Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines

GSK Comments

Introductory Note from GSK

GSK shares the concern that millions of people are denied access to life saving medicines in the developing world. We have developed a comprehensive programme aimed at playing our part in helping to address this challenge. We take an innovative, responsible and, above all, sustainable approach – an approach which we believe reflects good business practice and complies with several of the proposed Guidelines, either completely or in general terms. However, we do not accept the suggestion - explicit throughout the draft Guidelines - that GSK's programme and ongoing commitment is in any way required by international legal norms, whether in the human rights or other areas.

Furthermore, as currently drafted, the Guidelines send out a wholly unbalanced and unfair view of the role that the R&D based pharmaceutical industry has or can play in addressing the access challenge. Poverty is the single biggest barrier to improving healthcare in the developing world. In many countries people do not have enough hospitals or clinics in which to receive treatment, or healthcare professionals to care for them. Experience with managing the HIV/AIDs crisis in the developing world suggests the challenge has less to do with ensuring access to medicines, and far more to do with ensuring the overarching issue of access to healthcare.

This healthcare challenge can only be addressed if it is tackled as a shared responsibility by all sectors of global society. The pharmaceutical industry, along with governments, international agencies, charities and academic institutions, undoubtedly has an important contribution to make. So too do high quality generic manufacturers, and yet it is not at all clear to GSK that they fall under the scope of these draft industry Guidelines. If the R&D based industry's research and development priorities merit focus, then so too do the commercial strategies of the generics industry and their commitment to manufacturing the high quality, low priced generics that are so fundamental to the healthcare mix in developing countries. Are separate guidelines planned to address this area, or are the generics to be allowed to select those Guidelines to which they are willing to be held to account based on their own competence? Ultimately however, States have the primary responsibility for ensuring access to healthcare and medicines, and for providing an environment which facilitates the discharge of these responsibilities.

While GSK recognises that the private business sector is listed by the UN Committee on Economic, Social and Cultural Rights (referenced in the Guidelines) as a contributory partner regarding "*realisation of the right to health",* the private business sector goes way beyond the R&D based pharmaceutical industry. However, there is little acknowledgment of this in the draft Guidelines or suggestion that other private sector industries should be similarly held to account. With the possible exception of vaccines, the provision of clean water, effective sanitation and adequate nutrition have arguably had a greater impact on improving standards of healthcare in the North than any medical intervention over the past 100 years. It would therefore be incorrect to equate the private sector purely with the pharmaceutical industry; multiple private sector players have fundamental roles to play. This fact is reflected widely recognised by institutions such as the Global Fund to Fight AIDS, TB and Malaria and the UN Global Compact.

GSK is also concerned that the proposed Guidelines are based on a number or inaccuracies and misconceptions about the challenges associated with developing world healthcare. Specifically, it is simply wrong to state that 15% of the world's population consumes over 90% of the world's pharmaceuticals. This may be true if calculated by expenditure, but it is untrue if based on volumes. In the context of any debate around access to medicines, volume not expenditure should be the benchmark.

The draft Guidelines state that medical care and access to medicines are vital features of the right to "the highest standard of health". GSK of course acknowledges we have a role to play in supporting efforts to this end. Our track record in the access field is evidence of this role and of our commitment to best practices. However, the 2000 UN Committee on Economic, Social and Cultural Rights, also confirmed.

> "*The right to health is closely related to and dependent upon the realization of other human rights, as contained in the International Bill of Rights, including the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the right to health.*"

The proposed Guidelines fail to reflect this context and shared responsibilities. Despite the explicit recognition in the Introductory Note section that "*States have primary responsibility for enhancing access to medicines"* GSK is unaware of Professor Hunt seeking to prescribe similar detailed guidance as to how Governments and other stakeholders should act or be audited.

The healthcare problems of the developing world need to be addressed collectively and cooperatively. GSK's comments on the proposed Guidelines reflect this reality.

DRAFT UN GUIDELINES – GSK Comments

General

1. *The company's corporate mission statement should expressly recognise the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company.*

GSK Comment: We have a clearly stated policy on human rights and we are fully committed to playing a key role in the global partnership that is required to improve access to medicines and healthcare, in both developed and developing countries. A commitment to improving the quality of people's lives across the world is fundamental to what we do. Responsibility for defining and enforcing a legal human rights framework that accords with international laws and agreements, however, lies with Governments. Governments alone are legally responsible for promoting the health of their citizens in line with the expectations set out in various instruments, including the Universal Declaration of Human Rights.

2. *The company should integrate human rights, including the right to the highest attainable standard of health, into the strategies, policies, programmes, projects and activities of the company.*

GSK Comment: GSK supports and is committed to upholding the Universal Declaration of Human Rights. Our most effective contribution to upholding human rights in general is made through pursuing policies in our own operations that respect the rights and interests of all those affected by and involved in our business. Our most effective contribution to supporting the right to the highest attainable standard of health is via our research and development programmes. Improving the quality of people's lives across the world is fundamental to what GSK does.

