11 POOLED PROCUREMENT AS A PANACEA FOR ACCESS TO MEDICINES IN THE SOUTHERN AFRICAN DEVELOPMENT COMMUNITY REGION

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ABSTRACT

In 2011, the United Nations Conference on Trade and Development (UNCTAD) reported that nearly two billion of the world's population, many of whom live in least developed countries (LDCs), lacked access to essential medicines. Two years later in 2013, access to medicines has improved marginally and the total number of people who lack access to essential medicines is estimated to be between 1.3 and 2.1 billion people. Access to essential medicines is crucial for developing countries, particularly those in Sub-Saharan Africa, as they are vulnerable to deaths caused by preventable diseases. Currently, African countries are now most vulnerable to the spread of the Ebola epidemic. In August 2014, the World Health Organization (WHO) Director-General, Margaret Chan, declared the West Africa Ebola crisis a 'public health emergency of international concern', triggering powers under the 2005 International Health Regulations (IHR). Southern African Development Community (SADC) countries remain in desperate need for access to essential medicines that are patented in developed countries. The need to access essential medicines and drugs, especially generic drugs, is made dire by the high disease burden, attributable mainly to HIV/AIDS, tuberculosis, and malaria. With such a dilemma still unresolved, questions arise about improving the efficacy of TRIPS flexibilities for developing countries in general and the SADC region in particular. This article proposes pooled procurement as the panacea for the problems facing SADC concerning access to medicines.

Keywords: *access, medicine,* Southern African Development Community, *SADC, patents, public health, TRIPS flexibilities, developing countries*

I. INTRODUCTION

Over a decade ago, in March 2004, the World Health Organization (WHO)[1] estimated that one third of the world's population lacked access to essential drugs.[2] Further, the WHO estimated that over 50 per cent of the population in Africa and Asia had no access to basic and essential drugs.[3] On a closely related note, five years later, a comparison between access to essential drugs in the public and private sectors painted a worse picture.[4] In 2011, the United Nations Conference on Trade and Development (UNCTAD) reported that nearly two billion of the world's population, many of whom live in LDCs, lacked access to essential medicines.[5] By 2013, the situation with respect to access to medicines had improved marginally and the total number of people without access to medicines was estimated to be between 1.3 and 2.1 billion people.[6] Access to essential medicines is important for developing countries, particularly those in sub-Saharan Africa as they are vulnerable to deaths caused by preventable diseases.[7] African countries are now most vulnerable

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[1] The WHO, a specializied agency of the United Nations, was established on 7 April 1948; a day now celebrated across the globe as World Health Day. The WHO constitution came into force on this date, thus giving the Global Health Organization its legal existence. Broadly speaking, the mandate of the WHO straddles *inter alia*, providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends (see WHO website at <http://www.who.int/about/en/, last visited 04/10/2014>).

[2] See WHO, 'Equitable Access to Essential Medicines: a Framework for Collective Action' in *WHO Policy Perspectives on Medicines* (2004) 1 available at <http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf> (accessed 10 January 2014). The actual number was estimated to be between 1.2 and 1.3 billion. At the time of writing, these were the most recent statistics on the subject.

[3] Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness (see note 1 above).

[4] According the United Nations report dated 4 September 2008, titled 'Delivering on the Global Partnerships for Achieving the Millennium Development Goals', available <http://who.int/medicines/mdg/en/>(accessed 9 April 2014), in the public sector, generic medicines are only available in 34.9% of facilities, and on average cost 250% more than the international reference price. In the private sector, those same medicines are available in 63.2% of facilities, but cost on average about 650% more than the international reference price.

[5] UNCTAD *Investment in Pharmaceutical Production in Least Developed Countries: A Guide for Policy Makers and Investment Promotion Agencies* (2011).

[6] WHO 'Essential Medicines and Health Products Information Portal: A World Health Organization Resource' at <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html> (accessed 13 October 2014).

[7] Examples that easily come to mind are malaria, cholera, Ebola and avian flu among other diseases that are easily curable in an environment where drugs are accessible and available. One other nagging health problem is the issue of HIV/AIDS and access to antiretroviral and other immunity - boosting treatment. With specific reference to access to medicines in the context of HI/AIDS, see generally D Mushayavanhu, 'The Realisation of Access to HIV and AIDS – Related Medicines in Southern African Countries: Possibilities and Actual Realisation of International Law Obligations' in F Viljoen and S Precious (eds) *Human Rights Under Threat: Four Perspectives on HIV, AIDS and the Law*

to the spread of the Ebola epidemic. In August 2014, the World Health Organization (WHO) Director-General Margaret Chan declared the West Africa Ebola crisis a 'public health emergency of international concern', triggering powers under the 2005 International Health Regulations (IHR).[8]

Access to medicines, a concept with no clear definition, is generally considered as a collection of different dimensions[9] such as accessibility[10], affordability[11], acceptability[12], and availability.[13] In developed nations, over 70 per cent of drugs are publicly funded or reimbursed, whereas in Africa, 50 to 90 per cent of pharmaceutical expenditure is funded out of pocket.[14] This is not good news regarding access, because unregulated drug prices create 'affordability barriers'.[15]

