SADC GUIDELINES FOR DRUG DONATIONS

2007
INTRODUCTION

These Guidelines aim to improve the quality of drug donations. There are many different scenarios for drug donations. They may take place in acute emergencies or as part of development aid in non-emergency situations. They may be corporate donations (direct or through private voluntary organizations), aid by governments, or donations aimed directly at single health facilities. Although there are legitimate differences between these scenarios, there are many basic rules for an appropriate donation that apply to all. The Guidelines aim to describe this common core of “Good Donation Practice”.

1. **Before a donation is sent to a SADC members state, the recipient should be contacted by the potential donor (or vice versa) in order to establish the need for such medicines at that time.**

   This provision stresses the point that it is the prime responsibility of the recipients to specify their needs. It is intended to prevent unsolicited donations, and donations which arrive unannounced and unwanted. It also empowers the recipients to refuse unwanted gifts.

2. **Donations must consist only of medicines of known good quality that are included in the ‘list of essential drugs’ supplied by the SADC member state, or in the absence of such a list are on the WHO Model List of Essential Drugs.**

   It is expected that donors would comply with National Drug Policies and essential drug programmes and hence aim at the implementation of their components, such as the provision of medicines which are considered to be necessary in the treatment of diseases afflicting most people in a SADC member state.

3. **All donated medicines must be registered in the countries of origin, and manufactured in conformity with the guidelines on Good Manufacturing Practices (GMP) and certified according to the WHO Certification Scheme On the Quality of Pharmaceutical Products Moving in International Commerce.**

   This provision prevents double standards: drugs of unacceptable quality in the donor country should not be donated to other countries. Donated drugs should be authorized for sale in the country of origin, and manufactured in accordance with international standards of Good Manufacturing Practice (GMP). This also guards against fake or substandard products.
4. **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.**

Patients return unused drugs to a pharmacy to ensure their safe disposal; the same applies to drug samples that have been received by health workers. In most countries it is not allowed to issue such drugs to other patients, because their quality cannot be guaranteed. For this reason returned drugs should not be donated either. In addition to quality issues, returned drugs are very difficult to manage at the receiving end because of broken packages and the small quantities involved.

5. **All drugs should be labelled in at least one official language of the recipient members state; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.**

All donated drugs, including those under brand name, should be labelled also with their INN or the official generic name. The INN's are internationally known and understood in any country where Roman script is used. Most training programmes are based on the use of generic names. Receiving drugs under different and often unknown brand names and without the INN is confusing for health workers and can even be dangerous for patients. In the case of injections, the route of administration should be indicated.

6. **After arrival in the recipient member state 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.**

This is because there may be a logistic problem in distribution, which may cause the medicines to reach the patient after expiry. 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. 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.

7. **If medicine is sent to the same place or programme regularly, it is highly appreciated if the strength and dosage of such medicine could remain constant.**

The reason for this is that health workers at different levels of the health care system have been trained to use medicines in relation to a particular dosage and strength, and treatment schedules have been developed accordingly. Also, health workers with insufficient training in making necessary calculations to modify schedules may end up giving wrong dosages.

8. **As much as possible, donated drugs should be presented in larger quantity units and hospital packs.**

These are less bulky, and therefore easier and cheaper to handle.

9. **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.**

This provision prevents the recipient from being forced to spend effort and money on the clearance and transport of unannounced consignments of unwanted items, and also enables the recipient to review the list of donated items at an early stage.