# Drug Donations:

## corporate charity or taxpayer subsidy?

by

**Mark Thomas**

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# Preface

"Drug dumping" is not a common phrase in the UK, so you could be forgiven for thinking the words have something to do with a Fabulous Furry Freak Brothers cartoon or a Ceech and Chong sketch. However, the phrase has little to do with hippies and police busts and a lot to do with irresponsibility, exploitation and corporate greed.

The problem of “drug dumping” occurs when useless or dangerous pharmaceutical products are donated to poor countries, particularly after a humanitarian disaster. Medical staff at the receiving end of such donations are then forced to spend a great deal of their valuable time, sometimes up to 70%, sorting out the bad from the good donations in emergency areas.[1]

Sometimes the donations are made by well-meaning individuals; sometimes by thoughtless NGOs and often by Western drug companies offloading their unwanted and unsellable products. Emptying your drug cabinet in order to help those worse off is a bad idea and causes far more problems than it solves even if your motivation is good. No such caveat exists for corporations donating bad drugs in order to increase their profits and corporate PR.

US tax legislation is designed to encourage companies to make ‘gifts in kind’ to the developing world. However there is significant evidence that it offers incentives for the wrong kind of donations, and contains a number of loopholes which are exploited by the pharmaceutical industry to suit their own interests, often at the expense of the health needs of the developing world.

For decades US pharmaceutical companies have taken advantage of tax laws that enable them to offload stock they may otherwise not be able to sell as "charitable donations" to developing countries. Often the best time to make these donations is at a crisis point such as an earthquake or mass migration due to conflict. Although the companies love to exploit this veneer of altruism and promote a caring sharing image, the reality of "drug dumping" is cynical and destructive. Under US tax law companies can claim twice the cost of the drug against tax. Given that inappropriate drugs are often, for one reason or another, unusable in the US, this represents a substantial reward for clearing the shelves.

If a company has a product that is reaching the end of its shelf life or has an overrun of a product, or has a product that is being discontinued, it usually has two choices. It can either incinerate the product, which has to be conducted in a regulated and controlled environment and will incur a cost to the company[2]. Or the company can donate the drug in question, clear shelf and warehouse space and claim money back from the tax payer. One wonders which option lead to the dumping of appetite stimulants in Sudan[3]….or which option lead to thousands of tubes of lip balm, haemorrhoid cream and anti smoking inhalers being dumped in refugee camps in Albania[4]…or indigestion tablets sent to Rwanda[5].

These kind of donations also beg the question, for whose benefit are these donations being made? Are they there to serve the health needs of the particular nation or a company’s financial obligations to its shareholders.

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[1] Interview with an aid worker
[2] Costs of incineration are lower in the US than in Europe, and companies can off-set some of the cost of disposing of stock against their tax bill, but the tax break is lower than for donating the same drugs.
[3] Electronic Mail & Guardian, 22 April1997
[4] New York Times, 3 November1999
[5] Electronic Mail & Guardian, 22 April1997

It is an ironic situation when tax payers subside corporations to donate products to the needy that they wouldn't use themselves. But more importantly, medicines can be highly dangerous substances if used inappropriately. Often donated drugs aren't labelled correctly, often they are patent rather than generic drugs that local healthcare worker will have no experience of using, often they are high-end very expensive drugs that have problems of sustainability. Any complication like this has severe consequences. In Lithuania women have been temporarily blinded by worming medicine meant for animals[6].

And it doesn't stop there. In Bosnia so much pharmaceutical rubbish was dumped that the authorities had to spend $34 million on an incinerator to get rid of it all[7]. In the middle of the horrors of ethnic cleansing some drug companies got a very good return for some very bad drugs.

If a country has had out of date or inappropriate drugs dumped in the middle of a crisis, has had to sort the drugs and safely dispose of the bad ones and has had to pay the import duty for the privilege of having to do all of this, then it seems a far cry from the words "charitable donation." Pharmaceutical companies are amongst the most profitable on the planet, in the US they donate more money to political parties and politicians than any other industry, they can afford to be generous. "Drug dumping" adds a sinister meaning to the phrase " it is better to give than to receive".

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*Email: mailroom@waronwant.org Website: waronwant.org*

[6] 't Hoen, E, Milkevicius D. 'Harmful human use of donated veterinary drug'. Lancet, 1993; 342: 308-9
[7] Miami Herald 20 June 1999

# Introduction – changes to UK legislation

On 17th April 2002, the British Chancellor will announce in his Budget a series of measures, designed in collaboration with the Department for International Development (DFID), which are intended to tackle the crisis in access to essential medicines for many poor people living in the developing world. These measures will include a number of initiatives designed to encourage greater research and development into creating new treatments for the three 'target' diseases identified by the G8 and the UN: malaria, TB and AIDS[8]. In addition, the legislation will endeavour to encourage donations of medicines to the developing world by UK-based pharmaceutical companies, through the tax system.

