An Approach to Middle Income Countries: Options and Potential Impacts

Executive Summary

Fifty-five countries are classified as Lower Middle Income (LMIC) under the World Bank criteria which indicates they fall within the ranges of USD906 - USD3,595 GNI per capita (2006). Thirty-five of these countries fall into the USD1000 - USD3595 GNI per capita group of these are not eligible to apply for funding for new vaccine introduction and support from the GAVI partnership.

These thirty-five have a combined population of almost 2 billion and a combined birth cohort of about 30 million children>75% in just 5 countries. They have strong immunisation programs with a median DTP-3 coverage in 2006 of 93%, 97% have introduced vaccination against Hepatitis B but only 46% against Haemophilis influenza B. They have a high proportion of the population considered in need with greater than 252M people living below the poverty line. Ninety four percent have a budget line item for vaccines and 97% have government support for the immunization program. The majority are self procuring all their vaccines except for those utilizing the PAHO Revolving Fund, many are highly aware and actively engaged in developing National Regulatory Authorities and two are members of Developing Country Vaccine Regulation Network.

In the changing and challenging vaccine environment LMICs are facing increasing financial and technical challenges to maintain the same levels of access to newer technologies as Lower Income countries which have the benefit of financial and technical support for new vaccine introduction. The limited access to international support may result in LIMC beginning to trail behind the poorest countries in terms of attaining improved health outcomes for their populations from vaccination and reaching the challenges such as the Millennium Development Goal 4 (Reduce child mortality).

The GAVI partnership is the largest donor provider for vaccines and is one of the only major donors that specifically excludes LMIC from benefiting from programme funding and technical assistance.

There are a number of perceptions, assumptions and statements that should be revisited considered and discussed these can be summarized by the following:

- There is a perception that providing financial and technical assistance to LMIC would reduce the possible amount of assistance available for the poorest countries.
- Alternatively not providing financial and technical assistance to LMIC will perpetuate an environment where there is a disparity between the treatment available to the populations of LMIC and the poorest countries.
- LMIC have in some cases a large percentage of their population below the internationally recognised poverty line of $1 or $2 per day and are often suffering from vaccine preventable diseases as much as the poorest countries.
- There is the potential for positive global vaccine market impact by increasing the purchasing power of LMIC. The current prices for newer vaccines are many times greater than the traditional vaccines. There is minimal competition and reduced demand also influencing the price. LMIC are a large potential market with the potential to increase demand in a sustainable manner and influence supply and subsequently prices of these products not only within the LMIC market but also for the poorest countries.
- Another positive attribute of these countries is the strength and capacity of their existing health systems and their potential to sustain the implementation of newer vaccines after donor funding has been withdrawn.
At the new and under utilised vaccines implementation meeting (NUVI) in June 2007 six strategies were identified for all Middle Income Countries without prioritization, these included:

- Provide support to decision making in Middle Income countries.
- Enhance participation of the private health sector in provision of immunization services.
- Develop potential vaccine supply strategies.
- Develop a process to address the challenge of vaccine procurement.
- Strengthen regulatory systems.
- Define financing opportunities.

At a technical level there are a number of activities that could be employed to assist LMIC including providing technical assistance in disease surveillance, evaluation, decision making, prioritisation, advocacy, forecasting, introduction of new vaccines, vaccine specifications and vaccine management, , budgeting, financing, planning, public-private collaboration, procurement, intercountry collaboration, technology transfer, manufacturing, surveillance, clinical trials, quality assurance system and regulation,

At the financial level, there are a number of options to consider beginning with revisiting the GAVI eligibility criteria to include LMIC, to allowing LMIC access to the GAVI global prices for newer vaccines with funding coming from own government sources and differing levels of co-payment.

However the ability to provide such technical and funding assistance to LMIC requires the prioritisation and funding allocation of these activities for these countries to be addressed.

To further investigate the options available and the strategies that should be considered the following recommendations are made:

1. A partners meeting including all GAVI partners, plus strong representation from LMICs to focus and specifically define the next steps. Key agenda items will include:

   - Agreement on the countries to be included
   - Agreement on the objectives of a LMIC strategy
   - Agreement on the optimal mechanism to target countries
   - Agreement on priority topics and activities
   - Agreement on a mechanism to perform needs assessments in key countries or for the group as a whole
   - Agreement on the roles and responsibilities of each of the partners
   - Agreement on advocacy and resource mobilization for priorities.

It is suggested that WHO convene this meeting on behalf of partners and countries.

