Mapping of national laws and international and regional standards in health: Zimbabwe

Briefing document

Produced under the auspices of the Legal Working Group of the Advisory Board of Public Health: by Mr T Mugabe, Dr R Loewenson, Lt Col Dr K Mudambo, Mrs S Dube- Mwedzi, Dr C Nyatsambo[1]

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1. Background

This document has been produced as a briefing document on the public laws in Zimbabwe. The Advisory Board of Public Health is constituted in terms of the Public Health Act and one of its functions is to advise the Minister of Health and Child Welfare on areas of review of public health related law and its implementation in Zimbabwe. The legal working group to the Board mapped in 2010 the existing laws as an input to this. This document contains a mapping of national laws and international treaties in the area of public health. It was prepared as a resource document for wider reference. Comments and feedback are welcomed to phabzim@gmail.com. An updated version will be produced incorporating any feedback and comments received.

The document presents for Zimbabwe, in part 1: Acts relevant to public health, and in part 2: Major regional and international standards relevant to public health

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Part 1: Mapping of Zimbabwe's health laws

Zimbabwean law is what is commonly referred to as Roman – Dutch Common law influenced by local customs and traditions as modified from time to time by statute. Put simply this means the law is based on ancient Roman, Dutch, English and South African principles of law, justice and equity as established and applied centuries ago, perfected and or improved upon by our judiciary during the colonial and post colonial period as well as legislative pronouncements made to supplement and consolidate the said legal principles.

Where health is concerned, the starting point would be the acknowledgment by common law, custom and tradition, and indeed the legislature of the sanctity of human life. In this regard laws have existed and new ones created that recognize the sanctity of life, protect it, and put in place measures to prevent unnecessary and or preventable destruction of human life. This has taken the form of criminal law which makes it a criminal offence punishable by the most extreme punishments, the causation of loss to life, the infliction of bodily injury, the willful transmission of disease etc. Criminal law was until 1st July 2006[2], based mostly on common (unwritten law) with a number statutory offences created under various statutes. Now, and with the commencement of the Criminal Law (Codification and Reform) Act [*Chapter 9:23*] all criminal offences are written. This Code includes all crimes that seek to preserve and or protect human life from any threats to its existence.

The statute law of Zimbabwe is divided into thematic chapters numbered from one to twenty nine as of April 2009. For example *Chapter 7* and all 18 Acts of Parliament under that Chapter are about the courts and the administration of Justice.[3]

Public Health delivery and issues connected and or ancillary thereto mostly fall under Chapter 15. Usually the thematic chapters will represent a certain portfolio, so one finds that almost all Acts under Chapter 15 are administered by the Minister of Health and Child Welfare. Because health issues permeate many other facets of law there will be other enactments that affect public health outside this Chapter. For example, Chapter 27 deals with Professions and Callings. Under Chapter 27 one will therefore find the following Acts that are relevant to public health in Zimbabwe to the extent that health and allied professionals directly or otherwise influence public health by virtue of their professions and callings:
Traditional Medical Practitioners Act [*Chapter 27:14*];
Veterinary Surgeons Act [*Chapter 27:15*];
Health Professions Act [*Chapter 27:19*];
Social Workers Act [*Chapter 27:21*]

1.1 CHAPTER 15

Statutes under this or any other chapter are not arranged in any order of priority, so nothing should be read into the arrangement. After the 1996 revision and recompilation of statute laws they were all put into chapters and numbered first alphabetically and then now with the addition of new laws the alphabetical arrangement is replaced as acts of subsequent years naturally get later chapter numbers.

[2] Statutory Instrument 152 of 2006
[3] For example The Administrative Court Act [*Chapter 7:01*], The Customary Law and Local Courts Act [*Chapter 7:05*], the High Court Act [*Chapter 7:06*] and the Prisons Act [*Chapter 7:11*]

ANATOMICAL DONATIONS AND POST MORTEM EXAMINATION ACT [*Chapter 15:01*]

This Act came into operation on 1st July 1978 and has been amended only twice in the years 2000[4] and 2001[5] to introduce definitions of key terms and review the penalty clauses for the various offences contained therein. There are the Anatonomical Donations and Post Mortem Examinations Regulations, 1978 (GN 486/78)[6].The Act is presently administered by the Minister of Health and Child Welfare pursuant to the assignment by the President in terms of Statutory Instrument 141 of 2006.

This law is intended to provide for the donation of human bodies and human tissue for scientific and or therapeutic purposes, to provide for the removal, preservation and use of such tissue, to provide for the giving of consent to post-mortem examinations for certain purposes and to provide for matters connected or incidental thereto.[7] Put simply the Act is meant to regulate how, why and when members of the public can donate their bodies or body parts for purposes of scientific, educational or treatment of other humans.[8] It also regulates the instances when, how, by who and where a post mortem may be carried out after the death of a person. [9]The Act recognizes that only certain institutions and or persons can be allowed to accept such donations of bodies or body parts inasmuch as it is only persons of sound mind and above the legal age of majority that can make such donations. Central to the whole process of giving and receiving of bodies and or body parts of course is the element of informed consent of the donor.

