

Product Donations

The Issue

As a global healthcare company operating in countries throughout the world, GSK recognises a responsibility to make product donations in the form of ongoing humanitarian assistance and/or as emergency support when natural disasters hit. We are committed to ensuring that these donation programmes are managed in a responsible way and should not disrupt or undermine healthcare provision in recipient countries. GSK donations are therefore made in accordance with an established framework of legal obligations and internal processes, and in line with World Health Organisation (WHO) Guidelines on Product Donations. This paper sets out GSK's policy and the principles that underpin our approach to product donations.

GSK's Position

- GSK is a committed partner to improving healthcare in the developing world and believes that sustainable preferential pricing of critically needed medicines and vaccines is the best response to the challenges faced by these countries (see *Facing the Challenge* below).
- We believe, however, that targeted product donation programmes have an essential role in both saving lives, and improving the quality of life of people living in vulnerable situations.
- It is a fundamental part of GSK's community investment activities to support community healthcare in impoverished, remote communities and to provide medical products in times of natural disaster or conflict.
- GSK product donations are routinely directed through a select number of charitable Non-Governmental Organisations (NGOs), through International Public Health Organisations such as WHO, PAHO, and/or via local Ministries of Health.
- The majority of donation requests received by GSK are for broad spectrum antibiotics, although we do also donate vaccines. For example, in June 2007 we announced our intention to donate 50 million doses of our H5N1 pre-pandemic influenza vaccine to the WHO in support of its stockpile initiative. We do not routinely donate consumer healthcare products.
- In common with many other stakeholders, including the WHO, we do not believe that donations for the treatment of chronic diseases are a sustainable solution to the healthcare challenges faced by many countries. Products for the treatment of diseases, such as HIV/AIDs or asthma, will therefore only be donated under exceptional circumstances.
- All donations are formally approved by the local GSK general manager to ensure that medicines are registered and appropriate to the needs in-country.
- If GSK becomes aware that, for any reason, GSK donated product has not been distributed and used within the expiration date, GSK local management is responsible for obtaining documented confirmation that the product has been safely destroyed in a manner that meets local regulations.

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GlaxoSmithKline's Position

- We report the value of our programme via a number of publications including the company's Annual Report, Annual Review and annual Corporate Responsibility Report. We also routinely share our data with the widely respected, *Committee Encouraging Corporate Philanthropy* and the *London Benchmarking Group*.
- While the value of GSK's programme may fluctuate slightly from year to year, GSK is routinely amongst the leading FTSE 100 corporate donors.
- GSK is a member of Partnership for Quality Medical Donations, all members of which operate in line with the WHO Guidelines. This means we will only donate drugs that have been requested by the recipient and will ensure that all drugs are properly labeled and accompanied by clear packing lists. We do not donate drugs that are past their expiry date and we will only donate drugs with less than one year's expiry if the recipient organisation confirms they want and are able to use this specific product within the expiry date.

BACKGROUND

GSK's Donation Programmes

The majority of GSK's donations are managed by GSK's Global Community Partnerships team, directed through a select number of experienced charitable Non-Governmental Organisations (NGOs) or through International Public Health Organisations such as WHO and PAHO.

Our NGO partners are evaluated based on their submission of appropriate information including proof of charitable status, site visits assessing their capacity to secure, store, ship and utilize products properly. They must also have a proven track record in the region where the product is to be shipped/donated, of tracking distribution, reporting results and working with in-country governmental officials.

A small proportion of GSK's product donations are handled locally by GSK's Local Operating Units in response to specific requests and/or acute emergencies from Ministries of Health and NGOs. All local product donations are reported to Global Community Partnerships and included in the reported annual donations' figure.

Pharmaceuticals

GSK's corporate pharmaceuticals donation programme is managed centrally by Global Community Partnerships, working with five carefully selected charity partners AmeriCares, Project HOPE, Direct Relief, IMA (Interchurch Medical Assistance) and MAP International.

Each NGO with whom we partner has an annual allocation and can select medicines from GSK's inventory at the beginning of each year. The majority of requests are for broad spectrum antibiotics. The NGOs will also be offered excess stock which may become available during the year.

