

Pharmaceutical trade policies and access to medicines in Kenya

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Summary

The right to health requires the full integration of TRIPs Agreement flexibilities in pharmaceutical trade policies and the avoidance of TRIPs-plus standards to safeguard access to medicines nationally. The article argues that a human rights impact assessment, and specifically a right to health impact assessment, may resolve beforehand the adverse impacts of pharmaceutical trade policies on access to medicines in Kenya. However, Kenya, as in many other developing countries, has not yet embraced the HRIA tool in its trade policy processes even though the theory and methodology of HRIA or RHIA exist. The key finding of the article is that many trade policy makers in Kenya are not adequately prepared in terms of their knowledge and attitude to implement the HRIA or RHIA as a routine process in trade.

Key words: *access to medicines; free trade agreements; human rights impact assessment; pharmaceutical trade policy; Kenya*

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1 Introduction

Access to medicines is a fundamental element of the right to health. The right to health norms on access to medicines emphasise the full utilisation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) flexibilities in line with the Doha Declaration on TRIPs Agreement and Public Health, 2001,¹ as well as the non-adoption of higher standards (TRIPs-plus standards) than is required by the TRIPs Agreement. A failure to adhere to the above, therefore, may adversely impact on the right to health and access to medicines, which is an obligation of the government under international, regional and national legal instruments. Incorporating the full utilisation of TRIPs Agreement flexibilities and avoiding TRIPs-plus standards in pharmaceutical trade policy, therefore, are crucial in order to safeguard the right to health and access to medicines in the local context.

How to resolve the adverse impact of pharmaceutical trade policies on access to medicines at the national level, therefore, is critical to safeguard access to medicines. One way to address this concern is to integrate the mechanism of a human rights impact assessment (HRIA) in pharmaceutical trade policy processes.² Through HRIA, 'the human rights implications of a policy are considered when that policy is being developed (*ex ante*); or of assessing the impact of policy or practice on the rights of those affected once the policy is implemented (*ex post*)'.³ HRIA, therefore, ensures that the implementation of international trade rules do not prioritise trade imperatives at the expense of human rights.⁴ The main aim of HRIA is to build attention to human rights into trade policies.⁵ In this regard, the HRIA has the power to change policies and practices in favour of improving the lives of people.⁶

Developing countries are cautioned against negotiating or implementing trade-related intellectual property rights without first assessing their impact on human rights using HRIA as a tool.⁷ This is particularly crucial in relation to bilateral and multilateral free trade agreements (FTAs) that may be used to pressurise governments to accept more stringent standards of intellectual property protection

1 WT/MIN(01)/DEC/W/2, 14 November 2001.

2 R Mungoven 'Walking the talk: Exploring methodologies and applications for HRIA by the United Nations' (February 2016) 7.

3 J Harrison & M Stephenson 'Scottish Human Rights Commission 'Human rights impact assessment: Review of practice and guidance for future assessments' (1 June 2010) 14, <http://eqhria.scottishhumanrights.com/eqhriapolicyprocess.html> (accessed 27 February 2018).

4 G MacNaughton 'Human rights impact assessment: A method for healthy policymaking' (2015) 17 *Health and Human Rights Journal* 64.

5 As above.

6 MacNaughton (n 4) 16.

7 MacNaughton 117-118.

beyond what is required by the TRIPs Agreement.⁸ The HRIA should, therefore, be promoted as a routine process in trade worldwide.⁹

The article focuses on how the HRIA could be implemented in Kenya in relation to its motivational theory, methodology and trade policy makers' preparedness in terms of their knowledge and attitude in this area. The article is structured as follows: the government obligations under the right to health; the human rights and market theories underpinning the use of the HRIA mechanism; the emerging methodology of HRIA; and the preparedness of trade policy makers in Kenya to implement HRIA as a routine process in trade.

2 Methodology

This is a mixed method research study integrating data from diverse disciplines, including human rights, international trade law, intellectual property rights law, and impact assessment methodology. Both primary and secondary data has been used in this study.

The primary data has been sourced mainly from legislation, resolutions, court decisions and treaties. In addition, primary data has also been sourced from semi-structured interviews with trade policy makers, experts and civil society organisations working in the area of access to medicines in relation to the issue of the preparedness of trade policy makers in terms of their knowledge and attitudes in relation to HRIA. Clearance was obtained from the research ethics committee of the Faculty of Law, University of Pretoria. The responses received from each interviewee were transcribed and the file is with the author. There was no compelling need to obtain authorisation from the relevant review board in Kenya as the interviewees who participated in this study were consenting expert participants and were not vulnerable or at risk. Requests for anonymity by interviewees are accommodated in the study. Lastly, no private health information was requested from the interviewees.

The secondary data used in this study emanates from various sources, including journal articles, reports, books, and electronic sources from various databases.

8 L Forman & G MacNaughton 'Lessons learned: A framework methodology for human rights impact assessment of intellectual property protection in trade agreements' (2016) *Impact assessment and Project Appraisal* 1, <http://www.dlsph.utoronto.ca/wp-content/uploads/2012/02/Forman-MacNaughton-IAPA-final-.pdf> (accessed 30 July 2017).

9 MacNaughton (n 4) 64.

3 Right to health obligations of the government in relation to access to medicines

3.1 International instruments on the right to health

There are at least five human rights provisions that apply in the context of the TRIPs Agreement and access to medicines. The main provisions include the rights to health, life and human dignity. In addition to these, the right to information and the right to public participation have become increasingly important in fostering transparency and accountability in relation to trade negotiations.¹⁰ This part, however, focuses only on the right to health instruments as elaborated on below.

3.1.1 Global human rights instruments

At the global level, the right to health has been protected in many key human rights instruments. The most influential instrument besides article 25 of the Universal Declaration of Human Rights (Universal Declaration) at the global level is article 12(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR),¹¹ which provides: 'The state parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'

Article 12(2) of ICESCR further reiterates that the right to health extends to the underlying determinants of health, including 'food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment'.¹² Article 12(2) of ICESCR has been interpreted as follows. First, article 12(2)(a) dealing with maternal, child and reproductive health services requires the right to access anti-retrovirals (ARVs) in order to prevent mother-to-child transmission of HIV.¹³ Second, article 12(2)(c) on the right to prevention, treatment and control of diseases may be interpreted to mean 'the right of access to certain medicines, namely medicines necessary for immunisation and

10 D Ovetv 'Making trade policies more accountable and human rights-consistent: A NGO perspective of using human rights instruments in the case of access to medicines' in W Benedek, K de Feter & F Marrella (eds) *Economic globalisation and human rights* (2007) 183.

