her way home. After testing, B has a false negative result.

Based on the results of the HIVST kit, A and B decide to have unsafe sex, as both assume that no additional precaution needs to be taken in order to procreate.

Two months later, B discovers that she is pregnant and both go to hospital in order to undergo exams. The doctor advises B to also take an HIV test. B mentions that she has already taken one and the result was negative but she accepts to take another test anyway.

The results show that the HIVST kit had produced a false negative result. As a precautionary measure A asks to be retested and the results show that he has become infected.

A can seek moral and/or monetary compensation from the manufacturer due to the damages to his health. He can argue that if it were not for the result from the HIVST kit, he and B would not have had unsafe sex and he would have not been infected.

- 6.4 A third party would need to explain the reason why this General principle is being relied on to bring the claim. The claimant must also identify the legal right that was violated by the supplier and provide sufficient evidence that he/she suffered damage as a consequence. The relevant legal rights will vary case by case depending on the circumstances of each case. Depending on the facts, an inaccurate result from a self-testing kit could violate the constitutional right to health.
- 6.5 Consumers who purchase HIVST kits can rely on the General Principle if there is no specific provision providing relief under alternative legislation. However, the Consumer Defense Act specifically provides for consumers and, in most cases, this will be the appropriate basis for bringing an action against a supplier.

Consumer Defence Act (hereinafter referred to as “CDA”)

- 6.6 Under the CDA, in general terms, entities included in the production and trading chain of goods or services being sold or provided to consumers are under the obligation to:
- i) place goods in the market that do not bring any risks to the health or safety of consumers, except those that are deemed normal and expected due to their nature and use;
 - ii) provide adequate information on the goods/services regarding its characteristics, quality, amount, make-up, price, warranty, origin, and risks;
 - iii) guarantee the quality and working condition for a minimum period of 12 months for non-consumable moveable assets, which means that parties may agree to extend the warranty but not limit it;
 - iv) indemnify consumers for damages caused by defective goods/services. As a rule, those entities are joint and severally liable for the aforementioned obligations.
- 6.7 Further to our comments in paragraph (d), above, liability is applicable to all entities in the consumer chain i.e. entities carrying out activities of production, manufacturing, importation, construction, distribution and marketing of goods for consideration. Thus, whenever it is impossible to identify the producer, manufacturer or importer, the seller cannot exclude its own liability.

Information Requirements

- 6.8 The CDA requires consumers to be given clear, objective, and adequate information on all of the characteristics of any good or service purchased (including its price), as well as on the terms of the purchase agreement, any warranties, delivery deadlines, and any customer support provided after the sale. In particular, health and safety risks that may result from the good/service must be informed to the consumer.

- 6.9 The CDA further requires any information provided to consumers to be in Portuguese. This requirement covers any details about the characteristics, quality, amount, make-up, price, warranty, origin, and risks of any goods or services provided.
- 6.10 Entities involved in the production and trading chains of goods or services being sold or provided to consumers in Mozambique must provide (i) adequate information on the goods/services regarding their quality, technical features, price and risks involved in their utilization and (ii) guarantee the quality and working condition for a minimum period of 1 year for moveable non-consumable assets. This means that the parties may agree to extend the warranty, but not to limit it.
- 6.11 With regard to the lack of information, the CDA sets forth that consumers are entitled to return the good or service and be reimbursed for its price within 7 days as of receipt of the goods or execution of the services contract, whenever product information is not made available on adequate terms and such lack or shortage of information compromises the utilization of the good/service. In addition, entities providing goods/services in these circumstances are liable for any damages caused to consumers wishing to return the good or service.

Defective goods/services

- 6.12 Entities selling defective goods are required to remedy the defects within a period of 30 days. Service providers are liable for any quality defects or others which diminish the value of the service. Otherwise, consumers are entitled to:
- i) request the replacement of the good or the repeated provision of the service;
 - ii) reimbursement of the price paid for the goods/services (without prejudice to claiming damages); or
 - iii) request the reduction of the price paid for the goods. The re-execution of the services may be requested to a third entity, the costs of which shall be borne by the initial service provider.
- 6.13 Additionally, consumers may be entitled to claim damages as described below. Defects on goods or services must be claimed within a period of 30 days (for movable goods) as of the date the consumer became aware of the defect.

Damages

- 6.14 Entities selling goods/services that are defective or present features which do not correspond to those that have been advertised are required to indemnify consumers for damages arising from the supply of the good/service, except in cases where the consumer or any third party should be deemed exclusively liable for the damages occurred. This compensation is due regardless of any negligence or wilful misconduct of the entities providing the relevant goods/services.

