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Policy space for health and trade and investment agreements

MERI KOIVUSALO*
National Institute for Health and Welfare, PO Box 30, Helsinki FI 00271, Finland
**Corresponding author. E-mail: meri.koivusalo@thl.fi or merikoivusalo@yahoo.co.uk*

SUMMARY

New trade agreements affect how governments can regulate for health both within health systems and in addressing health protection, promotion and social determinants of health in other policies. It is essential that those responsible for health understand the impacts of these trade negotiations and agreements on policy space for health at a national and local level. While we know more about implications from negotiations concerning intellectual property rights and trade in goods, this paper provides a screening checklist for less-discussed areas of domestic regulation, services, investment and government procurement. As implications are likely to differ on the basis of the organization and structures of national health systems and policy priorities, the emphasis is on finding out key provisions as well as on how exemptions and exclusions can be used to ensure policy space for health.

Key words: health policy analysis; public policy; trade; HIA

NEW TRADE AGREEMENTS AND HEALTH IN ALL POLICIES

If Health in All Policies (HIAP) approach is taken up seriously and comprehensively, health needs to be considered as part of all policies, including those concerning trade and foreign direct investment. As commercial policy negotiations on trade and investment expand their focus, they affect more national policies and available policy space in future. The context of trade negotiations has changed from multilateral negotiations on goods under the World Trade Organisation (WTO) to bilateral and plurilateral negotiations that extend to investment and government procurement, exceeding what has been agreed under WTO agreements. These new trade and investment negotiations and agreements concern issues with respect to health regulation, health protection and health systems functioning as negotiations have shifted from reducing tariffs to 'beyond the border' and non-tariff issues. This includes, for example, such domestic regulation, which foreign investors and industries consider to—intentionally or unintentionally—restrict trade. The challenge ahead for health policies was aptly put by Director Chan in her speech addressing Health Ministers of Western Pacific (Chan, 2013):

> Your action plan includes a timely warning: 'Trade agreements should not hamper public health efforts to protect people from NCDs'. Be sure that health has a place at the table when ministers of trade and finance negotiate trade agreements.
>
> My dear ministers of health, if you are not at the table, you are on the menu.

Trade and investment agreements can be assessed in terms of: (1) *trade flows* of goods, services and capital and the impacts of this on population health and health systems and (2) impacts of trade-related *legal and regulatory commitments* to financial sustainability and regulation of health

systems for equity and quality of care and policy space for public health regulation (Koivusalo, 2006).

The first set of implications has been of concern, for example, in the context of tobacco consumption and migration of health professionals (Bettcher *et al.*, 2000; Wibulpolprasert *et al.*, 2004; OECD, 2008a). Trade flows may or may not be affected by specific trade agreements as the magnitude of trade or foreign investments is not a direct result of trade agreements. There is also illegal and unregulated trade in human trafficking, body parts, organs and reproductive health services, which would need more global regulatory oversight (Scheper-Hughes, 2000; OSCE, 2013).

In terms of the second set of implications, the focus is on how agreements made on behalf of commercial policy priorities affect policy space in other sectors. Irrespective of the quantity of trade, legal agreements can restrict policy space and freedom to regulate for health. This type of evidence is usually sought from interpretation of negotiated agreements, evidence from other sectors and in particular, legal dispute settlement and arbitration cases. It thus shifts the focus from magnitude of economic activity to legal rule setting and governance of national and local policies. Commitments made in trade and investment treaties can affect health. A number of WTO dispute settlement cases have dealt with health-related policies already, in particular with respect to tobacco and alcohol-related measures (e.g. WTO, 2011a, b, c, d, e). We have also cases, where corporations, through investment arbitration on the basis of investment agreements, have claimed compensation for impacts from health and environment-related public policy measures. The best known of these is the recent case against Australia's plain packaging law on tobacco (Government of Australia, 2013), which is now also being challenged in the context of WTO dispute settlement (WTO, 2012a, b, c; WTO, 2013a, b).

The knowledge on investment agreements (most of which are bilateral and some plurilateral or regional) is only emerging, with the number of such agreements and in particular investor-state dispute settlement (ISDS) increasing substantially during the last 10 years (Figure 1). According to UNCTAD (UNCTAD, 2013) of all cases completed so far ~42% have been judged in favour of governments, 31% in favour of investor and 27% settled outside formal arbitration. However, there is a rising trend in arbitration with a record number of 58 new cases initiated in 2012. Publicly available arbitration judgements in 2012 have also been more favourable to investors with 70% of investor claims approved at least partially (UNCTAD, 2013).

The focus of this checklist (Appendix, Table A1) is on trade in services and investment liberalization and protection, which remain a relatively less known area in health. This paper was initially developed as a screening tool for the purposes of Ministry of Social Affairs and Health in Finland for follow-up of key issues in relation to emerging trade negotiations. It was further developed as a checklist as part of European Union joint action on Health Inequalities (see http://www.health-inequalities.eu/HEALTHEQUITY/EN/projects/equity_action/, accessed 10 March 2014). It is based on prior analysis and focus on policy space for health, which has been defined as the 'freedom, scope, and mechanisms that governments have to choose, design, and implement public policies to fulfil their aims' (Koivusalo *et al.*, 2009).

The focus on investment, services and government procurement (i.e. publicly financed goods and services, outsourcing) in this checklist does not preclude the importance of other provisions of trade agreements for health. Tobacco plain packaging law, for example, has been challenged in the WTO under the agreement on Technical Barriers to Trade (TBT) and the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (WTO, 2012a, b, c; WTO, 2013a, b). Treaty obligations on intellectual property rights (IPRs), sanitary and phytosanitary measures and technical barriers of trade remain crucially important not only in terms of trade flows, but also for

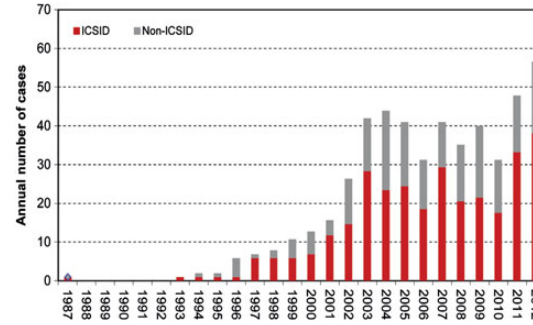

Fig. 1: UNCTAD account of known ISDS cases (UNCTAD, 2013, www.unctad.org/diae).

policy space. As these have been addressed extensively elsewhere, they are not addressed in this article (see, e.g. Correa, 2002, WHO/SEARO, 2010; Mitchell and Voon, 2011; McGrady, 2012; von Tigerstrom, 2013; Seuba *et al.*, 2010) Furthermore, there are broader regulatory issues that are of relevance for health, even though these have been discussed in relation to environmental or other public policy issues (Van Duzer *et al.*, 2012; Krajewski, 2013). Assessments of specific agreements, in particular TPP have also been published (see, e.g. Kelsey, 2010; Faunce and Townsend, 2011; Friel *et al.*, 2013; Fooks and Gilmore 2013).

HIAP ENSURING POLITICAL ACCOUNTABILITY FOR HEALTH IMPLICATIONS

Governments have obligations in relation to health of their populations as expressed in the constitution of the World Health Organization and national and international commitments with respect to human rights and the rights of the child (WHO, 1946; United Nations, 1948; United Nations, 1990). Governments have also more recently endorsed commitments with respect to improving universal health coverage within the United Nations (United Nations, 2012). These obligations cannot be seen as an afterthought, but need to be considered as part of trade negotiations and binding new legal commitments made as part of these negotiations.

The core function for HIAP with respect to trade and investment agreements is to ensure sufficient policy space for health and health systems governance, although it is also important for assessment of the ways in which trade and investment obligations might affect policy space in other key sectors that determine health, such as water, energy or agriculture.

