



**MSF POLICY FOR IN-KIND DONATIONS
OF MEDICAL PRODUCTS AND HEALTH TECHNOLOGY**

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POLICY GUIDING PRINCIPLES:

MSF does not accept in-kind donations of medical products or health technology. Under exceptional circumstances, and on a case-by-case basis, MSF may consider accepting such donations according to the criteria and conditions set forth in this policy.

PURPOSE OF THIS POLICY

This document outlines MSF's policy on accepting in-kind donations of medical products and health technology from a commercial entity (including not-for-profit entities associated with a commercial entity).

It is widely accepted that donations of medical products and health technology are not sustainable for ensuring access to treatment for patients, and are difficult for both treatment providers and Ministries of Health to manage effectively. Additionally, such programmes can undermine long-term efforts to incentivise pharmaceutical corporations and other stakeholders (e.g. product development partnerships) to develop, market and deliver new and existing products at affordable prices (such as in the case of paediatric formulations).

Given these serious risks, **MSF does not accept in-kind donations of medical products and health technology**. Under exceptional circumstances, in-kind donations may be considered for MSF programmes according to the assessment criteria and conditions set forth in this policy (see Section 2.3).

As per this policy, medical products and health technologies include: drugs and vaccines, therapeutic food, and diagnostic medical devices and software when either is related with clinical activities and diagnosis. Donations by non-commercial entities and other MSF sections are outside the scope of this policy (see Section 2.1), as are donations of medical products and health technology made in the context of research and compassionate use programmes.

1. GENERAL CONSIDERATIONS

As per this policy, medical products and health technologies include: drugs and vaccines, therapeutic food, and diagnostic medical devices and software when either is related with clinical activities and diagnosis.ⁱ

It is widely accepted that donations of medical products and health technology are not sustainable for ensuring access to treatment for patients, and are difficult for both treatment providers and Ministries of Health to manage effectively. Additionally, such programmes can undermine long-term efforts to incentivise pharmaceutical corporations and other stakeholders (e.g. product development partnerships) to develop, market and deliver new and existing products at affordable prices (such as in the case of paediatric formulations).

In 1996, the World Health Organization (WHO) released comprehensive guidelines on drug donation, which were later amended in 1999 and 2010. The four core principles of the WHO guidelines for accepting donations of health technologyⁱⁱ are:

1. Maximum benefit to the recipient

ⁱ A definition of health technology from WHO is presented in Annex 1

ⁱⁱ *Guidelines for Drug Donations*, WHO 1999, http://www.who.int/hac/techguidance/guidelines_for_drug_donations.pdf

2. Respect for wishes and authority of the recipient
3. No double standards in quality
4. Effective communication between donor and recipient.

The aim of the WHO guidelines is to improve the practice of donations based on the experience accumulated over the past two decades. The guidelines are not an international regulatory document, nor do they recommend adopting an anti-donation policy. However, the 2010 edition does sound the following note of caution: *“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.”* The guidelines also highlight the negative impact that drug donations can have on recipient countries: *“The negative impact that donations may have on sustainable access to medicines is often not well appreciated, especially where it concerns expensive medicines with few alternatives. Donations of these products may influence the market and suppress competition. The donation may eliminate or greatly delay the import of cheaper alternatives, which will be necessary once the donation programme has ended and regular provision from public health budgets is necessary.”ⁱ*

A study by Guilloux & Moon found that pharmaceutical corporations almost always stood to gain more by donating a drug than by lowering its price because the tax breaks they received almost always exceeded the cost of creating the additional supplies. These tax incentives make it more profitable to donate drugs than to use differential pricing. Furthermore, the authors found that drug donations cost the donor country more than four times as much as other models that improve drug access.ⁱⁱ

Once they've made donations to countries, pharmaceutical corporations are in a better position to negotiate deals on patent protection or acceptable use for a medical product, which expands the benefits they receive from their donations. Medical product donations also present a major public relations asset for corporations. Beyond the public goodwill they create, corporations may also reap benefits from government regulators as a result of their donations, such as improved access to their products. The impact of these benefits should be considered critically in evaluating the overall benefit of a donation.

Please see Annex 2 for the full details on current institutional medical products donation policies (Gavi, GFATM, MDM, UNICEF, WHO).

