

Trade and Health

An Enquiry into the Role of the World Health Organisation in promoting Policy Coherence across the fields of Trade and Health and in particular, the Origins, Implementation and Effectiveness of World Health Assembly Resolution 59.26 on International Trade and Health¹

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1. This paper presents the results of a study of WHO's role in trade and health prepared for the Lancet - University of Oslo [Commission](#) on Global Governance for Health by the [People's Health Movement](#). The development of the case study was led by David Legge.

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Executive Summary

Introduction

WHO's leadership role in global health has been challenged by alternative analyses, priorities and strategies being offered through the World Bank and other intergovernmental organisations, various philanthropies and a range of global health initiatives. WHO's effectiveness has been compromised by increasing donor dependence, excessive decentralisation and the lack of accountability on the part of member state representatives for their custody of the institution. Behind both the emergence of new competitors and many of the Organisation's disabilities are the intrigues and interests of big power engagement.

The global health environment has changed dramatically since 1948 including many changes associated with globalisation. Two salient changes associated with globalisation have been the rising role of trade and investment agreements in globalising policy and regulation (especially since the creation of the World Trade Organisation (WTO) in 1994) and the rise of the transnational corporation (with increasing influence over health care and the conditions which shape population health).

Now is a good time to reconsider WHO's leadership role in global health. The broad options are two: first, restrict WHO's mandate to a technical 'normative' role and find some other body to provide leadership in global health governance; or second, reform and strengthen the Organisation so that it can provide the leadership needed across those formal and informal networks through which global governance for health is effected.

Evaluating these two options should include consideration of the tasks involved in global governance for health; consideration of the scope for overcoming the barriers and disabilities that WHO is facing; as well as consideration of the potential capabilities of the alternative contenders for global health leadership.

The case study method provides a useful approach to this kind of assessment. Our focus in this case study is the trade and health policy interface, concentrating in particular on origins, implementation and effectiveness of the [2006 WHA trade and health resolution](#). Trade and health is not the totality of global governance for health but it is of growing importance and a study of the way WHO has managed this area provides a useful insight into WHO's role in global governance for health.

Background

In the background section we provide a summary of the intersections between trade and health:

- how trade relations (the flow of goods, services, people and capital) affect health;
- how trade agreements impact on health through their influence on regulation and governance, beyond their influence on trade flows;
- how the character of the different trading partnerships (eg North South versus South South) determine how different provisions in trade agreements can affect population health;
- how trade agreements affect health in their role as critical decision points which shape the evolution of the global economy; and
- how trade and investment agreements reflect and stabilise particular configurations of national and corporate power.

We conclude from this review that trade relations are an important focus of public health engagement and discuss four particular challenges which public health advocates face in trade health engagement:

- health impact assessment: principles, tools and limits;
- negotiating uncertainty: in evaluating possible outcomes of trade negotiations; and the management of public health uncertainty in trade law;
- assembling multidisciplinary teams and accessing specialist expertise; and
- managing the power dynamics.

In the last part of this background section we explore briefly the meanings and boundaries of the idea of policy coherence and review some of the strategies and preconditions for policy coherence, illustrated with reference to a number of case studies of policy coherence.

Origins of and adoption of Resolution 59.26 in May 2006

Under this heading we discuss some of the work which had been undertaken around trade health policy coherence before the adoption of WHA59.26 in May 2006 and we describe the adoption of the resolution. A brief post script to the adoption of the resolution is the disciplining of Dr William Aldis by the previous DG for providing advice to Thailand in accordance with the terms of WHA59.26.

Earlier work on trade health policy coherence

Member state concerns about the implications of trade agreements for health date back well before 2006. In surveying this earlier work we focus on:

- Resolution WHA49.14 (May 1996) on the Revised Drug Strategy in which the implications of the TRIPS Agreement for access to medicines is highlighted;
- The October 1998 Geneva workshop on the Revised Drug Strategy in which the importance of TRIPS flexibilities was highlighted and in which Dr Brundtland foreshadowed the importance of WHO engaging with the issues of policy coherence across trade and health;
- Resolution WHA52.19 (May 1999) again on the Revised Drug Strategy which requests the DG to assist members (at their request) in developing policies and regulations which address the implications for pharmaceutical and health policy objectives from trade agreements and assist countries to 'maximize the positive and mitigate the negative impact of those agreements';
- The Doha Declaration on Public Health adopted by the WTO Ministerial Council in 2001; clearly the discussions within WHO contributed to the support for the full use of TRIPS flexibilities which is reflected in that Statement;
- The 2002 WHO and WTO report on the intersections between trade and public health which foreshadows clearly the institutional mechanisms needed to support policy coherence across trade and health;
- Resolution WHA56.27 in 2003 on Intellectual Property, Innovation and Public Health which highlights the need for member states to make full use of the flexibilities of the TRIPS agreement in enacting the corresponding domestic law;
- The 2003 WPRO² report on The Use of Domestic Law in the Fight Against Obesity which includes an extended discussion of the implications for the Agreement on Agriculture, the SPS Agreement and the TBT Agreement in seeking to reshape the Pacific food environment;
- The inter-regional workshop on trade and health hosted by SEARO in 2004 which explored the full range of issues associated with trade health policy coherence and clearly laid the ground work for what became WHA59.26.

2. Western Pacific Regional Office of WHO

Negotiation of WHA59.26

The first version of what became WHA59.26 was tabled at the EB meeting (EB116 in May 2005) as a response to a Secretariat report on trade and health (EB116/4). The report commences with a review of previous relevant resolutions, most of which were centred on access to medicines; then a review of the WTO and its agreements; and then a review of the key issues at the trade health interface. The report then reviewed work which had been undertaken by WHO on trade and health, including: analysis and research, tools and training materials, technical support and capacity building. The report highlighted the need for policy coherence and provides detailed guidance regarding how this might be achieved.

There was a warm discussion of the report at EB116; most of the contributions commended it but the US (observer) criticised the report as superficial and accused the Secretariat of being 'against industry, free trade, and intellectual property'. Following this discussion a draft resolution was tabled by Thailand and 13 other member states. This resolution was subject to vigorous discussion (Australia took the lead in seeking to soften the impact of the resolution) but in the end the Chair elected to defer further consideration to EB117 in Jan 2006.

A revised resolution was submitted to the EB in January 2006 and was adopted without discussion (EB117.R5). It had already been negotiated by certain member states prior to its being introduced.

The draft resolution (EB117.R5) was forwarded to the WHA in May 2006 where, after a minor amendment it was adopted (as WHA59.26). During the debate the draft resolution was supported by all of those who spoke although the USA "cautioned the Secretariat on its technical competency to advise Member States accurately on the potential implications of trade rules from a public health perspective. Any information on best practices in trade negotiations that WHO provided had to be unbiased and evidence-based and had to be cleared with WTO and WIPO³. To the extent that such work did fall within the Secretariat's mission, mandate and expertise, it must provide the Member States with information that was accurate and fairly represented the different views of Members."

It is worth noting that there is no mention of intellectual property in WHA59.26, apparently in deference to the opposition of the USA to any reference to the impact of intellectual property rights on access to health care.

3. World Intellectual Property Organisation

Post script to WHA59.26: the recall of Dr William Aldis

The recall of Dr William Aldis from Bangkok provides a shadow play running in parallel to the debates in the EB and the WHA.

In a news report on June 17, 2006, three weeks after the adoption of WHA59.26 it was revealed that a senior and widely respected official in the WHO Bangkok office had been recalled to Geneva, on March 24, by the Director General (Dr Lee). It appears that Aldis wrote an opinion piece in the Bangkok Post on Jan 17 (before the Jan EB) urging that Thailand think carefully about the possible implications regarding access to medicines if it proceeded with the mooted bilateral trade agreement with the USA. It appears that a US diplomat visited Dr Lee on March 23 to express his government's displeasure and that Aldis was recalled the following day. What is particularly noteworthy is the claim that press reports regarding Aldis's recall were initiated on the basis of information provided by a US official. A senior WHO official was quoted as saying that he or she believed that "Lee's decision and its subsequent leak by the US government was specifically designed to engender more self-censorship among other WHO country representatives when they comment publicly on the intersection of US trade and WHO public-health policies".

In disciplining Aldis for pursuing the 2003 mandate of WHA56.27 Dr Lee was clearly conscious of the degree to which the Organization depends on extrabudgetary funding from the US.

Implementation of WHA59.26

A mix of activities driven from Geneva and from some of the regional offices has followed the passing of A59.26 although it is not clear that all of them were directly as a result of the resolution. Under this heading we review the implementation of WHA59.26 in relation to Headquarters first and then through the regional directorates of WHO.

Trade issues are never very far from the kinds of issues that preoccupy WHO in Geneva: access to medicines, innovation for neglected diseases, the International Health Regulations, non-communicable diseases, health workforce, etc. Rather than attempt an exhaustive review of Headquarters' engagement with the different facets of the trade health interface in the six years since 59.26 was passed we focus on a number of specific episodes all of which offer somewhat different perspectives on the effectiveness of WHO in the trade/health field and on the barriers it faces. These episodes are:

- the US criticism of the Musungu Oh research paper for the CIPIH⁴ and the subsequently adopted WHO publications policy in 2006;
- an unfortunate remark made by the DG in Bangkok in Jan 2007 emphasising the need to find the right balance in policies regarding compulsory licensing;
- the long delayed production of a promised 'tool' for assessing the health implications of trade issues;
- the ongoing debate over WHO's definition of 'counterfeit' and the conflation of IP issues with QSE issues;
- European seizures of generic drugs in transit;
- the drafting of the political declaration of the HLM of the UNGA on NCDs.

The story of the recall of Dr Aldis tells us a bit about the willingness of the US to exert pressure on the DG to prevent criticism of its trade policies. It has been suggested that the leaking of the details, allegedly by a US official, one month after the adoption of WHA59.26, was a deliberate warning to other WHO employees.

The story about the CIPIH research study and the subsequent publications policy tells us something further about the pressure that the US is able to exert over WHO, in this case demanding that the DG censor any criticism of its trade policies from within the Secretariat. Clearly, the status of the US as a major donor to WHO lends weight to such demands. While the CIPIH study had been widely discussed from March 2005 it was not until August 2006 that Dr Steiger wrote to the (new) DG demanding more effective censorship. It is possible that this eruption was intended as a further warning to WHO regarding the implementation of WHA59.26 (adopted three months earlier).

It is difficult to make sense of the unfortunate remark in Bangkok. It seems clear that it was a diplomatic mistake; perhaps the worst place and time to make such a comment about balancing access against innovation. The naiveté of the DG in this matter may reflect the policy environment within which she had been working. As comes clear in the later story regarding IMPACT⁵, WHO had been working closely with officials of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in the months before the meeting in Bangkok (IMPACT was officially launched in November 2006, just two months before the meeting in Bangkok).

4. WHO Commission on Intellectual Property Rights, Innovation and Public Health

5. International Medical Products Anti-Counterfeiting Taskforce

The story of the definition of counterfeit and the conflation of IP with QSE dates back to well before WHA59.26 but the Secretariat continues to defend this definition to this day. This is clearly not naiveté. This is a matter on which the IFPMA, its members and nation-state supporters, have a clear agenda which is directed to transferring responsibility for the policing of alleged breaches of IP from the putative owner of the IP to the state. This agenda has been advanced in trade agreements through 'data linkage' as well as through IMPACT. (Under data linkage provisions in bilateral and regional trade agreements drug regulatory authorities are required to fully investigate IP status, including communicating with putative owners of such IP, before giving marketing approval.)

The story of the Tool is quite disgraceful. The idea of health impact assessment of trade policy is a cautious, technician approach to the implementation of WHA59.26. It is not clear why the process was allowed to grind to a halt; perhaps lack of money, perhaps lack of enthusiasm.

The final story, regarding the negotiation of the UN Political Declaration on NCDs, simply serves to show that the barriers to policy coherence include the vested interests and political muscle of transnational food corporations (and their nation state sponsors) as well as transnational pharmaceutical companies. This is reality and not something to be wished away. The challenge is to develop and implement a strategy which can progressively change the balance of forces around such decisions.

An informant with extensive experience in the governing bodies, in commenting on these episodes, emphasised the importance of the negotiations at home and in Geneva long before the draft resolution is considered by the Board or the Assembly.

This lobbying of governments by industry starts way before an item gets to the WHA. I have seen correspondence from the liquor industry ... reporting their off-the-record chats with the [...] government outlining the 'acceptability to the liquor industry' of certain WHA resolutions long before they are tabled.

This informant commented that many member state representatives were quite explicit about defending the interests of their industries. A US delegate who opposed any reference to equity in the PHC resolution confided later that he was in Geneva to represent American companies, and equity was not in their interests. Similar concerns with corporate interests were evident (the informant added) in the EU position on the breast feeding code and the US and Brazil insistence on removing a scientific reference to safe sugar levels from the Global Strategy on Diet, Physical Activity and Health.

Another informant commented that WHO had been very late in responding to the WTO agreements and has still not got to grips with the various bilateral and regional agreements.

“In many ways, WHO missed the boat with the TRIPS agreement. It is now missing the boat with bilateral and regional trade agreements forging ahead. WHO is like a guest arriving chronically late at major parties - and then complaining that all the food is gone!”

In relation to the regional offices and regional committees the picture is very varied. EURO approaches the question of policy coherence with one eye on corporate revenues and the other on its role as a donor. The substantial support from the EU for IMPACT suggests an interpretation of policy coherence as referring to the interests of big pharma and the policies of WHO.

EMRO does not seem to have done anything by way of following up WHA59.26.

AFRO appears quite conflicted with the Regional Director pursuing a ‘trade in health services’ agenda and the Regional Committee asking for more substantive action on trade and health. It may be that the Regional Director is more sensitive to donor interests than the Regional Committee.

SEARO has been working on policy coherence across trade and health for a long time. It is likely that the content of WHA59.26 reflects in part the experience of SEARO nations in trying to achieve policy coherence at the national level. The region does not include any ‘advanced industrialised’ countries and large countries such as India, Thailand, Indonesia and Bangladesh may be less subject to donor pressure, better advised technically, and more conscious of the costs of medicines than in some other regions.

WPRO has recognised the disaster that is NCDs in the Pacific and has continued to promote understanding of trade health policy coherence in the Pacific. However, it has not been particularly active in relation to the proposed Trans Pacific Partnership Agreement nor the various configurations of ASEAN.

PAHO appears to be paralysed in relation to the trade and health interface by the deep divisions between the countries of Latin America and the USA.

Published information regarding WHO expenditure does not allow for a precise estimate of resources directed to supporting trade health policy coherence but it is clearly miniscule in comparison to the health gains or

losses which are at stake. This is clearly a reflection of the donor chokehold over WHO's budget.

The Secretariat's evaluation of its own effectiveness in implementing its trade health policy coherence mandate is extraordinarily positive. In relation to Organization-Wide Expected Results (OWER) 7.2 ('Initiative taken by WHO in providing opportunities and means for intersectoral collaboration at national and international levels to address social and economic determinants of health, including understanding and acting upon the public health implications of trade and trade agreements, and to encourage poverty-reduction and sustainable development') WHO reports that this result was fully achieved. For Indicator 7.2.2 ('Number of tools to support countries in analysing the implications of trade and trade agreements for health') the target is fully achieved.

The result for Indicator 7.2.2 is particularly surprising given the continued delay in producing the trade assessment tool, discussed earlier. It appears that the 'tools' referred to have not been published on the web. The report elaborates on its self-assessment in the following terms:

During the biennium, WHO continued to support Member States in capacity building for assessing trade and its impact on health outcomes. Several publications, including books, briefing documents and fact-sheets were produced during the biennium. WHO has now established an active trilateral cooperation with WIPO and WTO at global level and the three organizations have started to organize a series of joint technical symposiums on issues covered by the Global strategy and plan of action on public health, innovation and intellectual property."