Not being able to access essential drugs and vaccines limits the enjoyment of the right to health and by extension the right to life on the part of the citizens of the developing countries.[16] For example, to safeguard Zimbabweans' right to health, the Patents Act[17] was amended[18], in order to 'enable the state or a person authorized by the Minister in terms of Section 34 of the Act' to make or use any patented drug used in the treatment of persons suffering from HIV/AIDS-related conditions or import any generic drug to treat HIV/AIDS.[19] While the right to health has traditionally been regarded as a civil and political right[20], it has, nevertheless, been increasingly applied broadly and has been extended in some instances to cases involving access to medicines.[21] The right to health is one among a range of socioeconomic rights for which States accept an obligation at international law.[22]

The right to life is part of the International Covenant on Civil and Political Rights[23], while the right to health is part of the International Covenant on Economic, Social, and Cultural Rights.[24] It may be argued that the separation of the two is artificial and misleading, because the right to life not only

in Southern Africa (2007) 127 -169. In this paper, essential drugs and essential medicines are used interchangeably and should be regarded as carrying the same meaning.

[8] See WHO Statement on the Meeting of the International Health Regulations Emergency Committee Regarding the 2014 Ebola Outbreak in West Africa. <http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/>. 8 August 2014. (accessed 30 October 2014).

[9] EK Tetteh 'Providing Affordable Essential medicines to African Households: The Missing Policies and Institutions for Price Containment' (2008) 66 Social Science and Medicine at 570.

[10] Referring to health services coverage.

[11] This relates to prices and volumes of consumption.

[12] This refers to quality, safety and efficacy.

[13] This refers to drug production, procurement and distribution.

[14] Tetteh note 9 above at 570.

[15] Ibid.

[16] The right to health and the right to life are closely intertwined and are not mutually exclusive. The right to life is encapsulated in article 3 of the Universal Declaration of Human rights and most, if not all constitutions of civilised nations of the world contain the right to life. For example, section 11 of the South African constitution of 1996 provides that everyone has the right to life. The applicability of that provision was tested by country's constitutional court in the landmark South African case of *S v Makwanyane and Another* 1995 (3) SA 360 (SCA) on 6 June 1995. In the case, the majority decision of the court was that the death penalty is inhuman and degrading hence unconstitutional. The Universal Declaration of Human Rights indirectly provides for the right to health in article 25 in which it is stated among other things, that everyone has the right to a standard of living that is adequate for their wellbeing and that of the family inclusive of medical care. The right to health is also recognised in article 12(1) of the International Covenant on Economic, Social and Cultural Rights while article 16 of the African Charter on Human and Peoples' Rights recognizes the right of every individual to enjoy 'the best attainable state of physical and mental health'. Other international instruments relevant to the right to health are the International Covenant on Civil and Political Rights (article 6), the Convention on the Rights of the Child (article 24), Convention on the Elimination of all forms of Discrimination against Women (article 12) and the Convention on the Elimination of all Forms of Racial Discrimination (art 5). On a related note, see O Olowu 'Environmental Governance and Accountability of Non-state Actors in Africa: A Rights–Based Approach' (2007) 32 *South African Yearbook of International Law* 261 at 279. For a general overview of the right to health and in its democratic context, see A Hassim A, M Heywood, and J Berger (eds) *Health and Democracy: A guide to Human Rights, Health Law and Policy in Post-Apartheid South Africa* (2006). For a comprehensive compilation of essential documents, international agreements and treaties pertaining to the right to health, see G Bekker (ed) *A Compilation of Essential Documents on the Right to Health* (2000).

[17] Chapter 26:03 of 1972.

[18] This was done by the then Justice Minister (Zimbabwe), the Honourable Patrick Chinamasa, in terms of sections 34 and 35 of the Patent Act and thus General Notice 240 of 2002 was introduced as an emergency measure for six months.

[19] See paragraphs 2(a) and (b) of the Declaration of Period of Emergency (HIV/AIDS) Notice, 2002.

[20] See for instance Article 6(1) of the International Covenant on Civil and Political Rights which provides that the right to life shall be protected by law and provides further, that no one shall be arbitrarily deprived of his life.

[21] Mushayavanhu above at 135. For example, in the case of *Odir Miranda v El Salvador* cited by the author in footnote 26 on page 136, the Inter-American Commission held that El Salvador's refusal to purchase triple therapy HIV medication amounted to a violation of the rights to life and health as provided for in the America Convention.

[22] See T Evans, 'A Human Right to Health?' (2002) 23 *Third World Quarterly* 197.

[23] Per Article 6 of the International Covenant on Civil and Political Rights.

[24] Per Article 12 of the International Covenant on Economic, Social and Cultural Rights.

depends on the realisation of the right to health ,but also on other composite rights such as the right to food and nutrition.

Although the Southern African Development Community (SADC)[25] Protocol on Health (the Protocol)[26] does not expressly refer to the right to health, the Protocol does highlight the importance of access to essential medicines for the SADC region.[27] So important is the issue of access to medicines that the African Union[28], the European Parliament[29], and the World Trade Organization (WTO)[30] have been seized with the matter for more than a decade now. To ameliorate the problem of access to medicines in the SADC region, the SADC Pharmaceutical Business Plan[31] was adopted. It outlines the specific flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and spells out a concrete plan to take full advantage of the flexibilities from 2007 to 2013 and beyond[32].