1.2 DANGEROUS DRUGS ACT [*CHAPTER 15:01*]

As the name suggests this law seeks to control the importation, exportation, production, possession, sale, distribution and use of dangerous drugs. It also seeks to provide for other matters incidental to the foregoing.[10] The Act came into operation on 15th April 1956 and has been amended a number of times since then in 1971, 1989, 1996[11], 2001[12] and 2004[13]. There are also the Dangerous Drugs Regulations, 1975 (GN 1111 of 1975) and the amendments thereto, the last of which was in 2008 in terms of which the Minister of Health and Child Welfare and or the Secretary for Health are empowered to make further provisions for the better attainment of the main purpose of the Act stated above. The Act is administered by the Minister of Health and Child Welfare.[14]

The Act specifically restricts the importation into Zimbabwe or the exportation from Zimbabwe of certain specified drugs[15], their constituents or other derivatives that are specifically deemed dangerous drugs.[16] The phrase dangerous drugs in the Act is given the meaning contained in section 156 of the Criminal Law (Codification and Reform) Act [*Chapter 9:23*] i.e 'any coca bush, coca leaf, raw opium, or cannabis plant; prepared opium,

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[4] Health Professions Act [*Chapter 27:19*] (Act No. 6 of 2000)
[5] Criminal Penalties Ammendment Act, 2001 (Act No. 22 of 2001)
[6] Yet to find these
[7] Preamble to the Act
[8] Section 3 as read with Section 10 of the Act
[9] Section 4 of the Act
[10] Preamble to the Act
[11] Drugs and Allied Substances Control Ammendment Act, 1996 (No.1 of 1996)
[12] Criminal Penalties Ammendment Act, 2001 (Act No. 22 of 2001)
[13] Criminal Law (Codification and Reform) Act, 2004 (Act No. 23 of 2004)
[14] Statutory Instrument 141 of 2006
[15] Section 14 of the Act as read with Section 156 of the criminal Law (Codification and Reform) Act [*Chapter 9:23*] and the Schedule to the Act
[16] Section 11 of the Act

prepared cannabis or cannabis resin; or a scheduled drug'. The Act has, at its end a Schedule that contains a comprehensive list of drugs considered dangerous. The Minister may, by Statutory Instrument or General Notice, add, vary or delete from this list. The last of such amendments to the Regulations were made in 2008.

1.3 MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

This Act which came into operation on 1st September 2009 has as its purpose the establishment of a Medicines Control Authority (formerly the Drugs Control Council), conferring of powers and functions on the said authority to enable it to discharge its functions which are the registration of medicines. The Act also creates a Regional Medicines Control Laboratory whose function is to test medicines . It provides for the keeping of a Medicines Register and for certain prohibitions, controls and restrictions relating to medicines and other allied substances.

In terms of Statutory Instrument 141 of 2006 the administration of this Act was assigned to the Minister of Health and Child Welfare. There are a number of Regulations made under and in terms of this Act that make declarations regarding prohibited and or specified drugs.[17] Of note would be the following:

- The Medicines and Allied Substances Control (General) Regulations, 1991 SI 151/1991 and amendments thereto, the most recent of which was Ammendment No. 23 of 2008[18];
- The Drugs and Allied Substances Control (Declaration of Prohibited Drugs) Notice, 1991[19];
- The Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008[20];
- The Medicines and Allied Substances Control (Import and Export of Precursors and certain Chemical Substances) Regulations, 2008[21].

The Act provides for the carrying out of clinical trials for medicines in Zimbabwe and the requirements therefore. In terms of Section 22 the Authority[22] is empowered to suspend clinical trials should there be any matters of concern to it.

The Act provides for the establishment of a Regional Medicines Control Laboratory whose functions includes but is not limited to the verification of the quality, efficacy, safety, standards of specifications of medicines and training of persons in the analysis of medicines.[23]

Part IV of the Act provides for the registration of medicines in Zimbabwe in a Medicines Register. Specified and Prohibited drugs notifications to the public, retailers and other stakeholders are to be provided for by Statutory Instrument such as the ones listed above. Such medicines may be prohibited or restricted from sale to members of the public.[24].

Section 36 provides for the labeling of medicines. The Act requires the registered name of the medicine, its registration number and any other prescribed requirements. Sections 38 and 39 provides for the prohibition of the sale of what may be termed undesirable medicines, such as

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[17] Section 74 of the Act
[18] Statutory Instrument 178/2008
[19] Statutory Instrument 251B of 1991
[20] Statutory Instrument 57 of 2008
[21] Statutory Instrument 56 of 2008
[22] The Act still reads 'council' in reference to the Authority's predecessor. There is need for this to be corrected.
[23] Section 25B paragraphs (a) to (d)
[24] Section 38 of the Act

skin lightening or bleaching preparations as well as medicines that have not been subjected to the rigors of the Medicines Control Authority and Laboratory. *It is here that the Board is encouraged to review medical preparations such as herbal preparations; faith based treatments as well as some of the traditional ones.*

Part VI of the Act provides for the licensing and control of pharmaceutical premises and persons.

Section 65 of the Act provides for the appointment of inspectors to enforce the provisions of the Act and its subsidiary regulations.

1.4 FOOD AND FOOD STANDARDS ACT [CHAPTER 15:04]

This is an Act to provide for the sale, importation and manufacture for ale of food in a pure state; to prohibit the sale, importation and manufacture for sale of food which is falsely described; and to provide for the fixing of standards relating to food.[25] The Act came into force on 28th May 1971 and is administered by the Minister of Health and Child Welfare.[26]

Section 4 of the Act lays out in detail what amounts to and what does not amount to adulteration or false descriptions of food. For example food shall be deemed to be adulterated if it contains, or is mixed or diluted with, any substance or ingredient not present when the food is in a pure or normal state and in sound condition.[27] On the other hand food shall be deemed to be falsely described if it is an imitation of and is sold under the name of any other food or by a name so closely resembling that of another food as to be likely to deceive.[28] Section 4 (2) of the Act then lists a number of instances where food that is apparently adulterated and or falsely described is deemed to be excluded from that definition.