Barriers and enablers

Under this heading we consider the pre-conditions, enablers and barriers for promoting trade health policy coherence in terms of

- institutional barriers,
- political dynamics,
- disabilities of WHO, and the
- wider financial and ecological crisis of capitalism.

The institutional barriers are the easiest to identify and strategies for institutional strengthening would be reasonably easy to implement given adequate resources and political will. We provide a brief overview of these strategies of institutional strengthening.

The challenge of policy coherence requires more than addressing the institutional barriers; it is also necessary to address the political issues. The existence of vested interests and power imbalances is an inevitable reality. The question is how to negotiate this field.

Ultimately this a political question and it depends on the willingness of member states to defend truth and integrity and the accountability of the member states for how they discharge these responsibilities. One informant commented that the BRICS and other middle income countries could be much more influential in the governing bodies but, apart from Brazil, Thailand and India, most are quite passive.

The accountability of member states, in turn, depends on openness in decision making including technical decisions and it depends upon an active civil society at the national and global levels watching the global governors and ready to advise and criticise as appropriate.

There are certain disabilities specific to WHO which also need to be addressed as part of strengthening global governance for health. These include:

- the donor choke-hold; continuing freeze on assessed contributions plus donor dependence and donor leverage; and
- the lack of member state accountability for decisions and directions in WHO.

At some stage the threat that the USA holds over WHO needs to be confronted. This requires other countries to come forward and agree to increasing their assessed and voluntary contributions. This will require a wider social movement which cares about global governance for health and the leadership role of WHO in that context.

In our view recommendations directed to strengthening the accountability of WHO, and its individual member states, to civil society at the local, national, regional and global levels should be given the highest priority.

The stakes are very high. Capitalism is in crisis; an economic, development and ecological crisis. The policy paradigm of global economic integration has exacerbated the imbalance between global productive capacity and global demand. As fewer and fewer workers are needed to produce for larger and larger markets the role of decent wages in supporting consumption has progressively weakened and the opportunities for investment in new capacity has lagged. For a while consumption was supported by increasing debt but this strategy was sustained by asset price inflation and when the asset bubbles burst the credit markets froze.

The prevailing development paradigm of the last two decades has failed. Progressive global economic integration has seen a continuing net transfer of value from the poor to the rich both globally and within

countries. The magnitude of these transfers far outweighs the value of international financial assistance and domestic welfare transfers.

The crisis of global warming has brought into sharp focus the limits to continuing material growth. However, the invisible hand of market forces has proven unable or unwilling to mobilise the investment required to contain carbon dioxide release or to adapt the processes of capital accumulation and investment to a steady state economy.

The ideology of global economic integration has been accompanied by a progressive downsizing of government and a naïve faith in (or cynical myth regarding) the power of market forces to deliver public goods.

These are the deep contradictions which frame the present enquiry into global governance for health. Recommendations regarding global governance for health which do not address these contradictions will not be of any lasting significance.

Alternative mechanisms for projecting leadership in trade and health

There are no credible alternatives which could take over WHO's leadership role in relation to trade health policy coherence or in the broader tasks of global governance for health. Under this heading we discuss potential candidate structures but conclude that the multilateral intergovernmental character of WHO is critical to its fulfilling its role in global governance for health and that this could only be replicated by creating another WHO.

Conclusions

Trade relations affect health through their effects on: the availability of goods and services and price levels/relativities; the wealth of communities and how that wealth is grown, distributed and applied; and the structure and dynamics of the global economy including levels and the distribution of employment, accumulation, investment, debt, sustainability and crisis. Trade agreements affect health through these mechanisms and, in addition, through their effects on: regulatory environments; structures and processes of governance, nationally and globally; and changing configurations of corporate and national power.

Trade relations are an important focus for public health engagement and in this context the idea of policy coherence is useful. Policy coherence between trade and health requires that health policy makers and health advocates understand how trade relations affect health and are able to work with economic policy makers to find policy settings which achieve

win win outcomes. Likewise it implies that economic policy makers and commercial advocates need to understand and be accountable for the health effects of their policies.

WHO has a mixed history in dealing with the trade health interface. Some useful work has been done in SEARO and by WPRO in the Pacific. The investment in this work is far below its importance as a field where health is determined.

Strengthening WHO's ability (and that of member states) to promote policy coherence across trade and health will require significant capacity building. However, this is a fundamentally political arena, in which the stakes are high and the game is tough. Assuring WHO's role is played with truth and integrity will depend on strengthening its accountability and that of its member states for their custody of the Organization. Civil society has an important role to play in relation to both the specifics of trade and health and the accountability of WHO. There is no alternative.

Introduction

The World Health Organisation is widely recognised as the preeminent leadership body in global health governance; that is, across the network of organisations and countries through which health care and the determinants of health are governed globally. However, this position is not universally accepted. Many of the richer countries have sought, since its establishment, to restrict WHO's autonomy through control over its budget. In recent years there has been increasing pressure to restrict WHO's mandate to the development of biomedical norms and standards, avoiding any topics which are politically contested.

WHO's leadership role in global health has been challenged in terms of alternative analyses, priorities and strategies being offered through the World Bank and other intergovernmental organisations, various philanthropies and a range of global health initiatives (GHIs). In addition to external competition WHO's effectiveness has been compromised by increasing donor dependence, excessive decentralisation and the lack of accountability on the part of member state representatives for their custody of the institution (Legge 2012). Behind both the emergence of new competitors and many of the Organisation's disabilities are the intrigues and interests of big power engagement. These are not new; they have been part of WHO's reality from the Cold War onwards (Farley 2008).

However, the global health environment has changed dramatically since 1948 including many changes associated with globalisation (understood variously as the global village, global economic integration, and new structures of global governance). Two salient changes associated with globalisation have been the rising role of trade and investment agreements in globalising policy and regulation (especially since the creation of the WTO in 1994) and the rise of the transnational corporation (with increasing influence over health care and the conditions which shape population health). WHO has found it hard to achieve a proper balance in its dealings with the corporate sector (in particular, big pharma and big food; it has done well in relation to big tobacco).

For all of these reasons now is a good time to reconsider WHO's leadership role in global health. The broad options are two: first, restrict WHO's mandate to a technical 'normative' role and find some other body to provide leadership in global health governance; or second, reform and strengthen the Organisation so that it can provide the leadership needed across those formal and informal networks through which global governance for health is effected. Evaluating these two options should include consideration of the tasks involved in global governance for

health; consideration of the scope for overcoming the barriers and disabilities that WHO is facing; as well as consideration of the potential capabilities of the alternative contenders for global health leadership.

The case study method provides one useful approach to this kind of assessment. Our focus in this case study is the trade and health policy interface, concentrating in particular on the [2006 WHA trade and health resolution](#). Trade and health is not the totality of global governance for health but it is of growing importance and a study of the way WHO has managed this area provides a useful insight into WHO's role in global governance for health. In this paper we explore first, the implications for health of increasing economic integration and the proliferation of trade and investment agreements; second, the concept of policy coherence as a way of managing potential policy contradictions; third, the barriers and disabilities facing the WHO in seeking to promote policy coherence (and what might be needed to overcome those barriers and disabilities); and finally, an assessment of alternative ways of projecting leadership with respect to policy coherence across trade and health; nationally and globally.

Data collected for the case study centres around the trade and health policy nexus; the [2006 trade and health resolution](#); and the role of WHO in promoting policy coherence across trade and health. Data were collected through literature search; direct searching through WHO websites and on line archives; and through a key informant survey.

Background

Overview of this section

The interface between trade and health is complex, too complex to be treated exhaustively here. Useful accounts of this relationship are provided by Labonte and his colleagues (Labonte, Schreker et al. 2007; Labonte 2010), Blouin and Hawkes and their colleagues (Blouin, Heymann et al. 2007; Hawkes, Blouin et al. 2010). Fidler, Drager and Lee (2009) provide a useful historical review of the intersections between trade and health and open the question of coherence.

In this background section we provide a summary of the intersections between trade and health:

- how trade relations (the flow of goods, services, people and capital) affect health;
- how trade agreements impact on health through their influence on regulation and governance, beyond their influence on trade flows;

- how the character of the different trading partnerships (eg North South versus South South) determine how different provisions in trade agreements can affect population health;
- how trade agreements affect health in their role as critical decision points which shape the evolution of the global economy; and
- how trade and investment agreements reflect and stabilise particular configurations of national and corporate power.

We conclude from this review that trade relations are an important focus of public health engagement and discuss four particular challenges which public health advocates face in trade health engagement:

- health impact assessment: principles, tools and limits;
- negotiating uncertainty: in evaluating possible outcomes of trade negotiations; and the management of public health uncertainty in trade law;
- assembling multidisciplinary teams and accessing specialist expertise; and
- managing the power dynamics.

In the last part of this section we explore briefly the meanings and boundaries of the idea of policy coherence and review some of the strategies and preconditions for policy coherence. These are illustrated with reference to a number of case studies of policy coherence from the collection edited by Blouin, Heymann and Drager (2007).

Trade and health

Trade relations affect health.

The term 'trade relations' is used here to include the flow of goods and services and the flow of capital. The flow of people is in some contexts also treated as a form of trade. For two contrasting perspectives on the trade in health professionals see Chandra (2007) who explores the scope for a GATS⁶ visa to promote professional mobility and Kanchanachitra and colleagues (2011) who counsel caution regarding the risks to local health care provision.

Trade relations, so defined, affect the availability of goods (eg insecticide treated bed nets (Bora 2007) or pharmaceuticals (Abbott, Bader et al. 2012)) and services (Price, Pollock et al. 1999; Pachanee and Wibulpolprasert 2007; Smith, Chanda et al. 2009) and price levels and price relativities which can have a profound effect on health, eg through

6. The General Agreement on Trade in Services (GATS) provides for four modes of trade in services including Mode 4, the movement of natural persons.

the impact of food supply on nutrition (Cassels 2006; GHW2 2008; Hawkes, Blouin et al. 2010; Lobstein 2010).

Trade relations affect the wealth of communities and how that wealth is distributed and applied, with clear implications for health, eg through government expenditure on urban infrastructure. See Shea and colleagues (Shea, Ross et al. 2007) for a more in-depth treatment of trade, wealth, equity and health.

Trade relations reflect and affect the structure of the global economy, including its stability and sustainability (Ropke 1994), again with clear implications for population health. The global financial crisis from 2007 – and its manifold influences on population health (Horton 2009; Stiglitz 2009) - reflect in part structural imbalances which had been building up in the global economy over the last three decades through changing patterns in the flow of goods, services, people and capital.

Trade and investment agreements affect health

Trade and investment agreements affect health, partly through their effects on trade relations, the flow of goods, services, people and capital (as above), but also because of their impact on regulatory environments and the dynamics of governance.

Regulatory environments

Trade agreements affect the regulatory environments which shape the delivery of health care (eg intellectual property rights and access to medicines (Westerhaus and Castro 2006; Chatterjee 2011); migration of health personnel) and which shape the social and environmental determinants of health (eg product, marketing, labour (Earle, Shea et al. 2007), professional and environmental standards). Provisions in trade agreements which impact on regulatory environments are generally rationalised in terms of trade facilitation but they can have very significant adverse consequences beyond their influence on trade, eg barriers to regulating the marketing of junk food (Cassels 2006; GHW2 2008; L'Abbé, Lewis et al. 2010; Lobstein 2010; Lobstein, Orden et al. 2010).

Governance relations

Trade agreements also reflect and reshape the structures and dynamics of governance at all levels: community, national and global. The processes of trade negotiations involve the movement of important public policy questions out of public spaces and into protected elite fora. Legal commitments made in trade agreements are much harder to reverse or revise than are autonomous national laws. Dispute settlement arrangements what are mandated through trade and investment

agreements enshrine jurisprudential principles which are very different from those in national law. The shifts in governance relations associated with trade agreements are generally rationalised in terms of trade facilitation but they too can have far reaching implications beyond their influence on trade, including for health, eg the practical irreversibility of GATS and many other trade agreements and the chilling effect of ISDS⁷ on public health regulation (Lee, Sridhar et al. 2009; Tienhaara 2010; Voon and Mitchell 2011; Kelsey and Wallach 2012; Vallely 2012).

The commitments agreed to in trade negotiations generally require ratifying legislation and in many cases implementing legislation. This phase, the implementation of trade commitments through domestic law, can involve some discretionary policy space, as in the revision of patent law in accordance with the principles of the TRIPS agreement⁸. The TRIPS agreement sets out principles but how these are expressed in domestic law can vary. From a health perspective it is important to use the flexibilities embedded in the TRIPS agreement to create domestic law which supports access to medicines in the most effective way. Trade agreements can constrain the framing and implementation of health policy. However, there is generally some scope for designing health policies which use to the full such discretion as may be available in trade law to promote public health objectives (Chigas, Fairman et al. 2007; Correa 2007; Fidler 2007; Tuerk and Mashayekhi 2007).

Trade agreements linking different groups of economies can have very different economic implications

Trade agreements, and particularly trade liberalisation, can have different economic effects depending on the nature of the economies being linked.

There are particular risks where a trade agreement promotes liberalisation of trade between advanced economies and developing economies ('North South' trade). In many cases the advanced economy has advanced manufacturing capability and is able to sell high quality manufactured goods more cheaply than any locally produced competing products; this has employment consequences. The advanced economies also have strong technology intensive and energy intensive agricultural sectors, often supported by extensive subsidies, and may be able to sell agricultural commodities more cheaply than farmers in developing countries can produce them; this may weaken the farming sector, jeopardising domestic food security, and accelerate urbanisation. Foreign

7. Investor protection provisions in trade and investment agreements provide scope for foreign corporations to sue governments (investor state dispute settlement or ISDS) when they believe the value of their investment has been diminished by government policy.

8. The Agreement on Trade Related Intellectual Property Rights

investors may be happy to invest in extractive industries (mining, drilling, timber, factory fishing) with short to medium term benefits to the host economy but longer terms costs in environmental terms.

For small economies with a small number of exports, access to the US and European markets can make a big impact on employment and export revenues and it may be judged necessary to accept some longer term disabilities (reduced tariffs, high intellectual property protection, investor state dispute settlement) in order to gain access for those exports. From the point of view of the corporations and politicians of the advanced economies the gains to be achieved from normalising intellectual property protection, investment protection and non agricultural market access may be worth small concessions to small producers.

The dynamics are very different when trade agreements bring together diverse economies which are broadly at the same level of economic development and comparable political power. Trade liberalisation in this situation can provide real benefits in terms of larger markets, economies of scale and regional specialisation. Competition between enterprises which have similar endowments and the same regulatory environment can promote efficiency and innovation. Efficiencies from scale and from competition can contribute to capital accumulation, new investments and increased employment. The development of free trade between states of the USA after the Revolution provided just such an environment (with combined with high protection against imports). The establishment of the European Common Market from 1957 created a similar dynamic. Various initiatives directed at South-South trade agreements seek to exploit these potential benefits.

These different dynamics are directly relevant to some of the key concerns of public health advocates (such as treatment access and policy space). However, of greater importance to health are the core issues of employment and capital accumulation and the flow-ons to housing, education, nutrition and health care. Increasing incomes (equitably distributed) and a growing capital base (allocated to support sustainable development) are central to the promise of trade liberalisation and these are outcomes which matter hugely to health advocates. However, the promise of increasing incomes and a growing capital base, as the consequence of trade liberalisation, is generally part forecast and part hustle and the balance between these two is not always clear.