Trade negotiators tend to be informed, in particular, by national industries with export interests or major national or multinational industries seeking to expand and safeguard their markets and minimize operational costs and risks. National and regional policy priorities are usually strongly informed by particular corporate interests and specific interest groups. These 'stakeholders' are also usually able to follow-up and provide detailed commentary on proposals. If those representing health do not have anything to say in detail with respect to what is actually on the negotiation table, it is often assumed that there are no concerns.

HIAP approaches as well as the WHO Political Declaration on Social Determinants of health have emphasized transparency, political accountability and health prioritization as focus for government action (Rio Political Declaration, 2011; Ollila *et al.*, 2013). If the purpose of HIAP is to influence national stands on trade and investment-related issues, these are best addressed *ex ante* when governments/parliaments give mandates for negotiation or at a relatively early stage of negotiation process. Furthermore, it is important as part of the aim of political accountability and transparency, that decision-makers are aware of health and health policy implications of trade and investment agreements so that these cannot be set aside, while the assumed benefits of treaty provisions for national and multinational industries are emphasized and drive negotiation priorities.

The HIAP and SDH call for greater transparency and political accountability implies that such trade and investment negotiations, which affect national policy space for health, should be scrutinized before negotiation priorities and treaty provisions are agreed upon. The focus of HIAP at the point where decisions are made is important for trade policies as these are often negotiated at the national level or, as in the context of European Union, at a regional level. Yet what is negotiated often applies also to national, federal, state and local government levels, unless these are explicitly carved out from the agreements. As trade negotiations are undertaken as a 'whole package', decisions to address health concerns need to be done early on, rather than at the point of final negotiations, when it may only be possible to protect health policy space if a government is willing to turn down a complex and fully negotiated agreement. Given the long negotiation processes and substantial resources invested in negotiation, this is unlikely to take place.

ASSESSING IMPLICATIONS OF THE NEW GENERATION OF TRADE AND INVESTMENT AGREEMENTS

This article is based on a screening checklist as well as commentary on arguments with respect to the general context and each section of the checklist. While the checklist in Appendix, Table A1 provides the actual tool, the broader arguments for the checklist are made below. The checklist may not be fully applicable with respect

to any bilateral investment agreement as these can vary substantially, but forms a framework for where to focus and what types of issues to consider. Its basic mode of operation is based on excluding health services and health-related regulation, rather than changing actual provisions. While governments will in the end of the day decide, how they prioritize health issues within different types of health systems, political and developmental contexts, the purpose of the checklist is to provide those working on health a means to detect, where potential issues of concern reside as well as to understand what is at stake for health in the agenda of services and investment. It is thus a first screening tool, which then needs to be complemented by assessment of implications of specific provisions in the national context. It is based on two major frameworks guiding trade negotiations as these relate to services and investment: General Agreement on Trade in Services (GATS) and North American Free Trade Agreement (NAFTA).

THE BASIS OF NEGOTIATIONS

A general starting point for new rounds of trade and investment negotiations is that they seek to extend commitments made further and deeper on each negotiation round. They are usually negotiated to extend already negotiated older trade agreements under WTO. This tendency to build on previous agreements creates a problem of precedence as sloppiness with one trade agreement can result in difficulties to keep limitations in another. Bilateral trade and investment treaties usually go further than multilateral agreements and WTO agreements thus currently form in practice the baseline for all new trade and investment negotiations.

World Health Organization (WHO) has provided for an overall legal analysis of health policy implications of GATS (Fidler *et al.*, 2003). An assessment has also been made with respect to health and domestic regulation provisions (Luff, 2003). This paper has its focus more on provisions, which exceed WTO agreement (so called WTO+ negotiations) with respect to services liberalization, investment liberalization and protection, domestic regulation and government procurement. These areas feature prominently in negotiations on new generation of free trade agreements (FTAs). These include trade agreements and broader 'partnerships', such as EU-Canada Comprehensive Economic and Trade Agreement (CETA), bilateral FTAs, Economic partnerships of the European Union (EPAs), the proposed Transatlantic Trade and Investment Partnership agreement (TTIP) negotiated between USA and European Union, Trans-Pacific Partnership (TPP) negotiated between USA and 11 other countries (02/2014) and the new Trade in Services Agreement, the so-called TiSA, which is building on the GATS framework of negotiations between ~20 WTO members.

Pre-ambular and general statements

Trade agreements often include pre-ambular statements; however, they remain *aspirational* and do not carry the full weight of actual negotiated articles. While pre-ambular statements give additional support to a particular interpretation of treaty provisions, they may give false sense of security due to their limited relevance, circular nature or inferiority in comparison with actual articles of the Treaties.

Trade agreements may also include articles, which emphasize the right to regulate or right to regulate for given aims (e.g. universal coverage). However, these can be limited to further (circular) clauses, which subject these aims to compliance on what has otherwise been written in the treaty, which is what is in general assumed in any case. Thus, this type of provisions merely clarify the fact that governments can regulate under the broader legal framework established by the given agreement itself.

Statements are often made with respect to not lowering existing health or environmental standards; however, this is not sufficient for future measures seeking to tighten these standards. What is at stake is primarily the right to regulate at a level deemed appropriate by the government. It is also important to note what kind of reference is used, for example, with respect to labour standards. While recognition or adherence to core ILO labour standards can be a step further in some countries, it is far from adequate for trade and investment treaties between high income countries.

Most-favoured nation principle

Most-favoured nation principle (MFN) is often negotiated as a general principle as part of trade agreements [WTO website explains MFN as follows: 'In general, MFN means that every time

a country lowers a trade barrier or opens up a market, it has to do so for the same goods or services from all its trading partners—whether rich or poor, weak or strong' (WTO, 2014)]. It is a concern, where new and more comprehensive agreements are negotiated bilaterally with a particular country, but where further negotiation compromises may then become applied to other agreements on the basis of MFN. While trade proponents may call impacts of MFN as upward harmonization, it does create challenges with respect to wider impacts that may not be anticipated particularly in negotiation of bilateral agreements. The use of the principle in the context of investment arbitration can create unanticipated challenges (see, e.g. UNCTAD, 2010). This increases the scope for 'bringing in more favourable terms from third treaties considered more favourable to solve issues relating to admissibility and jurisdiction over a claim' (UNCTAD, 2010, p. xiv; Radi, 2007). Application of MFN to investment treaties can allow 'treaty shopping' by investors, seeking the best terms upon which to make a compensation claim.

However, it is possible, as part of trade negotiations, to limit the scope of MFN use as part of trade and investment agreements, in particular, chapters on investment liberalization and protection. It is also possible to include MFN exemption to the agreement or restrictions with respect to existing regional agreements or policies (e.g. REIO clause, exemptions for cooperation between Nordic countries).

NEGOTIATION PRACTICES

Listing practices, understanding annexes and use of ratchet, standstill and roll-back

Trade negotiation practices can have important implications. When negotiations are based on negative listing commitments apply to all sectors, unless they are specifically exempted or excluded from negotiations in an annex. Negative listing is an example of *top-down* negotiation, where governments can bargain for flexibilities or carve outs from a set level of commitments. In the context of WTO agreements, the TRIPS Agreement is an example of top-down negotiation. NAFTA is another example of top-down negotiation. GATS is a 'bottom-up' approach agreement, based on positive listing, where only those service sectors government wishes to liberalize are affected by the treaty commitments.

