

# LEGAL DEFENSE FOR SUPPLIERS AND DISPENSERS OF ESSENTIAL MEDICINES FOR SEXUAL REPRODUCTIVE HEALTH SERVICES



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#### Center for Health, Human Rights and Development

### LEGAL DEFENSE FOR SUPPLIERS AND DISPENSERS OF ESSENTIAL MEDICINES FOR SEXUAL REPRODUCTIVE HEALTH SERVICES



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#### **ACKNOWLEDGEMENTS**

#### **Authors:**

- 1. Mulumba Moses
- Nakibuuka Noor Musisi
- 3. Nsereko Ibrahim
- 4. Rose Wakikona
- 5. Wasswa Paul
- 6. Nakalembe Judith

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**Disclaimer:** This document should not be construed as medical or legal advice but the recommendations made are drawn from international best practices.

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#### 1. KEY DEFINITIONS USED IN THIS PUBLICATION

**Abortion:** Abortion is the ending of a pregnancy by removal or expulsion of an embryo or fetus before it can survive outside the uterus.

**Abortifacient:** An abortifacient is a substance/drug that induces abortion. Common abortifacients used in performing medical abortions include misoprostol and mifepristone, which can either be used independently or together.

**Dispense:** To supply a medicine or poison on and in accordance with a prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon.<sup>1</sup>

**Dispenser:** A dispenser is someone who dispenses/carries out the act of dispensation

**Drug:** Any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes.<sup>2</sup>

**Essential Medicines:** World Health Organization (WHO) defines these as Medicines that satisfy the priority health care needs of the population. These are the medications to which people should have access at all times in sufficient amounts.<sup>3</sup>

**Harm Reduction:** Harm reduction, or harm minimization, refers to a range of public health policies and practices designed to lessen the negative social and/ or physical consequences associated with various human behaviors, both legal and illegal.

**Prescription:** A piece of paper on which a doctor writes the details of the medicine or drugs that someone needs

**Supplier:** A person who supplies or agrees to make available a good or service.

<sup>1</sup> Section 1 of the National Drug Policy and Authority Act Cap 206.

<sup>2</sup> Section 1 of the National Drug Policy and Authority Act Cap 206.

<sup>3</sup> https://www.who.int/medicines/services/essmedicines\_def/en/

#### 2. INTRODUCTION

Uganda is burdened with a high maternal mortality rate that currently stands at 336 maternal deaths per 100,000 live births<sup>4</sup> and 26 percent of those maternal deaths are due to unsafe abortions. These unsafe abortions are largely due to inadequate access to contraceptives, teenage pregnancies and the restrictive legal and policy environment that criminalizes termination of pregnancy and this has a negative effect on the lives of several adolescent girls and young women as documented by the Center for Health, Human Rights and Development in its publication titled "Facing Uganda's Law on Abortion: Experiences of women and service providers".<sup>5</sup>

Women who have abortions have been subjected to stigma and discrimination and have faced the negative impact of the Law due to the criminal sanctions contained in the Penal Code Act, cap 120 that criminalize abortion. Due to the said criminal sanctions imposed by this law which was enacted in 1950, this has influenced the negative societal, religious and cultural perceptions towards abortion and this continues to be a huge challenge in realizing sexual and reproductive health rights in Uganda.

While the Constitution of Uganda mandates the Parliament of Uganda to enact a law that prescribes the circumstances under which an abortion can be done<sup>6</sup>, the Parliament has not yet fulfilled its mandate. As such, the Ministry of Health formulated and passed the National Policy guidelines on sexual and reproductive health 2006 that prescribe the circumstances under which an abortion be carried out. However, because the Penal Code Act supersedes these guidelines, the guidelines are simply directory and have no legal force.