Most countries in Southern Africa remain in desperate need for access to essential medicines that are patented in developed countries. Specifically, in the SADC region, the need to access essential medicines and drugs, especially generic drugs, is made dire by the high disease burden, attributable mainly to HIV/AIDS, tuberculosis, and malaria. With such a dilemma still unresolved, questions about improving the efficacy of TRIPS flexibilities for developing countries, in general, and the SADC region, in particular, arise.

A number of solutions have been suggested to mitigate the problem of access to medicines in the SADC region.[33] One of the most touted solutions has been the suggestion that SADC Members should take full advantage of TRIPS flexibilities provided by the WTO framework since the introduction of the Doha Declaration in 2001. While we acknowledge the availability of various TRIPS flexibilities such as compulsory licences, parallel imports, research exceptions, bolar-type exceptions, and others, we equally bemoan the difficulty of using the flexibilities and suggest that other solutions ought to be pursued.

In the spirit of pursuing alternative solutions, this article argues that pooled procurement may be the panacea for SADC access to medicines problems. In a bid to make a case for the adoption of pooled procurement as a solution in the SADC, this article explores the following pertinent themes: firstly, it lays the background for the introduction of pooled procurement as an access to medicines solution in the region by rendering an expository account of the pertinent regional instruments that may be used as legal solutions to the access to medicines problem in the SADC. The article then introduces pooled

[25] Current Member States of the SADC are Angola, Malawi, Namibia, Mauritius, Botswana, Lesotho, South Africa, Seychelles, Democratic Republic of Congo, Tanzania, Swaziland, Zambia and Zimbabwe. Each member state has a responsibility to coordinate a sector or sectors on behalf of others. Angola coordinates energy, Botswana livestock production and animal disease control, Lesotho environment and land management, Malawi forestry and wildlife, Mauritius tourism, Mozambique transport and communications, Namibia marine fisheries and resources, South Africa finance and investment, Swaziland human resources development, Tanzania industry and trade, Zambia mining and Zimbabwe food, agriculture and natural resources. For detailed discussion of the SADC institutional history and its gradual evolution into a free trade area, see PC Osode, 'The Southern African Development Community in Legal Historical Perspective' (2003) 28 Journal for Juridical Science 1; SADC Secretariat, The Official SADC Trade Industry and Investment Review (1997) 5-9, C Chipeta C and I Mandaza 'The Future of the SADC' (1998) 11 Southern African Political and Economic Monthly 35; R Kamidza 'Is SADC Ready For Free Trade?' (2000) 14 Southern African Political and Economic Monthly 23; S Moyo, P O' Keefe and M Sill, 'The Southern African Environment' (1993) 28 -36; C Jenkins, J Leape and L Thomas (eds) *Gaining from Trade in Southern Africa: Complementary Policies to Underpin the SADC Free Trade Area* (2000) 1-20; and RH Thomas 'The World Trade Organization and Southern African Trade Relations' (1999) 3 *Law, Democracy and Development* 105 at 105-106.

[26] The Protocol on Health was approved by the SADC Heads of State in August 1999 and entered into force in August 2004. The full text of the Protocol is available at <http://www.sadc.int/index/browse/page/152> (accessed 12 October 2014)

[27] See generally Article 29 of the Protocol dealing with pharmaceuticals.

[28] See Article 3(n) of the Constitutive Act of the African Union, which was adopted in Lome, Togo on 11 July 2000 and entered into force on 26 May 2001. The full text of the Constitutive Act is available in C Heyns and M Killander (eds) *Compendium of Key Human Rights Documents of the African Union* (2007) 4 – 12. One of the African Union's paramount objectives is to work with progressive partners in eradicating preventable diseases and promoting good health in the continent.

[29] By passing a resolution on the WTO TRIPS Agreement and Access to Medicines on 12 July 2007. The Resolution is Available at: <http://www.un.org/esa/policy/mdggap/mdggap_matrix_drugs.html>(accessed 2 October 2014).

[30] Important decisions and declarations in this regard are the Declaration on TRIPS and Public Health (2001); the Decision of the General Council to implement paragraph 6 of the Doha Declaration (2003); and most recently, the Amendment of the TRIPS Agreement, commonly known as Article 31 *bis* of TRIPS (2005).

[31] Available at: <http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf> (last visited 13/10/14).

[32] See operational paragraph 4.1.8 of the SADC Pharmaceutical Business Plan.

[33] See for instance, E Munyukwi and R Machemedze 'Implementing the TRIPS Flexibilities by the East and Southern African Countries: Status of Patent Law Reforms by 2010' (2010) 80 Equinet Discussion Paper at 9.

procurement and contextualizes it within access to medicines in the SADC region. It then becomes necessary to evaluate efficacy in the SADC by drawing from WTO guidelines and actual practice in the region. Finally, the article draws conclusions and recommendations, making a strong case for pooled procurement.

II. THE RIGHT TO HEALTH AND ACCESS TO MEDICINES IN THE SADC REGION: AN OVERVIEW OF PERTINENT LEGAL INSTRUMENTS

Apart from the SADC Strategy on Pooled Procurement[34], there are a number of instruments that are important in any discussion on the right to health and access to medicines in the SADC region.

