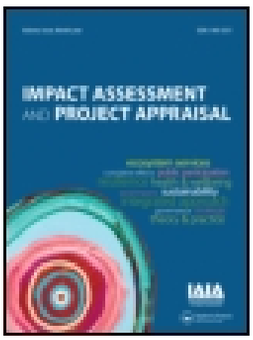

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Lessons learned: a framework methodology for human rights impact assessment of intellectual property protections in trade agreements

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ABSTRACT

Currently, two billion people lack regular access to essential medicines in contradiction of their right to health under international law. With the rapid growth of intellectual property provisions in international trade agreements in recent years, governments are increasingly bound to provide stringent patent protection to pharmaceuticals, resulting in higher drug prices, which exacerbate the inaccessibility of medicines. As a result, there is a growing consensus in human rights and public health communities that policy-makers should ensure that trade agreements do not negatively affect the right to health, and moreover that human rights impact assessment offers a pragmatic and increasingly well-considered framework for achieving this aim. Drawing on numerous case studies and international human rights standards, this article proposes a pragmatic framework methodology for non-governmental organizations to carry out human rights impact assessment of trade-related intellectual property protections as part of their advocacy campaigns.

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Introduction

Over the past decade, there has been growing interest in health and human rights impact assessments both within public health and human rights communities, as well as in the established domain of impact assessment practice (Kemp & Vanclay 2013). Environmental and social impact assessments have been widely employed over the past 40 years, and more recently, numerous other types of impact assessments – to gage potential effects on specific populations or sectors – have proliferated (Harrison 2011, p. 164–165). Yet health and human rights impact assessment are relatively new and consequently draw on the methodologies of those impact assessments that have preceded them (Walker 2009, p. 3–5). The need to develop new methodologies attentive to both international human rights standards and impact assessment practice is apparent in the growing focus on human rights impact assessment (HRIA) including within the pages of this journal (Graetz & Franks 2013; Harrison 2013; Kemp & Vanclay 2013).

The development of health and human rights impact assessment methodologies has arisen from the practical imperative to mitigate the health and human rights impacts of policy and trade in a range of domains. As a result, health and human rights impact assessments have been used to predict the health and human rights consequences of interventions in multiple arenas, including at the level of clinic operations, state and local policy and foreign direct investment projects (Rights & Democracy 2007; United Kingdom Department of Health 2008; Bakker et al. 2009). One particular area that has drawn considerable attention from public health officials, nongovernmental organizations (NGOs), and international human rights experts is the potential negative health and human rights impacts of intellectual property provisions in international trade agreements on the price, and therefore accessibility of medicines (Walker 2011; Forman 2013). With the rapid increase in intellectual property provisions in bilateral and multilateral trade agreements over the past decade, governments are increasingly bound to provide stringent patent protection to pharmaceuticals. Because of their significant adverse impact on drug prices, trade-related intellectual property provisions threaten to exacerbate the drug gap in low- and middle-income countries (LMIC) in particular, where 2 billion people continue to lack regular access to essential medicines (World Health Organization 2004; Millennium Development Goals (MDG) Gap Task Force 2013).

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Indeed several studies confirm that high medicine prices contribute to the poor availability of essential medicines in many LMIC (Niens et al. 2010, p. 2; Cameron et al. 2011, p. 2; MDG Gap Task Force 2013, p. 60). For example, a 2010 study exploring the affordability of medicines for asthma, diabetes, hypertension, and adult respiratory infection in sixteen LMIC found that up to 86% of the population would fall below the poverty line by purchasing these medicines (Niens et al. 2010, p. 1). When essential medicines are not affordable, ill people may be forced to decide whether to impoverish themselves by purchasing drugs at prices they cannot afford or forego treatment for painful and life-threatening health conditions (Niens et al. 2010, p. 2; Cameron et al. 2011, p. 6). The human consequences of unaffordable medicines was brought into stark relief by dramatic death rates from the HIV/AIDS pandemic in Sub-Saharan Africa, which illustrated that the protection of intellectual property provisions could not be divorced from the devastating health and human rights impacts of inaccessible medicines. Indeed, in large part because of the AIDS experience, access to essential medicines is now explicitly recognized as a fundamental element of the right to the highest attainable standard of physical and mental health ('the right to health') (United Nations 2013, para. 2). This situation has generated a growing consensus amongst international human rights bodies and other institutions that policy-makers should take the right to health into account when entering trade agreements, and moreover that human rights impact assessment (HRIA) offers a pragmatic and increasingly well-considered framework for doing so (United Nations 2004a, 2004b, 2006a, 2006b, 2006c, 2007, 2008; World Health Organization 2008, p. 14–15, 46, 135–137).

This article draws from extant literature and practice to propose a framework methodology for HRIA of trade-related intellectual property provisions in relation to access to medicines. By 'framework methodology,' we mean an outline and guidance for an HRIA into which users may develop further context specific details. This methodology draws substantially from the intersection of three previous publications on HRIA. The first publication, by Paul Hunt, then United Nations Special Rapporteur on the right to health, and Gillian MacNaughton, proposed a right to health framework for impact assessment as a case study for developing human rights impact assessment methodology (2006). The second is a detailed human rights-based methodology of trade-related intellectual property provisions, developed by Simon Walker and applied to a prospective free trade agreement (FTA) in Costa Rica (Walker 2009, 2011). The third is a report by Olivier De Schutter, then United Nations Special Rapporteur on the right to food, which proposed guiding principles on HRIA of trade and investment agreements (2011). In addition, we draw on other scholarship and studies that have focused specifically on the health and human rights consequences of intellectual property provisions in trade agreements on the cost and accessibility of medicines.

The framework methodology we propose differs from the three primary models cited above by providing a user-friendly and narrow focus on the human rights impact of intellectual property rights on access to medicines alone. We foresee this narrow focus being used in two potential ways. First, and primarily, the proposed methodology may be used as a stand-alone impact assessment exercise to be conducted *ex ante or ex post* by non-governmental organizations to assess prospective or existent trade or intellectual property laws and agreements in order to generate an evidence-based advocacy tool. As NGOs, especially those in low- and middle-income countries are unlikely to be able to carry out complex multidimensional HRIAs, a narrow focus and a user-friendly pragmatic HRIA methodology is most likely to be adopted for such campaigns on access to medicines. Second, the proposed methodology may be used as an add-on methodology to be integrated into existing *ex ante* tools used by policy-makers to assess trade and social impacts, including trade sustainability assessments, economic modeling and causal chain analysis. We do not attempt in this paper to address these broader impact assessment methods, which would be beyond the capacity of the vast majority of NGOs. More specifically, we believe that our framework methodology makes a distinctive contribution through its focus on 'usability' – privileging ease, brevity, and affordability in order to assure that this tool can be used relatively quickly and cheaply according to context and need. We believe that these aspects of this tool differentiate it from others in usage, and permit it to make a distinctive contribution to practice in this domain.