Some NGOs like Médecins Sans Frontières believe the practise and culture of corporate drug donations to be unproductive. They point out that corporate donations do not encourage local production of generic drugs and if anything will undermine those local economies which in the long term is the only effective way of meeting the needs of developing countries. MSF also note that corporate tax credits for donations is an inefficient use of public funds. However given that the current system is not about to change overnight and the UK law is about to be passed, this report tries to see if there is a way to discourage bad donations.

This briefing paper looks at how the corporate drug-donation system functions in the US – and examines the successes and weaknesses of the American model. The report also makes a number of recommendations to the British government to maximise the quality and appropriateness of drug donations made from the UK.

# The 'access to medicines' crisis

*"Pharmaceutical companies would rather treat a bald American than a dying African"[9].*

Much has already been written about the acute crisis in access to essential medicines for much of the world's population. It is not our intention to repeat it all here. In short, one-third of the people in the world has no access to essential medicines; in the poorest parts of Africa and Asia, this figure rises to one-half. This year alone, there will be over 40 million deaths in developing countries, one-third among children under age five. Ten million will be due to
acute respiratory infections, diarrhoeal diseases, tuberculosis, and malaria - all conditions, which can be cured if only the medicines and health care, were available.

According to the World Health Organisation, "the economic impact of pharmaceuticals is substantial -- especially in developing countries. While spending on pharmaceuticals represents less than one-fifth of total public and private health spending in most developed countries, it represents 15 to 30% of health spending in transitional economies and 25 to 66% in developing countries. In most low income countries pharmaceuticals are the largest public expenditure on health after personnel costs and the largest household health expenditure. And the expense of serious family illness, including drugs, is a major cause of household impoverishment."[10]

There are several different problems that people face: sometimes the medicines exist, but they are unaffordable for those who need them; on other occasions the medicines are withdrawn from production as there is no profitable 'market' for them, despite millions of

[8] Specifically those strains of HIV prevalent in the developing world.
[9] Richard Holbrooke, former US Ambassador to the UN,
[10] www.who.int/medicines/rationale.shtml, updated 18 March 2002

people being in need. Then there are some specific diseases, which affect only the poor, so no profit-driven company is willing to spend time and money researching new cures. In short, the 'market' system by which the international pharmaceutical industry operates fails the poor and sick of the world: it is much more profitable to develop new treatments for baldness and impotence, or veterinary medicines for American dogs, than it is to find a cure for fatal diseases such as African sleeping sickness or visceral leishmaniasis.

Many possibilities are being considered to overcome these problems, of which the increase in drug donations from western-based pharmaceutical companies is one. In fact, it is the option most commonly proposed by the companies themselves. Many activists, such as the medical
humanitarian organisation Médecins Sans Frontières as already said, oppose drug donations as a solution to the access crisis, arguing that they are unsustainable, put the highest cost on the public purse and fail to meet the treatment needs of the developing world.

Donations of inappropriate or expired drugs in emergencies have been of particular concern to healthworkers, NGOs and the authorities in the recipient countries. A series of high-profile instances of bad practice in donations over the last couple of decades led to the World Health Organisation (WHO) and a group of leading aid agencies issuing the first internationally-accepted Guidelines for Drug Donations (hereafter called simply the Guidelines) in 1996. The Guidelines were then revised, following consultation and review of the previous version, in 1999. The Guidelines can be found in full in the Annex, but the most significant problems identified by the Guidelines' authors are summarised below.

## So what's wrong with drug donations?

Donations of inappropriate or expired drugs in emergencies have been of particular concern to healthworkers, NGOs and the authorities in the recipient countries. A series of high-profile instances of bad practice in donations over the last couple of decades led to the World Health Organization (WHO) and a group of leading aid agencies issuing the first internationally-accepted Guidelines for Drug Donations (hereafter called simply the Guidelines) in 1996. The Guidelines were then revised, following consultation and review of the previous version, in 1999[11]. In the forward to these Guidelines some of the problems associated with unregulated drug donations were set out.

- Donated drugs are often not relevant for the emergency situation, for the disease pattern or for the level of care that is available. They are often unknown to local health professionals and patients, and may not comply with locally agreed drug policies and standard treatment guidelines; they may even be dangerous.

- Many donated drugs arrive unsorted and labelled in a language, which is not easily understood. Some donated drugs come under trade names which are not registered for use in the recipient country, and without an International Nonproprietary Name (INN) or generic name on the label.

- The quality of the drugs does not always comply with standards in the donor country. For example, donated drugs may have expired before they reach the patient, or they

[11] It is important to note that the Guidelines do not form "international regulation" but are intended "to serve as a basis for national or institutional guidelines, to be reviewed, adapted and implemented by governments and organisations dealing with drug donations". Nevertheless, they are widely understood to set the international standard for good drug donation practice.

may be drugs or free samples returned to pharmacies by patients or health professionals.

- The donor agency sometimes ignores local administrative procedures for receiving and distributing medical supplies. The distribution plan of the donor agencies may conflict with the wishes of national authorities.

- Donated drugs may have a high declared value, e.g. the market value in the donor country rather than the world market price. In such cases import taxes and overheads for storage and distribution may be unnecessarily high, and the (inflated) value of the donation may be deducted from the government drug budget.