11 UN General Assembly International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations Treaty Series Vol 993 3, <http://www.refworld.org/docid/3ae6b36c0.html> (accessed 3 March 2016); adopted and opened for signature, ratification and accession by General Assembly Resolution 2200A (XXI) of 16 December 1966; entered into force 3 January 1976, in accordance with art 27.

12 General Comment 14: The right to the highest attainable standard of health (art 12), adopted at the 22nd session of the ESCR Committee on 11 August 2000 E/C 12/2000/4) para 4.

13 Z Strauss & D Horsten 'A human rights-based approach to poverty reduction: The role of the right of access to medicines as an element of the right of access to health care' (2013) 16 *Potchefstroom Electronic Law Journal* 304.

medicines specifically required to combat particular epidemics (such as ARVs which, although they do not combat the epidemic, are essential in the management and control thereof).¹⁴

Third, article 12(2)(d) relating to the right to health facilities, goods and services also include the provision of essential drugs.¹⁵

ICESCR is supplemented by many thematic global human rights instruments, including article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW);¹⁶ article 24 of the Convention on the Rights of the Child (CRC);¹⁷ article 5(e)(iv) of the Convention on the Elimination of All Forms of Racial Discrimination (CERD);¹⁸ and article 25 of the Convention on the Right of Persons with Disabilities (CRPD).¹⁹ The purpose of these thematic instruments is to reinforce the importance of the right to health in different thematic sectors.

3.1.2 African human rights instruments

At the continental level, the African Charter on Human and Peoples' Rights (African Charter) is the starting point. The African Charter enshrines the right to health in article 16(1) as follows: 'Every individual shall have the right to enjoy the best attainable state of physical and mental health.' Unlike ICESCR, article 16(2) of the African Charter is brief and only requires state parties to 'take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick'. Accordingly, this provision is the basis on which the state is under an obligation to

14 Strauss & Horsten (n 13) 305.

15 General Comment 14 (n 12) para 17.

16 UN General Assembly Convention on the Elimination of All Forms of Discrimination Against Women, 18 December 1979, United Nations, Treaty Series, Vol 1249 13, <http://www.refworld.org/docid/3ae6b3970.html> (accessed 7 March 2016). Art 12(1) provides: 'States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.'

17 UN General Assembly Convention on the Rights of the Child, 20 November 1989, United Nations, Treaty Series, Vol 1577 3, <http://www.refworld.org/docid/3ae6b38f0.html> (accessed 7 March 2016). Art 24(1) provides: 'States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.'

18 UN General Assembly International Convention on the Elimination of All Forms of Racial Discrimination 21 December 1965, United Nations, Treaty Series, Vol 660 195, <http://www.refworld.org/docid/3ae6b3940.html> (accessed 7 March 2016).

19 UN General Assembly Convention on the Rights of Persons with Disabilities Resolution/adopted by the General Assembly, 24 January 2007 A/RES/61/106, <http://www.refworld.org/docid/45f973632.html> (accessed 7 March 2016). Art 25 of CRPD provides: 'States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation.'

provide health and medical services for their populations despite implementation challenges.²⁰ From the text, the link between access to medicines and the right to health under the African Charter may be found in the context of providing medical attention when people are sick.

The African Charter is also supplemented by other regional human rights instruments, including article 14 of the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (African Women's Protocol);²¹ and article 14 of the African Charter on the Rights and Welfare of the Child (African Children's Charter).²²

Since Kenya has ratified both the African Women's Protocol and the African Children's Charter, it has additional obligations to provide access to medicines for these categories of people.

3.1.3 *Sub-regional instruments on the right to health*

There are documents at the sub-regional level that recognise the right to health. In relation to Kenya, article 33 of the East African Community Human and Peoples' Rights Bill²³ provides for the recognition of the right to health. However, it should be noted that this document is still pending before the East African Community Legislative Assembly (EALA). There also is thematic legislation enacted by the sub-regional body that provides for the right to health, which is the East African Community HIV and AIDS Prevention and Management Act, 2012.²⁴ In this regard, the right to health is particularly crucial in relation to the prevention and management of HIV and AIDS in the EAC.

20 J Rehman *International human rights law* (2010) 320.

21 African Union Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa, 11 July 2003, <http://www.refworld.org/docid/3f4b139d4.html> (accessed 7 March 2016). Art 14(1) provides: 'States Parties shall ensure that the right to health of women, including sexual and reproductive health is respected and promoted.'

22 Organisation of African Unity (OAU) African Charter on the Rights and Welfare of the Child, 11 July 1990, CAB/LEG/24.9/49 (1990), <http://www.refworld.org/docid/3ae6b38c18.html> (accessed 7 March 2016). Art 14(1) provides: 'Every child shall have the right to enjoy the best attainable state of physical, mental and spiritual health.'

23 East African Community on Human and Peoples' Rights Bill, 2011, http://www.kenyalaw.org/kl/fileadmin/pdfdownloads/EALA_Legislation/BILLSUPPLEMENT12thAugust20121.pdf (accessed 7 March 2016). This Bill is yet to be enacted into law.

24 East African Community HIV and AIDS Prevention and Management Act, 2012, adopted during the 5th session of the East Africa Legislative Assembly, held in Nairobi, Kenya, on 23 April 2012 and entered into force on 14 December 2014.

3.2 Interpretation of the right to health in relation to access to medicines

At the international level, to determine the nature and scope of the right to health in relation to access to medicines, reliance is often placed on 'soft' law. A 'soft' law is a non-binding but persuasive instrument, which usually is relied upon to clarify the normative standards applicable in relation to the rights defined under an instrument, such as the right to health discussed above. Moreover, unlike the 'hard' laws discussed above, the link between the right to health and access to medicines, including in the context of intellectual property rights, is clearly explained in detail in many examples of 'soft' law as discussed below. There are three main positions that are discernible in the soft laws. The first approach is that only access to essential medicines is part of the right to health. The second is that the right to health encompasses only life-saving medicines. The last approach is that access to all medicines is part of the right to health.