We acknowledge the challenges of carrying out HRIAs of proposed provisions for international trade agreements in the context of secretive trade negotiations in which key aspects are not publicly accessible until already agreed upon. The secretive aspects of trade negotiations complicate the task of NGOs wishing to conduct *ex ante* impact assessments. However, we hope that increased use of HRIA by NGOs will pressure governments into making the proposals for trade agreement more transparent, and ultimately conducting their own comprehensive, participatory and transparent HRIAs of proposed trade agreements to assess the human rights impacts of trade related intellectual property rights commonly protected in trade agreements.

Following this introduction, part B of the article outlines how trade-related intellectual property provisions affect access to medicines, and overviews relevant human rights standards applicable in this context. Part C explores key health and human rights impact assessments, including those that have specifically addressed the potential consequences to medicine prices and

access of proposed intellectual property provisions in international trade agreements. Part D considers the lessons learned from these experiences over the past decade in order to propose a framework HRIA methodology, pointing to specific issues for practitioners to consider at each stage of the impact assessment process. The paper concludes with thoughts about the future development of methodologies for HRIA of intellectual property provisions in international and bilateral trade agreements.

Trade-related intellectual property provisions and their impact on human rights

Since 1995, any country acceding to the World Trade Organization (WTO) must adopt the Agreement on trade-related intellectual property rights (TRIPS), which requires WTO members to provide 20-year exclusive protection to pharmaceutical patents (World Trade Organization 1994; article 33). In particular, TRIPS prevents WTO members from manufacturing or importing cheaper drugs, unless they use the limited exceptions in TRIPS called 'flexibilities' which enable policy-makers to access cheaper drugs when necessitated by public health needs. TRIPS flexibilities include compulsory licenses (where governments manufacture or import generics under strict limitations) and parallel imports (where governments import lower priced patented medicines) (World Trade Organization 1994; articles 31, 6). The TRIPS rule on compulsory licenses is however complex and circumscribed, and can only be used if the drug in question will be used for public non-commercial use, national emergency or extreme urgency. However, these key terms are not defined within the TRIPS agreement, so that countries issuing compulsory license under almost any circumstances are likely to attract real or threatened trade sanctions, litigation, or corporate drug removals (Forman 2011).

The implementation of TRIPS in countries introducing pharmaceutical patents for the first time has resulted in significant increases in drug prices. This impact is demonstrated in Malaysia, where the introduction of patents saw drug prices rise by 28% on average *per year* between 1996 and 2005 (Smith et al. 2009). TRIPS will eventually phase out generic manufacture of patented medicines in totality unless it is done under compulsory licensing (Forman 2011). Even stricter intellectual property rights in regional and bilateral FTA are further restricting the use of compulsory licensing and other TRIPS flexibilities. These intellectual property provisions are termed 'TRIPS-plus rules' because they exceed the standards in that agreement, and serve to extend monopoly pricing and limit market entry for generics (Forman & MacNaughton 2015). For example, the US has negotiated bilateral or regional FTAs with approximately 60 countries (Forman & MacNaughton 2015), and the European Union and European Free Trade Association with approximately 50 countries (European Commission 2012; European Free Trade Association 2012). TRIPS-plus intellectual property provisions are being advanced in a range of other bilateral agreements, including the Trans-Pacific Partnership recently concluded between the USA, Canada, and 10 Pacific Rim countries (including Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam). A proposed Anti-Counterfeiting Trade Agreement attempts to challenge the movement of counterfeit or pirated goods, without adequately distinguishing between counterfeit medicines and legitimate generics produced under compulsory license or where no patent is in force.

The advancement of TRIPS-plus rules continues despite the 2001 WTO Doha Declaration, which explicitly endorses the right of WTO members to protect public health and promote access to medicines for all, and to use TRIPS flexibilities to the fullest extent, including compulsory licenses (World Trade Organization 2001, para. 4). While the Doha Declaration sought to confirm that compulsory licenses could be used legitimately for epidemics like HIV/AIDS, tuberculosis and malaria (World Trade Organization 2001, para. 5.c), in practice pharmaceutical companies (and their host governments) attempt to limit use of compulsory licenses to these three diseases alone, and to limit their use within Sub-Saharan Africa (Forman 2012). The impact is to maintain high drug prices, restrict access to generics and sustain and even exacerbate the drug gap at great human cost (Forman 2013).

This outcome threatens the realization of a range of human rights primarily the right to health protected extensively in international law, including most comprehensively in the International Covenant on Economic, Social and Cultural Rights (ICESCR) (United Nations 1966). The right to health in the ICESCR has been authoritatively interpreted by the United Nations Committee on Economic, Social and Cultural Rights (CESCR) to impose a state duty to provide universal access to essential medicines as a core and hence prioritized duty under this right (United Nations 2000). Moreover, the general duty to assure that all health care services are available, accessible, acceptable and of good quality (the 'AAAQ' framework) implies a general state duty to ensure access to affordable and safe drugs (United Nations 2000).

The CESCR has further interpreted a state's core obligation with regard to essential medicines to extend to preventing unreasonably high costs for essential medicines from undermining the rights of large segments of the population to health (United Nations 2006c, para. 35). The United Nations General Assembly has confirmed that 'access to medicines is one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (United Nations 2013, para. 2). These duties appear to be in conflict with the intellectual property provisions

in TRIPS and subsequent trade agreements which give strictly enforced exclusive protection to pharmaceutical patents, contributing to rising drug costs and limited access to cheaper medicines whether generic or patented.

Human rights and intellectual property-related impact assessments

To develop this framework methodology, we conducted an extensive search of scholarly literature in the areas of health impact assessment; human rights impact assessment; and trade impact assessment. We similarly conducted a broad but not exhaustive search of prominent methodologies in use in each of these three aforementioned fields. The results of this search are presented in Tables 1 and 2, which also summarize key developments. Table 1 describes important advances in human rights impact assessments, and Table 2 outlines key impact assessments of trade-related intellectual property provisions from health and/or human rights perspectives. Based on this review, the HRIA we propose in this article draws from key developments within two converging lines of scholarship and practice: first, we focus on the significant growth in methodologies and scholarship exploring HRIA related to health, and primarily the methodology developed by Hunt and MacNaughton in 2006. Second, we draw from the development of human rights specific impact assessments focused on trade agreements, especially the HRIA developed by Simon Walker in 2009 addressing how intellectual property rights affect access to medicines, and the guidelines for conducting HRIA of trade and investment agreement developed by De Schutter in 2011. Certainly aspects of trade agreements other than intellectual property rights can impact on access to medicines – we do not however focus on mechanisms such as investment dispute settlement or health care transparency as our intention is to create a user-friendly framework methodology that is narrowly focused. It is our hope that the current methodology can be adapted by other users or researchers to these areas accordingly.