- Drugs may be donated in the wrong quantities, and some stocks may have to be destroyed. This is wasteful and creates problems of disposal at the receiving end.

## Industry priorities

Pharmaceutical companies often use the defence of research and development costs to justify the high cost of drugs. However, the industry spends a greater proportion of its revenues on marketing than research[12].

It also spends a good deal of money lobbying US political parties. During the 2002 election cycle ten drugs companies donated over $9 million to Congress[13].

The Congressional Research Service reported in 1999 that the drugs industry has the lowest average effective tax rate of all industries.

## An introduction to the US tax incentive system

The American tax system has for decades rewarded companies, which donate product for relief programmes. Provided the donation meets certain criteria, it is possible for the donating company to claim a tax break up to twice the cost of manufacturing the donated goods.

A company is usually allowed to claim the cost basis of its product against tax if it is donated. However if that donation can be said to be for the needy, the ill and for humanitarian purposes and the donation is to a registered charity, the law allows the company to claim either:

twice the cost basis of the drug
or
the cost basis of the drug plus half of the "fair market value", which ever is the lesser.

A cap is set at twice the cost basis so that companies do not over inflate the ‘fair market value’ of their product. In order to claim more tax benefit. This figure can then be used to offset against corporation tax, which is 35% in the US.

It is important to note here that cost basis is not the incremental cost of the drug but rather an average cost of making the drug taking into account other overheads, such as labour, warehousing, account keeping etc. It will therefore reflect costs that have long been paid

[12] Financial Times 24 July 2001
[13] www.opensecrets.org

for and allow companies to recoup investment that they would otherwise stand as a commercial loss.

This kind of tax credit is called an enhanced deduction.

So, for example, if a company donates drugs with a cost basis of $2 that has a fair market value of $10, it is entitled to claim either twice the cost basis of the drug ($2 x2 = $4)
or the cost basis of the drug plus half of the fair market value ($2 + 1/2 of $10 = $7) as long as it does not exceed twice the cost basis, which it does in this case. So the company can claim $4 against corporation tax of 35% which equals a cash equivalent of $1.4 for the company.

The problem comes partly because pharmaceutical companies can donate drugs that they aren't allowed to sell in the US. The Food and Drug Administration regulates very stringently the drugs that can be sold in the US. One of their provisions is that the drug must have an expiry date of more than a year. However, no such restriction applies on donating drugs to other countries. If you cannot sell the drugs then you have the problems of warehousing them and then of disposing of them which is a very costly business. Echo International, a UK NGO, estimates the cost of destroying drugs as $1 per kilo. Companies can claim this against tax but this credit is far lower than if they donate them and claim an enhanced donation.

Apart from short dated drugs, companies can also donate drugs that they no longer want. Perhaps the drugs are an old variety which have been replaced with a newer, more effective version. Perhaps the drugs are bad sellers. Perhaps they have excess stock. Perhaps they want to open up new markets in developing countries. The list goes on especially when you take into account that it is not just prescription drugs that can be donated in this way but vitamins, cough medicine, lip balm, bandages, sanitary towels, shampoo, in fact anything at all that can be said to be for the needy, even clothes (although clothes do not need to be stored and destroyed in the same way, so their donation is more annoying than dangerous). All qualify for this preferential tax deduction.

There is another way that companies can claim a better tax deduction by being 'charitable'.
If a company sells drugs to a charity for a lower than its fair market value then the company is deemed to have made a 'bargain sale' which for accounting purposes is treated as a part sale and part charitable donation. The donation portion can then be subject to the same enhanced deduction rule discussed above. The donation portion is calculated by finding the excess of the fair market value over the donor's cost basis. The sale price is divided by the fair market value the resulting fraction is applied to the cost basis. That amount is then subtracted from the transaction's bargains sale price. So, for example:

A company sells a drug with a cost basis of $3 to a charity for $2 and it has a fair market value of $10 this is a sale of $2 and a gift of $8. However it has cost the company $3 to produce the drug and this cost basis would be allocated between the gift and sale portions according to the fair market value of each part. So in our example 2/10s of the cost basis ($0.6) would be allocated to the sale part, and 8/10s of the cost basis ($2.4) would be allocated to the gift part:

| | | | |
|---|---|---|---|
| Fair market value | $10 | Gift | $8 |
| Sale price | $2 | Sale | $2 |
| Cost basis | $3 | | |

Cost basis of $3 divided by fair market value of $10 x 2/10s for sale portion and 8/10s for the donation or gift portion

Gift 8/10s of $3 = $2.4
Sale 2/10s of $3 = $0.6

For the gift portion, the company is then entitled to claim an enhanced deduction of twice the $2.4 which would be $4.8. This would allow $1.68 to be taken off the corporation's tax bill. The company has already received $2 in the sale and once the cost of the drug is subtracted, the company have received a 'profit' of $0.68 on what initially looks like a philanthropic gesture - selling a drug below your cost price.

