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ПООЩРЕНИЕ И ЗАЩИТА ВСЕХ ПРАВ ЧЕЛОВЕКА, ГРАЖДАНСКИХ, ПОЛИТИЧЕСКИХ, ЭКОНОМИЧЕСКИХ, СОЦИАЛЬНЫХ И КУЛЬТУРНЫХ ПРАВ, ВКЛЮЧАЯ ПРАВО НА РАЗВИТИЕ

Доклад Специального докладчика по вопросу о праве каждого человека на наивысший достижимый уровень физического и психического здоровья, Пола Ханта[*]

Миссия в компанию "ГлаксоСмитКлайн"[**]

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[*] Настоящий доклад был представлен с опозданием с целью включения в него самой последней информации. Мандат Пола Ханта в качестве Специального докладчика завершился 31 июля 2008 года. Его доклад распространяется в качестве добавления к докладу сменившего его Ананда Гровера, мандат которого начался 1 августа 2008 года.

[**] Резюме настоящего доклада распространяется на всех официальных языках. Сам доклад, содержащийся в приложении к резюме, распространяется в полученном виде только на том языке, на котором он был представлен.

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Резюме

Специальный докладчик по вопросу о праве каждого человека на наивысший достижимый уровень физического и психического здоровья посетил штаб-квартиру "ГлаксоСмитКлайн" - одной из ведущих в мире исследовательских фармацевтических компаний - в июне 2008 года с целью проведения предметных бесед с ее высокопоставленными руководителями.

В своих предыдущих докладах Специальный докладчик рассматривал вопрос об обязанностях государств в связи с обеспечением доступа к медикаментам. Вместе с тем расширение доступа к медикаментам является общей обязанностью. Согласно Целям в области развития, провозглашенным в Декларации тысячелетия, фармацевтические компании обязаны содействовать расширению доступа к медикаментам.

В настоящем докладе Специальный докладчик освещает обязанности фармацевтических компаний, включая компании, выступающие с новациями, разрабатывающие аналоги патентованных препаратов и занимающиеся биотехнологиями, в связи с осуществлением права на здоровье в контексте доступа к медикаментам. С точки зрения осуществления права на здоровье Специальный докладчик рассматривает некоторые стратегии "ГлаксоСмитКлайн", касающиеся доступа к медикаментам, в особенности применительно к развивающимся странам. Помимо освещения некоторых видов позитивной практики, Специальный докладчик называет некоторые препятствия, сдерживающие усилия компании по расширению доступа, такие, как несовершенные системы здравоохранения, и представляет целый ряд рекомендаций, адресованных "ГлаксоСмитКлайн", фармацевтическим компаниям в целом, государствам и другим заинтересованным сторонам.

Специальный докладчик выражает признательность руководству "ГлаксоСмитКлайн" за направление ему предложения о подготовке настоящего доклада и за его сотрудничество в ходе всей миссии.

СОДЕРЖАНИЕ

Annex

Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health on his mission to GlaxoSmithKline

I. INTRODUCTION

1. The Constitution of the World Health Organisation (WHO) affirms that the highest attainable standard of health is a fundamental human right of every human being. The Universal Declaration of Human Rights lays the foundations for the international framework for the right to health. This human right is now codified in numerous national constitutions, as well as legally binding international human rights treaties, such as the International Covenant on Economic, Social and Cultural Rights (E/CN.4/2003/58).

2. Although medical care and access to medicines are vital features of the right to health, almost two billion people lack access to essential medicines, leading to immense avoidable suffering. Improving access to essential medicines could save 10 million lives each year, four million of them in Africa and South-East Asia. Gross inequity is a shocking feature of the world pharmaceutical situation (A/61/338).

3. Between 2002-2008, the Special Rapporteur regularly scrutinized States' duties and practice in relation to access to medicines (see also A/61/338; E/CN.4/2006/48/Add.2; E/CN.4/2005/51/Add.3; E/CN.4/2004/49/Add.1).

4. On numerous occasions over the last six years, Ministers, senior public officials, civil society and others have informed the Special Rapporteur that, when endeavouring to implement the right to health, States encounter many obstacles. Among the obstacles they have mentioned, one was the policies of some pharmaceutical companies, including excessively high prices for medicines. While the Special Rapporteur has been on country missions, however, Ministers and senior public officials have also acknowledged that the pharmaceutical sector has an indispensable role to play in relation to the right to health and access to medicines.

5. Enhancing access to medicines is a shared responsibility. If access to medicines is to be improved, numerous national and international actors have a vital role to play. The Millennium Development Goals recognize that pharmaceutical companies are among those sharing this responsibility. Goal 8, a global partnership for development, has a number of targets e.g. "In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries".

6. Throughout his mandate, the Special Rapporteur engaged in many discussions on access to medicines with numerous parties, including pharmaceutical companies. These substantive discussions took place at symposia and workshops, as well as informal visits to pharmaceutical companies. They also occurred in clinics, hospitals and civil society consultations during the Special Rapporteur's country missions. These discussions were informed by the voluminous literature on access to medicines. During these discussions, the human rights duties of States in relation to access to medicines were reasonably clear, and these duties are now explored in the Special Rapporteur's various reports (see para. 3). However, it became apparent that the nature and scope of pharmaceutical companies' human rights responsibilities in relation to access to medicines were not clear. The Committee on Economic, Social and Cultural Rights, for example, confirms that the private business sector has responsibilities regarding the realisation of the right to health, but it has not taken further steps to specify these responsibilities.[1]

7. In a recent report, the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises observed: "Companies need to adopt a human rights policy. Broad aspirational language may be used to describe respect for human rights, but more detailed guidance in specific functional areas is necessary to give those commitments meaning" (A/HRC/8/5, para. 60). The Special Rapporteur strongly supports this point of view. It is very important that we move from the general to the specific.

8. Building on the general lessons learned in recent years, this report considers the right-to-health responsibilities of business enterprises in relation to one specific sector: the pharmaceutical industry. It focuses on one specific pharmaceutical company: GlaxoSmithKline (GSK). Moreover, it gives particular attention to aspects of one crucial part of GSK's portfolio: access to medicines, especially in relation to developing countries. The report aims to promote the transition from the general and abstract to the specific and operational.

9. The Special Rapporteur approached GSK with a view to undertaking this report because it is regarded as one of the leading exponents of corporate social responsibility in the pharmaceutical sector. It was anticipated that a review of GSK's policies would be especially instructive, enabling the Special Rapporteur to identify good practices, as well as the obstacles facing such a company.

10. After some months of research on GSK, the Special Rapporteur visited the company's headquarters in London on 2 and 3 June 2008, and also had numerous teleconferences with senior management officials based in Europe and USA in June and July 2008.

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[1] CESCR, general comment 14, para. 42.

11. The programme of the visit to GSK's headquarters was prepared with the company's management team. The Special Rapporteur discussed with Dr Jean-Pierre Garnier, the former Chief Executive Officer; Mr Peter Bains, Senior Vice President; Dr Lynn Marks, Senior Vice President; Ms Julia King, Vice President; Dr Justine Frain, Vice President; Mr Robert Court, Vice President; and Mr Jon Pender, Director, Government Affairs. The Special Rapporteur also had the opportunity to speak with Sir Christopher Gent, Chairman of GSK and its Corporate Responsibility Committee.

