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In this document the PPC requests the GAVI Alliance Board to approve a revised in-kind donation policy.

In 2008, Wyeth offered to donate 7-valent pneumococcal vaccine (PCV7) for use in Rwanda and Gambia (the first donation offer to GAVI since 2000), and GAVI accepted this donation on behalf of the countries. However the Executive Committee requested that GAVI's existing vaccine donation policy – adopted in 2000 – should be reviewed and revised if necessary.

This work was undertaken by the Secretariat, under the guidance of the Policy & Programme Committee (PPC) during 2009. The PPC discussed the potential benefits and risks associated with in-kind vaccine donations and related health products and reached consensus on the following recommendations. The Secretariat's analysis and PPC discussions highlighted that the issue is not straightforward, particularly given the unique characteristics of public sector vaccine markets, and the Alliance's innovative operating model. Even in these financially uncertain times, donations of vaccines and related health products to GAVI accepted on behalf of developing countries may not serve the best interest of either party. Therefore, the PPC recommends to the Board that it

- **Adopt** a new in-kind donations policy (Annex 2) which includes the following:
 - GAVI will not accept in-kind donations of vaccines except under the following circumstances:
 - For stockpiles to address emergencies particularly when another institution cannot accept the donation
 - In a situation where GAVI faces a severe supply shortage due to problems with allocated supply (e.g. due to batch contamination)
 - 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 now donating vaccines anyway
 - If GAVI does accept in-kind donations of vaccines according to the above circumstances, it should do so with the following conditions:
 - Donations must comply with UNICEF/WHO Vaccine Donations Guidelines
 - Countries receiving in-kind donations must still pay co-financing in line with the applicable GAVI co-financing policies at the time
 - 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
 - In-kind donations of other health products will not be accepted.

In-kind donations of non-health goods (e.g. computers, office equipment) and services (e.g. consulting or financial services) are not considered in this policy.

FOR DECISION**GAVI Alliance Vaccine Donation Policy****Background**

In March 2000 Merck offered to donate 5 million doses of hepatitis B monovalent vaccine (6-dose vials) to GAVI. In June 2000, the GAVI Alliance Board adopted a vaccine donation policyⁱ (Annex 1), based on the WHO/UNICEF vaccine donation guidelines.ⁱⁱ In 2008, Wyeth offered 3.1 million doses of 7-valent pneumococcal vaccine (PrevenarTM) to GAVI on behalf of Rwanda and the Gambia for the 2009-2010 period. The Executive Committee accepted this donation, but requested that GAVI's existing vaccine donation policy – adopted in 2000 – should be reviewed and revised if necessary.ⁱⁱⁱ

This work was undertaken by the Secretariat, under the guidance of the Policy & Programme Committee (PPC) during 2009.

Process

To understand how decisions based upon GAVI's current vaccine donation policy had played out in practice; the Secretariat reviewed recent experiences with in-kind vaccine donations, and assessed how other global health organisations and GAVI constituencies approach in-kind donations. Drawing upon these findings, the Secretariat considered the potential risks and benefits of in-kind donations of vaccines as well as related health products (e.g. injection safety equipment) for GAVI – specifically reflecting on the unique nature of public sector vaccine markets and the innovative operating model that GAVI uses.

Scope of this policy

This document proposes a new policy for GAVI towards in-kind donations of vaccines and other health products used in the delivery of vaccines (e.g. injection safety equipment, needles).

Due to the diversity of products and services and potentially unique issues, as well as a lack of available evidence, in-kind donations of non-health goods (e.g. computers, office equipment) and services (e.g. consulting or financial services) are not considered in this policy.

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.

Individual members, partners and constituencies of the GAVI Alliance such as WHO, UNICEF or developing country governments are not bound by this policy. These institutions or sovereign governments may have their own policies towards in-kind donations,^{iv, v} and of course are free to make their own choices with respect to in-kind donations should situations arise. This policy however determines whether GAVI might actively participate in the in-kind donations either as an intermediate recipient on behalf of developing countries and/or to fund potential additional costs

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associated with the donations (e.g. freight, shipping costs or costs associated with needles or safety boxes).

The policy does not cover the use of in-kind donations of vaccines for (i) demonstration projects, or (ii) phase IV trials. These studies/projects are conducted for scientific rather than philanthropic reasons, and so vaccine manufacturers do not classify these as donations (for tax purposes)^{vi}. Furthermore, as described in GAVI's operating principles, GAVI does not focus on "upstream research and development activities" or directly carry out such efforts, therefore donations for these purposes are not considered here.¹

Finally, while not directly relevant to GAVI's policy decision, this paper provides some additional guidance to GAVI-eligible countries that might consider accepting in-kind donations of vaccines outside of GAVI's processes.