HRIA is a relatively recent idea and practice that has drawn significantly from extant advances in the long-standing fields of health and social impact assessments. In 1994, Gostin and Mann's pioneering article proposed developing a methodological tool to assess and mitigate the human rights impact of potentially coercive public health policies on vulnerable populations (Gostin & Mann 1994). Since that time, human rights and right to health-specific methodologies have been developed by NGOs and social groups, including the Canadian NGO Rights and Democracy, the Dutch NGO Aim for Human Rights, and the transnational People's Health Movement (People's Health Movement's 2006; Rights and Democracy 2007; Bakker et al. 2009). A key development in human rights-related impact assessment came in 2006, when Paul Hunt (then the Special Rapporteur on the right to health) and Gillian MacNaughton proposed mainstreaming human rights into other forms of impact assessment, demonstrating this approach with a methodology for integrating the right to health into *ex ante* impact assessment to assess prospective human rights impacts of proposed policies (Hunt & MacNaughton 2006, p. 4–5). The authors proposed seven general principles for human rights-based impact assessment: (1) use an explicit human rights framework, (2) aim for progressive realization, (3) promote equality and non-discrimination in process and policy, (4) ensure meaningful participation by all stakeholders, (5) provide information and protect the rights to freely express ideas, (6) establish mechanisms to hold the State accountability, and (7) recognize the interdependence of all human rights. They also proposed considerations for integrating the right the right to health into a six-step process for the impact assessment: (1) preliminary check, (2) assessment plan, (3) information collection, (4) rights analysis, (5) debate options, and (6) decision and evaluation.

While the Hunt and MacNaughton methodology was recommended for governments to carry out in the context of domestic policy-making, crucial decisions were being made at the international level, limiting the policy space for improving health and realizing human rights. Indeed, the health impacts of trade-related intellectual property provisions has prompted a rising consensus that states should assess the impact of intellectual property provisions in trade agreements on access to medicines, and do so from a human rights perspective. At least three United Nations treaty-monitoring committees have called on countries to conduct assessments of the effect of international trade rules on the right to health (United Nations 2004a, 2004b, 2006a, 2006b, 2006c, 2007, 2008). Similar calls have been made by other international institutions including the World Health Organization's Commission on the Social Determinants of Health, which urged countries considering new global, regional, and bilateral trade and investment commitments to use health equity impact assessments to establish flexibilities that would allow modifications in the event of adverse impacts on health or health equity (World Health Organization 2008, p. 14–15, 46, 135–137). Similar views are expressed in scholarship, which widely views impact assessment as offering a practical tool to minimize the negative impacts of foreign policy and trade agreements on health and human rights (Lee et al. 2007; Scott-Samuel & O'Keefe 2007; Walker 2009; Harrison 2011).

Joan Rovira, a Spanish academic, developed a widely used methodology called the intellectual property rights impact aggregate (IPRIA), a user-friendly computer-assisted simulation model to assess the impact of changes to intellectual property provisions on domestic

Table 1. Human rights impact assessments.

Name	Nature of IA	Primary user	Human rights component	Methodology	Findings	Applied/Impact
Gostin and Mann (1994)	HRIA for public health; non-discrimination focus	Gov and NGOs	Integrated into questions	Set of questions to balance public health benefits against human rights burdens (explore necessity and proportionality	–	–
Lor and Hinman (2004, 2011)	Based on Gostin and Mann; Broad human rights focus	Gov and NGOs	Integrated in steps	Set of questions to establish impact and alternatives	–	–
Rights and Democracy (2008)	HRIA methodology for investment projects	NGOs	Follows rights-based approach of transparency, accountability, non-discrimination, focus on vulnerable groups, and recognizing indivisibility of rights	Ten step methodology to scope, collect, report and recommend, monitor, and evaluate	–	Case studies in Argentina, Peru, Tibet, Democratic Republic of Congo, and Philippines
Aim For Human Rights (2010)	Women's health rights methodology; Domestic policies; stand alone; *Ex ante*; Advocacy tool	NGOs	Integrates standards from ICESCR and CEDAW	Step-wise approach to identify, describe, and recommend	–	Kenya, 2007/8–Netherlands, 2008:
HeRWAI						
Hunt and MacNaughton (2006)	A human rights method to be integrated into HIA; *ex ante*; policy focus; focus on right to health	Governments	Integrated into steps, as well as providing 7 guiding human rights principles (explicit use of human rights, progressive realization, equality/non-discrimination, participation, transparency, accountability, and interdependence)	Six-step approach to check, plan, collect, draft report, distribute, and finalize	–	–
People's Health Movement's (2006)	Based on HeRWAI; Focus on right to health care and government responsibilities	NGOs	Explicit focus on human rights responsibilities of governments, and integration into the remaining steps	Five step assessment: commitments, policies, health system, health status, and realization of rights	–	–
Thai National Human Rights Commission (2006)	US-FTA *Ex ante*	HRC	Explicit reference to UDHR and Thai Constitution; no mention of ICESCR or Thai right to health	Uses IPRIA model; uses secondary data to compare drug prices (generic/branded) and estimate price increases from longer patents	Found that prospective IPR would increase drug prices beyond people's purchasing power and exceed annual health budget Recommended delaying negotiations, and not considering IPR in the negotiations	Studies; used in advocacy; compliant legal reform and policy
Ruggie (2007)	Methodological questions for HRIA of business		Frame with international bill of rights; catalog human rights standards; use rights-based approach (participation, non-discrimination, vulnerable groups, accountability, identify rights holders and duty bearers)	Describe activity, law, human rights conditions, impacts; recommend; monitor, consult; publish	–	–
Walker (2009)	HRIA of CAFTA on Costa-Rica; *ex ante*; stand alone; IPR and medicines		Four elements of HRIA: explicit human rights, participation, develop duty bearers, and rights holders, involve human rights mechanisms and actors	Step-wise methodology to prepare, screen, scope, analysis, recommend, evaluate, and monitor	Market exclusivity likely to put additional pressure on budget with increased spending as much as USD 331 million to avoid significant drop in consumption of pharmaceuticals supplied through the public sector	–

(*Continued*)

Table 1. (*Continued*).