2. Once this agreement is reached, the priority activities can be launched and strengthened. Two of the analyses are so instrumental to the strategy that it is proposed that they be conducted as soon as practicable:

   Consider the market and financial impact of:
   
   a. allowing LMIC access to the GAVI global prices for HepB and Hib containing vaccines and newer vaccines Pneumococcal and rotavirus, with funding coming from own government sources and technical assistance provided by UN agencies; and
   
   b. providing financial support to LMIC for the same vaccines, currently supported by GAVI, in low income countries. (HepB and Hib containing vaccines and newer vaccines Pneumococcal and rotavirus) including at differing levels of co-payment.
1. Introduction: middle income (MI) countries in the global immunization continuum

The purpose of this paper is to provide further substance to the consideration of how to address the needs of Lower Middle Income Countries (LMICs) in the context of the changing vaccine environment and to map a path for further consideration and potential activities. With the advent of newer more expensive vaccines of high quality and significant public health impact, the issue of inequity in access to these vaccines is not being completely addressed since in the absence of the same levels of technical and financial support offered to the poorest countries, LMICs are not benefiting from the life-saving potential of these vaccines.

LMICs are not currently accessing the same level of technical and financial support available to the poorest countries. The impact of this is that LMIC could be beginning to trail behind the poorest countries in terms of attaining improved health outcomes for their populations from vaccination and achieving key global goals such as the Millennium Development Goal 4 (Reduce child mortality). A justification for enhanced actions for LMICs is that the WHO and UNICEF Global Immunization Strategy (GIVS) is a global framework, and not just limited to the poorest countries. Moreover, the WHO Director General’s advisory group on immunization, the SAGE has recommended that WHO activities in immunization not be limited only to the poorest countries.

35 countries currently belong to the World Bank Lower Middle Income category and are not eligible to apply for funding to support new vaccine introduction and support from the largest donor provider for vaccination, GAVI. These countries have a combined population of almost 2 billion and a combined birth cohort of about 30 million children.

There are essentially three simple issues one that argues against the provision of support for LMICS and the two others that favour the provision of such support that are raised on this subject which will be further investigated and discussed in this paper.

- The first issue is that providing financial and technical assistance to LMICs could reduce the assistance available for the poorest countries.

- On the other hand, not providing financial and technical assistance to LMICs will create an environment where there is a disparity between the public health interventions available to the populations of LMIC and the poorest countries perpetuating inequity in access to key health interventions.

- Finally, the third aspect of the debate is that current prices for newer vaccines are high in comparison those for traditional vaccines. Increasing the market size through expanding it to the large LMIC market could increase competition and lower prices more rapidly to mature levels.

The paper aims to develop options, benefits, potential implications, and implementation steps. Inputs to this paper were received through written, telephone, and personal
communication with the people listed in Annex 1. Their responses were focused around a questionnaire found in Annex 2. It is intended that this paper serve as a centerpiece for a partners meeting to achieve consensus on prioritization of strategies and activities and to agree on responsible agencies and timelines for their implementation.

1.1 Country Financial Support Levels

When the GAVI Alliance was launched in 2000, the decision was made to focus on the poorest countries, in order to prioritize impact to those needing outside financial support to strengthen their immunization programs and introduce priority new vaccines. At that time, 75 countries were included in the World Bank (WB) classification of the poorest countries (GNP/capita – now GNI/capital – < US$1000 per year). This classification at the time included also India, China and Indonesia.

The basis for the prioritization of GAVI support to countries based on income levels comes from a series of policy decisions taken by WHO, UNICEF, and the World Bank in the mid-1990s, relating to prioritization of immunization funding support based on work by the Children’s Vaccine Initiative Task Force on Situation Analysis. A corollary to the targeting strategy was a pricing strategy that advocated for prices that were tiered according to national financial resources. In fact, vaccine prices have historically been tiered, with the lowest prices often given to large procurement bodies in international agencies buying vaccines on behalf of developing countries. Whether a strict policy of price tiering is still desirable or even possible in today’s vaccine market remains a question for discussion and debate.

Since GAVI’s inception, some countries, including China, have become richer, and have “graduated” to MI country status. Despite their higher income level, many of these countries will still be dependent on outside support, both technical and financial, for new vaccine introduction. Thus the question has arisen of what kind of support, technical and/or financial, is best provided to middle income countries, given that United Nations agencies represent all countries, not just the poorest ones.

There are justifications for enhanced support to at least some LMIC. The major one is the increased global public goods that will be achieved in terms of enhanced public health by ensuring access to new and underused vaccines that will help in reaching Millennium Development Goal 4 (Reduce child mortality). From the point of view of equity, many LMIC are unable to introduce vaccines that are already being introduced by lower income countries because of GAVI support to the latter group, although these LMIC may have significant levels of population below the poverty line. In fact, for the 35 countries in Table 1, there are at least 252 million people living below the poverty line, taken as US

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$1/day, compared to 733 million people below the poverty line in the 72 poorest countries receiving GAVI support.\(^3\)

From the point of view of the vaccine market, expansion of the use of these vaccines to a larger population will help increase stable demand, leading to a larger market and the ability to realize lower prices for these products. A further benefit could be the demonstration to manufacturers of a stable and lucrative market for vaccines that are priorities in developing countries.