Refunds and statutory cancellation rights

- 6.15 Pursuant to the CDA, a consumer has a right to withdraw from a contract for goods or services within seven days of receiving them whenever the agreement is entered into outside of a commercial establishment. Any amounts paid under the agreement must be returned.
- 6.16 Furthermore, the CDA grants consumers the right to rescind a sales agreement and demand a refund whenever a defective good is not repaired within 30 days of a complaint being made by the purchasing consumer.

Supplier Concept

- 6.17 The CDA applies to all entities in the consumer chain, i.e. entities carrying out activities of production, manufacturing, importation, construction, distribution and marketing of goods or rendering of services to consumers for consideration. The wording of the law usually refers to the provider of the service or of the goods (the seller) and clearly states that in those cases where the constructor, the producer or the importer may not be identified, the seller may not exclude its own liability.

Applicability

- 6.18 The CDA is applicable to entities involved in the production and trading chain of goods or services sold or provided to consumers. For the purposes of the CDA, a “consumer” is defined as any person to whom goods are provided, services are rendered, or rights are given, for non-professional use, by another acting in the course of a professional economic activity for gain.

Mozambican Civil Code

- 6.19 Further, the Mozambican Civil Code (“CC”) sets forth various general rules (not exclusive to consumer relationships) on sale of defective goods, granting certain rights and remedies to the buyer when the goods sold:
- i) Suffer from a defect which implies a reduction in their value;
 - ii) Suffer from a defect which prevents their use for the purpose they were manufactured and are commonly used;
 - iii) Do not possess the qualities claimed by the seller; or
 - iv) Do not possess the qualities necessary to serve the purpose they were manufactured and purchased for.
- 6.20 In the above cases the buyer is entitled to, alternatively:
- i) Have the good repaired;
 - ii) Have the good replaced, if necessary and if the good can be freely replaced by another good of the same kind;
 - iii) Terminate the contract and receive a compensation for damages; or
 - iv) A reduction in the price in case seller produces evidence that the buyer would have bought the goods with the defects that impair their full enjoyment, but at a lower price.
- 6.21 The remedies referred to in (i) and (ii) above do not apply if the seller did not know the defect or lack of quality, provided said lack of knowledge is not due to seller’s fault.
- 6.22 If the lack of qualities or defects can only be attributed to simple error on the part of the seller:
- i) Damages for loss of profits are expressly excluded (i.e. those benefits that were not gained as a consequence of the unlawful action or omission) meaning that immediate damages suffered, e. g. diminished value of the defective product; physical consequences of the use of the defective product, etc. are still subject to be compensated by the seller;
 - ii) Damages are completely excluded if the vendor was not aware without fault that the product was defective or lacked qualities i.e. all and every damage that the client may have suffered for having purchased a defective product, including immediate damages and loss of profits. The CC sets forth a presumption of fault for the vendor of defective products, which means that the vendor of defective products has to prove he did not act with fault in order to avoid liability and having to compensate the client. In practice, such proof will be very difficult to make.
- 6.23 The buyer must file a complaint with the seller within 30 days of the buyer gaining knowledge of the situation, and within 6 months of delivery of the goods, unless the seller acted with wilful misconduct in which case no notice is necessary.
- 6.24 The minimum warranty period – which is not specific for a consumer and is overruled by any provisions of the CDA – is 6 months, counting from the delivery of the product to the customer. This warranty period cannot be excluded or limited by agreement of the parties.
- 6.25 Furthermore, the purchaser may claim either the repair or replacement of the product in case the vendor is obliged, by agreement between the parties or by custom and usage, to warrant that the product functions properly, regardless of whether there is fault of the vendor or error from the purchaser. This warranty may be excluded by parties. If the contract is silent, an implied warranty of 6 months or other that follows from market practice applies. Within the warranty period the client shall notify the vendor of any defect no later than 30 days of finding the defect.
- 6.26 It must be noted that all the above warranties do not apply in case of normal wear and tear or misuse.
- 6.27 On the other hand, whenever goods are supplied free of charge, the donor cannot be held responsible for the damages arising from defective goods, except if same have expressly undertaken such responsibility or have had a wilful misconduct.

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

7.1 Must a person consent to testing (is written consent required)?

- 7.1.1 Article 25(1) of the Law on the Rights and Duties of the Persons Living with HIV and AIDS establishes the prohibition of HIV testing without prior consent as well as the exceptions to such rule. Please refer to question 5. 3 above which describes the circumstances in which consent is not required. Do note that the law only demands for “consent”, not specifying if it is written or not. Nonetheless, and in order to avoid any doubt, most of the private clinics in Maputo require patients to sign a written consent form before being submitted to HIV testing. The form has a brief explanation on how tests are performed and what help can be sought or is available should the result be positive.
- 7.1.2 Although this law fails to stipulate a consequence for the testing without consent, the General Articles of the State’s Officers and Agents (EGFAE) – approved by law no. 14/2009 of 17 March, 2009 – states that officers are required to comply with all applicable legislation during the performance of their services. As such, should any medical officer perform the testing in breach of the stipulated in article 25(1) of the Law on the Rights and Duties of the Persons living with HIV and AIDS, the same can be subject to disciplinary proceedings, which can culminate with a disciplinary sanction (from a mere reprimand to expulsion).
- 7.1.3 Aside from that, civil actions may also apply, based on the principle referred to in paragraph 6.3., above. What is the legal age to give consent and what powers do parents/guardians hold in relation to consent process?