GAVI's existing vaccine donation policyⁱ and experience to date

The current policy contains five minimum specifications for vaccine donations:

1. The vaccine is epidemiologically appropriate for the immunisation programme;
2. The vaccine is subject to prescribed licensing and/or other control procedures set up by the governments receiving donations, and is in compliance with quality standards in both donor and recipient countries;
3. The vaccine is consistent in presentation and specifications with other vaccines in the programme;
4. Responsible officials in the country receiving the donation are informed of the donations and the vaccine should be shipped on their request;
5. Efforts should be undertaken to assure sustainable use of the vaccine after the donation.

Looking at GAVI's recent experience with in-kind vaccine donations, and in implementing the PCV7 donation, a number of issues were highlighted. The most significant related to GAVI's co-financing policy. Since the start of GAVI's second phase of support in 2006, countries have been responsible for providing a co-payment for vaccines in order to purchase a proportion of doses from the manufacturer or UNICEF Supply Division. In order to ensure the recent donation did not disrupt the functioning of this policy, these copayments were still required. However, the provision of the donation meant that no doses needed to be paid for by the countries, so the copayments were used to contribute to the costs shipping (i.e. freight and insurance). Unlike usual co-financing, GAVI bore these costs up front, with the understanding that the countries would reimburse GAVI at a later date. This has been working well but the set up of this unique process took time. In addition, the negotiation on the legal documents with the manufacturer was more extensive than envisioned and also took time to resolve. GAVI, UNICEF Supply Division, and the manufacturer had to work together to ensure that the donation of PCV7 was

¹ In instances where firms want to conduct phase IV activities in GAVI-eligible countries, these activities could be done directly with countries and/or through GAVI's Accelerated Vaccine Introduction (AVI) Technical Advisory Consortium (TAC), and specifically, the AVI-TAC's Special Studies unit. These types of donations could be made directly to one of the consortium's appropriate partners (e.g. PATH, Johns Hopkins, CDC).

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bundled with needles that were appropriate for developing country markets. And the two developing countries due to receive the product, worked with GAVI, UNICEF and WHO to ensure sufficient provisions were made for cold chain capacity and waste management – necessary given the nature and size of the packaging, and which was likely to have inhibited the uptake of the vaccine in other developing countries.^{vii} Thus, the donation was associated with significant transactional costs which were not immediately apparent, although GAVI judged that these were outweighed by the benefits (accelerated access to life-saving preventative medicines)^{viii} of the donation. In any case, transaction must be considered

How other organisations approach in-kind donations

Relevant policies and positions of other institutions and initiatives were reviewed. The findings, included in Appendix II, are summarised here:

- Clinton HIV Initiative (CHAI)
- Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund)
- GlaxoSmithKline (GSK)
- Médecins Sans Frontières (MSF)
- Oxfam
- The Partnership for Quality Medical Donations (PMQD)
- World Health Organisation (WHO)
- Innovative Medicines Initiative (IMI)
- Roll Back Malaria (RBM)
- Stop TB Partnership/UN Foundation

Each of the institutions and initiatives has a different strategic focus and operating model. Some organisations are donors of in-kind goods/services while others are recipients; another (the PQMD) operates as a centre of excellence for good in-kind donations practices for health products. In some instances, the items donated/received are very different from those that GAVI might receive.

There was near universal acceptance of the WHO guidelines on drug donations^{ix, x}. Several organisations in addition to WHO, including the International Committee of the Red Cross, International Pharmaceutical Federation, MSF, Oxfam, PQMD, UNICEF and the World Bank, were part of the interagency group that produced these guidelines

Four core principles underpin the 12 guidelines which are largely consistent with GAVI's existing vaccine donation policy:

- *The donation should bring maximum benefit to the recipient*
- *The donation should be made in a way that respects the wishes and authority of the recipient*
- *There should be no double standards in quality*
- *Effective communication must be assured between donor and recipient.*

As a result of these universally accepted principles and the WHO/UNICEF Guidelines for Product Donations on which GAVI's current policy is based, many of the historic and well-documented problems^{xi, xii, xiii, xiv, xv, xvi} with product donations

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(such as product labelling problems, out of date stock)² have largely been addressed, although there is evidence that isolated problems still exist, some argue because of challenges associated with monitoring and enforcing the voluntary guidelines.^{xvii,xviii, xix, xx}

Nonetheless, there seem to be other issues which are more unique to the processes of new global health partnerships or the specific needs of relief organisations that have not been addressed by the guidelines and which adds complexity when considering whether or not such organisations should accept in-kind donations.