Trade agreements are decision points which powerfully influence the structure of the global economy

The changing structure of the global economy is powerfully influenced by the growing number of international agreements on the flow of goods, services, people and capital. The global economy is presently characterised by imbalances, instabilities and incapacities all of which are directly relevant to health.

Over the last 30 years the USA has progressively exported manufacturing jobs to low wage platforms but has maintained living standards by borrowing from the rest of the world (in particular China) and has maintained employment through a financial sector which, rather than distributing capital for real investment, has converted capital directly into consumption through irresponsible lending and an explosive growth in financial sector employment with obscene salary and bonus levels. This growth model is rapidly disintegrating with falling living standards, widening inequality, gridlocked politics and a confused and angry public.

In the Europe likewise two decades of prosperity have been supported in large part by borrowed money, pushed by banks which were too big to fail. When they did fail the rules of the game require that they are bailed out by tax payers, including through fierce austerity programs.

The fundamental instability associated with global trade liberalisation is the imbalance globally between productive employment and salaried consumption. If fewer and fewer employees are needed to produce goods for the global market, the flow of wages is insufficient to fund consumption (to buy the goods being produced); particularly while production continues to shift to lower wage platforms. Expansion of the service sector may not be sufficient to balance the loss of jobs in manufacturing.

As fewer and fewer employees are needed to produce goods for the global market, so there are fewer and fewer opportunities for greenfields investment. So the profits of the corporations who control the global production chains go into consolidation (mergers and acquisitions), portfolio investment (bidding up the capital value of existing enterprises) and speculation and the financial sector takes its slice as it mediates all of these transformations.

The focus of most financial commentary is generally on China, the US and Europe but there are serious implications for those populations who are not engaged in manufacturing nor servicing the financial hubs. There are some opportunities for those regions who supply raw materials to the manufacturing complexes and for a few niche exporters but many millions

of people are simply spectators to this confusing, writhing, pumping, knotting global economy.

In 2008 Queen Elizabeth II asked why the global financial crisis had not been predicted. In Dec 2012 she got her answer from Sujit Kapadia from the Bank of England's Financial Services Committee (Associated Press 2012).

[Kapadia] told her that financial crises are like earthquakes — rare and difficult to predict. Kapadia also said that growing complacency since markets were stable had led people to think regulation wasn't necessary. Third, people didn't realize how interconnected the financial system had become.

In fact some economists had predicted the crisis, for example, the Australian economist Steve Keen (2011) who had argued for some years that growing levels of debt (corporate and household debt as well as public debt) was creating pressures which had to end in crisis. Keen develops a far reaching critique of neoclassical economics; touching upon its assumptions, its dependence on static equilibrium models and its failure to accommodate debt in its basic modelling.

The technical debates among economists will not be resolved by public health experts but it is important to recognise that there are fundamental debates going on within economics and that the promises of the trade liberalisers are based in some degree on contentious assumptions.

Trade negotiations are decision processes which powerfully influence the structure and trajectory of the global economy. The direction of the global economy has profound implications for population health.

Trade and investment agreements reflect and stabilise particular configurations of corporate and national power

Trade relations have a certain intrinsic logic associated with the freely chosen exchange of products to mutual advantage. However, market access and the terms of trade are not just shaped by the costs of production and levels of demand. They are also shaped by corporate and national power, including military, diplomatic and trade sanctions (exemplified in the slave trade, the arms trade and the drug trade). Trade agreements reflect and perpetuate the prevailing power relations across interlocking networks of countries, corporations and industries. This is exemplified in the use of trade sanctions as a tool for forcing small countries to agree to join trade agreements and their use as one of the main disciplinary options in dispute settlement (Correa 2007; Gale 2011).

The consequence of this political dimension of trade relations is that the distribution of beneficial and adverse effects of trade and investment agreements is in large degree determined politically. This is intrinsic to trade relations and historically self-evident but not always acknowledged. It is a common expression of power to pursue self-interest under the banner of balanced and mutual advantage.

The role of large tobacco companies in mobilising farmers and in paying small countries to run disputes on their behalf illustrates the significance of power in shaping trade relations (Voon and Mitchell 2011). Likewise the pursuit of higher IP protection but lower patenting standards by those companies and countries who export knowledge-intensive goods and services (and who depend upon profits associated with monopoly pricing) illustrates the role of self-interest in trade policy and of political power in the pursuit of such self-interest.

Trade relations are an important focus for public health engagement

Public health advocates cannot restrict their attention to health-specific concerns such as treatment access and policy space. They are obligated to evaluate the core promise of trade liberalisation (on income and capital) in the context of specific trading relationships. Trade relations affect health and are an entirely appropriate focus for public health engagement. The broad avenues through which public health advocates may seek to influence trade relations include:

- participating in trade negotiations; reducing the risks (eg through carve outs and exceptions), strengthening the benefits (eg promoting decent employment);
- designing implementing legislation (eg enshrining the flexibilities built into TRIPS in the design of national implementing legislation, see for example, (Correa 2007; Roffe, Braun et al. 2007));
- making trade law work for health (eg exploring how the Codex Alimentarius⁹ might be used to help to achieve health objectives, (L'Abbé, Lewis et al. 2010));
- making health policy support the goals of economic policy (eg domestic procurement for health system inputs); and
- promoting economic policies which support health (eg encouraging fruit and vegetable agriculture for domestic and export purposes, rather than relying on commodities such as tobacco or sugar for export, see Thow and Priyadarshi (2013)).

9. The Codex Alimentarius, jointly sponsored by WHO and FAO, is recognised in the Sanitary and Phytosanitary Agreement (SPS) and other trade law as authorising internationally applicable food standards.

There is a need for public health advocacy and collaboration at both the national level, where national trade policy is formed and where trade commitments are implemented, and at the international level, where trade agreements are negotiated and the broader assumptions of trade health policy coherence are debated. Some of the pre-conditions for public health engagement in the health - trade interface include:

- knowledge and skills involved in prospective impact assessment (projection) in relation to the health implications of trade relations;
- strategies for managing the irreducible uncertainties associated with health impact assessment studies (HIAs) in relation to trade and health;
- capacity for respectful dialogue with other stakeholders who have legitimate interests in trade negotiation but different priorities from public health advocates;
- public health lawyers with trade expertise;
- collaborative relationships with trade lawyers and legal drafts people to render trade commitments into domestic law in ways that do least harm to health;
- an understanding of the many different ways in which the health system articulates with (and is part of) the broader economy;
- creative approaches to ways in which health system development can contribute to economic development; and
- principles and strategies to manage the political / power dimensions of trade negotiations and trade policy generally.

Health impact assessment

Health impact assessment, projecting the likely implications for health of particular provisions in trade agreements calls for consideration of:

- trade relations, as in the movement of goods, services, people and capital and how specific trade relations affect health;
- the generation, distribution and application of wealth acquired through trade and the implications of these for health; (the distribution of wealth is a function of both market factors (employment and wage levels) and post-market (tax and transfer) re-distribution);
- implications for health of regulatory provisions and constraints associated with trade agreements;
- the impact of trade on the structure, stability and sustainability of the global economy and implications for health; and

- implications for health of the changes in governance dynamics as a consequence of trade negotiations.

Health impact assessment needs to be interpreted broadly (Lee, Ingram et al. 2007; Nathan Associates 2007). It should include impact assessment through more specialist lenses also including gender impact assessment and human rights impact assessment (Morgan, Sami et al. 2010).

Negotiating uncertainty

There is an irreducible uncertainty involved in projecting the likely influences of particular trade or investment provisions and health outcomes. Greater certainty is possible in certain cases such as tobacco which ‘...is the only legally available consumer product which kills people when it is used entirely as intended.’ (WHO 2008, citing The Oxford Medical Companion 1994). However, many of the links between trade agreement provisions, food supply, dietary patterns and health outcomes are complex and indirect. Likewise the links between trade policy, employment, and wealth distribution are complex and indirect. However, while such links are complex and indirect the influences can be very powerful. Nevertheless, there are limits to the foresight of health impact assessment and it would be a mistake to promise too much certainty (Cooke, Curran et al. 2008; Curran 2008; Schrank 2008; Ahmed 2010).

There is also widespread scepticism regarding conventional econometric modelling to project the outcomes of particular trade policy scenarios. Such modelling is generally undertaken in computable general equilibrium models which bear only an indirect relationship to how real economies work (Keen 2011). As a consequence, the evaluation of particular trade policy scenarios generally focuses on a small number of industries where there is a clear promise of benefit or detriment for one of the negotiating parties. The negotiations then involve trade-offs between the ambit claims of the various negotiating partners who are seeking to gain or defend such benefits.

This process of negotiating trade-offs is conducted within a miasma of overstated promises and warnings; it is a poker game with high stakes (which flow to powerful sectional interests). The bluff and counter-bluff is complicated by the power imbalances among the negotiators so that bluff is mixed with threat. The debate between innovation versus access in relation to IPRs¹⁰ and medicines illustrates this. The transnational pharmaceutical industry (‘Big Pharma’) argues that monopoly prices are necessary to support high profits which support innovation. Treatment

10. Intellectual property rights

access advocates argue that preventing access to life-saving medicines in order to maintain profits is a denial of the right to health; further that profit-directed innovation is more likely to produce me-too drugs for high income markets, with no net therapeutic gain. This game carries very high stakes for both the companies and communities and the debate is conducted within a field charged with political and financial power.

The principles for managing this kind of uncertainty are well known. They include:

- exercise caution and leave a wide safety margin;
- ensure commitments are tentative and have a capacity for reversal;
- ensure continuing research and review; and
- monitor and mitigate.

Unfortunately these principles run counter to some of the interests and norms of the commercial and legal worlds. Investors seek to reduce the uncertainty associated with investment decisions and to this end they prefer to have any new (and beneficial) trade rules locked in.

Trade lawyers are suspicious of health and environmental advocacy on the grounds that it provides excuses for trade barriers which are really about gaining economic advantage over trading partners. For this reason a requirement of 'evidence' to support health exceptions is built into many trade agreements; a requirement which is generally interpreted by trade dispute panels in the most reductionist way possible. It can be difficult to argue on the basis of complex and indirect causality in such fora.

Public health advocates engaging with trade policy need to have a sophisticated understanding of uncertainty and a degree of scepticism regarding corporate claims and denials.

Multi-disciplinary teams

The field is huge. Effective engagement requires a grasp of detail as well as an understanding of the big picture. Advocacy for health requires a breadth of expertise within public health including public health law. It also calls for collaborative relationships with trade lawyers and legal drafts people who can render trade commitments into domestic law in ways that do least harm to health. The team must also include economic expertise; an understanding of the ways in which the economy affects health and the different ways in which the health system articulates with (and is part of) the broader economy.

Assembling such teams within one institution is beyond the resources of all but the largest corporations and countries. However, comparable outcomes can be achieved through network building; drawing on the

different expertises located in academia, government and the NGO sector. However, such network building requires deliberate strategy and resources.

Networking for health advocacy calls for a certain generosity of spirit with respect to disciplinary boundaries and norms. The experts whom the health sector needs also have their own values, aspirations and sectoral objectives and are also working with advocates in other sectors (Fidler 2007; Fidler 2010).

Building a dialogue with officials and stakeholders from other sectors requires respect for the good faith of negotiators and advocates who are pursuing policy objectives other than population health gain. Public health advocates may in fact have some sympathy with some of these non-health objectives, as citizens, rather than as narrowly defined public health advocates.

There is a special role for WHO in linking national health ministries and health advocates to the kinds of networks of expertise that they will need to engage in trade related policy making and implementation.

Managing the power dynamics; value of human rights framework

Trade negotiation and trade policy implementation take place within a highly charged atmosphere of promise, bluff and threat. Transnational corporations play for very high stakes (as do their executives) and have access to levers of power (money, public relations and the leverage they exercise over host governments) that public health advocates can only dream about. Large rich countries (and their politicians) are likewise playing for high stakes, including employment, export revenues and repatriated profits from foreign investment.

The export earnings associated with monopoly pricing (easy patenting and high levels of IP protection) are matters of intense corporate and political concern in those countries (the US and Europe particularly) whose competitive advantage lies in knowledge-rich industries (Kökény 2011).

The fact that asymmetric power relations shape the outcomes of trade negotiations is well known but sometimes difficult to speak about; partly because of intimidation but also the difficulty of naming bullying without accusing individuals of bad faith. On the other hand it is pointless to engage in advocacy which is predicated on the assumption that all parties basically agree on the value of human life and the importance of environmental sustainability and all parties are equal in negotiating power.

Health advocates need a normative framework which enables them to name the power dimensions of trade policy and to engage in good faith in the mobilisation of power to advance legitimate health objectives. The currencies of such power will be very different from that deployed by large corporations and countries. It will involve research, information dissemination, popular mobilisation and alliance building, including alliances between civil society and governments.

The concept of health as a human right, and the broader principles of human rights generally, may provide such a framework. Human rights principles have powerful authority which comes from widely shared values and broad international consensus. They provide normative guidance for health advocates to name injustice and intimidation and to mobilise communities while not replicating corporate artifice and political pragmatism (Morgan, Sami et al. 2010).

Policy coherence

From a health point of view policy coherence is a means to an end. The end is the achievement of trade relations which support health development or at least do not generate new or heightened threats to population health.

Expressing this objective in terms of 'coherence' is an acknowledgement of the legitimacy of other goals of trade policy, beyond health. Paradoxically, these 'other goals' include increasing incomes and domestic capital formation which, equitably distributed and allocated to sustainable development, are basic conditions for better health.

Policy coherence is one pathway to this end; it concerns the formation of policies at the national and international levels which will achieve such a balance. National level policy coherence will be reflected in the policy positions advanced by trade negotiators. Fidler refers to these as internal and external policy coherence (Fidler 2007). Chigas and her colleagues (2007) speak about:

- negotiating *up* to shape rules and actions at the global level;
- negotiating *across* to achieve national policy coherence; and
- negotiating *out* to build coalitions with diverse actors.

Resolution 59.26 (WHA 2006) is broader than just focusing on trade negotiations and their outcomes. It also includes reference to 'relevant issues through policies and legislation' which suggest that it may be taken as referring to implementing legislation and the use of trade agreement flexibilities as well as the original negotiations.

The focus on *policy* coherence reflects a pre-occupation with the formal decision-making of governments and intergovernmental

organisations. However, given the power dimensions of trade policy, it is evident that to achieve policy coherence will often require advocacy, education, information dissemination and popular mobilisation. It is not clear how far the mandate of 59.26 extends, beyond formal policy analysis and development. However, the resolution urges Member States 'to ... address the potential challenges that trade and trade agreements may have for health' and the corresponding SEARO resolution requests the Regional Director to 'mobilize resources to support the works related to Trade and Health' (SEARO 2006).

Strategies for promoting policy coherence

David Fidler (2007) introduces the concept of double dose stove piping to describe how health ministries have been excluded from both the domestic policy process and the trade negotiations. He suggests that often health ministry officials have more contact with their counterparts abroad than with trade or foreign ministry officials at home. Fidler identifies some key strategies which could help to promote policy coherence:

- building the evidence base for policy;
- monitoring the implementation of existing agreements related to trade and health;
- integrating public health expertise into negotiations of new agreements and arrangements;
- networking trade epidemiology (more support through WHO and WTO for health officials);
- trade-for-health initiatives (systematically reducing tariffs and other barriers to trade in medical products and technologies).

Chigas and her colleagues (2007) suggest strategies for building shared understanding between health and trade officials at the national level. They emphasise 'joint fact-finding' exercises through which health officials and trade officials might learn each others' languages. These authors emphasise the challenges involved in orienting health officials to issues of trade:

- closer familiarity with current issues in international politics
- building relationships with 'a far-flung network of like-minded colleagues and unlikely allies with complementary interests';
and
- skill development in negotiation and advocacy.