3. The company should join the United Nations Global Compact.

GSK Comment: It is not clear to us how joining the UN Global Compact is relevant to improving access to medicines. However, GSK signed up to the Global Compact in July 2007.

4. *The company should always comply with the national law of the State where it operates, as well as any relevant legislation of the State where it is domiciled.*

GSK Comment: GSK is fully and publicly committed to observing all the laws and requirements of all countries in which we operate.

5. *The company should refrain from any conduct that will or may encourage a State to act in a way that is inconsistent with its obligations arising from national and international human rights law, including the right to the highest attainable standard of health.*

GSK Comment: GSK respects the laws wherever we operate. We would never encourage a State to act in a way that might breach its obligations arising from national and international human rights law.

6. *Whenever formulating and implementing its strategies, policies, programmes, projects and activities that bear upon access to medicines, the company should:*

    i. *give particular attention to disadvantaged individuals and communities, such as those living in poverty;*

    ii. *give particular attention to gender-related issues;*

    iii. *give particular attention to the needs of children;*

    iv. *give particular attention to the very poorest in all markets;*

    v. *be transparent;*

    vi. *encourage and facilitate the participation of all stakeholders, including disadvantaged individuals and communities.*

GSK Comment: Improving the quality of people's lives across the world is fundamental to what GSK does. This necessarily includes seeking to address the needs of all the communities listed above. However, addressing the needs of vulnerable groups is not something that industry can tackle on its own. We would therefore welcome more focus on the need for action by other stakeholders – particularly governments - in this area.

Management

7. *The company should have a governance system that includes direct board-level responsibility and accountability for its access to medicines strategy.*

GSK Comment: GSK's Corporate Responsibility Board, comprising non-Executive Directors, annually reviews the Company's access to medicines' strategy; while the Company's Corporate Executive Team collectively and/or individually reviews key policy decisions associated with the Company's ATM strategy.

8. *The company should have a public global policy on access to medicines that sets out general and specific objectives, time frames, who is responsible for what, and reporting procedures.*

GSK Comment: "Facing the Challenge" – sponsored by our CEO, JP Garnier sets out GSK's ATM policy; Russell Greig, head of GSK's International Business is the lead executive with responsibility for ATM.

9. *The company should have clear management systems, including quantitative targets, to implement and monitor its access to medicines strategy.*

GSK Comment: GSK has export and management systems in place to oversee and manage our Facing the Challenge programme. Likewise, R&D management will regularly review progress made in the discovery and development of new drugs targeting diseases of the developing world. Our Community Investment activities are also regularly reviewed. We do not set quantitative targets as the importance of partnerships and shared responsibility in addressing the access challenge make achieving such targets realistically beyond our unilateral control.

10. *The company should have mechanisms that encourage and facilitate stakeholder engagement and participation in the formulation, implementation and management of its medicines strategy.*

GSK Comment: We are not sure what is meant here by the term '*medicines strategy*'. GSK has an external affairs team which meets regularly with external stakeholders to review the company's access to medicines strategy, formulation and implementation. This takes the form of numerous ad hoc and more formal meetings, as well as a programme of discussion roundtables with NGOs, academics, healthcare professionals, investors and other stakeholders. The company's R&D strategy for diseases of the developing world was also subjected to external review by an Advisory Board comprising public health and scientific experts from both developing and developed countries back in December 2003.

11. *The company should produce a comprehensive, public, annual report, including qualitative and quantitative information, enabling an assessment of the company's strategies, policies, programmes, projects and other activities that bear upon access to medicines.*

GSK Comment: We report annually in publications such as the GSK CR Report, our Annual Review and Annual Report, on progress made with the company's ATM strategy. These reports cover ARV sales made by GSK and our licensees under our FtC; an update on our DDW portfolio; our advocacy activities; as well as external legislative developments of importance to the programme.

Public policy influence, advocacy and lobbying

12. *The company and its subsidiaries should disclose all current advocacy and lobbying positions, and related activities, at the regional, national and international levels, that impact or may impact on access to medicines.*

GSK Comment: GSK wants to play a leading role in improving access to medicines. This includes advocating for a environment that would help us maximise our contribution. This can involve a variety of advocacy and lobbying activities at the regional, national and international levels. It would not be practical to disclose the details of all of these activities. However, GSK has published in hard copy and online, our Access to Medicines' policy – "Facing the Challenge". This sets out the principles that underpin our programme and our lobbying objectives with government, including the need for price protection and adequate global funding to support healthcare provision in developing countries.

