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Trade negotiations in the WTO: implications for access to HIV treatment and care

The Australasian Society for HIV Medicine (ASHM) is Australia's peak organisation representing medical practitioners and health professionals working in HIV and related disease areas. In recent years, the Society has expanded its interest in international and development issues – particularly in the Asia Pacific region. In doing so, the Society has been responding to an increased international focus on access to HIV treatment and care in developing countries.

In our sector there is great concern that the massive steps forward in treatment of HIV with the introduction of antiretroviral therapy have benefited such a small percentage of HIV-infected persons worldwide. An inter-related concern is the promotion of strong public healthcare systems in developing countries (and the continuation of a strong public healthcare system in countries like Australia) to ensure affordable and coordinated treatment and care for patients with complex diseases with expensive treatments, such as HIV.

The two main areas of negotiations within the World Trade Organisation (WTO) which are currently of most concern to us are those around Trade Related Intellectual Property Rights (TRIPS) and the General Agreement on Trade in Services (GATS). We believe that an urgent solution needs to be found to allow developing countries to make use of compulsory licensing when addressing major epidemics such as HIV/AIDS. We believe that trade agreements should not compromise the public healthcare sector.

TRIPS

In initial negotiations for the TRIPS agreement, developed countries and pharmaceutical companies were able to successfully lobby for strengthened international patent law – such as extending patents from 10 to 20 years, increasing the range of patents, and strengthening punitive measures.

The issue of patents and access to medicines in the developing world was brought into the spotlight when a number of US pharmaceutical companies took the South African government to court over a government bill which aimed to increase access to cheaper essential medicines in certain circumstances. The companies argued that the bill contravened patent rules as outlined in TRIPS.

However, in the face of an international outcry, due to the disastrous impact of HIV in sub-Saharan Africa, the pharmaceutical companies backed down in 2001.

Our organisation is concerned about the impact of TRIPS on affordable medicines – particularly in the developing world. This impact will continue to expand in the future as more countries become compliant with strengthened patent law, and new, patented medicines come onto the market. The argument made by the companies is that patents ensure a return on the research and development needed to produce pharmaceuticals. This argument does not take into account that a large amount of research and development is carried out at publicly-funded institutions. In addition, increased patent protection is unlikely to lead to increased research and development into infectious diseases. These diseases predominantly affect the developing world, which only accounts for a fraction of the global market in pharmaceuticals. This has led to strong arguments for specific measures to increase access to medicines for the developing world – including measures permitting the wider use of generics, differential pricing and increased public funding within both developing and developed countries.

Compulsory licensing and generics

At the WTO ministerial in Doha, November 2001, the developed world responded to developing countries' concerns about access to medicines by delaying the deadline for least developed countries to implement patent law consistent with TRIPS to 2016, officially recognising that nothing in the TRIPS agreement should be interpreted to prevent members taking action to defend public health objectives, and reconfirming the ability of countries to use compulsory licensing. We support the use of compulsory licensing in the setting of a generalised HIV epidemic in a developing country – to permit the manufacture or registration of cheaper generic versions of patented medicines.

A deadline was set for the end of 2002 to find a solution to the problems countries face in making use of compulsory licensing – particularly due to lack of adequate domestic manufacturing capacity. At the moment, TRIPS requires that production under compulsory licensing be primarily for a domestic market. It is ambiguous on whether countries can export generics to poor countries without patenting, or to countries which want to issue a compulsory license but can't manufacture the medicines themselves. This issue is important in terms of whether countries can import generics from major manufacturers such as Brazil and India. By the end of 2002 no agreement had been made – partly due to US attempts to limit compulsory licenses to a set list of diseases. HIV/AIDS is included on the list, but many other common causes of mortality in the developing world are not. The US has continued to block consensus on agreements to resolve the issue.

We believe that an agreement is urgently needed to allow developing countries to make use of compulsory licensing. In addition, we believe that increased technical support should be given to developing countries to allow them to do so – addressing problems such as fear of litigation and inexperience in contesting patent law.

The production and trade of generics has received much publicity, and will be a major issue at the Cancun meeting. However, we believe that there is a need to consider other measures to ensure treatment access. While these do not directly form part of TRIPS negotiations, they will form part of the debate and discussion. We have chosen to address some of these here.