$1.68 + $2 -$3 = $0.68

**IT IS IMPORTANT TO NOTE THAT COMPLIANCE WITH THE WHO GUIDELINES IS SPECIFICALLY NOT INCLUDED IN THE CRITERIA FOR DECIDING TAX BREAK ELIGIBILITY.**

## The middlemen

At the heart of this system are US-based tax-exempt organisations hereafter known as Private Voluntary Organisations (PVOs) which accept donations in kind from businesses, and place these donations overseas. They exist entirely to facilitate such donations and are dependent on them for their very existence. There are many such organisations, but the leaders in the field are Americares, MAP international, Catholic Medical Mission Board, Project HOPE and Heart-to-Heart.

These charities solicit medicines (and often other relief materials) from corporations, and arrange the delivery of such donations to countries, institutions and organisations in the developing world. Advising the corporations of the tax benefits of donating medicines is part of the role of the Procurement and Corporate Departments of these organisations: most are very up-front about the financial advantages to companies of making donations in kind to their charity and market their services to companies on this basis. They also highlight the PR advantages to a company of making a donation. When they accept the donations from the companies they give in return a standardised receipt which enables the company to claim the tax break. At this stage even though the drugs may not have left the US, they become the responsibility of the charity.

Each of these organisations operates slightly differently: some take a handling charge for their services; some make the recipient pick up the cost of shipping and import duties; others make no charge either to the company donating or to the recipient of the drugs.

## What's going wrong?

During the research for this report, interviewees from both the PVO organisations and recipient countries identified a number of negative consequences of the current drug donation system:

**Short-dated medicines**

*"It's usually in an environment where they've got products on their hands, they're taking up warehouse space, or it's unsaleable for whatever reason. What happens with pharmaceuticals is that they reach their expiration date and you have to consider what to*

*do with them. So you get them back from the distributor if you make the pharmaceuticals, or if you're a distributor you're sitting with stuff that is sitting on the your shelf not selling. And if it's got 6 months dating on it they can donate it to me and that alone is a benefit regardless of what their tax deduction is."* [14]

Despite the WHO Guidelines which clearly recommend "**After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year",** corporate drug donations from the US regularly include drugs with less than 12 months before expiry. Whilst it is important to note that the WHO Guidelines themselves acknowledge that there are occasional, exception circumstances in which shorter-dated drugs might still prove useful[15], the fact remains that the US pharmaceutical companies and their partner PVOs refuse to accept 12 months before expiry as the norm. Indeed, they have rejected this normative standard at every step, using their lobbying muscle to fight against initiatives such as that put forward by US Congressman Doggett to make the tax break conditional upon this criteria. US corporate drug donations regularly break the spirit, if not the letter, of the WHO Guidelines.

## Drugs donated suit the giver, not the recipient

*"I'd say about 70% of my donations tend to be company initiated…I have a certain amount of product coming into my warehouse that's part of a procedure that the company has instigated rather than I go ask for it"* [16]

A significant flaw in the current US drug donation system is that the medicines that are donated are generally chosen on the basis of the stock management needs of the pharmaceutical company, and not the recipient health system. The needs of the two parties may, on occasion, collide, but this is a case of happy coincidence, rather than design. This leads to many donations of drugs that are inappropriate for the health system in the country to which they are sent. It is very difficult for Ministries of Health and medical workers in developing countries to instigate nation-wide treatment protocols when drugs may be donated which do not fit with the nationally-recommended treatment. A common problem occurs with anti-biotic medicines. Many of the anti-biotics produced and used in the West are several generations more advanced than those used in the developing world. Badly-managed drug donations of higher generation medicines can distort national treatment protocols and may lead to the development of resistance to medicines which were meant to

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[14] Interview with employee of American 'PVO' charity

[15] **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.**

*Justification and explanation*
In many recipient countries, and especially under emergency situations, there are logistical problems. Very often the regular drug distribution system has limited possibilities for immediate distribution. Regular distribution through different storage levels (e.g. central store, provincial store, district hospital) may take six to nine months. This provision especially prevents the donation of drugs just before their expiry, as in most cases such drugs would only reach the patient after expiry**.** It is important that the recipient official responsible for acceptance of the donation is fully aware of the quantities of drugs being donated, as overstocking may lead to wastage. The argument that short-dated products can be donated in the case of acute emergencies, because they will be used rapidly, is incorrect. In emergency situations the systems for reception, storage and distribution of drugs are very often disrupted and overloaded, and many donated drugs tend to accumulate.

*Additional exception*
Besides the possible exception for direct donations mentioned above, an exception should be made for drugs with a total shelf-life of less than two years, in which case at least one-third of the shelf-life should remain. [Quote, WHO Guidelines for Drug Donations, 1999, Section 6]

[16] ibid.

remain the arsenal for future use. Furthermore, donating drugs with which the medical staff on the ground are unfamiliar can lead to damage being done to the patient.