Central to much of our public advocacy work around access-related issues is GSK's fundamental belief in the role that intellectual property protection plays in supporting the development of medicines to meet unmet medical needs around the world. GSK supports the TRIPS Agreement, and acknowledges the flexibilities it contains. Our position on many IP-related issues, such as Voluntary and Compulsory Licensing, PEPFAR and counterfeiting are all posted on gsk.com and are often summarised in publications such as the CR Report. We are happy to discuss the details of these positions, and other ATM related issues, with legitimate parties. We see no reason to go further than this.

Our advocacy efforts will often target specific stakeholders on access related issues, for example the G8 Governments on Africa and Innovation; the WHO on pandemic flu planning; and the European Commission on paediatric medicines.

Advocacy has also been a key element of GSK's support for HIV/AIDS since our Positive Action HIV programme was launched in 1992. Advocacy is also a key part of our role in the Global Alliance to Eliminate Lymphatic Filariasis - GSK campaigns for new funds and for the endemic countries to give priority to the elimination programme. GSK's malaria programme, Mobilising for Malaria, is exclusively focussed on addressing European and African advocacy on action for malaria.

13. *The company should annually disclose its financial and other support to key opinion leaders, patient associations, political parties and candidates, trade associations, academic departments, research centres and others, through which it seeks to influence public policy and national, regional, and international law and practice. The disclosure should extend to amounts, beneficiaries and channels by which the support is provided.*

GSK Comment: This guideline appears to go much broader than just access to medicines. All GSK interactions with healthcare professionals, patient groups and think tanks conform to high ethical, medical, and scientific standards that are determined by law and regulation, interpreted by industry associations and embraced by the company. That said, it is not clear to us how disclosing our financial and other support for these group would improve access to medicines.

There are numerous examples of GSK's commitment to transparency. We publish an overview of our charitable giving in our Annual Report, Annual Review and Corporate Responsibility Report and highlight major grants. The reported figures comprise corporate donations of money and product managed by our Global Community Partnership group, plus giving by each business across the company. Each GSK business records cash, product and in-kind contributions to charitable organisations plus management costs. Grants made by GSK foundations are also included. We make no political donations in the EU; while in the US, in line with federal law, political donations are only made to candidates, political parties and organizations at the state and local levels. In 2007 we were the first pharmaceutical company in Europe to detail the amount of financial support we provide to all patient groups across Europe.

However, to replicate this level of transparency for every group cited in the draft Guidelines would impose a major administrative burden on the company. Privacy issues associated with greater transparency would also need to be addressed. It is also important to remember that the pharmaceutical industry is governed by a strong framework of legal obligations and self-imposed business ethics. A lack of transparency should therefore not be equated with a lack of ethical practices. Nevertheless, subject to these constraints, GSK is committed to continuous review and improvement of our approach to transparency.

14. *The company board should give prior approval to all lobbying positions (guideline 12) and financial support (guideline 13). The board should also receive reports on such lobbying positions and financial support. The requirement of prior approval by, and reporting to, the board is subject to the nature and scale of the activity. Where the relationship between the activity and access to medicines is significant, or likely to be significant, there should be prior approval by, and reporting to, the board.*

GSK Comment: GSK's Corporate Executive Team is routinely (either collectively and/or individually) called upon to review and approve policy positions (subject to the nature and scale of the activity). As noted above, this includes key policy developments in the Access to Medicines sections of our Corporate Reports, which are also reviewed annually by GSK's Corporate Responsibility Board, comprising non-Executive Directors.

Research and development for neglected diseases

15. *The company should make a public commitment to contribute to research and development for neglected diseases.*

GSK Comment: Depending upon the therapeutic portfolio, associated expertise and geographic reach of a company, this may not be possible or appropriate. That said, GSK has one of the industry's most extensive portfolios of novel products and development projects for neglected communicable diseases. We believe we are the only company currently involved in R&D into both prevention and treatment of all three top priority diseases of the WHO; we are involved in a number of Private/Public Partnerships; and we have dedicated DDW R&D efforts into new drugs and vaccines for malaria and TB and other neglected tropical diseases based at sites in the UK, US, Spain and Belgium. This commitment is ongoing and regularly reported on in numerous company publications, as well as on gsk.com.

16. *The company should consult widely with WHO, WHO/TDR,[1] Drugs for Neglected Diseases Initiative and other relevant organisations with a view to enhancing its contribution to research and development for neglected diseases.*

GSK Comment: It is entirely appropriate that a company consult with public health experts in developing its R&D strategy for neglected diseases. Almost all GSK's R&D efforts into malaria, TB, and other neglected tropical diseases are undertaken in partnership with groups such as the ones mentioned. WHO-TDR is our partner in the development of one anti-malarial, all our malaria and TB efforts are in collaboration with either MMV or TB Alliance, and we meet frequently with DNDi and the Gates Foundation on these matters.