Generally, in terms of the United Nations General Assembly Resolution 179 of 2003[35], access to medication in the context of pandemics such as HIV/AIDS[36], tuberculosis and malaria, is a fundamental element of the right to health. Consequently, the obligation to respect access to medicines as part of a human right to health, culminating in the respect of the 'human right to medicines', are identifiable in international customary law.[37] The provisions relating to access to medicines as a human right are, however, imprecise and international instruments, such as the Alma Ata Declaration on Primary health Care[38] and the UN General Assembly Resolution (2003)[39], explicitly commit state parties to the promotion of access to medicines as part of human rights law.[40] Jonathan Mann[41], cited in Heywood[42], is said to have once argued that the 'contribution of medicine to health, while undeniably important (and vital in certain situations), is actually quite limited'. However, side by side with the foregoing observation, when one looks at the emergence of 'treatable pandemics (HIV/AIDS), the resilience of others (tuberculosis), breakthroughs in some crucial areas of medicine and paralysis in others', access to drugs as part of the right to health remains extremely crucial.

In the SADC context, the most important instruments dealing with the right to health and access to medicines are the SADC Protocol on Health[43], the SADC Pharmaceutical Business Plan[44] and the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Commodities.[45] The three documents are identified as crucial in the enhancement of regional integration in the context of health and have been developed to underpin the implication of the SADC health programme.[46] The health programme has developed, taking into account the global and regional health declaration and targets.[47]

None of the three SADC instruments mentions the right to health directly. However, they mention the right to health as a fundamental principle underpinning regional integration in terms of the SADC treaty.[48] This is no surprise given SADC's main objective has always been on regional integration.

A. THE PROTOCOL

The Protocol does not define health nor expressly references access to medicines.[49] Instead, the Protocol talks about 'coordinating and supporting individual and collective efforts of the Member States to attain an acceptable standard of health for

[34] See a detailed discussion of the strategy in paragraph III below.
[35] See UN General Assembly Resolution 179 (2003), UN Doc A/RES/58/179, paragraph 1.
[36] In the acute context of HIV/AIDS, access to medicines is a crucial factor to ensure health and life for millions who are now infected (Van Gulik above 9).
[37] Niada above at 708.
[38] Declaration of Alma Ata 1978 available at: <http://www.euro.who.int/__data/assets/pdf_file/0009/113877/E93944.pdf> (last visited on 12 October 2014), provides in Article I that *Health is a fundamental human right* [emphasis added] and that the attainment of the highest possible level of health is a most important worldwide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.
[39] See note 35 above.
[40] Ibid.
[41] J Mann, S Gruskin, M Grodin and G Annas (Eds), 'Medicine and Public Health, Ethics and Human Rights' in J Mann *Health and Human Rights: A Reader* (1999) 439 -452.
[42] M Heywood 'Drug Access, Patents and Global Health: "Chaffed and Waxed Sufficient"' (2002) 23 Third World Quarterly 217 – 231 at 220.
[43] SADC Protocol on Health (1999) signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004.
[44] SADC Pharmaceutical Business Plan 2007 – 2013, published by the SADC Secretariat on 27 June 2007.
[45] Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013 – 2017, published by the SADC Secretariat in September 2012.
[46] See executive summary of the SADC Pharmaceutical Business Plan paragraph 2 at 3.
[47] Ibid.
[48] See the 'Values and Principles' of the SADC Strategy on Pooled Procurement of Essential Medicines and Health Commodities (hereafter SADC Strategy document) 5, wherein the values of human rights, transparency, equity, gender, sustainable ownership, efficiency, and the principle of subsidiarity are expressly mentioned as guides. The Protocol does not expressly recognize individuals' right to access medicines, but instead bluntly observes that in its preamble that a healthy population is a prerequisite for sustainable human development and increased productivity in Member States and calls for closer cooperation in the area of health.
[49] The closest defined term is 'health promotion', defined as 'the process of enabling people to increase control over and to improve their health' (Article 1 of the SADC Protocol on Health).

all their people'[50] and to promote health care for all 'through better access to health services'[51] (not medicines). The most logical implication would be to view access to medicines within the context of 'better access to health services'. The preamble to the Protocol begins by acknowledging that SADC Member States are aware that a healthy population is a prerequisite for sustainable human development and increased productivity.[52] Furthermore, the preamble points out clearly that rendering coordinated and comprehensive health services in a concerted manner is a prerequisite for the improved health status of the people in the region in the 21st century and beyond.[53]

SADC Member States are urged to cooperate in addressing health problems and challenges facing them through effective regional collaboration and mutual support for the purpose of identifying and supporting those initiatives that have the potential to improve the health of the population within the region;[54] promoting education, training, and effective utilization of health personnel and facilities;[55] fostering cooperation and coordination in the area of health with international organizations and cooperating partners;[56] developing common strategies to address the health needs of women[57], children, and other vulnerable groups;[58] and progressively achieving equivalence, harmonization, and standardization in the provision of health services in the region.[59]

Noteworthy, the Protocol does not refer to intellectual property rights in general terms, neither does it refer to the flexibilities provided by the TRIPS Agreement. However, intellectual property rights are only mentioned in the context of establishing a regional databank of traditional medicines and attendant procedures, ensuring the protection **of medicinal plants in accordance with the regimes and related intellectual property rights (emphasis** added) governing genetic resources, plant varieties and biotechnology.[60] The fact that intellectual property rights relating to medicines are not specifically mentioned in the Protocol remains a serious omission, because health is synonymous with medicines or medication, produced by pharmaceutical companies holding patents (intellectual property rights) over the medicines.