The generally strong health infrastructure in most of these LMIC would allow the rapid roll-out of these products once they are adopted for use, allowing the definition of strategies that can be used to inform introduction and related issues, such as regulation, logistics and procurement, in weaker countries. And finally, because of the generally higher economic status of these MI countries, financial sustainability can be achieved more rapidly, contributing to a more stable market.

1.2 The NUVI work plan

Accordingly, in June 2007, at a meeting to develop a work plan for WHO and its partners on New Vaccine Introduction (NUVI) strategies (seen in Annex 3), one element of the work plan was devoted to strategies to support middle income countries. Subsequent discussion defined the focus of this work plan element as countries in the WB Lower Middle Income Country (LMIC) classification, with those that are GAVI-eligible removed, as there is some overlap in GNI levels. Table 1 shows the current status of countries in WB LMIC classification\(^4\) – GNI/capita $906-$3595 – from which countries that are GAVI-eligible (GNI< $1000) have been removed. There are 35 such countries.

<table>
<thead>
<tr>
<th>Table 1. Lower-middle-income economies (35)</th>
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<tbody>
<tr>
<td>Albania</td>
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<td>Belarus</td>
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<td>Bosnia and Herzegovina</td>
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<td>Cape Verde</td>
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<td>China</td>
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<td>Dominican Republic</td>
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<td>Ecuador</td>
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<td>Egypt, Arab Rep.</td>
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<td>El Salvador</td>
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<td>Fiji</td>
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\(^3\) Taken from data in Table 2.7 at [http://siteresources.worldbank.org/DATESTATISTICS/Resources/table2-7.pdf](http://siteresources.worldbank.org/DATESTATISTICS/Resources/table2-7.pdf)

It can be seen at a glance that while these countries may have income level in common, there is a great variation in population levels, total wealth, and needs. These must be taken into consideration and addressed by any strategy directed towards this group of countries.

1.3 GAVI policy on countries moving from GAVI-eligible to LMIC status

Because the GAVI Alliance is just embarking on Phase 2, for which a co-financing requirement has been defined for GAVI support, and because of uncertainties due to the declining US dollar and the changing GNI of countries that are in the upper register of those that are GAVI-eligible, WHO asked the GAVI secretariat to clarify the status of countries who might receive GAVI assistance for a specific vaccine and who might subsequently be reclassified as a MI country. The response is as follows: “Countries that are currently GAVI eligible will be able to apply for and benefit from all current GAVI windows up to 2015 (ISS, INS, NVS, HSS)\(^5\). It has not yet been decided whether eligibility criteria will be changed in 2010 and this will be looked into while finalizing the new vaccine investment strategy. Co-financing policy will be reviewed in 2009/2010 to see if there will be changes for 2011-2015; there might be slight increases.”\(^6\)

This means that even if countries that are now currently GAVI-eligible are later classified as MI countries, they will still be eligible to apply for and benefit from all GAVI windows currently in force, and they can apply for assistance up until 2015, regardless of whether their income status has been reclassified or not.

2. The Current Status of LMICs

2.1 Objective of increased support to LMICs

In developing strategies to address an issue, knowing the desired outcome is crucial. Thus the objectives must be defined at the outset. The primary objective of increased support to LMIC is a public health objective: to save lives and improve health in these countries. However, along with this go two additional objectives: to increase equity by extending initiatives to support new vaccine introduction to the many children who are living in a state of poverty equivalent to those in the GAVI-eligible countries; and to expand the market for priority new vaccines essential to the public health of children in developing countries, in order to develop financial incentives towards their affordability.

These objectives will help focus and define the prioritization of strategies and activities to be employed. It is worth noting in considering strategies toward these objectives that GNI/capita obscures the proportion of the population living below the poverty line, and, in fact, as noted above, there are a significant number of people LMICs that are living in poverty.

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\(^5\) Immunization Services Support, Injection Safety Support, New and underused Vaccine Support, Health Systems Strengthening

2.2 Characteristics of LMICs

The 35 countries listed in Table 1 have a combined population of almost 2 billion and a combined birth cohort of about 30 million children. They have strong immunization programs, with a mean DTP-3 coverage in 2006 of 88.5% and a median coverage of 93%.

They have a history of introducing new vaccines into their immunization programs: 97% (34/35) have introduced Hepatitis B (HepB). Introduction of the more expensive Hib vaccine has been slower with only 46% (16/35) having introduced the vaccine, due to a combination of higher vaccine cost and lack of certainty of the burden of disease in their respective countries. (Figure 1).