12. The Special Rapporteur also met with Mr Charles Clift and Mr Saul Walker from the UK Department for International Development (DFID). In early June 2008, he had the benefit of a half-day consultation on GSK with representatives of civil society organizations and academia working on access to medicines issues. Later, there were a number of bilateral consultations with civil society organizations and academics working in this field. While these consultations focused on the policies and practices of GSK, the Special Rapporteur's mission was also informed by the numerous, wide-ranging consultations he undertook between 2002-2008, including visits to clinics and hospitals in several developing countries (see paras. 3 and 6).

13. This report is primarily based on the company's public, official policies and programmes provided by staff members based at GSK's headquarters, as well as independent commentaries on those policies and programmes. The Special Rapporteur neither visited GSK's country offices, nor checked the degree to which the company's policies and programmes are implemented on the ground, nor scrutinised the role of GSK's subsidiaries. These are important limitations because headquarters may adopt more progressive positions than country offices are willing to implement, and some vital issues (e.g. on patents and court cases) may be decided locally. Nonetheless, a company's public, official policies and programmes are important and demand scrutiny from the right-to-health perspective. This report should be seen as one step in the long journey towards the sustained application of the right to health to the pharmaceutical sector.

14. As the Special Rapporteur prepared for the mission to GSK's headquarters, he was revising the draft Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines that were placed in the public domain for consultation between September 2007 and May 2008. The Guidelines were not finalised when the mission to GSK's headquarters took place in June 2008. The final version of the Guidelines was published in the Special Rapporteur's report of August 2008 to the General Assembly (A/63/263). The mission and Guidelines influenced each other, but this report does not explicitly apply the Guidelines to GSK. However, for those interested in the application of the right to health to the pharmaceutical sector, the Guidelines and this report (especially the next chapter) should be read together.

15. The Special Rapporteur is very grateful to GSK's senior management for their invitation to review the company's policies and programmes regarding access to medicines and for their cooperation throughout the mission. He is also very grateful to all those in GSK, DFID, civil society and elsewhere, who gave him the benefit of their expertise.

II. RESPONSIBILITIES IN THE FIELD OF THE RIGHT to health OF PHARMACEUTICAL COMPANIES IN RELATION TO ACCESS TO MEDICINES

16. The Special Rapporteur's report of September 2006 makes some general observations about the right-to-health responsibilities of pharmaceutical companies in relation to access to medicines and those remarks will not be repeated here (A/61/338). The present chapter looks more closely at the scope and content of these right-to-health responsibilities. It begins to move beyond broad, generalised, aspirational human rights language of limited operational utility, towards "more detailed guidance in specific functional areas" (A/HRC/8/5, para. 60). This chapter is not specific to GSK. Because access to medicines is a shared responsibility, whether or not a pharmaceutical company is able to fully discharge all its right-to-health responsibilities will sometimes depend upon States, donors and others fulfilling their human rights responsibilities.

A. Framework of the Special Representative

17. The Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises has recently provided "a framework to anchor the business and human rights debate" (A/HRC/8/5). His framework has three core principles, the second of which is "the corporate responsibility to respect human rights" (para. 51). According to the Special Representative, this responsibility requires "due diligence" which has a number of elements, for example, the company must have a human rights policy and use impact assessments in appropriate cases. The Special Representative confirms that the corporate responsibility to respect "is not merely a passive responsibility for firms but may entail positive steps" (para. 55). Crucially, the responsibility to respect is the "baseline responsibility" that applies to all companies, in all sectors, in all countries (para. 24). As the Special Representative observes, "companies may have additional responsibilities, for example, where they perform certain public functions" (para. 24). Also, according to the Special Representative, "human rights-related due diligence is determined by the context in which a company is operating, its activities, and the relationships associated with those activities" (para. 25). These last two points are important. A company may have human rights responsibilities beyond what the Special Representative regards as its "baseline responsibility"; and the "human rights-related due diligence" expected of a company is contextual. The Special Representative also explains

that the corporate responsibility to respect human rights is based in "social expectations - as part of what is sometimes called a company's social licence to operate" (para. 54).

18. While the Special Representative's focus is the "baseline" human rights responsibility of all companies, the Special Rapporteur's focus is the right-to-health responsibilities of pharmaceutical companies. What are the "expectations" that society may legitimately have of a pharmaceutical company? What are the terms of a pharmaceutical company's "social licence to operate"? These are complex questions, not least because the pharmaceutical sector encompasses a range of diverse companies, including innovator, generic and biotechnology companies. For example, the "social expectations" of a company holding a patent on a life-saving medicine are different from a pharmaceutical company that does not hold such a patent (see below).

19. When approaching these important issues, it is logical to seek guidance from the right to health. Fundamentally, this human right is concerned with the dignity and well-being of individuals and communities. It is an integral part of the international bill of human rights. Every country in the world has affirmed, in one treaty or another, the right to health. Moreover, the Committee on Economic, Social and Cultural Rights and others have developed a framework for analysing or "unpacking" the right to health with a view to making it easier to understand and apply. Crucially, by enhancing access to medicines, a company is making a major contribution to the realisation of the right to health. For these reasons, when considering the "social expectations" and "social licence to operate" of pharmaceutical companies, it is instructive to examine this compelling, fundamental human right.

B. Right to health framework and pharmaceutical companies in general

20. The Committee on Economic, Social and Cultural Rights (and others) developed the right-to-health framework as a tool to better grasp the duties of States. Of course, the human rights responsibilities of pharmaceutical companies are not identical to the human rights duties of States e.g. a State's human rights duty includes enacting appropriate legislation and, obviously, such a responsibility cannot fall upon private businesses. Nonetheless, the framework provides a useful tool for clarifying the right-to-health responsibilities of non-State entities. These responsibilities reflect society's "expectations" of pharmaceutical companies and they should be read into the "social licence to operate" of these companies. As emphasised in chapter I, many of these responsibilities are shared with States and others. Also, pharmaceutical companies have other responsibilities e.g. to enhance shareholder value. Here, however, the focus is on the

right-to-health responsibilities of all pharmaceutical companies, including innovator, generic and biotechnology companies[2]

A human rights policy statement integrated throughout the company

21. The right to health must be consistently integrated across all relevant policies, programmes and projects of a pharmaceutical company, including those relating to pricing, intellectual property, research and development, clinical trials, and marketing. An important pre-condition for such integration is the company's adoption of a human rights policy statement that expressly recognizes the importance of human rights generally, and the right to health in particular. Pharmaceutical companies should use impact assessments to help them ensure that their human rights policy is consistently integrated across all of the company's activities (A/HRC/8/5, paras. 60-62).