17. *The company should either provide in-house research and development for neglected diseases; or support external research and development for neglected diseases; or both. In any event, it should disclose how much it invests in research and development for neglected diseases.*

GSK Comment: Depending upon the therapeutic portfolio, associated expertise and geographic reach of a company, this may not be possible or appropriate. That said, GSK has one of the industry's most extensive portfolios of novel products and development projects for neglected communicable diseases. We believe we are the only company currently involved in R&D into both prevention and treatment of all three top priority diseases of the WHO; we are involved in a number of Private/Public Partnerships; and we have dedicated DDW R&D efforts into new drugs and vaccines for malaria and TB and other neglected tropical diseases based at sites in the UK, US, Spain and Belgium.

The complexity of the R&D function, the breadth of areas it covers, our activities with external partners, and the use of shared services with our mainstream R&D, are such that GSK cannot provide a detailed breakdown of R&D expenditure on neglected diseases. Additionally, we do not believe that a financial figure provides a good measure of our commitment to this area. R&D expenditure can go up and down year on year depending upon development progress and clinical trial activity. A decline in one year, or a substantial increase could give a misleading figure. Our commitment is better valued by our actions and outputs.

18. *The company's contribution to research and development for neglected diseases should focus on formulations for low-income and middle-income country use and for all key affected patient groups, including especially disadvantaged individuals and communities*.

GSK Comment: When developing products for developing countries, any R&D organisation would obviously need to consider the needs that exist in those countries. The target profiles for all our projects into neglected communicable diseases focus clearly on the needs of the target patient community, and emphasise the particular needs of these disadvantaged groups (*e.g.* cost, shelf-life, limitations of healthcare facilities).

[1] UNICEF, UNDP, World Bank, WHO Special Programme for Research and Training in Tropical Diseases.

Patents and licensing

19. The company should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports. The company should make a public commitment not to lobby for more demanding protection of intellectual property interests than is required by TRIPS, such as additional limitations on compulsory licensing ('TRIPS-plus' standards). Also, the company should not, in practice, lobby for 'TRIPS-plus' standards.

GSK Comment: GSK supports the TRIPS Agreement, and acknowledges the flexibilities it contains. However, these flexibilities are designed to provide exceptions to the rules. As we respect the right of governments to use them, governments must respect the spirit of the TRIPS agreement, and recognise that IP is an essential element in incentivising biomedical innovation.

GSK acknowledges that compulsory licenses (CLs) are one of the flexibilities in TRIPs and that their sparing use can be appropriate. However, we consider CLs to be an option not a solution to the access crisis in the developing world. Systematic use of CLs weakens the Intellectual Property (IP) system. The IP system underpins the ability of the private sector to undertake the R&D that is essential if we are to see advances in treatments and vaccines for diseases of the developed and developing world. The more the IP system is weakened, the less R&D is likely. Widespread use of CLs may therefore contribute to a reduction in R&D.

In a similar way, widespread use of parallel trade will necessarily undermine the R&D based industry's ability to introduce and maintain a tiered pricing policy, encouraged elsewhere in the draft Guidelines. It may also deprive the patients who are intended to receive lower-priced products of those products. Furthermore, the arbitrage opportunities it creates generally benefit the middlemen not the end payer or patient. If GSK is to continue playing its part in meeting the needs of the world's poorest and invest in R&D, then wealthier nations – including middle income developing countries – must meet their responsibilities. GSK would therefore discourage middle income countries from using parallel trade as a means of accessing the same prices offered to the very poorest countries,

Industry, NGOs and other interested third parties are all free to advise Governments over how best to translate TRIPs into national legislation, to meet certain goals. (eg. to stimulate investment, support innovation,). GSK reserves the right to encourage countries to introduce innovation-friendly implementation of TRIPS. Where appropriate, this may include calling for what others consider to be "TRIPS-plus" provisions

20. The company should always respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health that recognises a State's right to protect public health and promote access to medicines for all.

GSK Comment: GSK respects the Doha Declaration, while acknowledging that there are different ways of interpreting it. By the same token, other stakeholders should acknowledge the value of IP, for example the Doha Declaration states: "We recognize that intellectual property protection is important for the development of new medicines."

21. The company should support States that wish to implement the WTO Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003), and issue compulsory licenses for exports to developing countries without manufacturing capacity.

GSK Comment; GSK acknowledges that compulsory licenses for export, as defined by the August 2003 31f Agreement, are one of the flexibilities in TRIPs. In August 2007, we did not oppose grant of a compulsory licence to a Canadian generic company to manufacture an ARV fixed dose combination containing GSK's molecules under the 31f agreement for supply to Rwanda.