It is useful to complement the more general commentary with the details from experience in the field. Tuerk and Mashayekhi (2007) have documented four illuminating case studies of health–trade policy coherence.

The story from Pakistan concerns re-negotiating Pakistan's commitments under GATS during the post Doha GATS renewal. There had been a continuing discussion of Pakistan's involvement in WTO agreements for some time. The Ministry of Commerce promoted inter agency consultation regarding GATS commitments in consultation with the Geneva negotiators. The MOH initiated further discussion with health professional groups and was able to feed the outcomes of these discussions back into the inter-departmental consultations. The outcome was a public sector carve-out with respect to market access and national treatment obligations. The main lessons drawn from this episode include the importance of an ongoing and inclusive national discussion regarding trade issues (including officials and stakeholders from the health sector) and the need for a diverse range of capacity building activities.

The story from the Philippines was actually centred in Geneva where Philippines diplomats were actively involved in negotiating the 2003 Decision regarding the Para 6 waiver authorised by Doha 2001. Philippines had an established interest in the use of parallel importing under TRIPS to support access to medicines and was interested in strengthening their position in this respect through the provisions of the 2003 Decision. The highlight of this story was the role of the diplomats in Geneva in providing the links between international experts, including specialist NGOs, and domestic policy makers with a view to widening the scope of the 2003 Decision and making maximal use (in domestic legislation) of the flexibilities available under TRIPS as modified after 2003.

The Uganda story explores a wide incoherence between Uganda's advocacy in international fora for universal access, under the Ministry of Tourism, Trade and Industry supported by the Ministry of Health, and the development, under the Ministry of Justice, of draft legislation that would forego the exploitation of TRIPS flexibilities. It is a complicated story with significant roles played by domestic and international NGOs, intergovernmental organisations and bilateral donor agencies. The basic lessons include: the importance of an ongoing inclusive public conversation about the wider implications of trade policy; the critical role of domestic and international NGOs in providing access to technical expertise and advocacy resources; and the potential role of intergovernmental organisations in providing capacity building. The alleged role of USAID in advising Uganda to adopt TRIPS Plus provisions in its domestic legislation (limits on compulsory licensing, the patenting of second uses and criminalising patent infringement) raises important questions about the role of bilateral donors in providing policy advice.

From Peru comes a story about TRIPS Plus provisions in the US Andean FTA, as ratified by Peru. At stake were a series of provisions including data exclusivity, limits on compulsory licensing, extended patent terms, data linkage and second use protection. A wide array of official and civil society organisations were opposed to these provisions because of their projected impact on the cost of medicines. The campaign against these provisions extended over several years and involved the Ministry of Health, domestic NGOs, international NGOs, academics and intergovernmental organisations (including PAHO and the UNHCHR's Health Rapporteur). Arrayed against this seemingly impressive front were the US based pharmaceutical corporations supported by a delegation from the US Congress and ultimately Peru agreed to include data exclusivity provisions in the Agreement. The critical sanction which the US deployed was the threat not to extend preferential access to the US market for certain Peruvian agricultural products which would have led to significant unemployment and loss of export revenue. The lesson from this story is that in some circumstances the threat of trade sanctions can overwhelm the health agenda, no matter how well informed and well organised are the efforts to achieve policy coherence.

A very different story (in the same collection, edited by Blouin, Heymann and Drager, 2007) explores trade barriers to reducing the cost of insecticide treated mosquito nets (Bora 2007). Bora commences with a brief introduction to malaria and the importance of ITNs. He mentions the Abuja commitment to waive taxes and tariffs on ITNs and demonstrates that tariffs on imported yarn (prior to being woven into bed nets or any other fabric) and shipping costs within Africa are the two items of cost, in production and distribution, which reduce the international competitiveness of African producers in terms of supplying their domestic market and exporting to other African countries.

Bora discusses two strategies for reducing tariffs on ITNs: first, reducing the tariffs on imported yarn (before it has been used in the manufacture of any fabrics); or second, using the discretionary codes within the Harmonised Commodity Description and Coding System to identify bed nets and then exempt them specifically from tariffs. Bora, who works in the Economic Research and Statistics Division of the WTO in Geneva clearly favours the first option and speaks somewhat dismissively of African countries' reluctance to proceed with the NAMA negotiations under the Doha round (and blames 'prominent NGOs' such as Third World Network, for this reluctance).

It appears that the ministers' commitment to waive tariffs on ITNs has been held up by an uncomfortable choice between dropping tariffs on all imported yarn – with predictable implications for domestic fabric

manufacturers – versus dropping tariffs on ITNs specifically and eliminating any domestic capacity to produce such nets. A third alternative would be some kind of import tariff credit scheme through which the tariff costs of imported yarn would be recouped by the domestic ITN manufacturers. In other words, tariffs paid by domestic ITN manufacturers on imported yarn would be returned as subsidies to the manufacturers allowing them to compete with tariff-free imports of ITNs. This solution is not discussed by Bora, presumably because it would comprise a subsidy (and hence proscribed by the tariffication principles of WTO). However, there may be technical strategies through which such a subsidy could be allowed.

The ITN case illustrates the importance of health ministries having access to high level trade law advice through which it may negotiate complicated health objectives in trade law compatible ways.

Origins of and adoption of Resolution 59.26 in May 2006

Earlier work on trade health policy coherence

Member state concerns about the implications of trade agreements for health date back well before 2006.

In Resolution [WHA49.14 'Revised drug strategy'](#) (WHA 1996) the Assembly requests the DG [...] "to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs...". In response to this mandate WHO published in 1998 a document (Velásquez and Boulet 1998) informing Member States of the relevance and implications of the new international trade agreements and particularly the implications of the TRIPS Agreement in the health sector. In a speech the same year the Director-General set out the principles of policy coherence across trade and health and affirmed WHO's commitment to this line of work (Brundtland 1998, from pp 67-73).

In Resolution [WHA52.19 'Revised drug strategy'](#) (WHA 1999), the Assembly requests the DG, "to ... cooperate with Member States, at their request, and with international organizations, in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements".

In a speech later that year, to a regional consultation on trade agreements and their implications for health, focusing specifically on TRIPS, Dr Uton Muchtar Rafei, the previous SEARO Regional Director (Rafei 1999), commented on the concerns which had motivated WHA52.19. [Dr Rafei's speech](#) is worth reading in full. He locates concerns about access to medicines in the context of the WTO, TRIPS and trade liberalisation. He recognises the contradictions between innovation and access but places this in the context of the South East Asian region of WHO. He calls for dialogue and sets forth a persuasive picture of policy coherence. He affirms that continuing health improvement should be part of economic development and commits WHO to helping Member Countries to ensuring equity and social justice in health. He commits WHO to monitoring the implications of the TRIPS Agreement on the health sector, as mandated by its governing body [in WHA5219].

Just two years later the WTO Ministerial Council adopted the [Doha Statement on Public Health](#) (WTO Ministerial Council 2001). Clearly the discussions within WHO contributed to the support for the full use of TRIPS flexibilities which is reflected in that Statement. On the other hand, the support (in the Doha Statement) for the full use of TRIPS flexibilities (including compulsory licensing and parallel importation) stands in some contrast to the support which the WHO Director General gave in May of 2001 to differential pricing as the preferred solution to the challenge of treatment access (WHO, WTO et al. 2001).

In 2002 WHO and WTO published a [comprehensive report](#) on the intersections between trade and public health (WTO and WHO 2002) including an extended section on health trade policy coherence. This section starts with a useful review of the structures and processes adopted in Thailand and Canada to promote policy coherence across trade and health (and with other sectors). This is followed by a discussion of some specific provisions within WTO agreements of particular relevance to health and then a consideration of strategies for policy coherence:

- processes for addressing health issues in WTO rules;
- processes for addressing trade issues in international health rules;
- investment in evidence to inform policy;
- the involvement of health people in the negotiation and review of WTO agreements and in accession negotiations;
- capacity building;
- leadership; and
- intersectoral institutions.

In 2003, in a resolution ([WHA56.27](#)) focusing on intellectual property, innovation and public health, the WHA (2003) urged member

states “to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)” and requested the Director General “to cooperate with Member States, at their request, and with international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements”.

Also in 2003 WPRO published a report on [the use of domestic law in the fight against obesity](#) (WPRO 2003) which explored various strategies for addressing obesity in some depth (pricing controls, regulating supply, and labelling requirements) and discussed ways in which the requirement of the Agreement on Agriculture, the SPS Agreement and the TBT Agreement might be negotiated.

In October 2004 SEARO hosted an inter-regional workshop on trade and health (SEARO 2007). This was clearly an important event in the development of WHO thinking and the [report of the workshop](#) is worth reading in full. The workshop concluded with recommendations for member states and for the Secretariat which provide a very clear set of guidelines for achieving policy coherence across trade and health.

In his concluding remarks Dr Abdul Sattar-Yoosuf, Director, Department of Sustainable Development and Healthy Environments, WHO/SEARO stated that:

“Expansion of international trade and the growing importance of multi/bilateral trade agreements present a wide range of opportunities and challenges for public health. The continuous expansion in scale and scope of international trade poses key challenges for the health community. There is a growing demand for information about the possible implications of international trade and trade agreements for health and health policy at the national, regional and global levels.

“The health community must be equipped with a better understanding of the world trading system, notably the legal framework for international trade, and comprehend the potential health implications of various bilateral, regional and multilateral agreements regulating trade today. There is a need to generate increasing awareness of the fact that ignoring health can lead to problems in the trade sphere. The health community should press for a much louder voice in the setting of trade policy at national and international levels. Ministers of health need to work together constructively with their colleagues in the ministries of trade, commerce, finance and foreign affairs to ensure that the interests of trade and of health are appropriately balanced.”

It is evident that this workshop laid the ground work for the preparation of what became WHA59.26.

Negotiation of WHA59.26

The first version of what became WHA59.26 was tabled at the EB meeting (EB116 in May 2005) as a response to a [Secretariat report on trade and health](#) (EB116/4, WHO 2005). The report commences with a review of previous relevant resolutions, most of which were centred on access to medicines; then a review of the WTO and its agreements; and then a review of the key issues at the trade health interface. The report then reviewed work which had been undertaken by WHO on trade and health, including: analysis and research, tools and training materials, technical support and capacity building. The report highlighted the need for policy coherence emphasising:

- greater interaction is needed between policy-makers and practitioners in the trade and health sectors in order to improve the coherence of domestic and international policy;
- closer collaboration between trade and health when trade policies and agreements are being formulated that have possible implications for public health;
- professional development within ministries of health so that they might become more aware of trade issues under consideration within WTO and other international organizations and better able to help colleagues in the ministries concerned with international trade to understand relevant aspects of public health;
- consultation with health providers, consumers and other key private and public stakeholders;
- research on the potential implications of trade agreements on health and of trade liberalization in health-related sectors on health-sector performance and health outcomes; including
 - systematic compilation of essential data sets, especially information on trade in health-related services
 - design of methodologies and indicators for assessing and tracking the possible health consequences of international trade and trade agreements;
- growing the number of experts who are knowledgeable and experienced in trade and health issues in Member States, including at national centres of excellence.

Khor (2005) provides a [detailed report of this discussion](#) that reflects the different perspectives offered. A number of countries (Thailand, Bolivia, Portugal, Namibia, Iceland, Brazil and Czech Republic commended

the Secretariat for the report. The US delegate criticised the report as superficial and accused the Secretariat of being 'against industry, free trade, and intellectual property'.

Following the discussion of the report Thailand introduced a resolution on "international trade and health " on behalf of itself, Benin, Bhutan, Bolivia, Brazil, Canada, China, Iraq, Jamaica, Kenya, Nepal, Sudan, Tonga and Vietnam.

The draft recognised the demand for information about the possible implications of international trade and trade agreements for health at national, regional and global levels. It was also "mindful of the need for ministers of health and their colleagues in ministries of trade, commerce, and finance to work together constructively in order to ensure that the interests of trade and of health are appropriately balanced."

The draft resolution urged WHO member states:

1.1. to promote dialogue at national level to consider the interplay between international trade and health;

1.2. to adopt policies, laws, and regulations that address issues identified in that dialogue and take advantage of the potential opportunities, and mitigate the potential risks, that trade and trade agreements may have for health;

1.3. to create constructive and interactive relationships across the public and private sectors for the purpose of generating coherence in their trade and health policies;

1.4. to continue to develop capacity at national level to track and analyse the potential opportunities and risks of trade and trade agreements for health-sector performance and health outcomes.

The draft also requested the WHO Director-General to:

2.1. provide support to Member States (at their request and in collaboration with the competent international organizations) to frame coherent trade and health policies;

2.2 to respond to Member States' requests for support of their efforts to build the capacity to understand the implications of international trade and trade agreements for health and to address relevant issues through policies and legislation that take advantage of the potential opportunities, and mitigate the potential risks, that trade and trade agreements may have for health;

2.3. to continue collaborating with the competent international organizations in order to support policy coherence between trade and health sectors at regional and global levels and to foster the development of a global evidence base on the effects of international trade and trade agreements on health;

2.4. to report through the Executive Board to the Sixty-first World Health Assembly on progress made in implementing this resolution.

Australia submitted a number of amendments which several other countries argued amounted to watering down the resolution. After some discussion the Chair deferred the item to the next meeting of the EB (January 2006).

A revised resolution was submitted to the EB in January 2006 for forwarding to the WHA. Khor and Shashikant (2006) reported that the decision to adopt the revised resolution was taken without discussion. "It is understood that the final document ([EB117.R5](#), [(EB 2006)]) had already been negotiated by some member states prior to its being introduced and adopted on Wednesday".

The draft resolution (EB117.R5) was forwarded to the WHA in May 2006 where, after a minor amendment it was adopted. During the debate (WHA 2006) the draft resolution was supported by all of those who spoke although the USA "cautioned the Secretariat on its technical competency to advise Member States accurately on the potential implications of trade rules from a public health perspective. Any information on best practices in trade negotiations that WHO provided had to be unbiased and evidence-based and had to be cleared with WTO and WIPO. To the extent that such work did fall within the Secretariat's mission, mandate and expertise, it must provide the Member States with information that was accurate and fairly represented the different views of Members." It is worth noting that there is no mention of intellectual property in WHA59.26, apparently (according to an informant to this study) in deference to the opposition of the USA to any reference to the impact of intellectual property rights on access to health care. This did not stop the US delegate from requiring clear its work on trade and health with WIPO. The US delegate did not require that WHO work with either UNCTAD or UNDP in its work on trade and health.

Implementation of WHA59.26

A mix of activities driven from Geneva and from some of the regional offices has followed the passing of A59.26 although it is not clear that all of them were directly as a result of the resolution. We shall review the implementation of WHA59.26 in relation to Headquarters first and then the regional directorates of WHO.

Headquarters

Trade issues are never very far from the kinds of issues that preoccupy WHO in Geneva: access to medicines, innovation for neglected diseases, the International Health Regulations, non-communicable diseases, health workforce, etc.

Rather than attempt an exhaustive review of WHO (Headquarters) engagement with the trade health interface in the six years since 59.26 was passed we shall review a number of specific episodes all of which offer somewhat different perspectives on the effectiveness of WHO in the trade/health field and on the barriers it faces:

- the recall of Dr William Aldis
- WHO publications policy
- an unfortunate remark in Bangkok
- the tool for assessing the health implications of trade issues
- the debate over counterfeit medicines
- European seizures of generic drugs in transit
- the drafting of the political declaration of the HLM of the UNGA on NCDs

The recall of Dr William Aldis

The recall of Dr William Aldis from Bangkok provides a kind of shadow play running in parallel to the debates in the EB and the WHA.