One-off drug donations cause particular problems in terms of continuity of treatment: a prescriber forced to used countless different drugs and brands in ever-changing doses; patients on long-term treatment suffer because the same drug may not be available next time. Whilst some of the US-based middle men charities or PVOs, we spoke to were aware of this problem, and were reluctant to ship, for example, anti-psychotic medicines in a one-off short dose donation, it was suggested to us that not all PVOs held the same high standards.[17]

**Medicines are not labelled in a language used locally**

The WHO Guidelines are clear that: "**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"[18].**

In research for this report, we were unable to find a single example of a US pharmaceutical donation that had been modified to included explanations for physicians in the recipient country's language (obviously if the recipient country's national language was English there was no problem). The example from Lithuania where women lost their sight due to a veterinary drug being given in error demonstrates the dangers this poses.

**Donations tampering with the market**

**A. Gaining brand recognition**

*"[By donating overseas] you're gaining a product recognition, like you're getting people comfortable using your pharmaceuticals and people who aren't buying them today will potentially be in a position to buy them a couple of years down the road"* [19]

Drug donations to developing countries can be used by the pharmaceutical donor as a means of developing brand recognition in a potential new market. In 1993, the US pharmaceutical company Connaught Laboratories Inc, donated $13 million of polio vaccines to Russia through AmeriCares. Connaught's president at the time, David Williams, explained part of the rationale behind the donation: "Someday Russia will be a market. So while meeting a need, maybe we can plant seeds"[20].

*"Usually companies don't want to donate in the US because it impacts their market."* [21]

It is reported that companies chose to donate medicines overseas which would be more appropriate to donate in their own country, but won't do so in order not to undercut their home market. Sometimes donations can cause serious distortions in the recipient country, either because the donation damages the local generic drugs industry, or because the medicines are given away for free. Whilst free medicines sounds like a universal 'good', it can undermine a developing country's Ministry of Health's attempts to develop a sustainable cost-recovery programme.

[17] ibid.
[18] Recommendation number 7, WHO Guidelines for Drug Donations
[19] interview with employee of American PVO charity
[20] Quoted in Forbes Magazine, 29 March 1993, page 90
[21] interview with employee of American PVO charity

## B. Damaging local industry

*"[Countries like India or Brazil] have a generic industry that can produce almost anything that we can do here…they look at me as something like a salesperson intruding into their market…because I'm bringing in rival companies products and giving them away free"*[22]

Massive amounts of donated drugs can have an adverse effect on local generic drug manufacturers, who may find their sales decreasing because of the donated drugs. In the long run it is the local drug companies that will have to supply the medical needs of the area. This was particularly the case after the Gujarat earthquake where it would have been cheaper, easier and more supportive of the local economy to have purchased the medicines locally rather than fly them in from the US.

### Fiddling the figures

The drug donation system at present allows for a great deal of creative accounting within American charities. It is natural for charitable organizations to wish to keep their overheads as small a percentage of their revenues as possible. According to a former employee of a US PVO, and now a voracious critic of the system, many US charities involved in accepting donations in kind, report in-kind donations as revenue, based on the wholesale list price of the donated drug. This may be described as misleading, as many medicines and other items are donated because they are no longer fit for the American market. Thus many charities report extraordinarily low overhead costs as percentage of revenue, such healthy figures encouraging financial donors to donate cash. Such cash donations are then much more likely to be used to cover overhead costs. Some charities are recognized as the most efficient in America by reputable sources based on this approach to valuation of drug donations.

Such inaccuracies can spread from one organization to another as a donation can pass from the accounts of one charity, to the next, each one recording the goods in their accounts as worth their original wholesale list price. With two organizations, or possibly more, each recording the donation in their accounts, it seems to the public that much more has been donated than actually has.

### No guarantee of getting there

The US tax break seems to be awarded with a minimum level of proof that the donation will ever make it to the intended recipient. In order for the company to qualify for the tax allowance, they need only to have a receipt from a US charity[23] that takes delivery of the goods. There is no paper trail directly back to recipient demonstrating that the donation actually makes it to the patients – it is up to each PVO charity to take responsibility for the donation from then on. Whilst some organisations do operate in a principled and responsible manner, others may well not.

### Donations – the hidden costs to the US tax payer

According to a substantial MSF report released in October 2000, drug donations have hidden costs to the tax payers – costing the public sector of the US over four times as much as other methods of getting medicines to the developing world, namely buying the branded product at a differential price or purchasing the lowest-cost generic drugs available internationally. In fact, the report concludes that donations and concessionary

[22] interview with employee of American PVO charity

pricing are the most costly options to the US tax payer, whilst being the least effective solution to the global public health crisis.

**Donations – costs to the recipient nation**

In many countries there is an import tax to be paid to customs and excise. This cost may not be met by the donating company or organisation but by the local health service budget. In the case of the Gujarat earthquake it meant the Indian Ministry of Health (who receive about 1% of the countries GDP) paid for the import tax.

## Disguising sales as donations?

There is even an instance of a pharmaceutical company packaging a sale of medicines as a donation: US-based company Bristol Meyers Squibb [BMS], which holds the patent on two important anti-retroviral medicines used in the treatment of HIV/AIDS.