7.2 What is the legal age to give consent and what powers do parents/guardians hold in relation to consent process?

- 7.2.1 In Mozambique a person is deemed minor until the age of 21. The Law on the Rights and Duties of the Persons Living with HIV and AIDS provides that HIV tests in minors can only be performed with their parents’ prior authorization, which must be informed on the reasons for conducting such testing. However, said authorization is excluded in the situations referred to in section 5. 3, above. Do note that for minors from 16 to 21 years old, HIV tests may be performed with their acceptance, regardless of their parents’ authorization.

7.3 What are the rules/norms concerning the provision of counselling to those with a positive diagnosis?

- 7.3.1 As mentioned in paragraph 3.1., above, Ministerial Order No. 201/ 2009, of 10 August 2009, governs the HIV Counselling and Testing for all users of the National Health System.
- 7.3.2 Do note that counselling is also done by the National Health System before HIV testing in order to prepare the person for an eventual positive result and if positive, the post-counselling is free of charge. Additionally, pursuant to the Law on the Rights and Duties of the Persons Living with HIV and AIDS, HIV citizens benefit from free health care in all National Health System.
- 7.3.3 There are no specific rules concerning the provision of counselling to those with positive diagnosis when the test is performed in private clinics. We are aware that some private clinics offer post-counselling for positive diagnosis, upon patient’s request. However these are not free of charge.
- 7.3.4 The Ministerial Order does not contain any information on the required standard of the counselling. However, same refers to the requirements and types of counselling.
- 7.3.5 With reference to the requirements, article 8 of said Ministerial Order states that the counselling process involves: (i) the presence of an health care provider / counsellor and the beneficiary user, (ii) a confidential dialogue, and (iii) privacy and confidentiality of the information obtained in said dialogue.
- 7.3.6 It is further mentioned that such counselling process aims to capacitate the user with knowledge on the risks of transmission, promotion of positive behaviours, emotional support for the taking of the test or for the decision-making subsequent to the test.
- 7.3.7 With regards to the types of counselling, the Ministerial Order stipulates two: the one that is given prior to the testing (“prior-testing”) and the one given afterwards (“post-testing”).
- 7.3.8 Pursuant to article 10 of the Ministerial Order, Prior-testing counselling is the confidential dialogue between the health care provider / counsellor and the user on his/hers health condition with regards to HIV and AIDS, in which the risk of transmission, his/hers apprehensions, doubts and the implications of possible outcomes are assessed so that the user can consciously give his/hers consent for the HIV testing. This counselling can either be individual or collective (for couples, families, group education and pregnant women in pre and post natal consultations).

- 7.3.9 Article 11 of the Ministerial Order stipulates that Post-testing counselling corresponds to the confidential dialogue between the health care provider / counsellor and the user on his/hers health condition with regards to HIV and AIDS, in which the result of his/hers test is explained to him/her. An immediate plan of life is made, references to emotional, social and clinic support are given, as well as an orientation towards the disclosure of his/hers clinical condition. Preventive measures are also emphasized. This counselling can either be continuous and of a follow-up nature (applicable to HIV positive users, in order to provide them medical care as well as institutional, emotional, and social support) or monitored (applicable for non-positive HIV users to positively influence their way and habit of life and reinforce the preventive measures).

7.4 Confidentiality of test results

- 7.4.1 The results of the HIV tests are strictly confidential. Inclusively, the Law on the Rights and Duties of the Persons Living with HIV and AIDS stipulates that anyone that reveals the confidential records of a HIV test result, to which accessed by means of his/hers professional duties, will be punished with a 1 year imprisonment and subject to fine in the amount up to six months.

7.5 Duties of disclosure to partner/employer/insurer

Partner

- 7.5.1 Pursuant to article 13(1.g), of the Law on Rights and Duties of Persons Living with HIV/AIDS, persons living with HIV/AIDS have, amongst others, the obligation of informing their spouse or sexual partner about their HIV condition.