Name	Nature of IA	Primary user	Human rights component	Methodology	Findings	Applied/Impact
				• Collect using economic modeling, surveys, legal analysis, causal chain analysis, participatory case-studies, and expert opinion • Use qualitative and quantitative indicators • Staged causal chain analysis (FTA impact on market exclusivity, price impact on market exclusivity, and price impact on human rights and government capacity • Acknowledge external causal factors for market exclusivity in law, policy, and actor responses		
Wu (2010)	RTHIA of intellectual property rights	Governments		Set of questions to examine burdens, effectiveness, alternatives, proportionality. Core entitlements require stricter burden of proof	–	–
Berne Declaration (2010)	HRIA for trade and investment		Principles include flexibility, user-friendliness, independent multi-disciplinary team, valid and reliable indicators; focus on trade process and outcomes Actors include human rights commissions, parliament, UN agencies, human rights mechanisms and CSO	Step-wise approach to select team, screen, scope, analyze, conclude, and recommend, monitor and evaluate *Ex poste* HRIA of IPR should identify issues/provisions; model drug prices, before/5/10 years after, disaggregate impact on essential/ non-essential medicines	–	–
			Argues need for international benchmarks on independence, fairness, transparency, stakeholder participation, quantitative and qualitative indicators, financing and implementation	Analyze impact beyond economic modeling, including availability, domestic production, decreased generic availability, and reliance on exports		
De Schutter (2012)	Guiding principles for HRIA of trade and investment		Principles including duty to HRIA, duty to avoid inconsistent duties, use for negotiations and follow *ex post*, guided by principles; explicit human rights, human rights indicators, non-discriminatory, consultative and non-retrogressive trade-offs, six-step methodology	Six-step approach of screening, scoping, evidence-gathering, analysis, conclusion and recommendations, and evaluation	–	–

Table 2. Impact assessments of TRIPS.

Name	Nature of IA	Primary user	Methodology	Findings	Applied/impact
Rovira et al. (2009)	Economic simulation model; IPR and medicines; *Ex ante* and *ex post*; government user	Policy makers	Define 40-year time horizon; calculate drugs under exclusivity, calculate impact on consumption, expenditure and domestic production. Uses primary data, empirical studies, foreign estimates, expert opinion, assumed values. Key elements: market competition/exclusivity, price variations; access impacts, and industrial impact	–	Colombia, Guatemala and Costa Rica, Bolivia, Malaysia, Vietnam, Thailand, South Korea, Uruguay, India, Jordan, Dominican Republic, and Costa Rica
IPRIA-Intellectual Property Rights Impact Aggregate		Also used by NGOs, researchers			
European Union, Trade Social Impact Assessments (TSIA)	Social, economic environmental impacts	Policy makers	Step-wise process to study baseline, select indicators, gather evidence, research and consult, analyze, recommend. Quantitative and qualitative analysis (causal chain analysis, expert opinions and civil society involvement)	–	Canada, Central America, India, Korea, and Libya
3D, 2004	Report to CESCR on US-Andean FTA in Ecuador	NGOs	No formal HIA methodology, rather outlines concerns about impact of FTA on human rights	Possible curtailing of policy space; IPR should be implemented to conform with human rights duties	CESCR concluding observation calls for impact assessment
3D, 2006	Report to CESCR on US-Morocco FTA	NGOs	No formal HIA methodology, rather outlines concerns about impact of FTA on human rights	Undertake HRIA; ensure transparency and participation	CESCR concluding observation calls for impact assessment
Faunce et al. (2009): Australia-US FTA and medicines	Focus on Pharmaceutical Benefits Scheme (PBS); data exclusivity and reference pricing	Researchers	Explores reference pricing impacts by comparing before/after drug prices and price trends. Explores impact of ever-greening regulatory changes	Positive impacts (increased transparency' new innovation definition). Legal changes likely to increase drug prices; reduce incentives for generic manufacturers	–
Shaffer & Brenner 2009 (CPATH)	Focus on CAFTA in Guatemala and data exclusivity	Researchers	To explore impacts on access to generic/lower price drugs: reviewed law; data collection (prices; public and private availability). Explore data exclusivity impact on pricing using pricing, brand/generic price comparisons	Data exclusivity limited access to cheaper generics; revoked 4 generic registrations for Plavix (myocardial infarction); denied generic market entry; caused major price differences	–
IFARMA (2009)	Impact of the EU-Andean Trade Agreement on Access to Medicines in Peru; Advocacy tool focused on increased patent terms and data exclusivity	NGO	Uses IPRIA: basic scenario compared to 2 alternatives extending patent and DP terms. Explores public and private drug market; 40 years timeframe; API; expenditure; market growth; industry actions; patent duration; time between application and registration; patent extensions; time to generic competition; exclusivity periods; price elasticity of expenditure	Estimates that data exclusivity and 4 year patent extensions would lead to USD459 million increase in pharmaceutical expenditure by 2025; Cumulative increase of USD 1267 million; 11% increase in API protected would lead to 26% price increase; 10 year data exclusivity result in USD300m expenditure increase; cumulative increase of USD899m by 2025; Enforcement would deter competitors	–
Oxfam (2007): Impact of US-Jordan FTA on access to medicines	*Ex post* IA of 2001 FTA, focus on data exclusivity	NGO	Analyzed 103 medicines after 2001; interviewed generic manufacturers, doctors, administrators, public health officials; Compared prices for drugs with/without DP in Jordan and Egypt; explored market share of medicines without generic equivalent	20% increase in drug prices since 2001; growing market share for drugs without generic equivalents (3–9.4%); companies relying on 5 year DP rather than patents and increased patent applications (21 companies used DP provisions) DP produced significant price differences between Jordan and Egypt	–

(*Continued*)

Table 2. (*Continued*).

