Gavi Alliance
Vaccine Donation Policy
Version 1.0

DOCUMENT ADMINISTRATION

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1.0	Prepared by: Nina Schwalbe, Policy and Performance	
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	Next review:	At the request of the Board

1. Purpose

1.1. This policy sets out GAVI's policy towards in-kind donations of vaccines, and other health products used in the delivery of vaccines (e.g. injection safety equipment, needles).

1.2. The policy is intended to guide decisions in the instance that the GAVI Secretariat is approached by manufacturers of vaccines and other health-related products about possible in-kind donations.

2. Scope

2.1. This policy does not extend to individual members, partners and constituencies of the GAVI Alliance such WHO, UNICEF or developing country governments.

2.2. This policy does not consider in-kind donations of non-health goods (e.g. computers, office equipment) and services (e.g. consulting or financial services).

3. Principles and policy

3.1. GAVI will not accept in-kind donations of vaccines except under the following exceptional circumstances:

3.1.1. For stockpiles to address disease outbreak emergencies, particularly when another institution cannot accept the donation;

3.1.2. In a situation where GAVI faces a severe supply shortage due to problems with allocated supply (e.g. due to batch contamination); or

3.1.3. When, in the absence of the donation, GAVI would have funded the procurement of the vaccine on behalf of a country from the specific manufacturer that is proposing to donate the vaccines.

3.2. If GAVI does in the above mentioned exceptional cases accept in-kind donations of vaccines, it will do so with the following conditions:

3.2.1. Donations must comply with UNICEF/WHO Vaccine Donations Guidelines which can be found at http://whqlibdoc.who.int/hq/2010/WHO_IVB_10.09_eng.pdf (and attached as Annex 1);

3.2.2. Countries receiving in-kind donations must still comply with their co-financing obligations in line with then applicable GAVI co-financing policy; and

3.2.3. Donation of vaccines for routine use should be equivalent to at least one full year's provision (at current levels of coverage plus buffer stock as necessary, and excluding co-financed doses) for a country so as not to disrupt the implementation of national programmes.

3.3. In-kind donations of other health products will not be considered due to the transactional costs of taking a case-by-case approach.

4. Definitions

4.1. "Donations": products being offered to GAVI at no cost.

5. Effective date and review of policy

5.1. This policy comes into effect on 1 January 2010.

5.2. This policy will be reviewed and updated as and when required. Any amendments to this policy are subject to GAVI Alliance Board approval.

Annex 1

UNICEF/WHO Vaccine Donations Guidelines

Vaccine Donations - WHO-UNICEF Joint Statement, August 7, 2010 (WHO/IVB/10.09)

A vaccine donation is defined as supply and acceptance of a quantity of vaccine for which a government does not pay. Properly managed, vaccine donations may be useful to immunization programmes or serve an urgent need such as responding to an epidemic or other emergency. However, if there is no control over the specifications of the vaccine, or if the donated vaccine does not meet the needs of the government's immunization programme, the donation could have a negative impact. Furthermore, if the vaccine donation is meant to be used in the national programme and be part of the routine immunization schedule, there must be provision for sustainable vaccine supply. Once the donated supply is exhausted, if there is no provision for procuring and funding the vaccine, the sustainability of the immunization programme is threatened.

The aim of this joint statement is to improve the management of donated vaccines, and not to hinder donations. Vaccines procured by UNICEF Supply Division in Copenhagen and financed by donors are not considered as donations because their specifications are developed in collaboration between national officials and UNICEF/WHO country staff, and their quality is assured.

WHO has already published recently updated guidelines for receipt of donations of medicines (Guidelines for Medicine Donations, WHO/EMP/MAR/2010.1). These guidelines are applicable and can be restated as five minimum requirements for vaccine donations as follows:

1. **Suitable:** The vaccine is epidemiologically and programmatically appropriate for the immunization programme: that is, the donated vaccines are consistent with the goals, priorities and practices of the immunization programme of the country for which it is being donated.

2. **Sustainable:** Prior to the donation of a vaccine that is new to the recipient country, efforts should be undertaken to assure sustainable use of the vaccine (including negotiation of price) after the period of donation, if the vaccine is meant to be included in the routine immunization programme of the country.

3. **Informed:** Responsible officials of the national immunization programme in the recipient country should be informed of all donations that are being considered, prepared, or actually under way, and the donation should only be accepted and the vaccine shipped upon their confirmation.

4. **Supply:** All vaccine that is donated should have at least 12 months shelf life remaining or have a shelf life sufficient to fulfill the intended purpose of the donation, e.g. mount a response to an epidemic or emergency or used in a preventive campaign. Donations of vaccine for use in routine immunization programmes should provide for a minimum of 12 months' supply. Injectable vaccines should be provided with auto-disable syringes and safety boxes for safe disposal. All donations must be delivered to the designated site(s) with all costs of transport and insurance paid for by the donor. The cost of customs clearance, in-country distribution and other systems costs should be precisely assessed and funding secured before acceptance of the donation.

5. **Licensed:** The vaccine is subject to prescribed licensing and/or other control procedures set up by the recipient government. It should also be licensed for the intended use by the National Regulatory Authority of the producing country; the WHO list of prequalified vaccines identifies vaccines that have been found suitable for supply by United Nations Organizations to national immunization programme.

Exceptional Situations

There may be exceptional situations when it is not possible to meet the minimum requirements outlined above. These commonly include:

Donations to research projects: The use of vaccine donated for research purposes must be guided by the International Ethical Guidelines for Biomedical Research Involving Human Subjects issued by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (http:\\www.cioms.ch\frame_guidelines _nov_2002.htm), the Declaration of Helsinki, and supplemented by other internationally and nationally accepted statements of ethical guidance adopted by the recipient country. Such projects must also comply with other national regulations and requirements related to medical research involving human subjects. New vaccines or devices that have not received regulatory approval in the country should not be used on human subjects without the appropriate approval being obtained from the National Drug Regulatory Agency for their use under the conditions of the study. Under these circumstances, it is especially important to ensure the suitability of the product, its presentation, and its schedule, as it may not be yet licensed in the recipient country nor WHO prequalified.

Vaccines donated for emergency, epidemic or pandemic situations when it may not be possible to apply all the minimum specifications above: In some instances the vaccine specifications and presentation may vary from what is in routine use, the remaining shelf life may be limited, and sustainability is not an issue. In such cases the most important considerations are that the vaccine is suitable to the country's needs from the public health perspective and that the responsible officials in the recipient country are in full agreement with shipping the vaccine, and are able to respond to quality and storage aspects of the donation. In addition, as with any other donation, the vaccine is subject to prescribed licensing and/or other control procedures set up by the recipient government. In such cases it is also useful for recipient countries to have an immunization plan.

Country responsibility

Many, but not all, recipients of vaccine donations are countries dependent on UNICEF and other donors for their supply of vaccines. Even if countries are dependent on external donors to supply vaccines, countries should still strive towards adequate capacity to receive and assess the quality of all vaccines that are received. WHO recommends that all countries exercise at least two essential national regulatory functions:

1) a published process for registration of vaccines for use within the country; 1) and
2) surveillance of vaccine field performance, including monitoring of adverse 2) events following immunization.

Further, countries should have the expertise to be able to analyze documents accompanying vaccine shipments on vaccine shipping and storage conditions in transit,

the capacity to properly store the vaccines until they are administered, and an immunization plan detailing how the vaccines will be used.

Finally, WHO and UNICEF recommend that all countries develop and implement national donations policies, and suggest that they use this joint statement as a basis.