

ACCESS TO MEDICINES IN DEVELOPING COUNTRIES: A BMA POSITION PAPER

SUMMARY AND RECOMMENDATIONS

Communicable diseases such as HIV/AIDS have reached crisis proportions in the developing world. NGOs such as Oxfam are arguing that prices charged by the major pharmaceutical companies are deepening this problem. They argue that these companies are using the intellectual property agreements of the World Trade Organisation (WTO) to strengthen their patent rights. A high-profile case has recently been concluded between the South African government and 39 pharmaceutical companies on this issue. Although the pharmaceutical companies withdrew their case under considerable international pressure, the issue is far from resolved. The South African government has admitted that it has no intention of buying antiretrovirals in spite of their 'victory' – and the Aids crisis was the banner under which the activists fought the court case. Furthermore, another action is pending in Brazil. This time the US government is taking Brazil to court over its use of generic drugs. This paper explores these issues and suggests suitable areas for advocacy. It will argue the following:

- That the debate can only be understood in the context of general beliefs about the effect of global trade agreements on the economic well-being of the least-developed countries.
- That the position of some development NGOs does not necessarily reflect the policies of the administrations of some developing countries.
- That the NGOs have an important humanitarian voice, that their concerns are vital, but their concentration on price and on the pharmaceutical industry is too narrow.
- That the pharmaceutical industry is primarily concerned with maintaining the global price of its products. It will not behave like a development agency, nor should it be expected to.
- That a combined response involving all sectors of society is required including industry, NGOs, government and international bodies such as the World Bank.

Having looked in more detail at the main aspects of the issue this paper makes the following suggestions for advocacy:

- That the BMA should consider the adequacy of the public health exemptions in the TRIPS agreement.
- That the BMA consider lobbying for robust protection for these public health exemptions.
- That the BMA consider working with the Department for International Development (DFID) and other relevant government bodies where appropriate.

- That the BMA also consider lobbying for the provision of legal support for developing countries within the WTO.

ACCESS TO MEDICINES IN DEVELOPING COUNTRIES: AN INTERNATIONAL COMMITTEE BRIEFING PAPER

Two hundred thousand people die every week from communicable diseases. Almost all of these deaths are in the developing world and almost all of them are preventable. Drugs that are readily available in the west are not getting through to the people in developing countries that need them. This is a public health emergency. Many people in the developed world argue that a concerted response is an ethical imperative. Recently a series of high-profile campaigns by development NGOs such as Oxfam, VSO and Médecins Sans Frontières have argued that prices demanded by large pharmaceutical companies contribute to this problem. Moreover they argue that these companies are using the intellectual property right agreements of the World Trade Organisation (WTO) to close down their generic competitors. Generic drug companies, located in countries that do not enjoy tight patent protection, manufacture extremely cheap copies of the drugs that are controlled by patents in the developed world. NGOs argue that if the intellectual property agreements in the WTO are enforced and these companies are closed, the price of drugs in crisis-hit areas of the world will escalate, deepening the public health disaster.

This paper has several objectives. Firstly it will examine the claims made by these NGOs. Secondly it will look more widely at the issue of patent protection within the WTO. Finally it will suggest areas of policy on which the BMA, as an association of doctors, can make a contribution to the debate.

ACCESS TO MEDICINES IN THE DEVELOPING WORLD

Access to medicines in context: the WTO and the developing countries

The debate about access to medicines needs to be understood in the wider context of the effect of the World Trade Organisation on developing countries. Is the WTO good for development? Will the WTO's several agreements enrich the developing countries or further impoverish them? Will it kindle their infant industries or will it enable transnational corporations to plunder their resources? Opinion is divided. What is clear however is that without significant economic growth, the least developed countries will remain desperately impoverished. Aid alone will never be sufficient to lift the burden of disease and poverty. Furthermore, the WTO at least offers the possibility of a rules-based, transparent and enforceable global trading system. Without it, the developing countries are vulnerable to aggressive unilateral bargaining by western governments.

The NGO position on the WTO does not always find favour with the governments of developing countries. As one Malaysian Minister put it recently, 'The governments of developing countries are becoming more and more exasperated that NGOs that claim to be concerned about development speak so often in their name and often make arguments with which they do not agree... A lot of it is well meant, but it is sort of

this romantic idea of the noble poverty of the rural poor of Africa and South Asia living at peace with nature and their environment and spiritually at one.’¹

Given these considerations, it would be inappropriate for the BMA to link itself too closely with an NGO perspective on the effects of the WTO on development.