Having described what constitutes adulterated and or falsely described food, the Act then explicitly prohibits the sale, importation for sale or manufacture for sale any food which is falsely described or unwholesome or unfit for human consumption.[29] The Act further prohibits the sale of compounded foods whilst restricting the sale of blended foods to instances where the food is really a blend of certain ingredients.[30]

Part III (Sections 8 to 15) of the Act deals with the enforcement and administration of the measures contained therein. Section 8 provides for the searches for, inspections of and in some instances seizure of foods that are found to be contrary to the Act. Inspectors and members of the Police are authorized t o issue notices prohibiting sale, manufacture of such food and may even detain it for analysis, criminal prosecution and destruction on the strength of a court order.[31] The Minister is empowered to request particulars of foods suspected to be contrary to the provisions of the act and the persons to whom such a request is sent are duty bound to act accordingly.[32]

Section 18 provides for the establishment of a Food Standards Advisory Board whose functions are to advise the Minister on all matters relating to food and food standards.[33] The

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[25] Preamble to Act
[26] Per Assignment by the President – Statutory Instrument 141 of 2006.
[27] Section 4 (1) (a) (i) of the Act.
[28] Section 4 (1) (b) (i) of the Act.
[29] Section 5 of the Act
[30] Sections 6 and 7 of the Act
[31] Section 12 and 14 of the Act
[32] Section 15 of the Act
[33] Section 18 (5) of the Act.

Act then provides for the appointment of Inspectors and Analysts and the delegation of the power to make such appointments to local authorities.[34]

The Act provides for the making of Regulations by the Minister regarding the regulation of food and food standards. The Regulations are meant to provide standards for, among many other things, the composition, strength, potency, purity, quality or other property of any food or of any ingredient or component part thereof;[35] the nature or proportion of any foreign matter which may be present in any food as a result of unavoidable or necessary admixture therewith during collection, preparation or manufacture;[36] the composition of any mixed or compounded food;[37] the proportions in which any substance or ingredient that may be contained in any food or which may be added to or mixed or diluted with food or prescribe any substance or ingredient which may not be contained in, added to or mixed or diluted with food.[38]Notable examples of such regulations are the following:
Food and Food Standards (Advisory Board) Regulations, 1995[39];
Food and Food Standards (Alchoholic Beverages) Regulations, 2001[40];
Food and Food Standards (Food Additives and Prohibited Substances) Regulations, 2001[41];
Food and Food Standards (Food Labelling) Regulations, 2002[42];
Food and Food Standards (Natural Mineral Water and Bottled Drinking Water) Regulations, 2002[43].

1.5 PNEUMONOCONIOSIS ACT [CHAPTER 15:08]

This is an Act to provide for the control and administration of persons employed in dusty occupations.[44] It came into operation on 1st August 1971 and is administered by the Minister of Labour and Social Welfare.[45] The Act is reinforced by a number of very old Regulations pursuant to Section 52 of the Act namely the Pneumonoconiosis Regulations, 1973[46]; Pneumonoconiosis (Labourer's Specified Wages) Notice, 1972[47]; Pneumonoconiosis (Medical Examination) Notice, 1972 as ammended[48]; Pneumonoconiosis (Validity of Periodical CCertificates) Notice, 1977[49] and the Exempted Mining Locations Notice, 1962[50].

There is established a Pneumonoconiosis Board whose functions include, but are not limited to, determining instances of workers suffering from pneumonoconiosis, studying measures for prevention of pneumonoconiosis in Zimbabwe, advising the Minister on the welfare of workers.[51] A Medical Bureau is also established and it has as its functions; the making of any and all recommendations to any body or person as required by the Act, to conduct and direct

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[34] Sections 19, 20 and 21 of the Act
[35] Section 27 (2) (a) (i)
[36] Section 27 (2) (a) (ii)
[37] Section 27 (2) (a) (iii)
[38] Section 27 (2) (b)
[39] Statutory Instrument 322 of 1995
[40] Statutory Instrument 25 of 2001
[41] Statutory Instrument 136 of 2001
[42] Statutory Instrument 265 of 2002
[43] Statutory Instrument 263 of 2002 as amended by Statutory Instrument 104 of 2004
[44] Preamble to the Act.
[45] Per Assignment by the President in terms of Statutory Instrument 149 of 2006.
[46] RGN 131 of 1973
[47] RGN 341 of 1972
[48] RGN 1116 of 1972 as amended by Ammendments 1, 2 and 4 in Statutory Instruments 232 of 2005; 52 of 2007 and 30 of 2007 respectively
[49] RGN 848 of 1977
[50] RGN 88 of 1962
[51] Sections 3 to 13 of the Act

all medical examinations under the Act and to issue certificates to workers under the Act.[52] Section 19 establishes a Medical Appeal Board which deals with appeals emanating from decisions of the Medical bureau above. Section 22 provides for the prohibition, with a criminal sanction, against the employment of persons with or reasonably believed to be suffering from pneumonoconiosis.