The most relevant and pertinent provision of the Protocol deals with pharmaceuticals.[61] The Protocol calls upon Member States to explore and share with other States in searching for additional financing to acquire medicines, technology, and other resources needed by the citizens in the respective States.[62]

The pharmaceutical provision of the Protocol provides that State parties shall cooperate and assist one another in the various ways ranging from the production, procurement and distribution of affordable essential drugs;[63] development of an essential drugs' programme and the promotion of the rational use of drugs;[64] establishing quality assurance mechanisms in the supply and conveyance of vaccines, blood and blood products;[65] conducting research and documenting aspects of traditional medicine and its utilization;[66] and establishing a regional databank of traditional medicines.[67]

The SADC Protocol on Trade spells out in general terms the envisaged health outcomes for the region. The Protocol on Trade recognizes that close cooperation in the area of health is essential for the effective control of communicable and non-communicable diseases and for addressing common health concerns.[68] The specifics are later laid down in more detail in later instruments, namely the Pharmaceutical Business Plan and the Draft Strategy for Pooled Procurement of Essential Medicines (discussed immediately below).

B. THE SADC PHARMACEUTICAL BUSINESS PLAN 2007-2013

The business plan was launched against the background of the need to develop and implement a pharmaceutical programme in line with the SADC Protocol on Health and SADC health policy.[69] The purpose of the programme is to enhance the

[50] Article 2(b) of the Protocol.
[51] Article 2(d) of the Protocol.
[52] The Protocol, preamble paragraph 3.
[53] Ibid paragraph 6.
[54] Article 3(a). The Draft SADC Strategy may be regarded as an example of such cooperation.
[55] Article 3(c).
[56] Article 3(e).
[57] This resonates with the provisions of the SADC Protocol on Gender and Development, wherein in Article 26 thereof, state parties are urged to have implemented, by 2015, legislative frameworks, policies, programmes and services to enhance gender sensitive appropriate and affordable health care.
[58] Article 3(g).
[59] Article 3(h). Once again, the Draft SADC Strategy on Pooled Procurement may be regarded as a good example of an attempt at standardization/harmonization.
[60] Article 29(f) of the SADC Protocol on Health.
[61] See generally, Article 29 of the SADC Protocol on Health. See further, A Moyo 'The Protection and Promotion of Socio-Economic Rights in the SADC Region' (2010) 11 ESR Review 12 – 15 14.
[62] Moyo above at 14.
[63] Article 29(b).
[64] Article 29(c).
[65] Article 29(d).
[66] Article 29(e).
[67] Article 29(f).
[68] See 'Introduction and Background information' to the SADC Pharmaceutical Business Plan 3.
[69] SADC Pharmaceutical Business Plan, executive summary 3.

capacities of the Member States to effectively prevent and treat diseases that are of major concern to public health in the region.[70]

The overall goal of the Business Plan is to ensure the availability of essential medicines, including traditional medicines, in the region in a sustainable way.[71] The Pharmaceutical Business Plan identifies priority areas, objectives, and major activities that will be implemented, both at the regional and national levels, to improve access to quality and affordable essential medicines including African Traditional medicines.[72] These priorities resonate with the pertinent provisions of the ICESCR and the 2008 Resolution of the African Union Commission on Access to Health and Needed Medicines in Africa.

In order to achieve its objective of improving access to quality and affordable essential medicines, the SADC Pharmaceutical Business Plan will adopt the following strategies[73]:

- Harmonizing standard treatment guidelines and essential medicine lists;
- rationalizing and maximizing the research and production capacity of the local and regional pharmaceutical industry of generic essential medicines and African traditional medicines;
- strengthening the regulatory capacity, supply, and distribution of basic pharmaceutical products through ensuring a fully functional regulatory authority with an adequate enforcement infrastructure;
- promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy, and quality at affordable prices;
- establishing a regional databank of traditional medicine, medicinal plants, and procedures in order to ensure their protection, in accordance with the regimes and related intellectual property rights governing genetic resources, plant varieties, and biotechnology;
- developing and retaining competent human resources for the pharmaceutical programme;
- developing mechanisms to respond to emergency pharmaceutical needs of the region; and
- facilitating the trade in pharmaceuticals within the region.

In summary, the Pharmaceutical Business Plan emphasizes:

(1) harmonization of treatment guidelines and essential medicines lists;

(2) maximization of research and the production capacity of the pharmaceutical industry in the region, so that essential generic medicines and their traditional counterparts may be produced;

(3) harmonization within the regulatory infrastructure applicable to pharmaceuticals, so that there will be a positive improvement in the supply and distribution chain of pharmaceuticals;

(4) promotion of joint procurement of essential medicines in the region, where necessary; and

(5) development of a pharmaceutical databank on traditional medicines, and the respect of intellectual property rules will be one of the key objectives of the business plan.

The SADC Pharmaceutical Business Plan also aims to develop and retain human resources while at the same time establishing mechanisms to respond to regional pharmaceutical emergencies. Finally, the plan aims to facilitate intra-regional pharmaceutical trade.