Availability

22. All pharmaceutical companies must do all they reasonably can to ensure that medicines are available in sufficient quantities in the countries where they are needed. While this responsibility is discussed below in the particular context of patent holders (para. 35), it must be emphasised that research and development in the pharmaceutical sector has inadequately addressed the priority health needs of developing countries and that all pharmaceutical companies have a responsibility to take reasonable measures to redress this historic imbalance. For example, they should either provide in-house research and development for neglected diseases, or support external research and development for such diseases. Sometimes known as 'diseases of the developing world', neglected diseases are those that mainly afflict the poorest people in the poorest countries (E/CN.4/2006/48/Add.2).

Accessibility

23. In addition to being available, medicines must also be accessible. Accessibility has various dimensions, for example, medicines must be accessible in all parts of a country, including remote rural areas as well as urban centres. Of course, the responsibility to ensure access in all rural and urban areas does not fall exclusively on pharmaceutical companies, but they must do all they reasonably can. For example, pharmaceutical companies should ensure that medicines are packaged appropriately for different local climates.

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[2] Pharmaceutical companies have responsibilities arising from other human rights, such as the labour rights of their employees, but this report focuses on pharmaceutical companies' right to health responsibilities.

24. Medicines must be affordable (i.e. financially accessible) to all, including those living in poverty. Medicines are often too expensive for poor communities in developing countries. In addition to the price charged by the manufacturer, other factors determining the final price paid by the patient include import tariffs, freight costs, VAT, and the mark-up added by wholesalers and retailers. While the State has a responsibility in relation to these other factors, pharmaceutical companies must ensure that their prices are affordable to as many individuals and communities as possible. In this regard pharmaceutical companies must put in place a differential pricing policy not only between countries but also within the same country (e.g. market segmentation). Of course, a generic company has a right-to-health responsibility to take all reasonable steps to make a medicine it is producing as widely accessible as possible.

25. Reliable information about medicines should be accessible. A pharmaceutical company should take effective measures to ensure that all statutory and other information bearing upon a medicine's safety and possible side effects are easily accessible so individuals can take informed decisions about its possible use (also see Transparency below).

Acceptability

26. As well as being available and accessible, medicines (and associated processes e.g. clinical trials) must be respectful of medical ethics, culturally appropriate and sensitive to gender and life cycle issues. For example, pharmaceutical companies should give proper attention to the needs of children and the elderly, and ensure that clinical trials observe the highest ethical and human rights standards, including the requirements of informed consent.

Quality

27. Pharmaceutical companies have a responsibility to ensure that their medicines are of good quality, safe and efficacious, for example, they must comply with national and global manufacturing standards e.g. the current World Health Organization Good Manufacturing Practice Guidelines.

Transparency

28. Transparency is a cardinal human rights principle upon which several other human rights considerations depend, such as accountability. In the right-to-health analysis this principle is reflected in the requirement, already mentioned, that as much health-related information as possible should be accessible. For example, pharmaceutical companies and their subsidiaries should disclose all advocacy and lobbying positions, and related activities, at the regional, national and international levels, that impact, or may impact, upon access to medicines.

Advocacy bearing upon the public sphere must be disclosed in the public sphere. Pharmaceutical companies should also disclose the amount they spend on research and development, and research and development for neglected diseases. Of course, outputs are critically important, but levels of investment regarding neglected diseases are a useful indicator of corporate commitment. Other examples of the application of the transparency principle are provided in chapter IV in relation to GSK's policies. While there is a presumption in favour of the disclosure of information, held by the company, which relates to access to information, this presumption may be rebutted on limited grounds, such as respect for the confidentiality of personal health data collected during clinical trials.

29. The principle of transparency not only requires that information be made publicly available, but also that the information be made available in a form that is accessible, manageable and useful. In conjunction with other companies in the sector, a pharmaceutical company should agree to standard formats for the systematic disclosure of company information and data bearing upon access to medicines, thereby making it easier to evaluate the performance of one company against another, as well as the performance of the same company over time. This will enhance public accountability and investor confidence.

Monitoring and accountability

30. Human rights empower individuals and communities by granting them entitlements and placing obligations (or duties or responsibilities) on others. Crucially, rights and obligations demand accountability: unless supported by a system of accountability they can become no more than window dressing. A right-to-health approach emphasises obligations and requires that all duty-holders be held to account for their conduct.

31. All too often, 'accountability' is used to mean blame and punishment. But this narrow understanding of the term is much too limited. A right-to-health accountability mechanism establishes which health policies and practices are working and which are not, and why, with the objective of improving the realisation of the right to health for all. Accountability comes in many forms. In relation to a human right as complex as the right to health, a range of monitoring and accountability mechanisms is required, and the form and mix of devices will vary from one jurisdiction to another.

32. Although challenging issues remain, in recent years some pharmaceutical companies have made significant progress in relation to corporate social responsibility. However, there is a striking absence of accessible, effective, transparent and independent accountability mechanisms in relation to their policies and corporate social responsibility. Some reporting initiatives are impressive such as GlaxoSmithKline's external assurance of the access to medicines chapter in

its Corporate Responsibility Report (2007). Nonetheless, the reporting of pharmaceutical companies on access to medicines is largely self-reporting, with limited exceptions such as the Access to Medicine Index (see chap. III). While public candid self-reporting is welcome, it is no substitute for monitoring and accountability by an independent body.

33. There is an urgent need to devise appropriate monitoring and accountability mechanisms to monitor whether or not a pharmaceutical company is doing what it is required to do in relation to the right to health and access to medicines. Internal mechanisms are required, such as a governance system that includes direct board-level responsibility and accountability for the company's access to medicines policy. Also external (i.e. independent) mechanisms are needed, such as an Ombudsman with oversight of a company's human rights responsibilities, including those relating to access to medicines. The Ombudsman, or equivalent, may have oversight of all pharmaceutical companies, a group of companies, or an individual company. Of course, pharmaceutical companies are already subject to several forms of internal and external monitoring and accountability, however, these mechanisms rarely monitor and hold a company to account in relation to its human rights responsibilities to enhance access to medicines. Chapter IV considers these issues in the context of GSK.

Conclusion

34. Many of the right-to-health responsibilities briefly considered here apply to all pharmaceutical companies, including innovator, generic and biotechnology companies. For example, all pharmaceutical companies must be respectful of medical ethics; ensure their medicines are of good quality, safe, efficacious, and affordable to as many people as possible; disclose their advocacy and lobbying positions; establish internal and external right-to-health monitoring and accountability mechanisms; and so on. However, some right-to-health responsibilities only apply to some pharmaceutical companies. The next section briefly explores the additional responsibilities that apply to a company, like GSK, that holds a patent for a life-saving medicine.

C. Right to health framework and patent-holding pharmaceutical companies

35. A pharmaceutical company that develops a life-saving medicine has performed a vitally important medical, public health and right-to-health function. By saving lives, reducing suffering and improving public health, it has not only enhanced the quality of life of individuals, but also contributed to the prosperity of individuals, families and communities. The company, and its employees, has made a major contribution to the realisation of the rights to life and the highest attainable standard of health. The "reward" for fulfilling this critically important social function

is the grant of a patent - a limited monopoly - over the relevant medicine, enabling the company to make a profit, enhance shareholder value, and invest in further research and development.