2. MSF'S ACCEPTANCE POLICY

2.1 Scope of application

MSF's policy for accepting in-kind donations of medical products and health technology from a commercial entity (including not-for-profit entities associated with a commercial entity) refers to the or provision of medicines, vaccines, therapeutic food, diagnostics, medical devices and software (when they are either related to clinical activities or diagnosis)ⁱⁱⁱ with the intended use to improve and enhance clinical or preventive care for patients, either free of charge or at less than production cost. Donations by non-commercial entities and other MSF sections are outside the scope of this policy (see Section 2.4).

ⁱ *Guidelines for Medicine Donations*, WHO 2010, http://apps.who.int/iris/bitstream/10665/44647/1/9789241501989_eng.pdf

ⁱⁱ *Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives*, Guilloux & Moon 2001, 203-204, <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.620.1237&rep=rep1&type=pdf>

ⁱⁱⁱ A definition of health technology from WHO is presented in Annex 1

MSF Operational Directorates (OD) have the primary responsibility and accountability in this matter. The exception process (see below) at the international level will be launched unless the OD can demonstrate that the donation meets the quality requirement for medical products and will have no impact on MSF. In reality, the threshold that the donation must have no impact on MSF excludes in-kind donations of medical products and health technology by a multinational company or a company with a global market, a donation that will be used for marketing or corporate social responsibility, or a donation that will be used for a company to develop or restrict market entry.

Donations of medical products and health technology made in the context of Research and Compassionate Use do not fall within the remit of this policy. Similarly, “medical donations” defined as “*donating human cells, tissues or organs intended for human applications*”ⁱ are not covered by this policy.

MSF’s Corporate Fundraising Statement is aligned with this policy. Financial donations from the pharmaceutical, medical product and health technology industries will be managed through the Corporate Fundraising Statement, while in-kind donations fall under the Acceptance Policy for In-kind Donations of Medical Products and Health Technology.

2.2 Guiding principles

- **MSF DOES NOT ACCEPT IN-KIND DONATIONS OF MEDICAL PRODUCTS AND HEALTH TECHNOLOGY.** Evidence shows that in-kind donations are not a pathway to creating sustainable access to these products for populations in need. MSF field teams, sections and procurement centres are not to individually accept or request medical product donations.
- This policy is in accordance with MSF’s Corporate Fundraising Statement, which excludes financial donations from companies deriving income from pharmaceutical activities, and establishes a process for case-by-case assessment (including consultation to the MedOp platform) for the acceptance of financial donations from the medical products and health technology industry.

In practice, these principles mean that:

- MSF field teams, sections and procurement centres should not sign any certificates of donation from pharmaceutical, medical product and health technology companies unless a valid exception is approved (see exception process below).
- MSF should not be a direct participant in donation agreements between pharmaceutical corporations and national authorities, except to support an (independent) evaluation of whether the proposed donation is in the best interests of the country.
- Field teams and procurement centres should report offers of medical product donations to their OC headquarters, so that MSF can respond to them in a consistent, coherent way.

2.3 Possible exceptions to consider

MSF acknowledges that the complexity of diseases, medical products, donation programmes, country’s operating and regulatory environments, and the wider problem of access to medicines makes it sometimes difficult to simply reject a donation. In some exceptional circumstances, it might even seem pertinent to consider accepting an in-kind donation of medical products and health technology. This decision would clearly constitute an exception to the rule, which should meet agreed-upon criteria. When considering accepting a donation offer, MSF should evaluate it using a set of objective medical, economic and political criteria, and carefully weigh competing factors

ⁱ Global Glossary of Terms and Definitions on Donation and Transplantation, WHO 2009, Geneva, Nov. 2009

before deciding on a position. These criteria may also serve as guidelines for negotiating donation agreements when a valid exception is approved.