Vaccines

Requests received by our local operating companies or by GSK Biologicals based in Rixensart, Belgium, will be reviewed on a case-by-case basis. Most requests and/or donations provided in response to an emergency situation occur from developing countries. Any donations made will be on condition that cold chain supply and appropriate administration can be guaranteed. GSK does not operate a formal vaccines donation programme.

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Consumer Healthcare

Donations of OTC and consumer products are made in response to specific requests by aid agencies or governments, on a case by case basis. GSK Consumer Healthcare does not operate a formal donation programme.

Patient Assistance Programmes

GSK also operates a number of Patient Assistance Programmes in the US. These are managed by the US business and under US tax laws must be included in GSK's annual figure on the value of our product donations. However, given the nature of the programmes, they are not subject to the WHO Guidelines (*see below*).

Donations for Chronic Diseases

Donations can have a role to play in addressing humanitarian disasters or short term discrete programmes where there is an identifiable and achievable end point, such as in disease elimination. GSK is, for example, a key partner in the global programme to eliminate lymphatic filariasis (LF), also known as elephantiasis. This is a disabling and disfiguring disease that currently affects 120 million people, and threatens a further 1.2 billion, in some of the poorest nations of the world. Over the anticipated 20 year life of the programme, our donations to this important endeavour will build to an estimated six billion albendazole tablets, valued at \$1 billion.

However, in common with many other stakeholders, such as the European Union, WHO and Oxfam, GSK does not believe that donations of products for the treatment of chronic diseases such as HIV and asthma offer a sustainable solution to the healthcare challenges facing many of the countries to which we donate.

As Oxfam said in their Fatal Side Effects publication, *"Giving drugs is inappropriate, however, when it distorts local priorities, when not accompanied by support for related health-care infrastructure, or when it is only for short periods.*

In exceptional circumstances we have donated ARVs. For example to UNICEF's Prevention of Mother-to-Child Transmission programmes; as initial support for national treatment programmes or; when there have been interruptions in supply due to conflict situations.

GSK and Facing the Challenge

GSK is committed to playing a full part in addressing the healthcare challenges of the developing world. We believe we are making a vital contribution to developing country healthcare through action in four areas: preferential pricing of our antiretrovirals (ARVs), anti-malarials and vaccines; investing in research and development (R&D) that targets diseases particularly affecting the developing world; community investment activities and partnerships that foster effective healthcare; and, innovative partnerships and solutions.

Preferential Pricing

GSK has offered sustainable preferential pricing for ARVs since 1997 and for vaccines for over 20 years. In 2001, under the company's *"Facing the Challenge"* programme, we announced that our AIDS medicines and anti-malarials would be available at not-for-profit (NFP) prices to public sector customers and NFP organisations in 64 countries - all Least Developed Countries and all of sub-Saharan Africa (SSA). In addition, all private employers in SSA who provide care and treatment to their uninsured staff can purchase our ARVs at NFP prices.

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All CCM projects fully funded by the Global Fund to Fight AIDS TB and Malaria, are also eligible, which means that our NFP prices are now available in over 100 countries, including projects run by the US President's Emergency Plan for AIDS Relief. Our prices are sustainable – we do not make a profit on them, but we do cover our costs. This means that we can sustain supply of these high-quality products for as long as they are needed.

Product Donations & Tax Breaks

In recent years there has been much discussion in the medical and health policy community over drug donations — much of it focusing on inappropriate donations for which, at least by inference, blame is laid on multinational pharmaceutical firms. Distinctly non-altruistic motives are ascribed to such donations, e.g., it is cheaper to donate unwanted drugs to a developing nation than to dispose of them properly. The fact that U.S. tax policy encourages such donations is therefore criticized for contributing to the problem.

The truth is that a mix of factors affects drug donations and prospective donors respond to them differently. While deductibility of a donation may be conducive to any decision to donate, it is not a determinant of any decision. Additional factors are at least as important. Among them are:

- A company's sense of community;
- A company's cultural tradition of collaborating with humanitarian agencies;
- Knowledge that the medicines the company makes meet a particular need;
- Employee pride in being part of a socially accountable organisation;
- Encouragement and support from stockholders;

The majority of GSK donations originate from the US and are therefore eligible for tax relief. However, while tax relief is obviously welcome, this is not the motivating factor behind our donations; even with the additional tax relief, GSK still incurs a cost associated with our programme. Nor does tax relief preclude the donation of GSK product originating from outside the US, where routinely no relief is provided by governments. Our vaccines donations, for example, are generally sourced from are Biologicals HQ in Rixensart, Belgium, while our albendazole tablets for donation are all manufactured in Africa.