36. Different commentators use different terms to describe the relationship between society and patent-holder. Some characterise the relationship as a "social contract".[3] Others might regard a patent as forming part of a company's "social licence to operate". Some might describe the relationship as fiduciary i.e. the company holds the patent - for a limited period - on trust for society. Whether characterised as contract, licence or trust, the company holds the patent on express and implied terms. Society has legitimate expectations of a company holding the patent on a life-saving medicine. In relation to such a patent, the right-to-health framework helps to clarify what these terms, and expectations, are. Because of its critical social function, a patent on a life-saving medicine places important right-to-health responsibilities on the patent holder. These responsibilities are reinforced when the patented life-saving medicine benefited from research and development undertaken in publicly funded laboratories.

37. Having developed a life-saving medicine, the company has a human rights responsibility to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need. Of course, the responsibility is shared with States and others. The company is not expected to make the medicine immediately accessible to all those in need; analogous to a State's responsibility of progressive realisation, the company has to move expeditiously and effectively, by way of deliberate, concrete and targeted measures, to make the medicine as accessible as possible. What is required of the company is subject to its capacity; analogous to a State's responsibility to take steps "to the maximum of its available resources", more is required of a powerful transnational company with global networks, than a smaller business. Given market realities, the company must be permitted to make a reasonable profit and enhance shareholder value; in other words, it must be allowed to operate a viable business model.

38. When endeavouring to make the medicine as accessible as possible to all those in need, the company must use all the arrangements at its disposal, including differential pricing between countries, differential pricing within countries (e.g. market segmentation), non-exclusive commercial voluntary licences, non-commercial voluntary licences, donation programmes, public-private partnerships, and so on.

39. Crucially, the company may not market the medicine to social group A (i.e. wealthy urban elites), with little or no attempt to reach social groups B-E. The patent holder of a life-saving medicine has a human rights responsibility to take all reasonable steps to ensure that the medicine is accessible to all social groups. While it cannot be expected to make an overall loss, the company can sometimes be expected to operate, with respect to some of its activities, on a

not-for-profit basis, such as in relation to social group E (i.e. the rural poor). In such a case, the State may be required to provide a subsidy so that the company recovers its costs (e.g. freight and administrative charges) when making the medicine available to the rural poor on a not-for-profit basis. Donors may also be required to provide a subsidy, or other assistance, consistent with donors' human rights responsibilities of international assistance and cooperation in health (A/HRC/7/11/Add.2).

40. Pharmaceutical companies also have a responsibility to ensure that medicines are developed for children, the elderly, pregnant and lactating women, and for various climates so the medicines are resistant to extremes of heat and humidity.

41. In summary, there is an agreement between society and the patent holder of a life-saving medicine that grants privileges to, and places responsibilities on, the patent holder. The crucial right-to-health responsibility is to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need, within a viable business model. As soon as the new medicine is marketed at higher prices (usually in high-income countries), the patent holder has a right-to-health responsibility to put in place a range of mechanisms, such as differential pricing between and within countries, to enhance access for those who cannot afford those prices. These mechanisms must encompass, for example, the better-off in middle-income countries; the poorest in middle-income countries; and all those in low-income countries. Also, the patent holder has a right-to-health responsibility to develop formulations for children, the elderly, pregnant and lactating women, and extremes of climate. For the duration of the patent, only the patent holder is authorised (with limited exceptions) to take these steps. Thus, the agreement between society and patent holder includes a responsibility on the patent holder to take these steps, expeditiously and effectively, by way of deliberate, concrete and targeted measures. If the patent is worked without these steps being taken (i.e. without a range of mechanisms being put in place to enhance access, and without steps being taken to develop formulations for children), the patent holder is in breach of its right-to-health responsibilities. Of course, the success of the patent holder's actions will sometimes depend upon States, donors and others in the pharmaceutical sector fulfilling their responsibilities. Nonetheless, the patent holder has a right-to-health responsibility to do what it can.

D. Conclusion

42. Based on the dignity and well-being of individuals and communities, as well as globally recognised standards, the right-to-health framework helps to clarify what is socially expected of all pharmaceutical companies, including innovator, generic and biotechnology companies. These paragraphs are not an exhaustive application of the framework to the pharmaceutical sector.

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[3] PSG, The Public Health Crisis in Emerging Markets, 2004.

There are other issues, such as participation, that are not included here. Moreover, the elements of the framework that have been considered are only briefly discussed. Some are explored further in chapter IV.

43. This chapter has not tried to identify which are legal and which are ethical right-to-health responsibilities - that is a challenge for the future. Whether the responsibilities are legal, ethical or both, all pharmaceutical companies have to make some critically important decisions. Have they done all that is reasonably possible to enhance access to those in need? What is reasonable? Have they been as transparent as possible? Because of the importance and complexity of these and related questions, there must be internal and external monitoring and accountability mechanisms to provide guidance to the company and others. Chapter IV returns to this critical issue of right-to-health monitoring and accountability.

III. GLAXOSMITHKLINE: A BRIEF INTRODUCTION

44. This chapter, and the next, briefly introduce GSK and signal some of its initiatives that are reflective of its right-to-health responsibilities. Both chapters are based on material available, and interviews conducted, during 2008. In February 2009, however, GSK announced a number of important improvements to its access to medicines strategy, including significant price reductions in least developed countries, a specific commitment to invest in the health systems of these countries, and patent pooling.[4] In April 2009, GSK and Pfizer announced their intention to create together a new company for the discovery and delivery of treatments for HIV. While this report is based on the information and interviews of 2008, there are a few brief remarks concerning these very recent developments.

45. GlaxoSmithKline was formed in 2000 through a merger of Glaxo Wellcome and SmithKline Beecham. With its headquarters in London, GSK is one of the world's leading research-based pharmaceutical and healthcare companies.

46. GSK is one of the few pharmaceutical companies researching both medicines and vaccines for the World Health Organization’s three priority diseases, HIV/AIDS, tuberculosis and malaria. It produces medicines that treat six major disease areas: asthma, virus control, infections, mental health, diabetes and digestive conditions. In addition, it is a leader in the field of vaccines and is developing new treatments for cancer. GSK employs more than 100,000 people in over 100 countries across the world. It has one of the biggest research teams employing over 15,000 people based at 24 sites in seven countries.

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[4] GSK, Corporate Responsibility Report, 2008.

47. The company is listed on the London and New York Stock Exchanges. A Board of Directors and a Corporate Executive Team manage the company. In mid-2008, Andrew Witty became Chief Executive Officer, replacing Jean-Pierre Garnier who led the company from 2000. According to the figures for the year ending December 2008, the company had a turnover of over GBP 24,000 million and an operating profit of over GBP 7,000 million. GSK's profitability has increased in recent years. The pharmaceutical sector is among the most profitable industries in the world and GSK one of the most profitable companies in the sector.

