Good practice in international medicine donations

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INTRODUCTION

Medicine donations occur in very different circumstances; as a response to emergency situations, to humanitarian crises, or in long-term development aid projects. In emergency situations, part of the solidary response to the affected population is in the form of medicine donations. Although these contributions are almost always unquestionable and made in good faith, the rule "*something is always better than nothing*" is not correct. Even though; medicines are fundamental in humanitarian interventions they may have future negative consequences for the environment and for the health of the people of the receiving country. It has been found through the years, that medicines donated spontaneously do not always correspond to the needs of the emergency, the morbidity or the level of care of the recipient country. In these cases, not only can donations have negative effects for the receiving communities but may even go unnoticed by health personnel or patients in the area, and not in line with the local pharmaceutical policies or the treatment guidelines of the country.

It is also important to highlight the incorrect statement that "*in situations of serious emergencies medicines with a short expiration date can be donated because they will be used quickly*", because it is precisely in these situations, when the systems for receiving, storing and distributing medicines, as it happens with other supplies, can be disrupted and overloaded, causing accumulations before its final distribution. These delays are especially serious when it comes to medicines, when their expiry date comes into play. Local and international health organizations, as well as public and private entities, have repeatedly denounced over the years, the massive arrival of medicines not usable in the countries affected by crisis situations, and the problems that derive from their incorrect storage, irrational use and eventual destruction.

In 1996, the World Health Organization (WHO) [1] published for the first time a document of guidelines for medicine donations, reviewed and ratified in 1999 by this agency, as well as by social and international organizations, until the last update in 2010 [2]. These recommendations have served the international community as the basis for international legislation, such as the Guidelines on Good Distribution Practice of Medicinal Products for human use of the European Economic Community (EEC) [3] and national laws. In the case of the Spanish State, it is the Spanish Agency for Medicines and Health Products (AEMPS) [4] that regulates international medicine donations. These instructions for exports of medicines for humanitarian aid [5], are aimed at maintaining the quality standards of the medicines regardless of who the recipients are, and they forbid the donation of medicines that have already been used or that have left the pharmaceutical circuit.

GENERAL CONSIDERATIONS

The aim of the WHO recommendations and of Spanish legislation on international donations of medicines, is to ensure the quality of medicines to all people, whatever their circumstances. According to those recommendations and legislation, donated medicines must comply with all the international standards of quality, and not have abandoned the pharmaceutical circuit that ensures their traceability.

International donations of medicines must always be endorsed by pharmaceutical staff who assume the responsibility for their quality and who certify their validity for shipment.

It is also necessary that the recipient is informed, in good time, of the arrival date and the expiry dates of the medicines that, according to Spanish legislation, must be longer than 15 months. Only in very special circumstances and with the written acceptance of the recipient, medicines with lower expiry dates can be sent as a donation. This is so, because in many receiving countries, there may be logistical problems such as poor transport systems, storage problems or long distances between the ports of arrival and the final destination, delaying the delivery of the medicines. Similarly, the different storage levels from origin to destination (port or airport, central warehouse, provincial warehouse, district hospital, health centre) can lead to long delivery times of up to six to nine months, reducing the expiry dates of the medicines, before being delivered. Therefore, the recipients of the donation must be kept informed of the all stages of this process. They must also know the quantities and expiry dates of the medicines, because an excessive delay, in any of these phases, can imply quality deterioration of the medicines, affecting the stocks of the health centres, and generating harmful waste for the environment. The unusable medicines that arrive at destination should be eliminated in an appropriate manner, as they can become emerging organic pollutants, turning into an added problem for the recipient country, if it does not have adequate waste management processes.

Whenever possible, donated medicines should be sent in big formats and appropriately labelled for final administration by the health professionals.

Finally, it must be stressed that international donations of medicines cannot be managed by or sent to private individuals, but directly by non-

governmental organizations (NGOs) or humanitarian aid foundations, pharmaceutical laboratories, distributors of medicines, hospitals, health centres or governments, and addressed to governments or entities accredited by the Ministry of Health of the country of destination.

SELECTION OF MEDICINES

The medicines registered in Spain being selected for donation must always comply with all the international quality guarantees. In the case of medicines not registered in Spain, they must be:

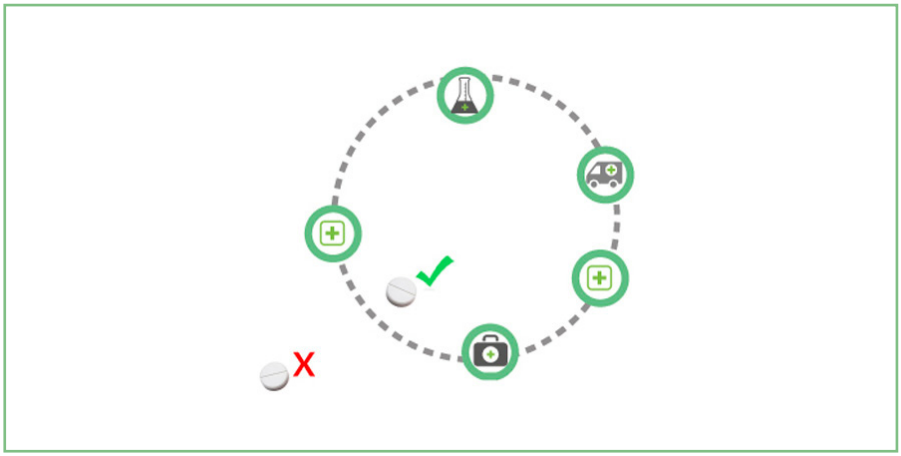
- registered in a European Union country (EU), or
- registered outside the European Union and have the corresponding Certificate of Good Manufacturing Standards (GMP) issued by the European Union to guarantee their quality. In these cases, and exceptionally, the export can be authorized as a humanitarian donation and must be accompanied by a declaration signed by the recipient health authorities that details:

