Access to Medicines: Ensuring People's Rights

A Discussion Paper

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ActionAid Alliance

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Summary

The WTO has amended the rules on intellectual property rights to recognise that the rights of countries to address public health concerns should come before those of patent holders. Unfortunately, recognition and implementation remain very far apart. A variety of reasons, including technicalities, lack of capacity, charity and arm-twisting, mean that in practice patent holders often win out. The rights of poor countries to protect their health systems will be further curtailed after January 2005.

This paper provides an analysis of the prospects that poor countries face in exercising their rights to address public health concerns, raises questions on whether charity should be a substitute for rights, looks at how the access to medicines agenda has been narrowly interpreted, and examines the implications of this for poor people in developing countries. Recommendations are made that access to HIV/AIDS medicines be made available in the spirit of the WTO provisions, rather than in a manner that robs poor countries of the opportunity to access the medicines they need.

Introduction

The WTO remains a central player in the globalisation arena – where the rules of trade are key. Supposedly, these rules are in the interest of all the world's citizens. In virtually all sectors, developing countries have found the rules favour the powerful, and the area of access to affordable medicines is no exception. If concessions are given, they are often strategic, and have more to do with making gains in other areas than with trying to help the poor and vulnerable.

The world today has more than 42[1] million people living with HIV/AIDS. Sub-Saharan Africa, with about 12% of the world's population, is home to a disproportionate 29.4 million (about 70%) of these people. An estimated 3 million people in Africa are currently in need of access to life prolonging antiretroviral (ARV) treatment. Of these, less than 1% have access to such treatment. The major impediments to accessing treatment have been the cost of the drugs and lack of funding for access to treatment programmes. Latin America, with an epidemic that is 1/20th that of Africa in absolute terms, has four times as many people on treatment. In the high-income countries of western Europe and North America 500,000 of the estimated 1.6 million

[1] Statistics are from AIDS Epidemic Update, UNAIDS, December 2002.

people living with HIV/AIDS were on treatment. Globally, 95% of people in need of HIV/AIDS treatment do not have access to it. The disparities in access to treatment largely reflect the differences in wealth between regions, as well as differences in the levels of pharmaceutical industry development.

Developing countries have not been complacent in seeking solutions to improve access to life-prolonging medicines for people living with HIV/AIDS, but cost and funding have been major barriers. Faced with very high costs, many countries have not developed the capacity to provide treatment to their populations on a large scale. Consequently, treatment in developing countries, with few exceptions has been the preserve of the richer members of society. Efforts to improve access to ARVs in developing countries have included various strategies including the importation of patented as well as generic copies of drugs and local production of generic drugs. The availability of strategies other than buying drugs from the companies that initially develop them has been further threatened by the Trade Related Intellectual Property Rights (TRIPS) Agreement.

The TRIPS Agreement is one of 18 WTO agreements. The WTO is charged with setting the legal ground rules for international trade. Its objectives are to promote:

1. non-discrimination
2. progressive liberalisation of barriers to trade
3. predictable policies and transparency
4. competition
5. special provisions for developing countries[2].

The TRIPS Agreement provides protection to owners of ideas (including knowledge and technologies), allowing them exclusive rights to profit from the use of their ideas to meet the needs of mankind.

Article 7 of the TRIPS Agreement states its objectives as follows:

> " ...The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

Article 66 and 67 of the TRIPS Agreement state:

> " Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base ...[and] shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members."

While the issue of access to drugs for HIV/AIDS in Africa and the rest of the developing world has placed a spotlight on the constraints created by the TRIPS Agreement, its provisions affect the production of generic medicines and raise issues of affordability of medicines across the globe. In 2001 the global generics market was estimated to be expanding at

[2] Quoted in Globalization, TRIPS and access to pharmaceuticals. WHO, 2001.