2.3.1 Criteria for assessing in-kind donations

For in-kind donations to be exceptionally considered for MSF programmes, the following criteria should be assessed:

- 1. Alternative sources of a proprietary (originator) medical product:** Do affordable, quality alternate sources of the branded medical product exist? Can they legally be used in the country in question (i.e. if they are off-patent, or through the use of flexibilities in the national patent law, e.g. with a compulsory license or through the presence of a relevant voluntary license?)? How long will it take to import them?
- 2. Anti-competitive impacts:** Could the donation significantly weaken or drive generic competitors out of the market?
- 3. Benefit for patients and populations:** Will the donation save lives? Is the product already accessible? Does the donated product meet international quality standards? Is the medical product appropriate or could the products distort rational use of medical products? Is there sound evidence of the safety and efficacy of the medical product for the purpose for which it is being donated? If the donation is a medicine, is it on both the WHO and the national essential medicines lists (EML)?
- 4. Burden on health system:** Will the vertical programme require extensive administrative work for the receiving country and divert human resources from or put an unreasonable additional burden on the existing health system?
- 5. Consultation with recipient country for a country specific donation (if applicable):** What level of consultation has occurred between the country and the donor, and what conditions or impact on the country's health policy and system have been included or considered? Does the recipient country actually want the medical product? Does it fit with the country's public health priorities? Is the product registered with the regulatory authority? Is the country already receiving the donated item, and under what conditions?
- 6. Cost-effectiveness:** What will the donation programme cost the receiving country to implement in terms of human, material and financial resources? Could recipient countries be burdened with extra expenses when accepting a medical product donation? A cost-benefit analysis for the recipient country should be performed. Any tax deduction the corporation will receive for the donation should also be considered.
- 7. Data sharing:** For donations of software or equipment that may require 'system of record' (SOR) material sharing clauses, is data-sharing required by the donor? What are the associated ethical risks or uncertainties? Is there a need for a material transfer agreement (MTA)?
- 8. Delivery:** Is there a supply system in place to make sure that the medical products are properly and safely delivered to the patients? Could the donations be integrated into the country's existing medical product procurement and distribution system or could they weaken it?
- 9. Impact on MSF:** Are the benefits to the patients commensurate with any additional costs? Is MSF's involvement rational and consistent with its mission?
- 10. Indication restrictions:** Does the donor restrict the indications for which patients the medical product, vaccine or test can be used? If yes, is this acceptable, or does it distort other public health goals?
- 11. Public relations value:** What kind of public relations boost will this donation give the donor? Is this boost justified, considering the real impact of the donation or other actions the donor has taken?

- 12. Safety monitoring and operational research:** Is there a pharmacovigilance or post-market surveillance system in place to monitor and report adverse events from use of the medical product? Has the corporation set aside funds for operational research?
- 13. Scale:** Does the volume of the donation meet the global/regional/national/local/project need?
- 14. Selection of recipient(s):** Does the donation have objective, justifiable criteria for the selection of recipient countries, communities or patients? Does the selection process present ethical risks or uncertainties?
- 15. Solutions by default:** Will the donation detract attention away from finding a real solution and push the access problem out of the spotlight? How much political leverage will it give the donor? Will responsible authorities (at the national or UN level) consider the problem solved, when in fact, it is not?
- 16. Strings attached:** Are there any 'strings' attached to this donation? For example, is the recipient country expected to reciprocate in some way, such as through: (i) guarantees for overly-strict patent protection, (ii) guarantees that medical products will not be diverted to other uses or re-exported, or (iii) guarantees that data produced by the donor's medical software will be shared with the donor? If yes, what are the potential negative effects? Overly-strict patent protection can handicap a country's ability to address accessibility of medicines in the long-term. Donor demands should be transparent, public and carefully weighed.
- 17. Sustainability:** Is there a set time limit to the donation? Is the time limit related to any public health goals or indicators, or is it arbitrary? What happens to programmes and patients when the donation ends?
- 18. Time delays:** How long or complicated is the negotiation process for this donation? What is the human cost of the delay? Do better alternatives exist that would be faster to implement?
- 19. What is the risk for MSF?** Could the donation create any reputational risk, or risk of MSF or the populations MSF serves being instrumentalised?

Short-term versus long-term solutions

If production of the medical product or vaccine has been abandoned and a donation is the only source available, or if there is no possibility of a competitor entering the market for an extended period of time, it may be a practical, short-term solution. However, a long-term solution must still be found. When no market exists for the medical product, long-term solutions may include guaranteed purchase funds. If all existing sources (proprietary and generic) of the medical product are unaffordable, a donation may be a practical short-term solution to improve access until other measures can be taken to make medical products more accessible. These could include competition through mandatory or voluntary measures, large-scale demand, R&D for cheaper production methods, or R&D for more affordable medical products.

2.3.2 Conditions for accepting an in-kind donation as an exception

In exceptional circumstances, the acceptance of a donation may be considered to be more beneficial than refusing the donation.