Figure 1. Hib vaccine introduction by 2008

![Map showing Hib vaccine introduction by 2008]

Source: IVB Database, October 2007 (193 WHO Member States. Data as of October 2007)

In terms of potential market, the number of doses of a three-dose series vaccine is over 150 million, which means, for pentavalent vaccine, a market of over US$530 million; and for rotavirus and pneumococcal vaccines, even more. If the birth cohort for just five of these countries, Egypt, Iran, China, Philippines, and Thailand, were combined, it would represent 23 million children, which is over 75% of the market. PAHO countries benefiting from the PAHO Revolving Fund, represent another 2.75 million, or 10%.
These countries also have good records of financial sustainability. Of the 35 countries, 94% (all but two) have a line item for vaccines, and 88% (all but 4) have a line item for immunization supplies in their national budget. In terms of government financing, the average level for both vaccines and for the immunization program is 97% in these 35 countries. Two-thirds have a costed comprehensive Multi-Year Plan (cMYP) for immunization.

The majority of these countries are procuring their own vaccines, with the exception of the PAHO countries, who are receiving vaccines through the PAHO Revolving Fund. Several of them, including Bosnia and Herzegovina, China, Colombia, Egypt, Iran, and Thailand, have, or have had significant levels of vaccine production, although that production effort is generally neither research-based nor innovative, except in the case of some manufacturers in China.

Finally, many of these countries are actively strengthening the capacity of their National Regulatory Authorities (NRAs) to assure the quality and suitability of the vaccines they use. Two, China and Thailand, are members of the Developing Country Vaccine Regulators Network (DCVRN), which means that they are being exposed to enhanced regulatory decision making methodologies for innovative vaccines.

2.3 Disparities in the introduction of newer vaccines

In contrast to the situation with Hep B introduction, most of these LMICs have been slow to introduce Hib vaccine and have not introduced either pneumococcal conjugate vaccine or rotavirus vaccine. With the exception of countries in Latin America, most have no plans for such introduction. In contrast, with the possibility of GAVI support, at least seven of the poorest countries have indicated their intent to introduce rotavirus and thirty, pneumococcal vaccine. This means that, with these vaccines already in use in industrialized countries, the largest group of children unprotected against these diseases will live in middle income countries.

3. Responses to Data Gathering on Strategies

3.1 Definition of strategies

The six strategies listed in Table 2 were defined by the NUVI meeting participants without prioritization. The following comments were made by those interviewed in general about the strategies and the prioritization process:

- the strategies need more focus and clear priorities;
- early on in the process the costs and timelines for each strategy should be estimated, and the strategies should be divided by cost, higher and lower, and by short- and long-term;
- the work plan should be selective if some progress is expected after three years;
- the effort to enhance NUlV uptake should be linked to the improved availability of global public goods associated with their use;
- the strategies are similar to routine EPI strategies but will require a lot of effort.

**Table 2. NUlV Strategies for LMICs**

<table>
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<td>Develop potential vaccine supply strategies.</td>
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<td>Strengthen regulatory systems.</td>
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<td>Strategy 6</td>
<td>Define financing opportunities.</td>
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Participants recognized that the current inequality must be addressed, and that LMIC need special support from WHO and partners, especially since the issues facing LMICs are similar to those facing GAVI countries. Furthermore, participants insisted that the approaches used should be tailored to the country situation and not top-down, which implies a mapping of needs and priorities before beginning work; a strong case was made for the different categories of countries and the differing needs in the different regions; it was noted that the impact of vaccine policy in one large country could strongly influence regional performance; and a plea was made to increase the role of these countries on current working groups at the global and regional level, to allow their inputs into the strategies that would be implemented.

3.2 Combined responses to questions

**Question 1. Do you agree with the strategies proposed during the NUlV June 2007 meeting?**

There was strong support for the strategies proposed, with the reservations noted above about their use. One respondent said, “This is the right time to be thinking about this.” The strategy felt to be the lowest priority was the involvement of the private sector, although it was regarded as a useful complementary activity. Virtually all responders supported Strategy 1 as the highest priority, with varying priorities for the others. In addition to the strategies proposed, there were suggestions for additional areas of focus, including more emphasis on strong demand forecasts that include LMICs and are not limited to just GAVI eligible countries, the use of pooled procurement systems to extend the lowest price (i.e, the “GAVI” price) to LMICs, and increased efforts by the international community to lower new vaccine prices.
Question 2. What are the most important characteristics related to new vaccine introduction?
As noted above, it was felt that needs assessments should precede the work. But most respondents felt that percentage of government financing and a strong program and human resource capacity were the most important characteristics. Other characteristics felt to be important were problems with procurement, donor support, or lack of it, the size of the country or size of its unimmunized population, and the impact of the country, or of country groupings, on the vaccine market. There was some sympathy for focusing on only the largest countries, and a statement that rolling out these products in the largest countries within the group would be a good test of the strategies.

Specific characteristics related to the region were also noted. For example, the countries in EUR were felt to be similar to each other, but different from those in other regions. There are 11 LMIC in EMR, almost half of the region, which are having difficulty introducing new vaccines, prompting a request from the Regional Director to the WHO Director General for more activity in this area.