Negative listing forms a greater challenge for future measures and changes as governments will need to know and anticipate any future regulatory needs. Furthermore, negative listing may consist of different annexes on the basis of the nature and extent of the exclusions sought by different governments. For example, the first annex may often permit non-conforming legislation only, that is, existing laws and regulations that would otherwise be seen in conflict with treaty provisions. However, if this legislation is amended to conform with treaty provisions, the sector is automatically included as part of the agreement. This is often referred as a ratchet—mechanism or indicated by notion that 'ratchet applies'. A second annex often applies to services where 'any future measures' are allowed for service providers. A third list is based on full exclusion from negotiations and agreement. While full exclusion would provide most protection of policy space, this is often opposed by trade negotiators who wish to keep the list very limited. It is important to fully check the basis of negotiations as well as the scope of exemptions (exemption is in here used for MFN exemptions written in text, exceptions are used for general exceptions in WTO agreements, whereas exclusions are used in reference to national listing practices, where governments may wish to exclude or exempt health services and health-related regulation. The more detailed understanding of exemptions, exceptions and exclusions can differ across countries) and exclusions, in particular in agreements, which may use both positive and negative listing practices with and without ratchet (e.g. CETA agreement between European Union and Canada, 2013).

In order to speed up and expand commitments, new mechanisms have been introduced. National legislation can be used as a starting point for inclusion of services under the agreement, whereby if legislation at the national level allows for market access for service provision or establishment by foreign providers without additional restrictions, this will be considered as part of that country's commitments to the agreement. In the context of previous negotiations of the Multilateral Agreement for Investment standstill and roll-back clauses were expressed as follows:

> The fundamental aim of the 'standstill principle' is to ensure an irreversible minimum standard for liberalisation through the exclusion of new or additional restrictions. Standstill is also the starting

> point for the removal, via rollback, of existing restrictions. [(OECD, 1996), p. 2].
>
> Rollback is the liberalisation process by which the reduction and eventual elimination of non-conforming measures to the MAI would take place. It is a dynamic element linked with standstill, which provides its starting point. Combined with standstill, it would produce a 'ratchet effect', where any new liberalisation measures would be 'locked in' so they could not be rescinded or nullified over time. [(OECD, 1996), p. 3]

Thus, existing legislation at the point of trade negotiations in effect becomes the baseline for liberalization and regulatory measures for health services. These provisions limiting scope for new legislation can become challenging. This would be the case if a government has just opened markets with very little regulatory legislation or if there have been overly ambitious expectations of the benefits it may obtain from free markets. As a result of the provision correctional moves to retract from fully liberalized policies could become more difficult and/or costly. It is thus important that decision-makers understand what is implied by application of ratchet or standstill in the currently negotiated and existing trade agreements to assess how extensive the commitments are that are being made and in relation to their implications on national regulations affecting health and health systems.

Another challenge is the use of separate *horizontal provisions*, which cover all sectors. Horizontal provisions are in practice negative listing for a set of commitments (e.g. domestic regulation) or a specific commitment (e.g. national treatment (NT) or MFN treatment). Horizontal listing includes just as negative listing all services, which have not formally been exempted or excluded. In trade negotiations, even when a positive listing is used, there can be horizontal elements due to broad categories of services included.

TRADE IN SERVICES

The new generation of trade and investment agreements often, but not necessarily, builds on the framework of GATS, including division of services into specific modes. The basic framework for GATS divides services in mode 1 for cross-border trade in services (e.g. radiology consultations in another country), mode 2 for consumption abroad (e.g. health tourism), mode 3 for investment in and establishment of services within a country (e.g. allow foreign investment in health services) and mode 4 for movement of natural persons (e.g. establishing and selling your professional services in another country). This implies that commitments made need to be checked with respect to all four modes of services trade. Furthermore, while negotiations may follow GATS structure in terms of different modes of services, this may not be the case with respect to other issues, such as domestic regulation (see below).

Exclusions, exceptions and exemptions

The exclusions and exemptions in trade agreements are usually interpreted narrowly. The general exceptions usually focus on limited measures and for health apply primarily to public health (GATS IV article b 'necessary to protect human, animal or plant life or health', which is essentially the same as the GATT Article XX b). Examples of general exceptions are GATS Article IV and GATT Article XX. The use of GATS IV and in particular, GATT Article XX, is further limited by additional requirements on conditions, when this can be raised. In addition, national governments can have more specific exemptions from MFN principle in their list, which has been utilized, for example, for audiovisual services for European Union countries in relation to the GATS agreement.

A reference to GATS Article 1.3 exclusion clause on the scope of the treaty with respect to services supplied in the exercise of governmental authority (GATS 1.3.c: 'a service supplied in the exercise of governmental authority' means any service which is supplied neither on a commercial basis, nor in competition with one or more service suppliers) (the so-called public services exclusion clause) has been used as a basis for, for example, the European Union negotiation mandate for EU-USA TTIP negotiations (Council of European Union, 2013). However, while this exclusion is necessary, it is not sufficient for exclusion of health services, when these are publicly funded, but provided by non-governmental or commercial providers or in competition with commercial providers (Krajewski, 2003, 2013). A reference to GATS Article 1.3 has been used also for the exclusion of statutory social security as part of financial services in GATS. The narrow interpretation of this Article is reflected in the fact that European Union has usually added a further exclusion for public

Table 1: Canada social services reservation for future measures in Annex II of the NAFTA

Sector:
Social Services
Sub-Sector:
Industrial Classification:
Type of Reservation:
National Treatment (Articles 1102, 1202)
Most-Favored-Nation Treatment (Article 1203)
Local Presence (Article 1205)
Senior Management and Boards of Directors (Article 1107)
Description:
Cross-Border Services and Investment
Canada reserves the right to adopt or maintain any measure with respect to the provision of public law enforcement and correctional services, and the following services to the extent that they are social services established or maintained for a public purpose: income security or insurance, social security or insurance, social welfare, public education, public training, health and child care

Source: NAFTA. https://www.nafta-sec-alena.org/Default.aspx?tabid=97&language=en-US (accessed 24 February 2014).

utilities. Where European Union member states have had a choice, they have often kept, in particular, publicly funded health and social services outside specific commitments. In NAFTA, which is based on negative listing, health services have been put in Annex 2 allowing for any measures (Table 1). NAFTA has also exclusion for local, federal and state level measures limiting the scope of application of particular provisions on the basis of level of governance.

In the services sector any exclusion would need to include and specify all four modes of services. However, these may not be listed in the same way as in GATS. In the new generation FTAs services can be dealt with in separate chapters with cross-border services covering modes 1 and 2, mode 3 as part of investment liberalization and mode 4 again in a separate chapter on professional or temporal mobility. Explicit exclusions under these four modes may include, for example, limitations on market access, national treatment, MFN treatment, or to governance and restriction of performance-related requirements for investment. Services sectors can be indicated by United Nations Central Product Classification (UN CPC)—services codes numbers (see http://unstats.un.org/unsd/publication/Seriesm/Seriesm_86e.pdf, accessed 10 March 2014) or International Standards on Industrial Classification of All Economic Activities (ISIC) categories (see http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=2, accessed 10 March 2014).

In services negotiations based on positive listing, the exclusion of a sector is usually indicated as unbound, whereas when there are no limits or restrictions on liberalization within the sector this is indicated as none. There can be exceptions presented as restrictions within the sector or from particular commitments, such as market access. The terms can be confusing for those not fully literate in legal trade-related language. When negative listing is used it is important to remember that unless a sector is dealt with wholly under a list or Annex listing exclusions or reservations allowing for future measures, it is included. Furthermore, if future measures (the term 'any measures' is usually considered to be equal to 'unbound' for positive listing) are to be allowed for some services, it is important that health services be part of such an annex allowing this, and not one based on ratchet mechanisms allowing only non-conforming measures to exist, but not any further non-conforming measures.