<sup>4</sup> Uganda Bureau of Statistics "Uganda Demographic Health Survey" 2016 <a href="https://health.go.ug/download/file/fid/1325">https://health.go.ug/download/file/fid/1325</a>

<sup>5</sup> Center for Health, Human Rights and Development "Facing Uganda's Law on Abortion: Experiences of Women and Service providers" July 2016 Available at <a href="https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/Uganda-Abortion-Law-Experiences.pdf">https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/Uganda-Abortion-Law-Experiences.pdf</a>

<sup>6</sup> Article 22(2) of the Constitution of the Republic of Uganda, 1995

This therefore leaves health service providers including drug dispensers and suppliers of abortifacients, in fear of providing accurate and adequate information on abortion and this hinders the supply of abortifacients such as mifepristone and misoprostolto women and girls of reproductive age. As such, many suppliers and dispensers of abortifacients have been arrested and charged under the Penal Code Act for supplying abortifacients and have suffered harassment from police and National Drug Authority (NDA) for being in possession of these drugs.

Given the circumstances, it is important to develop a legal defence for the suppliers and dispensers of abortifacients to protect them from police harassment but also to build their confidence to supply abortifacients within the confines of the law.



#### 3. SITUATIONAL ANALYSIS

In almost all circumstances where men and women exist, pregnancy will inevitably occur and in Uganda it is estimated that over 2.5 Million pregnancies occur annually (2013), with only just 48% actually planned. Unintended pregnancy is common and close to 700,000 births are as a result of unwanted pregnancies.

Over 314,000 induced abortions were estimated to occur with close to 120,000 women and girls suffering severe complications leading to a whopping 1500 deaths. WHO estimates that 22 million induced abortions occurred in 2012 globally. In Uganda alone, 14% of all pregnancies end in induced abortions and most of these end up as unsafe. Criminalizing abortions therefore, does not affect abortion prevalence but rather abortion safety and risk to maternal morbidity and mortality.

These unsafe abortions are largely as a consequence of unplanned pregnancies that finally become unwanted and end up being terminated. The incidence of induced abortions in both developed and underdeveloped countries is largely the same. However, the difference lies in safety. Where induced abortions are legal and accessible, there is less (minimal) abortion complications and morbidity. This legal defense will demonstrate to suppliers their role in providing care and commodities to a person requesting for an abortion in this restrictive environment

Uganda has maintained a restrictive legal and policy framework on termination of pregnancy however, women and girls of reproductive age suffer as a result of unintended pregnancies. This therefore leads many of them to have an abortion in unsafe and unsanitary conditions through using detergents, hangers, traditional herbs, sticks and may other harmful substances and practices and many of these practices have resulted into death which has contributed to Uganda's high maternal mortality rate.

<sup>7</sup> Leonel Briozzo, et al (2016) implementation of the risk and harm reduction strategy against unsafe abortion in Uruguay: From university hospital to entire country. International journal of Gynecology and obstetrics 134 (s1): S7 – S11.

<sup>8</sup> Ibio

<sup>9</sup> Guttmacher Institute factsheet on abortion and post abortion care in Uganda, February 2017

The laws also fail to recognize medical advancements which include medical abortion where abortifacients are used to get an abortion and, this makes it difficult for suppliers and dispensers to provide abortifacients given that they have little or no protection under the law.

The restrictive environment has therefore prevented health service providers from availing essential information and medicines such as abortifacients like mifepristone and misoprostol (as provided for on the World Health Organization list of essential medicines) yet these medicines are crucial to life and for survival. As such, the legal defence for the suppliers and dispensers will enable suppliers and dispensers to understand their legal rights and responsibilities while exercising their mandate in the supply and dispensing of essential medicines.

### 4. LEGAL STATUS OF ABORTIONIN UGANDA AND THE SUPPLY AND DISPENSING OF ESSSENTIAL MEDICINES.

Uganda's laws such as the Constitution of the Republic of Uganda and the Penal Code Act restrict the provision of abortion services. The Constitution, which is the Supreme law of Uganda, provides that abortion may be as authorized by law. <sup>10</sup> This means that the Constitution restricts abortion to what is provided for in law. A comprehensive law on abortion does not exist but there are snippets of provisions in various laws that give some guidance.