14% per annum, as many pharmaceutical patents came into the public domain.[3] The top ten generic markets alone were estimated to be worth 22 billion euros, with the USA representing 60% of the market.[4] The global market is expected to be worth 38 billion euros in 2003.[5] Within Europe, EU countries are importing generic medicines from regions that allow early development and testing, and also those that lack strong patent protection.[6]

European Union accession countries such as Hungary, Poland, Slovenia and the Czech Republic will significantly increase the size and importance of the EU generic industry. Yet, the application of EU rules to these countries will force them to transfer their pre-patent expiry generics development and first-wave generics manufacturing work outside the expanded EU. It is estimated that 14,000 jobs will be lost. The European Generic medicines Association (EGA) warns,

> "It must be recognised that Eastern Europe has a major health gap with the current EU. Real spending per capita on healthcare in these countries is less than 400 euros per annum compared with over 1,600 euros in the EU. Access to affordable generic medicines, which represent up to 70% of all medicines dispensed to patients at only 30% of the total budget spend on medicines, are absolutely critical to healthcare delivery in the region."[7]

A similar example on the likely impact of implementing the TRIPS Agreement is that of India. In a year, a billion Indians spend as much as seven million Swiss people on pharmaceuticals.[8] This, in part, reflects the low per capita income and health expenditures in India, as well as the availability of cheaper generic drugs. With the implementation of TRIPS rules, India will lose jobs, import more drugs and pay a higher price for drugs.

Much of the generic drugs debate in Europe has focused on the period of protection offered before generic manufacturers can begin to test and start registration of generic versions of patented drugs (known as the data exclusivity period). While the EU Health Council has opted for a 10- year period, the USA offers a shorter period of 5 years. The EGA states,

> "There is in fact no evidence that increasing the protection on branded original pharmaceuticals results in improved innovation. The US has a shorter period of data exclusivity of 5 years, but is more successful in pharmaceutical innovations."[9]

What have these decisions in Europe to do with access to medicines in poor countries?

The decisions are significant for two main reasons;

1. One of the early reasons for not supporting early testing and production for registration of generic drugs in the EU was that it was inconsistent with TRIPS. In March 2000, in a case brought by the EU against Canada, the WTO stated that the practice was not inconsistent with TRIPS, with the only exception being that stockpiles built during such a period should not be sold for commercial

[3] European Generic Medicines Association Director General, G.Perry in "The lack of TRIPS acceptance by the EU and how it impedes European generic firms". Eurohealth Vol. 6 No 4 Autumn 2000.

[4] Pharma Strategy Group Ltd. IMS.

[5] Financial Times Management Reports, 1997.

[6] European Generic Medicines Association, 2001.

[7] EGA press release, 8 July 2003. *EU Pharmaceutical Law Threatens Access to Medicines in Central and Eastern Europe.*

[8] Richard Gerster, D+C Development and Cooperation article. Available at http://pioneer.chula.ac.th/~ckieatvi/Patent_Obst_Dev.htm

[9] EGA press release, 4 June 2003. EU Health Council Increase Protection of Original Brand Pharmaceuticals.

purposes. Despite this decision, the EU has taken a decision to further strengthen the protection of original brand pharmaceuticals, effectively curtailing competition for a longer period of time. The decision reflects less the fair protection of patent holders and more the relatively greater influence of patent holders.

2 There is a battle for markets underway. The manufacturers of generic drugs have been pushing for amendments that would allow for the manufacture of generic medicines for export to least-developed countries facing public health crises. This would allow them to expand into developing country markets where 95% of all HIV/AIDS-infected people live and more than 16,000 new infections occur. Allowing such an expansion poses several risks for the originator firms.

First, the countries that are classified as 'developing' include countries that in the differential pricing practice of large pharmaceutical firms, would command higher prices, or else the pharmaceutical industries in such countries could dominate supplies to developing country markets – so there is a real element of giving away potentially lucrative markets.

Second, there is the risk that the flexibility that the TRIPS Agreement allows would see countries declare a wide range of diseases to be public health problems for which generic drugs could be manufactured or imported. Such a development would see large firms face serious generic competition, not only in the supply of HIV/AIDS drugs, but also those for other diseases. In the view of originator firms, they would bear the costs of research and development only to face generic competition in exploiting the outcomes of such investment. However, a battery of provisions including exclusive marketing rights and the 5 and 10-year data exclusivity periods offered by the USA and EU respectively, already address such concerns.

The countries hard hit by HIV/AIDS and those lacking access to other essential medicines represent potential markets. The constraint to exploiting these markets is the poverty that prevails among their peoples. Current estimates are that markets in least developed countries represent less than 1% pharmaceutical industry revenue. Even in India where Cipla, the manufacturer of generic drugs, has a market share of 80% for HIV/AIDS drugs, the drugs contribute only 1/350th of the company's income of USD$350 million.