48. Since 1998, GSK has been a leading contributor in the fight against lymphatic filariasis. GSK has donated over one billion albendazole (Albenza) tablets for the treatment of this terrible disease. The company produces antiretroviral (ARVs) such as zidovudine (Retrovir), lamivudine (Epivir), combination of zidovudine and lamivudine (Combivir), abacavir sulfate (Ziagen) and combination of zidovudine, lamivudine and abacavir sulfate (Trizivir). At its peak, the company held a 40% global market share in ARVs; today, it has a global market share of approximately 20%.

49. Established in 1992, Positive Action is GSK's long-term, international HIV/AIDS community investment programme, facilitating access to treatment by supporting HIV education, care and other related community initiatives. During 2007, Positive Action supported 17 programmes in 19 countries. The programme mainly focuses on stigma reduction and awareness-raising. The initiative enables communities to enhance their response to HIV/AIDS by providing up to date information, sharing of best practice between stakeholders, and empowering communities affected by HIV/AIDS.

50. GSK is currently conducting research and development into ten diseases of particular relevance to the developing world: bacterial meningitis, chlamydia, dengue fever, hepatitis E, HIV/AIDS, leishmaniasis, malaria, pandemic flu, pneumococcal diseases and tuberculosis.

51. In 2001, GSK launched Facing the Challenge focusing on: reducing prices for least developed countries and sub-Sahara Africa; investing in research and development for diseases that are particularly prevalent in the developing world; and playing a leading role in community activities that promote effective healthcare.[5]

52. GSK participates in a number of partnerships (e.g. TB Alliance), several of which are noted later in this report.

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[5] GSK, Facing the Challenge, 2001.

53. The company has been favourably ranked in various corporate social responsibility indices e.g. Good Global 100 Index, Global Dow Jones Sustainability Group Index and Financial Times Stock Exchange. In 2008, the Access to Medicine Foundation published an index ranking 20 pharmaceutical companies on how they treat the poor and enhance access to medicines.[6] GSK was ranked first.

54. However, GSK has also been heavily criticized. In 1998, for example, GSK's predecessors and over 30 other pharmaceutical companies filed a case against the Mandela government challenging the validity of South Africa's Medicines and Related Substance Act. According to the pharmaceutical companies the Act, which provided for compulsory licensing, parallel importation and other TRIPS 'flexibilities', undermined intellectual property rights. The case generated fierce criticism of the pharmaceutical industry and was eventually the subject of an out-of-court settlement. This proved to be a turning point. Shortly afterwards, the prices of ARVs, including GSK's, fell from R1000 to under R100 in South Africa. In other areas, too, GSK has been criticized. In 2007, for example, a BBC documentary alleged that GSK provided misleading information about the efficacy of one of its products, Seroxat, and that GSK-employed ghost writers influenced 'independent' academics.[7]

Obstacles to improving access to medicines

55. There are major barriers to enhancing access to medicines in developing and developed countries. The barriers are especially formidable in low-income countries. Some of these obstacles are rooted in poverty: the poor cannot afford even the cheapest medicines. In some countries, taxes and tariffs, as well as cultural factors, such as stigma and discrimination, impede access to medicines. Some of these obstacles make it difficult for pharmaceutical companies to enhance access to medicines. Obviously, some barriers cannot be tackled by the pharmaceutical sector alone. Here it is only possible to mention some of the obstacles that impede GSK's attempts to enhance access to medicines:

(a) *Weak health systems*: chronic under-investment has led to a lack of clinics and hospitals, poor distribution networks for medicines, low numbers of trained health workers, and so on. Failing and collapsing health systems are a very major obstacle to enhancing access to medicines;

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[6] ATM, The Access to Medicine Index, 2008.

[7] BBC, Secret of the Drug Trials, 29 January 2007.

(b) *Weak regulatory environments*: an efficient, competent and fair regulatory environment is important to the pharmaceutical industry. When the enforcement of pharmaceutical legislation is weak, counterfeiters thrive and poor quality medicines are commonplace;

(c) *Corruption*: is endemic in some medicine supply systems. Unofficial "fees" are required for customs clearance, counterfeit medicines are permitted to circulate, and so on;

(d) *Distribution channels*: another key challenge facing GSK is the lack of effective distribution channels. In many cases, intermediaries impede access to medicines. For example, they may create an artificial scarcity of medicines and add excessive mark-ups making drugs unaffordable to those living in poverty;

(e) *Reference pricing*: some high-income and middle-income countries try to use, as benchmarks for the prices at which they buy, the preferential prices offered to low-income countries;

(f) *Leakage or diversion*: some drugs priced for developing countries have found their way into the European market. In European pharmacies, for example, a dose of Combivir sells for about GBP 3.80. Under an agreement with GSK, a dose of Combivir in Africa sells at the cost price of about GBP 0.40. However, tablets sold in Africa have appeared in the European markets.[8]

56. Because there is uncertainty about the scale and nature of reference pricing and diversion, the Special Rapporteur recommends that research be undertaken to establish firm facts. If differential pricing between and within countries is to become more widespread, it is very important that data and information on reference pricing and diversion is current, detailed and reliable.

IV. RIGHT TO HEALTH ISSUES

57. This chapter briefly considers a selection of GSK's policies through the right-to-health lens set out in chapter II. Numerous important issues, like clinical trials, are omitted for lack of space.

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[8] Dyer, "Cost price drugs for developing countries are found in Belgian markets", BMJ. 2002; 325 (7368): 794.

A. Pricing

58. States, pharmaceutical companies and others have a right-to-health responsibility to do all they reasonably can to ensure that medicines are accessible to all (see chapter II). One critical dimension of access is affordability. GSK has a number of price reduction initiatives, including the following.[9]

Not-for-profit prices

59. GSK, whose portfolio includes ARVs and anti-malarial treatments, has made a commitment to increase access by providing these medicines to Least-Developed Countries (LDCs), and all of sub-Saharan Africa, at not-for-profit (NFP) prices. NFP prices are also available to countries included in the U.S. President's Emergency Plan For AIDS Relief (PEPFAR), as well as eligible projects of The Global Fund to fight AIDS, Tuberculosis and Malaria. According to GSK, NFP prices are sustainable prices i.e. the company covers its costs, including insurance and freight.[10] NFP prices are not dependent upon the size of the order.

Preferential pricing

60. On a case-by-case basis, GSK negotiates preferential prices for ARVs with middle-income countries.[11] Also, GSK has had a policy for some years whereby its vaccines are available at preferential prices to some developing countries using a tiered pricing system. Prices are linked to gross national incomes as defined by the World Bank, size of an order, and length of a particular supply contract.[12] In 2008, GSK shipped 1.1 billion vaccines and 79% of these went to the developing world.

Tearing down the barriers

61. GSK's Corporate Responsibility Report (2007) explains that the company is piloting a new approach to marketing medicines in middle-income countries. Called Tearing down the barriers, the approach has some similarities with GSK's preferential pricing policy for vaccines (see preceding paragraph). It considers the different socio-economic groups within middle-income

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[9] GSK, Corporate Responsibility Report, 2007.

[10] Ibid., p. 37.

[11] Ibid., p. 35.