In [an article in the Asia Times Online](#) on June 17, 2006 (Williams 2006), three weeks after the adoption of WHA59.26 it was revealed that a senior and widely respected official in the WHO Bangkok office had been recalled to Geneva, on March 24, by the Director General (Dr Lee). It appears that Aldis wrote an opinion piece in the Bangkok Post on Jan 17 (before the Jan EB) urging that Thailand think carefully about the possible implications regarding access to medicines if it proceeded with the mooted bilateral trade agreement with the USA. It appears that a US diplomat visited Dr Lee on March 23 to express his government's displeasure and that Aldis was recalled the following day. What is particularly noteworthy is the claim that press reports regarding Aldis's recall were initiated on the basis of information provided by a US official. "A senior WHO official who spoke to Asia Times Online on condition of anonymity believes that Lee's decision and its subsequent leak by the US government was specifically designed to engender more self-censorship among other WHO country representatives when they comment publicly on the intersection of US trade and WHO public-health policies".

It is self-evident that the TRIPS Plus provisions which the US (and its pharmaceutical corporations) insist on including in US bilateral and regional trade agreements remove certain important flexibilities in the TRIPS agreement, in particular the use of compulsory licensing, and as a consequence have serious implications for the prices of medicines. It appears that Dr Aldis was merely fulfilling the mandate of WHA52.19 'Revised drug strategy' (WHA 1999), which requested the Director General, "to ... cooperate with Member States ... in monitoring and

analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements”.

It is not possible that, in bending to US pressure to discipline Aldis, Dr Lee was unaware of the degree to which the Organisation depends on extrabudgetary funding from the US and the willingness demonstrated by previous US administrations to cut funding to the Organisation over similar issues.

WHO publications policy

In August 2005 the WHO Commission on Intellectual Property Rights, Innovation and Public Health published a [paper](#) in its series, CIPIH Studies, on the use of TRIPS flexibilities by developing countries (Musungu and Oh 2005). It is a specialist paper which goes into the fine detail of TRIPS and national IP legislation. In the first part it reviews all of the flexibilities available under TRIPS and reviews how they have been treated in the implementing legislation in different developing countries. In the second part the paper reviews the IP policies of major industrial countries. In the third part of the paper it reviews a number of bilateral and regional trade agreements and explores how the provisions of these agreements impinge on the use of TRIPS flexibilities.

The paper carries a disclaimer on the front page: “This study has been commissioned by the CIPIH. The views expressed in this study are, however, the views of the authors and do not necessarily represent the views of the CIPIH or the organizations and/or Member States of the organizations to which the authors are affiliated”.

A late draft of the paper was presented to and discussed at a CIPIH workshop held in Geneva on 30-31 March 2005. US officials were present at this meeting and contributed to the discussion. There was no suggestion that the paper should be withdrawn.

In August 2006, 16 months after this workshop but only three months after WHA59.26, Dr William R Steiger, Special Assistant to the US Secretary for International Affairs, [wrote](#) to the Acting Director General of WHO (Gerhardsen 2006) criticising the paper and criticising WHO for having allowed it to be published. It appears that the most offensive part of the paper was the section which reviewed in some detail US policy on IPR in trade agreements, including the institutionalised influence exercised by US corporations over US policy. The paper made some suggestions about the kinds of changes to US policy regarding bilateral

and regional trade agreements which would be needed to facilitate wider use of TRIPS flexibilities by developing countries. Dr Steiger wrote:

“This latest publication ... spuriously characterises the trade policy of the United States as a threat to public health and it makes unnecessarily inflammatory and prejudicial recommendations as to how the United States can improve its trade policies”.

Assessed in relation to the relevant section of the [CIPIH paper](#) (from page 43) it is clear that it is Dr Steiger’s letter which is inflammatory and prejudicial rather than the content of the CIPIH paper. While it is understandable that US officials might be offended at the clarity with which their trade policies were characterised in the paper, what is more offensive is the bullying tone of Dr Steiger’s letter and the proposition that WHO should have censored the paper before allowing it to be published.

Following Dr Steiger’s letter, WHO publications policy was reviewed and redeveloped. The [version circulated](#) for the May 2008 meeting of the EB (WHO 2008) provides that publications that “have policy implications for the Organization and/or raise potentially controversial health-related issues” need to be cleared through the Office of the Director General. This appears to cover many different types of documents and it is self-evident that such restrictions can have significant downsides. In the case in question, the paper was commissioned by a WHO Commission and carried appropriate disclaimers. It would be a troubling prospect if discussion and information papers produced by WHO commissions were to be subject to ODG censorship.

(The flurry over the Musungu Oh paper on TRIPS flexibilities was just one episode in an eventful sequence of policy making in relation to innovation and access and the role of intellectual property in funding innovation. The underlying issue here is whether alternative funding arrangements to support innovation (other than the profit from monopoly pricing) might contribute to lower prices and improved priority setting in medicines innovation. This [story is told in some detail](#) by Velásquez (2011) up to January 2011. Subsequently the 65th Assembly (May 2012) received the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG 2012) which recommended a binding agreement on financing for medicines innovation. The Assembly (WHA 2012) adopted WHA65.22 which called for an open ended member state meeting to progress the recommendations of the report.)

An unfortunate remark in Bangkok

The Bangkok Post, 2 Feb 2007 (Treerutkuarkul 2007) reports the new Director General, Dr Chan, as cautioning Thailand over its move to adopt compulsory licensing for producing generic versions of heart disease and anti-Aids drugs. Dr Chan is quoted as saying, "I'd like to underline that we have to find a right balance for compulsory licensing. We can't be naive about this. There is no perfect solution for accessing drugs in both quality and quantity". The paper reported Dr Chan as saying she truly felt that the pharmaceutical industry was part of the solution to better drug access and that the government should open negotiations with drug firms over the issue.

The remarks came at a time when the Thai government had recently announced that it was planning to initiate a third compulsory license to reduce the costs of treatments for both heart disease and AIDS. The publicity given to the DG's remarks initiated a storm of criticism from AIDS activists and from advocates for the wider use of compulsory licenses.

In a subsequent letter to the Minister for Health in Thailand (Love 2007) Dr Chan clarified WHO's position, saying, *inter alia*:

"WHO unequivocally supports the use by developing countries of the flexibilities within the TRIPS agreement that ensure access to affordable, high quality drugs. This includes the use of compulsory licensing, as described in paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health. The decision whether to issue a compulsory license for a pharmaceutical product is a national one. There is no requirement for countries to negotiate with patent holders before issuing a compulsory licence. As a global community we need to ensure the right balance between the immediate and urgent pressing need to provide affordable medicines to the many that need them, and the need for provide continuous incentives for innovation. It is in this regard that I noted that prior negotiations with industry is a pragmatic approach that may ensure countries have access to high quality medicines at affordable prices. Where there are urgent needs, the bottom line is that people need access to medicines."

Advising Thailand of the need to achieve a balance between access and innovation was probably not the most diplomatic intervention at this particular time and place but the episode highlights the intensity of the politics around IPRs.

The Tool

The most prominent of the direct consequences of WHA59.26 was the Tool for assessing the health implications of trade issues. The tool

appears to have been born at an expert group meeting in New Delhi in March 2007 (Expert Group 2007) which concluded with the following remarks.

The issues that were discussed are complex and multifaceted, but the discussions have helped to enriched the sketchy initial framework. Apart from the numerous technical issues that were raised, the importance of engaging others in this exercise was highlighted. It is important to draw on expertise available in other international organizations, such as the WTO and World Bank, but also to work with other stakeholders such as civil society and the private sector to improve and complete the toolkit.

Attention was also drawn to the fact that countries are at different levels of awareness and even interest in these issues. This should be taken into account during the development of the toolkit.

The participants looked forward to seeing the toolkit, which will be useful to assist Member States in this area. The WHO Regional Offices for South-East Asia and the Western Pacific are ready to contribute to its development by providing inputs and comments.

The forthcoming release of the Toolkit was announced on the WHO Trade & Health website as early as 2009 but as of early 2013 it had not been released. [A leaflet on the Trade and Health website](#) (WHO ND) promises that the Toolkit would be delivered by 2010 and describes what it will offer. The leaflet refers to the importance of trade agreements in shaping the conditions for health and to the resolution A59.26. It describes the purpose of the tool and the processes of field testing which were then in progress.

In their excellent collection on trade, food, diet and health, published in 2010, Hawkes and her colleagues (Hawkes, Blouin et al. 2010) refer to an unpublished manuscript prepared for WHO in 2009 entitled "Toward building a national strategy on trade and health: a diagnostic tool for policymakers".

It is appears that either the Secretariat leadership has had no enthusiasm for the proposed Toolkit or that there were no donors who wanted to invest in the proposed Toolkit or both. Recent advice is that work on the Toolkit is progressing although constrained by lack of resources and may be published during 2013.

Defining 'counterfeit' medicines

The roots of the debate over counterfeit medicines lie well before the passage of WHA59.26 but the controversy continues to the present.

At the heart of the debate is a definition of counterfeit medicines adopted by WHO (in a meeting cosponsored by the International Federation of Pharmaceutical Manufacturers and Associations, IFPMA) in

1992 (Shashikant 2010). This definition (see [pages 11-19 of Shashikant \(2010\)](#) for an extended discussion) confuses, within the concept of 'counterfeit', two separate issues: the IP status of the medicines in question and their quality, safety and efficacy (QSE). Given the active participation of the pharmaceutical industry in both the original definition and the 2008 revision there are grounds for speculating that this definition was deliberately constructed in order to achieve this outcome.

In the world of public health the manufacture, distribution and sale of medical products which are compromised with respect to quality, safety or efficacy is, or should be, a crime defined in therapeutic goods legislation. It is the role of national drug regulatory agencies (or in some cases regional) to prevent, detect and prosecute the manufacture, distribution and sale of QSE compromised drugs. (It has been the responsibility of WHO to support the development and operations of drug regulatory bodies. WHO's performance in this respect has suffered, like many of its functions, from the continuing donor chokehold.)

In the world of intellectual property 'counterfeit' refers to an imitation of an original which breaches intellectual property rights in the relevant jurisdiction (WTO 2013)¹¹. Breaches of IP law are civil wrongs which require the offended party to bring an action against the alleged counterfeiter under the laws of the relevant jurisdiction. In most jurisdictions it is a civil wrong but not a crime. It would be very much in the interests of innovator pharmaceutical industry to convert breaches of IP law from a tort to a crime and to harness the combined resources of the police and of national drug regulatory agencies in policing such crimes. (In North America mail order pharmaceuticals from Canada to the USA are a continuing cause of concern for US based pharmaceutical corporations. However their angst would be much greater if Indian generic companies were to establish similar mail order services for the rest of the world. It appears that the need to establish a regime which can protect consumers (or perhaps corporations) from world-wide internet provision has been a significant factor in the movement for anti-counterfeiting action.)

In many countries there are circulating medical products which are substandard with respect to quality and/or are not be safe and/or are not efficacious. These are a real danger to public health and it is the job of drug regulatory agencies to prevent and detect and prosecute those involved. In many countries there are medical products circulating which are of good quality, are safe and are effective but which have not been

¹¹. The WTO defines counterfeit as the 'Unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered, with a view to deceiving the purchaser into believing that he/she is buying the original goods'.

licensed by the company which, in certain jurisdictions, owns IP associated with such products. The proposition that drug regulatory agencies should be involved in policing intellectual property claims in these circumstances is highly contentious. The proposition that QSE compromised medical products are in some sense the same as unlicensed products and that they can be treated in the same ways would be bizarre if it did not make such commercial logic.

The formation of IMPACT (the International Medical Products Anti-Counterfeiting Taskforce) in 2006 (IMPACT 2011) has involved WHO working closely with the pharmaceutical industry. IFPMA representatives chair several of the committees of IMPACT and the industry provides financial support. (IMPACT was initially conceived as a step towards a framework convention on counterfeit medical products (WHO Health Technology and Pharmaceuticals 2006). It is a surprise to find a unit of WHO advocating for something as significant as a framework convention without any mandate from the governing bodies.)

One of IMPACT's principal strategies has been to encourage countries to adopt the IMPACT definition of 'counterfeit' in their therapeutic goods and IP legislation. For example Kenya in 2008 (Shashikant 2010) adopted an anti-counterfeiting law which defines counterfeiting very clearly in terms of intellectual property (even covering situations where the intellectual property rights in question do not exist under Kenyan law). A second strategy has been to undertake a 'communications' campaign to raise public and professional concern regarding the term 'counterfeit', through emphasising the public health risks of QSE compromised medicines while promoting legislative changes which ensure that medical products which are not licensed (by a corporation who may not necessarily hold IPRs in this jurisdiction) are also included in the sweep.

The controversy over IMPACT erupted after a number of seizures by EU authorities of medical products in transit in European ports. These were medical products originating in India and bound for South America; products which were not patented in either India or the destination country and which were only transiting through those ports. The EU seizures served to raise awareness in developing countries and among treatment access activists regarding the anti-counterfeiting movement, including the Anti-Counterfeiting Trade Agreement (ACTA), IMPACT (and WHO's close involvement with IMPACT) and the EU regulation under which the in transit seizures had been authorised.

As a consequence, when a Secretariat report and a draft resolution were brought to the World Health Assembly (without having being

considered by the Executive Board) there was considerable concern expressed and the draft resolution was rejected.

Following this debate there was considerable criticism of the Secretariat for the closeness of its relationships with the pharmaceutical industry in IMPACT. Since then a sequence of reports, discussions and resolutions in the EB and WHA under the clumsy rubric of substandard/spurious/falsely-labelled/falsified/counterfeit medical products (or SSFFCMP) have led to the establishment of a 'member state mechanism' (WHA 2012) to address QSE compromised medical products (and which met for the first time in Buenos Aires in November 2012).

There may be some lessons from this saga which are of relevance to WHO's effectiveness in promoting policy coherence across trade and health. While the problematic definition dates back to well before WHA59.26, the conference out of which IMPACT was formed was held just weeks after the EB adopted the draft resolution which became WHA59.26 and WHO's website still carries numerous pages which continue to promote the ambivalent definition of 'counterfeit'.

It could be argued that WHO has been unwittingly manipulated by big pharma, partly as a consequence of the Organization's close collaboration with the private sector. However para 10 in WHA 62/14 (WHO 2009) suggests that the Secretariat is well aware of the ambiguity of its definition:

"There is clear consensus among the Taskforce's partners that "counterfeit" medicines should not be confused with issues relating to medicines that are not authorized for marketing in a given country, nor with trademarks or related intellectual property rights issues. Health-related aspects of counterfeit medical products fall within WHO's remit, and the other aspects come under the mandates of other bodies or international organizations."

The continuing defence of a definition of counterfeit which conflates QSE and IP suggests a continuing wish to maintain close relations with big pharma and its nation-state sponsors.

The decision of WHO to host and legitimise IMPACT may in part be attributable to the persuasive power of big money, for an organisation which has been starved of funding. WHO's Essential Drugs Program is of global importance for treatment access and the quality use of medicines but for years it has received little or no extra-budgetary funding. Likewise, WHO has been trying for years to support the development and operations of national drug regulatory agencies, again with very limited funding. Against this background the prospect of real money to support

the development of drug regulatory systems would have been very attractive.

It appears that the relevant cluster has been allowed considerable autonomy during the period in review. During the early 2000s WHO clusters and regions were encouraged to explore the interests of possible funding partners as a solution to the Organization's financial difficulties. Against this background the compromises involved in WHO's work with IMPACT are understandable although not admirable.