The landscape of trade agreements is challenging and further complicated by different definitions. Splitting up of service sectors, for example, to publicly and privately funded services was introduced in EU-CARIFORUM bilateral agreement (EU-Cariforum, 2012), one of the new bilateral partnership agreements. A further challenge for oversight is that sectoral commitments can become divided into separate parts under different actors (e.g. 'European Union Member States' and common 'EU commitments'). While European Union has earlier in the internal markets context emphasized services of general interest and has had a specific public utilities limitation for GATS, there is scope for ensuring that future EU agreements would include sufficient and clear exclusion clauses for public services (Krajewski, 2013). The broadest policy space for publicly funded services is allowed if public funding is defined on the basis of *any public funding* and applying this also to MFN principle.

However, while ensuring sufficient exclusion is important for a range of public services, it can be insufficient for health services, where safety and quality need to be maintained also for privately funded services. It also makes it more difficult to curb inappropriate charging, operating, advertising or advisory practices in privately funded practice, in particular, if the aim is to seriously restrict or ban aspects of these practices. While governments may not be as eager to take each other to dispute settlement on this type of issues, it is likely that private sector providers would be

more willing, in particular, if new regulations would seek to limit or end a particular commercial operation or market.

Domestic regulation, mutual recognition of professional qualifications

Governments use a number of technical measures for health and health services regulation, such as licensing, granting permissions and recognition of qualifications. These can apply to health professionals, health facilities and health-related services, such as laboratory and diagnostic services so as to ensure health and safety of patients within health systems as well as appropriate and adequate quality of care. Technical requirements can also apply to other sectors for the purpose of health promotion (e.g. tobacco, alcohol), health and safety-related matters and for health protection. These can all be affected by domestic regulation provisions in trade agreements. Some can be affected by separate provisions negotiated more independently as has been the case with mutual recognition of professional qualifications.

Depending on the architecture of the agreement, domestic regulation provisions can be applicable horizontally to all sectors irrespective of specific commitments or only those sectors, which are included as part of specific commitments with market access commitments. This is the case with respect to GATS. However, trade and investment agreements can include either 'lite' provisions, with focus only on the *process* of application of licenses, permissions and professional qualifications (e.g. licensing procedures) or 'full' provisions (e.g. licensing requirements), which would go further in terms of seeking to limit the extent to which these regulatory measures affect markets and trade. The problem of precedence emerges, when approval of 'lite' provisions as a horizontal commitment could become later changed to a much deeper commitment as part of further negotiations, without full consideration of consequent implications for health systems. The same applies to negotiation of mutual recognition of qualifications as part of trade agreements, which can initially concern only the application process, but can in practice lead to difficulties in safeguarding that those working within health system will have actually required the technical capacities, have valid qualifications and that they have an adequate knowledge and capacities to work appropriately within the given health system.

The challenge is to ensure that less extensive 'lite' commitments that are more easily acceptable do not slide into more binding commitments in future treaty negotiations. As part of screening process particular attention should be drawn to the tendency of trade negotiators to assume that if existing legislation is compatible with proposed provisions in new treaty negotiations, this will be fine, yet it is likely that many health systems are 'under-regulated' for the more commercial context that health services liberalization will create. This implies that, from the perspective of maintaining policy space for health, commitments should never be made on the basis of existing legislation or lack of 'non-conforming legislation'.

If new problems and needs to tighten regulation do emerge, deep standstill commitments in multilateral agreements may make it difficult or impossible to implement more market restrictive legislation. Finally, a judgement must be made whether a government wants to seek and prioritize further development of international regulation of health systems from a health or from a trade policy perspective. While domestic regulation disciplines under WTO might be able to accommodate more flexibility in this regard, such flexibility may be undermined by the negotiation of more extensive bilateral and plurilateral agreements.

Professional services, temporary stay, intracorporate transferees

Mobility of health professionals is usually negotiated under professional services or so-called mode 4 on movement of natural persons. This includes often, but not always, provisions on mutual recognition of qualifications for commitments made, which can also be negotiated as a separate issue. In health, professional services include, for example, medical doctors, nurses and midwives. Governance on professional qualifications is important for securing that health professionals are able to work within the health system and have adequate levels of skills and expertise, in particular, when health professionals are able to establish an independent practice.

Trade agreements may not explicitly focus on actual contents of qualifications, but they may frame the process by which qualifications are judged, the extent to which governments can require additional measures from foreign professionals in comparison with national health professionals, and whether a government can require, for example, adequate knowledge of national

health-care system or a period of practice as a condition for establishment of a private practice.

Mode 4 commitments are usually made under more restricted entries, but in principle this implies a binding obligation of states to admit non-nationals on to their territory. While most of the migration of the health work-force has taken place without the influence of trade agreements, provisions on professional services have been of major interest in developing countries with the potential of becoming traded against other commitments in final stages of negotiations. Trade in health professionals is often promoted as a business, although the lack of health professionals, notable in low- and middle-income countries where out-migration is more frequent, has resulted in the negotiation of the WHO Global code on the Ethical Recruitment of Health Professionals (WHA, 2010). The lack of mode 4 commitments in health or exclusion of health from horizontal commitments does not prohibit governments or public or private health services from inviting foreign professionals to visit and practice or enhancing their share of the national work force.

INVESTMENT LIBERALIZATION AND ESTABLISHMENT

Investment liberalization and establishment can be negotiated as part of trade in services (mode 3), separately or together with investment protection. Investment liberalization is of importance if publicly funded health care is contracted out, as making commitments in the health sector could limit scope for returning to public service provision from contractual markets, reducing future health policy space. Investment liberalization is divided in a similar way as services into requirements for national treatment, market access and performance requirements. Particular attention needs to be put on performance requirements—or in practice prohibition of putting performance requirements to foreign investors—as this could restrict the scope for governments to set requirements for contractual providers, for example, with respect to hiring local personnel, teaching local personnel or using local contractors as part of services provision. Investment liberalization obligations can have relevance to all types of health systems, in particular, if statutory social security obligations are understood narrowly as the core management obligations for social insurance. Furthermore, investment liberalization provisions would apply also to health promotion measures and public health responsibilities, in particular, if these are contracted out to private sector or non-profit providers.

Investment liberalization provisions concerning establishment are important as scope for governments to make requirements for the establishment of a private practice would be affected, should a government wish to limit provision of particular types of services or impose regulatory measures or requirements for those establishing a private practice. Governments have generally not been keen to make investment liberalization commitments in publicly funded health services; however, it is difficult to separate fully publicly and fully privately funded services. Moreover, investment liberalization in privately funded services could pose challenges for governments to cope with different regulatory regimes within their overall health system. In health promotion, particular attention will need to be drawn with respect to the role of national and local non-governmental organizations in provision of publicly funded services. Where non-governmental organizations have been given preferential treatment in contracting out health promotion services, this could be eroded (this risk could apply also commitments in trade in services, government procurement and investment protection.).

Investment protection and investor-state arbitration

Investment protection is generally considered to be the most controversial part of investment agreements as it opens new public policies to claims by foreign investors through investor-state-dispute settlement provisions (see, e.g. Van Harten, 2007; Schneiderman, 2007 or the Public Statement on the international investment regime by 35 academics, see http://www.osgoode.yorku.ca/public_statement, accessed 15 October 2012). Investors are not able to directly challenge other governments in the context of WTO dispute settlement as only other Member States can bring in claims in the context of WTO dispute settlement (WTO dispute settlement body seeks to resolve disputes through consultations, but can allow trade sanctions to be used under the agreement and if possible on the same sector. In contrast investment protection process is based on claims for compensation, leading to direct financial compensation to an investor).

Investment protection can be negotiated as part of an overall chapter on investment or as a separate chapter. This implies that investment protection provisions can include services and sectors excluded from investment liberalization or establishment, undermining the policy space that governments have sought in the form of exclusions and reservations made otherwise.