1.6 PUBLIC HEALTH ACT [CHAPTER 15:09]

This Act has as its stated purpose the provision for the public health.[53] It was enacted in 1924 and has been on the statute books since then. In addition to the President assigning its administration to the Ministry of Health,[54] the Act itself specifically envisages a situation where it will always fall under the health ministry.[55]

The phrase 'public health' appears 31 times in the whole statute but is not defined for the public or anyone else's benefit. Consequently any meaningful deliberations on public health risk being very subjective as they will be based on each individual's understanding of the meaning of the phrase. Perhaps the meaning may be inferred from Section 3 which provides for the administration of the Act by the Ministry as follows: "… to prevent and guard against the introduction of disease from outside; (b) to promote the public health, and the prevention, limitation or suppression of infectious and contagious disease within Zimbabwe… (d) to promote and carry out researches and investigations in connection with the prevention or treatment of human diseases…"[56]..

Section 4 of the Act provides for the establishment of an Advisory Board of Public Health at the Minister's discretion.[57] The function of the Board being to give advice to the Minister on all matters relating to public health in Zimbabwe.[58] The day to day running of the Board is governed by the Public Health (Advisory Board) Regulations, 1966 as amended.[59]

1.7 TERMINATION OF PREGNANCY ACT [CHAPTER 15:10]

This is a 1978 Act passed with the intention of "changing the law relating to abortion by defining circumstances in which a pregnancy may be terminated…"

The Act reflects a pro-life as opposed to pro-choice approach to the abortion debate. At the very least there is an attempt to strike a balance between the two.

The Act starts off by explicitly prohibiting the termination of a pregnancy in any circumstances other than those that it prescribes. Any person who terminates any pregnancy other than in accordance with the Act does so at the risk of penal sanction in the form of imprisonment of up to five years, a level 10 fine or both such fine and such imprisonment.

There are basically three sets of circumstances where a pregnancy may be terminated legally and in any event according to law namely where going through with the pregnancy will endanger the life of the expecting mother, the life of the unborn child or where the pregnancy is as a result of unlawful intercourse such as rape or incest.

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[52] Sections 14 to 18 of the Act
[53] Preamble to the Act
[54] Statutory Instrument 142 of 2006
[55] Section 3 as read with definition of 'minister; in section 2 of the Act
[56] Section 3 (2) paragraphs (a) – (c) and (d) of the Act
[57] Section 4 (1) of the Act
[58] Section 4 (5) of the Act
[59] Statutory Instrument 233 of 1966 as amended by 910 of 1967

In addition to these circumstances the Act goes on to prescribe conditions under which termination may be made namely that of a medical practitioner doing so in an emergency; a medical practitioner doing so with the written permission of a Superintendent of a designated institution in cases of danger to life of an expecting mother or unborn child; and a medical practitioner with the written authority of a superintendant of a designated institution after the former has received written confirmation by a Magistrate that there was unlawful intercourse.

The Act provides for an appeals framework to cater for situations where one may request a termination of pregnancy and it is refused. The Appeal lies with the Secretary for Health.

All medical personnel are not obliged to carry out or assist in terminations of pregnancies.

The niceties of the procedures and paperwork contemplated by the Act are provided for in the Termination of Pregnancy Regulations, 1977

1.8 ZIMBABWE NATIONAL FAMILY PLANNING COUNCIL ACT [CHAPTER 15:11]

This 1985 law establishes the Zimbabwe National Family Planning Council, provides for its structure, functions and powers; provides for reproductive health and family planning services in Zimbabwe and the promotion and implementation of population and development primary health care and other community based development programmes relating to family health and for the integration and coordination of other relevant activities in Government departments, NGOs and the Private sector.

The Zimbabwe National family Planning Council is established pursuant to Section 3 of the Act, and Section 4 thereof creates the Zimbabwe National Board of Family Planning whose function is to be the governing body of the Council responsible for the general policy and the control of the operations of the Council. The Board shall consist of not less than seven and not more than ten members of whom one shall be appointed by the Minister from the Ministry responsible for health; one shall be the Executive Director of the Zimbabwe National Family Planning Council; one shall be a registered legal practitioner; not more than four persons representing an association, organisation or institution shall be appointed by the Minister for their knowledge, experience or expertise in any one or more of the following— (i) public health; (ii) reproductive health; (iii)demography; (iv) finance and human resources; (v) marketing and communications; not more than three persons shall be appointed by the Minister to represent the interests of women, youths, religious and trade unions.

In terms of Section 22 of the Act, the functions of the Council shall be, among other things to popularize and promote the provision of adequate and suitable facilities in Zimbabwe for reproductive health and family planning; to provide facilities for the investigation and treatment of infertility among persons in need of such investigation or treatment; to participate actively with other organizations or institutions in the formulation and implementation of primary health care programmes and other community development activities related to family health; and to carry out or assist in the carrying out of research into reproduction health and the effects of contraceptives on the health of the users of contraceptives and other persons. It also provides for functions to undertake work connected with the diagnosis and treatment of diseases, including, but not limited to, sexually transmitted infections including HIV and AIDS and cancers of the reproductive system; to stimulate and develop an awareness among medical students and medical personnel generally regarding the scientific basis of reproductive health and family planning and the practical implementation of related programmes by medically acceptable methods and practices; to provide and manage facilities for performing surgical operations for infertility and sterilization, and develop and provide a cytology service to persons in need of such service. The Act provides for Council functions generally to encourage, foster and promote safe reproductive health practices and take such measures as are necessary or desirable for

alleviating the problems associated with infertility among persons; to co-ordinate and monitor the provision of integrated reproductive health and family planning services in Zimbabwe; to plan, design and implement adequate and sustainable reproductive health and family planning services for special target groups such as men and youths in Zimbabwe; to procure and distribute adequate and appropriate contraceptive and reproductive health commodities in Zimbabwe; to provide leadership in sexual and reproductive health programmes in Zimbabwe; and to ensure that public, private and non governmental organisations providing reproductive health and family planning services in Zimbabwe adhere to prescribed standards, guidelines and procedures.