Robert Kuttner notes that, while large firms are happy to benefit from low labour costs in India, they oppose the US sale of cheaper drugs made in India on the basis of patent violation and safety regulations. He further notes that the USA pharmaceutical industry is also battling legislation that would allow consumers in the USA to import cheaper drugs from Canada, which are manufactured or purchased under license from USA pharmaceutical firms and conform to or exceed USA safety standards. The argument against imports from Canada is that when Canada negotiates cheaper drug prices the drugs are intended for Canadians. Consequently, if the USA wants cheaper drugs for everyone the issue should be contested directly.[10] This case illustrates that, while the pharmaceutical industry is willing to offer concessionary prices, it wants to retain discretion on who should benefit – and to what extent – on a case-by-case basis. Prices offered in various markets are related to the industry's strategic considerations and the pressures faced in each market. The pharmaceutical industry is not about to give up anything for free. More likely, what is offered by the industry is a trade-off that protects the long-term interests of individual companies. The heavy influence of the pharmaceutical industry is clear. They are not about to brook any competition, even where the financial value of the market is very small.

In the face of the devastation caused by HIV/AIDS, it is clear that developing country markets have the potential to contribute a much larger share of revenue, depending on the willingness of international bodies and donors to fund access to

[10] Double Standard on Globalisation. Robert Kuttner, Boston Globe, 30 July 2003. www.global policy.org/globaliz/econ/2003/0731double.htm

treatment in poorer regions. The moral arguments for improving access to medicines in these regions cannot be ignored. They are powerful arguments that can strengthen the reach of either originator or generic firms in developed countries, or spawn new competition from new manufacturers in developing countries. The pharmaceutical industry thus has an interest in how access to HIV/AIDS treatment is improved in developing countries. Furthermore, a solution that addresses a problem such as HIV/AIDS also has implications for other diseases. Hence, much of the discussion on access to medicines at the WTO has centred on interpretation of the Doha Ministerial Declaration on TRIPS and public health.

Rules of Access and Production: Rights are confirmed but fulfilment is not facilitated.

At the 4th WTO Ministerial in Doha in 2001, the Doha Declaration was signed. This was a consensus that TRIPS should not stand in the way of government responses to public health problems such as HIV/AIDS, tuberculosis and malaria. Further, the meeting recognised cost as a major impediment to access to treatment.

Prior to the Doha Declaration, efforts to reduce the cost of drugs had seen countries such as India, South Africa and Brazil take measures to produce cheaper generic copies of patented drugs. South Africa faced a three-year long lawsuit for its actions. Brazil, India and the Dominican Republic faced threats of sanctions and loss of trading privileges from the USA, with Brazil also facing an official complaint at the WTO.[11] The introduction of generic versions of patented drugs reduced the cost of drugs in some instances to one-tenth of previous levels, (Kenya is one case in point). The positive effects of generic drugs on prices have been evident with the prices of some drugs dropping by as much as 70% once there was competition from generics.[12]

After January 2005, none of the countries currently making generic drugs will be allowed to export the products or processes for such drugs, including raw materials. Least developed countries (LDCs) are not obliged under the TRIPS Agreement to provide pharmaceutical patent protection until 2016.[13]

Recent developments have brought into question whether this exemption has been treated in local legislations in the best way. In any case, the exemption is of limited use given the state of development of LDC pharmaceutical industries, the blockade on access to raw materials, and the requirement that drugs produced under compulsory licence must largely be for domestic use. LDCs without manufacturing capacity do not have the know-how or the technology to produce generic drugs. The above notwithstanding, many developing countries (including LDCs) are in a situation whereby they are under obligation under bilateral and regional obligations to protect patents. Examples include bilateral free trade agreements signed by the USA with Jordan, Chile and Singapore which go well beyond the benchmarks set in the TRIPS Agreement.[14] As it stands, TRIPS provides an opportunity, but one that cannot be utilised in the short to medium term or at reasonably low cost.

The Doha Declaration reaffirmed the right of countries to use compulsory licensing (the practice of issuing a licence to use the subject matter of a patent without the authorisation of the patent holder) to allow local manufacture of drugs required to address public health problems. However, Article 31(f) of the TRIPS Agreement requires that drugs produced under compulsory licence must primarily be for domestic use. The Doha Ministerial recognised the implications of the TRIPS Agreement and instructed the TRIPS Council to find, by 31 December 2002, a solution enabling countries with insufficient or no manufacturing capacity to use the flexibility in the TRIPS Agreement to address public health problems. Such a solution has not been forthcoming. Just when a solution was in sight, the USA opposed it.

[11] Making Trade work for the Poor. UNDP, 2002.