Pricing

Recently, differential pricing has recently received increased support. It has come to be seen as important because newer medicines, and the widest range of medicines, will not always be available in generic form. In October 2002, the European Commission recommended a system which would allow developing countries access to medicines across the board at 80% of the normal price.

Pharmaceutical companies have argued that to allow poor countries access to cheap drugs would be the thin end of the wedge. In general, this has led to a bizarre situation where many drugs are more expensive in Africa than anywhere else in the world. In these circumstances, it is not surprising that some have tried to make use of parallel importing – the purchase of patented medicines from another country where they are cheaper, rather than from the manufacturer.

Pharmaceutical companies have raised concerns that differential pricing would encourage parallel importing and reference pricing – i.e. countries would trade the discounted medicines, and developed countries would also demand lower prices. We believe that the political will currently exists internationally to create a system which ensures that the benefits of any price reductions would remain with those who need them most.

Existing arrangements have not produced price reductions that have been significant enough or generalised enough to facilitate adequate levels of treatment access. The emphasis on differential pricing is in part a response to problems encountered under the Accelerated Access Initiative launched by UNAIDS in 2000, where developing countries were encouraged to negotiate special prices with the pharmaceutical companies. This scheme produced small (0.1%), uneven and uncoordinated results in terms of treatment access, and eventual prices were generally higher than those of generic medicines.

While we welcome discounting offers from pharmaceutical companies, these apply only to specific medicines, and can run out or be withdrawn in the future. Some countries are also in a better position to negotiate discounting than others. In addition, one-off offers do not encourage or assist long-term, sustainable healthcare planning in developing countries. For these reasons, we believe that there is a need to consider a generalised system which allows developing countries access to discounted medicines.

Public funding

Attempts have also been made to procure more public funds for treatment and care. One example of this is the Global Fund to Fight AIDS, Tuberculosis and Malaria, set up in 2001. However, the level of funding is still much less than the amount the UN estimated the fund would require to meet its targets – US$10 billion a year. As of October 2002, only US$2.1 billion had been pledged. Australia is yet to announce a financial commitment to the fund – which we believe it should.

In addition, we feel that there is a need for Australia to promote a coordinated approach across international agencies in terms of prioritising public money to aid HIV treatment, and public health more generally. As one example of the problems in this area, earlier this year, the International Monetary Fund announced that under the structural adjustment program in Uganda, provision of the US$52 million the country requested from the Global Fund would have to be accompanied by a corresponding reduction in the health budget. In addition, we feel that in trade negotiations through the WTO, Australia should promote the development of strong public healthcare systems in the developing world. This will be returned to in the next section of the paper.

In general, affordability of medicines is of great importance in terms of HIV, because of the expense of the medication, and the wide range of opportunistic infections requiring treatment. Strengthening the public healthcare system is also important in the case of HIV – due to the complexities of addressing prevention, treatment and care. While the epidemic has occurred later in the region of which Australia is part, it is still a large problem which will grow without adequate treatment and intervention. In 2002, UNAIDS estimated that 7.2 million people were infected in the Asia Pacific region – a 10% increase on 2001. While national prevalence rates remain low in most countries, underreporting obscures the probable scope of the epidemic. Addressing issues of treatment access and systems of care now could help to avert disaster in the future.

GATS

Our concerns about negotiations for the GATS relate to its potential impact on public services – particularly healthcare – both in developed and developing countries. These services are essential to ensuring an effective and coordinated response, especially in terms of complex diseases such as HIV.

At the moment, GATS does not apply directly to public services, but it does apply to services which are provided on a commercial or competitive basis. The increased corporatisation of public services, and the existence of a parallel public/private health system, means that it is possible that in the case of a dispute, GATS could be interpreted to cover public healthcare. There are other proposals on the negotiating table to bring all public services into GATS. This could be achieved, for instance, by defining any government payments to organisations (like public hospitals) as a subsidy, which should

be open to competitive tender. Health care is a lucrative service area, considered to be a 3.5 trillion dollar market worldwide.

The implications of this for the future of public healthcare in Australia are significant. GATS could mean further steps towards a privatised health system, such as exists in the US. Under this system many cannot afford health insurance or access to healthcare, and the price of basic medicines is three times the price of those in Australia.