Section 23 of the Act provides that 'for the performance of the functions of the Council in terms of section twenty-two, the Board shall have special responsibility—
(a) to ensure the involvement of the various disciplines associated, whether directly or indirectly, with child spacing and family planning and the application correspondingly of a multi-pronged approach in the implementation of related programmes;
(b) to ensure that the policies, programmes and operations of the Council are formulated and implemented as an integral part of the overall national development programme;
(c) within the scope of its competence. to provide effective liaison between the public and the appropriate governmental agencies engaged in activities relating to child spacing and family planning;
(d) to tender advice and make recommendations to the appropriate governmental agencies on matters relating to or affecting the functions and operations of the Council;
(e) to define policies on matters relating to the functions and operations of the Council and give directions to the Executive Committee as to strategies for implementation of such policies.

1.9 MENTAL HEALTH ACT [CHAPTER 15:12]

The Mental Health Act was made to consolidate and amend the law relating to the care, detention and after-care of persons who are mentally disordered or intellectually handicapped, whether for the purposes of treatment or otherwise; to provide for the establishment of various boards and the functions of such boards among other things. The current Act came into operation on 1st January 2000 and repealed the previous version of the same law, Mental health Act [Chapter 15:06] of 1996.

The rationale of the Act is to provide a framework for defining mentally disordered or intellectually handicapped persons within society, how such status is determined, by whom, at whose instance, at which places and with what consequences. In terms of this Act therefore no person may be detained in a mental facility other than by virtue of a court order or otherwise in terms of the Act. In short, the Act is a protection for mentally challenged persons and affords them due process rights.

In terms of the Act "mentally disordered or intellectually handicapped", in relation to any person, means that the person is suffering from mental illness, arrested or incomplete development of mind, psychopathic disorder or any other disorder or disability of the mind.
The Act thereafter lays out the procedure to be followed before a person can be found to fall within the above definition and prescribes where they may be detained for purposes of treatment etc in terms of the Mental health regulations, 1999 as read with the various General Notices designating institutions , special institutions or places in lieu of special institutions.

1.10 MEDICAL SERVICES ACT [CHAPTER 15:13]

The purpose of this Act is to ensure the provision and maintenance of comprehensive hospital services in Zimbabwe; to provide for the admission of persons to Government hospitals and the fixing of fees in respect of services provided thereat; to provide for the granting to medical

practitioners and dental practitioners of the privilege of access to certain Government hospitals and for the appointment of consultant medical and dental practitioners; to provide for the registration of medical aid societies; to set conditions for the registration of private hospitals among other things.

The Act came into force on 9th February 2001, is administered by the Minister of Health and Child Welfare and is mainly supplemented by two pieces of subsidiary legislation in the form of the Medical Services (Government and private Hospitals) Regulations, 2001 and the Medical Services(Medical Aid Societies) Regulations, 2000.

For all intents and purposes this is a progressive piece of law that infers a right to access to health care. It does so by obliging the Minister of Health and by inference the State to 'as far as possible provide and maintain comprehensive and constantly developing medical services; and encourage local authorities and other persons to provide such services.'

The Act proceeds by defining government hospitals, the rights of medical practitioners to access those facilities and empowering the Ministry to set fees charged thereat. It then lays out the framework for the establishment and operation of medical aid societies whose detail is further elaborated in the Regulations.

Part IV of the Act (sections 11 – 13) is the framework for establishment and operation of Private Hospitals and is elaborated on in the Regulations as well.

Section 12 of the Act prohibits discrimination in the exercise of the right to admit patients by private hospitals. Section 12 (3) allows the Minister to commandeer private hospital facilities in the public interest on such terms and conditions regarding fees as he may deem fit. Section 13 has a prohibition against unilateral fee increases for medical services.

1.11 NATIONAL AIDS COUNCIL OF ZIMBABWE ACT [CHAPTER 15:14]

This law provides for the establishment of the National AIDS Council of Zimbabwe and to provide for its structure, functions and powers; to provide for measures to combat the spread of the Human Immuno-Deficiency Virus and the Acquired Immune-Deficiency Syndrome and the promotion, co-ordination and implementation of programmes and measures to limit or prevent their spread among other things. The law came into force on 1st September 2000 and is the responsibility of the minister of Health and Child Welfare.

Section 3 of the Act establishes the National AIDS Council and Section 4 spells out its functions as being to ensure the development of strategies—
(i) to combat HIV and AIDS; and
(ii) to control and ameliorate the effects of the HIV and AIDS epidemic.
The National AIDS Council also has functions to promote and co-ordinate the application of such strategies and policies; to mobilise and manage resources, whether financial or otherwise, in support of a national response to HIV and AIDS; to enhance the capacity of the various sectors of the community to respond to the HIV and AIDS epidemic and to co-ordinate their responses. The Act provides further for functions to encourage the provision of facilities to treat and care for persons infected with HIV and AIDS and their dependants; and to monitor and evaluate the effectiveness of the strategies and policies referred to in paragraph (a) and, generally, the national response to HIV and AIDS; to promote and co-ordinate research into HIV and AIDS; to ensure the effective dissemination and application of the results of such research; and to disseminate, and to encourage the dissemination of, information on all aspects of HIV and AIDS. The Council should be law submit regular reports to the President, through the Minister, concerning the HIV and AIDS epidemic; and exercise any other function that may be conferred on the Council by or in terms of this Act or any other enactment; and generally, to do all things which, in the Board's opinion, are

necessary or appropriate to combat HIV and AIDS and to ameliorate the effects of those diseases. It is debatable the extent to which these functions have been duly exercised as prescribed.