The available law which is the Penal Code Act, cap 120 of Uganda, which gives the most guidance, is rather archaic. This 1950 law criminalizes the provision of abortion services but also provides a defense for a health worker who provides an abortion in good faith to save the life of a pregnant woman. It provides in section 224<sup>11</sup> that "A person, who in good faith and with reasonable care and skill, performs a surgical operation upon an unborn child for the purpose of saving the pregnant woman's life, is legally protected". This means the law permits surgically executed abortions that are intended to save a pregnant woman's life.

#### 4.1. Restrictions in the law

The Penal Code Act cap 120 specifies instances in which abortion is not permitted. These include:

• In section 141<sup>12</sup> where unlawfully administering to any woman any substance or using any force or any means on her for the purpose of terminating a pregnancy is prohibited. Once a person is tried and is convicted of this offense, the maximum penalty is imprisonment for fourteen years. This means that health workers and others are prohibited from taking any of the above-mentioned actions as they will be violating the law.

<sup>10</sup> Article 22(2) The Constitution of the Republic of Uganda, 1995

<sup>11</sup> Penal Code Act, cap 120 Laws of Uganda

<sup>12</sup> Ibid.

- In section 142<sup>13</sup>, a woman unlawfully administering to herself any substance or using any force or any means on herself or even permitting such a thing to be used on her with the purpose of terminating a pregnancy and the maximum penalty if convicted is seven years imprisonment. This means no woman is allowed to terminate or even allow another person to terminate her pregnancy unlawfully.
- In section 143<sup>14</sup> where a person supplying anything well knowing that it will be used unlawfully to terminate a pregnancy does so in violation of the law and policy guidelines this means not even the pharmacist is allowed to provide anything to a woman or to any person knowing that it is to be used for termination of a pregnancy. If a person is convicted of supplying an abortifacient, the imprisonment term is a maximum of three years.
- In section 212, any person through any act or omission who prevents a child about to be delivered from being born alive commits an offence. Here the law does not look at intention to terminate. It goes an extra step to protect a child that is about to be born.

#### 4.2. Preferring charges on abortion

In determining whether a person committed a crime generally and in abortion related offences specifically, there are 2 issues to consider.

- Persons state of mind \or intent (mens rea)
- The actual physical act of committing a crime (actus reus)

In order for a person to be convicted of having committed a crime it must be proven that he or she engaged in some physical act or took action to do so and he had the intention to do so.

<sup>.....</sup> 

<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

#### 4.3. Status of Supplying and dispensing essential medicines

Though, the Penal Code Act provides for some restrictions that are detrimental for the supply and dispensing of medicines including abortifacients, the National Drug Policy and Authority Act Cap 206<sup>15</sup> under Section 8 provides for a list of essential drugs and on the Ministry of Health Essential Medicines and Supplies list of 2016,<sup>16</sup> misoprostol is on the list of essential medicines. This means that suppliers and dispensers of such medicines are legally mandated to supply or dispense such drugs/medicines as and when requested.

As such, the National Drug Policy and Authority act offers some protection to dispensers and suppliers of misoprostol.

#### 4.4. Definition of comprehensive abortion care (CAC)

We also have the 2006 National Policy Guidelines and Service Standards for Sexual and Reproductive Health and Rights provide that Ugandans are entitled to "comprehensive abortion care services (CAC)." This is defined as "... health care provided to a woman or a couple seeking advice and services either for terminating a pregnancy or managing complications arising from an abortion." In 2012, new guidelines were made but Ministry of Health stayed them and therefore cannot be used.