The Global Fund discussed in-kind donations in multiple fora over several years drawing upon several analyses and studies.^{xxi, xxii} After much deliberation, their board finally decided that the Global Fund would not accept in-kind donations of health products, for a number of reasons (noted below³). Some of these reasons were specific to drugs and especially, antiretrovirals (ARVs), some to the Fund's new procurement arrangements and some were in part due to concerns about the potential market impact of such donations.^{xxiii}

The Clinton HIV/AIDS Foundation (CHAI) similarly does not routinely accept donations of ARVs because of the effects that these could have on their procurement consortium; however, CHAI does accept and would actively seek in-kind donations in emergency situations; e.g. stock-outs or other supply problems.^{xxiv}

MSF also does not accept in-kind donations of medical equipment or drugs,^{xxv} and neither does Oxfam for their relief efforts but for reasons unrelated to procurement or market distortion; e.g. uniformity of product, cost, speed, use of local manufacturers. MSF however is involved in the distribution of in-kind donations which have been received by other organisations; e.g. MSF worked in partnership with WHO and the company Aventis to distribute a multi-year donation of medicines for African Sleeping sickness.^{xxvi}

Vaccine manufacturers seem to have a variety of approaches to in-kind vaccine donations. Merck for example states that the company “does not believe that donating medicines and vaccines is a sustainable solution to the global challenge of improving access to medicines”^{xxvii} although they go on to state that they donations to be an important mechanism for expanding access to vaccines where appropriate. GSK on the other hand takes vaccine donations on a case by case basis.^{vi} To date, GSK and sanofi-pasteur, CSL and MedImmune have also committed to donate some of their influenza A (H1N1) vaccines for developing countries however, Novartis took a different stance stating that they would not be donating vaccines

² Most of the documented problems have related to drugs for treatment of infectious diseases or drugs to treat sick individuals with poor access to healthcare often in emergency situations (e.g. areas of conflict such as Kosovo and Sudan) rather than for routine immunisations. The differences between drugs and vaccines as they pertain to in kind donations are explored later in this document.

³ The Global Fund Board's decision not to support in-kind donations was based upon from the recommendations from the Global Fund's In-Kind Donations Work Group. The Working Group's recommendation was driven by the following reasoning: (1) The Global Fund did not have the capacity to undertake and manage a large donation programme; (2) It did not feel it made sense to institute a parallel system for drug donations at the same time that the Fund was establishing a Voluntary Pooled Procurement (VPP) mechanism since in-kind donations had the potential to distort markets, and that, instead, the Fund should wait until after the VPP was operational before considering whether to add donation component onto that mechanisms; and (3) It felt that recipients preferred to have the funds to procure the drugs of their choice rather than to have to accept available donated antiretroviral drugs.

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because financial incentives were necessary to create sustainable production of vaccines.^{xxviii}

Overview of the potential benefits and risks of in-kind vaccines donations

The review of in-kind donation policies of other institutions provided a starting point for the revision of GAVI's in-kind donation policy. However, the PPC recognised the uniqueness of vaccines as compared with other health care products and in particular drugs, as well as issues that relate to GAVI rather than other global health institutions. As such, the analysis of benefits and risks of in-kind donations was tailored to take account of, and highlight these vaccine- and GAVI-specific facets.

A detailed explanation of each of the potential benefits and risks associated with in-kind donations of vaccines can be found in below. The discussion focuses on the benefits and risks for GAVI but also considers the issues most relevant to the two main actors in health product donations – developing countries and manufacturers.

Potential benefits of vaccine donations

The benefits of in-kind vaccine donations can be looked at from multiple perspectives. Of most relevance to this policy, are the benefits for the GAVI Alliance overall. However, the perspective of countries and vaccine manufacturers are also described below.

Benefits for GAVI Alliance as a whole:

- *Short-term financial savings:* Product donations can substantially reduce the short-term direct costs faced by the GAVI Alliance for provision of vaccines, syringes and safety boxes. For example, at current prices, a donation of one million doses of pentavalent vaccine would save GAVI around US\$ 3 million. The savings would be larger still for similar sized donations of the newer more expensive vaccines that GAVI is planning to introduce.
- *Conduits for partner contribution to the GAVI Alliance:* As members of the GAVI Alliance, both industrialised and developing country manufacturers might be able to use in-kind donations of vaccines as a way to contribute to GAVI. Similarly, research and technical institutes and independent experts (particularly from the financial community) could donate in-kind services to GAVI.
- *Ease short-term supply constraints:* In exceptional circumstances (e.g. supply issue caused by a manufacturing problem), a donation can potentially overcome a short-term supply constraint. In this situation, an in-kind donation of vaccine could have an important health benefit since vaccine stock-outs can leave children in countries unprotected against vaccine-preventable diseases.⁴

Benefits of in-kind donations from perspective of developing countries:

⁴ It should be noted that as GAVI's main procurement agent, UNICEF Supply Division takes its direction from GAVI's Supply Strategy and the procurement principles defined within it. One of these principles is 'to ensure vaccine security'. Therefore, it is likely that UNICEF's efforts to maintain vaccine security minimise the need for donations to ease short-term supply constraints.