The political declaration of the HLM of the UNGA on NCDs

The High Level Meeting within the UN General Assembly on NCDs is a huge achievement for WHO, the DG and the advocacy groups who have driven this agenda with passion and commitment.

However, the Political Declaration (UN General Assembly 2011) does not suggest that WHA59.26 was very influential in the drafting process. There are three mentions of trade in the Declaration, two of which refer to the use of TRIPS flexibilities in ensuring treatment access for people living with chronic diseases. The remaining mention of trade refers to 'industry and trade' in a list of thirteen other sectors with which the health sector needs to collaborate. 'Regulation' is referred to twice; first, as one of a long list of strategies for reducing risk factors; and second, in a list of areas of health care where best practices need to be more widely implemented.

The general tenor of the Declaration, in terms of addressing the political and economic determinants of NCDs, is reflected in para 54: "Engage non-health actors and key stakeholders, where appropriate, including the private sector and civil society, in collaborative partnerships to promote health and to reduce non-communicable disease risk factors, including through building community capacity in promoting healthy diets and lifestyles". The Declaration calls upon 'the private sector' to: "Take measures to implement the World Health Organization set of recommendations to reduce the impact of the marketing of unhealthy foods and non-alcoholic beverages to children, while taking into account existing national legislation and policies". Given the careful work of scholars such as Fidler (2007; Fidler 2010), Chigas et al (2007), Lobstein et al (2010), L'Abbé et al (2010), Atkins (2010) and Magnusson and Patterson (2011) who have demonstrated how trade agreements and international law could be used to assist in the control of NCDs the reliance on corporate social responsibility and the absence of any commitment to regulatory strategies is stark. If regulation with a feather is what is needed this Declaration meets the call.

Clearly there is much that can be achieved through partnerships and voluntary action but it is self-evident that much more could be achieved through a different approach to trade agreements. It is hardly surprising nor a new finding that transnational food corporations lobby against policies which might impact on their profits nor that governments, sensitive to threats of unemployment, reduced export earnings and reduced returns on foreign investment, provide diplomatic support to the food corporations. Nevertheless, for countries like the Pacific Islands who are facing a tsunami of NCD morbidity, the failure to mobilise all effective strategies is a betrayal.

Cohen (2011), writing in the lead up to the meeting reported that the proposal for a target of below 5g per day for dietary salt had been rejected during the drafting negotiations. She describes the close involvement of the processed food and beverage industry in the negotiations under the rubric of 'civil society'. Not surprisingly, a group of non profit NGOs, also belonging to 'civil society' submitted a petition to the UN calling for a code of conduct to protect public policy making from conflicts of interest (Lincoln, Rundall et al. 2011).

The story of the Political Declaration of the HLM in the UNGA on NCDs concerns the UN rather than WHO specifically. Nevertheless it is usefully included in this review of the implementation of WHA59.26 simply because it underlines the nature of the environment within which policy coherence across trade and health is to be achieved. In no sense can WHO be 'blamed' for the environment within which it works but there is a need for careful strategic thinking if effective policies for population health are to be implemented.

Regional offices of WHO

WHO is a large and sprawling institution with regional offices exercising considerable autonomy. The problems being addressed in each of the regions and the politics of the regional committees differ widely.

These differences are evident in a review of the role of the regional offices in the implementation of WHA59.26.

EURO

There is no evidence of regional action at the trade health intersection on the EURO website with two interesting exceptions.

[Resolution EUR/RC60/R6](#) ('Health in foreign policy and development cooperation: public health is global health', EURO 2010) deals with the interface between foreign policy and development cooperation from the perspective of rich world countries. The resolution calls on member states

to consider health in the formulation of foreign policy and to promote policy coherence between health and foreign policy and development cooperation and it calls on the regional director to support member states in these directions.

The other exception is an article in Eurohealth entitled '[The effects of parallel trade on affordable access to medicines](#)' (Glynn 2009) which compares access to medicines and drug company profits across Europe for different scenarios, including a single price for the whole EU or differentiated prices adapted to buying power. The author argues for 'optimally differentiated prices' and considers the regulatory requirements needed to control leakage under such a regime.

These two mentions encapsulate the rich country perspective: first, a recognition that the health of L&MIC peoples is influenced by foreign policy, clearly including trade, as well as international assistance; and second, a concern for the profitability of European enterprises. The need to balance these concerns was articulated clearly by Dr Mihály Kökény, the former chairman of WHO's Executive Board, who was [quoted in late 2011](#) (Kökény 2011) as saying:

The healthcare industry has a significant part in preserving EU's competitiveness in the world markets. Just in 2010 only the research-based pharmaceutical industry invested an estimated €27 billion in R&D in Europe. It directly employs 640,000 people and generates three to four times more employment indirectly – upstream and downstream – than it does directly.

These reasons led to an increasing EU interest in international health and WHO reform. In May 2010 the Foreign Affairs Council Meeting adopted conclusions on the EU role in global health. This document recognises WHO's key mandate in the global health arena by supporting "the leadership of WHO at global, regional and country level, in its normative and guidance functions addressing global health challenges as well as in technical support to health systems governance."

The statements of the EU Presidency during the subsequent sessions of the WHO governing bodies encourage changes in the same way: "the efforts to make WHO fit for the future had the European Union's full backing...The time is right for consolidation rather than expansion; hence the importance of WHO's efforts to increase efficiency, effectiveness, accountability and transparency..."

[...]

In general, through coherence between an increased number of policy arenas for health, EU and WHO together can have a strong European voice in global health governance and be an advocate for sustainable European commitment to global health."

EMRO

There is very little about policy coherence across trade and health on the EMRO website. It appears that there has not been a matching resolution at the regional level, corresponding to WHA59.26.

The references to trade on the website are mainly about tobacco control, with some references to the IHRs and trade, and some references to restrictions on travel and trade associated with communicable diseases.

The somnolence of EMRO stands in sharp contrast to the well known impact of the Jordan US FTA on the price of medicines in that country (Abbott, Bader et al. 2012).

AFRO

Following the 59th WHA (May 2006) the Regional Director for the African Region prepared for the Regional Committee (56th from 28 Aug – 1 Sept, 2006 in Addis Ababa) a report entitled 'Poverty, trade and health: an emerging health development issue' (AFRO 2006). This report is interesting for a number of reasons. It makes no mention of the WHA59.26 although it does recommend that member states ensure that there are cross portfolio mechanisms to promote the "harmonization of work between ministries responsible for health, trade, commerce and legislation so as to ensure that public health concerns are duly taken into account". The term policy coherence does not appear in the report. The document presents the case for trade liberalisation:

"Trade liberalization can be a powerful tool in fostering development, reducing poverty and improving health. Growth in trade through trade liberalization has been found to induce a significant increase in productivity. Pressure on domestic industries by competing imports stimulates technological innovations and productivity. Trade openness contributes significantly to productivity gains and impacts on a country's risk premium. The major gains to developing countries accrue from improved allocative efficiency; access to superior technology and intermediate inputs; greater variety of goods; advantages of economies of scale and scope; increased domestic competition; and creation of growth externalities through knowledge transfers."

The benefits of trade liberalisation in this report are unqualified. There is no reference to the conditions under which trade liberalisation does reduce poverty and promote growth or the conditions under which it is more problematic. There are no references to the differences between North South versus South South trade. The report appears to focus solely on multilateral trade agreements under the aegis of the WTO. There are no mentions of bilateral or preferential trade agreements, such as the economic partnership agreements (EPAs) between the EU and the ACP

countries although this was a time when there was a vigorous debate taking place in Africa around the implications of EPAs, including the health implications (South Centre 2006; Machededze and Chizarura 2011).

The main focus of the document is on the GATS agreement and the benefits of cultivating regional cooperation in health care delivery through trade liberalisation in health services. There is no argument advanced as to why cooperation in health care delivery among African countries should be constructed as trade liberalisation under GATS in contrast to a more specific program of health care cooperation.

Following the discussion of this agenda item the Regional Committee adopted [AFR/RC56/R4](#) (AFRO RC 2006) which contrasts sharply with the Regional Director's report. The resolution does refer to WHA59.26 and the need for policy coherence. The resolution addresses the public health implications of trade in a much broader and more balanced way, including the importance of making use of the flexibilities inherent in trade agreements, a clear reference to TRIPS.

Even more striking is the contrast between the Regional Director's report (August 2006) and a paper coming out of WHO Headquarters and published in the African Journal of Health Sciences (Agu, Correia et al. 2007) which provides a very clear discussion of the scope for strengthening health cooperation in Africa through the regional economic communities. The paper reviews the recommendations of the African Union's Conference of African Ministers of Health regarding regional cooperation for health. The paper considers health cooperation within the New Partnership for African Development (NEPAD, Organization of African Unity 2001) and canvasses a very wide range of strategies and possibilities. These include working on policy coherence across trade and health as well as regional cooperation in health care delivery and resource development.

The Regional Director's to the 58th session of the Regional Committee in 2008 includes a follow up report on Resolution AFR/RC56/R4 (AFRO 2008, page 59) which suggests that most of the regional office's attention has in fact gone to pursuing the trade in health services agenda as well as supporting member states' access to international assistance for health:

“297. Twenty-one Member States received support to undertake preliminary studies on trade in health services. The Regional Office prepared terms of reference for a guide to conducting in depth country studies on trade in health services in the Region.

298. Activities relating to poverty and poverty reduction strategies continued to be a key aspect of country approaches to development. Technical support was provided to countries to develop or improve the health component of their Poverty Reduction Strategy Papers.

Participants from Cameroon, Kenya, Mozambique, Rwanda and Uganda attended a capacity building workshop on health, human rights and poverty reduction strategies. Most of the countries in the Region participated in at least one of three capacity-building workshops on health, poverty reduction and economic development organized by the Regional Office. Technical support was also provided to six countries as regards health SWAps, MTEF and the costing of the health component of PRSPs.”

There appear to be no further reports on progress with respect to this resolution to subsequent regional committee meetings (despite the request, in para 3(e) of the resolution, for the regional director to report every two years).

The picture which emerges from this review is a significant degree of policy incoherence with divergences between the headquarters office of the WHO secretariat and the African regional office; divergences between regional office priorities and those of the regional committee; and a certain distance between work being undertaken through the regional economic communities and the regional office of WHO. The priorities of the regional office may be in some degree influenced by the priorities of its donors. It is not clear from the material on the website who the donor was who supported the ‘preliminary studies on trade in health services’.

SEARO

SEARO appears to have taken the trade and health interface more seriously than some of the other regions.

We have cited the speech by Dr Rafei in 1999 (Rafei 1999) in which he provides a comprehensive survey of the main issues linking IP and access. We have also noted the inter-regional workshop on trade and health which was hosted by SEARO in 2004 (SEARO 2007) although the proceedings were not published until 2007. The regional office also has a very useful webpage with [FAQs about IP and Trade and Health](#)

The regional committee adopted a resolution on International Trade and Health in 2006 following the adoption of WHA59.26 (SEA/RC59/R9, SEARO 2006). The resolution basically covers much of the same ground as 59.26 but also includes reference to utilising the flexibilities in TRIPS and the strengthening of national regulatory agencies.

In 2009 SEARO also launched [a reference guide](#) in international trade and health (SEARO 2009). This is a comprehensive and technically informed guide for public health officials engaging with trade policy. It includes briefing notes on:

1. Globalization, TRIPS and access to pharmaceuticals
2. TRIPS, intellectual property rights and access to medicines

3. Data exclusivity and other “TRIPS-plus” measures
4. Innovation for diseases that mainly affect developing countries: issues and ideas
5. Country experiences in using TRIPS safeguards
6. Implications of bilateral free trade agreements on access to medicines
7. GATS and health related services

It also included the text of Selected Resolutions from both SEARO Regional Committee meetings and the WHA.

SEARO includes both India and Thailand who have been among the most articulate advocates for attention to trade health policy coherence. It seems that the regional office has been happy to provide support.

WPRO

WPRO has been concerned about trade and health since well before 2006, primarily in the context of NCDs in the Pacific. We have mentioned the [2003 WPRO report](#) on the use of domestic law in the fight against obesity (WPRO 2003) which canvasses in some detail the intersections between regulation for health and the Agreements on Agriculture, SPS and TBT.

One of the more contentious issues has been the attempts of some Pacific Island countries (in particular Samoa) to restrict the import of turkey tails (largely from the US) and Fiji and Tonga to restrict the import of mutton flaps (from Australia and New Zealand). Thow and her colleagues (Thow, Swinburn et al. 2009) documented the decision making in Samoa, Fiji and Tonga up until the finalisation of their paper, published in 2009. An update is provided in a 2011 report from Bloomberg (2011).

Thow describes how the Government of Samoa banned turkey tail imports in August 2007¹².

“The ban was a response to concern over both the impact of fatty meat on health and the ‘dumping’ of perceived ‘low quality’ food on the market. Samoa has very high rates of non-communicable diseases (NCDs), and medical treatment costs are also high. Fatty meat consumption is perceived as a major risk factor for NCDs, and the Ministry of Health has actively raised awareness among policy makers of the importance of healthy diets for disease prevention. In relation to dumping, there has been longstanding awareness and concern regarding the import of large quantities of cheap, perceived ‘low quality’ food.”

“As a direct outcome of the ban, turkey tail imports ceased from August 2007. As turkey tails imports were duty free, banning them did not cause a

12. References deleted from the excerpts from Thow et al.

loss of government revenue. The Ministry of Commerce and retailers reported receiving only a few consumer complaints – there was a slow decrease in turkey tail supply and customers knew that they were banned. Retailers and wholesalers did not report any loss of profits from the ban...”

Thow reports that Samoa received a request from the USA for further information about the ban. “Samoa was at that stage in the process of acceding to the World Trade Organization (WTO) ... concerns were raised by public servants that the ban was never ‘justified’ appropriately.”

A subsequent [report from Bloomberg](#) (Gale 2011) updates this story.

“After a 13-year wait, the South Pacific island nation of Samoa should win approval to join the World Trade Organization next month after dropping its ban on turkey tails. The WTO welcomed the nation, with a population of about 193,000 (a bit more than Knoxville, Tenn.) once Samoa agreed to end its ban on the fatty poultry scraps and impose import tariffs instead. That’s good news for U.S. turkey farmers, who will regain a market for the low-value trimmings that often end up in pet food, says Roman Grynberg, a trade official for the Pacific region until 2009.

“For Samoa, one of the world’s most obese nations, the deal is a mixed blessing. “These are the contradictions we have to face—where health is compromised for the sake of trade and development,” says Palanitina Tupuimatagi Toelupe, Samoa’s director general of health. The U.S. food industry sees the issue differently. “We feel it’s the consumers’ right to determine what foods they wish to consume, not the government’s,” says James H. Sumner, president of the USA Poultry & Egg Export Council.

“Samoa negotiators defend ending the ban as the only way to enjoy the increased trade and lowered costs of imports that WTO membership confers. “It filters down to the normal customer who will now have access to a wider variety of goods,” Namulauulu Sami Leota, president of the Chamber of Commerce, told the Samoa Observer newspaper. Reaching an agreement “was not an easy task,” added Namulauulu, who was involved in the final talks. Keith Rockwell, a spokesman for the WTO in Geneva, says the ban “was an issue on which Samoa took quite a tough line.”