In 2009 the Special Rapporteur on the Right to Health published a report on access to medicines and the right to health from an intellectual property point of view. According to him, as a result of product patents, intellectual property law has an impact on the right to health by allowing a patentee to set higher prices.²⁵ Thus, in order to promote competition by lowering the number of patents granted, countries should adopt higher as opposed to lower patentability criteria.²⁶ Noting the importance of generic medicines in lowering prices of HIV medications from as high as US\$ 10 000 per patient per year to US\$ 350 per patient per year, the Special Rapporteur noted that the post-2005 TRIPs Agreement period will pose challenges in terms of the manufacture and the importation of generic medicines owing to the new obligations of states under TRIPs.²⁷ In the interests of public health, the Special Rapporteur argued that countries should be allowed to use the following TRIPs flexibilities: (a) making full utilisation of the transition periods; (b) defining the criteria of patentability; (c) issuing compulsory licences and provide for government use; (d) adopting the international exhaustion principle to facilitate parallel importation; (e) creating limited exceptions to patent rights; and (f) allowing for opposition and revocation procedures.²⁸

The Special Rapporteur also noted the pressure imposed on developing countries by developed countries and multinational corporations in the context of utilising TRIPs Agreement flexibilities.²⁹

25 Report of the Special Rapporteur on the Right to the Highest Attainable Standard of Physical and Mental Health, Anand Grover, 31 March 2009 [A/HRC/11/12] paras 17-18.

26 Report (n 25) para 18.

27 Report paras 20-21.

28 Report para 27.

29 Report para 56.

Apart from the utilisation of TRIPs flexibilities, the Special Rapporteur on the Right to Health addresses the issue of Free Trade Agreements (FTAs) and Economic Partnership Agreements (EPAs), which he observed lack 'transparency or participation from the public, and often establish TRIPs plus provisions, which undermine the safeguards and flexibilities that developing countries sought to preserve under TRIPs'.³⁰ He urged countries to analyse such multilateral or bilateral agreements for potential health violations and to insist on transparency and openness at all stages of negotiations.³¹ In his view, the TRIPs-plus provisions in FTAs can serve one or more of the following purposes: 'extend the patent term; introduce data exclusivity; introduce patent linkage with drug registration and approval; and create new enforcement mechanisms for intellectual property rights'.³²

In October 2009 HRC Resolution 12/24 incorporated some of the proposals made by the UN Special Rapporteur on Health and encouraged 'all states to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures'.³³ The focus here was that the enforcement of intellectual property rights should not be a barrier to trade in medicines and that safeguards should be put in place to guarantee that such measures and procedures for enforcing intellectual property rights will not be abused. Illustratively, a key safeguard for access to medicines in the context of anti-counterfeiting is to delink patents from anti-counterfeiting legislation.

In March 2011 HRC Resolution 16/28 was adopted focusing on enforcement. The Resolution 'encourages all states to apply measures and procedures to enforce intellectual property rights in a manner that avoids the creation of barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures, taking into account, inter alia, the [Doha Declaration]'.³⁴ The key addition here is the fact that the Doha Declaration should at all times be taken into account while enforcing intellectual property rights domestically. At around the same time the Special Rapporteur on the Right to Health had identified as one of the emerging challenges in the area of access to medicines the issue of 'ensuring access to medicines for non-communicable or chronic diseases'.³⁵ It would be important in the future that the Doha Declaration is expanded to include also non-communicable diseases in addition to HIV and AIDs, tuberculosis and malaria.

30 Report para 69.

31 Report para 70.

32 Report para 75.

33 HRC Resolution 12/24, 2009, UN Doc A/HRC/RES/12/24 para 6.

34 HRC Resolution 16/28, March 2011, UN DOC A/HRC/Res/16/28 para 19.

In July 2011 the HRC adopted Resolution 17/14, which called on states '[t]o promote access to medicines for all, including through the use, to the full, of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, which provide flexibility for that purpose, recognising that the protection of intellectual property is important for the development of new medicines as well as the concerns about its effects on prices'.³⁶ It should be noted that this Resolution focused on the development of medicines and not only access to medications and, thus, the moderate language which calls for intellectual property protection as well as the utilisation of TRIPs flexibilities.

In 2013 the Special Rapporteur on the Right to Health undertook another extensive study focusing on the existing challenges and good practice with regard to access to medicines in the context of the right to health as mandated by the United Nations (UN) HRC Resolution 17/14.³⁷ According to the Special Rapporteur, the right to health framework is composed of the following key elements that ensure access to medicines as derived from paragraph 12 of General Comment 14 of the Committee on Economic, Social and Cultural Rights (ESCR Committee): availability, accessibility, acceptability and quality as key elements of the right to health.³⁸ This report is especially relevant to this study and will be referred to throughout the subsequent parts of this study. Thus, the substantive contents of this report will not be set out here in order to avoid unnecessary duplication.

Perhaps the clearest indication that the HRC intended to broaden the scope of the right to health beyond access to ARVs to all medications is the June 2013 Resolution 23/14 of the HRC. This Resolution focused on access to medicines for everyone as opposed to ARVs only that had been stressed hitherto. Most importantly, it 'recognises that access to medicines is one of the fundamental elements in achieving progressively the full realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.³⁹ In this regard, therefore, unlike sub-Commission on Human Rights Resolution 2001/33, access to medicines as a right to health is not limited to pandemics such as HIV and AIDS.

Among other things, HRC Resolution 23/14 urged states to 'use, to the full of the provisions of the [TRIPs] Agreement which provide

35 Report of the Special Rapporteur on the Right to the Highest Attainable Standard of Physical and Mental Health: Expert consultation on access to medicines as a fundamental component of the right to health, Anand Grover, 16 March 2011 [A/HRC/17/43] para 48.

36 HRC Resolution 17/14, July 2011, UN Doc A/HRC/Res/17/14 para 7(g).

37 Report of the Special Rapporteur on the Right to the Highest Attainable Standard of Physical and Mental Health, Anand Grover, 1 May 2013 [A/HRC/23/42] para 1.

