

GSK Public policy positions

“Technology Transfer”, Capacity Building and the Developing World

The Issue

In recent years, increasing emphasis has been put on the role that multinational companies and developed world Governments should play in supporting technology transfer into developing countries. The context for much of this debate has been Paragraph 66.2 of the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement which 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 country¹ (LDC) Members in order to enable them to create a sound and viable technological base”.

Despite this reference to technology transfer in TRIPs, there is no universally recognised definition of what “technology transfer” means. Definitions tend to differ from country to country and organisation to organisation, with some putting a disproportionate emphasis on manufacturing capacity as the most valuable form of technology transfer for developing countries. For GSK, technology transfer represents a mix of “resources” and “know-how” transfer which is made in a commercial and sustainable context. Furthermore, recipient countries are not necessarily LDCs but are those emerging markets where investment decisions are appropriate, viable and can realistically be forecast to succeed.

This paper sets out GSK’s approach to investing in, and supporting, developing countries; outlines some of the external conditions which are conducive to this investment; and provides an illustrative overview (at **Annex A**) of some of the capacity building projects we undertake in developing countries.

GSK’s Position

- GSK is a global research-based company whose business is to provide innovative medicines to those in need. We are committed to the communities where we operate and our business provides an important contribution to those communities.
- GSK is involved in a number of “know-how” transfer and/or capacity building programmes into the developing world, including voluntary licence arrangements, work with local medical and regulatory professionals, community partnership projects, and clinical trials programmes.
- Taken together these projects contribute markedly to local scientific, regulatory, medical and manufacturing capacity and thereby help to build the necessary sustainable infrastructure to attract and absorb new technologies from other companies and industries.
- GSK considers technology transfer opportunities when they can realistically be forecast to succeed, are practical and appropriate given local conditions, reflect best use of resources and are sustainable.
- Many factors contribute toward a conducive environment in which the pharmaceutical industry will invest in a country or partner with community members. Key amongst these factors are appropriate economic, scientific and market conditions. A robust legal framework is also important. Businesses will migrate naturally to where these conditions exist and are sustainable.
- GSK is involved in a number of manufacturing projects in the developing world. 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.

¹ As defined by the UN there are currently 49 Least Developed Countries (LDCs) of which 33 are in Africa. Structural weaknesses, poverty, susceptibility to natural and man-made disasters and to communicable diseases hamper the efforts of these countries to improve the quality of life of their people.

- A strong intellectual property (IP) system alone will not provide sufficient an incentive to transfer IP protected technology to a country; however, its absence will undoubtedly constitute a major disincentive. Steps that weaken IP protection, such as widespread compulsory licensing, ineffective anti-counterfeiting measures and inadequate data protection, could therefore act as a serious disincentive to investment in developing countries.

Background

Conditions Conducive to Inward Investment and Capacity Building

GSK is acutely aware of the economic and related healthcare challenges facing millions of people in developing countries and the link between health and wealth. We are committed to playing a part in helping to address these challenges and the existing unmet medical need in many developing countries. Our response, however, must be sustainable. Our willingness to invest in and partner with developing countries is, therefore, heavily dependent upon suitably supportive “in-country” business and scientific environments comprising;

- Economic and political stability: There are a number of reasons why a local economic climate can be an attractive place for business in general. These include steady economic growth, stable inflation rates, and low and stable interest rates, open and outward looking markets, with deep and enduring economic linkages with the rest of the world. These factors all support the predictability of the commercial environment.
- Market size and potential: While it is not easy to define the market size or type that will make for viable economic production, it is generally the case that the larger the country or geographic bloc, the greater the market potential and investment appeal.
- Skilled workers: To carry out R&D and high-tech manufacturing, it is necessary to have access to highly specialised staff. The availability of scientific research skills and infrastructure will generally outweigh financial incentives or a low tax climate, although financial factors may be decisive in a choice between two locations with the necessary science-base.
- Supportive regulatory environment: A good registration process for pharmaceutical products that enables medicines to meet stringent criteria on quality, safety and efficacy. This will encourage pharmaceutical companies to conduct clinical trials and launch innovative products early.
- A well developed national infrastructure of natural resources, public utilities and transport, along with a robust legal framework will all be considered as part of any investment decision.
- IP protection: The existence and enforcement of an IP system in a recipient country is generally a prerequisite for any out-licensing / joint venturing decisions. While a strong IPR system alone will not provide sufficient an incentive to transfer IP protected technology, its absence will undoubtedly constitute a major disincentive.