Thow et al also describe how Tonga considered a similar ban on the import of lamb flaps:

“In early 2004, the Tongan Minister for Health and other members of Cabinet offered in-principle support to the development of a draft cabinet paper restricting mutton flap imports. The paper was commissioned by the WHO Western Pacific Regional Office as a component of the recently developed NCD strategic plan, and the work was carried out by a team from Deakin University, Australia. The resulting draft ‘Fatty meat import quota Act’ was part of a

broader paper designed to support the Government of Tonga in developing and implementing legislation to support healthy food consumption. However, the Act was not submitted to Cabinet due to concerns that it would complicate Tonga's negotiations for accession to the WTO, which was in process at the time.

"The proposal was to apply an import quota (restriction on volume imported) to any product that had >40% energy from fat, was readily identifiable by import coding, and contributed significantly to fat and saturated fat consumption of Tongans. At the time, only mutton flaps fulfilled all criteria. The authors calculated that replacing 50% of mutton flap consumption with the same weight of fish would reduce energy intake by a clinically important magnitude of about 400 kJ/week per person (approx 100 kCal). An import quota was chosen as the strategy because availability appeared more significant than price in determining consumption. [...]

"The detailed proposal included strategies for policy implementation and monitoring. The proposal acknowledged the potential issues with the WTO inherent in restricting trade through the use of a quota, but concluded that the restriction was justified because of the obvious health effects. High levels of mutton flap consumption, linked to rising rates of diet-related chronic disease, had been perceived as a problem in Tonga for at least a decade. [...]

The proposal was first articulated at an NCD workshop in October 2003, at which "participants recommended reducing availability of imported fatty meats as a priority activity to prevent obesity". The Minister for Health supported this recommendation and raised the proposal at a Cabinet meeting. However, concerns about the policy's acceptability in light of ongoing WTO accession negotiations by the Ministry of Labour (focus for WTO negotiations) resulted in the submission of the paper to Cabinet being postponed. Under WTO trade rules quotas are perceived as highly trade distorting because they prevent (international) supply from responding completely to (domestic) demand. Additionally, the fact that Australia and New Zealand are the main source country for flaps – as well as being significant sources of aid for development – means that Tongan policy makers on the WTO accession committee were concerned that proposing an initiative to reduce the supply of mutton flaps would reopen negotiations with Australia and New Zealand.

[Bloomberg](#) (Gale 2011) provides further detail:

"Fiji and Tonga waged a fight similar to Samoa's a decade ago when they tried to curb imports from New Zealand and Australia of an especially fatty cut of meat known as lamb or mutton flaps. Fiji banned flaps in 2000. When Tonga considered imposing a quota, New Zealand embarked on a campaign against it, says Timothy Gill, principal research fellow at the University of Sydney's Boden

Institute of Obesity, Nutrition, Exercise, and Eating Disorders. “We couldn’t work out why there was such a big thing about a relatively small segment of the market,” Gill says, adding that the New Zealanders pressed their case at a Commonwealth Health Ministers meeting in Christchurch in November 2001. “From the Prime Minister down, they were all there lobbying.”

“Trade bans on selected items are unlikely to be effective in addressing obesity and health issues,” a spokeswoman for Tim Groser, New Zealand’s Minister of Trade, said in an e-mail. [...]

“Tatafu Moeaki, Tonga’s Secretary for Labour, Commerce and Industries, says that after studying the issue in more detail, policymakers found that higher import duties on the flaps wouldn’t dent demand enough to improve public health. Moeaki says Tonga, which joined the WTO in 2005, is now preparing food standards that will determine which items fall outside a healthy range and warrant higher taxes to deter consumption. He says the importing nations have been left to figure out which foreign goods are detrimental to health—a “relatively expensive” process for a small country.”

Further insight into the stories from Samoa and Tonga comes from the debate within the WPR Regional Committee in 2008 over the [WPR Regional Action Plan for NCDs](#) (WPRO 2009). The draft regional action plan submitted to the Regional Committee includes a passage (page 13) which says that Member States shall “engage with other Member States and relevant regional and international bodies to address NCD risk factors and disease issues that cross national borders. As examples, consider the public health impact on respiratory health during cross-country discussions on haze control, and *incorporate health impacts of unhealthy products in trade agreements*, such as those arising from the Association of South East Asian Nations (ASEAN) and the Pacific Island Countries Trade Agreement (PICTA)” [emphasis added].

Further, on p 33, the draft Regional Action Plan included among the recommended actions for WHO: “assist Member States to establish and use cross-country alliances, networks and partnerships for NCD capacity-building, advocacy, research and surveillance (e.g. Alliance for Healthy Cities, MOANA). Cross-country alliances can also facilitate unified responses to transnational issues that affect non-communicable diseases, *such as trade issues and global marketing of unhealthy lifestyles*. For example, follow-up on the conclusions of the Meeting of the Ministers of Health of the Pacific Island Countries in Vanuatu, which call for engagement with the food and trade sectors to ensure that the health impact of trade agreements on diet is minimized” [emphasis added].

The intervention of the US in this [debate](#), intervening by virtue of its status as a colonial power in the Pacific, provides some insight into the underlying dynamics (WPRC 2008, page 147-8).

Mr Villagomez (United States of America), commenting that effective control of chronic diseases required wise programming and wise use of resources, said that the proposed Regional Action Plan overlapped with a number of others that had been adopted globally. Rather than duplicating those initiatives, the Regional Office should ensure that Member States fulfilled their obligations to implement the global strategies. They were relevant throughout the Region, for all political, language, cultural and at-risk groups; therefore, their implementation would be effective and sustainable and improve health at country level.

Globalization and urbanization were important factors in the treatment and surveillance of non-communicable diseases, *but they were not "conduits for the promotion of unhealthy lifestyles"*. Furthermore, the document advocated transnational environmental control by regional forums such as the Association of South East Asian Nations (ASEAN), whereas the Regional Office's primary role was to make health-based interventions. The key to reducing morbidity and mortality from non-communicable diseases was prevention. The Regional Office should focus on surveillance, setting norms and standards and designing models for the organization of care. Prevention should be done at the community or even individual level, whereas the document focused on interventions by governments, industry and nongovernmental organizations. *Diet, physical activity and health behaviour involved complex personal choices and individual priorities. The Regional Action Plan should address those complexities and the responsibility of individuals in changing their behaviour.* [Emphasis added]

As a consequence of Mr Villagomez's intervention a new clause was added to the resolution adopting the regional action plan, acknowledging the importance of personal responsibility for individual behaviour. However the Regional Action Plan was adopted by the Regional Committee.

Many of the same issues came up at the Pacific Food Summit held in April 2010 in Port Vila, Vanuatu¹³. Out of the Food Summit came '[Towards a Food Secure Pacific: Framework for Action](#)' (Food Secure Pacific 2010). This Framework includes a number of practical recommendations,

Strategy 1/4.5: Ensure food security is a priority consideration within Free Trade Agreements such as PICTA/PACER, and that resources

13. Organised by WPRO with the UN Food and Agriculture Organization (FAO), the Global Health Institute (GHI) (Sydney West Area Health Service), the Pacific Island Forum Secretariat (PIFS), the Secretariat of the Pacific Community (SPC) and the United Nations Children's Fund (UNICEF).

promoting free trade agreements support progress towards a food secure Pacific.

Strategy 2/1: Strengthen relevant legislative frameworks and harmonize standards, based on internationally-recognized standards in accordance with national needs and international trade agreements.

Strategy 3/1.3: 3. Strengthen capacity in data collection, analysis and dissemination of agricultural production and trade findings as well as develop more robust trade policy formulation and negotiation.

Strategy 3/5.4: 4. Support WTO-consistent, non-trade distorting special measures aimed at creating incentives for smallholder farmers, enabling them to compete on a more equal footing in world markets.

In another context, that of alcohol control, WPRO has also promoted a clear understanding of the intersections between health and trade. WHO's "[Western Pacific Regional Strategy to Reduce Alcohol-Related Harm: How to develop an action plan to implement the strategy](#)" (WPRO 2009) includes a full chapter on international trade and economic agreements.

On the other hand the proposed Trans Pacific Partnership Agreement (TPPA) yields no hits on the WPRO website. The TPP looks set to bring a number of WPR countries (Australia, New Zealand, Malaysia, Singapore, Vietnam, Brunei) together with the US, Canada, Mexico, Chile, Peru in a significant new trade agreement with very significant implications for health. These include TRIPs Plus provisions, ISDS and restrictions on pharmaceutical reimbursement schemes (Gleeson, Tienhaara et al. 2012). The negotiation of the TPP involves small countries with only a few officials confronting scores of specialist negotiators from the rich participating countries. In these circumstances the support of WHO for policy coherence could have made a significant difference to outcomes.

PAHO

PAHO has very little on its website referring to trade or related issues.

The exception is a [report from 2004 on TRIPS and access](#) (Working Group 2004) which contains a number of quite stringent recommendations on negotiating international trade agreements and addressing health in the context of trade agreements. The introduction explains the background to the formation of the Working Group:

"In the Region of the Americas, the amendment of national intellectual property laws has been dictated primarily by the need to ensure that national legislation is compliant with TRIPS. However, a number of bilateral and regional free trade negotiations and agreements have recently been initiated that go beyond TRIPS in

protecting the rights of innovators, and establishing regulations that imply additional restrictions on access to medicines in the countries of the Region”.

The recommendations of the Working Group are very explicit; some examples:

- Negotiate within the framework of the Doha Declaration
- Broadly disseminate the meaning of “TRIPS-Plus” and its implications for access to medicines.
- Do not accept provisions that exceed the provisions of the WTO TRIPS agreement
- Establish transparency in these negotiations. The texts being negotiated should be disclosed during negotiations and not only after they have been concluded.
- Develop the necessary regulatory and production capacity (if feasible) for the utilization of compulsory licenses. This has been an important negotiating tool both in developing and developed countries: for example, in Brazil (medicines for HIV/AIDS) and in the United States (for anthrax, (Ciprofloxacin)). New trade agreements should not restrict their use.
- Instruct officials in patent offices in the application of high standards of patentability to avoid the granting of evergreen patents and spurious or frivolous patents.

It is evident that these recommendations (and there are more) run directly counter to the thrust of the US bilateral and regional trade agreements model. It appears that there have been no further ventures into this territory since 2004.

Expenditure

On publicly available figures it is not possible to estimate the resources flowing to implement WHA59.26 or more broadly on trade health policy coherence. This work is part of WHO’s Strategic Objective 7 (‘to address the underlying social and economic determinants of health through policies and programmes that enhance health equity and integrate pro-poor, gender responsive, and human rights based approaches’) and expenditure on SO7 taken from papers tabled at WHA and RC meetings is summarised in Table 1 below. (EMRO doesn’t seem to report expenditures against PB10-11.)

2010-11 Biennium: Spending on SO 7			
	Spent/committed on SO7 (\$m)	SO7 as % of total for unit	SO7 regional as % of SO7 global WHO
WHO	37.0	1.7	100.0

Africa	7.0	0.7	18.9
Euro	6.0	3.3	16.2
PAHO	14.8	2.8	40.0
SEARO	2.9	0.8	7.9
WPRO	1.8	0.7	4.9
EMRO	-	-	-

Table 1. Spending on Strategic Objective 7 for WHO generally and for five regions. Data taken from documents tabled at WHA65 (May 2012) and RC meetings late 2012 (AFRO 2012; EMRO 2012; EURO 2012; PAHO 2012; SEARO 2012; WHO 2012; WPRO 2012).

WHO spent a total of \$37m on SO7 in 2010-11. This was more than previous biennia, presumably because of the 2011 Rio Conference on Social Determinants of Health (SDH) and related activities. The expenditure on SO7 by PAHO would also reflect the extra expenditure on the Rio Conference.

It is evident that most regions spend very little on SO7. This is presumably due to the dependence of WHO generally on donor funding. Expenditure on SO7 for WHO as a whole came \$16m from assessed contributions and \$42m from voluntary contributions. Most regional offices do not publish the AC/VC breakdown at the level of strategic objectives. WPRO is the exception which reports that its \$1.8m total expenditure on SO7 was mainly from voluntary contributions (\$1.6m) with only \$200,000 coming from assessed contributions.

WHO's own evaluation of its effectiveness

WHO Headquarters reports on its own performance in "[Programme budget 2010–2011: performance assessment: summary report](#)" (A65/28, WHO 2012). In relation to Strategic Objective 7 ('To address the underlying social and economic determinants of health through policies and programmes that enhance health equity and integrate pro-poor, gender-responsive, and human rights based approaches') WHO Headquarters reports:

152. Despite increasing global political attention, health inequities continue to grow within and between countries aggravated by rapid urbanization, man-made and natural disasters, economic recession, and unemployment. Tackling inequities in health is a major public health priority.

153. Member States increasingly seek innovative ways to foster intersectoral collaboration on the social and economic determinants of health and see the need to integrate equity-enhancing, pro-poor, gender-responsive and ethically sound approaches into their health

sectors and social policies and programmes. Member States expressed their increased political commitment to this during the World Conference on Social Determinants of Health, held in Rio de Janeiro, Brazil in October 2011. As a result, the demand from Member States for support from WHO has increased sharply and 84 Member States requested technical support this biennium. These approaches have also been integrated into a number of disease-specific programmes across the Organization.

[...]

In relation to Organization-Wide Expected Results (OWER) 7.2 ('Initiative taken by WHO in providing opportunities and means for intersectoral collaboration at national and international levels to address social and economic determinants of health, including understanding and acting upon the public health implications of trade and trade agreements, and to encourage poverty-reduction and sustainable development') WHO Headquarters reports:

Result: Fully achieved

Indicator 7.2.1: Number of published country experiences on tackling social determinants for health equity (baseline 10, target 14, achieved 28).

Indicator 7.2.2: Number of tools to support countries in analysing the implications of trade and trade agreements for health (baseline 8, target 9, achieved 9).

The result for Indicator 7.2.2 is particularly surprising given the continued delay in producing the trade assessment tool, discussed earlier. It appears that the 'tools' referred to have not been published on the web. The report elaborates on its self-assessment in the following terms:

156. Countries are embarking on changes to their intersectoral governance practices to increase their impact on health equity, at both national and international levels. New public health legislation addressing health equity and health-in-all-policies has been introduced in some countries. At global and regional levels, WHO promoted the development of international consensus on the key elements of a health-in-all-policies approach through the Adelaide Statement on Health in All Policies and the Rio Political Declaration on Social Determinants of Health.

157. Globalization and trade have a major influence on health outcomes. During the biennium, WHO continued to support Member States in capacity building for assessing trade and its impact on health outcomes. Several publications, including books, briefing documents and fact-sheets were produced during the biennium. WHO has now established an active trilateral cooperation with WIPO and WTO at global level and the three organizations have started to organize a series of joint technical symposiums on issues covered by the Global strategy and plan of action on public health, innovation and intellectual property."

In view of the evidence assembled earlier in this paper, this self-assessment appears to be unduly positive. The exclusion of UNCTAD from the 'active trilateral cooperation' is unfortunate given the fact that UNCTAD is the UN system's own expert body on trade.

Conclusions regarding the implementation of WHA59.26

WHA59.26 sets out an ambitious vision: trade agreements which support health development. Against this vision, the effort which has gone into implementation of WHA59.26 is completely inadequate. This is self-evident. What call for closer attention are the reasons why WHO has failed to implement this resolution and what could be done to strengthen WHO's effectiveness in this field.

We have reviewed the implementation of WHA59.26 by WHO Headquarters through a number of episodes. The story of the recall of Dr Aldis tells us a bit about the willingness of the US to exert pressure on the DG to prevent criticism of its trade policies. It has been suggested that the leaking of the details, allegedly by a US official, one month after the adoption of WHA59.26, was a deliberate warning to other WHO employees.