In addition, while GATS is supposed to form part of the WTO's "development" round launched at Doha, specific measures to assist development or minimise potential negative effects on developing countries have been limited. Agreements are currently being held up by disagreement between developed and developing countries over emergency safeguard measures (ESM). Agreement on ESM has been moved back until March 2004.

In response to community lobbying, the Australian government made its initial GATS offer public for the first time in April – and it did not contain any new offers on healthcare services. However, the government has stated that its initial offer can be changed at any time over the next 18 months of negotiations – without any public discussion. The government has not agreed to calls to specifically quarantine public healthcare from GATS. Meanwhile, the already existing limited commitments in podiatry, chiropody and dentistry remain.

One indication of what could happen to healthcare services if listed under GATS is the requests made by the US in current negotiations for a US/Australia Free Trade Agreement (FTA).

FTA

Partly because negotiations on TRIPS and GATS seem to have stalled to some degree, the US and Australia are pursuing a range of bilateral negotiations which would further their agenda of trade and investment liberalisation – and potentially push forward multilateral talks in the WTO.

In FTA negotiations with Australia, the US has put changes to the Pharmaceutical Benefits Scheme (PBS) on the table. US pharmaceutical companies have stated that they want to remove price controls and push for full market access. Despite publicly recognising the importance of the PBS to Australia, neither side has fully clarified its negotiating position. It is possible that the while PBS subsidies may remain, other changes may be proposed – such as changing the price control mechanisms and allowing advertising direct to the public – which would have substantial cost implications.

The Coalition government has already pursued a number of policies aimed at opening up the healthcare system to private competition. The May federal budget included changes to Medicare which would allow doctors to charge co-payments for higher income earners in addition to bulk-billing, and promote the use of health insurance to cover gap payments for out of hospital costs. It has also previously flagged changes to the PBS. This raises the possibility that trade negotiations could be used to push forward unpopular changes to healthcare and other public services.

The main demands of the US in FTA negotiations relate to public policies which it sees as restricting full market access in terms of trade and investment. One important, and perhaps less publicly-understood, part of current bilateral and multilateral trade negotiations relates to removal of control over investment. In FTA negotiations, the US has put Australia's already very limited controls on the table – legislative requirements of Australian ownership in key areas; and the abolition of the Foreign Investment Review Board. The US also wants the ability to sue the Australian government for any laws which restrict trade and investment. The EU has also targeted Australia's investment controls in requests submitted in GATS negotiations.

The removal of public protection in areas such as this would greatly increase the power of US companies to access Australian markets and determine prices, and directly influence government policy. For these reasons, we are concerned about the impact of possible moves within the WTO for further agreements on investment.

Summary of main issues

As an organisation promoting quality and affordable treatment of HIV worldwide, the main issues of concern for ASHM are:

- Access to affordable medical care and medicines for all those in Australia infected with HIV. This is important for HIV patients due to the wide range of opportunistic infections, and the high cost and complexity of HIV anti-retroviral therapy. A strong public healthcare system is essential in ensuring: adequate access to care and treatment for poorer patients or marginalised population groups who suffer from HIV; the coordinated care needed in patients with HIV; the formulation of adequate public responses in terms of prevention, treatment and legal/ethical concerns; the promotion of coordinated clinical and public health research. In this regard, we are concerned about the possible impact of GATS, and multilateral or bilateral agreements on investment.

- Access to affordable medicines in the Asia Pacific region, along with humanitarian aid to build up public healthcare systems. Experience has shown that adequately addressing the epidemic requires a long-term, coordinated approach aimed at treatment, prevention, education, poverty-reduction and improvements in general healthcare – which is only likely to occur with strong public involvement. As above, we are concerned about the possible impact of GATS, and agreements on investment. We also believe that there is a need to expedite a solution within the WTO to problems that countries face in making use of compulsory licensing.

- The need for adequate public consultation over the negotiating stance and final position of the Australian government in these negotiations. TRIPS, GATS and the FTA have significant implications for the future of HIV treatment access and the care available through public healthcare systems. Those working in the sector have significant input to make, and should be made aware of the potential impact.