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- *Access to life-saving products:* As with vaccines provided with GAVI funding, in-kind donations offer an opportunity to save lives. In-kind donations can also provide countries with access to vaccines that they might not be able to access through GAVI. Of course, if not available through GAVI, then they are not within the purview of this policy.

While there is no published evidence about the specific benefits from a vaccine donation, evidence from a drug donation programme in Tanzania highlights that medicinal donations are generally appreciated by stakeholders in developing countries and, to some extent relied upon, to ensure sufficient supply and access to medicines.^{xxx, xxxi, xxxii, xxxiii} The benefits of other drug donation programmes in terms of lives saved, disease eradication and indirect benefits are also well documented.

- *Gain experience; Add to the evidence base:* Before making a decision on country wide introductions, donations can enable countries to gain experience with new products which may require new delivery systems on a smaller scale.^{xxxiv} However, these types of efforts should be formalised within demonstration or so-called ‘formative research’ projects and phase IV trials to ensure such efforts are designed properly, evidence is collected consistently and analysed rigorously to maximise the benefits to countries from these initiatives.

Benefits of in-kind donations from perspective of vaccine manufacturers

- *Corporate social responsibility:* Beyond what’s described above (a means to contribute to the Alliance), in-kind donations provide manufacturers with an opportunity to demonstrate corporate social responsibility
- *Facilitate access/start saving lives when normal delivery channels cannot be used:* For example, donations enable use of vaccines in countries where clinical trials were performed but the vaccine is not yet available for procurement (e.g. because awaiting SAGE recommendation or WHO prequalification). Since GAVI only supports vaccines where there is a WHO SAGE recommendation and where the GAVI Board has approved financial support and the opening of a New Vaccine Support (NVS) window, such situations are not relevant to GAVI. In-kind donations can provide an initial or supplementary means to low/no cost vaccine when the policy environment might make it difficult to offer GAVI the lowest possible prices. Since GAVI is committed to accessing the lowest prices for eligible countries, and to working within the existing policy environment, this is not directly relevant either.

Potential risks for vaccine donations

There are several risks associated with in-kind vaccine donations, many of which are interrelated, and overlapping. Unlike the analysis of benefits, there is less need to separate out the risks by constituency.

Market distortion risks: GAVI is able to access the lowest prices for vaccines in part

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by pooling vaccine procurement for the poorest countries. One of GAVI's operating principles is 'to render vaccines and related technologies more affordable for the poorest countries through market impact and innovative business models'. It is likely that in-kind donations of vaccines can distort market by influencing demand and supply. For example, depending on the magnitude, vaccine donations reduce the procurement quantities that could be tendered and have the potential to disrupt the functioning of the market. In the short-term, at a simplistic level, reductions in the volume procured could lead to increases in the average weighted price paid. Of course, the donation quantities would need to be significant enough to affect the overall average weighted price for a particular vaccine. Such a situation is quite possible. While the donation of PCV7 to Rwanda and the Gambia is not associated with any direct market distortion issues since GAVI is not purchasing PCV7 for other countries, this donation covers the supply for two countries for two full years so these are not insignificant quantities.

In addition, if donations for routine vaccinations are taken up on an ad hoc basis, demand could become less predictable. Again, depending on the scale of in-kind donations, unpredictable demand could be problematic for both the procurement agent and competing vaccine manufacturers since both parties require a degree of predictability to ensure sufficient supply/demand.

Both of the market distortion risks mentioned above could be handled to some extent, by limiting the amount and length of in-kind vaccine donations and by ensuring that donations are only applied to 'allocated demand'; i.e. where a manufacturer who would otherwise be supplying doses as part of a supply agreement, provides these to a GAVI-eligible country with an existing approved application for New Vaccine Support at no cost.

In the longer-term, in-kind donations of vaccine routine could be used by a supplier as a "seeding" strategy to capture global market share by inducing the adoption (or switching) to a particular vaccine. This is possible because UNICEF procures vaccines for GAVI-eligible countries on the basis of three procurement objectives⁵, one of which relates to satisfying the preferences (with respect to vaccine presentation) of individual countries. It is possible that a donation of supply could influence a country's decision to continue using a particular vaccine even after the donation has ended. This is because different products often have different administration requirements. Once infrastructure has been tailored and local immunisation officials trained to administer a particular vaccine, it may prove costly (in time, effort and monetary terms) to switch to a different product.