  a) identification of the medicines: name of the medicine, presentation and name of the manufacturing laboratory.

  b) express acceptance of the shipment, stating that they are aware that the donated medicine is not registered in the European Union.

Donated medicines **must have:**

- **the same guarantees of quality, safety and efficacy as those being used in the country of origin** and therefore remain within the pharmaceutical circuit, that is, in the legal chain of custody, **until their final delivery.**
- **a minimum expiry time** of fifteen months upon arrival in the receiving country, with the exception of direct donations to certain health facilities. In these cases, a declaration from the recipient health personnel is necessary, acknowledging the expiry dates, storage conditions, and the amount being sent to prepare for the appropriate administration, before the expiry date.



- **the prior authorization of the recipient,** who has had to specify its needs. The legislation authorizes the recipient to refuse unsolicited donations, those that arrive without prior notice, or are not necessary, in order to guarantee the pharmaceutical policies and essential drug programmes of the recipient country, and maximize the positive impact of the donation, preventing the arrival of unnecessary and/or unknown medicines.

- **the presentation, dose and formulation as similar as possible to those of the recipient country to facilitate the work of its health personnel** who are used to administering certain formulas and following dose guidelines without modification, so as not to affect the quality of their work.

Neither medicines that come from patients' returns, nor those provided as free samples to health personnel, can be donated, as it is not possible to guarantee their quality.

Restrictions and exceptions

* Psychotropic drugs, blood products, narcotics, heat-labile medicines or those with special storage and/or transportation conditions are given special consideration and their donation must be duly justified. These medicines

require a special export authorization, which is processed by the Narcotics and Psychotropic Area of the AEMPS, that will accompany the export authorization of medicines for humanitarian donations.

* Vaccines, which apart from having special storage and/or transport conditions, are usually administered under national vaccination plans and international agreements, and consequently, not being part of smaller scale donations, between entities

PRESENTATION, PACKAGING AND LABELLING

To facilitate the administration, storage and distribution of international medicine donations, especially in emergency situations, clear identification of the boxes and their contents is very important, otherwise, the shipping operations can become very slow and laborious, delaying the delivery of medicines to the recipient.

- **The packaging must allow for clear identification of the medicines,** that is, include the International Common Denomination (ICD) or generic name, dosage, pharmaceutical form, batch number, manufacturer and

expiry date. Receiving medicines with different or unknown names, can be a source of confusion for the heath personnel. In the case of injectables, the route of administration must also be clearly indicated. It is also recommended that the language of the labelling is intelligible for the health professionals of the receiving country.

- **It is advisable to adapt the packaging (commercial or hospital)** to the conditions of the recipient, taking also into account issues like the price of different formats or means of transport, to maximizing the resources assigned to the donation.

TRANSPORT

At no time during the transport of the medicines, that is, from the warehouse of origin to their arrival in the receiving country, can the boxes that contain the medicines be opened, to add or remove any items. Until that moment, the number of boxes, weights and contents must correspond to the associated export documentation: commercial invoice, packing list and donation letter

stating that the donated goods will have, at destination, a non-commercial and assistance use.

Medicines must be packed in separate boxes to the rest of the products, not mixing them with other types of supplies. To facilitate the handling of the shipment, without the need for special equipment, the boxes should not weigh more than 23kg.

Costs

Transportation costs (local and international), deposit and custody, customs clearance, storage or appropriate handling are borne by the donor entity, unless otherwise agreed in advance with the recipient, so as not to force it to allocate funds and efforts for the payment of customs and transport costs.

INFORMATION AND MANAGEMENT

The export of medicines, as an international donation, together with the compulsory authorization of the AEMPS must accompany, for tax purposes, the necessary documentation:

1. **commercial invoice** based on the wholesale price of their generic equivalent in the local market. If this information is not available, one must consider the wholesale price in the world market of their generic equivalent. The declared value may also include management expenses.
2. **packing list.**
3. **letter of donation** issued by the donor entity indicating the destination, the value of the medicines, and a statement indicating that the donated medicines will be used for health purposes, and not commercial use.
4. **information of the customs office of departure** (port or airport).

Because the documentation for the export includes the list of contents of each box, the authorization to the AEMPS must be requested, once the order is fully assembled.