#### 4.5. Who can access a legal abortion?

The 2006 Policy Guidelines on CAC indicate that such service should be made available to persons with:

- Severe maternal illnesses threatening the health of a pregnant woman e.g. severe cardiac disease, renal disease, severe pre-eclampsia and eclampsia;
- Severe feotal abnormalities which are not compatible with extra-uterine life e.g. molar pregnancy and anencephaly;
- Cervical cancer;

<sup>15</sup> https://www.fia.go.ug/sites/default/files/publications/National%20Drug%20Policy%20and%20Au thority%20Act.pdf

<sup>16</sup> http://health.go.ug/download/file/fid/1366

- HIV-positive women requesting for termination in accordance with bullet one above; and
- Victims of rape, incest and defilement whose pregnancy is affecting the health of the mother.

#### 4.6. Facilities that can provide CAC

The 2006 Policy guidelines further outline the level of facility in which termination of a pregnancy may be performed and what cadre of health workers can perform such procedures;

- A medically induced abortion can be performed in a general or referral hospital, or a health center IV (HC IV) by a midwife, nurse, clinical officer, medical officer, or gynecologist/surgeon;
- A surgical abortion can be performed only in a general or referral hospital and must be done by a gynecologist/surgeon.
- Evacuation for incomplete abortion in PAC can be done in a Health Centre II-III (HC II-III) facility, HC IV facility, general hospital, or referral hospital; and midwives, nurses, clinical officers, medical officers, and gynecologists may all offer evacuation for incomplete abortion and post-abortion family planning services.

#### 4.7. Post Abortion Care (PAC)

The 2006 Policy Guidelines also allow for and define PAC as "health care given to a woman who has had an abortion due to any cause." The care is to be provided on a 24-hour basis as an integral part of sexual and reproductive health services. The services are to be provided in all health facilities adequately equipped to handle such cases. Services under PAC include:

- Emergency care to respond to abortion complications including resuscitation, evacuation of the uterus for incomplete abortion and other surgical interventions
- Appropriate referrals

- Post abortion counseling including self-care, post treatment expectations, post-abortion family planning and services. This will include information on emergency contraception
- Linking of PAC clients to other existing SRHS including STI/HIV/AIDS treatment and counseling, infertility and screening for gynecological cancer, among others.
- The guidelines further state that for a surgical intervention on an incomplete abortion a health worker can employ the use of an MVA or D&C procedure, or any type of surgical intervention.

Target and priority groups for PAC in these guidelines identified as all women and girls who have had abortions and are faced with abortion complications, including their partners and caretakers who may need counseling to provide the necessary support to ensure quick recovery.



### 5. LEGAL RISKS AND OPPORTUNITIES OF SUPPLIERS OF ABORTIFACIENTS

#### 5.1. Laws specific to suppliers

As seen in the above provisions suppliers of abortifacients are even more restricted in section 143<sup>17</sup> which states that a person supplying anything well knowing that it will be used unlawfully to terminate a pregnancy does so in violation of the law and policy guidelines this means suppliers of abortifacients work within an even more restricted environment when providing abortifacients.

The Pharmacy and Drug Act, cap 280 impose a duty on pharmacists to supply drugs<sup>18</sup> and establishes the Pharmaceutical Society of Uganda<sup>19</sup> which provides guidance to suppliers on their work. This law imposes an obligation a pharmacist to supply drugs when presented with a valid prescription to a client or to a medical profession when they request for it.

There is also the National Drug Policy and Authority Act, cap 206 which establishes the essential drugs list<sup>20</sup> to which Misoprostol is listed for PAC<sup>21</sup>, ulcers and haemorrhage and Mifepristone is listed for medical abortion. These are the major abortifacients we have in the country and a supplier can supply these without fear of prosecution as long as they do so to a medical professional or a person who has a valid prescription.

<sup>17</sup> Penal Code Act, cap 120 Laws of Uganda.

<sup>18</sup> Section 28 of the Pharmacy and Drug Act, cap 280 - If a pharmacist carrying on or employed in a pharmacy business is requested during normal business hours to dispense a valid prescription, or to supply any drug to a registered medical practitioner, a veterinary surgeon or dentist for use in immediate treatment, he or she shall comply with the request unless there are reasonable grounds for his or her failing to do so.