[12] Ibid., p. 41.

countries: 'A' represents the wealthiest section of society and 'E' the poorest. While hitherto GSK's marketing has focused on the 'A/B' categories, Tearing down the barriers is piloting ways of enhancing access to the 'C/D' sections of the market e.g. tiered pricing within, as well as between, countries; gauging the relationship between price and volume for selected products in some middle-income countries; differential branding strategies; and local sourcing or manufacturing designed to address cost issues.[13] Interestingly, Tearing down the barriers is absent from the GSK's Corporate Responsibility Report (2008) published in early 2009, although the company still seems to be pursuing the general approach e.g. relevant pilot programmes remain in place.

Patient assistance programmes and discount cards

62. Like other pharmaceutical companies, GSK has introduced Patient Assistance Programmes (PAPs) and discount cards in the USA to help patients without insurance. PAPs provide prescription medicines free, or at minimal cost, to patients without insurance.[14]

Comments, conclusions and recommendations

63. More than 80 countries benefit from GSK's NFP prices for ARVs and anti-malarial medicines.[15] Since the introduction of preferential pricing for ARVs in 1997, GSK has reduced the price several times, including in February 2008. On this occasion, GSK introduced significant new price reductions averaging 21% across a range of ARVs.[16] The most significant reduction (almost 40%) was for abacavir sulfate oral solution (Ziagen), which WHO recommends for use within resource-limited settings. Combination of zidovudine and lamivudine (Combivir) was reduced by 17% to US 0.54 cents per day.[17] Of course, these price reductions are commendable and consistent with GSK's right-to-health responsibilities. Crucially, generic competition played a vital role in driving down these prices. In most cases, generic companies have pushed their prices below the NFP prices of innovator companies.

64. Tearing down the barriers is (or was) a promising initiative with the potential of enhancing access to medicines for many people, especially those in socio-economic groups C/D, in

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[13] GSK, Corporate Responsibility Report, 2007, p. 42.

[14] Ibid., p. 45.

[15] Ibid., p. 37.

[16] GSK, Facing the Challenge, 2001, p. 6-7.

[17] Ibid.

middle-income countries. As explained in paragraph 61, Tearing down the barriers is absent from GSK's latest literature but its general approach appears to remain part of the company's strategy. GSK's pilots will need careful study (i.e. actual volume, prices, results) to understand the approach's implications for enhancing access across different socio-economic groups.

65. GSK is exploring ways of enhancing access to its cervical cancer vaccine, Cervarix, in developing countries where most deaths from cervical cancer occur.[18] Today, however, Cervarix remains very costly (approximately UD$300) in both developed and developing countries, meaning it is largely unaffordable where it is most needed. As the patent holder of a life-saving medicine, GSK has a right-to-health responsibility to do all it reasonably can to put in place, as a matter of urgency, mechanisms that enhance access to Cervarix in middle-income and low-income countries (see para. 41). Access to medicines being a shared responsibility, others must also do all they can to help GSK enhance access to Cervarix.

66. GSK deserves credit for significantly reducing some of its prices, including the reductions announced a few weeks ago, and enhancing access to medicines. Such measures are reflective of its right-to-health responsibilities. However, some prices remain beyond the reach of many millions of people for whom the medicine is literally a matter of life and death. The price of Cervarix, for example, remains a cause of deep concern. The Special Rapporteur urges GSK to take all reasonable measures to ensure that its medicines, including vaccines such as Cervarix, are affordable to people living in middle-income and low-income countries.

67. Commercial interests and right-to-health requirements are sometimes aligned. Entering a new market may be good for a company's business and also required by its right-to-health responsibility to take all reasonable steps to enhance access to medicines. The Special Rapporteur welcomes the approach signalled in Tearing down the barriers that includes tiered pricing within, as well as between, countries. He strongly encourages GSK to include, in its strategy, access to category E (the poorest section of society). He calls on States, donors and others to work closely with GSK to ensure access to medicines of those living in poverty.

68. Although GSK publishes the prices of ARVs and other medicines, such as anti-malarials, the price offers to some (e.g. the private sector and pharmacies) are still not disclosed. Greater transparency of pricing policies, and their rationales, will enhance monitoring and help ensure better access to medicines.

69. When calculating NFP prices for LDCs, GSK and other pharmaceutical companies are urged to use their marginal costs i.e. the additional costs incurred by the company in making the

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[18] GSK, Corporate Responsibility Report, 2007, p. 41.

medicine available in LDCs, such as the additional manufacturing cost generated by providing the additional volume, freight charges, and so on. However, the calculation of marginal costs should exclude, for example, research and development for the medicine, marketing in the developed world, as well as a return for shareholders.

70. The Special Rapporteur calls on States to adopt WHO recommendations requiring Governments to remove tariffs and taxes on medicines.[19] Such tariffs and taxes are State-imposed obstacles to the realisation of the right to health.

B. Patents and licensing

71. The right to health requires a company that holds a patent on a life-saving medicine to use all the arrangements at its disposal to make the medicine as accessible as possible (see para. 41). Here the Special Rapporteur's main focus is on patents and licences.

72. GSK endorses the industry position that patent protection stimulates and fundamentally underpins research and development and is not an obstacle to access to medicines. The company supports the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and acknowledges the Agreement's flexibilities, such as compulsory licences and the 31(f) solution to allow compulsory licences for export. In August 2007, for example, GSK became the first company to grant consent under the 31(f) agreement for supply to Rwanda and it agreed to waive royalties.

73. Decisions on whether to take action to uphold GSK's intellectual property rights in the event of infringement, as well as the nature of any action, are taken on a case-by-case basis.[20] GSK reserves the right to encourage countries to introduce more demanding protection of intellectual property interests than those required by TRIPS, such as additional limitations on compulsory licensing. It argues that such provisions are "innovation friendly" and good for the national economy.[21] GSK Philippines lobbied against the Philippines' House of Representatives passing the Cheaper Medicines Bill that aimed to incorporate TRIPS flexibilities into the country's intellectual property code.[22]

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[19] WHO CIPIH, Innovation and Public Health, 2006, p. 133.

[20] GSK, Facing the Challenge, 2001, p. 6-7.

[21] GSK's Comment on draft Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, 2008.

[22] Oxfam, Investing in Life, 2007, p. 43.

74. In 2006, GSK offices in Thailand and India were subject to demonstrations against the company's patent applications for combination of zidovudine and lamivudine (Combivir). GSK decided to abandon such patent applications wherever they existed.

Commercial and non-commercial voluntary licences

75. GSK considers granting voluntary licences on a case-by-case basis. While GSK does not believe that voluntary licences are a universal solution to tackling HIV/AIDS or diseases in general,[23] it granted its first voluntary licence in October 2001 for manufacturing and sale of ARVs to Aspen Pharmacare, sub-Saharan Africa's largest generics company. The licence now covers both public and private sectors across sub-Saharan Africa. In 2006, GSK granted its eighth voluntary licence for its ARVs in Africa. In 2008, GSK's licensees supplied over 250 million tablets of their versions of lamivudine (Epivir) and combination of zidovudine and lamivudine (Combivir) compared to 180 million in 2007. These voluntary licences are granted on a NFP basis that includes a royalty (4%-5%) for administrative purposes. GSK and Pfizer have declared that voluntary licences such as these will form part of the access strategy of their new specialist HIV company.