Name	Nature of IA	Primary user	Methodology	Findings	Applied/impact
Kessomboon et al. (2010): Impact of US-Thai FTA on access to medicines	*Ex ante* focus on patent extension, data exclusivity, patent linkage	Researchers	Used IPRIA to calculate impact of extended patents for 2, 5 and 10 years/data exclusivity terms for 5 and 10 years; 50 year time horizon; looked at patented AI on market; ran 35 scenarios	Found increased drug expenditure, reduced access to medicines, and shrinking domestic industry under all scenarios. Worst case scenarios (10 year patent extension for delays) showed 32–67% price increase, increased spending from USD11,191m–USD23,595m, domestic industry loss between USD 3370m–USD9, 000m.	–
US-Thai FTA	Looked at market exclusivity on drug expenditure	Researchers	Compared price differences for 74 innovative drugs and generic accounting for 49.9% of sales	Found that generics would have saved 104.5% of costs and increased access by 53.6%. Cost of market exclusivity would be USD6.2m in year 1. and USD5215.8m by 10th year	
Thai National Human Rights Commission HRIA of US-FTA (2006)		Human rights commission	Uses IPRIA model, draws data from scholarship to compare generic/branded prices and estimate price increases from extended patent terms	Existing study showed 2–10 × price difference between branded and generic ARV (USD 8.50–26.45 v USD 1.30–15, 1.5–4.7 times daily minimum wage (USD 5.60) Second study showed price increases from longer patent terms: 1 year extra causes 10-fold increase (USD 8–88 million); 10 year extension causes 6-fold increase (USD1.1–7.2b) Drug costs beyond people's purchasing power, exceeding annual health budget and would 'undermine any earnest attempt to manage the health system in Thailand, particularly the health insurance scheme'	Other studies, legal reform, advocacy use, policy compliance
Walker, HRIA of CAFTA on Costa-Rica (2009)	• HRIA • ex ante • stand alone • focus on trade intellectual property rights and medicines	Researcher	Uses explicit HRIA framework for 6 step IA methodology	Increased drug budget: $87–424m by 2020, $176–1052m by 2030; decreased drug consumption (up to 22% by 2020; 24% by 2030)	–

Table 3. Sample checklist on right to health duties.

Government obligation	Medicines
1. Minimum core duties	To provide accessible, available, acceptable, quality essential medicines Insert relevant national right to health duties
2. Duty to respect	To refrain from actions that would result in unreasonably high medicine prices Not to obstruct access to accessible, available, acceptable, quality essential medicines Insert relevant national right to health duties
3. Duty to protect	To prevent third parties from obstructing access to medicines To ensure international agreements do not adversely impact right to medicine To prevent third parties from imposing unreasonably high medicine prices Insert relevant national right to health duties
4. Duty to fulfill	To progressively realize access to affordable, accessible, acceptable good quality medicines Insert relevant national right to health duties

Table 4. Sample checklist on existing and prospective intellectual property rights and their impact on right to health duties.

Existing intellectual property rights	Prospective intellectual property rights	Impact on right to health duties?
Patent terms 15 years	Patent terms 20 years	May affect minimum core duty to provide accessible and available essential medicines May affect duty to fulfil access to affordable medicines
Compulsory licensing permitted	Compulsory licenses restricted	*May prevent realization of state duty to access affordable medicines*
Protection of undisclosed test data from unfair commercial use	Protection of test data for 5 years	*May delay realization of the state duty to access affordable medicines*

access to medicines (Rovira et al. 2009, p. 4–12). While the IPRIA model lacks any human rights components, it has significant potential for integration into HRIA or vice versa. The European Union Commission on Trade regularly conducts 'trade sustainability impact assessments' (TSIA) to assess the potential economic, social, and environmental impacts of trade agreements including in relation to intellectual property and medicines (European Commission 2009, p. 11). Yet HRIA of trade agreements at government behest have been relatively uncommon. Only one HRIA of intellectual property provisions has been conducted at LMIC government behest, when in 2006, the Thai National Human Rights Commission (TNHRC) considered the human rights implications of an FTA being negotiated with the United States upon agriculture, the environment, intellectual property, and services and investment (Forman 2012). However, the report offers little guidance for other HRIA of intellectual property provisions, since it primarily uses a non-human rights-specific methodology based on Rovira's IPRIA and existing secondary data to conclude that the proposed trade agreement would raise drug costs beyond people's purchasing power and the government's annual health budget (Thai National Human Rights Commission 2006, p. 22, 56).

The most detailed HRIA methodology of TRIPS to date was developed by Simon Walker who proposed an *ex ante* methodology using the common step-by-step methodology, including preparation, screening, scoping, analysis, conclusions, and recommendations, and evaluation and monitoring (Walker 2011, p. 191–2). The screening stage identifies hypothetical positive and negative impacts of the prospective trade agreement on human rights, establishing a baseline of the current state of human rights enjoyment within a country, looking at ratification of human rights treaties, national laws and policies, drug spending, and the position of vulnerable groups. At the scoping stage, actors identify qualitative and quantitative indicators and the most appropriate data collection techniques, including economic modelling, surveys, legal analysis, causal chain analysis, participatory case studies, and expert opinion (Walker 2011, p. 198–99). At the analysis stage, actors collect and analyze data to confirm or reject potential impacts identified during the scoping stage, using the baseline scenario of current human rights enjoyment and measuring impact against the indicators chosen during the scoping stage. This stage also identifies the stakeholders most likely to be affected by changes in trade policies (Walker 2011, p. 192). At the conclusion and recommendation stage, actors make an overall assessment of impact and factors that may positively or negatively impact human rights in the future, and make recommendations to ensure that negative impacts are avoided and positive impacts enhanced. The final stage of evaluation and monitoring assures that the assessment itself undergoes its own assessment to consider if it has met its objectives and been acceptable to stakeholders as well as to identify lessons learned (Walker 2011, p. 192).

In addition, Walker proposes four basic elements of a HRIA. First, human rights should be the explicit subject of a HRIA, which should cite international human rights law instruments and norms, identify rights-holders affected by the policy as well as state and non-state duty-bearers, identify human rights indicators to measure impact, and articulate its conclusions in terms of impact on human rights (Walker 2009, p. 30–32). Second, the process of the impact assessment should respect human rights, including using participatory assessment methods that ensure rights-holders are active participants in the assessment

Table 5. List of potential indicators.