<sup>19</sup> Section 5 of the Pharmacy and Drug Act, cap 280

<sup>20</sup> Section 8 of the National Drug Policy and Authority Act, cap 206 - There shall be a national list of essential drugs which shall be revised from time to time.

<sup>21</sup> Republic of Uganda Ministry of Health – Essential Medicines and Health Supplies List for Uganda – 2016 at page 70

There is the classifications of drugs that need a prescription as restricted<sup>22</sup>. This law imposes an obligation on suppliers to have the necessary skill to dispense drugs according to the regulations set by the National Drugs Authority which require the dispensation of abortifacients to be as against a valid prescription and only to responsible persons. Supply of restricted drugs can be done by a licensed person and a person registered or enrolled under the Nurses and Midwives Act or any other authorized person in accordance with regulations made by the Minister in that behalf

#### 5.2. The risks suffered

- Supplying abortifacients which are classified as restricted means that they
  require a prescription to dispense and many people do not seek medical
  services in order to access a safe abortion which hinders supply.
- Suppliers ran the risk of harassment from the NDA enforcement officers
  which enforces the National Drug Policy and Authority Act and they usually
  use mystery clients to entrap them and levy huge fines which affect supply.
  This makes suppliers a soft targets for entrapment as people who supply
  abortifacients even when they just have them in stock.
- Employing unqualified and unlicensed people to dispense the drugs may cause them to do so wrongly and if there are repercussions and there is need for post abortion care and this brings them problems.
- Suppliers being unaware of the legal environment may lead them to operate in a knowledge vacuum which puts them in conflict with the law.
- Some abortifacients like combipac are not on the essential medicines list which makes it difficult to supply the same.
- Supplying abortifacients presents the risk that something might go wrong and not having a referral points for PAC with friendly facilities may prove problematic.

<sup>22</sup> Section 13 of the National Drug Policy and Authority Act, cap 206 - no person shall mix, compound, prepare, supply or dispense any restricted drug unless that person is a registered pharmacist, medical practitioner, dentist or veterinary surgeon or a licensed person.

#### 6. MITIGATING THESE RISKS USING THE HRM

#### 6.1. Definition and origin of the HRM

The Harm Reduction Model has been defined as:

"An evidence-based public health and human rights framework that prioritizes strategies to reduce harm and preserve health in situations where policies and practices prohibit, stigmatize and drive common human activities underground."

Originally developed to prevent the spread of HIV/AIDS by encouraging the exchange of used syringes for new ones to limit syringe sharing, the HRM was re-conceptualized by the Uruguayan organization Iniciativas Sanitarias to prevent unsafe abortion in what has been referred to as the Harm and Risk Reduction Model which we now call the Harm Reduction Model.

The HRM seeks to prevent unsafe abortion by ensuring that women and girls of reproductive age facing an unintended pregnancy receive comprehensive information and care so that they can make autonomous decisions. It also mobilizes health professionals so that they become agents of change, training them on medical ethics and clients' right to information, health and confidentiality, and by providing opportunities for them to champion efforts to reduce the harm caused by unsafe abortions.

#### 6.2. Goals of the HRM.

The HRM is purposed to:-

- a) Reduce morbidity and mortality related to unsafe abortions,
- b) Reduce the risks of unsafe abortion,
- c) Reduce the number of pregnancies that are terminated in unsafe conditions.

#### 6.3. Guiding principles of the HRM

The harm reduction model is primarily based on three key principles: neutrality, humanism and pragmatism

#### **NEUTRALITY**

ealth service providers should not judge the underlying activity's legality or morality, but should concern themselves with the risks and harm associated with the given activity; unsafe abortion is, above all, a contributor to maternal mortality and morbidity. Therefore, health service providers have the obligation to provide information about technologies and procedures that minimize the personal and social harms of unsafe abortion, even in contexts where abortion is legally restricted or prohibited.

