

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 our donation programmes are managed in a responsible way, are needs-based 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 systemic challenges faced by these countries.
- We believe, however, that targeted product donation programmes can 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. While the main focus of our programme is in developing countries, in emergency situations or in response to specific one-off requests, we will also donate product to developed countries.
- The majority of GSK product donations are routinely directed through a select number of charitable Non-Governmental Organisations (NGOs) or through International Public Health Organisations such as WHO and PAHO. A small proportion of GSK's donations are handled locally by GSK's Local Operating Units in response to acute emergencies and/or specific requests from Ministries of Health and NGOs
- The majority of donation requests received by GSK are for broad spectrum antibiotics, although we do also donate vaccines. For example, during the 2009/2010 H1N1 influenza pandemic, we donated over 24 million doses of our pandemic vaccine to the WHO for use by developing countries. We do not routinely donate consumer healthcare products.
- In common with many other stakeholders, including the WHO, we do not believe that long term donations and/or 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 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.

GLOBAL PUBLIC POLICY ISSUES

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*.
- In 2008, in order to provide a more accurate reflection of the true cost of GSK's donations, we decided to move to a system of valuing our programme using "average cost of goods" rather than the more widely used and higher "wholesale acquisition prices".
- 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 community partnerships team and are 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 acute emergencies and/or specific requests from Ministries of Health and NGOs. All local product donations are reported to GSK's community partnerships team and included in the reported annual donations' figure.

Pharmaceuticals

GSK's corporate pharmaceuticals donation programme is managed centrally by our community partnerships team, 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.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

Vaccines

Requests received by our local operating units or by GSK Biologicals based in Wavre, Belgium, will be reviewed on a case-by-case basis. Most requests and/or donations are provided in response to emergency situations in 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.

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*).

Long-term Donations

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 long-term donations of products offer a sustainable solution for patients or 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*".

GSK and Developing World Healthcare

Improving sustainable access to medicines is core to GSK's overall strategy and is prioritised from the highest levels of the company. Our access strategy focuses on areas where we can make the most difference through our core business activities, skills and resources. In particular this means initiatives to improve affordability and to conduct and encourage more investment in R&D for the developing world.

In July 2010, we announced the creation of a new operating unit dedicated to the world's Least Developed Countries (LDCs) which has integrated GSK's pharmaceutical business in all 48 LDCs into one group. The Unit's primary focus is on the strategic approaches needed to expand access to medicines for patients living in these countries. The announcement built on a previous commitment by GSK to reduce the prices of our patented medicines in LDCs by an average of 45% and to reinvest 20% of LDC profits from medicines back into projects that strengthen healthcare infrastructure and help widen access to medicines.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

As well as pursuing progressive pricing policies for the world's Least Developed Countries (LDCs), GSK is also focusing on increasing access to medicines in other developing countries. In the past, the majority of our revenue in countries like India, Indonesia and China came from selling our medicines and vaccines to higher-income sectors of society. However, to achieve sustainable growth we need to go beyond the high-income sector, and increase access and affordability for patients at lower-income levels in all countries. To this end, we are using in-licensing, joint ventures and acquisitions to expand our portfolio in middle-income countries to better reflect the local disease burden and demographic profile in each market as well as transferring manufacturing and research expertise to key markets as appropriate.

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 criticised 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, it 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 Biologics HQ in 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. This practice, however, is seen as part of GSK's established educational activities and not part of our donation programme.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

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.

WHO Guidelines for Drug Donations

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 WHO Guidelines for Drug Donations were prepared in 1996 by an "Interagency Group" ¹ under the WHO, to address these kind of reports. A second revised edition followed in 1999 and work is currently underway around a third edition.

The Guidelines (see *Appendix for 1999 version*) 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.

Revised: July 2011

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.