The definition of investment in current investment treaties is usually broad. The definition of investment usually includes IPR. Challenges on the basis of IPR provisions cannot only affect prices of medicines and other measures with respect to pharmaceutical policies (Baker, 2013), but also public health and health promotion policies, which could affect trademark protection or other IPR provisions (e.g. plain packaging in tobacco).

Investment protection provisions usually pose governments obligations for minimum standards treatment (MST; for further briefing on potential issues, see, e.g. http://www.ciel.org/Publications/investment_10Nov03.pdf, accessed 23 February 2014), fair and equitable treatment and full security, although actual wording and context can differ across countries. These provisions allow foreign investors scope to claim compensation through investor-state arbitration on the basis that these obligations have been breached. These provisions are present in addition to claims of expropriation, for example, in the Philip Morris claim that relates to Australian plain packaging law (Philip Morris, 2011; McGrady, 2012; Government of Australia, 2013). Expropriation has been a more general cause for concern with respect to investor-state arbitration. Direct expropriation can take place, for example, if a government breaches a contract or other direct measure that prohibits the investor to conduct their investment. Particular health-related concerns focus on in-direct expropriation, which has relevance for regulation and subsidies that can be based on legitimate and non-discriminatory legislation. This type of regulation can be of relevance, for example, when government shifts from contractual markets back to public service, bans or restricts provision of services. Further concerns have been drawn to speculative and short-term investment protection and the basis of which investor-state-arbitration functions in practice. In turn, so-called umbrella clauses [umbrella clauses cover contractual investor-state obligations and generally have been included in support of investor rights. The clauses in agreements can vary with broader or narrower implications and focus on contractual obligations or broader 'any obligations' for investors that the host state has assumed or entered into (see e.g. OECD 2008b)] can have significant implications for domestic legal systems, in relation to compensation for indirect expropriation and fair and equitable treatment of investments (Dolzer, 2006). Philip Morris (Philip Morris, 2011) used umbrella clause in its claim with respect to Australian plain packaging law. UNCTAD has described a number of measures that can be used to improve the current state of investment treaties with specific suggestions for sustainable development, which could be considered for mitigation of undesired health policy impacts arising from investment treaties (UNCTAD, 2012a; see also Van Duzer *et al.* 2012).

In terms of policy space for health, most scope would be achieved for health systems in exclusion of health and social services as well as health-related regulation from the scope of investment protection measures. Where this is not possible, scope for health-related regulation would benefit from further distinction between in-direct expropriation and more narrow direct expropriation measures and their distinction from legitimate acts of regulation (see, UNCTAD 2012b for example: http://unctad.org/en/Docs/unctaddiaeia2011d7_en.pdf.

Investment protection chapters can have specific provisions, which carve out policy space for regulation for purposes of public policy either as part of the chapter or in annexes. Explicit carve outs can have relevance in relation to compulsory licensing and issues related to access to medicines and cost-containment [IPRs are usually considered under the scope of investments and claims have been made that issuing a compulsory license equals to expropriation; however, it is also possible to exclude issuing of compulsory licences from expropriation. As issuing of compulsory licenses has taken place for medicines, it is an issue which requires consideration by Ministries of Health (see UNCTAD report below http://unctad.org/en/Docs/unctaddiaeia2011d7_en.pdf, p. 134)]. Furthermore, investment agreements are negotiated agreements and governments should be able to carve out 'sensitive' sectors from investment protection, in particular, if they have wished to keep these outside investment liberalization commitments in the first place. While there is a trend of including more general exceptions into bilateral investment treaties (Houde, 2006), these remain strongly conditional with

focus on 'human life' or protection of health. The language is often similar as in related general provisions of the GATS agreement (see exclusions, exceptions and exemptions). Specific provisions have also been used to restrict scope for investment arbitration. However, while bringing support to public health policies, these remain narrow for broader health policy purposes related to access to medicines, medical devices, new health technologies, health services or sustainability of financing of health systems. While public health exceptions are necessary, they are not sufficient and can leave many health promotion measures vulnerable if these seek to change diets at a population level or limit consumption of unhealthy, but not directly toxic, carcinogenic or otherwise 'dangerous' products.

The scope of investment protection can be important for health promotion, in particular, in areas with strong global industries, such as alcohol, tobacco, food and soft-drinks industries. It can also become important if a government wishes to retract from privatization levels in its health system, and if investment protection clauses are considered as a horizontal overarching requirement. For example, if a government would prefer to return from contractual service provision to public service provision or remove subsidies, this could become subject to expropriation claims. If investment protection is horizontally applied to all new investments and a government had allowed new investors in the sector, investors could challenge these measures on the ground of investment protection provisions, in spite of the exclusion of health services from investment liberalization.

Another aspect of investment protection clauses is their more systemic implication to routine health-related regulation and standard setting, that could affect investors in other sectors. It would affect, in particular, such measures, which would ban or seriously restrict a commercial practice or market. While the tobacco plain packaging law is an example of this type of a measure, it is an area, where there is ample potential for challenges. These could be raised in relation to health promotion efforts with respect to, for example, restrictions on alcohol advertising and sale or advertising and labelling of unhealthy foods. Different kinds of safeguards could be applied to limit this as part of investment agreements. Wording which makes both explicit exception for legitimate regulation for public policy purposes (general) as well as excludes particular measures or sectors (e.g. health sector, public health and environmental policy, social services) outside investment protection is a stronger articulation of a carve out. A weaker, but broader provision is a specific emphasis on legitimate 'police powers' of state for the public interest (UNCTAD report on expropriation clarifies and presents potential formulations: http://unctad.org/en/Docs/unctaddiaeia2011d7_en.pdf). Specification on the right to regulate for public health and environmental purposes is, as articulated before, narrow and does not address broader health system-related cost-containment and regulatory issues.

HEALTH-RELATED OTHER SERVICES SECTORS

In some countries, there are health-related limitations that apply to other services sectors. Distribution of medicines and medical products (pharmacies), medical devices and health-related technologies may have been kept outside trade-related commitments in order to ensure adequate professional advice or equal availability of products across sub-national regions. These restrictions may include or separately apply to internet sale of medicines and health products. If these restrictions are to be maintained, they need to be considered as part of trade-related negotiations and exceptions specified within the field.

Public health-related regulatory measures and policies may include restrictions, which can apply to distribution services of alcohol, tobacco or other products. Undertaking regulatory measures in other sectors included as part of trade and investment agreements can and need to be undertaken. For example, advertising services are often included as part of trade agreements, but are often sought to be restricted on the ground of health priorities. Ensuring sufficient regulatory policy space for public health, health protection and health promotion requirements in other sectors thus remains a further challenge for HIAP.

GOVERNMENT PROCUREMENT

Government procurement has become part of negotiations on bilateral trade agreements and has been subject to plurilateral negotiations. Government procurement applies both to goods and services and in this respect has particular implications for health systems, which are government funded, but use services private suppliers

and contracts. In addition to health services, government procurement provisions have importance to markets for medicines, health technologies and ICT products for health systems.

An important aspect of government procurement is the level on which it applies. For example, government procurement obligations in trade and investment agreements have traditionally not applied lower levels of government in the USA and Canada, with the consequence of limited influence on health and social care. On the other hand, these areas are now under negotiation due to major European Union interests in the area. According to OECD brief on TTIP: 'On government procurement, the goal is to achieve further market opening at all levels of government' (OECD, 2013).