[12] Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries. MSF, 2003.

[13] TRIPS Council Decision of 27 June 2002.

[14] Investment Agreement in the WTO: Opening Pandora's Box? Kavaljit Singh, Znet, 25 July 2003. www.globalpolicy.org/globalisation/econ/2003/0728wtomia.htm

US President George Bush has referred to the fight against HIV/AIDS as 'God's calling'. However, in December 2002, the USA, by not supporting the relaxing of drug patent laws to allow LDCs to import cheap generic drugs after 2005, failed to act to place affordable drugs in the hands of people living with AIDS – a clear case of placing the trade interests of large pharmaceutical firms ahead of people living with AIDS.

Noting the ready availability of funds for the war in Iraq (US$48 billion compared to US$200 million for the Global Fund against AIDS, tuberculosis and malaria), Ruth Somerville[15] concludes:

> "Such budget 'choices' show that, with regard to aid at least, rich countries remain committed only to schemes that further their economic agenda. …But in a world where EU cows are worth more than human beings, and the US military budget is thirty times its aid budget, reality and sentiment remain very far apart."

Present debates and positions – On paper it is 'life first' but practice is a different kettle of fish!

Having agreed that TRIPS should not stand in the way of public health, and having removed the risk of countries facing legal action through the WTO for making generic drugs, the next challenge has been how to ensure that countries without manufacturing capacity can exploit the flexibility allowed under the TRIPS Agreement (commonly referred to as the 'paragraph 6 problem'). The TRIPS Council has missed the deadline set in the Doha Declaration and a solution does not appear to be in sight.

The Chair of the TRIPS Council proposed a draft solution on 16 December 2002. The adoption of the draft solution was blocked by the USA. The draft solution would have allowed more leeway for the import of cheaper generic drugs.

The USA initially sought to limit the scope of diseases to be covered by the solution to HIV/AIDS, tuberculosis and malaria. Later the proposed list was expanded to 23 diseases and provisions made to include similar future epidemics.[16] The US proposal was also conditional on an understanding that developed countries would not utilise the new compulsory licensing provisions, and the inclusion of provisions for countries to voluntarily opt out of utilising compulsory licensing. Following the breakdown of negotiations, the USA announced it was adopting an interim moratorium and would not be challenging any WTO member that breaks WTO rules to export drugs produced under compulsory licence to a country in need. The interim moratorium however covers only HIV/AIDS, tuberculosis and malaria, and does not extend to developed countries. The USA and European pharmaceutical industries would like the US government to limit the use of the paragraph 6 solution to the world's poorest countries and to utilise criteria such as GNP and assessments of manufacturing capacity to determine eligibility.

The European Commission (EC) has come out in favour of tiered pricing. On 26 May 2003, European governments adopted a regulation that seeks to facilitate the delivery of medicines to combat HIV/AIDS, tuberculosis and malaria at reduced prices to developing countries. Both patented and generic drugs would be eligible. The regulation sets out the pricing structure (75% discount on average prices or cost of production plus 15%) for drugs to be eligible. Seventy six countries are eligible, there are labelling requirements, and re-importation to the EU is prohibited. This latest solution is aimed at preventing countries invoking compulsory licensing. Prior to this development, the EC had, on 10 January 2003, put forward a proposal to involve the World Health Organisation (WHO) in deciding whether a particular disease would be covered by the solution. The EU

[15] Countdown to Cancun. Ruth Somerville. War on Want, 25 July 2003. www.globalpolicy.org/socecon/bwi-wto/wto/2003/0725down.htm

[16] International Centre for Trade and Sustainable Development (ICTSD), Bridges Update – 2 January 2003. Available at http://www.ictsd.org/ministerial/cancun/TRPs_update.htm

also joined the USA and Switzerland in their decision not to act against the export of drugs produced under compulsory licence to needy countries. The EU went further by not limiting the range of diseases to just HIV/AIDS, tuberculosis and malaria.

Part of the response from **large pharmaceutical firms** (clearly aimed at discouraging 'adverse' actions on the part of developing country governments and at outdoing generic competition that has not been restricted by legislative measures) has been to offer drugs at concessionary prices for those countries that meet defined criteria. Through such arrangements, least developed countries can access patented drugs at a huge discount, provided measures are taken to ensure that the drugs do not find their way back to developed country markets. But securing these discounts involves a process of negotiation, and developing countries must have a fallback position that makes it more costly for the pharmaceutical firms if the negotiations fail. The Brazilian example is particularly instructive in this regard. To achieve price reductions Brazil threatened to invoke local legislation that would allow it to issue compulsory licences to other producers of similar drugs.