Programmes Falling Outside GSK's Donation Programme

Phase IV Studies

As part of our commitment to conduct post-registration trials (ie. Phase IV) GSK provides free product to certain third party collaborators running studies either on our behalf or as part of their own research programmes. These studies however are conducted for scientific not philanthropic reasons. They are not classified as donations and are therefore not reflected in our annual donation total.

Drug Samples

In accordance with national laws and regulations, free samples of a particular medicinal product may be supplied to healthcare professionals by a pharmaceutical company in order to familiarise them with the product. Again, however, this practice is seen as part of GSK's established educational activities and not part of our donation programme.

Commercial Agreements

GSK will on occasion agree commercial deals with customers, including Governments, whereby discounts may be made on bulk orders. These arrangements are not valued or reported as donations. They are part of established commercial trade and would be reflected as such on P&Ls

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GlaxoSmithKline's Position

WHO Guidelines for Drug Donations

The WHO Guidelines for Drug Donations were first prepared in 1996 by an "Interagency Group" ¹ under the WHO, to address reports of expired, irrelevant or otherwise inappropriate drug donations. A second revised edition followed in 1999. Reports from Turkey, Croatia and Kosovo during the mid-1990s had indicated that 15%, 30% and, in some cases, up to 60% of drug donations were inappropriate because the drugs had expired, they were inadequately labelled, or simply unknown to local health providers. The Guidelines (see *Appendix*) were designed to improve the quality and appropriateness of donations and to address the assumption that industry was largely to blame - especially the US industry given the tax breaks afforded donors under US tax laws.

The Guidelines are not international *regulations* but are intended to serve as the basis for national or institutional guidelines. Four core principles underpin the 12 Guidelines:

- The donation should bring maximum benefit to the recipient
- The donation should be made in a way that respects the wishes & authority of the recipient
- There should be no double standards in quality
- Effective communication must be assured between donor and recipient.

GSK aims to ensure that all our donations reflect these core principles.

GSK and the PQMD

GSK is a member of the Partnership for Quality Medical Donations (PQMD), a group comprising seven private voluntary organizations and ten donating pharmaceutical companies². The group grew out of the industry-NGO Steering Committee convened in 1996 to voice their concerns about the revised Guidelines. It meets several times a year and addresses issues of relevance to all participants. Following efforts to obtain necessary changes in the original guidelines, the PQMD publicly endorsed the revised version in 1999 and continues to maintain an ongoing dialogue with the WHO's Essential Drugs Group.

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¹ Caritas Internationalis, International Committee of the Red Cross, International Federation of Red Cross and Red Crescent Societies, International Pharmaceutical Federation, Médecins Sans Frontières, Oxfam, Pharmaciens Sans Frontières, UNAIDS, UNHCR, UNDP, UNICEF, UNFPA, the World Bank, the World Council of Churches, WHO.

² AmeriCares, Catholic Medical Mission Board, Direct Relief International, , Heart to Heart International, International AID, MAP International, Project Hope, Abbott Laboratories, Becton-Dickinson, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, Merck & Co., Inc, Pfizer Inc, Pharmacia & Upjohn, GlaxoSmithKline and Wyeth-Ayerst Laboratories.

The WHO Guidelines on Humanitarian Drug Donations

1. All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent by the recipient.
2. All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO's Essential Medicines List, unless specifically requested otherwise by the recipient.
3. The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those of drugs commonly used in the recipient country.
4. All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.
5. No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.
6. After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year. An exception may be made for direct donations to specific health facilities, provided that: the responsible professional at the receiving end acknowledges that (s)he is aware of the shelf-life; and that the quantity and remaining shelf-life allow for proper administration prior to expiration. In all cases it is important that the date of arrival and the expiry dates of the drugs be communicated to the recipient well in advance.
7. All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Nonproprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.
8. As much as possible, donated drugs should be presented in larger quantity units and hospital packs.
9. All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.
10. Recipients should be informed of all drug donations that are being considered, prepared or actually under way.
11. In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.
12. Costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.