GSK’s role in generating many of these conditions is limited. Equally, in the context of Paragraph 62.2 of TRIPs, the ability of developed world governments to encourage investment in a commercially unattractive country through incentives will be limited. Appropriate in-country macroeconomic conditions are not easily created or problems overcome by third-party incentives.

“Technology Transfer” and Manufacturing

For many in the developing world, “technology transfer” is seen simply in terms of developing local manufacturing capacity. They argue, post-Doha, that only by transferring and building manufacturing capacity in developing countries will their access to affordable medicines be assured. GSK would question this view. The access debate should not be confused with local industrial policy. The value of “technology transfer” should not be limited to providing manufacturing capacity for products, still less for patented pharmaceutical products.



Manufacturing medicines is a complex, time-consuming, capital intensive, highly regulated process requiring an efficient supply chain and supporting infrastructure of highly qualified staff, and reliable and continuous supplies of water, gas and electricity. A World Bank commissioned study of 2005² acknowledged these challenges when it concluded that a critical level of industrial and socioeconomic development and human and technical resources must be reached before any indigenous industry can survive. As a result, manufacturing tends to be concentrated in a limited number of sites in the world.

Manufacturing offers substantial benefits of scale in operation. That is, the lowest costs will be achieved with high volumes and high capacity utilisation – concentration in large plants in a limited number of locations. Manufacturing capacity for pharmaceuticals (if not for vaccines) currently far exceeds demand. Even if current excess capacity were absorbed by increased supply to patients, further demand would, for the most part, best be met by scaling up current efficient operations, not by creating new manufacturing sites.

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² Kaplan WA, Laing RO, Waning B, Levison L, Foster S. Is local production of pharmaceuticals a way to improve pharmaceutical access in developing and transitional countries? Setting a research agenda.

GSK and Capacity Building in the Developing World

Manufacturing Operations

GSK has 41 manufacturing sites outside Europe and North America. The list includes sites in Algeria, Nigeria, Sri Lanka, Kenya, Pakistan and the Philippines, and one in an LDC (Chittagong, Bangladesh). Collectively they form part of the company's business strategy and were established in response to a business need or, in some circumstances, because of local government insistence on "local working" as part of the product registration process. By operating these manufacturing sites, GSK promotes the development of skills and technical expertise of the workforce in those countries.

GSK also has a programme of "know-how" transfer to local manufacturers whereby we outsource production of products as part of a carefully managed production cycle aimed at freeing up GSK production capacity for the development of new drugs and vaccines. Transfer of production usually occurs post-patent expiry for products which local operating units consider of strategic and/or commercial importance in local or regional markets. They remain GSK branded products, sold and marketed by the company; however production is done by a third party contractor, with the necessary regulatory and technical support from GSK to ensure compliance with local and international standards.

Horlicks Production

- India: GSK has three Horlicks factories in India dating from 1959, 1973 and 2002 (one in Punjab in the North, one in Andhra Pradesh in the South, and the third in Haryana, which commenced production in 2002). Two of the factories - in Punjab (Nabha) and Andhra Pradesh (Rajahmundry) - buy cow/buffalo milk from around 12,000 local farmers.

From initially supporting farmers to produce milk, GSK is now engaged in aiding the process of increased milk production in around 250 & 152 village milk-sheds in Nabha & Rajahmundry respectively, through organised village-level collection (including installation of bulk milk coolers at village level, chilling milk at near farm-level itself). GSK also provides back-end support by aiding dairy development activities in form of animal health care, breed improvement, farm management and clean milk production to improve value generation for farmers.

- Bangladesh: Bangladesh receives Horlicks, Junior Horlicks, Mother's Horlicks and Women's Horlicks as DMI (Dry Mix Ingredient) from India in bulk. Skimmed milk powder, fine crystalline sugar, ferric pyrophosphate, vitamins, flavours & DHA (basis product formulation) are added to the DMI at a third-party, Mutual Foods Bangladesh, and packed into the consumer pack. Maltova is supplied in bulk from India and packed at Mutual Foods Bangladesh. Horlicks Lite is supplied in retail SKU's (Jars).