It is important to point out that the SADC Pharmaceutical Business Plan forms part of the broad SADC health programme, which takes into account global health declarations and targets.[74] In the context of access to medicines that cure

[70] Ibid.

[71] SADC Pharmaceutical Business Plan 4. The main object is to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines.

[72] SADC Pharmaceutical Business Plan, executive summary 4.

[73] See SADC Pharmaceutical Business Plan Executive summary 4 for a list of objectives that are regarded as crucial, reproduced verbatim here in the form of bullet points.

[74] SADC Pharmaceutical Business Plan, paragraph 1.2. The global and regional health declarations and targets include *inter alia*, the Millennium Development Goals; the New Economic Partnership for Africa's Development; the Abuja Declaration on HIV/AIDS; Tuberculosis and Other Related Infectious Diseases (2001); the United Nations General Assembly Special Session on HIV and AIDS (UNGASS) 2001; the Maseru Declaration on HIV and AIDS (2003); the Brazzaville Commitment on Scaling-Up towards Universal Access to HIV and AIDS Prevention, Treatment, Care and Support in Africa by 2010 (2006); and the Lusaka Declaration on African Traditional Medicine (2001).

common epidemics in the SADC region, the business plan specifically seeks to enhance the capacities of the Member States to effectively prevent and treat diseases that are of major concern to public health in the region.[75] The plan focusses on HIV/AIDS, tuberculosis, and malaria, as well as other communicable and non-communicable diseases.[76]

With specific reference to access to medicines in the context of this article, the business plan identifies 'outdated medicine laws and intellectual property laws which are not TRIPS compliant' as a major weakness of SADC countries' pharmaceutical regulatory framework.[77] To address this major weakness, the plan acknowledges that the TRIPS Agreement does contain flexibilities which allow countries to 'import or manufacture pharmaceuticals that are still under patent without the consent of the patent holder'. The plan urges Member States to take advantage of this opportunity which has been utilized before by three SADC Member States.[78] Another opportunity urged by the plan is for more than half of SADC Members that are LDCs to trade within that block without restrictions.[79] These two opportunities can improve accessibility, thereby lowering medicine prices in the region.[80]

The suggested methodology for taking advantage of and coordinating the implementation of the TRIPS flexibilities to improve access to medicines within the SADC region will involve a three-pronged approach.[81] First, a regional assessment of intellectual property and medicines legislation in SADC countries will be conducted to determine TRIPS compliance and adaptability.[82] Second, specialized legal resources from within and outside the SADC region will be identified to give reliable and specialized legal advice.[83] A roster of legal and other experts, who are able to offer technical assistance on TRIPS, will be maintained.[84] Finally the SADC region will collaborate with regional development partners to protect and take advantage of TRIPS flexibilities and assist in bilateral trade negotiations to sign agreements not detrimental to public health.[85]

The other weakness identified by the SADC Pharmaceutical Business Plan having a direct bearing on access is the fact that the region has an acute overdependence on imported medicines, both patented and generics.[86] The overdependence may be alleviated by enhancing the 'regional capacity for pharmaceutical manufacturing, as well as conducting research in medicines and other pharmaceutical products including African Traditional Medicines.'[87]

The SADC Pharmaceutical Business Plan, though ambitious, realistically and correctly identifies SADC access issues to medicines and proffers honest and plausible strategies as solutions. The Pharmaceutical Business Plan provides the priorities and focus for the SADC pharmaceutical programme.[88]

To further bring about the harmonization in the pharmaceutical procurement field, the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities was adopted in September 2012. The next section of this article introduces pooled procurement generally and focusses on the pertinent provisions of the SADC Strategy in that context as a panacea of access to medicines.

III. POOLED PROCUREMENT AS AN ACCESS TO MEDICINES STRATEGY IN THE SADC REGION

A. WHAT IS POOLED PROCUREMENT?

Pooled procurement, also known as joint procurement or procurement cooperation occurs when part or all of the procurement processes of different procurement entities are jointly executed by one of those procurement entities or a third party procurement entity.[89]

The SADC region decided to embark on the strategy of pooled procurement, because studies conducted in the region between 2009 and 2011 found considerable differences in pharmaceutical procurement practices of Member States, as well as in the application of regulations and other procedures such as quality assurance.[90]

The region, therefore, agreed that through the establishment of the SADC Pharmaceutical Procurement Services, pooled procurement would be used as a vehicle **to improve sustainable availability and access to affordable, quality, safe,**

[75] See the SADC Pharmaceutical Business Plan paragraph 1.3.
[76] Ibid.
[77] SADC Pharmaceutical Business Plan paragraph 2.2(i).
[78] Namely Mozambique, Zambia and Zimbabwe in the context of compulsory licences.
[79] This is provided for in paragraph 6 of the WTO Decision of 30 August 2003.
[80] SADC Pharmaceutical Business Plan, paragraph 2.3(iv).
[81] Ibid paragraph 4.18.
[82] This suggestion is in line with the approach that was adopted by this study in chapter 4.
[83] SADC Pharmaceutical Business Plan paragraph 4.18(ii).
[84] Ibid.
[85] Ibid paragraph 4.18(iii).
[86] Ibid paragraph 2.2(vii). About 85 per cent of generic ARV medicines used in the region are imported from India and 15 per cent are manufactured in the region.
[87] SADC Pharmaceutical Business Plan paragraph 1.3.2.
[88] See Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017, discussed in detail in paragraph 3.5.2.3 below 1.
[89] SADC Draft Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017 (2012) at viii.
[90] SADC Draft Strategy for Pooled Procurement above at v.