76. While most voluntary licences to date have been to supply ARVs to countries in sub-Saharan Africa, GSK recently signed an agreement with Simcere, a Chinese company, to manufacture zanamivir (Relenza) in China, for sale in China, Indonesia, Thailand, Vietnam and all 50 LDCs. Zanamivir (Relenza) is an anti-viral for influenza.[24] This is one example of a voluntary licence granted by GSK whereby it receives commercial benefits from the generic manufacturer.

Patent pooling

77. GSK considers voluntary patent pools, with appropriate safeguards, as one mechanism for fostering research and development for neglected diseases. One of the company's improvements to its access to medicines strategy, announced in February 2009, is the creation of its own patent pool.

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[23] GSK, Corporate Responsibility Report, 2007, p. 36.

[24] Ibid., p. 42.

Comments, conclusions and recommendations

78. GSK's use of commercial and non-commercial voluntary licences has significantly enhanced access to some medicines, while the company's recent announcement on patent pooling is commendable.

79. However, GSK is not using voluntary licensing enough. Consistent with a company's responsibility to enhance shareholder value, commercial voluntary licences generate revenue for the patent holder. Non-exclusive licences are more likely to enhance access than exclusive licences: an exclusive licence may replace GSK's monopoly with the monopoly of a local licensee. Of course, a voluntary licence must include appropriate safeguards, for example, requiring that the medicines meet the standards of quality, safety and efficacy signalled in paragraph 27. They should also include any necessary transfer of technology. The terms of the licences should be disclosed. When discussing with GSK, sometimes one had the impression that commercial voluntary licences were seen as inconsistent with the current intellectual property regime. Of course, this is not the case. Commercial voluntary licences respect, and depend upon, today's intellectual property regime.

80. During one high-level interview in GSK's headquarters, it was acknowledged that there was some reluctance to issue more commercial voluntary licences. While the explanation offered for this reluctance was lack of trust, it was also recognized that it was time to give such licences renewed consideration. However, if GSK is to enter into a commercial voluntary licence, it has to be confident that its commercial interests are adequately safeguarded. It has to be able to trust generic manufacturers and States' regulatory environments. If its licence is broken, GSK can seek damages and other remedies in the courts. Understandably, however, this is small comfort to GSK. If there is a real risk that it will end up in the courts, GSK cannot be blamed for declining to enter into a voluntary licence (see also paras. 107 and 108).

81. It is critically important that GSK enters into more commercial and non-commercial voluntary licences across a range of medicines and markets. Generic and innovator companies, States, international organisations, and others, must do all they can to create an environment that facilitates the issuance of such licences.

82. Although GSK is not usually considered to be an industry hardliner on intellectual property issues, some of its positions, such as those in India, Thailand and Philippines, undermine its leadership position. The Special Rapporteur urges GSK to respect the right of countries to use, to the full, TRIPS flexibilities and encourages GSK to make a public commitment not to lobby for TRIPS 'plus' standards.

83. Today, there are serious attempts to find new ways to generate research and development other than by way of patents. GSK and all pharmaceutical companies are urged to engage positively with these initiatives. All parties are encouraged to respond constructively to GSK's recent announcement on patent pooling.

C. Research and development: neglected diseases and paediatric formulations

84. The right to health not only requires that existing medicines are accessible, but also that much needed new medicines and their formulations are developed and thereby become available to those who need them. Like other human rights, the right to health has a particular pre-occupation with disadvantaged and vulnerable individuals, communities and populations. For this reason, the right to health requires the development of medicines for e.g. neglected diseases, children, the elderly, pregnant and lactating women, and for various climates (see chap. II). In this section, the focus is on neglected diseases and paediatric formulations.

85. The record confirms that research and development has not addressed the priority health needs of low-income countries. Although some pharmaceutical companies are taking active measures to reverse this trend, research into these diseases remains fragmented and neglected.[25] Also, there is relatively little knowledge about the effects certain medicines can have on children, partly because fewer clinical trials are conducted on children than adults. As alternatives to missing paediatric formulations, healthcare workers and parents often use fractions of adult dosages, or prepare makeshift prescriptions of medicines by crushing tablets or dissolving portions of capsules in water. These alternatives may be unsafe for children. In short, there is an urgent need to develop paediatric formulations of medicines.

86. Surveying the history of research and development, it appears that the primary reference point has been the health of some better-off men living in temperate climates.

87. GSK undertakes research and development into diseases of the developing world, including WHO's three priority diseases of malaria, HIV and tuberculosis. It has drug development programmes regarding leishmaniasis and helminths. In addition to its work on vaccines, GSK has approximately 19 pharmaceutical research and development projects, some of them collaborative, targeting diseases of particular relevance to the developing world. GSK has a dedicated drug discovery unit in Tres Cantos, Spain, with about 100 full-time scientific staff (half supported by external partners such as TB Alliance), which leads research and development in malaria and tuberculosis. A research center in North Carolina, USA, leads GSK's research on

[25] Moran, The New Landscape of Neglected Disease Drug Development, Wellcome Trust, 2005.

new therapies for HIV/AIDS. GSK's facility in Rixensart, Belgium, undertakes research and development on vaccines, including for malaria, tuberculosis and HIV.

88. The company has developed a number of ARV liquid formulations for children, available at NFP prices in the world's poorest countries. The company is also committed to support four paediatric clinical trials in resource-poor countries to determine how to enhance access to HIV/AIDS treatment for children. In 2007, GSK gained approval from the European Medicines Agency for new scored tablets for Epivir, Combivir and Ziagen. A scored tablet can be broken into two smaller doses simplifying treatment for children. GSK has confirmed that the new company to be created by GSK and Pfizer will enhance research efforts into treatments and formulations for children living with HIV.

89. Recently, GSK and Drugs for Neglected Diseases initiative have announced collaborative research targeting the most neglected diseases, such as visceral leishmaniasis (kala azar). All new medicines developed through public-private partnerships are made available to the developing world at reduced prices.

Comments, conclusions and recommendations

90. The Special Rapporteur welcomes the increased attention into neglected diseases. The work done by GSK and some other companies, as well as philanthropic institutions and civil society organisations, to promote research into these diseases is commendable. It is imperative for the success of these initiatives that States, especially donor countries, participate fully and contribute financially and technologically so as to ensure sustained research into neglected diseases. A joint effort of the international community is needed to ensure scientific advances result in new treatments that help control and eradicate diseases of the developing world.

91. However, the gravity and scale of the problem continues to dwarf the global response to neglected diseases. The neglect of poverty-related diseases, that maim and kill the world's most disadvantaged individuals, communities and populations, continues to be one of the most serious human rights issues confronting the world today.

92. Recently, there have been attempts to devise new research and development models that would reward innovation but also generate new medicines for those living in developing countries. The Special Rapporteur encourages GSK to play a leadership role in these endeavours as they evolve.

