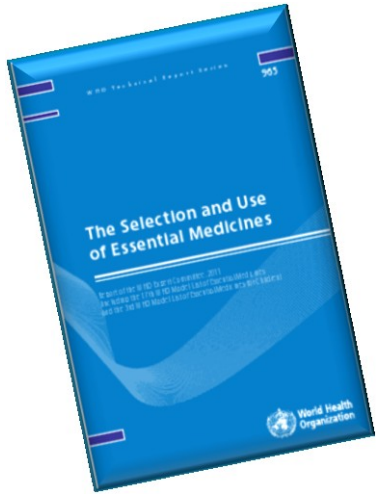
WHO Essential Medicines List
Concept and Process



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World Health Organization

Essential Medicines

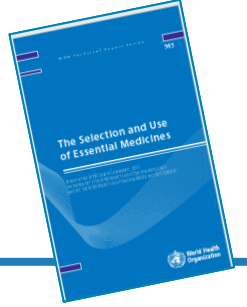
Guiding principle: A limited range of carefully selected essential medicines leads to better health care, better medicines management, and lower costs

Definition: Essential medicines are those that satisfy the priority health care needs of the population

Selection: Selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.

World Health Organization

… 38 years of EML



1977 1st Model list published, 208 active substances

- List is revised every two years by WHO Expert Committee
- 2002 Revised procedures approved by WHO (EB109/8)
- Last revision (April 2013) contains 374 medicines

The first list was a major breakthrough in the history of medicine, pharmacy and public health

Médecins sans Frontières, 2000

World Health Organization

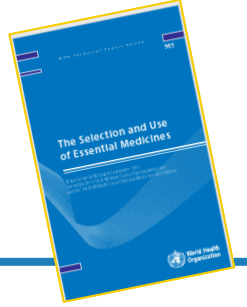
The Essential Medicines List and concept

- ***"The concept of essential medicines is one of the major public health achievements in the history of WHO.***

- ***It is as relevant today as it was at it inception over 30 years ago."***

Dr Margaret Chan — Director-General, WHO

Why is it 'model'



- Model for its selection process
- Model to facilitate efforts to 'improve health' of population
  - Regulation
  - Quality
  - (Rational) Responsible and evidence-based use
  - Procurement and Supply

Access: Availability, Affordability, Accessibility and Acceptability

World Health Organization

Guidelines for Medicine Donations

Revised 2010

World Health Organization (WHO)

Ecumenical Pharmaceutical Network (EPN)

International Pharmaceutical Federation (FIP)

International Federation of Red Cross and Red Crescent Societies

International Health Partners

The Partnership for Quality Medical Donations (PQMD)

United Nations Development Programme (UNDP)

United Nations Population Fund (UNFPA)

United Nations High Commissioner for Refugees (UNHCR)

United Nations Children's Fund (UNICEF)

The World Bank

Roll Back Malaria Partnership

Donazioni: 4 principi OMS

Guidelines for medicine donations is based on four core principles that form the basis of good medicine donation practice, namely:

1. Donations of medicines should benefit the recipient to the maximum extent possible. All donations should be based on an expressed need. Unsolicited medicine donations are to be discouraged.
2. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of the recipient country.
3. There should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties.
4. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

Donating returned medicines (LG OMS)

Donating returned medicines (unused medicines returned to a pharmacy for safe disposal, or free samples given to health professionals) is an example of a double standard because in most countries their use would not be permitted owing to regulations on quality control. Such donations also frustrate management efforts to administer medicine stocks in a rational way. Prescribers are confronted with many different medicines and brands in ever-changing dosages, while patients on long-term treatment suffer because the same medicine may not be available in future. For these reasons this type of donation is forbidden in an increasing number of countries and is discouraged elsewhere.

Donazioni: principi OMS

Clear guidelines that are endorsed by the major international donors and development agencies can be helpful. In summary:

Donors and international development agencies generally are well-intended, but do not always realize the possible inconveniences and unwanted consequences in recipient countries.