That said, GSK continues to believe that the best way to address the access challenges facing many developing countries is for governments to devote more resources and political will to healthcare and to engage with the pharmaceutical industry in a constructive dialogue around its provision, financing and affordability. CLs should be considered an option of last resort, not a solution to the access crisis in the developing world. Widespread use of compulsory licensing could weaken the global IP framework and have an impact on incentives for innovation. We do not believe therefore that it is either appropriate or desirable for us to "*support States*" who issue CLs as demanded by this guideline.

22. Given that some least-developed countries are exempt from granting and enforcing patents until 2016, the company should not lobby for such countries to grant or enforce patents.

GSK Comment: GSK fully acknowledges the General Council Decision of November 2001 with respect to TRIPs and LDCs. As proponents of the value of IPRs to public health and economic development, however, GSK reserves the right to encourage countries (including LDCs) to maintain or to introduce innovation-friendly TRIPS provisions.

23. The company should develop arrangements with other manufacturers for licenses and technology transfers to enhance access to medicines for HIV/AIDS, tuberculosis and malaria, as well as an increasing number of other treatments.

GSK Comment: In cases where we think it is appropriate, GSK is willing to discuss with all genuine partners on a case by case basis how to maximise affordable access to medicines in developing countries via voluntary licences. By granting licences, initially to Aspen Pharmacare, and subsequently to number of other generic companies, for the provision of ARVs across sub-Saharan Africa, GSK has demonstrated our active commitment to this approach. However, it is important that the debate around "technology transfer" or capacity building does not focus disproportionately on local manufacturing. Within the context of the access to medicines debate, locally produced products are not always more affordable.

24. *The company should have non-exclusive voluntary license agreements to increase access to medicines in low-income and middle-income countries; the terms of such agreements should be disclosed.*

GSK Comment: In cases where we think it is appropriate, GSK is willing to discuss with all genuine partners on a case by case basis how to maximise affordable access to medicines in developing countries via voluntary licences. By granting licences, initially to Aspen Pharmacare, and subsequently to number of other generic companies, for the provision of ARVs across sub-Saharan Africa, GSK has demonstrated our active commitment to this approach. To reflect the unique challenges posed by HIV/AIDS, we agreed a royalty of only 5% from Aspen for the licence; the subsequent seven VLs agreed by GSK for SSA were on terms substantially similar to those of the Aspen licence.

The HIV/AIDS situation in sub-Saharan Africa calls for a special response. GSK's decision to grant VLs is determined partly by the local situation with regard to the HIV/AIDS epidemic and partly by the healthcare and economic environment of the area. Similarly, GSK's decision to grant the Chinese generic manufacture, Simcere, a VL to manufacture and sell our antiviral, Relenza, to a select number of developing countries, was driven by a concern to ensure sufficient supplies of the treatment in the event of a global flu pandemic. These circumstances do not routinely exist.

We will consider with our licensing partners what terms, if any, should be disclosed.

25. *In low-income and middle-income countries, the company should consent to National Drug Regulatory Authorities using test data/override test data exclusivity for registration purposes.*

GSK Comment: Data exclusivity recognizes the proprietary nature of data submitted to regulatory authorities as part of the product registration process. It also protects (and thus provides incentives for) the substantial financial investment involved in drug discovery and development. Without data exclusivity, research might also focus only on patentable compounds to the detriment of other innovation. Therefore, where we feel it is appropriate, GSK will encourage countries to protect propriety data via robust data exclusivity laws. We will always oppose any laws which allow for the disclosure of test data we submit to national authorities,

26. *The company should not extend patent duration, or file patents for new indications for existing medicines, in low-income and middle-income countries.*

GSK Comment: This guideline is unrealistic and misunderstands the nature of innovation. Middle-income countries represent the greatest commercial growth potential for the industry over the next 20 years and it is unrealistic to expect us to ignore that reality. Patent law does not distinguish between inventions consisting of "brand new products" (for example, a new compound) and inventions relating to improvements (eg. a new formulation of the compound). Patents for modifications of existing products, or improvement patents, are necessarily narrower in scope than what goes before. It follows that, following expiry of an earlier patent, an improvement patent cannot preclude a generic competitor from selling products defined in that earlier patent and which are not covered by the improvement patent. GSK reserves the right to operate within this framework wherever we deem appropriate and to seek improvement patents including patents for new indications.

Quality and technology transfer

27. The company should manufacture medicines of the highest quality.

GSK Comment: Quality is at the heart of everything we do from the discovery of the molecule, through product development, manufacture, supply and sale. We operate to a common set of GMP standards across our manufacturing network.

28. The company should enter into technology transfer agreements with local companies in low-income and middle-income countries.