The Africa Group, with the support of Brazil, India and other developing countries has been insisting that the solution should be long-term, not so cumbersome as to paralyse those that should use it, and should not entail re-writing the Doha Declaration or narrowing its scope. The concern of the Africa Group has centred on the various attempts by the USA and EU to limit the situations to which the Doha Declaration relates. There have been attempts to substitute references to public health with 'emergencies', attempts to narrow the diseases to which the Doha Declaration relates, and attempts to narrow the range of countries that may utilise the option of compulsory licensing and import drugs. The first two are tantamount to re-writing the Doha Declaration while the third offers a solution that creates two classes of countries; those with manufacturing capacity who can invoke compulsory licensing to address any public health concerns, and those without manufacturing capacity who are subjected to limitations on which public health concerns they may address using the solution.

Direct funding for access to medicines and treatment – access now but no future guarantees

Focusing on getting the TRIPS Agreement 'right' on public health has served the specific purpose of affirming the overriding importance of protecting public health over profit, and providing room for governments to put pressure on drug prices through the potential use of compulsory licences. Countries without manufacturing capacity face many operational challenges in utilising the TRIPS provisions. A logical step from a human rights perspective would be for the WTO and World Intellectual Property Organization (WIPO) to help such countries utilise the TRIPS provisions – assisting with legislation, supporting the set up of manufacturing capacity, etc. This course of action seems very unlikely. While the provision of assistance with legislation is a familiar role for both WIPO and WTO, providing assistance to strengthening manufacturing capacity is a role that neither WTO nor WIPO has played before. Yet, if the WTO is a part of the United Nations system and human rights are at the centre of its development agenda, the WTO would not be satisfied with the mere acknowledgement of a right. It would take an active interest in the extent to which the exercise of the right is respected, protected, facilitated and fulfilled. Clearly there are areas that would be beyond the mandate of the WTO, but these could be addressed through co-operation arrangements.

The World Health Organization (WHO) has set a target of extending access to treatment to 3 million people by 2005.[17] The Global Fund for AIDS, TB and Malaria (GFATM) has set itself a target of reaching 500,000 people with treatment by the same year. The USA, in announcing its US $15 billion plan on HIV/AIDS, has set itself a target of providing treatment to 2 million people in 14 countries – 12 in Africa and 2 in the Caribbean. The WHO target is a

[17] WHO, 2003.

global target that most likely includes reach through other actors. The policy of the GFATM in terms of whether or not it will finance access to generic medicines remains unclear (it has been suggested that a country could test the waters by submitting a proposal to set up local manufacturing capacity[18]). While the GFATM may state it will use cost criteria, it is barely feasible that manufacturing for local use in small markets would, in the short-term, be cheaper than purchasing patented drugs at concessionary prices. Besides, many donors, in putting money into the GFATM, have stated that the money should go towards programmes rather than treatment, thus, a significant part of the treatment funded by the GFATM is likely to be based on American contributions.

The US has actively sought to protect patents and has only grudgingly accepted the current flexibility in the TRIPS Agreement. It has prevented the continued existence of the importation option for generic drugs beyond 2005. Against the backdrop of its actions, including those against South Africa, Brazil and India, it is unlikely to accept the use of its funding to purchase generic drugs or the manufacture of such drugs. US-funded treatment is likely to constitute at least two-thirds of available treatment for people in LDCs, and nearly all of the treatment provided in the 14 countries[19] that will benefit from direct US funding (expected to total US$14 billion over five years). In these countries the issue of local manufacturing capacity will be put to rest. Of the 12 countries in Africa that will benefit from US funding, 10 are part of a preferential trade arrangement with the US,[20] and would need to seriously consider the costs of US displeasure. Possible exceptions could be the 'big boys' of the continent, South Africa and Nigeria. Even these could be offered a larger share of the cake that would dissuade them from taking 'adverse' action. A USAID policy statement says: "The principal beneficiary of America's foreign assistance programmes has always been the United States".[21] True to this statement, most of the treatment funding will end up in the hands of US pharmaceutical firms.