Extent of ratification of international and regional human rights treaties that protect right to health
Recognition of access to essential medicines or technologies, as part of the fulfillment of the right to health, in the constitution or national legislation
Accessible accountability mechanisms in relation to the right to health and medicines
Proportion of right to health complaints heard by courts, human rights commission, ombudsman
Existence of national policy to assure universal access to essential medicines
Existence of a national essential drug list and extent of coverage
Inclusion in national policy of TRIPS flexibilities (including those confirmed in the Doha Declaration and WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property), such as transition periods, parallel imports, experimental use, research exception, compulsory licensing and exclusions
Effort in state policy to reduce trade and distribution markups, promote generic substitution policies and encourage pharmaceutical companies to apply differential pricing practices
Proportion of the populations covered by public or private health insurance
Public per capita expenditure on medicines
Sufficient resources available for health generally
Trends in pharmaceutical consumption
Proportion of household income spent on medicines
Generic and branded pharmaceutical prices for key essential medicines
Average availability of selected essential medicines in public-health facilities
Average availability of selected essential medicines in private-health facilities
Days wages needed by the lowest paid unskilled government worker to buy treatment for common acute and chronic conditions (WHO/HAI)
Percentage of the population living below the international poverty line of $1 per day

rather than passive objects of study (Walker 2009, p. 35–6). Third, impact assessment should contribute to developing the capacities of states and other actors to fulfil their duties to protect and promote human rights, as well as of individuals and groups to claim their human rights (Walker 2009; 10). Fourth, impact assessment should involve human rights mechanisms and actors, including UN and regional treaty bodies, national human rights institutions, human rights NGOs and academics (Walker 2009, p. 10, 37).

A similarly important development came in 2011 when Olivier De Schutter, then United Nations Special Rapporteur on the right to food, submitted to the UN General Assembly *Guiding Principles on Human Rights Impact Assessments of Trade and Investment Agreements* for policy makers to carry out HRIA in the context of trade and investment negotiations (2011). In the first guideline, De Schutter recommends that all states 'prepare human rights impact assessment prior to the conclusion of trade and investment agreements' to ensure that they do not enter into agreements that conflict with pre-existing human rights obligations (United Nations 2011, p. 5). In this respect, De Schutter points out, human rights impact assessment is 'a tool to ensure consistency and coherence between obligations of States under international law' (United Nations 2011, p. 5). The second guidelines provides that States must ensure that the concluding trade or investment agreements do not impose obligations inconsistent with treaty duties to respect, protect and fulfil human rights (United Nations 2011, p. 6–8). Third, HRIA should be prepared before the conclusion of agreements in time to influence negotiations and followed, if necessary, by *ex post* evaluation. Fourth, while HRIA methodologies will differ from context to context, they should be guided by key human rights principles such as executive independence, transparent, and non-discriminatory methodology, inclusive participation of affected communities, appropriate expertise and funding to conduct the HRIA, and parliamentary debate over HRIA recommendations (United Nations 2011, p. 9–11). Fifth, while there may be methodological variations, HRIA should make explicit reference to the normative content of human rights, incorporate human rights indicators into the assessment, and ensure that decisions on trade-offs are consultative, non-discriminatory, and non-retrogressive (United Nations 2011, p. 11). Six, trade-offs should be managed through processes that are participatory, non-discriminatory, non-retrogressive and with gains or losses equitably distributed (United Nations 2011, p. 12–13). Finally, the guidelines set out six steps for HRIA in many respects similar to those of Hunt and MacNaughton, namely, screening, scoping, evidence gathering, analysis, conclusion and recommendations, and identification of evaluation mechanisms (United Nations 2011, p. 14).

While the methodologies proposed by Hunt and MacNaughton, Walker and De Schutter provide overall guidance for HRIA in their respective areas, over the past decade, numerous other impact assessments have been carried out at the intersection of their focus on the health and human rights impacts of trade-related intellectual property provisions on access to medicines. Table 2 lists those impacts assessment that have aimed specifically at predicting the consequences of intellectual property provisions proposed for trade agreements on the cost of medicines.

Lessons learned: towards a pragmatic framework methodology

Drawing on the framework set out by Hunt and MacNaughton (2006), the methodology outlined by Walker (2009, 2011), and the guidelines authored by United Nations (2011), we propose a pragmatic framework for conducting HRIA of TRIPS. We do not propose a fixed tool, but rather a flexible framework methodology

that can be adapted to national context. The framework is intended to operate *ex ante* to assess prospective trade or intellectual property rights laws or agreements. It could also be used in conjunction with other models, including economic modelling (using the IPRIA described above and in Table 2) and causal chain analysis; however, we do not attempt to describe these other processes in any detail within this article. The HRIA framework we propose is primarily to be used by social actors as part of advocacy campaigns but may be integrated into larger HRIAs carried out by governments to inform policy formation. It is also intended to be adaptable to varying resource availability, permitting the use of secondary data and comparative information from other countries where resources do not permit the gathering of primary data or commissioning of studies.

In addition to the specific recommendations made below in relation to each stage of the HRIA, we draw from extant literature and practice to propose what we interpreted to be overarching and cross-cutting guiding principles.

First, HRIA should be flexible, robust and user-friendly, draw on an independent multi-disciplinary team, use a transparent and non-discriminatory methodology, draw on appropriate expertise and funding, and result in parliamentary debate over HRIA recommendations (Berne Declaration 2010, p. 9–13; United Nations 2011, p. 9–11; Forman & MacNaughton 2015).

Second, explicit human rights frameworks should be integrated into HRIA, citing international human rights law instruments and norms, identifying the rights-holders affected by the policy and state and non-state duty-bearers, identifying human rights indicators to measure impact, and articulating conclusions in terms of impact on human rights (Hunt & MacNaughton 2006, p. 33–34; Walker 2009, p. 30–32; United Nations 2011, p. 11).

Third, broad participation in the HRIA is important as a key human rights principle, as a critical method of gathering evidence of impacts, as a means to assure transparency and accountability, and as a measure to enhance ownership of the decision that is adopted.

Fourth, HRIAs should be used with other human rights strategies such as mobilization, campaigning, advocacy, research, and policy analysis, and should involve domestic human rights mechanisms and actors such as national human rights institutions, NGOs and academics, and international mechanisms such as UN and regional treaty bodies (Walker 2009, p. 10, 37; Berne Declaration 2010, p. 15).

Finally, if conducting HRIA is a human rights duty, then HRIA should be institutionalized within domestic laws and within the international system (Forman & MacNaughton 2015). At the domestic level this might include legislation, regulation, or policy guidelines regarding impact assessments (Lee et al. 2013, p. 11). At the international level, international human rights treaty bodies should require states to report on HRIA conducted of intellectual property provisions within their regular reports (Forman & MacNaughton 2015).

Our HRIA uses the step-wise methodology common to HRIA that proceeds as follows: (1) screening (a preliminary check on potential impact), (2) scoping (development of an assessment plan 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), (3) evidence collection, (4) rights analysis requiring a comparison of the evidence gathered to the human rights obligations, (5) finalization of the report and methods of implementation, and (6) evaluation and monitoring. These steps are elaborated below as are specific factors to consider at each stage. In addition, sample worksheets for some of these stages are provided in table format.