Seeding could be a significant problem associated with vaccine donations particularly for new vaccines where a GAVI price has not been negotiated at the outset. In any case, since at this time, a country's decision to adopt a vaccine are completely de-linked from the price of vaccines, seeding could be associated with financial and sustainability risks with a country unable to afford to sustain the immunisation programme after the donation has ended.

⁵ Procurement principles: (i) Ensure a healthy market, i.e. sustainable quantity of supply, through a diverse supplier base; (ii) Select products and presentations that best meet the need of client countries; (iii) Achieve long-term affordable prices that countries can eventually sustainably finance

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Reputational risks: If GAVI brokers a donation between a particular firm and a country, GAVI could be perceived as facilitating a company's demand generation activity. While accelerating access to vaccines is implicit within GAVI's goals, paving the way for individual firms to gain a foothold within a particular country would undermine the Alliance's credibility. Aside from demand generation, a donation programme can yield public relations (PR) benefits for the particular firm in question. How donations are communicated needs consideration particularly and needs careful consideration, particularly by GAVI which must maintain neutrality in its dealings with vaccine manufacturers, and to avoid potential misperceptions about motives in accepting donations and the consequences whether intended or unintended.

Financial, sustainability and predictability risks: These are all interlinked. Both GAVI's and a country's decision to accept a donation should be built upon an assessment of

- (i) the ability to access affordable prices for the vaccine when the donation period comes to an end
- (ii) the availability of financial resources (e.g. national budget, support from GAVI for countries; and long-term donor funding for GAVI)

For both countries and GAVI, if they accept a donation without knowing the end price, they could be left with unsustainable vaccine programmes in the longer term. Donation programmes are also criticised for being unsustainable because donating firms are under no obligations to continue providing the donation in the long term. Sudden cessation of the donation can therefore leave future cohorts of donation recipients reliant on the donation's continued supply. In order to ensure sustainability, financial resources need to be available to ensure that when the donation comes to an end, procurement of the vaccine can (re)commence. Having to keep the resources easily accessible to removes the potential financial benefits of accepting the donation since funding cannot be completely reallocated to support other long-term efforts.

As aforementioned, evidence from a drug donation programme in Tanzania highlights the value of in-kind donations for developing countries, however this study also highlights that limited supply is the main challenge as it hampers sustainability^{xxix}.

Conflicts with GAVI's operating principles

Looking at GAVI's guiding principles, in-kind vaccine donations could work against the following principles (because of the aforementioned market distortion, financial and sustainability risks)

- *support activities that over time become financially sustainable...*
- *through market impact and innovative business models render vaccines and related technologies more affordable...*

Special Circumstances

Up until now, the discussion has focused on donation of vaccines for routine vaccinations, however, there are other instances, and special circumstances when

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in-kind vaccine donations might be made.

1. *Donations for Stockpiles to Address Emergencies:* Firms may wish to donate vaccines for stockpiles and emergencies.⁶ However, where GAVI funds the procurement of these vaccines, these activities are still subject to the same procurement principles as for routine vaccines (i.e. to shape markets to make prices more affordable). As such, donations for these purposes can also create market distortions. Reputational risks are also an issue and would need to be considered carefully. Conversely, it is likely that market distortion risks would be secondary to rolling out an emergency vaccination campaign in response to an epidemic. Also, unlike drug donations in emergencies where evidence suggests that incorrect labeling and out-of-date stock has been an issue, vaccine stockpile donations are less prone to these problems. This is because manufacturers reserve a specified amount of vaccine in bulk (unfinished) form in case of disease outbreaks. The bulk needs to be processed (finished) prior to being packaged and sent out to emergency outbreak settings. This means it is ‘fresh off the manufacturing line’ and can be appropriately labeled depending on the country of intended use at that time.

While the use of vaccine stockpiles are administered by the WHO’s International Coordinating Group on Vaccine Provision for Epidemic Control (ICG) and UNICEF, the fact that the ICG is not a legal entity means that this body cannot act as a recipient;⁷ similarly, because UNICEF is a procurement agent its policy and procedures prevent the agency from accepting in-kind donations. It is therefore possible that there may not be a recipient who can pool donations for stockpiles for emergencies other than GAVI.

GAVI has a unique position as a funding intermediary able to pool resources and as an Alliance that can facilitate vaccine introduction. As such, GAVI could also play a roll in supporting the global response to an emergency outbreak or pandemics such as might be necessary with H1N1.

2. *Phase IV studies and demonstration projects:* In certain instances, vaccine manufacturers donate products to certain entities for the conduct of post-registration trials (i.e. phase IV studies) or demonstration projects. As aforementioned, because these studies/projects are conducted for scientific rather than philanthropic purposes, firms often do not classify these as donations (for tax purposes). However, as described in its programme funding principles, GAVI does not focus on “*upstream research and development activities*” or carry out such studies/projects, therefore donations for these purposes are not relevant here. In instances where firms want to conduct phase IV activities in GAVI-eligible countries and provide vaccines for these investigative purposes at zero cost, these donations could be

⁶ GAVI currently supports two investment cases for Yellow Fever and Meningitis stockpiles.