GSK Comment: This is far too broad and sweeping to be desirable or practical. Technology transfer is often neither appropriate nor desirable, as recognised by the WHO. That notwithstanding, GSK is involved in a number of "know-how" transfer and/or capacity building programmes into the developing world, including work with local medical and regulatory professionals, community partnership projects, and clinical trials programmes. We are also involved in a number of manufacturing projects in developing countries. We consider technology transfer initiatives when they can realistically be forecast to succeed, are practical given local conditions and are sustainable.

We would however challenge any suggestion that the R&D industry is or should be, obliged to undertake such projects. Any legal obligations with respect to technology transfer, in so far as they exist, fall on developed country governments. Specifically, Paragraph 66.2 of the TRIPs Agreement states – "*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".*

It should also be noted that generic companies can equally engage in technology transfer and, indeed, other industries which could contribute to the right to health might have a role to play.

Pricing, discounting and donations

29. The company should ensure that its pricing and discount schemes:

i. conform to guidelines 6(i)-(vi);

ii. take into account a country's stage of economic development; prima facie, the price of a medicine in a low-income country should be less than the price of the same or equivalent medicine in a middle-income country, which should be less than the price of the same or equivalent medicine in a high-income country;

iii. progressively extend its differential pricing and discount schemes to all medicines; such arrangements must not be limited to the company's flagship products; they should encompass non-communicable diseases, such as heart disease and diabetes.

GSK Comment: The price of our products is generally determined on a market-by-market basis. Prices are negotiated with governments, national healthcare systems and other healthcare payers.

GSK's ARVs and anti-malarials are available to developing countries at under a "preferential pricing' policy. This includes not-for-profit (nfp) prices for the world's poorest countries, and discounted prices for wealthier developing and middle-income countries.

GSK vaccines are also available at preferential prices. We use a tiered pricing structure for vaccines – prices for the developing world can be as little as a tenth of those for developed countries. We work with multinational organisations such as UNICEF, the World Health Organization and the Pan American Health Organisation, governments and non-governmental organisations, to provide appropriate and affordable vaccines for developing countries. This includes basic polio vaccines as well as specially developed combination vaccines that target several diseases.

30. The company should have a board-approved policy that fully conforms to the WHO's Guidelines for Drug Donations.

GSK Comment: GSK has both internal and external policies in place setting out our approach to product donations. We aim to ensure that all our donations reflect the core principles underpinning the WHO Guidelines.

31. The company should disclose the absolute quantity and value of its drug donations.[2]

GSK Comment: GSK reports the value of our drug donations annually in our Annual Report, Annual Review and Corporate Responsibility Report. The reported figures specify donations for the Lymphatic Filariasis elimination programme (quantity and value); GSK's Patient Assistance Programs (number of patients and value); and humanitarian donations (value – difficult to estimate number of patients reached and/or absolute quantity because of the large scale of the programme). GSK uses the industry standard of Wholesale Acquisition Cost (WAC) in the country of supply to report value of product donated. WAC is equivalent to the price paid by a wholesaler for drugs purchased from the drug manufacturer. The WHO formula based on generic equivalents is not always appropriate and can be difficult to calculate.

32. The company should disclose the amount of any tax benefit arising from its donations.

GSK Comment: All GSK product donated from the USA qualifies for tax benefit according to US tax laws. All our US Patient Assistance Programs are "ex USA", so too, is the bulk of our humanitarian donations. There is no tax benefit for donations made from other countries such as GSK's albendazole which is manufactured and donated from Africa.

GSK is fully transparent about the value of all our donations; however, to provide a breakdown of each and every tax benefit derived from each section of our business (way beyond our donations programme) would involve a disproportionate amount of work. We therefore do not publish a figure for tax relief on our Donations. However, while tax relief is obviously welcome, this is not the motivating factor and, as noted, does not preclude GSK donations originating from outside the US, where routinely no relief is provided by governments.

[2] 'Value' as defined in Guideline 11 of WHO's Guidelines for Drug Donations.

33. The company should ensure that its discount and donation schemes and their delivery channels are:

i. as simple as possible e.g. the schemes should place the minimum administrative burden on the beneficiary health system;

GSK comment: The majority of GSK's donations are managed by GSK's Global Community Partnerships team, directed through a select number of experienced charitable Non-Governmental Organisations (NGOs) while vaccine donations are managed through International Public Health Organisations such as WHO and PAHO. Our NGO partners must also have a proven track record in the region where the product is to be shipped/donated, of tracking distribution, reporting results and working with in-country governmental officials

ii. as inclusive as possible e.g. the schemes should not be confined to restrictive delivery channels that, in practice, exclude disadvantaged individuals and communities.

GSK Comment: GSK's donations typically reach around 100 countries each year and specifically target the most disadvantaged communities. We work with NGO partner organisations that have the experience and skills to deliver product to remote communities that would otherwise not have access to these medicines. The delivery channels include refugee camps, mobile clinics and disaster areas – and are limited only by the available infrastructure.