Step 1: screening: preliminary checklist (preparation/screening)

The preliminary check considers whether prospective trade-related intellectual property provisions may potentially negatively impact on the right to access affordable medicines. This assessment is conducted using the analytical framework of the right to health, including the entitlements of rights holders and obligations of duty-bearers. The preliminary check proceeds as follows: First, applicable human rights laws are scanned, including international and regional treaties ratified by the state in question, national laws and national case law to provide a framework of applicable and binding entitlements and duties related to medicines. This scan explicitly adopts a right to health approach focused on minimum core obligations to assure accessible, available, acceptable, quality essential medicines, as well as on state obligations to respect, protect, and fulfill the right to health. Second, existing intellectual property rights are identified, looking at international agreements such as TRIPS, other multilateral or bilateral agreements, and national laws and policies. Third, prospective changes within an anticipated intellectual property law are identified, focusing in particular on those provisions most likely to affect the affordability and availability of medicines. Fourth, the proposed intellectual property rights are provisionally assessed according to the analytical framework of the right to health, asking how these rights may impact the state's ability to realize its right to health duties, with relevant duties specified at the outset, supplemented with additional specified duties drawn from national law and cases. These prospective comparisons are intended to identify potential breaches of the right to access affordable medicines that would result from adopting the proposed changes to intellectual property law, and illustrate whether a full assessment should be

Table 6. Sample worksheet comparing duties against data.

Government obligation	Data
1. To realize minimum core duty to provide essential medicines	• Change in accessibility of essential medicines in public and private sector • Change in intellectual property rights law/policy • Change in medicines policy
2. To prevent unreasonably high medicine prices	• Intellectual property rights law/policy • Medicines policy • Trends in public & private sector prices • Increases in drug consumption • Affordability measured by 1 days wage/$1 per day
3. To prevent third parties from obstructing access to medicines	• Nature of interference (corporate, foreign government) • Relevant government law/policy

conducted. Tables 3 and 4 are sample worksheets to be used to carry out this preliminary check or screening.

Additional factors to consider at Step 1

The preliminary check is a desktop analysis based on comparing existing laws with the proposed changes to the intellectual property laws and estimating the potential impacts of the cost and accessibility of medicines. In the event that proposed intellectual property rights are likely to impact on the right to health, there are additional considerations in determining whether to carry out a full impact assessment. For example, this decision will be affected by how much time assessors have to carry out the HRIA, which will depend again on the timeline for negotiations of the trade agreement. If the HRIA is carried out too early in the negotiations, then the proposals may change substantially before the HRIA is concluded. On the other hand, if the HRIA is carried out too late in the negotiations, it may not have any influence on the decisions made. In addition to the availability of time and timing considerations, another factor to consider in deciding whether to carry out a full HRIA is the availability of funding. A full HRIA may cost tens of thousands of dollars and take three to five months to carry out. Further, the full HRIA will require an interdisciplinary team with expertise in human rights as well as several other fields.

In sum, at the end of the preliminary check, the determination of whether to carry out a full HRIA must take into account the timeline of the trade agreement negotiations, the funding and expertise available to carry it out and the potential for the HRIA to influence the negotiations or have other long-terms benefits. Importantly, if time is of the essence and the particular State is sensitive to human rights concerns, a preliminary check can be used to draft a short report that may be sufficient to prompt policy responses. It may be important to issue a short report at this juncture in any event with an announcement on the conclusions of the preliminary check any recommendations of next steps.

Step 2: scoping (planning the assessment)

If a full assessment is both feasible and necessary, the second step will build on work done in the first stage in order to plan the assessment. The planning process will include (1) identifying key actors to perform the assessment, (2) identifying key stakeholders and determining their respective roles in the assessment, (3) devising a work plan, timetable and budget for carrying out the assessment; (4) determining sources and methods of data collection; and (5) choosing indicators.

(1) *Key Actors:* The team conducting the assessment should be multidisciplinary, including people with knowledge and/or expertise of human rights and the right to health, TRIPS, public health, and economic modelling. Team members should be drawn from academia, domestic social groups, and international human rights bodies and should ensure independence from the executive.

(2) *Key stakeholders*: Key stakeholders should include populations and/or communities likely to be most affected; policy-makers with direct responsibilities in relation to medicines and intellectual property provisions; social actors who will participate in the assessment and international actors who may contribute to the assessment. Importantly, participation of populations likely to be affected in the assessment should be considered more than simply as a source of evidence. Participation should be assured at all steps of the assessment. At this planning step, representatives of the people mostly likely to be impacted should be involved to ensure that their views are considered in designing the HRIA plan and budget, as important factors may be overlooked by establishing an assessment plan without including those most likely to impacted.

(3) *Work plan, timetable and budget*: In developing the work plan, timetable and budget, actors should assess the actors, activities, duration, and beginning and end dates of each component of the HRIA, taking into account available resources and personnel, and the timelines for ensuring that HRIA results have maximum impact on trade negotiations.

(4) *Methods of data collection*: Actors conducting the exercise will need to choose methods in accordance with resource availability and timeframes. In low-resource settings, methods may include analysis of existing studies, secondary sources, and economic modelling. Secondary sources should include existing literature exploring the impact of intellectual property rights on access to

medicines, including journal articles, previous HRIA and reports by national and international governmental, non-governmental, and intergovernmental organizations. In medium- to high-resource settings, methods may include commissioned studies, expert opinion, public consultations with affected communities, and causal chain analysis.

Public consultations are a crucial source of evidence for the HRIA, providing individual testimony regarding the health and human rights impacts of inaccessible medicines. This kind of information is used extensively and effectively in human rights campaigns, reports and litigation to convey the human experience underlying challenged laws/policies or actions, and the human rights dimensions of the problem under scrutiny. Such consultations may be useful sources of data and evidence to illustrate both how stricter intellectual property provisions could exacerbate existing gaps in access to medicines, and to animate the health and human rights impacts of the growing inaccessibility of medicines.

(5) *Choice of indicators*: Potential indicators should be reflective of human rights, and should be both qualitative and quantitative. A representative list of human rights and other relevant indicators drawn from scholarship and practice is provided in Table 5.

Additional factors to consider at Step 2

Considerations of cost and time may arise again with respect to public consultation. To resolve these concerns, a variety of possible means of consultation should be considered. For example, in some contexts, public consultation could be conducted online, via a single hearing that is video broadcast, and in various locations with NGOs assistance with planning and mobilizing for the hearings. Public consultations may also be used as a forum for education on the proposed reforms, as well as on human rights and duties in relation to health. The plan should include a reasonable budget to ensure that the plan is feasible and supported. It is also important to have key policy-makers involved in the HRIA at this early stage.