⁷ Of note WHO is currently trying to create a stockpile for pandemic flu vaccines, and manufacturers have already pledged their willingness to make in-kind donations to this cause⁷. WHO or a donor will need to cover the cost of other materials (e.g. syringes, safety boxes) and this would be the same case for GAVI. Furthermore, as highlighted earlier, since this policy does not preclude partner organisations or constituents that are part of the GAVI Alliance from accepting donations, WHO can continue to accept donations to create the planned H1N1 vaccine stockpile.

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channelled directly to countries and/or through the Accelerated Vaccine Introduction (AVI) initiative, Technical Advisory Consortium's Special Studies unit. As such, these types of donations could be made directly to an appropriate partner (PATH, Johns Hopkins, CDC, in-country health care expert, etc).

Technical support to developing countries

GAVI could also offer technical support to recipient countries on donations through the Accelerated Vaccine Initiative (AVI). For example, if a GAVI-eligible country and a vaccine manufacturer are planning a sub-national phase IV trial/demonstration project, GAVI acknowledges that such targeted efforts can provide useful information about delivery challenges of new vaccines and is willing to advise countries on such issues through the experts within the AVI team. Technical guidance on these issues however, can and should also be sought from other partners within the GAVI Alliance, as appropriate.

Finally, GAVI and technical partners could help countries' who might be offered vaccines donations to consider the following important questions:

- Do planned phase IV/demonstration initiatives have data collection methods in place? Will they collect information that will be valuable to informing future country activities to delivery new vaccines – The value of these initiatives is predicated on the collection of sufficient information to credibly augment the evidence base.
- Do such initiatives explicitly request governments to consider the short-term nature of the endeavour and the potential sustainability challenges when the donation ends? – If a GAVI funding window does not exist for the vaccine or a country application has not been approved, then there is a chance that at the end of the donation, there may not be funding to continue providing the vaccine. Has the country made contingency plans for the ending of the donation?

In-kind donations for vaccines versus drugs

The PPC recognised that in-kind donations for drugs and vaccines present very different challenges. Almost all of the published evidence regarding the historic problems ^{xi, xii, xiii, xiv, xv, xvi, xvii} with in-kind donations as well as the recent successes relate to drug donations. **Error! Bookmark not defined.** ^{, xxix, xxx, xxxi, xxxii, xxxiii}

Furthermore, while the experiences and policies of other institutions are valuable for GAVI, most other organisations involved with in-kind donations of medicinal products tend to deal with drugs rather than vaccines. There are certain features about vaccines (as compared to drugs) that mean GAVI's approach towards in-kind vaccine donations must reflect the unique nature of public sector vaccine provision.

1. *Within country homogeneity:* Countries tend to use one type of vaccine product/presentation, often from one manufacturer, across the entire country. This makes training of healthcare professionals easier when rolling out nationwide immunisation programmes and facilitates the completion of a full schedule.
2. *Country preference/Not all vaccines and presentations are equivalent:* While there might be multiple vaccines available (or soon to be available) against various diseases, product characteristics mean that certain vaccines may be

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better suited to certain countries. For example, a large populous country may prefer to use vaccines that come in large multi-dose (typically 5 or 10 doses) vials. This enables the country to reduce wastage and cost and choices may relate to practical considerations such as the ‘fit’ with national cold-chain capacity.

3. *Limited provider choice:* Unlike in the case of ARVs or drug treatments, in most public sector settings, physicians or healthcare professionals do not have to make a choice between competing products or about product titration; instead the clinics at every level will use the vaccine selected for them by immunisation officials at the national level, and procured on their behalf by national (government) or international (UNICEF) procurers.
4. *Importance of consistency and sustainability of national provision:* Unlike drug treatments, the maximum benefits of many vaccination programmes are often reaped through high levels of coverage and use across a target population to reduce transmission rates and create herd immunity. As such, once a vaccine is introduced on a national scale, it is difficult and possibly problematic for a country to stop the immunisation programme. It is therefore crucial that the decision to adopt a vaccine is considered within the context of the long-term sustainability, either through self-financing or through approved access to GAVI support (in the case of GAVI-funded vaccines).
5. *Lack of competition/local alternative:* Whereas with many drugs, there are generic alternatives, for vaccines most GAVI eligible countries import product from a limited number of global suppliers. Further, as noted above, product presentation may differ dramatically from supplier to supplier, making post donation replacement difficult.
6. *Stockpiles less prone to out-of-date stock and incorrect labelling issues:* As already mentioned, unlike drug donations in emergencies where evidence suggests that incorrect labeling and out-of-date stock has been an issue, vaccine stockpile donations are less prone to these problems. This is because manufacturers reserve a specified amount of vaccine in bulk (unfinished) form in case of disease outbreaks. The bulk needs to be processed (finished) prior to being packaged and sent out to emergency outbreak settings. This means it is ‘fresh off the manufacturing line’ and can be appropriately labeled depending on the country of intended use at that time.