In principle commitments with government procurement are negotiated in the anticipation that these lead to lower spending and increase choice as new providers enter into the market. On the other hand, provisions of trade agreements can cause problems and affect: (1) maintaining quality of products and services, when there is obligation to choose the lowest bid, (2) sustainability, continuity and cross-subsidization of services provision within the health system, (3) maintaining national or local knowledge-base and capacities and (4) lack of flexibility and problems of oversight and continuity for contracts between local or state governments.

Cross-subsidization of service provision or measures which enhance geographical equity can thus become contested. Governments can implement government procurement requirements at a national level without making formal commitments on such procurement rules as part of trade agreements. Keeping these under national jurisdiction may be wise in particular in such sectors, where flexibility and cooperation is required and where non-governmental organizations remain important providers at a national level.

CONCLUSIONS

Transparency, adequate consultation and understanding of policy implications remain challenges for the negotiation process of trade and investment agreements as well as their increasingly complex, overarching and extensive reach. While negotiations under WTO and its GATS have been slow, these have provided more scope for adequate consideration of implications from commitments made. Negotiation practices with respect to so-called new generation of trade and investment agreements can result in unanticipated impacts on policy space for health. Commitments to HIAP require improved governance in the field.

In terms of commercial policies and health, six processes can be emphasized as potential avenues for HIAP in the context of future negotiation of trade and investment agreements: (i) explicit and transparent policy guidance by bipartisan parliamentary or government high-level stance on priorities to guide negotiations preferably already in the initial stages, (ii) open and transparent political decision-making and reporting of trade negotiations, (iii) human and knowledge capacities of Ministries of Health to draw from sufficient substantive and legal expertise so as to be able to adequately analyse negotiated details of trade agreements and where necessary, offer alternatives, (iv) timely access to documents and good communication across sectors, (v) working relations with other ministries and stakeholders to explore common interest and support to health priorities as part of overall national negotiation priorities and (vi) legal obligation and appropriate structure to undertake a formal health impact assessment, including specific guidance of how impacts could be avoided as part of negotiations, how national policy space could be protected, and where necessary, how negative implications could be mitigated.

While screening and checklists can give sectoral ministries and those working on health scope on understanding where health issues are likely to arise, they are not sufficient to point out issues of relevance in more detail to all governments as health systems and national policy priorities do vary. This screening checklist has focussed, in particular, on policy space for health and health systems regulation. Furthermore, it does not preclude bad regulation, laissez faire or failure of implementation of health-related obligations at a national level. However, if health and social determinants are a priority, it can help in making first steps towards ensuring that national, federal and local governments do have sufficient policy space to act and respond to emerging health problems as well as to fulfil health-related obligations without the fear of being challenged on the basis of trade or investment treaties.

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CONFLICT OF INTEREST

My salary is funded by public health institution, I have worked as consultant for public authorities and governments, the institution in which I work has also private sector financing. M.K. works for the National Institute for Health and Welfare.

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Appendix Table A1. Checklist for screening on health-relevant provisions in trade agreements as they relate to services and investment. The starting point is on screening with a view for maintaining policy space.

1. The Basis of negotiations

1.1. Are negotiations based on positive or negative listing?

1.2. Are there intentions for changing listing practice?

-It is possible that negotiations are introduced based on positive listing, but can later be changed to negative listing.

1.3. Find out what are the criteria for exclusion for negative listing ?

1.4. Are there horizontal provisions ? (see 3.1.)

1.5. How services or sector can be excluded for future measures ? (see 4, 5 and 6)

-Positive listing is generally easier for leaving sectors outside the agreement as services need to be included, rather than excluded and thus is the preferable negotiation basis for policy space.

-If a negative listing is used, check that health services provisions include any measures/provision for future measures, not only non-conforming legislation

2. Preambular and general statements

2.1. Are there statements on right to regulate, health or labour as part of preambular statements or part of the agreement ?

-Preambular statements can be supportive, but bear less legal weight than actual treaty provisions.

-If statements are made under specific sections or articles it may apply only to some provisions

2.2. Do general statements make a reference to "not lowering existing standards" or is it explicitly acknowledged that governments can make tighter regulations ?

-From a public health viewpoint "not lowering" is not sufficient for future health policies.

2.3. Does the agreement have any reference to other international agreements, convention on the rights of the child, ILO core labour standards, human rights or WHO constitution on government obligations for health?

2.3.1. If yes, are these in the preambular part, general provisions or as part of more specific provisions?

2.3.2. If yes, check wording as national standards are often set above international treaties and further reference might be needed.

2.3.3. If no, check why this is the case

2.4. Are rights to regulate conditional to compliance with other provisions of the Agreement ?

-statements on rights to regulate can be made conditional to compliance with other provisions in the agreement. This limits the relevance of this type of statements, although with compulsory licensing it has been important to health policies.

2.5. Does the agreement have any other statements in support policy space for tightening standards or towards higher level of health protection (see section 4,6 and 9) ?

3. Negotiation practices

3.1. Are there horizontal provisions for some aspects of the Agreement, e.g. national treatment?

3.1.1. If there are, check how it is possible to exempt from horizontal provisions

-From the viewpoint of policy space, horizontal provisions are problematic as they lead easier to broader commitments than was intended.

3.1.2. Are there general overarching clauses on domestic regulation or investment protection?

3.1.3. If there are, check how services and measures can be excluded as governments should not be pushed to accept rules for such sectors and services they have not wished to commit as part of the treaty.

3.2. Is there a general or explicit ratchet, roll-back and/or standstill clause? Are sectors to be included on the basis of existing legislation?

3.2.1. If so, does this apply to all/some commitments and/or exclusion

-Inclusion of all services on the basis of existing legislation seeks faster inclusion of service sectors. However, negotiation practices should not oblige governments to list services on the basis of legislation as governments should have the choice to keep services outside the agreement irrespective of legislation in the sector.

-In negative listing health services need to be in an annex, which allows for any future measures and where ratchet or standstill provisions do not apply

4. Exemptions, exceptions and exclusions

4.1. Does the agreement have general provisions on Most Favoured Nation Treatment (MFN) or does it apply to only part of the Treaty?

-MFN is usually applied as a general clause and can lead to unanticipated broadening of obligations made on the basis of a MFN clause in another treaty, unless it is specified that it does not apply. It can be specific that it does not apply to parts of the agreement, e.g. investment protection and liberalisation.

4.1.1. Check if health services or health-related requirements are part of listing of MFN exemptions?

-Specific exemptions from general principles of MFN are usually part of national listing in an Annex for MFN exemptions. In principle health services and statutory social security related financial services could be included as part of general exemptions from MFN.

4.2. Does proposed General exceptions language correspond to general GATS exception clause VI (b) language on measures " necessary to protect human, animal or plant life or health"?

-Any new trade and investment treaties should have a general exceptions clause. This type of exception has been used also more specifically for investment arbitration and investor-state-dispute-settlement. However, it is a narrow exception and does not allow sufficient regulatory policy space for health.