Joint Ventures

GSK is involved in several joint ventures (JVs), the rationale for which is based on a number of contributory but essential factors. Careful consideration is given to all aspects of the agreement between GSK and the JV partner, including the rights and liabilities of the contracting parties, confidentiality matters, intellectual property, training requirements, development needs, respect of GMP, independent QC or National Control Authorities. External factors also play a large part such as market size, a favourable climate for foreign direct investment and opportunities for export. Examples of existing projects include:

- GSK (via its legacy companies) has a long history of JVs in China, starting with SK&F discussions in 1983 which resulted in the first Tianjin JV TSK&F in 1987. This ownership was 55:45 and it was one of the three most successful foreign pharmaceutical businesses in China throughout the 1990s. In 1996, it reached a production level of more than 1.2 billion capsules per year, mostly of OTC-type products Contac (for colds) and Fenbid (the non-steroidal ibuprofen for a variety of aches and pains). Both achieved market leadership. These volumes have remained at a steady level since.

- Over the last 25 years we have forged a unique partnership - notable in the global health community for its duration, scope and sophistication - with the Brazilian Government's Fundação Oswaldo Cruz (Fiocruz) delivering technology-transfer projects, covering several vaccines (polio, meningitis (Hib), MMR, rotavirus, pneumococcal & MMR-V).
- In January 2013, we entered into an agreement with Biological E Limited (Biological E.), a leading Indian vaccines company, to form a 50/50 JV for the early stage research and development of a six-in-one combination paediatric vaccine to help protect children in India and other developing countries from polio and other infectious diseases. The partnership reinforces the commitment of both companies to support the World Health Organisation's (WHO) global polio eradication programme.

Scientific Research

R&D Investment

- In May 2007, GSK R&D created a new R&D centre in Shanghai, China, with the initial objective of creating new medicines for severe disorders such as multiple sclerosis, Parkinson's disease, and Alzheimer's disease. The centre now directs the global discovery and development activities within the neuro-degeneration therapeutic area, from drug-target identification to late-stage clinical studies, while collaborating with research institutions elsewhere in China and other countries. R&D in China is also conducting late-stage clinical development work on therapy area medicines from across GSK's pipeline for launch in China, for example, Tykerb for breast cancer. It is hoped that up to 1,000 high-skilled jobs will be created at the site by Year 10, making it GSK's third largest R&D base.

Transfer Programmes

- In 2000, GSK signed an agreement with the Shanghai Institute Materia Medica whereby initially two chemists from Shanghai spent three months in GSK high-throughput chemistry laboratories being trained in state-of-the-art chemistry techniques. These Chinese chemists then went back to their Institute to spread the technology within their own group. Over ten years on, GSK remains committed to this initiative; we now support eleven scientists in Shanghai who synthesise quality chemical arrays in collaboration with GSK and to the benefit of the local academic science-base in Shanghai.
- The UK-India Education and Research Initiative is a joint initiative between R&D and GMS (our manufacturing division). Through collaboration with The British Council, over the past five years, GSK has trained 56 graduate chemists in our laboratories for a period of one year.
- In July 2005, GSK and Oxford University's Department of Clinical Pharmacology established a collaboration (INDOX) creating the first Indian cancer-trials network comprising a number of India's leading comprehensive cancer centres. Each Indian site has a clinical coordinator who has received on-line training from the University of Oxford prior to visiting Oxford to acquire additional hands-on experience working for a brief period in the Oxford clinics. The primary purpose of this training is to increase the Indian clinicians knowledge of Good Clinical Practice in order that they can take this back to India and put it into practice. To date, a total of 94 Principle Investigators, sub-investigators, INDOX Site Coordinators and site research staff have been trained through the collaboration.
- In 2011, GSK agreed to continue the INDOX agreement for an additional year and to extend the training from India into Turkey and the Middle East and North Africa Region.

Scientific Collaboration

'Trust in Science' was established in 2010 as a principal element of GSK's efforts to build long-term, meaningful partnerships with key scientific stakeholders. It sees GSK provide funding to top local research institutions for the development of patient-focused research programmes that address the treatment of relevant diseases and meet local community needs. The company's support is matched by government research funding agencies. Programmes are selected by an independent scientific panel of eminent local scientists and endorsed by the relevant GSK Discovery Performance Units (DPUs). The overall aim is to help build understanding of globally and locally relevant diseases, which will help their treatment and prevention. It also aims to create a strong collaborative framework, promoting GSK as a partner of choice.

Trust in Science was launched first in Brazil but now includes projects in Argentina, and in early 2013 was extended to Africa (Uganda, Kenya and Tanzania).