Ethical promotion and marketing

34. The company should take effective measures to ensure that all information bearing upon the safety, and possible side effects, of a medicine are easily accessible to individuals so they can take informed decisions about its possible use.

GSK Comment: All GSK marketing and promotion is based on valid scientific evidence, is consistent with the national prescribing information documentation and complies with all applicable laws and regulations established at national levels by regulatory agencies. Health authorities regulate product approval, labelling, information provided to the patient and product claims. In some countries, health authorities regulate promotional materials and the provision of samples, while in other markets independent third parties or industry guidelines govern those same issues. GSK also publicly discloses the results of GSK-sponsored clinical trials that are relevant for patient care irrespective of whether the results are positive or negative for GSK prescription medicines and vaccines.

35. The company should have a board-approved code of conduct and policy that fully conforms to WHO's Ethical Criteria for Medicinal Drug Promotion. In the context of this code and policy, the board should receive regular reports on its promotion and marketing activities.

GSK Comment: GSK has mechanisms in place at a number of levels to govern its sales and marketing activities. Our Corporate Policy on Pharmaceutical Marketing and Promotion Activity, has been approved by the Corporate Executive Team and applies to all employees, suppliers, contractors, and agents everywhere in the world.

GSK also abides by industry guidelines and codes established by national industry associations as well as the key guidelines from major international industry associations. These codes and guidelines supplement government regulation and provide guidance and self-discipline for ethical marketing practices through the industry's own high standards and ethical principles. There is head office oversight of GSK's marketing and sales practices. Various parts of the organization, including Finance, Human Resources, Legal, Compliance and Internal Audit, work together to ensure compliance with applicable laws and regulations, industry guidelines and our Codes.

GSK complies fully with the main global industry code set by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Code of Pharmaceutical Marketing Practices. This in turn is based on and is consistent with the WHO Ethical Criteria for Medicinal Drug Promotion. For clarity, however, we would point out that the WHO Ethical Criteria apply to WHO member states not to companies.

However, when it comes to improving access to medicines in developing counties, the promotion of medicines is a marginal issue, compared to the many other barriers to access that exist. Of more relevance is the *rational* use of medicines. Whilst promotion has a role to play in this, in many cases healthcare professionals in the developing world will prescribe what is available, rather than what is most medically appropriate. This can lead to the development of resistance and sub-optimal health outcomes. This practice is less down to the promotion of medicines than to inefficient procurement practices and supply chains.

Clinical trials

36. A company's clinical trials should observe the highest ethical and human rights standards. This is especially vital in those States with weak regulatory frameworks.

GSK Comment: GSK-sponsored clinical trials world-wide are conducted according to the same fundamental ethical principles. The studies meet international and national regulatory and legislative requirements and follow the research methodologies outlined in the International Conference on Harmonisation (ICH) Good Clinical Practice guidelines.

37. The company should conform to the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects and the WHO Guidelines for Good Clinical Practice.

GSK Comment: All GSK-sponsored interventional clinical trials follow the principles contained in the World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects. We do not routinely reference the WHO Guidelines as these were developed subsequent to European GCP Guidelines and FDA legislation, and around the same time as the ICH Guidelines, which are generally considered more rigorous than the WHO Guidelines. As noted above, GSK-sponsored studies are conducted in compliance with ICH GCP as embodied in its policies and SOPs. The WHO Guidelines were developed to provide guidance to local regulators. In the event that any of the WHO Guidelines are incorporated into local CTX regulations then GSK will fully comply with them when conducting trials locally.

38. Additionally, when undertaking clinical trials, the company must respect the inherent dignity of the individual and all human rights principles, such as non-discrimination and equality.

GSK Comment: In any clinical research study conducted by GSK, the rights, dignity, safety and well being of trial participants are paramount. GSK sponsored clinical trials in the developing world are conducted according to the same fundamental ethical principles that are applied to those conducted in the developed world.

Public Private Partnerships

39. When participating in a Public Private Partnership, a company should continue to conform to these Guidelines.

GSK Comment: GSK considers working in partnership an essential element of addressing the healthcare challenges of the developing world. We undertake our work in PPPs to the same standards and ethical rigour as we do all our operations and we seek to work with partners who share these standards.

40. If a company joins a Public Private Partnership, it should disclose any interest it has in the Partnership's decisions and activities.

GSK Comment: The governance of any PPP should be transparent and we agree that the role of each stakeholder in a partnership should be clear.

41. So far as these guidelines bear upon the strategies, policies, programmes, projects and activities of Public Private Partnerships, they shall apply equally to such Partnerships.

GSK Comment: GSK is confident that our approach to access is broadly consistent with the principles set out in the draft Guidelines. We undertake our work in PPPs to the same standards and ethical rigour as we do all our operations and we would encourage our partners to operate in a similarly ethical and appropriate fashion.