4.3. Are there general or specific exclusion clauses with respect to public services, subsidies and/or taxation?
- 4.3.1. Does public services exclusion correspond to language in Article I.3 in GATS ?
  - -It is unlikely to be sufficient for exclusion if health services have been contracted out of if there is private sector competition. Carve outs in financial services are defined on similar basis and can become understood very narrowly. It does not provide sufficient regulatory policy space in most health systems.
- 4.3.2. Is there an additional horizontal carve out on the basis of level of governance (e.g. not covering state or federal level services) under main agreement or under more specific sections on services or investment ?
  - -exclusions may be limited on the basis of level of governance (e.g. federal, state, local), type of service or investment and type of obligations or disciplines involved (services, investment, mode of service, market access, national treatment, performance requirements, domestic regulation) (see sections 5-9).
  - -a horizontal state or local level carve can reduce impact for local services, when these are organised and regulated at that level.
- 4.3.3. Is there exclusion clause for public utilities or social services, is this as part of the main agreement or more specific sections on services or investment?
  - -For example, public utilities exception in European Union trade agreements can be horizontal covering a number of different services, but it is narrow in focus and not sufficient for ensuring regulatory policy space for health (see sections 5-9)
- 4.3.4. Check if there are exceptions or broader exclusions for taxation and/or subsidies either as part of general provisions or respective chapters on services or investment ?
  - -Health systems can be affected by more general public policy changes with respect to subsidies and taxation when these have, for example, implications to obligations for universal service provision or controlling costs

5. Services trade (exclusion)

5.1. Check services and potential to exclude services relevant to national health system, consider at least the following
- 5.1.1. Financial services (statutory social security, publicly and privately funded health insurance)
- 5.1.2. Publicly and privately funded health and social services, professional Services (NHS type of health system)
  - -Governments have responsibilities for oversight on both publicly and privately funded health services as well as professional services, but exclusions often focus on publicly funded services only. In many countries health services are provided on the basis of a public/private mix of services.
- 5.1.3. Ambulance services and other supporting services
  - -Depending on how health system is organised and financed, there can be supporting services, which are not listed under health services, but may remain under research, IT or other categories of services.

5.2. Check on what basis sectoral exclusions are made?
- 5.2.1. Do sectoral exclusions rely only on social security exclusion, GATS public services exclusion or reference to public utilities? Does it cover all modes and specific commitments?
  - -Relying on exclusions based on GATS Article I:3 is likely to be insufficient in a more commercialised context of services provision and financing. This is likely to be the case if social security exclusion relies on this Article as well. Sectoral exclusions need to apply to market access (MA), national treatment (NT) and, if possible, most favoured nation treatment (MFN) for services to be fully excluded. When services exclusion is made as part of a chapter on cross-border trade it may not apply to investment liberalisation and protection or government procurement. It is also necessary to ensure that domestic regulation/performance requirement provisions do not apply. When UN CPC/ISIC –categories are used to indicate it is necessary to check that all required categories of services are included.
- 5.2.2. Do commitments vary between publicly and privately funded services and if so how this is defined ?
  - -The broadest definition is that “any public funding" is equal to publicly funded. This should not be restricted by further requirements.
- 5.2.3. Are there state or state or local government level general or specific exclusions ?
  - -There may be a broader horizontal exception at a different level of governance. As long as this remains sufficient to policy space there is no need for specific exclusion. However, if this type of carve outs become part of negotiations there is a need to ensure respective carve out for health and social services separately.
- 5.2.4. Check language on inclusion and exclusion of services on positive or negative listing
  - -Language used to indicate unbound (provision of any measures: not included as part of respective chapter in the trade agreement) or none (no restrictions; included as part of respective chapter in the trade agreement). When negative listing is used, all four modes and categories for services, should be as part of an annex allowing future measures and not applicable to ratchet. A very limited number of services are usually fully exempted fully outside the agreement. This would give greatest policy space, but as this list is kept short it is difficult to have services in the category. Excluding services does not require non-conforming legislation within the sector. (see 6-8)

5.3. Check the situation with all modes (1-4) and commitments (market access, national treatment, MFN) of health services, whither private and publicly funded services are included/excluded and whither respective professional services (also for mode 4) are included/excluded. When negative listing is used, check that all these are in a correct Annex. (see 6,7)

-Trade agreements are negotiated until agreed and situation may change requiring oversight, if these are not based on a strong brief concerning policy space for health.

6. Domestic regulation and rule-setting

6.1. Check how domestic regulation is dealt with in the agreement and whither it is to apply to all sectors or only those sectors with market access or where other specific commitments are made ?

-Bilateral trade agreements on services and investment can follow either NAFTA (US) or GATS (EU) framework. Regional agreements can have mixed provisions. While domestic regulation disciplines often build on GATS, what is negotiated can include elements from other trade agreements.

6.2. Check what is included under domestic regulation and mutual recognition of qualifications ?

-Decisions on licenses, technical standards and qualifications are important part of overall regulatory measures and context. Domestic regulation negotiations apply to licensing requirements and procedures. Negotiations may apply to both requirements and procedures or only procedures. As actual decisions take place at state or local government level it is necessary to ensure that national negotiations and stances are sufficiently informed of the policy space and priorities that is required.

6.3. Check where and how mutual recognition of qualifications is dealt with in the agreement text.

-Mutual recognition of qualifications can be addressed as a separate issue or treaty and be dealt with separately from other disciplines in domestic regulation. Provisions may not affect formal qualifications, but can set limits of what can be required if these are fulfilled. It is also necessary to be clear what negotiations would imply for fake or inadequate qualifications and regulatory oversight, in particular, if some services could be provided in another country.

6.4. Check if any further commitments for regulatory cooperation are made in another part of the agreement.

-For example, TTIP negotiations between USA and European Union include specific negotiations concerning pharmaceuticals, medical devices and regulatory cooperation.

7. Professional services and movement of natural persons (mode 4)

7.1. Check whither health services-related exclusions include professional services?

-Mode 4 and professional services may be negotiated as a separate category or sub-category on temporary movement. Specific concerns relate to recognition of qualifications and potential rights to establishment a private practice. Regulatory concerns relate also to the ways in which private practitioners have to operate under a broader health policy framework, regulation and guidance.

7.2. Check how recognition of qualifications is to be dealt with and what will be the regulatory burden for health administration?

-This can have implications to administrative processes and measures on recognition of qualifications as well as with respect to oversight of qualifications within the broader health system. Even though negotiations may formally apply only to qualification procedures, these can affect also broader qualification requirements.

7.3. Check if provisions on specific issues, such as temporary stay and intracorporate transferees or other potential subcategories apply to all sectors or only those where commitments have been made ("scheduled sectors") ?

-Movement of natural persons can negotiated on the basis sub-groups with more extensive commitments. It is possible to exclude health professionals from these more specific commitments. It is also important to clarify what is meant, for example, by intracorporate transferees and how these commitments relate to administrative oversight over broader professional work-force within a country.

8. Investment liberalisation and establishment (exclusion)

8.1. Check whither health services are included as part of investment or investment liberalisation commitments or mode 3 as part of listing under trade in services?

-Investment liberalisation provisions are usually not equal to mode 3 in services trade due to different types of requirements, such as performance requirements. It is important to check where and how investment liberalisation is negotiated so as to ensure that the exclusion has a correct focus.

8.2. Check that all modes and types of commitments (market access, NT, MFN, performance requirements) are excluded (see 4,5 and 6)

-Performance requirements can have broad implications for national policy space as these limit requirements that can be made from foreign investors and service providers. This can limit the scope for coordination, cooperation and sharing of risk and resources within the overall health system as well as requirements for investments in local service provision or use of local personnel. From policy space perspective it is thus important to ensure that performance requirements are not included.

8.3. Check that exclusions from establishment and liberalisation include existing investments and new investments

-Exclusions need to apply to all investments within a sector irrespective of their timing. Exclusion from investment liberalisation does not prohibit or exclude foreign investments to the sector, but allows more policy space for regulation, if there is a need to intervene.

8.4. Check if investment liberalisation exceptions/exclusions apply to investment protection ?

-If not, then investment protection measures would require separate exclusion as well. This will be required also in the case that investment liberalisation and protection applies to new investments only.

8.5. If negotiations apply formally only to cross-border trade in services, check provisions, exclusions and commitments for mode 3. (section 6)

8.6. Check that all modes and both publicly and privately funded services are appropriately excluded (unbound) or if negotiated under negative listing in an Annex allowing any future measures (see sections 4-7)

8.7. Check that exclusions apply to all levels of services provision, including for federal, state and local governments

9. Investment protection

9.1 Check the language on scope for investment protection?

-From health policy space perspective removal of the whole investment protection chapter is likely to allow most policy space for health as it would limit both potential claims affecting health systems and those related to health promotion and public health measures.