Members of the Council are drawn from a wide cross section of stakeholders and are appointed by the President, presumably on the advice and recommendation of the Minister. In terms of Section 20, the Minister may, with the approval of the President and after receiving input from the NAC, give the NAC directions on policy for implementation.

The NAC receives its funding from the fiscus, donations etc in terms of Section 25 of the Act. Section 35 of the Act provides for Regulations to be made by the Minister for the implementation of the Act. These are not yet in place.

1.12 RADIATION PROTECTION ACT [CHAPTER 15:15]

This law commenced on 1st July 2005 , is administered by the Minister of Health and Child Welfare and presently admits of no subsidiary legislation in the form of Regulations, General Notices or other. It has as its stated object and purpose as being to establish a Radiation Protection Authority and to confer powers and functions on such an Authority in relation to protecting the public and workers from dangers resulting from the use or abuse of equipment, devices or materials capable of producing ionizing radiation among other things.

It is also a domestication of the provisions of the International Atomic Energy Agency (IAEA) Statute of 26th October 1956 and in particular Articles 13 and 14 of that Agency's Code of Conduct on the Safety and Security of Radioactive Sources.

To the above end the Act establishes a Radiation Protection Authority of Zimbabwe , whose functions include but are not limited to the issuing of standards and norms governing exemption, notification, registration and licensing of radiation sources and radiation protection and safety; to define in regulation standards and norms the exposures that are excluded from regulatory requirements on the basis that they are not capable of being subjected to regulatory control; to issue authorisations for the possession and use of radiation sources; and to define in regulations and authorisations the detailed obligations to be placed on those who possess radiation sources. The Authority also has functions to conduct inspections and obtain performance information concerning radiation sources; to take such action as is necessary to enforce any prescribed requirements; to protect the health and safety of workers and the members of the general public; and to accredit persons or suppliers of certain services or facilities necessary to enable licensees, registrants or notifying parties to comply with conditions or requirements imposed by or under this Act. The Authority has functions to approve persons with specified radiation protection responsibilities; to ensure that adequate national arrangements for response to radiological accidents are established; to initiate, recommend or provide support for intervention, as appropriate; to advise on matters relating to the safety of radiation sources and the disposal of radioactive waste materials or irradiating devices; and to establish and maintain registers of importers, exporters, manufacturers, users and operators of devices or materials capable of producing ionizing radiation.

Sections 5-8 provide for the composition of the Board of the Authority, the staff of the Authority and the Minister's powers to issue directives on policy, whilst Sections 9 – 13 deal with the financial affairs of the Authority.

Section 14 of the Act prescribes the prohibited acts in an effort to protect the public and workers from radiation whilst section 15 prescribes the instances where authorizations and or other dispensations may be issued to certain persons or classes thereof to deal with or otherwise handle radioactive material or conduct radioactive activities.

Section 22 provides for the making of regulations for the elaboration of what is envisaged in the Act. These are not yet immediately available.

1.13 HEALTH SERVICES ACT [CHAPTER 15:16]

This law provides for the conditions of service of health service personnel and its relevance to public health discourse is in the fact that a disgruntled or poorly organized national health service leads to poor health service delivery and a consequently compromised public health regime

Part 2: Relevant International and regional standards and protocols and Zimbabwe's law

This part provides a brief on the contents of relevant international and regional conventions, codes and protocols and the coverage in Zimbabwe.

2.1 THE INTERNATIONAL HEALTH REGULATIONS (IHR) (2005)

Adopted by the World Health Assembly in 2005 and entered into force on 15 June 2007, the IHR aim to "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."

In the IHR, states should in summary have capacities and authorities to

- detect, assess on site, monitor, collect and communicate timely, accurate and sufficiently detailed public health information (including cases, deaths, determinants) on events and notify and report urgent events within 48 hours; including to WHO
- plan, provide staff and laboratory support to investigations and implement in liaison with other ministries control measures to prevent domestic and international spread;
- obtain travel information, require medical examinations; vaccinate; observe; quarantine; isolate, treat affected persons; trace contacts; refuse entry of suspect and affected persons, and monitor, inspect, treat, or quarantine cargo, containers, goods, post, parcels and human remains to ensure they are free of sources of infection or contamination;
- Ensure facilities used as points of entry (air, road and water) are maintained in a sanitary condition, free of sources of infection or contamination,
- Supervise the removal and safe disposal of any contaminated water or food, human or animal waste, wastewater and any other contaminated matter from a conveyance;
- Provide, by the most efficient means of communication available, links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas
- Establish and operate a national public health emergency response plan, including multi-sectoral response teams and focal point, coordinator, and contact points

Zimbabwe's Public Health Act currently includes provisions for the definition of, the institutional mechanisms for response to, requirements for notification of "formidable infectious diseases", and management of outbreaks. In its definitions section it refers to the International Sanitary Regulations of 1951, to which the State is a party and any amendment thereto to which the State becomes a party.