42. A company that joins a Public Private Partnership should take all reasonable steps to ensure the Partnership fully conforms to these guidelines. If, despite warnings, a Partnership fails to conform to these guidelines, a participating company should withdraw from the Partnership.

GSK Comment: We undertake our work in PPPs to the same standards and ethical rigour as we do all our operations and we would encourage our partners to operate in a similarly ethical and appropriate fashion. A failure to act appropriately, in contravention of the any agreed governance structure for the PPP, may well result in GSK's withdrawal from the Partnership.

Corruption

43. A company should adopt effective anti-corruption policies and measures, and comply with relevant national law implementing the United Nations Convention against Corruption.

GSK Comment: GSK has adopted numerous written policies dealing with different aspects of preventing corruption. They mandate that all employees must ensure that all dealings with third parties, particularly governments and government personnel, are carried out in compliance with all relevant laws and regulations, and with the standards of integrity required for all GSK business.

44. In collaboration with States, the company should take all reasonable measures to address counterfeiting.

GSK Comment: GSK recognises that the pharmaceutical industry has a role to play in helping to minimise the counterfeiting of our products and is committed to a comprehensive programme of action against counterfeiting. We rigorously investigate and where appropriate take legal action against the manufacturers, distributors, retailers and other parties involved in counterfeiting our products. Furthermore, in countries where counterfeiting of our products is prevalent, the product and packaging incorporate features that discourage the manufacture of counterfeits and help detection. It is a condition of GSK business that wholesalers must report any offers to supply suspected counterfeit GSK products and to report, isolate and withhold from sale any such stock that is received. Procedures are in place to apply controls to the sale and disposal of GSK products, manufacturing equipment, packaging and other materials used in the production of GSK products. GSK also works in close co-operation with pharmacists, wholesalers and other pharmaceutical companies to ensure that suspected counterfeiters and their intermediaries are thoroughly investigated and, where appropriated, prosecuted.

However, GSK cannot tackle this issue alone. The prevention and detection of counterfeits is primarily a matter for national governments worldwide which must be encouraged to recognise the dangers associated with the practice and ensure its effective regulation by the relevant authorities.

Associations of pharmaceutical companies

45. So far as these Guidelines bear upon the strategies, policies, programmes, projects and activities of associations of pharmaceutical companies, they shall apply equally to all those associations. For example, the Guidelines on lobbying (Guidelines 12 and 19) and financial support (Guideline 13) shall apply equally to all associations of pharmaceutical companies.

GSK Comment: GSK encourages the Trade Associations of which we are a member, to adopt practices that reflect our approach and views, much of which is consistent with the draft Guidelines. Ultimately, however, the overall strategy of industry trade associations must be determined by their entire membership.

46. A company that is a member of an association of pharmaceutical companies should take all reasonable steps to ensure the association fully conforms to these guidelines. If, despite warnings, an association fails to conform to these guidelines, a member company should resign from the association.

GSK Comment: GSK encourages the Trade Associations of which we are a member, to adopt practices that reflect our approach and views, much of which is consistent with the draft Guidelines. Ultimately, however, the overall strategy of industry trade associations must be determined by their entire membership.

Monitoring and accountability

47. In the context of access to medicines, internal monitoring and accountability mechanisms have a vital role to play, but they should also be supplemented by a mechanism that is independent of the company. There should be an effective, transparent, accessible and independent monitoring and accountability mechanism that:

i. assesses the impact of the company's strategies, policies, programmes, projects and activities on access to medicines, especially for disadvantaged individuals and communities;

GSK Comment: GSK's R&D strategy for diseases of the developing world was subjected to external review by an Advisory Board comprising public health and scientific experts from both developing and developed countries back in December 2003. However, no formal independent review of GSK's overall access policy is conducted. As noted in response to Guideline 10 above, GSK meets regularly with external stakeholders to review the company's access to medicines strategy, formulation and implementation. This takes the form of numerous ad hoc and more formal meetings, as well as a programme of discussion roundtables with NGOs, academics, healthcare professionals, investors and other stakeholders.

ii. monitors, and holds the company to account in relation to, these Guidelines.

GSK Comment GSK reports annually on its efforts in the access area both externally via our CR Report and internally to the CR Committee of the Board. We are confident that our approach to access is broadly consistent with the proposed Guidelines. However, we do not accept the suggestion that GSK should be formally held to account in relations to the Guidelines. GSK's approach to access to medicines is based on best practice and a desire to play our part in the global response. It is not based on any legal obligations. These reside with Governments not the private sector.

48. Where such a monitoring and accountability mechanism already exists, the company should fully cooperate with it. If it does not yet exist, the company should establish such a mechanism.

GSK Comment: See our comments in relation to Guideline 47.