93. Given the critically important social function of the pharmaceutical sector, as well as the gravity and scale of the challenge, all pharmaceutical companies have a responsibility to take

reasonable measures to redress the historic neglect of poverty-related diseases. This responsibility is not confined to innovator companies. All pharmaceutical companies should either provide in-house research and development for neglected diseases, or support external research and development for such diseases.

94. While GSK deserves credit for taking a leadership position within the industry with respect to neglected diseases, it is extremely important that it invests more and collaborates more effectively. Consistent with the right-to-health requirement of transparency, the Special Rapporteur urges GSK and other pharmaceutical companies to disclose their investment in research and development for neglected diseases, as well as their investment in research and development overall.

95. The Special Rapporteur encourages GSK and other companies to consistently make their compound libraries available for screening for neglected diseases.

96. The Special Rapporteur urgently calls on GSK and other companies to attach a much higher priority to the development and manufacture of paediatric formulations of their medicines, and to disclose the scale of their investment.

D. Accountability

97. Accountability, which includes monitoring and redress, is a vital feature of all human rights, including the right to health (see chap. II).

98. In addition to national courts and tribunals (e.g. employment tribunals), GSK's existing internal and external (or independent) accountability mechanisms include the following:

- Board of Directors and its Committees e.g. the Corporate Responsibility Committee
- GSK's publicly available reports, reviews and quarterly results, including its annual Corporate Responsibility Report
- Annual General Meeting
- A company department that audits GSK's systems and processes e.g. sales and marketing
- Internal whistle-blowing procedure
- Integrity Helpline for "interested outside parties" who may wish to report alleged misconduct

- Independent ethical review committee on the company's clinical trials
- PricewaterhouseCoopers' annual audits of GSK's financial statements

99. Bureau Veritas, an independent third party, externally assured the information supplied in the access to medicines section of GSK's Corporate Responsibility Report (2007). While on mission, the Special Rapporteur was informed that Bureau Veritas asked GSK for clarification of some passages in the draft section and requested that textual changes be made. Also, they recommended that GSK "should provide greater detail on the governance, accountability and management structures for access to medicines and the relationship with external stakeholders." GSK responded to these recommendations as part of its Corporate Responsibility Report (2008). Inexplicably, GSK did not subject its 2008 Report to external assurance.

100. GSK has actively participated in independent evaluation exercises, such as *Investing in Life*, Oxfam's 2007 review of pharmaceutical companies' approach to access to medicines, as well as the recent Access to Medicine Index. Launched by the Access to Medicine Foundation, the Index considers the efforts of the world's largest pharmaceutical companies, inter alia, to help solve the global medicines crisis. The Index scores companies according to their performance on a wide range of criteria; as already observed, GSK scored better than any other company.

101. GSK's research and development strategy for diseases of the developing world was subject, in 2003, to external review by an advisory board comprising public health and scientific experts from both developing and developed countries. Although an important step in the right direction, this review did not include all those dimensions that are important from a right-to-health perspective. Moreover, it has not been repeated since 2003.

Comments, conclusions and recommendations

102. The Special Rapporteur has not closely examined all the accountability mechanisms noted in paragraph 98. He welcomes the external assurance of some passages in GSK's Corporate Responsibility Report (2007); all pharmaceutical companies should emulate this development as a matter of urgency. He greatly regrets GSK's failure to subject its recent Corporate Responsibility Repor*t* (2008) to external assurance.

103. The most striking feature of the accountability mechanisms briefly signalled in the preceding paragraphs is that they rarely, if ever, monitor and hold GSK to account in relation to its right-to-health responsibilities. None, for example, assesses whether or not GSK is doing all it reasonably can, within a viable business model, to enhance access to medicines for all. While the external assurance of the Corporate Responsibility Report (2007) is commendable, it checked

whether or not the information was accurate and sufficiently detailed, it did not assess if GSK was fulfilling its right-to-health responsibilities.

104. Some of the accountability mechanisms mentioned in the preceding paragraphs are indispensable, such as those designed to ensure financial probity and shareholder confidence. But they provide insufficient independent scrutiny of the critically important medical, public health and right-to-health functions of GSK. They do not independently assess, for example, whether or not GSK is fulfilling its responsibilities as a patent holder of life-saving medicines. Understandably, GSK robustly defends, in the courts and elsewhere, its privileges as a patent holder, but where are the independent mechanisms to check that it fulfils its corresponding responsibilities as the patent holder of life-saving medicines? To its credit, GSK is committed to upholding the Universal Declaration of Human Rights. In its human rights statement it says: "As a marketer of pharmaceutical products with life saving and enhancing properties, we will strive to make them as widely available as possible while running our business in a sustainable way", but there are no independent mechanisms designed to monitor and hold GSK to account for this important medical, public health and right-to-health commitment.

105. Whether its right-to-health responsibilities are legal, ethical or both, GSK must strengthen its accountability in relation to access to medicines. GSK should consider, for example, appointing an independent Ombudsman with oversight of the company's right-to-health responsibilities relating to access to medicines. GSK should also work with like-minded companies to establish an independent mechanism to monitor and hold accountable the relevant companies in relation to access to medicines and the right to health. GSK should also consider working with an association of pharmaceutical companies with a view to establishing such a mechanism. As one step in the right direction, it may wish to establish an independent mechanism that focuses on one particular dimension of access to medicines and the right to health, such as disclosure of information (see para. 28). Critically, GSK needs an accountability mechanism that uses right-to-health standards and is independent, accessible, transparent, and effective.

V. CONCLUSION AND RECOMMENDATIONS

106. **This report includes numerous conclusions and recommendations for GSK, all pharmaceutical companies, States, international organisations and others - and they will not be repeated here.**

107. **A member of the senior management of an innovator pharmaceutical company recently remarked to the Special Rapporteur that the company's patents were "its crown jewels". The image was revealing. In one sense, the image is legitimate - patents are**

immensely valuable. In another sense, the image reflects a profound misunderstanding of the role of a company that develops a life-saving medicine. As discussed in chapter II, such a company has performed a critically important social, medical, public health and right-to-health function. While the company's "reward" is the grant of a limited monopoly over the medicine, enabling it to enhance shareholder value and invest in further research and development, the company also has a right-to-health responsibility to take all reasonable steps to make the life-saving medicine as accessible as possible, as soon as possible, to all those in need. For a limited period, the company holds the patent for society - but the patent must be worked, so far as possible, for the benefit of all those who need it.

108. **The status of innovator companies would be immeasurably enhanced if they did not see, and treat, patents as their "crown jewels". Companies must grasp, and publicly recognize, their critically important social function and right-to-health responsibilities. They must demonstrably do everything possible, within a viable business model, to fulfil their social function and human rights responsibilities. Presently, this is not happening. If it were to happen, it would not only greatly enhance companies' status but also pressurize States, generic manufacturers and others to provide the environment that companies need if they are to enter into arrangements, such as commercial voluntary licences, that enhance access to medicines for all.**

109. **In 2008, the Special Rapporteur presented to the General Assembly Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (A/63/263). These provide detailed guidance for all pharmaceutical companies on their right-to-health responsibilities, as well as society's legitimate "expectations" of the pharmaceutical sector.**