Employer

- 7.5.2 With regards to employers, the Law no. 5/ 2002, of 13 February, 2002 (which approves the General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/AIDS) stipulates, in its article 6(1), that employees cannot be forced to inform their HIV status to the employer.
- 7.5.3 Having said that, please note that the Labor Law stipulates, in article 104 (1), that if an employee is absent from work for an uninterrupted period of more than 15 days due to illness, the employer can present him/her to the Board of Health (which is composed by practitioners from MISAU) or to other licensed body, in order to obtain a ruling on his/hers capacity to work. Employees that have their productivity affected due to health reasons or that, due to illness, are absent from work for more than 5 interrupted times for each trimester, can also be presented to said Board for the same purposes.
- 7.5.4 Furthermore, since employees cannot be dismissed based on their HIV status, pursuant to article 9 of the General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/AIDS, employers are required to train and reorient the employee that, being infected with HIV, is unable to perform his/hers job functions, giving him/her a job compatible with his/hers residual capacity. The law is silent as to whether the employee would need to disclose his/her HIV status in order for the employer to accommodate the employee. However, one may assume that such disclosure would have to occur at some point (either by the employee or, if the employee is submitted to the Board of Health, by the Board), so that the employer can comply with its training and reorientation obligation.

Insurer

- 7.5.5 Pursuant to Law no. 1/2010 of 31 December, 2010 (which approves the Insurance Legal Framework) the parties are subject to an information duty. With reference to the policy holder, such duty implies that he/she needs to provide the insurance company with all information and facts that he/she may or should be aware of, which may influence the insurance company's assessment of the risk.
- 7.5.6 In case of health insurance, should the policy holder fail to provide the relevant information, such as his/hers HIV status, the insurance company is entitled to terminate the insurance agreement due to breach of the information duty.

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

- 8.1 The Law on the Rights and Duties of the Persons Living with HIV and AIDS establishes the following criminal implications for HIV transmission:
- i) If anyone knowing his/hers HIV status intentionally transmits it to others, same will be punished with 2 to 8 years imprisonment;
 - ii) Such punishment will also be applicable to whom, being reckless, transmits the HIV to others.
- 8.2 In case someone, even by negligence, transmits the HIV in mass, using any kind of transmission process, excluding sexual transmission, such person will be punished with 8 to 12 years imprisonment.
- 8.3 The following facts are also deemed criminal offenses by the referred statute and subject to penalization:
- i) Discrimination – depending on the circumstances it can be punished with a 3 months' imprisonment and a fine in the amount up to one month;
 - ii) Unauthorized publication of the image of a person that is HIV positive without his/hers consent – punished with imprisonment and fine;
 - iii) Libel, defamation or slander – punished with up to 1 year imprisonment and fine in the amount up to six months;
 - iv) Providing third parties with confidential information regarding HIV results – punished with up to 1 year imprisonment and fine in the amount up to 6 months; and
 - v) Falsifying HIV tests results – 2 to 8 years imprisonment.
- 8.4 Although the above, we were not able to determine whether there is any criminal case regarding this type of crime.

9. FURTHER INFORMATION

- 9.1 Since the Mozambican law is silent regarding HIV self-testing, in order to safeguard the importer's position, we believe that it would be wise to submit an application to MISAU requiring its authorization for the importation and trade of such tests, before importing same. Said application should provide along with all necessary information regarding the composition and usage of the self-testing kits.
- 9.2 We hope the above to be of assistance and remain at your entire disposal to clarify and/or further discuss any aspect of our advice.

Pimenta Dionísio e Associados

April 2014

10. REFERENCES

- 10.1 Please find bellow a list of the current domestic legislation addressing (directly or indirectly) issues relating to HIV/ AIDS:
 - 10.1.1 Constitution of the Republic of Mozambique (2004);
 - 10.1.2 Resolution No. 44/ 2009, of 19 August 2009 – Strategy of Response to HIV/ AIDS in Public Servants;
 - 10.1.3 Resolution No. 73/ 2008, of 30 December 2008 – Strategy to Accelerate the Prevention on HIV;
 - 10.1.4 Resolution No. 27/ 2000, of 31 October 2000 – ratifying the SADC Protocol on Health;
 - 10.1.5 Law No. 12/ 2009, of 12 March 2009 – Law on the Rights and Duties of the Persons Living with HIV and AIDS;
 - 10.1.6 Law No. 23/ 2007, of 1 August 2007 – Employment Law;
 - 10.1.7 Law No. 5/ 2002, of 13 February 2002 – General Principles of Protection Against Discrimination of Employees or Candidates and in employing people living with HIV/ AIDS;
 - 10.1.8 Law No. 4/ 98, of 14 January 1998 – Medicine Law;
 - 10.1.9 Decree No. 22/ 99, of 4 of May 1999 – Regulation on the National System for Medical Registration;
 - 10.1.10 Ministerial Order No. 201/ 2009, of 10 August 2009 – Regulation on HIV Counselling and Testing for the users of the National Health Service;
 - 10.1.11 Governmental Policy about the Health National System for the Assistance and Treatment of People Living with HIV/ AIDS (2001).

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