The Cost of Medicines in the Developing World: an NGO perspective.

NGOs enjoy a privileged position in the west. They are able to focus exclusively on the humanitarian content – to highlight the human cost – of areas in which they have a concern. This at once gives a powerful ethical charge to their voices and, to an extent, frees them from the messy contingencies of actual policy. Their humanitarian emphasis also ensures significant media attention and therefore, in democratic regimes, considerable power.

Although NGOs do not speak with a common voice on these issues, the position of leading UK NGOs such as Oxfam and VSO can be summarised as follows. The cost of medicines is a vital factor in the delivery of public health care. Although there are many other difficulties facing health care delivery in developing countries, price remains crucial. It is important therefore to campaign vigorously for pharmaceutical companies to lower their prices and, where appropriate, relinquish their patents. In one sense their argument is incontrovertible. All health care systems could deliver better health care if their drugs were cheaper. However, such a response invites several initial questions. Firstly, would a free supply of drugs avert the health crisis in the developing world? And, secondly, if it is acknowledged that the cost of medicines is a vital issue, should the pharmaceutical companies, operating in volatile and highly competitive markets, alone be asked to shoulder the burden of reducing them?

To answer the first question, even in countries where cheap generic drugs are readily available, they are not getting through to those in need. It is clear that in the absence of a suitable infrastructure, medicines cannot be successfully delivered. Many developing countries lack even the most rudimentary health systems. An emphasis on price alone is therefore misleading. Another key issue is spending priorities and the inequitable distribution of resources in developing countries. Should countries that maintain aggressive armed forces at the expense of their citizens’ health be recipients of aid? As a recent letter in *The Guardian* put it, ‘if South Africa can afford to buy submarines, it can afford to buy drugs.’ This has been made clearer following the South African governments court victory against the pharmaceutical industry: it still has no interest in buying generic antiretrovirals even at a massively reduced cost. Furthermore, should some of the world’s so-called ‘kleptocracies’, regimes whose senior officials enrich themselves with foreign aid while their people starve, be supported by the governments of the west? Any future BMA policy needs to take account of these issues.

The second question is the role of the pharmaceutical companies in this. Development NGOs have called on drug companies to waive their patent rights in poor countries. Should pharmaceutical companies be forced to forgo ownership of their intellectual

¹ 10th Report from the House of Commons’ Select Committee on International Development, Session 1999-2000, After Seattle: The World Trade Organisation and Developing Countries, p.x.

property on a unilateral basis – thereby acting as *de facto* charities – or should their investment be rewarded by the payment of royalties with, perhaps, international aid agencies and western governments shouldering the financial burden?

The cost of medicines in the developing world: the industry's position

The position of the pharmaceutical companies is easily put: like all other commercial organisations they wish to maintain their intellectual property rights to secure the price of their products. They are not development agencies, charities or civil society groups, nor should they be expected to behave like them. However, the peculiar difficulty – and indeed the blessing – for the pharmaceutical industry is their product. On the one hand they have to operate in a ruthless and unstable global market, a market, moreover, in which they have to invest enormous sums in research and development. On the other hand their products save lives and those that cannot afford them die. Drug companies are consequently in a difficult position. Where they are seen to favour the interests of their shareholders over the lives of the world's poor they are a target for understandable – if sometimes incompletely thought out – moral revulsion.

There is no doubt that, in the short term, drug companies, by acting philanthropically, could improve access to medicines. The question is whether, if they were compelled to do so, their share price – and the companies themselves – would survive, even if a tide of moral applause accompanied their rapid decline. And without the drug companies, and the patent protection that guarantees control of their intellectual property, many of the drugs in question would not be available. In some respects any principled response to the drug companies' position must depend on how the market economy in general, and the profit-motive in particular, is seen. Given the current neo-liberal economic climate, with its belief that the free market is the only efficient means of distributing resources, it would be unrealistic for the BMA to call for the drug companies to act unilaterally, or to involve itself in their demonisation. A combined response is required, involving all sectors of society including industry, governments, NGOs and international bodies such as the World Bank. Given the structure and relationships of the BMA, it might consider working more closely with the Department for International Development (DFID) and other government departments where appropriate.