The commitment to countries through the PAHO Directing Council was mentioned, which includes the uniform price strategy across all countries served by the PAHO Revolving Fund (RF). The ProVac Initiative in place in the PAHO Region will undoubtedly be an important part of that region’s approach to NUVI, through a framework for vaccine introduction decision making including technical, programmatic and operational, and social criteria. Moreover, PAHO is moving quickly to support licensing of innovative vaccines by the NRAs in countries of the region.

In some regions, for example EMR, vaccine procurement is not working well in many countries, while this was felt not to be an issue by at least one WPR staff member. Identifying similarities and differences in order to initiate appropriate strategies for each region and LMIC within the regions is essential.

Question 3. What are the main constraints to new vaccine introduction?
There was a strong consensus on this: the major constraints are (1) financial resources vs vaccine prices and (2) lack of awareness of the burden of disease and the utility of the vaccine.

Question 4. What should be the basis for grouping/targeting countries?
Most respondents felt that countries should be grouped in terms of:
- income, financial sustainability and ability to pay;
- impact of the introduction of a new vaccine on national and regional health measures; and
- the proportion of the population below the poverty line.

However, one respondent came up with the following formula: If your policy objective is just to influence the market, just work on the three largest countries. Come up with a blend that incorporates all these indicators. If the objective is to reward national

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financing, the policy should be that countries that do the most with their own financing get the most from outside.

**Question 5. Of the potential interventions, what approach(es) would you favor and why?**
The largest number of respondents felt that providing technical support to decision making and advocacy on vaccines was the single most acceptable approach. However, there was strong support for a number of different approaches to the financing issue. These included work by the international community to lower vaccine prices, group procurement activities, support to financial planning, and provision of funds, either for vaccine purchase, through co-financing, or for health systems support. Several people mentioned considering the possibility of allowing LMICs to receive vaccines through the “GAVI” procurement system, that is, the procurement by UNICEF for the GAVI awards, which has paid generally the lowest price for new vaccines, but potentially still financing the vaccine from government funds. There was some discussion of need for support for countries with their own national production source, through technology transfer and/or support to the regulatory process, by WHO.

**Question 6. Are there any approaches that would be unacceptable?**
Generally, respondents stated what they would like, so what would be unacceptable is found by implication. It was felt that any approaches chosen should allow the countries to direct them, and should not be “top-down.”
The current GAVI country eligibility strategy should not be followed for LMICs; that is, there should be a different way of targeting countries for assistance.
It was also mentioned that this should really be a partner effort, not just the work of WHO.
Respondents felt the need to revisit policies on user fees, for example, for limited introduction in parts of a country, and would oppose a continued ban on this strategy.
In addition, there was support for revisiting the tiered pricing strategy for international procurement. In particular, PAHO could not accept an approach that interfered with their ability to purchase vaccines through the Revolving Fund at a single low price for all their eligible countries.

### 3.3 Comments on the strategies themselves

**Strategy 1. Provide support to decision making in MI countries**
The activities proposed for Strategy 1 include:
- Provide support to MI countries in prioritization of health interventions
- Support MI countries with the development and implementation of eMYP
- Provide training and capacity building for evidence-informed decision making
- Ensure that each MI country has an Immunization Advisory Committee
- Support disease surveillance that will generate the data needed to define the burden of disease and the impact of vaccination

This strategy was felt to be of very high priority, especially in terms of GAVI’s activities, and generic enough to be useful for all countries. It was noted that this strategy should include disease burden and cost-effectiveness analyses as a basis for in-country
discussions. It was strongly felt that advocacy was a part of this strategy (It is now found in Strategy 6), and this advocacy should start at the highest political level and go down to the family level. In fact, advocacy was deemed to be even more important than cMYPs in this strategy, and new tools and a comprehensive advocacy package should be developed. One suggestion was made that as part of the work to support country decision making, the possibility of introducing a new vaccine using a higher co-financing or short term donor support timeframe could be considered.

**Strategy 2. Enhance participation of the private health sector** in provision of immunization services

The activities proposed for Strategy 2 are as follows:
- Map the role the different segments of the private sector are playing
- Develop a framework to support countries in analysis of their vaccine delivery characteristics
- Develop training on introduction of specific new vaccines
- Develop training guidelines for private sector providers in vaccine handling and management and reporting of potential vaccine AEFIs
- Define collaborative mechanisms with the private sector.

Although this strategy had the lowest priority, it was noted that the private health sector including NGOs and faith based organizations are playing an increasing role, which must be well-regulated and well-managed. It was also suggested to work with medical and nursing societies.

**Strategy 3. Develop potential vaccine supply strategies**

The activities proposed for Strategy 3 are as follows:
- Establish a group of partners to explore needs for adequate supply
- Get clear demand forecasts from MI countries as a group
- Promote and facilitate the environment for technology transfer.