efficacious medicines (emphasis in original).[91] The Strategy includes cooperation-focussed initiatives, so that countries can learn and benefit from each other.[92] The Strategy allows for reducing the costs of medicines by creating economies of scale[93] through collaboration in procurement by SADC Members.[94] Should the Strategy be fully implemented, there will be harmonization in pharmaceutical registrations for the benefit of the Members who will adopt similar approaches in the future, theoretically cutting costs in registration and inspection of pharmaceutical facilities, thus creating savings across the region.[95]

With savings made through information and work sharing by procurement agencies in Member States, more funds will become available for procurement, which will in turn increase the availability of and access to essential medicines and health commodities.[96]

B. SALIENT ASPECTS OF THE SADC STRATEGY FOR POOLED PROCUREMENT OF ESSENTIAL MEDICINES AND HEALTH COMMODITIES

The Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities (Pooled Procurement Strategy) is a response to the objective of improving 'sustainable availability and access to affordable, quality, safe, efficacious essential medicines', as provided for in the SADC Pharmaceutical Business Plan.[97] Therefore, the Pooled Procurement Strategy is an important step in the pursuit of improving access to 'affordable, quality, safe, and efficacious essential medicines'. The pertinent question to ask at this stage will be how does the Pooled Procurement Strategy purport to improve access to medicines?

According to the Pooled Procurement Strategy, if SADC Member States can cooperate on issues such as pharmaceutical procurement and supply chain management, as well as procedural issues such as quality assurance and public procurement, then access to safe, high quality and efficacious medicines might be improved.[98] The Pooled Procurement Strategy argues for adopting a regional approach to the procurement of pharmaceuticals, including the application of 'good practices' in the pharmaceutical procurement and supply management systems.[99] One advantage of pooled procurement, also called joint procurement or procurement cooperation[100], is the considerable savings made through information and work sharing by procurement agencies in the Member States.[101] With such savings, more funds become available for procurement. This will, in turn, increase availability of and access to essential medicines and health commodities.

The Pooled Procurement Plan envisages the establishment of an entity called the SADC Pharmaceutical Procurement Services, which will manage the implementation of the strategy, relying on guidance from the relevant SADC structures for policy development, monitoring and evaluation functions, general oversight, and implementation processes.[102]

In summary, the main objective of the pooled procurement strategy is to achieve regional integration[103] in the procurement of essential medicines, a practice which will, in addition to fostering deeper integration, facilitate the adoption of a uniform pharmaceutical procurement strategy, ensuring access to essential medicines in the region. This overall objective should be applauded as a regional initiative, which will work alongside implementation of the TRIPS flexibilities. The SADC Pooled Procurement Strategy identifies a number of access issues and concerns which are directly relevant to this study.[104] This article will now

[91] SADC Pharmaceutical Business Plan 2007 at 4.

[92] M Potsanyane, 'Southern African Regional Programme on Access to Medicines to Medicines (SARPAM): a Key Partner in SADC's Pharmaceutical Sector' (2013) 80 South African Pharmacy Journal at 59.

[93] See on a related note a discussion of the possible use of paragraph 6/Article 31*bis* above.

[94] Government of Botswana 'The Implementation of Trade-Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities in the National Intellectual Property Legislation for Strengthening Access to Medicines in Botswana' (2013), A UNDP-SAPARM-Botswana Government Workshop held in Gaborone, Botswana from 25-27 March 2013 at 12.

[95] Potsanyane above at 59.

[96] Government of Botswana above at 13.

[97] See 'Executive Summary' of the Pooled Procurement Strategy paragraph 1 V.

[98] Ibid paragraph 2.

[99] Ibid paragraph 3.

[100] Pooled procurement (or joint procurement or procurement cooperation) is defined as 'the overarching term for procurement where part of all of the procurement process of different procurement entities (agencies or departments of bigger entities) are jointly executed by either one of those procurement entities or a third party procurement entity' (see 'Definition of terms') in the Pooled Procurement Strategy document viii.

[101] See 'Executive Summary' of the Pooled Procurement Strategy paragraph 3 v.

[102] Pooled Procurement Strategy 'Executive Summary' paragraph 4 v.

[103] The SADC common agenda includes the promotion of sustainable and equitable economic growth and socio-economic development that will ensure poverty alleviation with the ultimate objective of its eradication, enhance the standard and quality of life of the people of Southern Africa and support the socially disadvantaged through regional integration [emphasis in the Pooled Procurement Strategy original 1].

[104] See generally 'Situational Analysis' in the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017 3 – 9.

highlight briefly some of the issues and contextualize them.

Information on pharmaceutical procurement is not easily accessible in the SADC region due to different and disparate transparency levels in the private and public pharmaceutical sectors.[105] This implies that the availability of essential medicines will vary between countries of the region with serious access implications.[106] In light of these challenges, pooled procurement would be a possible solution in addressing access challenges and lack of uniformity in the relevant sectors.