38 Report (n 39) para 8.

39 HRC Resolution 23/14, June 2013 A/HRC/Res/23/14 para 2.

flexibility for that purpose, recognising that the protection of intellectual property is important for the development of new medicines, as well as the concerns about its effects on prices'.⁴⁰ This paragraph contains contradictions because on the one hand it notes that pharmaceutical patents are important for the development of new medicines, but on the other hand it also recognises that pharmaceutical patents have an impact on medicine prices. In this regard, it adopts a middle ground with regard to pharmaceutical patents.

HRC Resolution 23/14 also urged states to 'apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of affordable, safe, efficacious and quality medicines, and to provide for safeguards against the abuse of such measures and procedures'.⁴¹ This paragraph focuses on intellectual property enforcement by noting that it should be implemented in a manner that does not create a barrier to legitimate trade and also through providing safeguards against the potential abuse of such measures and procedures. Consequently, if pharmaceutical patents are to stay, then its enforcement should not undermine legitimate trade, for instance in generics.

The Resolution further urged states '[t]o ensure that investment, industrial or other policies promote development and access to medicines, in particular their affordability'.⁴² This paragraph notes the critical role played by investment and industrial policies in the development and affordability of medicines.

At the regional front, in 2013 the African Union (AU) in a progress report recognised that, among other things, 'a critical enabler to a sustainable AIDS and tuberculosis response remains an intellectual property framework that is sensitive to public health objectives'.⁴³ In that report, the following was recommended: '[S]trengthen review of laws and measures to fully incorporate and utilise all public health related [TRIPs Agreement] flexibilities and to avoid limits on the use of public health related TRIPs flexibilities'.⁴⁴

4 Theories underpinning the utilisation of the human rights impact assessment mechanism

The applicable theories in relation to HRIAs in relation to trade may be divided into two main categories, namely, traditional human rights theories and market or trade theories. The human rights theories are

40 HRC Resolution 23/14 (n 39) para (h).

41 HRC Resolution 23/14 para (j).

42 HRC Resolution 23/14 para (m).

43 Implementation of the Abuja Call for Accelerated Action Towards Universal Access to HIV and AIDS, Tuberculosis and Malaria Services, 2013, Progress Report 2010-2012 [Sp/Assembly/ATM/II(IV) para 44.

44 As above.

human rights as a source of substantive policy guidance in trade; human rights as a source of political, moral and legal pressure; human rights and fragmentation, coherence and constitutionalisation of international law; and human rights as a trigger for social learning in trade.⁴⁵ This review will only focus on human rights as a trigger for social learning in trade due to its popularity. The market theories discussed in this part of the article include semiotic methods and rational theory for morality.

4.1 Human rights theories underpinning human rights impact assessment

In relation to human rights as a trigger for social learning in trade, Harrison notes that the HRIA as a tool is currently more popular in other fields and is outwardly focused and, as such, it is possible that human rights can affect policy debates in new areas including trade.⁴⁶ The idea here is that HRIA facilitates the process by which human rights-based arguments can be introduced and supported in other sectors where it was previously not possible to do so. This view is shared by Forman who further argues that 'the tool's methodology and approach are best understood through theories of rights as drivers of social change, particularly constructivist theories of socially-driven normative diffusion'.⁴⁷ In Forman's view, the way the tool works is through playing 'a more subterranean normative role by diffusing and internalising new human rights norms around medicines, so that policy makers are forced to consider their right to health duties when dealing with intellectual property rights'.⁴⁸ Lang argues that unlike the other traditional human rights theories, the social learning theory is transformative in relation to the trading system because of its role of imposing a 'new thinking'.⁴⁹ In this manner, human rights rules and principles become the basis of producing new policy ideas to fundamentally question the present assumptions that have hindered progress in trade.⁵⁰

The social learning theory, as briefly articulated above, is persuasive in relation to HRIA but suffers from one major weakness, which is that it lacks legitimacy among trade policy makers and, therefore, it is not

45 ATF Lang 'The role of the human rights movement in trade policy-making: Human rights as a trigger for policy learning' (2007) 5 *New Zealand Journal of Public International Law* 77.

46 J Harrison 'Human rights measurement: Reflections on the current practice and future potential of HRIA' (2011) 3 *Journal of Human Rights Practice* 170.

47 L Forman 'From TRIPS-plus to rights-plus? Exploring right to health impact assessment of trade-related intellectual property rights through the Thai experience' (2012) 7 *Asian Journal for WTO and International Health Law* 355.

48 As above.

49 Lang (n 45) 101. According to Lang 'new thinking' means 'new ideas about the kind of trade policies which are desirable and legitimate, and about the kind of governance structures through which political power is constituted and exercised in the trading order'.

50 Lang (n 45) 101.

sufficient to motivate trade policy makers to view human rights as a routine process in trade. This constraint may be addressed using market theories, as discussed below.

4.2 Market theories underpinning human rights impact assessment

This part attempts to explain why trade and human rights should not be viewed as being inconsistent with each other but compatible using market theories.

4.2.1 *Semiotic methods*

One theorist is Malloy who introduces a concept known as the semiotic method, which he contends can 'help us to reflect on the social and cultural consequences of invoking and validating economic assumptions in law and social institutions'.⁵¹ In the semiotic method, Malloy contends that the focus is not only on 'what might be efficient, but on what the social significance might be of declaring an efficiency criterion to be of primary significance in determining social policy'.⁵² The semiotic method is significant in so far as it allows for the challenging of the dominant efficiency criterion in trade and economics.

4.2.2 *The rational theory of morality*

The rational theory of morality is advanced by Coleman who notes that there seems to be an inherent conflict between rationality and morality, which may be defined as utility maximisation and constrained utility maximisation respectively.⁵³ However, it is possible for one to derive morality from rationality if one considers that 'the theory of rationality must generate both the substantive and motivational components of moral theory'.⁵⁴ The substantive part has been tackled in relation to the right to health norms discussed above and, as such, this part focuses on the motivational aspect. Consequently, Coleman uses contractarian terms to explain that 'under conditions of perfect competition, the individually rational, self-interested behaviour of all agents induces a Pareto-efficient outcome ... in optimal equilibria, therefore, each actor does as well as he can – that is, his utility is maximised subject to the utility maximisation of others'.⁵⁵ It will be irrational to impose restrictions if all individuals are performing at an optimum level.⁵⁶ Consequently, it

51 RP Malloy *Law and market economy* (2000) 26.

52 As above.

53 J Coleman *Markets, morals and the law* (1998) 311. According to Coleman, the rational actor seeks to maximise his net (expected) utility and the moral actor sometimes acts so as to constrain the utility-maximising behaviour.