Besides the intention of extending access to treatment to poor people that must be celebrated, the funding will become an implicit subsidy or assured market for the US pharmaceutical industry, and will kill off potential competition from generic drugs manufacturers. Should we be concerned beyond securing access to life-prolonging medicines? After all, there appears to be a win-win outcome for both the pharmaceuticals and people living with AIDS.

Negotiations for access to life-prolonging medicines for HIV/AIDS must extend beyond existing medicines to encompass clear measures to ensure affordable access to new drugs. While the threat of generic drugs puts pressure on those drugs whose patents are near exhaustion, there is no such similar pressure on newer drugs. Without deliberate attention to this, drugs could be placed in the hands of those that need them today, but they may not be able to access newer and potentially more effective drugs in the future. Access would need to be negotiated all over again.

There are also questions of continued access. Accepting charity in the form of finished products from large pharmaceutical firms and donor countries alone is not enough to guarantee future access. Treatment is a long-term commitment, life-long for people who start on HIV/AIDS treatment. Donor-recipient relations are not always smooth. If relations went sour, where would that leave those heavily dependent on charitable acts? WTO rules must offer a practical alternative to charity.

Serious questions also arise in relation to technological transfer and development in LDCs. Accessing finished drugs means local capacity cannot be developed except in cases where the patent has been exhausted (after 20 years). In effect this means that LDCs cannot build on existing knowledge and strengthen their capacity so that in

[18] Stephen Lewis, UN Special Envoy for AIDS in Africa.

[19] The countries are: Botswana, Ethiopia, Guyana, Haiti, Ivory Coast, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia.

[20] Countries set to receive USA funding that are part of the AGOA initiative: Botswana, Ethiopia, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania and Zambia.

[21] USAID quoted in "Food Bully", Conn Hallinan, Znet, July 2003.

future they may develop locally appropriate drugs or rapidly make any new drugs that will become essential. An opportunity to pursue a developmental approach to access to medicines is being lost.

If subsidies are to be provided for research and development into drugs that are relevant for the poor regions of the world, the question is should such subsidies only focus on extending available medicines to such regions, or should they be made part of a bigger programme of research and development of medicines into the major illnesses affecting the poorest regions? HIV/AIDS, tuberculosis, malaria and other tropical diseases could be prime candidates for such subsidies, tax relief or grants.

Outstanding issues needing honest commitment

Practical implementation of the solutions to the famous 'paragraph 6 problem' (access to generic medicines for countries that do not have manufacturing capacity) will remain constrained. This is due to existing bilateral and regional provisions, a lack of capacity among LDCs to exploit the provisions, and the drying up of sources of raw materials and knowledge for making the generic drugs. The logical way to proceed would be for the WTO and WIPO to look at supporting needy countries to implement the Doha Declaration. Such measures would mean that the WTO and WIPO would need to expand the focus of their capacity building beyond simply looking at compliance to looking at utilising the opportunities in the TRIPS Agreement (including support to the establishment of manufacturing capacity).

The lobby for such actions is yet to emerge, but the large pharmaceuticals have come up with pre-emptive action by offering selected drugs to countries meeting certain poverty and need-related criteria. The set up costs of manufacturing capacity and the lead time for such capacity are unlikely to be accommodated in the current level of price differences, especially given that everything has to be set up for small individual country markets. Essentially, right now, the economic incentive for building manufacturing capacity has been removed. The strategic need for such capacity however continues to be strong.

An outstanding issue is whether or not LDCs would benefit in the long-term from establishing manufacturing capacity now. The range of drugs on which reduced prices have been offered is limited. There is the question of how such capacity could potentially be used for other health emergencies. The current solutions have focused on HIV/AIDS. There is also the question of new drugs that may be developed in future – can it be taken for granted that large pharmaceutical firms and generous donor governments will also make such drugs available at subsidised rates or will we have to fight the same war all over again?

Technically, the LDCs do not need to enforce patents until 2016, but other developing countries need to be compliant by end of 2005. The flexibility allowed under the Doha Declaration will have little meaning unless the deadline for developing countries in general is moved to 2016, or alternatively imports from other countries manufacturing under compulsory licensing allowed. Moving the deadline will permit LDCs who decide to make use of compulsory licensing to continue accessing raw materials, and will also allow them to import where the market is too small to justify building local manufacturing capacity.

While US funding may significantly expand access to treatment in sub-Saharan African countries[i], it excludes some of the hardest hit countries (Zimbabwe, Swaziland, Lesotho and Malawi). What solutions are envisaged for these countries? The possibility of US funding dilutes the voice (through a reduction in the number of LDCs) demanding a solution through the WTO that can be implemented. Can we afford similar unnecessary losses of life at some future date while we negotiate access all over again?