The story about the CIPIH research study and the subsequent publications policy tells us something further about the pressure that the US is able to exert over WHO, in this case demanding that the DG censor any criticism of its trade policies from within the Secretariat. Clearly, the status of the US as a major donor to WHO lends weight to such demands. While the CIPIH study had been widely discussed from March 2005 it was not until August 2006 that Dr Steiger wrote to the (new) DG demanding more effective censorship. It is possible that this eruption was intended as a further warning to WHO regarding the implementation of WHA59.26 (adopted three months earlier).

It is difficult to make sense of the unfortunate remark in Bangkok. It seems clear that it was a diplomatic mistake; perhaps the worst place and time to make such a comment about balancing access against innovation. The naiveté of the DG in this matter may reflect the policy environment within which she had been working. As comes clear in the later story regarding IMPACT, WHO had been working closely with the IFPMA in the months before the meeting in Bangkok (IMPACT was officially launched in November 2006 (Zucker 2006), just two months before the meeting in Bangkok).

The story of the definition of counterfeit and the conflation of IP with QSE dates back to well before WHA59.26 but the Secretariat continues to defend this definition to this day. This is clearly not naiveté. This is a

matter on which the IFPMA, its members and nation-state supporters, have a clear agenda which is directed to transferring responsibility for the policing of alleged breaches of IP from the putative owner of the IP to the state. This agenda has been advanced in trade agreements through 'data linkage' as well as through IMPACT. (Under data linkage provisions in bilateral and regional trade agreements drug regulatory authorities are required to fully investigate IP status, including communicating with putative owners of such IP, before giving marketing approval.)

The story of the Tool is quite disgraceful. The idea of health impact assessment of trade policy is a cautious, technician approach to the implementation of WHA59.26. It is not clear why the process was allowed to grind to a halt; perhaps lack of money, perhaps lack of enthusiasm. In view of the earlier warnings from the US and the generosity of the EU in supporting IMPACT the failure to proceed with the Tool suggests the victory of pragmatism over integrity.

The final story, regarding the negotiation of the UN Political Declaration on NCDs, simply serves to show that the barriers to policy coherence include the vested interests and political muscle of transnational food corporations (and their nation state sponsors) as well as transnational pharmaceutical companies. This is reality and not something to be wished away. The challenge is to develop and implement a strategy which can progressively change the balance of forces around such decisions.

An informant with extensive experience in the governing bodies, in commenting on these episodes, emphasised the importance of the negotiations at home and in Geneva long before the draft resolution is considered by the Board or the Assembly.

This lobbying of governments by industry starts way before an item gets to the WHA. I have seen correspondence from the liquor industry ... reporting their off-the-record chats with the [...] government outlining the 'acceptability to the liquor industry' of certain WHA resolutions long before they are tabled.

This informant commented that many member state representatives were quite explicit about defending the interests of their industries. A US delegate who opposed any reference to equity in the PHC resolution confided later that he was in Geneva to represent American companies, and equity was not in their interests. Similar concerns with corporate interests were evident (the informant added) in the EU position on the breast feeding code (WHO 1981) and the US and Brazil insistence on removing a scientific reference to safe sugar levels from the Global Strategy on Diet, Physical Activity and Health (WHO 2004).

Another informant commented that WHO had been very late in responding to the WTO agreements and has still not got to grips with the various bilateral and regional agreements.

“In many ways, WHO missed the boat with the TRIPS agreement. It is now missing the boat with bilateral and regional trade agreements forging ahead. WHO is like a guest arriving chronically late at major parties - and then complaining that all the food is gone!”

In relation to the regional offices and regional committees the picture is very varied. EURO approaches the question of policy coherence with one eye on corporate revenues and the other on its role as a donor. The substantial support from the EU for IMPACT suggests an interpretation of policy coherence as referring to the interests of big pharma and the policies of WHO.

EMRO does not seem to have done anything by way of following up WHA59.26.

AFRO appears quite conflicted with the Regional Director pursuing a ‘trade in health services’ policy agenda and the Regional Committee asking for more substantive action on trade and health. It may be that the Regional Director is more sensitive to donor interests than the Regional Committee.

SEARO has been working on policy coherence across trade and health for a long time. It is likely that the content of WHA59.26 reflects in part the experience of SEARO nations in trying to achieve policy coherence at the national level. The region does not include any ‘advanced industrialised’ countries and large countries such as India, Thailand, Indonesia and Bangladesh may be less subject to donor pressure, better advised technically, and more conscious of the costs of medicines than in some other regions.

WPRO has recognised the disaster that is NCDs in the Pacific and, despite the bluster of the US, it has continued to promote understanding of trade health policy coherence in the Pacific. However, it has not been particularly active in relation to the proposed Trans Pacific Partnership Agreement nor the various configurations of ASEAN. The WPR is a very heterogeneous collection bringing together Japan, China, Australia and New Zealand, Vietnam and Philippines, as well as the Pacific Island countries.

PAHO appears to be paralysed in relation to the trade and health interface by the deep divisions between the countries of Latin America and the USA.

Published information regarding WHO expenditure does not allow for a precise estimate of resources directed to supporting trade health policy coherence but it is clearly miniscule in comparison to the health gains or losses which are at stake. This is clearly a reflection of the donor chokehold over WHO's budget. The Secretariat's own evaluation of its effectiveness in fulfilling the mandate of WHA59.26 is overly optimistic, indeed incredible.

Barriers and enablers

It is useful to consider the pre-conditions, enablers and barriers in terms of

- institutional barriers,
- political dynamics,
- disabilities of WHO, and the
- wider financial and ecological crisis of capitalism.

Institutional barriers and enablers

These are the easiest barriers/enablers to address. They include:

- knowledge and expertise; health people require some knowledge of trade law and economics and access to specialist advice when necessary; trade people need to be aware of the significance of trade influences on health;
- institutional mechanisms at the national level for bringing trade and health people together; including mechanisms to address the cultural barriers to communication across silos;
- institutional mechanisms to support consultation and cooperation between regional economic communities and the regions of WHO; lack of congruence between these structures can lead to dispersion of effort;
- trade-health expertise in WHO including regional offices; this is a mixed picture because there have been individuals within WHO (headquarters and regional offices) who have provided outstanding leadership in technical analysis and in education and dissemination;
- stronger institutional links with UNCTAD and UNHCHR;
- personal links with non-government, not-for-profit sources of expertise, including NGOs such as TWN and KEI; intergovernmental groupings such as the South Centre; and academic centres.

One informant commented:

“The strengthening of WHO's role begins with having appropriate expertise to enable the public health community to engage with the complex technical issues that are being negotiated. WHO's ranks have been depleted and the networks that pre-existed have been left to wither. A designated programme of work and appropriate technical staff to lead it are what is needed. Higher up, WHO needs to take a leadership stance on trade issues and not continue to be scared away from the table by those arguing that this is not within the domain of health. Or that it is "too political". Show that there are clear links between trade and health, and don't be afraid to say so, backed by clear evidence, in trade policy forums.”

While it is easy to prescribe the kinds of institutional strengthening that would be needed (in WHO and in MOHs) to support the health sector in working towards policy coherence if neither the political will nor the resources are available to support such strengthening it will not happen.

The political field

The challenge of policy coherence requires more than addressing the institutional barriers; it is also necessary to address the political issues. The existence of vested interests and power imbalances is an inevitable reality. The question is how to negotiate this field.

The field is complex. It includes transnational corporations and peak bodies for various industrial sectors, nationally and globally as well as countries whose policies are shaped by 'national interests' and who have the power to unilaterally impose their interests on less powerful countries.

“I have heard the delegate of the biggest economy say openly that they need to defend their businesses; otherwise their economy (and people they say) will suffer.” (informant)

The field of political engagement also includes civil society advocates; such as IBFAN demanding accountability with respect to the marketing of breast milk substitutes; NCD activists in protesting against the watering down of the UN Political Declaration on NCDs; and AIDS activists protesting against the unfortunate remark in Bangkok.

One informant with experience in the governing bodies compared the success of the Framework Convention on Tobacco Control with the 'watered down' final Global Strategy on Diet, Physical Activity and Health (WHO 2004) and argued that the critical difference was the strength of civil society advocacy in the former case:

The only mechanism that seems to work is to take single issues, and set up a process that makes sure there is more transparency in what deals are done on the way. The FCTC was a standout in this

regard, where WHO effectively leveraged NGO activism to push countries into adopting a more public health position. The industry got marginalised in that process. The food industry was not slow to learn from this, and promptly recruited the architect of the FCTC (Derek Yach) to be their face of public health.

Those who argue that WHO should retreat to a technical or 'normative' role are effectively saying that WHO should not 'get involved' in the political field. However, there are political implications which flow from technical analyses. Articulating such implications is what led to the disciplining of William Aldis and the demand by the US that Musungu and Oh should have been censored. Integrity, in terms of the processes of global governance, demands that WHO is empowered to articulate the political implications of its technical analysis.

On the other hand in the case of IMPACT, WHO has promoted the conflation of IP and QSE in its definition of 'counterfeit'; a highly contentious 'technical' decision which has commercial and political significance. Indeed the decision to adopt this clumsy and incoherent definition was influenced by the innovator pharmaceutical industry which had much to gain from it. Despite repeated challenges from the floor of the Assembly WHO continues to defend this definition. Integrity, in terms of global governance for health, demands that WHO is fully accountable to the governing bodies for the ways in which it discharges its technical mandate.

We have commented earlier on the challenge of speaking explicitly about vested interests and bullying because of the power of the diplomatic convention that our interlocutors are people of good faith, working for a common good, and in accordance with shared values of truth, evidence, and logic. How then do we engage with literally incredible propositions, such as that of Mr Villagomez of the USA in the WPRC 2008 discussion of the Regional Action Plan for NCDs (see [report](#) page 147)? Integrity, in terms of global governance, demands that WHO officials are empowered to share with member state delegations the technical realities which give a different perspective on such misrepresentations.

There are two ways of responding to these cases. One is to affirm the principles of truth and integrity. The other is to ask how integrity in the institutions of global governance can be defended. Ultimately this is a political question and it depends on the willingness of member states to defend truth and integrity and the accountability of the member states for how they discharge these responsibilities. One informant commented that the BRICS and other middle income countries could be much more

influential in the governing bodies but, apart from Brazil, Thailand and India, most are quite passive.

The accountability of member states, in turn, depends on openness in decision making including technical decisions and it depends upon an active civil society at the national and global levels watching the global governors and ready to advise and criticise as appropriate.

It then needs to design a process, connected to but alongside of its formal mechanism, to develop the global policy position in a transparent way so that the "compromises" that are made are at least open to public scrutiny. The key point is that the process needs to be re-designed so that legitimate issues are properly aired and debated, even if they are uncomfortable for one or other party. (informant)

Barriers intrinsic to WHO

There are certain disabilities specific to WHO which also need to be addressed as part of strengthening global governance for health. These include:

- the donor choke-hold; continuing freeze on assessed contributions plus donor dependence and donor leverage; and
- the lack of member state accountability for decisions and directions in WHO.

At some stage the threat that the USA holds over WHO needs to be confronted. This requires other countries to come forward and agree to increasing their assessed and voluntary contributions. This will require a wider social movement which cares about global governance for health and the leadership role of WHO in that context.

In our view recommendations directed to strengthening the accountability of WHO, and its individual member states, to civil society at the local, national, regional and global levels should be given the highest priority.

The global crisis of capitalism

The stakes are very high. Capitalism is in crisis; an economic, development and ecological crisis. The policy paradigm of global economic integration has exacerbated the imbalance between global productive capacity and global demand. As fewer and fewer workers are needed to produce for larger and larger markets the role of decent wages in supporting consumption has progressively weakened and the opportunities for investment in new capacity has lagged. For a while consumption was supported by increasing debt but this strategy was

sustained by asset price inflation and when the asset bubbles burst the credit markets froze.

The prevailing development paradigm of the last two decades has failed. Progressive global economic integration has seen a continuing net transfer of value from the poor to the rich both globally and within countries. The magnitude of these transfers far outweighs the value of international financial assistance and domestic welfare.

The crisis of global warming has brought into sharp focus the limits to continuing material growth. However, the invisible hand of market forces has proven unable to mobilise the investment required to contain carbon dioxide release or to adapt the processes of capital accumulation and investment to a steady state economy.

The ideology of global economic integration has been accompanied by a progressive downsizing of government and a naïve faith in (or cynical myth regarding) the power of market forces to deliver public goods.

These are the deep contradictions which frame the present enquiry into global governance for health. Recommendations regarding global governance for health which do not address these contradictions will not be of any lasting significance.

Alternative mechanisms for projecting leadership in trade and health

There are no credible alternatives which could take over WHO's leadership role in relation to trade health policy coherence or in the broader tasks of global governance for health. The potential candidate structures include:

- a 'global fund for health';
- the OECD;
- the G20;
- the World Bank;
- the World Economic Forum.

The idea of a 'global fund for health', building on the Global Fund Against AIDS, TB and Malaria, has been floated by commentators associated with MSF (Ooms, Derderian et al. 2006; Ooms, Damme et al. 2007). This proposition is focused on international financial assistance for health but could presumably be extended to a more active role in global governance for health. The associated proposition, for a framework convention on global health (Gostin 2010; Gostin, Heywood et al. 2010;

Gostin 2012), could presumably be extended to encompass global governance for health.

It is hard to see a global fund for health replacing the leadership role of WHO in relation to trade and health or in global governance for health more broadly. It would not have the legitimacy which stems from WHO's intergovernmental base. It would be even more dependent on donor policy preferences than WHO is. It would have to assemble the institutional structures and knowledge base that WHO has, in effect replicating it.

It has been argued that the OECD is well placed to address the challenges of globalisation (Julin 2003) but while the OECD has expertise in financial, trade and other matters, it is the 'rich countries club' and would never have the legitimacy, in the eyes of L&MICs to project the kind of leadership expected of WHO.

Much the same is true of the G20. While the G20 provides an important forum for big countries to talk with each other it could not have the legitimacy of WHO in dealing with individual countries and regional issues.

The World Bank has projected itself as having an anti-poverty mission and has contributed extensively to policy discussions regarding health and health care. However, its own governance is dominated by its rich country shareholders, in particular, the USA. As we have seen, the interface between trade and health involves conflicts of interest between various groupings of countries and industries. The World Bank has consistently promoted economic policies which correspond to the interests of its principal shareholders. It does not have the legitimacy as an honest broker or open forum that WHO has. Much the same applies to the WEF although more so.

Conclusions

Trade relations affect health through their effects on: the availability of goods and services and price levels/relativities; the wealth of communities and how that wealth is grown, distributed and applied; and the structure and dynamics of the global economy including levels and the distribution of employment, accumulation, investment, debt, sustainability and crisis. Trade agreements affect health through these mechanisms and, in addition, through their effects on: regulatory environments; structures and processes of governance, nationally and globally; and changing configurations of corporate and national power.

Trade relations are an important focus for public health engagement and in this context the idea of policy coherence is useful. Policy coherence

between trade and health requires that health policy makers and health advocates understand how trade relations affect health and are able to work with economic policy makers to find policy settings which achieve win win outcomes. Likewise it implies that economic policy makers and commercial advocates need to understand and be accountable for the health effects of their policies.

WHO has a mixed history in dealing with the trade health interface. Some useful work has been done in SEARO and by WPRO in the Pacific. The investment in this work is far below its importance as a field where health is determined.

Strengthening WHO's ability (and that of member states) to promote policy coherence across trade and health will require significant capacity building. However, this is a fundamentally political arena, in which the stakes are high and the game is tough. Assuring WHO's role is played with truth and integrity will depend on strengthening its accountability and that of its member states for their custody of the Organization. Civil society has an important role to play in relation to both the specifics of trade and health and the accountability of WHO. There is no alternative.

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