2.2 WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL (2005)

The WHO Framework Convention on Tobacco Control (FCTC) entered into force on 27 February 2005 -- 90 days after it had been acceded to, ratified, accepted, or approved by 40 States. The objective of the WHO FCTC as stated in its preamble is "to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke." (WHO FCTC, 2005)
The FCTC provides that

1. Every person be informed of the health consequences, addictive nature and threat to life posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke.

2. States develop and support, at the national, regional and international levels, comprehensive multi-sectoral measures and coordinated responses, to protect persons from exposure to tobacco smoke; prevent the initiation, promote and support cessation, and decrease consumption of tobacco products in any form; promote the participation of indigenous individuals and communities in the development, implementation and evaluation of appropriate tobacco control programmes and address gender-specific risks when developing tobacco control strategies.
3. Countries provide and receive international cooperation, particularly transfer of technology, knowledge and financial assistance and provision of related expertise be provided for programmes, including technical and financial assistance to aid the economic transition of tobacco growers and workers whose livelihoods are seriously affected as a consequence of tobacco control programmes in developing country Parties
4. Countries clarify issues relating to liability, as determined by each Party within its jurisdiction
5. Civil society involvement is essential in achieving the objective of the FCTC.

Signatories to the Convention must in summary:

- Develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with this Convention and the protocols to which it is a Party.
- Establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control; and
- Adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.
- In setting and implementing their public health policies with respect to tobacco control, act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.
- Cooperate in the formulation of proposed measures, procedures and guidelines for the implementation of the Convention and the protocols to which they are Parties.
- Cooperate, as appropriate, with competent international and regional intergovernmental organizations and other bodies to achieve the objectives of the Convention and the protocols to which they are Parties.
- Cooperate to raise financial resources for effective implementation of the Convention through bilateral and multilateral funding mechanisms.

Zimbabwe has not signed the protocol. The law that deals with the issues covered in the WHO FCTC is the Public Health (Control of Tobacco) Regulations, Statutory Instrument 264 of 2002 in terms of section 94 of the Public Health Act, promulgated before the WHO FCTC entered into force. This statutory instrument

- prohibits smoking in public premises including educational or health care facilities, theatre, cinema, museum, youth centre, library or place of worship
- prohibits smoking on public transport including passenger aircraft, passenger train or vehicle for the conveyance of passengers for hire or reward (buses, taxis etc)
- obligates owners of public premises or transport referred to above to display clearly legible visible signs indicating areas in which smoking is prohibited or permitted
- prohibits the sale of tobacco or tobacco promoting products to persons below the age of eighteen years
- obligates tobacco traders to prominently display the following messages:
    1. ‘smoking is harmful to health’-for cigarettes, cigars, loose tobacco; or
    2. ‘smoking causes cancer’-for nasal and oral snuff; or
    3. ‘tobacco is addictive’-for snuffs

2.3 WHO INTERNATIONAL CODE ON MARKETING OF BREAST-MILK SUBSTITUTES (1981)

On 21 May 1981, the World Health Assembly adopted this voluntary WHO International Code on Marketing of Breast-milk Substitutes to contribute to protect and promote breast-feeding and ensure the proper use of breast-milk substitutes, when necessary, on the basis of adequate information and through appropriate marketing and distribution. The code provides in summary for:

- governments to ensure that objective, consistent information is provided on infant and young child feeding for use by families and those involved in.
- Informational and educational materials, should include clear information on all the following points: (a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; (d) the difficulty of reversing the decision not to breast-feed; and (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared.
- There should be no advertising or other form of promotion to the general public of products within the scope of the Code.
- The health authorities in Member States should take appropriate measures to encourage and protect breast-feeding
- No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code
- Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding.

Zimbabwe was among the sponsors of the International code, has signed it and has put in place the Public Health (Breast-milk Substitutes and Infant Nutrition) Regulations Statutory Instrument 46 of 1998. This provides for:

- Education and information concerning infant nutrition
- Screening of advertisement, informational or educational material on baby and young children. The advertisements are permitted if they provide clear information on, inter alia:
    - The importance and superiority of breast feeding
    - Maternal nutrition
    - The preparation for and maintenance of breast feeding
    - Adverse effects on breast-feeding of introducing bottle feeding
- Labelling of designated products including: the ingredients used; the composition and nutrient content; storage conditions; expiry dates; manufacturer's name and physical address and that the designated product is supplementary to breast milk stating clearly that 'breast milk is the best food for our baby'.

The legal provisions of SI 46 of 1998 are comprehensive.

2.4 SADC PROTOCOL ON HEALTH

The SADC Protocol on Health was adopted on 18 August 1999. It sets out principles for effective regional collaboration to formulate regional health policies and strategies to attain an acceptable standard of health, to apply the Primary Health Care approach; improve access to health services; and ensure equitable and broad participation in health. It provides for co-ordination of regional efforts on epidemic preparedness, mapping, prevention, control and where possible the eradication of communicable and non-communicable diseases; to promote and co-ordinate the development, education, training and effective utilization of health personnel and facilities; to facilitate the establishment of a mechanism for the referral of patients for tertiary care; to foster co-operation and co-ordination in the area of health with

international organizations and co-operating partners; to promote and co-ordinate laboratory services in the area of health; to develop common strategies to address the health needs of women, children and other vulnerable groups; to progressively achieve equivalence, harmonization and standardization in the provision of health services in the region; and to collaborate and co-operate with other relevant SADC Sectors.