The compilation of data for the Pooled Procurement Strategy on pharmaceutical budgets and expenditure was hard to obtain. Further complications came from the fact that most SADC Member States rely considerably on donor support for the purchase of essential medicines, especially in relation to HIV/AIDS, malaria, and tuberculosis.[107] It is submitted that, while reliance on donor support is inevitable, given that more than 50 per cent of SADC Member States are LDCs[108], this continued reliance on donors will frustrate access to medicines in the long term, because TRIPS flexibilities will not be exploited and the development of in-country pharmaceutical capacity will be compromised. Once again, with specific reference to the problem outlined briefly above, pooled procurement may be the solution in resolving the access problem in the specific context.

The SADC Pooled Procurement Strategy also bemoans the fact that four member states do not have a medicines regulatory authority responsible for regulating the quality of medicines in the market and five countries do not actively register medicines.[109] Therefore, in the region, the capacity and capability of the member states' regulatory authorities, responsible for the assessment and approval of medicines, are severely limited.[110] The global implication of the foregoing observation is that medicines allowed in one member state will not automatically be allowed to be used in other SADC Member States. One can envisage that once the region adopts pooled procurement, as suggested in the Draft Strategy, regulatory variations and inconsistencies will fade away and access to medicines will significantly increase.

The other pertinent observation made by the Draft Strategy is that countries provided no information on their use of TRIPS flexibilities in the national legislation to increase access to essential medicines.[111] This is noteworthy in light of the pertinent provisions of the SADC Protocol on Health and the Pharmaceutical Business Plan[112], as well as the objectives of this article.

On a positive note, the Draft SADC Pooled Procurement Strategy observes that despite the shortcomings identified above, national policy regulations are fairly similar in all SADC Member States. Additionally, all Member States have a national medicines policy and an essential medicines list in place, and all but South Africa have a public procurement act.[113]

From the situational analysis made in the Draft Pooled Procurement Strategy, it is clear that progress towards improving access to essential medicines has been registered across the region.[114] However, the identified progress is hampered by limited resources, lack of standardization in the public sector procurement practices, and lack of regional pharmaceutical market intelligence.[115] For pooled procurement to succeed in the SADC context, information and work sharing must be prioritized with the progressive move towards group contracting across Member States to reach the minimum standards of good practice.[116] Achievement of such an option should be viewed as a long-term rather than short-term goal, and its full realization will depend on whether technical assistance is forthcoming from fellow WTO Members and other development partners.

The common thread through all the three SADC instruments is that access to essential medicines' cries for regional attention and the solution to the access problem lies in taking advantage of TRIPS flexibilities in the context of pharmaceutical regional integration. It is quite clear that all three instruments are aware of the existence of TRIPS flexibilities, but why SADC Members are reluctant to take advantage of the flexibilities in an access to essential medicines context remains a mystery.

[105] Pooled Procurement Strategy paragraphs 2.2.1 – 2.2.2 at 3.
[106] Despite the fact that it would be simplistic to expect a uniform availability of essential medicines across the SADC, in an ideal world, the expectation would be that the basic medicines are available across the region.
[107] SADC Pooled Procurement Strategy, paragraph 2.2.4 at 4.
[108] SADC Member States which are classified as LDCs are Zambia, Malawi, Angola, Mozambique, Seychelles, Swaziland, Lesotho, Democratic Republic of Congo and Tanzania.
[109] See paragraph 2.2.6 of the SADC Pooled Procurement Strategy 4. The five countries, all of whom are LDCs, are Angola, Lesotho, Seychelles, Democratic Republic of Congo and Swaziland.
[110] Ibid.
[111] Ibid paragraph 2.2.8.
[112] See Article 29 of the SADC Protocol on Health and paragraph 2.3 VI of the SADC Pharmaceutical Business Plan.
[113] Draft SADC Pooled Procurement Strategy paragraph 2.3.1 at 4.
[114] Ibid paragraph 3 at 5.
[115] Ibid.
[116] Ibid.

(i) iPOOLED PROCUREMENT AS A POSSIBLE ACCESS TO MEDICINES SOLUTION IN SADC: A BRIEF EVALUATION

In August 2011, the Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM), which is funded by DFID and managed by Re-Action (South Africa), was appointed by the SADC Secretariat on a consultancy basis to help the region with, among other things, the development of a Pooled Procurement strategy.[117]

The goal of SARPAM is to increase access to affordable essential medicines in the SADC region through supporting the development of a more efficient and competitive regional pharmaceutical marketplace.[118]

While pooled procurement is, strictly speaking, not an intellectual property issue, its scope for improving access to affordable essential medicines is very high. Hence, it is highly recommended that the SADC region implement pooled procurement in line with the broad objective of ensuring access to medicines for all. Using pooled procurement would complement local pharmaceutical production and the use of regional compulsory licences in terms of Article 31*bis.* Pooled procurement is therefore recommended for the SADC region because it will protect the right to life, human dignity and health by ensuring that Members benefit from economies of scale and mitigate the impact of medicines' prices on access.

IV. CONCLUSION

Pool procurement creates economies of scale that result in low transaction costs and better leverage in price negotiations. It can ensure a continuous supply of medicines at low prices that this poor region could afford. There is political will in the region to make sure that this will be a success.

[117] PD Spivey Kashi and KB Carasso 'SARPAM Annual Review Narrative Report' (2012) at 2.
[118] Ibid.

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