Step 3: information collection

The information collection stage builds on the preparation and planning phase by: (1) focusing on the trade-related intellectual property provisions that may have the greatest impact on the right to affordable medicines; and (2) gathering information on the potential right to health impacts of the proposed provisions. The information gathering stage involves gathering information regarding relevant law or policy, focusing specifically on law and policy on intellectual property provisions, health, and medicines. The HRIA team will also gather health and human rights data from secondary sources, and hold consultations with experts and social actors and affected communities. The aim is to gather evidence that allows a valid estimation of how prospective intellectual property provisions may impact the right to access affordable medicines by affected communities, including by increasing drug prices or government expenditure, affecting policies to provide universal access to medicines and decreasing consumption of pharmaceuticals. It is essential at this stage to explicitly cite international and national human rights standards, and the impact of prospective intellectual property provisions on both individual entitlements and government duties. In carrying out assessments of the impact of proposed intellectual property laws on access to medicines, team members should analyze the impact of such provisions on drug accessibility, availability (including of generics), acceptability, and quality. Similarly, impact should be assessed on state health budgets, public health care systems, and the domestic pharmaceutical industry. Team members should disaggregate the impact on both essential and non-essential medicines.

Additional factors to consider at Step 3

The process of information collecting must respect human rights, provide information to all stakeholders, ensure that marginalized groups are consulted or at minimum considered and that differential impacts are assessed. Information on health impacts should extend beyond potential increases in drug costs to consider impacts on people's lives and human rights. For example, people should be asked whether increased drug costs results in medicine sharing or discontinuations. Data should also be collected in relation to identified entitlements and state obligations, using a data collection format that facilitates this result (including for example worksheets based on the tables in step one). Data collection could combine quantitative and qualitative analysis using economic modelling, causal chain analysis, expert opinions, and civil society involvement.

Step 4: rights analysis

Once collected, the assessment moves to rights analysis where data is compared against legal entitlements and obligations, so as to consider how right to health features will be affected and the extent to which State obligations will be implicated. In view of those potential consequences, the assessment then considers the kinds of measures that are necessary to prevent or mitigate these impacts. Moreover, the assessment should also encompass options that would improve access to medicines and other features of the right to health, not only those that prevent negative consequences. At this step spreadsheets that graphically lay out the information

gathered as against right to health entitlements and duties are useful (Table 6).

Additional factors to consider at Step 4

At this stage, many impact assessments narrowly focus on increases in medicine prices but are fairly thin in terms of human rights, mentioning them at the beginning of the study or report and then again at the end without actually using the human rights framework as a basis for planning, data collection or assessment of impacts. As in Step 3, it is important to analyze the data beyond the impact on cost of medicines to show how the proposed changes will impact on people's right to health entitlement to access affordable medicines as well as their health outcomes and other human rights. As the price of medicines increases, people may need to make choices in terms of what to cut from household budgets and therefore a variety of other rights may also be impacted. The inclusion of personal stories from public consultations may be useful at this stage to illustrate potential impact and to support related advocacy efforts.

Step 5: report, conclusions, and recommendations

The fifth step is to finalize the report, based on the analysis of impacts on the realization of State duties, health needs, and human experience. This report makes proposals for policy reform, implementation, monitoring, and evaluation.

Governments should consider a range of potential responses, including terminating negotiations or amending the proposed agreement, alternative formulations of TRIPS flexibilities, inserting safeguards, assuring compensation from third parties, third party compensation or adopting mitigation measures (United Nations 2011, p. 8). In choosing amongst these options, governments should assure that trade-offs between intellectual property protections and human rights impose the least restrictive impacts on human rights, (United Nations 1985; Wu 2010), and are consultative, non-discriminatory, and non-retrogressive (United Nations 2011, p. 11).

Recommendations should also include the means of assuring parliamentary debate on the report. All of the recommendations – the proposed policy reforms, recommendations, implementation and monitoring plan – must be justified in the report on the basis that they are the most appropriate measures for the government to take to move as expeditiously as possible toward the full realization of the right to health. To empower the stakeholders to hold the government accountable, the report must be widely disseminated and discussed.

Additional factors to consider at Step 5

The report should explain the proposal, the assessment process, the human rights framework, and the conclusions and recommendation based on the human rights rationale. Up front, the purpose of the assessment should be stated: to ensure that the government does not adopt policies in conflict with its prior international human rights legal obligations. It is important to make the report accessible to as many people as possible through wide distribution and by ensuring that the results are translated into accessible language.

Step 6: evaluation and monitoring

In order to assure monitoring and evaluation, benchmarks, and indicators should be identified to assist in measuring progress over the longer term towards the recommendations made in the final report, and to determine whether modifications to these recommendations are necessary. So too should actors be identified who are responsible for monitoring and evaluating compliance. This step could make the impact assessment an important component of measuring state compliance with the right to medicines more generally.

Additional factors to consider at Step 6

The impact assessment itself should be evaluated at this stage. The HRIA team should consider participatory processes at the monitoring and evaluation stage again, and request that the government establish mechanisms to enable people to bring complaints with regard to the policy implementation. Monitoring measures should include publication of a follow up reports.

Conclusion

The framework HRIA methodology proposed in this article seeks to synthesize recommendations from scholarship and practice and to apply human rights standards in order to assure positive policy and health outcomes. Our proposed HRIA is intended to provide social and political actors with a feasible framework that can be altered in practice for workability and to more suitably address local contexts. Our hope is that in conducting HRIA social actors and policy makers will be able to gather evidence about the impact of trade-related intellectual property provisions on drug prices and accessibility in order to substantiate changes to law, policy and programs to prevent or mitigate negative impacts (Forman 2012). Doing so may hold a host of corollary benefits, including mainstreaming right to health concerns into trade policies, empowering affected communities to voice concerns and thereby influence policy formulation, and enabling the building of networks and coalitions between social actors, policy makers and international actors that will

collectively work to assure that affordable medicines are more broadly accessible within countries (Forman 2012). Yet, these methodologies will remain little more than academic conjecture unless implemented within countries and advanced further in practice. We hope that the methodology advanced in this article will support the efforts of policy-makers and social actors globally to assure that health and human rights are protected in the advancement of trade interests, and that it will provide the basis for robust and practical assessments of the human rights impacts of trade-related intellectual property provisions.

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