Clinical Trials

GSK is increasing the number of patients we recruit into clinical trials from Central and Eastern Europe, Asia and South America (i.e. outside the traditional centres of Western Europe and North America). This has been supported by an appropriate increase in investment both in operational headcount and in infrastructure development including the placement of study-funded coordinators at selected high-recruiting sites. This enables investigators to focus on the patient-facing component of research, and to maintain their studies to the highest standards despite the increased flow of work.

GCP-training of staff is a high priority in all countries, but none more so than non-traditional markets where experience of conducting global trials is still growing. Investigator GCP-training workshops are sponsored by GSK in many countries. In Korea, for example, there is a well-established GSK-sponsored accreditation programme which receives excellent feedback.

In line with our commitment to develop medicines and vaccines for diseases disproportionately impacting on the developing world such as, TB, malaria, dengue, HIV and HPV, GSK is currently undertaking clinical trials in countries across the globe where such diseases are prevalent. For example, GSK has invested more than two decades in the effort to develop a successful malaria vaccine and in collaboration with leading research institutions based in Africa, a series of clinical trials are ongoing in Mozambique, Tanzania, Kenya, Gabon and Ghana.

In malaria treatment studies, GSK has worked with sites to improve internet connectivity, electricity supplies and requisite storage facilities for drug supplies and study documentation. There has also been upgrading of clinical rooms, wards and laboratories with training and improved capacity for specialist laboratory testing.

Regulatory Conferences and Workshops

Competent regulatory authorities are important to the pharmaceutical industry. They speed up product registration in support of public health and they relay a valuable message to the broader business community regarding the importance a country attaches to effective governance and high standards, as well as establishing regulations – allied to workable systems and processes – for ensuring protection of public health. As a global pharmaceutical company, GSK works closely with other companies to help build capacity in the regulatory area across the developing world. This commitment is ongoing, takes a number of forms and brings tangible benefits to both sides.

- Regional Regulatory Conferences: In collaboration with other members of EFPIA (the European Trade Association) and PhRMA (the Pharmaceutical Research and Manufacturers of America) GSK supports a series of annual regulatory conferences. The series began in 1996 with the Middle East Regulatory Conference and has been mirrored since in Asia and Latin America (in collaboration with the International Trade Association, IFPMA). Representatives from the local and regional regulatory bodies are invited to hear regulators from ICH countries, as well as the R&D-based industry discuss best practice. Horizon-scanning issues are also discussed, such as the likely impact of genomics on pharmaceutical regulatory processes. The World Health Organisation is closely involved in the development and delivery of these Conferences.
- Workshops: The Conferences outlined above are also supplemented by one-off workshops for Regulators on specific issues such as GMP and support for global clinical development. Again, representatives from ICH Regulatory Authorities, such as the FDA or EMA are invited by industry to speak/train their counterparts in developing countries and thereby facilitate know-how transfer. Such workshops generally supported by industry, include organisation and some degree of funding.
- Contact facilitation and Training: In recent years, industry has supported and delivered trainings to the Chinese Regulatory Authority to support the review of investigational new drug (IND) applications and IND variation applications, specifically in order to facilitate a common understanding of the product development process for new chemical entities and to improve understanding of the types of technical changes that may occur so that regulatory approval procedures and approval times can be adhered to. At a company-specific level, via GSK's dedicated International Regulatory Affairs Department, GSK regularly facilitates meetings between developing world regulators and their European or American counterparts. We also stand ready to work with regulatory authorities on training programmes.

Global Sourcing

Global Sourcing is about accessing world-class talent pools, patient pools and infrastructure in low to medium cost locations and sourcing direct materials from low-cost, high capability locations. Standardisation is about applying proven local best practices and processes more broadly across the company without adding bureaucracy, resulting in reduced complexity, increased productivity and improvements in the quality of outputs.

The areas of greatest opportunity for global sourcing and standardisation have been R&D (*see above*), manufacturing and IT, due to the size of their expenditure and the global potential of existing talent. We believe we are at the forefront of industry global sourcing in many areas and in IT in particular.

Specific GSK projects include:

- Significant amounts of IT work to India with over a thousand full-time equivalent (FTE) employees working on GSK projects at vendor offshore locations.
- A Global Pack Management Centre in India where GSK employs up to 140 FTE's in low-cost creation of packaging artwork, proof reading and completion, supporting EMAP markets and catering for work overflow from Europe.
- The creation of close to 500 FTE's across several functions in Finance, HR, R&D, and Commercial in several countries in the developing world. Outsourced services include processes such as accounts payable, general accounting, helpdesk and travel & expense, R&D processes such as data management, biostatistics & programming and medical writing.