These characteristics mean that once a national immunisation programme selects a vaccine, there is a certain amount of in-built rigidity that means the country is unlikely to quickly change either the presentation or the vaccine itself (for a slightly different multivalent vaccine). Thus it is important to ensure a country’s sovereign choices for particular vaccines are based upon technical (epidemiological and logistical) decisions rather than the availability of a short-term in-kind donation.

In the case of vaccine donations for emergency outbreak stockpiles as compared to drugs for emergency situations, the former may not be associated with some of the common problems of out-of-date stock and incorrect labelling as the latter. (Nonetheless, there may still be market distortionary effects from donations to stockpiles).

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Benefits and risks of in-kind donations of other health products

Turning the focus to other relevant health products (syringes, safety boxes), there do not appear to be any major risks for GAVI. As aforementioned, one of GAVI's guiding principles is to impact the market and render vaccines as well as related technologies more affordable. Since these markets are currently subject to rigorous competitive pressures, ad hoc donations of other health products are less likely undermine GAVI's 'market shaping' activity. However, as new innovative products enter the market, GAVI may again become more concerned with driving down prices.

Implications of the evidence and analyses for GAVI

Considering the benefits and drawbacks of in-kind donations to GAVI, there appear to be both potential benefits and potential risks associated with vaccine donations. There may be circumstances, for example when there is a short-term supply constraint, that an in-kind donation of vaccine could have an important health benefits ensuring children in countries are not left unprotected against vaccine-preventable diseases.

In-kind donations to replenish stockpiles and/or in response to emergency outbreaks/pandemics may also be very beneficial. However, since stockpiles are generally held by vaccine manufacturers, and since their administration is usually handled by WHO, GAVI need not act as the recipient. That having been said, there may also be situations where GAVI might be able to leverage its unique position to support a global response to emergency outbreaks/pandemics such as could be the case for H1N1. If GAVI did play such a role, it would need to be considered on a case by case basis.

Similarly, while in-kind donations of vaccine for phase IV studies and demonstration projects may be very valuable to inform the public health community about delivering new vaccines in resource-poor settings, since GAVI does not conduct upstream research, these types of efforts are not within GAVI's purview. As such, they could be made directly to one of GAVI's AVI consortium partners if such studies or projects were deemed to be necessary to contribute to the evidence base and/or facilitate the introduction of new vaccines.

Turning the focus to other relevant health products (syringes, safety boxes), there do not appear to be any major risks for GAVI. As aforementioned, one of GAVI's guiding principles is to impact the market and render vaccines as well as related technologies more affordable. Since these markets are large and currently subject to rigorous competitive pressures, ad hoc donations of other health products are less likely undermine GAVI's 'market shaping' activity. However, as new innovative products enter the market, GAVI may again become more concerned with driving down prices. Although in theory in-kind donations of other health products could be considered on a case by case basis because of transactional costs (including legal and programme resources at the Secretariat as well as at UNICEF, WHO and in countries), this approach is not recommended.

FOR DECISION**RECOMMENDATIONS**

In principle, GAVI will not accept in-kind donations of vaccines except under exceptional circumstances which constitute the following:

- i. For **stockpiles to address emergencies**, particularly when another institution cannot accept the donation
- ii. In a situation **where GAVI faces a severe supply shortage** due to problems with allocated supply (e.g. due to batch contamination)
- iii. 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 now donating vaccines** anyway

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

- Donations must **comply with UNICEF/WHO Vaccine Donations Guidelines**
- **Countries receiving in-kind donations must still pay co-financing** in line with the applicable GAVI co-financing policies at the time
- 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

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

Next steps

If the GAVI Board chooses to endorse these recommendations, the Secretariat will communicate the decision to GAVI's constituencies and enforce the new policy from January 1st, 2010.

ANNEX 1

Current GAVI Vaccine Donation Policy

Adopted by the GAVI Alliance Board, June 2000

A number of vaccine producers have indicated an interest in donating vaccines to GAVI. Following are proposed guidelines specific to a GAVI donation policy:

- To the maximum extent possible, vaccine donations will be considered as in-kind contributions to the Global Fund for Children's Vaccines.
- Donated vaccines would be directed to countries that have been approved through the GAVI review process for country support from the Fund.
- The active participation of the vaccine producer in the shipment, distribution, training and capacity-building relating to the safe use of vaccines is strongly encouraged.
- GAVI partners will need to consider whether the Fund should accept all types of vaccines or only newer vaccines and vaccine combinations that contain newer vaccines (such as DTP-hepB-Hib).

