Donations of medicines – general principles

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Individuals and organizations tend to respond to humanitarian emergencies and to people working in health programs in poor countries with an urgent desire to help. The media often highlight shortages of medicines. Donating medicines can seem a tangible way to express concern and solidarity. In both emergency and non-emergency situations requirements for pharmaceuticals should be determined through a comprehensive assessment of health problems and donations of cash can be a much more helpful response, allowing drugs relevant for the programs to be bought at a fraction of the cost of those bought and transported from the donor country.

Many countries have developed Essential Medicines Lists based on analysis of needs and determination of standard treatment guidelines. The medicines on this list are the most appropriate for use in that setting. The criteria for selection of drugs are appropriateness, efficacy, safety and cost-effectiveness. Essential generic drugs can be bought from reputable procuring agencies at much lower prices than the brand-name drugs from large multi-national companies. Staff are trained not only to use the medicines but to undertake all aspects of management including record-keeping, ordering from central stores, warehouse management and stock-control, and timely procurement based on accurate quantification. It is important that capacity is built throughout the whole essential drugs system, in order to maintain a reliable supply of essential medicines.

Medicines identified by international non-proprietary names (INN) rather than brand-names make training easier and overcome the confusion caused by different brand names. The use of INNs also facilitates ordering and storage. Donations of drugs on the standard list, in consultation with recipients, can be helpful at times. However it cannot be a sustainable solution and the provision of donations can undermine the development of a system that is attempting to build up management skills at all levels as well as costing far more than generic medicines bought from reliable international or local agencies.

In response to numerous experiences of the problems caused by inappropriate donations in emergencies and other situations several organisations produced guidelines for drug donations during the 1980s. The Essential Drugs Programme of WHO saw a need for a single comprehensive document and in 1996 published their Guidelines for Drug Donations, which was revised in 1999 and 2011. The document reflects consultation and consensus among the major international agencies active in humanitarian emergency relief.[i] Mechanisms for regular review are included as well as case-studies of inappropriate donations.

The twelve articles of the Guidelines for Drug Donations are based on a set of core principles. First there should be maximum benefit for the recipient; second there should be respect for the wishes and authority of the recipient, and support for existing government policies; third there should be no double standards in quality – if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation; and fourth, there should be effective communication between the donor and the recipient.

After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year. Distribution through different storage levels (eg central store, provincial store, district facilities) may take six to nine months. Drugs may lose their active properties after their expiry date. Even though some drugs may continue to be safe and effective after the expiry date their use would not be permitted in the donor country and so the donation of expired drugs is an example of double standards. Recipients do not like to feel that they are a dumping ground.

The guidelines note that many countries have developed a National Standard Drug List based on treatment guidelines for the most common diseases to ensure safe and reliable treatment and optimal use of resources. At the community level, irrelevant drugs in health facilities can interfere with appropriate management of common problems and may undermine a system

based on rational prescribing from standard drug lists, treatment protocols, and trained national health workers.

Despite the existence of published guidelines since the 1980s, each emergency produces new examples of inappropriate donations. In eastern Zaire in 1994, for example, one relief organisation chartered an aeroplane to deliver a huge shipment of a commercial soft drink used by athletes in the false belief that it could be used to treat persons with cholera. In fact, this product can prove dangerous if given to young infants. In addition, the product was not only bulky and difficult to store, but caused considerable waste and was neither appropriate nor cost-effective when compared with the standard oral rehydration salts used to treat diarrhoea and dehydration.

There are numerous documented cases of relief organisations, private companies, governments, and individuals providing culturally unacceptable and nutritionally inadequate foods; inappropriate, expired, poorly packaged, and even dangerous drugs; and other irrelevant relief supplies. Donations by pharmaceutical companies are often used to obtain tax deductions on unused stock or to stimulate a later market for certain products. In April 1999 growing concern about the appropriateness and the quality of the drugs donated to Albania during the Kosovo refugee crisis caused the WHO Europe Office to issue an appeal to *'follow the guidelines'.* Albania was assisted to develop national guidelines for drug donations and a standardised list of drugs.

The WHO audit in Albania during May 1999 revealed that around 50% of the donated drugs were inappropriate or useless and would have to be destroyed. Sixty-five per cent of drugs were due to expire within a year, and 32% were identified only by brand names, which were unfamiliar to Albanian health professionals. None of the short shelf-life donations were requested, and aid workers reported that they could not be distributed and used before the end of the year.

After the tsunami that affected Sri Lanka in 2004 donations flooded in but only 4% of medicines donated were useful. The rest had to be destroyed.[ii]

Inappropriate relief donations need to be prevented and recipients must feel comfortable to refuse unwanted gifts. Ideally, the government of a disaster-affected country should monitor the quality of assistance and ensure that inappropriate aid is rejected. In the absence of government controls, the lead UN agency in a relief program needs to pay more attention to exerting their authority over the monitoring of the quality of donations. Well-informed media could play a valuable role in monitoring and exposing agencies, companies, and governments that persist in this malpractice. Ironically, the agency that flew the soft drink into Zaire was praised for its ingenuity by the Wall Street Journal.

Donations can be troublesome before they even leave the donor. Transport to the destination can prove difficult with costs higher than the value of the drugs. At the destination, packages of all sizes and shapes appear, perhaps without any indication of the contents. Some units of drugs may have been opened and used. They may lack labelling, or be labelled in a language that cannot be read in the region. Sometimes consignments remain at the point of entry for months because arrangements were not made for their arrival. Storage costs and taxes may be demanded.

Storage and ultimate disposal also pose problems. Incompletely destroyed medicines have appeared in local markets. Between 1992 and mid-1996 in Bosnia and Herzegovina, an estimated 17,000 metric tons of inappropriate donations were received with an estimated disposal cost of US$34 million. There were neither high temperature incinerators nor specialist chemical waste treatment centres.[iii] Because of increasing problems associated with disposal, guidelines for disposal have been developed and published by WHO. [iv]

In most cases, a financial contribution is more appropriate than donation of medicines. It allows purchase and transport from specialist procuring agencies, at a fraction of the cost of supplying products from another country.

In the long term, this problem of inappropriate drug donations needs to be resolved by relief agencies through education of the public and the media, and through a commitment to

maintain high standards. According to Bernard Pecoul, of Médecins Sans Frontières 'We in humanitarian organisations are the only ones who can break this cycle of waste.'

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[i] WHO et al. Guidelines for medicines donations. 2010. Geneva: World Health Organisation. http://whqlibdoc.who.int/publications/2011/9789241501989_eng.pdf

[ii] Fernandopulle R et al. The expectations the reality and the burden of drug donations. Ministry of Health, Faculty of Medicine Sri Lanka 2007

[iii] Forte G, Alderslade B. Inappropriate drug-donation practices in Bosnia and Herzegovina. N Engl J Med. 1998 May 14;338(20):1473

[iv] WHO et al. Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies. 1999; Geneva: World Health Organisation. WHO/EDM/PAR/99.2 http://www.who.int/medicines/docs/pagespublications/supplypub.htm#donations