This strategy was felt to be a high priority and essential for all markets, being key for other strategies to work. It was however suggested that more attention be paid to demand forecasting, not just a global forecast but in individual countries as well. There was little feedback on the idea of technology transfer, other than that WHO might have a role in this.

**Strategy 4. Develop a process to address the challenge of vaccine procurement**

The activities proposed for Strategy 4 include:
- Undertake a mapping of procurement strategies and practices in MI countries
- Provide an options package analyzing procurement options
- HQ to collaborate with Regions to understand procurement challenges and opportunities
- Develop a structural framework for MI countries to assess their own procurement systems
- Explore intercountry and pooled procurement mechanisms in at least 2 regions.

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8 This might include also all immunization services not provided by the public health sector, including those provided by for-profit organizations, NGOs, and faith-based organizations.
This was felt to be of high priority. It was suggested to define more rational procurement mechanisms, prioritize procurement systems, and give pooled procurement more prominence and consideration. WB Country Procurement Assessment Reports may be useful for prioritization of countries overall and for this activity. It was also strongly suggested to explore the possibility of LMICs receiving vaccines through GAVI procurement mechanisms, at the GAVI price, although they may be paying for the vaccines with government funding.

**Strategy 5. Strengthen regulatory systems**
The activities proposed for Strategy 5 include:
- Strengthening the ability of MI regulatory authorities for decision making on marketing authorization of new vaccines
- Strengthen clinical trial oversight activities in MI countries
- Promote awareness of the "expedited" marketing authorization

This strategy was felt to be of high priority and useful to all countries, although there was some skepticism expressed of its success. It was suggested that regional regulatory initiatives be explored.

**Strategy 6. Define financing opportunities**
The activities proposed for Strategy 6 include:
- Explore how GAVI could support new vaccine introduction in MI countries
- Critical analysis by WHO, GAVI and others on the implications of establishing revolving funds for procuring vaccines for MI countries
- Revisit and re-analyze the WHO policy on user fees
- Develop new vaccines financing options and opportunities for MI countries
- Support countries in advocacy and resource mobilization at all national policy levels
- Support countries in identifying and initiating discussions with local organizations for immunization resources
- Work with finance institutions to identify the role of IBRD loans in this area

This was felt to be the highest priority activity of all. There was strong support for exploring GAVI co-financing, although it was also strongly expressed that this could damage the notion of sustainability in these countries. It was felt that the WHO user fees policy needed to be revisited to potentially reduce the severity of the policy in certain circumstances. There was also strong support for helping to mobilize additional resources for LMICs, such as, but not limited to, IBRD loans. One interesting suggestion was to advocate, in countries with health insurance mandates, to add specific new vaccines to a minimum benefits package.

There was much discussion about three potential means of GAVI and partner involvement, which would fit under the first activity mentioned above. The first was to consider ways to support countries financially, not necessarily by directly financing new vaccines but, for example, by supporting health systems in general. The second considered more work on the part of GAVI and partners to work to lower vaccine prices. And the third, which had support even from some emerging vaccine manufacturers, was to extend the GAVI procurement mechanism to LMICs, who could then reimburse the
money to the GAVI Alliance from government or other funds. This last suggestion drew by far the most comments, one of which was that laying out the advantages and disadvantages of any action on pricing was probably the most important issue.

4. Options for support and prioritization

4.1 Preliminary actions: agreement on objectives and target countries

Before prioritization of options, it is useful to achieve consensus on the desired result, because this will to a large extent dictate the priorities. The first part of this paper proposed three objectives:

1. A public health objective: to save lives and improve health of populations living in LMICs
2. An equity objective: to support new vaccine introduction to the many children who are living in a state of poverty equivalent to those in the GAVI-eligible countries
3. A market objective: to expand the market for priority new vaccines essential to the public health of the target population in developing countries, in order to develop financial incentives towards their affordability.

Keeping these three objectives in the forefront ensures that prioritized strategies will both increase the global public good of control of vaccine-preventable diseases, and will consider the needs of the poorest children, whether they live in LMICs or in GAVI-eligible countries.

Consensus should also be achieved on what subset(s) of countries will be prioritized in the implementation of these strategies, recognizing a limited timeframe and resources. GAVI resources have to date been targeted at the poorest countries, with some differentiation in the type of support offered, but basically with an equal focus on all those eligible. However, the responses from those interviewed suggests a strong consensus to target interventions where the most impact can be realized in the shortest time: to countries that are the strongest, contributing the largest proportion of government financing to their immunization programs and with high coverage, or to those that are the largest, or both. Keeping in mind the equity objective, the logical choice would be the largest countries; for developing a sustainable market, focusing on higher performing countries would be the choice. The public health objective would dictate providing support to all eligible countries across the board, while the need for some progress by the end of the first work plan and in terms of the MDGs would probably support focusing on those countries where disease burden is highest, but where programs were stronger so that results in terms of sustainable introduction of a life-saving vaccine would save lives in the least amount of time.