54 As above.

55 Coleman (n 53) 312.

56 As above.

follows that '[u]nder conditions of perfect competition ... the rational actor has no incentive to adopt constraints, moral or otherwise, on his utility-maximising behaviour. Compliance with moral principles would be irrational.'⁵⁷ However, in situations of market failures where conditions of perfect competition are non-existent, the reverse is true.⁵⁸ In this situation, 'the self-interested, utility-maximising behaviour for each individual leads to a Pareto-*inefficient* outcome – that is, one in which at least some individuals could be made better off without worsening the conditions of others'.⁵⁹ Constraining the utility-maximising behaviour may lead to better results for the individual than if she continues pursuing the unrestrained path.⁶⁰ Therefore, '[b]y introducing constraints on the utility-maximising behaviour of individuals, it may be possible to secure Pareto-*efficient* outcomes in which an individual fares better than she would were she to act as an unconstrained utility maximiser'. Moreover, '[t]here would then be a rational motivation for compliance with normative, possibly even moral, principles which requires constraint'.⁶¹

5 Methodology of human rights impact assessment

Limited scholarship exists in the area of methodology of HRIA and taking into account the practice and experience of implementing HRIA.⁶² However, a few critical scholars will be reviewed in this part. Harrison, for instance, notes that HRIA has developed in at least six main areas, including development; health and human rights; children's rights; multinational companies; international trade; public authorities; and others including anti-trafficking laws and policies and domestic violence.⁶³ It appears therefore that HRIA has multiple uses and has been used in many contexts, including international trade. The immediate problem, however, is that some actors will abuse the term HRIA to refer to a process that does not resemble any ideal-type instrument as known by human rights actors and commentators.⁶⁴ It therefore is crucial to understand the methodology of HRIA in order to distinguish it from other instruments employed by human rights or trade actors. According to Harrison, the ideal-type instrument developed from the practice of HRIA all over the world over a long period of time should have eight main elements as follows:⁶⁵

57 As above.

58 As above.

59 As above.

60 As above.

61 As above.

62 Harrison (n 46) 163.

63 Harrison 168-170.

64 Harrison 171.

65 Harrison 172-179.

screening;⁶⁶ scoping;⁶⁷ evidence gathering;⁶⁸ consultations;⁶⁹ analysis;⁷⁰ conclusions and recommendations;⁷¹ publication;⁷² and monitoring and review.⁷³ Suffice to note that the steps under HRIA actually are similar to most of the other types of impact assessments and as such the methodology of impact assessment is similar across the board.⁷⁴ Harrison notes that in order to enhance future practice, several things must be addressed, including⁷⁵ improving collective understanding of the process;⁷⁶ better guidance and support for those undertaking HRIAs;⁷⁷ and monitoring performance.⁷⁸ In the context of access to medicines, the health impact assessment (HIA), international trade agreements HRIA and right to health impact assessment (RHIA) are instructive. For a detailed discussion about HRIAs in the context of health policy-making, the work of MacNaughton is key.⁷⁹ However, since this study involves

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- 66 Harrison 172-173. 'Screening is the process of deciding whether a particular policy, practice, or project is suitable for a full impact assessment, and screening out those where an HRIA is not considered appropriate or necessary. It therefore performs a critical step in justifying a decision to undertake an assessment.'
- 67 Harrison 173-174. 'Scoping refers to the information that is gathered and questions that are asked once the decision to undertake an HRIA has been made (although in some forms of HRIA considerable scoping may be required before a screening decision is taken). Scoping essentially provides a road map for the rest of the assessment (what is being assessed, and how it is to be assessed).'
- 68 Harrison 174-175. 'This is the collection of information to inform analysis of the policy in question. This is at the heart of an impact assessment methodology. Without gathering evidence about the (potential) impacts of a policy, the conclusions of the decision-maker are likely to reflect simply their own knowledge, experience and prejudices.'
- 69 Harrison 175-176. 'There need to be procedures for ensuring that the voices of those who are, or are likely to be affected by the policy are heard and taken into account in the HRIA process. This requires effective consultations.'
- 70 Harrison 176-178. '[U]sing human rights obligations as the basis of impact assessment is not as obvious or as simple as it seem. In some extreme cases, there are assessments in which no real attempt is made to use human rights obligations as the basis for assessment at all ... HRIAs must be fundamentally rooted in human rights norms and standards if they are really to be considered HRIAs.'
- 71 Harrison 178-179. 'If he aim is to have an effect on actual policy and practice, then clearly this step is central – without clear conclusions and recommendations, action in response to the HRIA is highly unlikely.'
- 72 Harrison 179. 'Publishing HRIA is a vital part of the impact assessment process. It ensures that the body undertaking the assessment can be held to account by rights-holders and other interested actors.'
- 73 As above. 'Some form of monitoring process is vital in order to scrutinise whether recommendations in the original HRIA are properly implemented.'
- 74 MacNaughton (n 4) 66.
- 75 Harrison (n 46) 180-183.
- 76 Harrison 180-181. Some of the areas he identifies as in need of better understanding include 'evidence-gathering techniques that are appropriate to different forms of assessment, and the development of techniques that are appropriate to different forms of assessment, and the development and application of context-specific indicators that actually drive assessment processes'.
- 77 Harrison 181-182. This involves using toolkits and other aides, including principles.
- 78 Harrison 182-183.
- 79 MacNaughton (n 4) 69.

international trade agreements, the focus of the study mainly is on HRIAs and specifically RHIA but not HIA. The difference between HRIA and RHIA is in the norms that have been used with the latter emphasising only right to health norms as is the case in this study. HIA has a different methodology which does not put human rights at the core and, therefore, differs from HRIA. This author has no technical competence to articulate HIA in such a study since he is only conversant with human rights methodologies.