In early 2002, the international medical aid agency Médecins Sans Frontières [MSF], attempted to purchase a consignment of differently priced anti-retroviral drugs from BMS for use in its AIDS programme in Guatemala. During the negotiations BMS explained that they would "give" the drugs, but would charge an "administration fee"[24]. When challenged by MSF about why a straight-forward business transaction had to be structured in such a manner, the company replied that, "we fail to see how an internal decision by BMS to package the offer the way we did should be of any concern to MSF. We feel the offer should be seen for what it is: an effective reduction of close to 90% of the existing cost to a purchaser in Guatemala."

However, MSF is right to be concerned about BMS's desire to characterise this straightforward sale as a donation. The transaction could set a precedent for differential pricing of anti-retroviral drugs in Guatemala, potentially improving their accessibility in the local market. But by structuring the sale as a donation, the company seem to want to avoid setting an affordable price for their products in a market, in this case Guatemala, in which they may be able to derive a profit in the future. In addition, it is possible that the company could be in a position where they might be able to claim a tax deduction on the drugs they choose to "give" which have in fact been paid for already through the "administration fee". From a public policy perspective, this can only be viewed as a costly endeavour for the public sector: with the prices of BMS's anti-retroviral drugs in the US being so high taxpayers could be paying a tidy sum.

## Throwing out the bathwater, not the baby

It is important to emphasise that not all corporate drug donation programmes are bad. There are a handful of exceptional drug donation programmes that are of real benefit to the recipient health systems, generally when the western pharmaceutical company holds the patent on an effective medicine for the treatment of a particular eradicatible tropical disease. Two drug donation programmes deserve special mention for their corporate commitment to real health improvements in the developing world.

Merck's Ivermectin Donation Programme: Since 1988, the US pharmaceutical company Merck & Co has been providing its drug Mectizan® (non-proprietary name, ivermectin) for free to treat the disease onchocerciasis, more commonly known as River Blindness. This donation programme works through the WHO, the World Bank, many NGOs, ministries of

[24] BMS calculated the administration fee as $20 per bottle, breaking it down to an average cost of $2 per patient per day.

health and the UN to provide free treatment for the disease to over 25 million people in 31 countries. The programme has been hailed by many commentators as an example of a good corporate donation programme because it met the following criteria:

- Sustainability, without restriction to time or geography - the company have committed to continuing the programme until the disease is eradicated
- Part of Global Partnership with international institutions and local ministries of health and NGOs

Another laudable example of pharmaceutical corporate philanthropy is Aventis's partnership with the World Health Organisation and the medical NGO Médecins Sans Frontières to distribute medicines for African Sleeping sickness. Between 300,000 and 500,000 people in sub-Saharan Africa are thought to be suffering from this devastating disease, which is fatal if untreated. In 2000, following public condemnation of the company for stopping production of the most effective medicine for sleeping sickness[25], Aventis formed a partnership with WHO and MSF. Aventis have donated $25 million for the next five years and will provide three drugs, including eflornithine, to WHO, which will work with MSF to ensure the drugs are properly administered to patients suffering from sleeping sickness. Aventis will also provide support to health systems struggling to cope with the disease.

The tax system should be designed to reward companies for these sort of long-term, sustainable, WHO-led drug donation programmes, rather than offer incentives for one-off donations of unwanted stock.

## Case studies

"We estimate that 50% of the drugs coming into **Albania** donated by non-medical organisations are inappropriate or useless and will have to be destroyed. We are very concerned that some pharmaceutical companies are using this humanitarian crisis to get rid of unwanted stockpiles."[26]

50% of drug donations between 1990 – 1995 arrived past their expiry date in **Armenia**[27].

An estimated 17,000 tons of medical donations sent to **Bosnia and Herzegovina** between 1992 and 1996 were inappropriate. It cost US$34 million to dispose of them. A team of European Union hazardous waste experts found slimming agents from Britain, toxic chemicals from 1961 from the former East Germany, and a nasal decongestant from the US with an expiry date of 1990 which had been covered by a sticker saying 1993[28]**.** Lip balm and anti-smoking devices were also found to have been shipped to refugee camps[29]. Most dangerously, a consignment of an anti-leprosy tablet was also labelled as paracetamol. The drug could have caused blood, skin and psychiatric disorders had they been dispensed as paracetamol[30].

[25] Aventis was subject to some very negative PR following the revelation that they had stopped the production of eflornithine for sleeping sickness it was unprofitable Soon after Bristol Myers Squibb launched, together with Gillette, another product containing the same active ingredient, this time for the treatment of facial hair in women.
[26] WHO press release 30 June 1999
[27] Electronic Mail & Guardian 22 April 1997
[28] Electronic Mail & Guardian 22 April 1997
[29] An Assessment of US Pharmaceutical Donations. Edited by Michael Reich. Harvard School of Public Health. 1999.
[30] Electronic Mail & Guardian 22 April 1997

In 1992 large quantities of ampicillin that had expired 14 years before, and out-of-date skin cream with the expiry date covered were donated from the USA by Relief International to a hospital in Sarajevo. [31]

In **Eritrea** in 1989 during the war of independence seven truck loads of expired aspirin tablets arrived. They took six months to burn[32].