In line with this it provides for information sharing and regional disease surveillance, following a common set of indicators and for a SADC Regional Data of Health and Social services Indicators. It promotes co-ordination, information exchange and policy development and harmonisation in areas of health promotion- including on health lifestyles and reduction of substance abuse – on reference laboratories; case definitions for diseases; notification systems; and on prevention, treatment and management of major communicable diseases (HIV and AIDS, Sexually transmitted diseases, malaria, tuberculosis) as well as trauma, and non communicable diseases. It provides for co-operation on promoting health and health services for elderly people, people with chronic diseases, with disabilities and for advancing coherent, comparable, harmonised and standardized policies, strategies, programmes and procedures for promoting reproductive health, child and adolescent health, mental health, environmental and occupational health.

The protocol provides for states to co-operate in curriculum development for health professional and research training; and in the accreditation of health professionals. It provides for states to explore and share experience with regard to strategies for funding for health services and optimal and efficient mechanisms for allocation and use of funds. The protocol encourages states to develop mechanisms to regulate the practice of traditional healing and for co-operation with traditional health practitioners and to protect intellectual property in relation to traditional medicine, medical plants and procedures. It calls on states to co-operate in the co-ordination and management of disaster and emergency situations; in developing policies and strategies on health technology and equipment and in harmonising pharmaceutical quality assurance and registration, production, procurement and distribution of affordable essential drugs; rational drug use; quality assurance in the supply and conveyance of vaccines, blood and blood products; and on

Sanctions may be imposed against states which persistently fail, without good reason, to fulfil obligations under the protocol; or implement policies that undermine the protocol.

The SADC Regional Indicative Strategic Development Plan (RISDP), 1999 in Chapter 3 sets out the programme for health "to reach specific targets within the objective of Health for All …by 2020 in all Member States through the primary health care strategy". It sets out programmes to operationalise the protocol, including on multisectoral responses to the major communicable diseases, and regional strategies such as bulk purchasing of drugs.

2.5 WTO TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT FLEXIBILITIES TO PROTECT ACCESS TO MEDICINES AND THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

The TRIPs agreement sets out the minimum patent protection requirements for WTO members to enforce through their national laws. In 2001 the WTO ministerial conference agreed (Doha Declaration on TRIPs and Public Health) to allow member states of the WTO to use all flexibilities provided in the TRIPs agreement to ensure access to affordable medicines, and to prevent patent monopolies stopping access to medicines where they are needed for public health. These flexibilities include:

i. Giving transition periods for laws to be TRIPs compliant
ii. Providing for countries to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

iii. Providing for parallel importation or the rights to import products patented in one country from another country where the price is less and where there is insufficient or no manufacturing capacities in the pharmaceutical sector

iv. Giving member countries the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

v. Exceptions from patentability and limits on data protection

vi. Providing for early working, known as the Bolar provision, allowing generic producers to conduct tests and obtain health authority approvals before a patent expires, making cheaper generic drugs available more quickly at that time.

Zimbabwe is a member of the WTO hence a signatory to the TRIPs Agreement. Zimbabwe has amended its Patents Act (Chapter 26:03) in a manner that allows for the use of TRIPs flexibilities. The Patents Amendment Act (2002) relevant sections in summary provides for:

- Exceptions from patentability for:
  - diagnostic, therapeutic or surgical methods for the treatment of human beings or animals
  - plants and animals, other than micro-organisms
  - essentially biological processes for the production of plants or animals, other than microbiological processes
- Parallel importation of patented products which have been put on the market in another country by a patentee without the consent of the patentee if the cost of importing such a product is less than the cost of purchasing from the patentee
- Test batches of patented products may be produced without the consent of the patentee six months before the expiry of the patent (Bolar provision)
- Issuance of Compulsory licences in respect of dependent patents

Zimbabwe declared HIV/AIDS a national disaster in 2003 and invoked the provisions of the patents law amendments to make full use of the TRIPs flexibilities to enable manufacture generic anti-retroviral drugs (ARVs).

Despite having brought its law in line with use of the flexibilities Zimbabwe has not yet endorsed the agreed text to permanently amend the TRIPs agreement incorporating the full use of flexibilities, which needs to be done by December 2011. This text will only come into force when two thirds of WTO members have accepted it.

2.6 WTO TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT ARTICLE 51 PROVISIONS ON COUNTERFEIT TRADEMARK GOODS

The WTO TRIPs agreement Article 51 gives powers to customs authorities for the suspension of the release into free circulation of goods suspected to be imported counterfeit trademark or pirated copyright goods. The article obligates member states of the WTO to:

- adopt procedures for such suspension into free circulation but no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit
- enable an application for the suspension of circulation of such goods in respect of goods which involve other infringements of intellectual property rights

The provisions of Article 51 apply specifically to "Counterfeit trademark goods" meaning trademark violations, ie goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark. "Pirated copyright goods" means any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production.

Zimbabwe is a member of the WTO and hence has acceded to the TRIPs Agreement. The law in Zimbabwe that deals with the issue of counterfeits as trade mark violations is the Merchandise Marks Act [Chapter 14:13]. This (old) Act provides that any person who sells any goods to which a trade description has been applied shall be deemed to warrant that the trade description is not a false trade description, but it does not adequately provide for provisions on importation of goods. The (newer) Patents Act provides for protection of patents, and includes clear flexibilities in relation to patents applying to medicines (see above). In relation to substandard and falsified medicines the Medicines and Allied Substances Control Act (Chapter 15:03) provides for prohibition of sale of undesirable medicines if the Authority is of the opinion that it is not in the public interest that a specified medicine shall be available to the public, but may not adequately address all situations of falsified and substandard medicines.