Accordingly, Harrison and Goller observe that HRIA of international trade agreements will depend largely on how best the interlinkages between trade and human rights norms are treated in the methodology.⁸⁰ In this regard, they proceed to develop an appropriate methodology to cover the gap, noting that 'there is minimum guidance in relation to the appropriate methodologies from key institutional actors despite the numerous calls to conduct HRIA on trade agreements'.⁸¹ Most importantly, the authors note that

an HRIA of a trade agreement requires developing a methodological framework for exploring the impact of international legal obligations and how they are implemented at the national level, rather than the impact of a particular actors or set of actors and the impact of their actions on specified third parties as in the case of the activities of a multinational company or NGO.⁸²

The above quote is important because the focus of HRIA is on the impact of international trade rules at the national level.

The authors note that the main value of HRIA is the fact that human rights are at the core of its methodology.⁸³ The authors also warn that HRIAs commissioned by governments can be retrogressive if they are not appropriately conceived and implemented, because it may be 'utilised in future to short-circuit important decision-making by other actors'.⁸⁴ Finally, the authors note that

HRIAs should also facilitate identification of situations where government are not in fact constrained by international trade rules to act in a way that conflict with human rights norms. Governments may be making domestic policy choices and regulatory decisions in ignorance of the real ambit of international trade rules or for entirely different reasons at the behest of domestic lobbying groups.⁸⁵

Arguably, the development of FTAs and pharmaceutical trade policies that go beyond the TRIPs Agreement is often motivated by lobbying from the private sector and other interest groups as opposed to a clear obligation under international trade rules. In Kenya, the Kenya

80 J Harrison & A Goller 'Trade and human rights: What does "impact assessment" have to offer' (2008) 8 *Human Rights Law Review* 592.

81 Harrison & Goller (n 80) 592-593.

82 Harrison & Goller 594.

83 Harrison & Goller 605.

84 Harrison & Goller 613.

85 Harrison & Goller 615.

Association of Manufacturers (KAM) was responsible for championing the TRIPs-plus Anti-Counterfeit Act legislation in Kenya and the East African region.⁸⁶

Apart from HRIA on international trade agreements, there are special types of HRIA based on individual rights as opposed to the whole gamut of human rights norms and principles such as RHIA. The work of Forman and MacNaughton on RHIA in the context of international trade agreements is particularly important in this study.⁸⁷ The two authors note that in order to respond to the challenge of access to medicines in relation to the TRIPs Agreement in developing countries, the HIA and RHIA have been utilised.⁸⁸ Even so, the government has not been active in utilising these tools.⁸⁹

The two authors also develop some guidance borrowing from various articles as follows: They note that the methodology can be 'flexible, robust and user-friendly and draw on a multidisciplinary team that is independent from executive negotiating the agreement'.⁹⁰ The requirement for independence from the government is particularly controversial because, as argued in this study, HRIA should actually be conducted by states and not external stakeholders. States should therefore view the tool as being useful as opposed to something that can be manipulated and, as such, market theories of HRIA discussed above may play a role. Also, there is a proposal to use six steps as follows:⁹¹ (a) screening or preliminary analysis of the extent of the HRIA necessary; (b) scoping including team selection, development of the methodology, selection of an explicit human rights framework based upon applicable human rights obligations and identification of data sources and indicators; (c) data collection; (d) analysis, requiring the evidence gathered to be compared against the human rights obligations; (e) reporting the conclusion and recommendations of the analysis at the basis for weighing the options, decision making and holding decision makers accountable; and (f) monitoring and evaluating outcomes as they are implemented.

However, it should be noted that Harrison (discussed above) had eight steps in his methodology that should constitute an ideal-type HRIA as opposed to the six proposed by Forman and MacNaughton. However, the methodology proposed by Harrison is not sufficiently different from what Forman and MacNaughton have set out since what appears to be data collection and reporting the conclusions and recommendations for Forman and MacNaughton have been split in the case of the methodology for Harrison. With regard to the former,

86 See <http://kam.co.ke/policy-advocacy/counterfeit-goods-illicit-trade/> (accessed 27 June 2018).

87 Forman & MacNaughton (n 8) 109-138.

88 Forman & MacNaughton 122.

89 As above.

90 Forman & MacNaughton 129.

91 Forman & MacNaughton 129-130.

Harrison instead has evidence gathering and consultation as two separate steps. Similarly, with regard to the latter, Harrison has conclusion and recommendations and publication as two separate steps. Ultimately, therefore, the two methodologies are substantially the same. Further, HRIA should combine quantitative and qualitative analysis using economic modelling, causal chain analysis, expert opinions and civil society involvement.⁹² In this study, it is submitted that economic modelling and causal chain analysis is a best practice and, therefore, its absence is not fatal to any methodology that may be adopted. However, an explicit human rights framework should be integrated into HRIA without fail.⁹³ Also, broad participation is important since it is required by human rights principles and the imperatives of guaranteeing accountability.⁹⁴ Further, HRIAs should not be used in isolation but together with 'existing human rights strategies such as mobilisation, campaigning, advocacy and research and policy analysis, for achieving human rights-friendly trade and investment regimes.'⁹⁵ It is submitted that HRIA is not a replacement to other strategies but it is just one of the many strategies available in the human rights and trade context. Lastly, HRIA should be institutionalised within domestic laws and within the international system to enhance its effectiveness in promoting and protecting human rights in trade.⁹⁶

6 Trade policy process in Kenya and access to medicines

This part discusses the process of trade policy development at the Ministry of Trade and other government departments in Kenya.

6.1 Process of trade policy development within the Ministry of Trade

Apart from the actors, the process of trade policy development is also important. It is in the process where the methodology of HRIA belongs and should be implemented. As demonstrated below, the process of trade policy making in Kenya still assumes the situation of the perfect market and is blind to market failures. It is for this reason that the HRIA as a tool has been seen as being unnecessary in trade negotiations. In order to change this, the trade process should be able to identify and deal with situations of market failures, which entails the availability of more adverse impacts than actual benefits for a country in relation to a particular trade measure.