In such case, any deviation to the policy will have to be justified by meeting following criteria:

- The donation should serve to support the care of patients or the populations MSF serves.
- There should be an (urgent) need for the medical product either for individual(s) or for a community.

- Financial savings or supply opportunities cannot be justifications by themselves.
- The exception should result in significant positive impact – or potential impact – on patients and/or populations. This should take into account immediate consequences, as well as for the future, both for MSF and non-MSF-supported patients and/or populations.
- A similar level of medical/public health benefit, cannot be achieved by alternative actions.
- All reasonable measures are taken to minimise possible adverse consequences from accepting the donation.
- The exception contributes to improving collective knowledge and takes into account the impact on other health actors.
- There is an associated advocacy strategy – in consultation with and involving the Access Campaign where appropriate (see Annex 4).

2.4 The particular cases of mixed supply and local donations from non-commercial entities

2.4.1 Mixed supply

The term ‘mixed supply’ denotes a shared and systematic supply between MSF and a Ministry of Health (MOH).

Mixed supply can happen when MSF works with MOH staff in an MOH health structure or elsewhere, such as in an MSF location. It can take place in any setting where the MOH, with its own funds or with the support of donors, procures medicines or medical devices. This can be in vertical HIV and TB projects or in primary health clinics.

Mixed supply accounts for a significant share of MSF’s procurement. In 2013, OCG and OCB reported having mixed supply in 59% and 23% of their missions respectively. Mixed supply can include a substantial amount of donations (for example, antiretroviral medicines (ARVs) from the Global Fund).

These items are not considered direct donations to MSF and do not fall within the remit of the donation policy. However, substantial corporate donations into a mixed supply chain (e.g. Novartis Access non-communicable disease (NCD) donations into the Kenyan health system) need to be carefully evaluated. The mixed supply should be managed according to the recommendations described in the Mixed Supply Guidance (Annex 6).

2.4.2 Donation from a non-commercial entity

Donations of drugs, vaccines, therapeutic food, medical materials, etc. may be proposed directly to MSF teams at country level, by different entities and organisations, including other NGOs, UN organisations, MOHs, etc. Based on MSF experience, locally donated drugs, condoms and sterile medical materials can present a range of problems that may threaten patients’ health, even when they come from reputable donors:

- They may come from manufacturers that do not ensure appropriate quality.
- They may come from intermediate distributors that do not ensure transparency on the origin of the products.
- They may have been transported and/or stored improperly, so losing their original efficacy and safety.

Any ‘local donation’ should be handled, from a pharmaceutical point of view, exactly as local purchases: before accepting a donation, a list detailing each item and its origin (manufacturer, intermediate distributor if any, donor), should be sent to the HQ pharmacist for assessment and approval.

2.4.3 Donation from other MSF sections

In general, donations from other sections are acceptable if the drugs were supplied by one of the MSF procurement centres. In cases where the medicines were bought locally, they need to be cross-checked with the HQ pharmacist. In terms of storage conditions, it may be assumed that another MSF section is conscious of the appropriate storage conditions and is adhering to it.

ANNEX: Definitions related to medical products and health technology donations

Health technology: Defined by the World Health Organization as the "application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives." This includes the pharmaceuticals, devices, procedures and organisational systems used in health care. For MSF, this can also translate into therapeutic food, vaccines, diagnostics and software.

Compassionate use or Expanded access programmes:ⁱ Expanded access, sometimes called "compassionate use," is the use outside of a clinical trial of an investigational medical product (i.e. one that has not been approved by a regulatory agency). Expanded access programmes are only put in place if the medicine is expected to help patients with life-threatening, long-lasting or seriously debilitating illnesses, which cannot be treated satisfactorily with any currently authorised medicine. The medicine must be undergoing clinical trials or have entered the marketing-authorisation application process and, while early studies will generally have been completed, its safety profile and dosage guidelines may not be fully established.

In-kind donation: Instead of giving money to buy needed goods and services, the goods and services themselves are given. An in-kind donation may include nominal payments such that the purchase value is below the cost of producing the goods and services. For example, if a product is charged at \$1 and the cost of producing the product is \$2.

Mixed supply: A shared and systematic supply of health facilities between MSF and a Ministry of Health.

ⁱ www.fda.gov/ExpandedAccessCompassionateUse and www.ema.europa.eu/ema