Basic UNICEF/WHO vaccine donation guidelines are provided below.

UNICEF/WHO Vaccine Donations Guidelines

A vaccine donation is defined as a shipment of vaccine for which a government does not pay. Properly managed, vaccine donations are useful to immunization programmes. 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 leave a country vulnerable to problems and actually disrupt the programme. Furthermore, a vaccine donation must be part of a sustainable vaccine supply; if, once the donated supply is exhausted, there is no provision for sourcing the vaccine, the sustainability of the immunization programme is threatened.

The aim of these guidelines is to improve the management of donated vaccines, and not to hinder donations. Vaccines shipped through UNICEF Supply in Copenhagen may technically be considered as donations, but as their specifications are developed by a collaborative effort between national officials and UNICEF country staff, such vaccines are not included in these guidelines.

Most recipients of vaccine donations are countries dependent on UNICEF and other donors for their supply of vaccines. Many lack infrastructure to handle donations adequately. WHO recommends that all countries, including those which receive all their vaccines from UNICEF, exercise at least two essential national control functions: a published set of requirements for licensing or other control procedures appropriate to the country's needs, and surveillance of vaccine field performance (monitoring of adverse events following immunization). In the case of a problem in the field which may be vaccine related, or of doubt of vaccine potency because of a cold chain break in transport, UNICEF can be notified and, if vaccine testing is needed, WHO laboratories can be used.

WHO has already published guidelines for receipt of donations of drugs

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(WHO/DAP/96.2). For the most part, these guidelines are applicable for vaccines as well. Five proposed minimum specifications for vaccine donations restate these guidelines in a manner applicable to vaccines:

- the vaccine is epidemiologically appropriate for the immunization programme; that is, the donated vaccines are consistent with the goals of the immunization programme;
- the vaccine is subject to prescribed licensing and or other control procedures set up by the recipient government, and is in compliance with quality standards in both donor and recipient countries;
- the vaccine is consistent in presentation and specifications with other vaccines in the programme; that is, the donated vaccine should be familiar to the health professionals in the recipient country in such characteristics as potency, liquid or freeze-dried presentation, transport, shelf life, number of doses per vial, thermostability, and label language and information;
- responsible officials in the recipient country should be informed of all donations that are being considered, prepared, or actually under way, and the vaccine should be shipped only on their request;
- 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 after the period of donation.

ANNEX 2**GAVI Alliance Vaccine Donation Policy**
*For Board consideration***1. Goal and scope**

- 1.1. This policy proposes a new policy for GAVI 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.
- 1.3. Individual members, partners and constituencies of the GAVI Alliance such as WHO, UNICEF or developing country governments are not bound by this policy.
- 1.4. 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)

2. Principles

- 2.1 GAVI will not accept in-kind donations of vaccines except under exceptional circumstances which constitute the following:
 - 2.1.1 For stockpiles to address emergencies, particularly when another institution cannot accept the donation
 - 2.1.2 In a situation where GAVI faces a severe supply shortage due to problems with allocated supply (e.g. due to batch contamination)
 - 2.1.3 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 now donating vaccines anyway
- 2.2. If GAVI does in the above mentioned exceptional cases accept in-kind donations of vaccines, it should do so with the following conditions:
 - 2.2.1 Donations must comply with UNICEF/WHO Vaccine Donations Guidelines
 - 2.2.2 Countries receiving in-kind donations must still pay co-financing in line with the applicable GAVI co-financing policies at the time
 - 2.2.3 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
- 2.3. In-kind donations of other health products will not be considered due to

ANNEX 2

the transactional costs of taking a case-by-case approach.

3. Definitions

- 3.1. Donations: products being offered to GAVI at no cost
- 3.2. Health Care Products used in the delivery of vaccine (e.g. injection safety equipment, needles)
- 3.3. Non-health goods and services (e.g. computers, office equipment, consulting or financial services)

4. Timeline for implementation and updates

- 4.1 The new eligibility policy will be enforced as of 1 January 2010
- 4.2 The policy will only be updated at the request of the Board.

5. UNICEF/WHO Vaccine Donations Guidelines

A vaccine donation is defined as a shipment of vaccine for which a government does not pay. Properly managed, vaccine donations are useful to immunization programmes. 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 leave a country vulnerable to problems and actually disrupt the programme. Furthermore, a vaccine donation must be part of a sustainable vaccine supply; if, once the donated supply is exhausted, there is no provision for sourcing the vaccine, the sustainability of the immunization programme is threatened.

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- 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 after the period of donation.

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