The funding announced by the US covers a period of 5 years. Treatment is a life-long commitment. What will happen to the estimated 2 million people to be reached with treatment when this funding expires? Is it to be assumed that there will be

automatic renewal, or will the burden fall on the governments of recipient countries? If it is the latter, will these governments be able to afford the drugs offered at that time? Will they revisit the need for manufacturing capacity at that date and seek to again put pressure on drug prices?

While the US funding for HIV/AIDS reflects the commitment needed in the fight against HIV/AIDS, it would be better appreciated if it were passed through multilateral institutions and less open to use as an instrument of foreign policy. Part of showing commitment to the fight against HIV/AIDS – and remaining transparent – would be to channel more funding through the 'war chest for AIDS' – the GFATM. The US and EU could show a greater commitment by also offering grants, tax relief and other forms of subsidy for research and development into AIDS, TB, malaria and other tropical diseases that needlessly claim the lives of large numbers of people in developing countries.

The negotiations in the WTO have been about rights. The WTO has reaffirmed the precedence of the rights of countries over the rights of corporations in addressing public health problems. The focus on rights has seen the conditions under which states can override the rights of corporations defined.

What has been lacking, however, is evidence of a willingness to take forward those rights by providing the support that would facilitate it. The WTO and WIPO need to support the exercise of such rights and not let offers of charity divert attention from this pass. If there are as yet no demands to provide support, there should still be provisions within the TRIPS Agreement for it. The TRIPS Agreement defines a framework, but we see that those opposed to modifications to it (to take into account the specific challenges faced by poor countries) seem to find solutions that weaken the chances of the framework being implemented. Commitment to the framework requires that we find ways of supporting its implementation.

ActionAid's recommendations

What do we want to see as the way forward on TRIPS and Health

1. Interpretation of TRIPS provisions that is consistent with a developmental approach that is empowering and does not create perpetual dependency.
2. An extension of the enforcement deadline for patents to 2016 for all developing countries.
3. The provision of technical assistance to allow LDC Member states whose legislation may not be facilitative of the use of paragraph 7 of the Doha Declaration to utilise the provision.
4. WTO and WIPO making provisions for technical and financial support for LDC to exploit the flexibilities under the Doha Declaration. Such support should be an entitlement for countries meeting defined criteria.
5. Donors committing money to give practical force to countries that may find it necessary to use the provisions of the Doha Declaration.
6. Part of the USA funding for HIV/AIDS being committed to improve local manufacturing capacity rather than providing finished products and stifling possible competition.
7. Recognition that while charity is good and addresses the immediate problem, it is not a long-term solution. Charity must therefore be accompanied by specific measures that will enhance the chances of reaching a larger proportion of those in need and ensure that they can enjoy similar access should charity not be forthcoming.
8. Specific attention to the plight of poor people living with AIDS who reside in countries that beyond 2005 will have limited scope for accessing generics, and yet are not covered by the current USA and similar funding. As things currently stand, these countries will depend on the generosity of large pharmaceutical firms.
9. A commitment from developed countries to put more money into the GFATM and use this as a vehicle for addressing the imbalances in access to treatment.

ActionAid demands on TRIPS and Health in Cancun:

1. Any proposed solution should not take away from the Doha Declaration. Instead, focus should be on implementation of the Declaration.
2. Any proposed solution should not lead to disempowerment of the countries that lack manufacturing capacity in relation to those that don't.
3. The solution should not create a dependency on charity (be it of developed countries or pharmaceutical firms), or carry unnecessary risk and uncertainty of supplies for people living with HIV/AIDS.
4. Support is given to LDC member states who may not have made sufficient provision to utilise the 2016 deadline for patents, so that they can fully take advantage of the provisions of paragraph 7 of the Doha Declaration.
5. Adequate measures are taken to ensure that people in developing countries that will be affected by the January 2005 deadline are adequately protected against the negative effects of enforcement of the deadline. These may include increases in drug prices. Such measures may include the extension of the enforcement deadline for all developing countries to 2016.
6. In conducting negotiations on access to medicines, all WTO members keep in mind that more than 9,000 lives are needlessly lost to HIV/AIDS on a daily basis.