PATENT PROTECTION: BRAZIL, DEVELOPING COUNTRIES AND THE WTO

As we have seen, the debate between NGOs and the pharmaceutical industry centres on intellectual property rights, specifically patents. This debate has emerged following the development of the Trade Related Intellectual Property Rights (TRIPS) agreement in the WTO. Under this agreement, all member states must introduce a comprehensive intellectual property system with a 20 year term for all industrial patents, including medicines, or face costly disputes that could lead to trade sanctions. The Brazilian government, even though it has signed up to the TRIPS agreement, is shortly to be taken to court by the US government on the basis of this agreement. The US government claims that Brazil's domestic legislation – legislation that enables it to

produce generic drugs domestically, or import them from abroad – contravenes the terms of the TRIPS agreement.

The NGOs are arguing that Brazil, faced with an HIV epidemic – some 3.5 million people in Brazil are HIV positive – should be free from restrictions in its use of generics. Their line is clear: waive patent rights to essential medicines or people will die. For the industry the position is more complex and involves a longer, less morally urgent chain of thought. They are arguing that Brazil's proposed compulsory-licensing law will give the government too much discretion: it will be able to take their ideas without legal authority and without adequate compensation. Faced with a choice between the death of 3.5 million people or the rights that huge corporations have to their ideas, the argument would appear to be unambiguous. However, caution is required here and in order to understand what is at stake we need to understand what patents are and how they operate.

What is a Patent?

A patent is a monopoly right to the exclusive use of an invention for a designated period of time – 20 years in the UK. This monopoly gives the proprietors the freedom to exploit commercially their inventions unhampered by competition for the designated period. Patents attempt to reconcile two opposing goods: the need to provide a stimulus for innovation with the need for society to enjoy free access to knowledge.² Although it might be argued that, in an ideal world, medical research should be carried out entirely for the public good, in reality, pharmaceutical companies invest huge sums of money in their research and therefore need some level of patent protection. Undermining intellectual property rights, it is argued, could therefore have serious implications for the flow of new treatments and vaccines.³

However, although patents have an important role to play in developed economies, some commentators argue that in the context of development, they are protectionist. The inclusion of the TRIPS agreement in the WTO was, they suggest, something of a contradiction. Early industrial growth in many now-developed countries was facilitated by a lack of patent protection. The TRIPS agreement by contrast could enforce an automatic twenty-year time-lag on certain kinds of technology transfer.

TRIPS and public health exemptions: a way forward?

The TRIPS agreement recognises the need to balance intellectual property rights with the interests of public health. It contains several clauses that allow low-cost versions of patented medicines to be produced legally. The most important of these is compulsory licensing. Under this provision, a country can override the patent system and produce its own supplies of essential medicines. Exclusions are also permitted for 'diagnostic, therapeutic and surgical methods'. As prices of medicines vary significantly between countries, TRIPS also permits the parallel importation of pharmaceuticals. Under this scheme, countries are not obliged to accept medicines directly from nominated suppliers but can shop around internationally for low-priced versions. A clause in TRIPS also enables governments to set out in their patent law

² See BMA Ethics Department draft briefing paper, *Gene Patenting: A BMA Discussion Paper*.

³ See Jean-Pierre Garnier, 'Drug giants aren't the problem', *The Guardian*.

legal exceptions that permit the patent to be overridden without the permission of the patent holder.

Much of the argument in Brazil concerns the limits of these public health exemptions. The current wording is ambiguous and clarity can only emerge from legal challenges. This is why the Brazilian case is important. And this is an area in which the BMA can be active. It might like to consider lobbying in favour of robust public health protection clauses, both during the forthcoming court case in Brazil, and in the WTO generally.

Conclusion

This is a complex area and providing clear, unambiguous guidance is difficult. NGOs and apologists for the free market oppose each other from ideologically reinforced positions. However, the agreements of the World Trade Organisation do attempt to balance economic and public health interests. The BMA might therefore consider lobbying to guarantee the protection of these public health interests. Furthermore it might also consider lobbying the government to look at providing legal support for developing countries – known as ‘capacity-building’ – so they can argue their case convincingly at the appellate body of the WTO.