In 1994, one humanitarian organisation in **Georgia** (UMCOR) received, without prior acceptance, 20 tons of silver sulphadiazine ointment (used for the treatment of burns), which had expired one year before arrival. The load was so big it took months to incinerate. During a visit by Médecins Sans Frontières to government warehouses in Georgia, MSF recorded 12 tons of unnecessary or expired drugs. About 9 tons had arrived already past their expiration dates, or within three months of them. Most consisted of doctors' samples. There were also some items that were positively dangerous – ie 14,000 ampoules of expired dipyrone.[33]

In 1993 11 women in **Lithuania** were temporarily blinded after using an anthelmintic drug that should only be used in veterinary medicine but was given for a gynaecological complaint. The drug was donated by Caritas and came without product information or package insert. Doctors tried to identify it by matching the name on the box with the name on leaflets on other products. It turned out to be veterinary worm medicine. Caritas refused to help further investigations.[34]

"Odourless" garlic pills, ginseng extract and Tums indigestion tablets were sent to **Rwanda** during the conflict. But possibly the most high profile case was the "largest one-time pharmaceutical donation ever". Eli Lilly sent six million Ceclor CD tablets – an antibiotic which had not received licensing in the US. Neither was it in WHO's list of essential drugs for the treatment of refugees. At the time their press release said "this is yet another example of Lilly's commitment to giving, especially in times of human tragedy. We are responding to the dire needs of the Rwandan refugees". There were enough tablets to treat 1.3 million people accompanied by a few inserts in English as to how they should be used. Eli Lilly admitted the stock was nearing expiration and as it hadn't received FDA approval for sale in the US, the drugs were useless to the company. They also conceded that the tax benefits were "one facet" of the decision[35].

Appetite stimulants, contact lens solution and expired antibiotics were among the inappropriate medical material sent to **Sudan** during the famine. Furthermore, the donations were labelled in French – a language not spoken in Sudan[36].

In **Venezuela** 70% of donated medical aid sent after floods in 2000 had to be incinerated. Officials had to spend $16,000 on hiring extra staff to work longer hours in order to sort the drugs whilst a telephone support line set up to provide psychological support for the victims had to be shut down because of lack of funds[37].

And it isn't just with pharmaceutical products that poorer countries become the dumping ground for the West:

On a rural health assessment of war-struck Bahr-el-Gazal in southern **Sudan** in 1993, a co-ordinator from the medical aid agency Médecins Sans Frontières was confronted by

[31] Het Parool and Le Monde
[32] www.drugdonations.org
[33] Schouten, E. MSF, BMJ;311: 684
[34] Hoen, E, Milkevicius D. 'Harmful human use of donated veterinary drug'. Lancet, 1993; 342: 308-9
[35] Time 29 April 1996
[36] www.drugdonations.org
[37] BMJ, June 2000

elders coming to a meeting with tampons hanging from their ears. The women had sanitary towels stuck to their chests. All expressed delight with their 'new jewellery', which had arrived from an American PVO, with a pop star and a film crew in tow. The plane had landed in rural Sudan, the organisers having arranged no local contacts or supplied directions for the use of the drugs and medical materials. Also donated were slimming packs and sleeping pills.[38]

A consignment of bikinis was sent to earthquake torn **Gujarat** in India[39].

An American PVO charity sent crates of Double D bras to the earthquake stricken people of Kobi in **Japan**. [40]

A hospital in **Malawi** was sent three boxes of breast implants[41].

## Conclusion & recommendations

Whilst it has been impossible to accurately measure the proportion of drug donations that occur as a consequence of the tax deduction, the objective of this incentive should be clear: to help meet the needs identified by medical staff and aid workers in the developing world and in emergencies, rather than to encourage UK-based pharmaceutical companies to off-load unwanted stock in a tax-efficient manner. In order to ensure this goal is met in the new legislation, certain loopholes need to be closed, and accountability improved, over the American model.

The pharmaceutical industry is notoriously secretive and no-one from the pharmaceutical industry would speak to us about specific cases. Instead the information gleaned in this report has come from extensive discussions with those on the receiving end of inappropriate donations, from aid workers to government ministers. Why should this industry silence be rewarded by the UK taxpayer? Why should our money be used to encourage pharmaceutical companies to make donations that we have no idea are useful, let alone safe? Key to this entire process is transparency and accountability. Not all donations are bad but the only way of sorting the bad ones from the good is a simple system of checks.

1) i. We recommend that any UK pharmaceutical company that intends to take advantage of a deduction in its tax bill for donations should list the donation in its annual accounts. It should also be published in a publicly available register to be held by the Inland Revenue. This should be updated every month on a website and a hard copy published annually.

   The register should contain the following:

   a) Details of the donor company.
   b) Details of the drug donated including generic and brand name, if applicable, quantity, dosage, expiry date and sell by date.
   c) Details of any NGO/ charity involvement and date of shipment to the charity.

   ii. We recommend that the Interagency Guidelines have to be adopted as a condition in qualifying for any tax deductible benefits

[38] Internal MSF documents
[39] interview with aid worker
[40] Interview with former employee of American PVO charity
[41] Interview with Doctor

iii. We also recommend that should a charity or NGO accept such a donation that:
a) Its ability to accept such donations is dependent on keeping a comprehensive record keeping system which would mean all donations could be traced.
b) That such records can be made available to interested parties on request.