Community Partnership Programmes

While none of GSK's community partnership activities is designed to increase the sale of GSK products, they deliberately go beyond traditional philanthropy and are aimed at building strategic, sustainable partnerships that generate mutual benefit for GSK, its partners and beneficiaries of the programmes.

Given GSK's principle commercial activities and the skills of our people, the focus of our programme is on improving health and education – critical areas where we can really make a difference. The following are a few examples of the developing world projects we run:

- GSK's African Malaria Partnership supports three behavioural change initiatives to improve individual and community responses to malaria, encouraging the use of insecticide-treated bed nets (ITNs), intermittent presumptive treatment of pregnant women (IPT) and prompt, effective treatment of malaria fevers in young children. The partnership is reaching almost two million people at risk from malaria.
- GSK's PHASE (Personal Hygiene And Sanitation Education) programme is a simple hand washing programme for schoolchildren that saves lives. By teaching hygiene and sanitation skills, PHASE aims to reduce diarrhoeal related disease. Children are encouraged to act as agents of change by applying what they have learnt to their home environments and teaching their families. PHASE is implemented in partnership with a number of NGOs including Save the Children, AMREF, the Millennium Villages Project, Fit for School and Pratham.
- GSK's Thai Rural Nursing Excellence programme sponsors female high school graduates from rural areas to complete nursing degrees with the aim of training 200 nurses over five years. Once qualified, the nurses return to work in their communities for at least three to four years.
- In Vietnam, a similar GSK programme provides scholarships for 500 women to be trained in community healthcare. This is a unique training programme, based in Tu Du Hospital, Ho Chi Minh City, that aims to reduce childbirth complications and decrease newborn fatality from 6% to zero% in some of the more remote and poorest communities in Vietnam. The project is training midwives who will return to their villages to provide healthcare services for vulnerable mothers and newborn babies.
- We support the Pro Mujer programme in northern Argentina which works with low-income women who do not have access to affordable financial services or healthcare. Pro Mujer provides training and small loans to help women set up their own businesses and provides them with access to affordable healthcare services.



- In India we are working with PATH, community groups and other partners to improve vaccine coverage for people living in the Mumbai slums. The 18-month project will work within the existing health system to develop a sustainable model for the delivery of immunisations, which can be replicated in other areas. The project results will be carefully evaluated to help identify the key factors for improving immunisation programmes in poor urban environments.

Africa/Developing Countries Business Unit

GSK's Africa/Developing Countries Pharmaceuticals operating unit set up in 2014 (formerly the Developing Countries and Market Access operating unit established in 2010), consists of all countries across Sub-Saharan Africa and Least Developed Countries. The unit's aim is to increase R&D efforts on priority health needs in Africa, invest in our supply chain to enable business growth in the region and increase collaboration across Pharmaceuticals and Consumer Healthcare operations to ensure that our innovative healthcare products, including those that treat NCDs, reach more people.

In Africa alone, countries bear 24% of the global health burden, yet they have just 3% of the global healthcare workforce and 1% of the global health budget. GSK addresses unmet healthcare needs in developing markets by making our medicines and vaccines available, accessible and affordable to as many people who need them as possible. Our targets within this unit are focused on volumes rather than profit margins and we cap the price of our patented medicines at 25% the cost in developed countries.

At the same time, we re-invest 20% of the profit we make in each country back into those countries' health systems, by training healthcare workers, raising awareness of health services and providing basic public health education. We have forged global partnerships with AMREF, Save the Children and Care International to establish regional Healthcare Infrastructure Partnerships (HIPs) through which the 20% profits will be invested. The aim of the HIP is to strengthen the health workforce in LDCs, with a focus on frontline health workers in the most rural and marginalised communities. Thus far, we have invested £10 million and our target is to train 15,000 healthcare workers by 2015.

Through this business unit we have also developed innovative partnerships with Barclay's, Vodafone, the Tony Blair Faith Foundation and others to deliver strategic programmes that address complex barriers to quality healthcare in developing countries.

Three times, we have been ranked number 1 in the Access to Medicines Index, which rates the efforts of the top 20 pharmaceutical companies to improve access to medicines in the developing world. At GSK, we are proud of this recognition for doing good business for better public health.