4.2 Immediate need: needs assessment

There is strong support for having a better idea of the situation in the 35 countries, or at least representative ones, prior to embarking on a new strategy. Although the information on coverage, % government financing, and % population below the poverty line is for the most part known, inputs from the regions and more specifically the individual countries have yet to be systematically sought and collected. It would be useful to involve some key LMICs in this effort, in determining the scope of the assessment, its methodology and the application of the findings.
4.3 Categorization of activities into short and long term, and less and more resource intensive
Taking as a start the NUVI work plan attached in Annex 3, as well as activities for which there was support among those providing inputs, we have attempted to categorize them as whether they are needed in the short term and can be completed within 12 months (ST), or whether they will involve continued ongoing effort over the long term (LT). In addition, they have been categorized as to whether they are relatively less resource intensive (that is, amenable to being addressed by a meeting or a study - C), or whether they are relatively more expensive, E. Generally, strategies that will need implementation at a country by country level are categorized as E. Table 3 shows the results.

Table 3. Categorization of proposed activities by time frames and resources

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Activity</th>
<th>Time Frame</th>
<th>Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide support to decision making in LMICs</td>
<td>Support to prioritization of health interventions</td>
<td>LT</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Support for cMYPs</td>
<td>LT</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>CB for evidence-informed decision making</td>
<td>LT</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Ensure Immunization Advisory Ctte in each country</td>
<td>LT</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Develop an advocacy package for existing new vaccines</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Ensure infrastructure for determination of disease burden</td>
<td>LT</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Conduct relevant cost-effectiveness studies</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td>Ensure participation of private health sector</td>
<td>Map role of different private sector segments</td>
<td>ST</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Develop framework on analyzing vaccine delivery characteristics</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Develop introduction training, specific vaccines</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Develop training guidelines for vaccine handling and reporting of AEFIs</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td>Develop potential vaccine supply strategies</td>
<td>Establish a supply group</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Get composite demand forecasts from LMICs and pass to partners</td>
<td>LT</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Work with countries to improve demand forecasting for new vaccines</td>
<td>LT</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Promote and facilitate tech transfer</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td>Address vaccine procurement</td>
<td>Map procurement strategies and practices in LMICs</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Provide CB on procurement practices</td>
<td>LT</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>Collaborate with regions to understand procurement challenges</td>
<td>ST</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Develop framework for self-assessment of procurement systems</td>
<td>ST</td>
<td>C</td>
</tr>
</tbody>
</table>
**4.4 Prioritization of activities in different areas**

The analysis in Table 3 enables a way to then propose the highest priority activities that must be started now for optimal impact. This is done below in each of the four areas: technical, supply, advocacy, and financing. Technical includes some activities under Strategy 1 (disease burden, cost-effectiveness, training and capacity building, Immunization Advisory Committees), plus Strategies 2 and 5. Financial is covered by Strategy 6; Advocacy by Strategies 1 and 6; and Supply by Strategies 3 and 4.

4.4.1 Technical. The cost-effectiveness and disease burden studies are already in progress for all new vaccines proposed for inclusion into developing country immunization programs and this work will continue. The difference in this workplan is that it is for LMICs, which means a widening of the scope of studies already in progress. **Expansion of surveillance networks for disease burden studies, to LMICs where they do not already exist, will be a priority activity,** as without this, countries will have little basis for deciding to adopt a vaccine, nor for measuring its impact. **Immunization Advisory Committees are the obligatory clients of all the technical data to be assembled on a new intervention, and their establishment is a priority in all countries.** Capacity building for evidence-based decision making is a long term activity and will need to be done. Whether it needs formal training, or whether it can be best done through supported targeted through Immunization Advisory Committees is a topic for debate.
Enhanced involvement of the private sector for new vaccine introduction was the lowest priority activity, although some work is already in place for training private providers in vaccine management and safety, and this should continue. **One intervention that could be useful is the development of a framework to support countries in analysis of their vaccine delivery characteristics.** Since it is relatively less resource intensive, it could be selected as an immediate activity.

The regulatory authority (NRA) strengthening activities are of high priority in general, to strengthen immunization programs. However, they are important for all countries, are for the most part already ongoing, and are for the most part already funded; thus none of these activities has been selected as high priority for this intervention.

