The cost of donated drugs

With new WHO guidelines due out next year, **Elizabeth Sukkar** examines the problem of inappropriate drug donations

More than 4000 tonnes of medicines were donated to people in the Aceh region of Indonesia after the December 2004 tsunami. Of these, 600 tonnes were out of date or about to expire and cost an estimated €2.4m (£1.5m; €1.6m) to destroy.[1]

This is just one example of inappropriate drug donations that the World Health Organization has collated. Although WHO has had guidelines on drug donation for over a decade, with the last revision in 1999, adherence is often poor.[2] It is currently revising the guidelines to try to improve the situation.[2]

"Unfortunately, countries in crises are still suffering from bad donations. Roughly half of donations in emergencies that are evaluated are still reported as inappropriate. Although we have seen much improvement over the years, we still observe problems. Not all donations and relief efforts are evaluated or documented systematically," says Helene Moller, technical officer in WHO's department for essential medicines and pharmaceutical policies. Donors include individuals, governments, charities, humanitarian bodies, and drug companies.

The WHO guidelines say all donated drugs should be based on the needs of the recipient country, should be approved for use in that country, should not include returned unused drugs, and have a remaining shelf life of at least one year on arrival (although exceptions are made for short shelf life drugs and agreed donations to specific health centres).

To help prepare the new guidelines, WHO did a systematic review of drug donations during 1998 to 2008. It found that only 56% of donations were appropriate given the characteristics of the event and what the recipient needed, and only 12.5% of drugs requested by recipient countries were received.

Of the inappropriate donations, 57% had improper labels, including in languages not commonly spoken in the area, and 40% had expiry dates of less than one year. Up to 80% of appropriate donations were surplus to requirement. "The ensuing cost of drug destruction, where documented, was significant," says Dr Moller, one of the authors of the review.

The WHO recommends that drugs should ideally be destroyed by high temperature incineration, but developing countries do not always have these facilities and may have to resort to dumping drugs in unsecured landfill sites.

Ghislaine Soulier, head of communications for Pharmaciens Sans Frontières, says inappropriate drug donations "are a crime against the environment as most of the countries 'benefiting' from these donations have not the means to destroy them properly."

The irony of the situation is that while drug donations are not governed by any law, disposal of unwanted drugs in another country with appropriate facilities is highly regulated and subject to the Basel Convention on the Transfrontier Shipment of Hazardous Waste. The exact cost of destruction is hard to come by, but a 1999 WHO report estimated that it was around $4.10/kg and a UK company recently quoted £1.70/kg (€1.90; $2.80).[3] There may also be costs for storing unusable drugs until they can be redistributed.

Human resources are also limited in an emergency situation. Unannounced arrival of drugs, even if useful, often creates logistical problems.

Call for mandatory guidelines

Only a few countries have made the WHO guidelines mandatory, including Canada, and earlier this year France banned the collection of returned medicines from patients. The UK has not made the WHO guidelines mandatory and allows the collection of returned patient medicines (although guidance from the Royal Pharmaceutical Society of Great Britain recommends against the reuse of returned medicines). Relief agencies want to see the WHO guidelines being taken up more widely.

A spokesperson for the United Nations Children's Fund (Unicef) said, "Although many potential recipient countries have adopted these guidelines, unsolicited donations still get in. Enforcing guidelines is resource intensive, and there should be gate keeping mechanisms before the products leave the donor country."

It believes the problem is that the donors are probably not aware of the guidelines or the actual need of recipient countries.

Carine Werder, pharmacist coordinator for Médecins sans Frontières (MSF), says the current guidelines are very comprehensive, but the "challenge is to get everyone on board. WHO has not been very public about the guidelines—legislation may be a way of enforcing this."

Pharmaciens sans Frontières also wants to see the guidelines made mandatory, and more importantly, it wants donors to be given a penalty or forced to pay for the destruction of the medicines should they make inappropriate donations.

Role of drug companies

The current guidelines were written for emergencies, but WHO intends that the new guidelines will include other scenarios such as protracted emergencies, donations targeting specific diseases, and other forms of donations. We also need better wording on the quality of medicines and, of course, better adherence to the guidelines by member states, adds Dr Moller.