The need for medicines – both to ensure adequate health-care delivery and to manage emergency situations – may vary between countries and from situation to situation. The selection of medicines to be donated must be based on a sound analysis of needs. Their quantification must be done in close cooperation with recipients, and distribution must fit with existing policies and administrative systems. Unsolicited and unnecessary medicine donations are wasteful and should not occur.

Donations and long-term treatments

The quality requirements of medicines are different from those of other donated items such as food and clothing. Medicines can be harmful if used inappropriately. They need to be easily identifiable through clear and understandable labels and written information. As they may expire, there must be a professional means of destroying them.

- Long-term donations also include medicines that are required for lifelong treatment. Unexpected discontinuation of these medicines can have severe results as the disease may become recurrent. Also, resistance to the medicine may develop. At the start of a long-term donation programme, a plan should be prepared on how to phase out a donation and how to review the donation.

As a general rule, medicine donations are neither a long-term solution to underfunded health systems nor a solution to the lack of access to medicines in poor countries – especially for diseases that require lifelong treatment or large numbers of treatments. However, donations can be temporary solutions to defined problems.

Le raccomandazioni OMS (1/4)

3. Guidelines for medicine donations

3.1 Selection of medicines

1. All medicine donations should be based on an expressed need, should be relevant to the disease pattern in the recipient country, and quantities should be agreed between donor and recipient.

Justification and explanation

The prime responsibility for specifying needs is with the recipient. This implies that there should be a clear agreement on which the donation of medicines should be based. The recipient should also be responsible for determining the quantities of products to be donated since appropriate quantification of needs is an important component of quality donations. Unsolicited, unwanted or unneeded donations should not be made, as they may lead to over-stocking and expiry of donated products. There should be cooperation between the donor and the recipient from the initiation of the donation, through its planning, and until the final shipment.

Le raccomandazioni OMS (2/4)

2. All donated medicines or their generic equivalents should be approved for use in the recipient country and should appear on the national list of essential medicines or equivalent or in the national standard treatment guidelines, if the NEML is not updated. Or, if a national list is not available, it should appear on the WHO model lists of essential medicines, unless specifically requested otherwise and provided with a justification by the recipient.

Justification and explanation

Medicine donations must comply with national medicine policies, essential medicines programmes, and national treatment protocols.

Possible exceptions

An exception can be made for medicines needed in sudden outbreaks of uncommon or newly emerging diseases. Not all medicines appropriate for those conditions are also approved for use in the recipient country in question. In such cases, donors should duly inform recipients of the regulatory status of products to be donated, and should obtain agreement.

Le raccomandazioni OMS (3/4)

5. No medicines should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or that have been given to health professionals as free samples.

Justification and explanation

Patients return unused medicines to a pharmacy to ensure their safe disposal. In most countries it is not permitted to issue returned medicines to other patients as the quality cannot be guaranteed. In addition, returned medicines are difficult to manage because of broken packages and the small quantities involved. Free samples given to health workers should not be further distributed as donations to other health systems.

Le raccomandazioni OMS (1/4)

6. After arrival in the recipient country all donated medicines should have a remaining shelf-life of at least one year. Large quantities of donated medicines become a logistical challenge, even with a long shelf-life. Therefore, based on the national consumption and available quantities in stock or in the supply chain pipeline, all donated quantities should match the needs to be consumed before they are expired.

Justification and explanation

In many recipient countries, especially in emergency situations, logistical problems exist. Regular medicine distribution systems often have limited possibilities for immediate distribution, and distribution through the different storage levels (e.g. central store, provincial store, district hospital) may take a number of months. Donation of medicines just before their expiry should be avoided as in most cases they will reach patients after expiry. The argument that short-dated products can be donated in the case of acute emergencies, because of their immediate use, is incorrect. In emergency situations the systems for receipt, storage and distribution of medicines are often disrupted and overloaded, and donated medicines tend to accumulate.

EML criteria (EB 109/8, 2001)

- Disease burden
- Sound and adequate data on the efficacy, safety and comparative cost-effectiveness of available treatments
  - Need for special diagnostic or treatment facilities also considered
- "Absolute cost of the treatment will *not* constitute a reason to exclude a medicine from the Model List that otherwise meets the stated selected criteria"