92 Forman & MacNaughton 130.

93 As above.

94 As above.

95 As above.

96 Forman & MacNaughton 131.

It is important to note that the administration of intellectual property rights in Kenya faces severe institutional problems.⁹⁷ The problem is further exacerbated by the fact that many government institutions are unable to attract and retain a multidisciplinary work force, and in many instances they lose their best work force to transnational organisations.⁹⁸

Before embarking on trade policy making, it is important to clarify that pharmaceutical trade policies usually are trade policies and not health policies. However, as noted by Dr Wangai, a representative of the Ministry of Health, without medicines health providers may not be able to do much in healthcare facilities.⁹⁹ Despite the importance of medicines in health, the Ministry of Health has no mandate over the trade aspects of medicines, including issues of intellectual property rights protection. However, as noted by Dr Wangai, the Ministry of Health has some role to play when it comes to the regulation of medicines, and currently the Pharmacy and Poisons Board is responsible for guaranteeing the quality of medicines in the country.¹⁰⁰ According to Dr Wangai, Kenya aims at establishing the Kenya Food and Drug Agency, which will be responsible for regulating medicine and other non-pharmaceutical products used in the health sector.¹⁰¹ It therefore appears that the Ministry of Health focuses on quality assurance as opposed to trade. This may explain the lack of clear collaboration between the Ministry of Health and the Ministry of Trade including in the area of medicines.¹⁰² It is submitted, therefore, that the Ministry of Health has a very limited role to play in terms of making medicines affordable in the country, especially in relation to the adverse impact of pharmaceutical trade policies despite the fact that they stand to be most affected when medicines are inaccessible. The ministry that is directly responsible for policies is the Ministry of Trade through its trade policy development process, as shown below.

In Kenya the trade policy development process, including in the area of intellectual property rights, largely is a participatory process coordinated at the Ministry of Trade supported by other government departments.¹⁰³ As such, trade policy in Kenya is not an exclusive function for the Ministry of Trade. It should be noted, however, that

97 B Sihanya *Intellectual property and investment law in Kenya and Africa: Translating technology for sustainable development* (2016) 619.

98 As above.

99 Interview with Dr Mary Wangai on 23 May 2018 (Ministry of Health, Department of Regulation and Standards).

100 As above.

101 As above.

102 As above.

103 Interview with Bramah L Kaleve on 17 April 2018 (Principal Trade Development Officer, Ministry of Trade).

international trade has since 2017 been coordinated by the Ministry of Foreign Affairs and International Trade.¹⁰⁴

According to Kaleve, the process of trade policy development begins with a preparatory meeting organised by the Ministry of Trade in the country involving various stakeholders, usually government ministries and other departments to be affected in a particular trade process.¹⁰⁵ The various stakeholders usually are required to develop position papers in relation to the trade proposals that are on the table in a manner that will safeguard the interests of the government in the trade negotiation process.¹⁰⁶ The position paper is then compiled by trade experts or officials from the Ministry of Trade, and the position paper then forms the basis for negotiations.¹⁰⁷ At the multilateral level, the process is somewhat different since there usually is a peer review process or trade policy review process that is done in order to ensure that the proposals made do not negatively impact international trade.¹⁰⁸ The government then has to reach out to government departments that are affected to provide information that may be required to address any queries raised.¹⁰⁹ It is submitted that the peer review process is a good practice in as far as the implementation of trade obligations is concerned, and a similar practice in relation to human rights may be useful. Alternatively, Munyi notes that there needs to be a checklist akin to that used by the Dutch negotiators to check whether all elements have been complied with by an agreement before it is signed or enacted into law.¹¹⁰

However, since this article focuses on trade policy at the national level, it is crucial to understand whether there are safeguards in the trade policy development process in relation to human rights. Kaleve notes that human rights usually are introduced through specific trade instruments. For instance, the African Growth and Opportunity Act (AGOA) and the Cotonou Agreement have specific clauses addressing human rights in trade policy.¹¹¹ However, the Ministry of Trade has no internal mechanism to address human rights concerns in trade should it be necessary.¹¹² Trade experts mainly are individuals qualified in law, economics, trade development and business.¹¹³ However, staff of the Ministry of Trade attend seminars organised by

104 Interview with Leah Aywa Baraza on 15 May 2018 (Deputy Chief State Counsel, International Law Division).

105 Interview with Bramah L Kaleve (n 103).

106 As above.

107 As above.

108 As above.

109 As above.

110 Interview with Peter Munyi on 15 March 2018 (International Trade Lecturer, University of Nairobi).

111 Interview with Bramah L Kaleve (n 103).

112 As above.

113 As above.

civil society on trade and human rights.¹¹⁴ It is submitted that more seminars and training targeting trade policy makers may help narrow the capacity gap in terms of trade and human rights. This is especially so because, as noted by Kaleve, human rights do not form part of the work plan of the Ministry of Trade and it is unlikely that the Ministry will streamline it because the variable value on productivity is minimal.¹¹⁵ It is submitted that the above position generally is understood using market theories aimed at increasing the Pareto-efficiency. However, there are circumstances, including market failure, that actually may require inefficient response from the government, especially when it relates to the implementation of international intellectual property rights rules.

The role played by the Ministry of Trade in terms of the integration of the TRIPs Agreement flexibilities serves as a good lesson in relation to the access to medicines agenda. In 2001 the role of trade policy makers, including that of Minister Biwott, was instrumental in the incorporation of TRIPs Agreement flexibilities under the Industrial Property Act, 2001.¹¹⁶ It should be noted that during this time, the momentum was also in favour of developing countries since the Doha Declaration had also been adopted. In the period after the Doha Declaration, many developing countries have become less assertive, especially at the national level. The agency of the Doha Declaration serves to show that trade policy makers are actually desirous of tools that they can use to act in the best interests of the government.

At present the influence of the Doha Declaration is waning at the national level. Trade policy makers, therefore, have become very unpredictable since trade policy makers are usually assertive in Geneva but they do not follow up on their 'talk' in Geneva with appropriate actions in terms of implementation back home.¹¹⁷ It therefore appears that a national tool that is able to remind trade policy makers of their obligations, including under human rights such as the HRIA, may be an appropriate solution. It therefore is important to show that the HRIA methodology actually is a tool that serves rather than frustrates the interests of the government since trade policy development usually involves maximising the interests of the state.

In the absence of a clear integration of human rights norms and methodologies in the context of mainstream trade policy-development processes, it is useful to also look at the role of the Office of the Attorney-General (AG) as well as the Kenya National Commission on Human Rights (KNCHR) in relation to trade and human rights.