9.2. Do provisions allow existing or new investors to make claims in services and sectors otherwise excluded from investment liberalization?

-Exclusion of health services from investment liberalisation can become compromised if the same restrictions do not apply to investment protection.

9.3. Do provisions imply investment protection to investments already made or only after the agreement has been negotiated?

-When foreign investors are already within the sector, they may gain new rights through investment protection. When investment protection applies only investments made after signing of the agreement, maintaining policy space would require a government to deny foreign investments and market access to a sector, even if these have been previously allowed, to avoid potential negative consequences from investment protection provisions.

9.4. Check language that applies on portfolio, short-term or speculative investment? Does the definition include intellectual property rights?

-From policy space perspective narrow definition of investment is better and if this is to be kept broad, would require exceptions (e.g. for compulsory licensing, ensuring access to medicines and knowledge, limiting risky and destabilising practices in financial markets). Health systems often involve substantial funds and financial management as well as resource shifts through payments to providers and for health technologies, which need to be protected from speculative and malicious claims.

9.5. Check language on "minimum standards of treatment", "fair and equitable treatment" and "full protection and security"? Is there an umbrella clause ?

-Investment treaties differ in language. From policy space perspective it is important that obligations for the state are kept narrow and do not establish an absolute requirement for treatment of investors. It is necessary to ensure that exclusion for health applies also to these provisions. Umbrella clauses support investor rights in expanding focus to investor-state contracts and other obligations and may have unanticipated impacts. Not all agreements include an umbrella clause. These provisions can be important for investor claims in investor-state-arbitration.

9.6. Are there provisions on indirect and direct expropriation?

-Inclusion of impacts from legitimate non-discriminatory regulatory measures (indirect expropriation) with negative impacts on investors are likely to increase risk of claims, which restrict health policy space directly or indirectly. An exclusion can be made, but often this implies a more explicit narrow emphasis (see below).

9.7. Check the scope and nature of general and specific exclusions and how these relate to investment protection measures?

9.7.1. Is there a general sectoral exclusion for health and social services?

-If exclusion of health and social services from investment protection is a priority, then this can be done so that health is excluded comprehensively from all investment provisions. As a number of provisions have been used against health-related aims it is not sufficient to focus on in-direct expropriation only.

9.7.2. Does exclusion cover all investment protection obligations or only investor-state-arbitration/dispute settlement mechanism.

-From a policy space perspective a general exclusion is better than one with a focus on investor-state-dispute settlement only as it leaves less ambiguity in relation to what is covered. Changing investor-state to state-state dispute settlement is unlikely to solve the matter fully.

9.8. Check the language on investor-state –dispute mechanism

-From a policy space perspective no investor-state-dispute settlement mechanism (or state-state-dispute settlement) would be better than one with a number of clauses and exceptions. While state to state dispute settlement will limit some cases, governments can be willing to engage in disputes for key industries. (e.g. Canada-EU asbestos case and plain packaging under WTO).

9.9. Is there exception for public health, environment or public interest regulation?

-Focus on public health is insufficient for safeguarding health policy space for health systems cost-containment and health promotion. Exceptions for specific regulatory areas need to be seen complementary and not alternative to more general provisions on legitimate and public interest regulation.

9.10. Is there language for legitimate regulation ? Does this exclude or allow that claims can be made if regulation is legitimate and non-discriminatory in legal terms ?

-Explicit statement which states that investment arbitration is not applicable to legitimate regulation for public purposes is likely to be better than a more vague statements without explicit reference. While investment protection does not prohibit regulatory measures it can make these very expensive. Emphasis on right to regulate is thus not sufficient unless it makes reference to a carve out from investor-state arbitration/dispute-settlement mechanism. (see 9.11)

9.11. Is there other language that could provide a carve out of relevance stating that "nothing in this agreement,". . . or emphasises "police powers" of state.
-Investment agreement often include language emphasising right to regulate. This is supportive to health concerns, but is likely to be more ambiguous in practice and should not lead to removal of other exclusions/ exceptions. This kind of language can help in addressing the issues as part of the arbitration process and claims, but is of limited value to policy space if it subjects all such legislation to investor-state-arbitration and potential investor claims for compensation.

10. Government procurement

10.1. Check if there is a specific section or chapter on government procurement or subsidies in the treaty
-Government procurement is often negotiated separately and by different people than services and investment liberalisation and thus not necessarily cross-checked in terms of provisions and exclusions.

10.2. Do exclusions in government procurement and subsidies cover or correspond to exclusions made in health and social services in relation to services and investment

10.2.1. Does it include all government levels from national to state/federal and local governments?
-This is important as FTAs can have exclusions on the basis of state/federal or local government.

10.2.2. Are there any references to disciplines as these relate to subsidies or their exclusion
-Subsidies are important to ensuring universal service provision. From a policy space for health perspective an exclusion would be preferable

10.3. Is inclusion to government procurement based on conforming national legislation in the area?
-Exemptions or exclusions should not be based on national legislation, but allow policy space to change existing legislation on the basis of national policy concerns with more flexibility to operate at national level.

10.4. Check how provisions relate to non-profit sector, cooperation across local governments and cooperation with non-profit or for-profit sector through public/private partnerships?
-Government procurement provisions have implications to non-governmental organisations, which provide publicly funded services in the field of public health and health care.

10.5. Do provisions allow for contractual arrangements, which prioritise employment of local or previously unemployed personnel ?
-National legislation and practice may be open to more flexible implementation of government procurement, which may be lost in the international context more geared towards ensuring equal treatment of foreign providers.

11. Other services

11.1. Check if national public health legislation or health promotion measures require restrictions to particular service sectors?
-It is likely that influencing consumption of products and foods will affect their markets and public policy measures can require policy space, for example, with respect to distribution and advertising services

11.2. Distribution services for pharmaceuticals, alcohol and tobacco

11.2.1. Check that possible exceptions cover both services and investment provisions to allow monopoly for distribution services or other related measures
-There is a broad variation in how governments address sales of pharmaceuticals, alcohol and tobacco. These have a high likelihood of becoming a subject of investor-state-dispute. From a policy space perspective it would be important to ensure policy space both in terms of services commitments and avoidance of investor-state-dispute settlement.

11.3 Advertising services.

11.3.1 Check potential policy space for restriction of advertising of specific products, such as alcohol, tobacco, prescription medicines or obesinogenic foods

11.3.2 Check the scope for restricting advertising for children and youth or in particular spaces, such as schools and nurseries.
-This is an area, where policy space for health may have not been considered, but is likely to become more important in future. It is possible to include specific exclusions or requirements for advertising services as part of trade and investment agreements so as to allow policy space.

12. Amending, adjusting and complementing checklist

Trade and investment agreements vary in terms of their structure and content. This checklist is best used as indicative guidance and screening on where to focus and needs to be adjusted to particular country circumstances, national policy priorities and actual contents of negotiated agreements. It should be complemented with a checklist concerning intellectual property rights and enforcement, technical barriers to trade, sanitary and phytosanitary measures, regulatory cooperation and substantive negotiations concerning pharmaceuticals, medical devices and chemicals.

An alternative complementary route in support to health is to focus on international conventions and guidance on health, labour right and other measures that can provide a global legal framework or guidance and be used in support of health policy measures. The Framework Convention on Tobacco Control (FCTC) is an example of public health related international legislation that could help implementation of national health policies. WHO codes on international recruitment of health professionals and marketing of breast milk substitutes are other examples of potential other reference documents. Human rights and commitments made with respect to the Convention on the Rights of the Child (CRC) can also provide important support.