Some companies might argue that competitors might be able to infer or garner information from the register on the state of the donor company and will argue commercial confidentiality. However, this would be disingenuous on two counts. Firstly, if the public are forgoing tax revenue their right to scrutiny and transparency overrides company secrecy. Secondly, there is not a huge amount of information rivals can garner from such a register, if the donations are philanthropic.

We believe that we all have a unique opportunity to learn from the errors of the past and to create a genuine attempt to ensure these errors do not occur again.

2) The tax credits should be geared to providing the medicines needed on the ground. The main beneficiary of these credits has to be the recipient nation, not the company. Therefore the World Health Organisation guidelines on drug donations should be included as part of the UK legislation. Any donations that fall outside of the WHO guidelines should not be eligible for a tax credit. Any attempt to include drugs outside the WHO guidelines in a tax credit should be regarded as tax fraud and subject to the penalties of the law.

   These guidelines would include:

   - Donations only made from the recipient country's essential drug list or specifically required for a given medical emergency.
   - No out of date or short-dated drugs.
   - Generic rather than brand name drugs should be provided. If they cannot the drugs should be clearly labelled in the appropriate language of the recipient nation on the packaging. This label would gives the products generic or local name, detail dosage and expiry date. This would enable local doctors on the ground to effectively use the medicine.

Critics of this may argue that there are times when companies have stocks of drugs that are short dated and can't sell in their own country but these drugs may be of use in an emergency situation abroad. If a company wants to donate a short dated drug to a developing nation, then provided the recipient government health service wants these drugs and has a use for them before the expiry date, they should be able to. However, there is no reason the company should be able claim a tax credit. If a company can not legally sell their products in their own country why should they get tax credits for donating it to a poorer country in a crisis situation? It seems morally wrong that company benefits from donating a drug that would be illegal if they tried to sell it at home.

The company will still benefit from the donation, it will save on the costs incurred by incinerating the product, it will free up warehouse and shelf space for more profitable items and it will be able to take advantage of the good PR that charitable donations attract. Sometimes corporate philanthropy has to come without a tax reward.

The industry might also object to the issue of labelling brand name products. However, it is not a huge problem to find the appropriate local names and translate the information. If this small problem is such a hurdle one would have to question the company and/or NGO in question and their ability to negotiate the shipping, transport and delivery of drugs possibly in the middle of a disaster.

3) The tax credits should only cover the manufacturing cost of the donated product. The incentive should not be to claim back as much money as possible and thus donate as many products as a company can. The aim has to be to get the right drugs to the right place.

We have concentrated on the problems with corporate donations because this practise is rewarded but a large proportion of the problem on the ground is created by well meaning individuals and charities. DO NOT donate your old drugs or equipment. You aren't helping anyone. Why not give money to one of the many leading agencies that try to do their best to help those who most need it without poisoning them or ruining the local economy. You can make a real difference by joining our campaign to ensure that the pharmaceutical industry has to account for what it dumps abroad. Write to Gordon Brown and ask him to include these recommendations in the forthcoming legislation. Lobby your local MP to raise the issue. Write to the pharmaceutical companies and ask if they will support the recommendations. If not, don't add to their profits. Most UK drug companies don't just sell drugs, they sell soft drinks, shampoo and other consumables that you have a choice in purchasing.

As the Hippocratic Oath says "Do no harm". Make sure they don't.

## Methodology

The authors conducted extensive interviews with people working for the pharmaceutical industry, with private NGOs who act as middlemen, with international medical organisations including the WHO and with health staff working on the ground in receipt of donations.

Collecting information on drug dumping is notoriously difficult. In an emergency situation the medical professions primary objective is to save lives and prevent the spread of illness and disease. If badly donated drugs are arriving in the emergency area they are regarded as a problem that simply has to be overcome. Although there are examples of the worst excesses of drug dumping, the day to day grind is harder to monitor as the drugs are either rapidly dispersed or got rid of, either being disposed of or appearing on the black market.

Those health professionals that are aware of the problem and try to work against it often find themselves at odds with their own government. We note the example of the earthquake in Turkey last year. The problem of drug dumping was highlighted by health professionals and their relevant associations, in the first week after the disaster. The Turkish Ministry for Health organised pharmacists to sort the useful drugs from the inappropriate, however, since then there has been a reluctance to examine or report the issue. It is the author's belief that the health professionals concerned will not discuss, debate or report the issue openly for fear of coming into conflict with the Turkish Ministry for Health.

Sometimes Health officials in developing countries will be wary of confronting the pharmaceutical companies, who they feel, could jeopardise career prospects either directly or through the company's displeasure being expressed to the relevant Ministry of Health. The author's experience has been that aid workers are nervous of discussing the problems in case the donations stop. Those who were brave enough to speak have, hopefully, been fairly represented here based on contemporaneous notes or transcripts of discussions. The authors' reserve the right to protect their sources and have not published their names.

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