The application is free of charge and can be submitted:

- In the virtual office of the AEMPS, going to the LABOFAR application: https://labofar.aemps.es/labofar/inicial.do
- In paper format

The export authorization of medicines:

- is unique and exclusive for each donation, but not necessary for medical equipment and cosmetic products.
- is valid for three months

An authorized medicine donation may never have a commercial purpose.

There are two types of donour entities:

A) with European Tax Identification Number:

i. Shipments delivered in Spain; known informally as "suitcase shipments". In these cases, the donor entity acts as an exporter of medicines and is ultimately responsible for the shipment. It is this entity that applies to the AEMPS for the export authorization of medicines and is responsible for the rest of the customs documentation. The responsibility of the medicines' distributor ends with the delivery at the address given by the donor. Nonetheless, the distributor must provide the documentation and the advice, if necessary, for applying for the export authorization.

ii. Shipments delivered to the country of destination. The distributor acts as the exporter and is responsible for the processing of the export authorisation and related documentation.

B)) with a non-European Tax Identification Number:

Shipments are delivered in countries that are not members of the EU and are considered as commercial exports, thus not requiring a donation letter. In these cases, it is the distributor who is responsible for the export and custom procedures with the pertinent administrations.

To apply for the export authorization of medicines, you must submit:

1) **List of medication packaging i**ndicating:

- Name of the medicine (ICD).
- Registration number, when the medicine is registered for marketing in an EU Member State or a Certificate of Good Manufacturing Standards, in other circumstances.
- Holder of the marketing authorization.
- Presentation: pharmaceutical form, dosage and format and lot number.
- Expiry date.
- Number of boxes of each medicine.
- Mention: These medicines are a free of charge donation of humanitarian character by (name of the entity).

2) **Certificate signed by the responsible pharmacist** who guarantees the shipment according to the criteria established for the international donation of medicines.

MANAGEMENT OF USED MEDICINES

Left over medicines from our homes, as well as the empty packaging or with remnants of medicines, should be taken to the SIGRE Points [6] that are found in pharmacies, with their original boxes to facilitate their identification and their subsequent environmental treatment or other. Needles, thermometers, gauze and material for cures, chemicals, x-rays or batteries cannot be put into the SIGRE Points. As an exception, only when it is not possible to separate the needle, pre-filled syringes, insulin pens or other pens can they be taken to the SIGRE. In this case, they should always be deposited with the needle capped with their protective cap or similar. For safety and public health reasons, SIGRE Points are exclusively in pharmacies, so that the residues of medicines are always in the custody of pharmaceutical professionals.

Finally, according to the Packaging and Packaging Waste Law (Law 1/1997 of April 24) [7] is the pharmaceutical productive sector who is obliged to assume the management of the waste of medicines that have to be destroyed in a controlled manner, and the recycling of the cardboard, glass, paper, etc., so as to not contaminate the environment.

KEY CONCEPTS

Bioequivalence
Bioequivalence is the property wherein two drugs with identical active ingredients or two different dosage forms of the same drug possess similar bioavailability and produce the same effect at the site of physiological activity.

Emerging contaminant
Emerging contaminant is that previously unknown or not recognized substance, whose presence is not necessarily new, but what is new is the concern over its possible effects in the environment. The detection of these pollutants has only recently been possible thanks to the development of new and more sensitive analytical technologies.

Neglected diseases

Neglected diseases are those that persist when there is poverty and are concentrated almost exclusively in the poor and impoverished countries of the world. These populations, living in remote rural areas, marginal suburban neighbourhoods or conflict zones, tend to be the most affected by these diseases, to which little research and development is destined and are relegated from public health priorities because of their lack of political influence. Also, the lack of reliable statistics hinders initiatives to highlight them.

Essential medicines

Essential medicines are those that cover the priority health care needs of the population. Their selection is based on the prevalence of diseases and their safety, efficacy and comparative cost-effectiveness. National drug lists indicate the essential medicines that must always be available, in sufficient quantities, in the appropriate pharmaceutical forms, with a guaranteed quality, and at a price that is affordable for people and for the community.

The World Health Organization published the first list of essential medicines in 1977, that is reviewed and updated every two years to adapt it to the changing health challenges in the world, serving as a model for Member States. In March 2017, the twentieth revision of the Essential Medicines List was published and the sixth revision for children under 12 years of age [8]. The twentieth list includes 433 medicines to treat priority diseases such as malaria, HIV/AIDS, tuberculosis, reproductive health disorders and the increasingly chronic diseases, including cancer and diabetes.

Generic drugs

Generic medicines are those that have the same qualitative and quantitative composition in active principles and the same pharmaceutical form as the original medicines and have demonstrated bioequivalence with the original medicines.

Morbidity

Morbidity is the number of people considered ill or victims of illness in a given space and time. Morbidity is an important statistical data to understand the evolution or regression of any disease, the reasons for its emergence and possible solutions.

ACRONYMS

AEMPS - Agencia Española del Medicamento y Productos Sanitarios
AIDS - Acquired Immunodeficiency Syndrome
EEC - European Economic Community
EU – European Union
GMP – Good Manufacturing Practices
HIV - Human Immunodeficiency Virus
ICD - International Common Denomination
NGO - Non-Governmental Organization
WHO - World Health Organization

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