#### **HUMANISM**

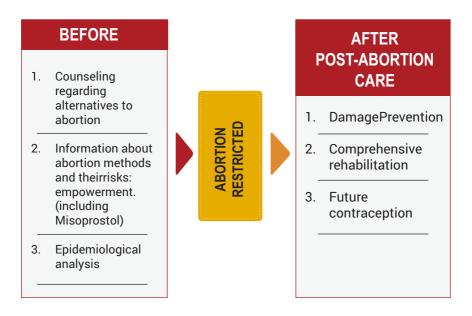
Regardless of how abortion may stand within the general moral opinion or legal norms, all women should be treated as deserving of concern for their health and lives. Irrespective of moral or legal considerations, women's health needs should be understood and addressed.

#### **PRAGMATISM**

environment, women may decide to have an abortion. Where there is evidence that women are continuing to attempt or undergo unsafe abortions, health service providers are obligated to attempt to mitigate as much harm as possible by providing women with information about the safest and most effective services and methods available to them.

#### 6.4. Guidelines of the HRM

The HRM identifies the health workers' intervention before the abortion, during the abortion and after the abortion.



#### 6.5. Legal framework of the HRM

The legal and regulatory framework on abortion in Uganda is largely restrictive, requiring health service providers to implement the HRM. The HRM is not focused on the legality of abortion, but rather on mitigating the harmful consequences related to unsafe abortion that impact women and girls of reproductive age in Uganda.

The HRM recognizes that clients have rights and providers have obligations;

#### **CLIENT RIGHTS**

- Right to access correct information
- Right to Privacy
- Right to Confidentiality
- Right to bodily autonomy
- Right to medical care

#### **PROVIDER OBLIGATIONS**

- O Do no harm
- Act professionally
- Provide privacy
- Obligation to provide care
- Provide correct and accurate information
- Non judgementally
- Confidentiality

#### 7. MITIGATING THESE RISKS USING THE LSN

#### 7.1. What is the Legal support network?

This is a group of lawyers constituted to form the legal support network with the mandate to provide legal services to health service providers who are arrested by the police for providing safe abortion services including post abortion care.

#### 7.2. Who forms the network?

LSN involves two stake holders namely the health workers who provide safe abortion services to the women or girls and the lawyers to defend the health workers who provide the service. It was agreed that CEHURD would take the overall lead and coordinate the LSN.

The LSN lawyers are mandated to provide legal advice and representation to a health worker caught in the criminal justice system. The network partners with lawyers and the health service providers through a memorandum of understanding which will require such conditions as undertaking of compliance checks of health service providers to ensure that minimum legal and clinical standard are observed while providing the safe abortion services.

The LSN uses 3 approaches to its work which include the preventive approach, the reactionary approach and advocacy. In the preventive approach we make sure that a health worker does not come into conflict with the law by ensuring they comply with the laws set and we vet this compliance through site visits to the facilities. The reactionary approach includes legal representation assistance provided by the LSN to the health service provider who falls within the ambit of the legal and clinical standards required and advocacy includes advocating for a more progressive environment on abortion care.

#### 7.3. Expectations of the Legal support network.

Expectations of LSN from the health service provider of safe abortion services are:-

- Expected to make referrals of relevant cases to the LSN.
- To operate within the legal requirements and clinical standards.
- To raise their legal needs while providing safe abortion services.
- To build the capacity of LSN lawyers such that their medical knowledge of the relevant, abortion-related issues can be improved.







## LEGAL DEFENSE FOR SUPPLIERS AND DISPENSERS OF ESSENTIAL MEDICINES FOR SEXUAL REPRODUCTIVE HEALTH SERVICES





#### **CENTER FOR HEALTH, HUMAN RIGHTS & DEVELOMENT**

Plot 4008, Justice Road, Canaan Sites, Nakwero, Gayaza - Kalagi Road.

Tel: +256 414 - 532283, Toll free - 0800 313 131 P.O. Box 16617, Kampala.

info@cehurd.org

www.cehurd.org

