

# GSK Public policy positions

## Product Donations

### The Issue

As a global healthcare company, 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.

### GSK's Position

- GSK is committed to widening access to our products via our equitable pricing strategy. We believe, however, that targeted product donation programmes can have an essential role in both saving lives and improving the quality of life for people in vulnerable situations.
- 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.
- 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's product donations are routinely directed through a select number of charitable Non-Governmental Organisations (NGOs) or through International Public Health Organisations such as the WHO. 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. We do not routinely donate vaccines, except through our Patient Assistance Programme. Nor do we routinely donate consumer healthcare products.
- All donations are formally approved by the local GSK General Manager to ensure that medicines are registered and appropriate to the needs in-country.
- 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. If we become aware that 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.
- We report the value of our programme donations via a number of publications including the company's [Annual Report](#). We also routinely share our data with the London Benchmarking Group, the global standard for measuring, benchmarking, and reporting on corporate community investment.
- In order to provide a more accurate reflection of the true cost of GSK's donations, we value 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, we are routinely amongst the leading FTSE 100 corporate donors.
- GSK is a member of the 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 labelled and accompanied by clear packing lists.

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### Background

#### GSK's Donations Programmes

Most of GSK's donations are directed through a select number of experienced charitable NGOs or through International Public Health Organisations.

Our NGO partners are evaluated based on submission of appropriate information including proof of charitable status and site visits assessing their capacity to secure, store, ship and utilise 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. Our NGO partners undergo rigorous due diligence controls including those relating to Sanctions & Export Controls clearance, Anti-Bribery and Corruption, Adverse Event Reporting and Ethical Standards and Human Rights.

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 donations programme is managed centrally by our community partnerships team, working with four carefully selected charity partners AmeriCares, Direct Relief, Health Partners International 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.

We also donate pharmaceuticals through our Patient Assistance Programme (*see below*).

#### Vaccines

GSK does not operate a formal vaccines donation programme, except for those donated through the Patient Assistance Programme (*see below*). Ad hoc requests received by our local operating units or by GSK Vaccines based in Wavre, Belgium, will be reviewed on a case-by-case basis.

Most vaccine donations are in response to emergency situations in developing countries. GSK aims to only make donations that complement sustainable vaccination programmes through experienced, charitable NGOs. Any donations made will be on condition that cold chain supply and appropriate administration can be guaranteed.

#### Consumer Healthcare

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

#### Patient Assistance Programme

GSK operates a Patient Assistance Programme for residents of the US and Puerto Rico. The GSK PAP is 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. The programme offers free prescription drug products and vaccines to eligible enrollees, with an annual enrollment cycle. Given the nature of the programme, it is not subject to the WHO Guidelines (*see below*).

#### Long-term Donations

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.

However, we accept that long term donations can have a role to play 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. Our long-term donation of albendazole treats both LF and the deworming of school-aged children. Working with the WHO to eliminate or control these two neglected diseases, GSK has committed to donate up to one billion tablets of albendazole each year through to 2020.

### Product Donations and Tax Breaks

There has been much discussion in the medical and health policy community over drug donations ascribing non-altruistic motives for 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.

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 and cultural tradition of collaborating with humanitarian agencies; knowledge that the medicines the company makes meet a particular need and employee pride in being part of a socially accountable organisation.

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 and albendazole tablet donations, for example, are sourced from our multiple locations around the world including Belgium, Africa and India.

### Programmes Falling Outside GSK's Donations Programme

**Phase IV Studies:** As part of our commitment to conduct post-registration trials (i.e. 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 donations' 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 donations 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.

### WHO Guidelines for Drug Donations

The [WHO Guidelines for Medicine Donation](#) were introduced in 1996 and are designed to ensure the quality and appropriateness of donations.

The Guidelines are not international *regulations* but are intended to serve as the basis for national or institutional guidelines. GSK aims to ensure that all our donations reflect the following core principles, which underpin the WHO Guidelines:

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