114 As above.

115 As above.

116 Interview with Peter Munyi (n 110).

117 As above.

6.2 Other relevant government departments

Ideally, the implementation of HRIA should be undertaken by legal offices in government. These offices actually have access to information regarding the nature of human rights obligations of the government. Suffice to note that the trade department may not be knowledgeable about or be able to competently interpret the full obligations of the government under human rights provisions in international, regional and national instruments. Therefore, where the Ministry of Trade fails, the other government departments supporting the trade policy development process should be able to act and provide appropriate guidance.

According to Ouma, when the government negotiates a trade agreement with other countries, the relevant line ministries often provide position papers in trade, health and agriculture.¹¹⁸ She notes that the legal issues relating to trade negotiations mainly are handled by the treaty department in the office of the Attorney-General of Kenya.¹¹⁹ It therefore appears that the AG has the final say on the legality of legislation or a trade agreement.

Accordingly, the AG usually is involved to ensure that the legal limits are observed in relation to the obligations of the government both at the international and national levels.¹²⁰ The AG office relies on the requests, proposals or documents presented to it by the Ministry of Trade. Thus far the office of the AG has yet to receive any request from the Ministry of Trade to evaluate a particular trade agreement from a human rights perspective, even though it is true that the capacity may be low in the department in relation to human rights.¹²¹ In this regard, the AG's office usually is focused on complying with the Constitution of Kenya and the World Trade Organisation (WTO) obligations and not human rights, including the constitutional human rights provisions.¹²² It is submitted that many government departments, including legal departments, are oblivious of their obligations in relation to trade and human rights. Indeed, Aywa notes that the stakeholders that usually participate in trade are not human rights specialists and, therefore, it usually is difficult for these people to understand human rights issues in trade. Thus far trade and human rights have been viewed separately.¹²³

Indeed, the sentiments expressed above in relation to the general perception in government about the separateness of trade and human rights is also reflected in the work of the Department of Justice under the AG's office. The Department is responsible for reporting on

118 Interview with Judy Ouma, 6 March 2018 (Former Trade Negotiator, Economist and USIU-Africa Lecturer).

119 As above.

120 Interview with Leah Aywa Baraza (n 104).

121 As above.

122 As above.

123 As above.

human rights violations in collaboration with other government departments including the KNCHR. Korir notes that there has been no complaint in relation to human rights and trade.¹²⁴ Korir further notes that the main problem is that the policy makers in many government departments are still operating under the old constitutional framework, which contained limited human rights, excluding socio-economic rights.¹²⁵ It therefore emerges that the quality of policy makers in government today has not adjusted to the new constitutional dispensation which also protects the right to health, including in a trade context.¹²⁶ The link between human rights and trade remains unclear for many officials in the Department of Justice.¹²⁷

However, taking into account the above process of trade negotiations, which involves various line ministries including the office of the AG, it is perplexing that the KNCHR, which is mandated to advise the government on human rights issues, plays no active role to support the office of the AG.¹²⁸ At the moment, even the relevant economic, social and cultural rights department under the KNCHR is yet to roll out a specific programme on trade and human rights, and it admits that it has not in the past collaborated in the area of pharmaceutical trade policies with government departments.¹²⁹ The KNCHR, however, currently focuses on business and human rights, especially focusing on extractive industries. Some of the activities being implemented include the putting in place of a national action plan and policies in this area.¹³⁰ The area of access to medicines has therefore been neglected by the KNCHR and, as such, the KNCHR has failed to push for and monitor compliance in terms of the implementation of the constitutional right to health, including the decision of the *PAO* case in anti-counterfeit legislation in Kenya.¹³¹

From the above it appears that the lack of input of the office of the AG, both the International Law Department and the Department of Justice as well as the KNCHR may have contributed to the low profile of human rights in the process of trade development and negotiations. The KNCHR, working closely with the office of the AG, may thus help advance the human rights agenda in trade, including the implementation of HRIA. However, the use of the HRIA tool still is best optimised if the Ministry of Trade and its agencies, including the

124 Interview with Stephen Kibet Korir on 3 May 2018 (State Counsel, Department of Justice, Human Rights Division).

125 As above.

126 As above.

127 As above.

128 Interview with Maina Mutua, 30 March 2017 (Head of ECOSOC Department, KNCHR).

129 As above.

130 Interview with George Morara, 14 March 2018 (Vice Chairperson, KNCHR).

131 As above.

ACA and KIPI,¹³² were capacitated to integrate the tool as a routine process in their work especially because pharmaceutical trade policies are in fact trade as opposed to health or human rights policies. This is the true spirit of the current constitutional framework, which binds all state and non-state officials and recognises that every state organ has a fundamental duty to observe, respect, protect, promote and fulfil the human rights protected under the Constitution.¹³³ This will also be in line with the current government priorities and interests, which include universal health coverage.

7 Conclusion

Developing countries are expected to implement their right to health obligations, including in the context of trade and specifically TRIPs Agreement implementation locally. The TRIPs Agreement affects many laws and policies at the national level, including pharmaceutical trade policies. In this regard, pharmaceutical trade policies enacted at the national level should therefore ensure that the TRIPs Agreement flexibilities are not compromised in line with the right to health norms and that adopting standards beyond what is required under the TRIPs Agreement is avoided. A failure to do so will have an adverse impact on access to medicines in the country and consequently violate the right to health. The best way to safeguard access to medicines locally, therefore, is to integrate the mechanism of HRIA in trade policy processes and implement them as a routine processes in trade in order to identify and resolve *beforehand* the adverse impact of pharmaceutical trade policies on access to medicines. The utilisation of the HRIA will ensure that trade imperatives do not supersede human rights obligations of the government, including with regard to access to medicines. The methodology adopted by each country should reflect the rights protected and countries where the right to health is protected should be encouraged to conduct RHIA, which is more specific on issues of access to medicines than HRIA, generally speaking. Lastly, trade policy makers should have adequate knowledge and the right attitude in relation to human rights and human rights methodologies to facilitate the implementation of HRIA. One way in which to adequately prepare trade policy makers both at the Ministry of Trade and beyond is to explain HRIA using market theories including rational theory of morality, which is a motivational theory, in order to achieve more acceptability of human rights tools and norms in the trade sector.

132 Telephone interviews with anonymous individuals at KIPI and ACA on 5 July 2018. In this interview it also emerged that these agencies do engage in trade policy development processes, especially in relation to the work they do, but still there is no clear appreciation of the link between human rights and trade.

133 Art 21(1) of the Constitution, 2010.