ActionAid and Azione Aiuto are members of the ActionAid Alliance, a network of non-governmental development organisations working together to promote structural changes to eradicate injustice and poverty in the world. ActionAid Alliance members are ActionAid (UK), ActionAid Hellas (Greece), ActionAid Ireland (Ireland), Aide et Action (France), Ayuda en Accion (Spain) and Azione Aiuto (Italy). ActionAid Alliance's members have the regular and active support of more than 600,000 EU citizens, and its programmes reach over 9 million people in more than 40 countries in Africa, Asia, Latin America and the Caribbean.

ActionAid is a unique partnership of people who are fighting for a better world – a world without poverty.

ActionAid Brazil
Rua Corcovado 252
Jardim Botânico
Rio de Janeiro
CEP 22490-050
Brazil

T +55 212 540 5707

F +55 212 540 5841

E–mail
actionaid@actionaid.org.br

ActionAid UK
Hamlyn House
MacDonald Road
London
N19 5PG

T +44 20 7561 7561

F +44 20 7561 7676

E–mail
mail@actionaid.org.uk

Website
www.actionaid.org

Azione Aiuto
Via Broggi 19/A
20129 Milano
Italia

T +39 02 742001

F +39 02 29533683

E–mail
info@azioneaiuto.it

Website
www.azioneaiuto.it

ActionAid Alliance
10 rue de la Science
B-1040 Brussels
Belgium

T +32 02 503 2422

F +32 02 502 6203

Website
www.actionaidalliance.org

ActionAid USA
1112 16th Street NW, Suite 540
Washington DC
20036-4023
United States

T +1 202 835 1240

F +1 202 835 1244

E–mail
rickr@actionaidusa.org
atilar@actionaidusa.org

ActionAid The Gambia
CBI Senegal
Cite Belvedere Lot
122 Dakar

T +221 832 1113

F +221 832 1139

E–mail
aasenegal@arc.sn

ActionAid Uganda
PO Box 676
Kampala
Uganda

T +256 41 510016

F +256 41 510363

E–mail
admin@actionaiduganda.org

ActionAid Kenya
PO Box 42814
00 100 Nairobi
Kenya

T +254 2 4440 449

F +254 2 4445 843

E–mail
admin@actionaidkenya.org

ActionAid Malawi
PO Box 30735
Capital City, Lilongwe 3
Malawi

T +265 1 757 500/504

F +265 1 757 330

E–mail
admin@actionaidmalawi.org

ActionAid Ghana
PO Box 19083
Accra North
Ghana

T +233 21 764 931/2

F +233 21 764 930

E–mail
aaghana@actionaid-ghana.org

ActionAid Ethiopia
PO Box 1261
Addis Ababa
Ethiopia

T +251 1 654 671

F +251 1 653 420

E–mail
admin@actionaidethiopia.org

ActionAid Mozambique
Preceta Moa-Tse-Tung n.22,
Quelimane
C.P.196
Mozambique

T +258 4 212 134

F +258 4 213 133

E–mail
aamozmp@virconn.com

ActionAid China
No 8, Room No 401
Julong Garden
No 68 Xin Zhong Jie
Dongcheng District Beijing
100027 P.R. China

T +86 10 6552 1869/8329

F +86 10 6552 8327

E–mail
public@actionaidchina.org

ActionAid India
C-88, South Extension, Part II,
New Delhi, 110 049
India

T +91 11 5164 0571

F +91 11 51641891

E–mail
aaindia@actionaidindia.org

ActionAid Pakistan
House No 10, St. 17, F-8/3,
Islamabad
Pakistan

T +92 51 228 2954

F +92 51 226 0678

E–mail
mail@actionaidpakistan.org

Website
www.actionaidpakistan.org

ActionAid Vietnam
521 Kim Ma Road
Ba Dinh
Ha Noi, Vietnam

T +84 4 771 7692

F +84 4 771 7693

E–mail
mail@actionaidvietnam.org

ActionAid Bangladesh
House CWN (A) 32
Road 43, Gulshan 2
Dhaka 1212
Bangladesh

T +880 2 881 5991/2

F +880 2 881 5087

E–mail
mail@actionaid-bd.org

Website
www.actionaidbangladesh.org

ActionAid Nepal
GPO Box: 6257
Lazimpat, Kathmandu
Nepal

T +977 1 4436477

F +977 1 4419718

E–mail
mail@actionaidnepal.org

Website
www.actionaidnepal.org

Asia Region Office
Bangkok

Africa Region Office
Harare

Latin America Region Office
Guatemala

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