Ms Werder says Médecins sans Frontières would like the guidelines to contain information on long term donations. Drug companies

BAY ISMOYO/AFP/GETTY IMAGES

US troops unload food, medicine and equipment for the inhabitants of Banda Aceh following the tsunami on 26 December 2004

are one of the key donors for long term programmes. They do so for several reasons: tax incentives, good public relations, cost saving (it is cheaper to donate a drug than destroy it), surpluses in the market, and a genuine desire to help.

The industry's attitude to donating has changed over the past two decades. "Ten or twenty years ago, the industry made more bad donations, but now they are careful because pharmaceutical firms know they are being watched on what they send," says Ms Soulier.

The UK based charity International Health Partners (IHP), which coordinates donations from the drug industry, also notes there has been a change. In the past, disasters were badly dealt with because they were supply driven. "This is not to say that there aren't supply opportunities, but you don't ship it unless you know there is a specific and defined need," says Anthony Dunnett, the charity's president.

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Sixty per cent of the donations that the charity receives are generic products, 30% branded products, and 10% over the counter drugs and medical supplies. It still has to reject 30% of all it is offered by drug companies, mostly because drugs are short dated.

International Health Partners wrote a submission to the WHO on behalf of the UK pharmaceutical industry, calling for a greater role for drug donations. It believes donated medicines could be part of a strategic plan for long term access to medicines in some countries. "The trouble is that where the largest access problem is—in what we call fragile states—you haven't got any form of market mechanism and you are not going to get one for 10, 20, or 30 years. International policy is totally empty in that area," says Mr Dunnett.

It is working with the UK Department for International Development and others to raise awareness of the role for donated medicines in providing access to drugs for countries that have come out of disasters but are not yet stable. Mr Dunnett says the WHO guidelines are "not a helpful document for a lot of what could take place in development."

Drug versus cash donations

Dr Moller thinks that the role of drug donations is limited. "Emerging evidence leans towards a conclusion that cash donations are more appropriate than product donations," she says.

The guidelines advise that once the acute phase of the emergency is over, a cash donation for the local purchase of essential drugs is usually more welcome than further drug donations. Cash contributions support the rapid response activities of local government, non-governmental organisations, and the local drug industry and may prevent confusion arising from multiple forms of similar products. WHO has discussed alternatives to drug donations in the past, such as the provision of emergency kits that contain standardised drugs and medical supplies.[4]

Unicef also believes cash donations are the better option. "There are other ways of supporting countries and patients in need—for example, through differential pricing where a product is provided to a recipient government at an affordable cost. Long term in-kind donations should be discussed in detail with each recipient country to ensure they are suitable in all aspects," a spokesperson said.

Albert Petersen, chair of the non-profit Ecumenical Pharmaceutical Network, which has more than 100 Christian organisations working to improve access to medicines in poor countries, remarks: "Sometimes broader donation programmes are blocking the competition in the market. Why register a generic version if the needs are almost covered by donated drugs? But when the donation programme ends, no cheap generic versions are available."

However, Stephanie Arsac-Janvier, head pharmacist of the International Committee of the Red Cross, questions how the money might be used by recipient countries: "Without doubt more financial support could reduce the incidence of inappropriate drug donations. However, such support can only help those in need if the money is used for the intended purpose."

So would it be better for drug companies to lower the prices of drugs in developing countries so that purchases are sustainable and predictable rather than making long term drug donations? IHP thinks it is not that simple.

"This would be the utopia," says Alex Harris, IHP's industry and government relations director. "We would love to see viable healthy local markets in a lot of these countries. Getting to that point takes more than just selling your drugs at the right price. A classic example is the Gambia, where you could sell your drugs at preferential prices, where the drugs get sent to the government's central medicines stores, but what happens to medicines after that point is anybody's guess."

Inappropriate drug donations will continue as long as there are no laws stopping them and the WHO guidelines are not widely known. The challenge for WHO and its agency allies is to ensure that the new guidelines, which are expected early next year, are followed.

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