**4.4.2 Financial.** A number of financing activities are defined for the short term, and consist of exploring and modeling out different policy options. **These should be given high priority for implementation:** revisiting the user fees policy, initiating discussions on options for loans, analyzing the implications of using GAVI support for an expanded Revolving Fund for procuring new vaccines for LMICs, as well as a serious assessment of the implications of a GAVI co-financing policy for new vaccines for LMICs and the length of donor support arrangements. In addition, several of the long term policies, such as expanding support for cMYP development to LMICs, and looking at additional financing options such as health insurance mandates, will also be of high priority, and need to be started or continued as soon as possible. Work by GAVI partners with manufacturers to lower prices would undoubtedly not be well received if there were no concomitant benefit to the manufacturers such as increased market size. Potentially partner efforts could be better focused on providing information on the value of vaccines to countries or on efforts to make the long term vaccine price sustainable through market expansion for the short term. **There is not general agreement on the question of whether or not GAVI should provide funding support per se for new vaccines for LMICs, rather than more general immunization support, or advocacy for different procurement options, and this needs to be investigated.**

**4.4.3 Advocacy.** Development of advocacy packages (work that has already been implemented for the GAVI-eligible countries) for the vaccines already available, was agreed to be of highest priority for the LMICs, as was supporting countries at the highest policy level to mobilize resources. Much of this work has been done by the ADIPs, the Hib Initiative (HI), and the PATH vaccine development projects, for example on Japanese encephalitis and meningococcal A conjugate vaccine. Some of this work will be taken over by the new Vaccine Introduction Support Initiative (VISI) for which applications are now being considered by GAVI. An extremely useful step would be to ensure that VISI will cover these activities for LMICs as well.

**4.4.4 Supply.** Supply includes development, production, procurement, and demand forecasting, and all the steps involved therein, and was agreed to be of high priority. **Development of supply strategies for each vaccine by a representative group is of the highest priority.** Improving demand forecasts at both the national and
global level are agreed as a high priority and should be implemented; this has already been agreed in other fora. Efforts to improve vaccine development and to expand know-how for vaccine production, while important, are general across the board, and are long term and labor-intensive. However, support to improve procurement in LMICs drew wide agreement as of high priority. Three short term activities are of highest priority in this area: a mapping of procurement strategies and practices in LMICs, developing a self-assessment framework for LMIC procurement practices, and modeling the global implications of allowing LMICs to benefit from UN agency procurement for new vaccines.

5. Potential roles of partners
5.1 Partner inputs for high priority activities
With the priorities identified, we can begin to look at the work load implications of these for GAVI, WHO, and other GAVI partners. Table 4 is an attempt to assign some of these for the priorities identified in part 4. It is important to recognize, however, that this work should be focused on the countries involved, and although assignments are made to partners, this should not be a top-down activity. Rather LMIC representatives must be engaged at every step.

Table 4. Partner inputs for high priority LMIC activities

<table>
<thead>
<tr>
<th>Category</th>
<th>Activity</th>
<th>Partner inputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical</td>
<td>Expansion of surveillance networks for disease burden studies, to LMICs</td>
<td>WHO, CDC, ADIPs/Hi/VISI/PATH vaccine projects where relevant</td>
</tr>
<tr>
<td></td>
<td>Immunization Advisory Committee establishment in all countries</td>
<td>UNICEF, WHO ROs</td>
</tr>
<tr>
<td></td>
<td>Development of a framework to support countries in analysis of their vaccine delivery characteristics</td>
<td>UNICEF, WB, WHO ROs</td>
</tr>
<tr>
<td>Financing</td>
<td>Revisit the user fees policy</td>
<td>WHO</td>
</tr>
<tr>
<td></td>
<td>Initiate discussions on options for loans</td>
<td>WHO, Regional Development Banks, WB</td>
</tr>
<tr>
<td></td>
<td>Analyze the implications of using GAVI support for an expanded Revolving Fund for procuring new vaccines for LMICs</td>
<td>GAVI, WHO, UNICEF, bilateral donors</td>
</tr>
<tr>
<td></td>
<td>Assess of the implications of a GAVI co-financing policy for new vaccines for LMICs</td>
<td>GAVI, GAVI partners</td>
</tr>
<tr>
<td></td>
<td>Expand support for cMYP development to LMICs</td>
<td>ADIPs/Hi/VISI/PATH vaccine projects, UNICEF, WHO ROs</td>
</tr>
<tr>
<td></td>
<td>Explore additional financing options such as health insurance mandates</td>
<td>WHO, WB</td>
</tr>
<tr>
<td>Advocacy</td>
<td>Develop advocacy packages</td>
<td>ADIPs/Hi/VISI/PATH vaccine projects, WHO</td>
</tr>
<tr>
<td></td>
<td>Support countries at the highest policy level to mobilize resources</td>
<td>WHO, GAVI, GAVI partners</td>
</tr>
</tbody>
</table>
### Supply

<table>
<thead>
<tr>
<th>Task</th>
<th>Responsible Parties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop supply strategies for each vaccine</td>
<td>GAVI, GAVI partners, ADIPs/Hi/VISI/PATH vaccine projects</td>
</tr>
<tr>
<td>Improve demand forecasts at both the national and global level</td>
<td>GAVI, GAVI partners, ADIPs/Hi/VISI/PATH vaccine projects</td>
</tr>
<tr>
<td>Map procurement strategies and practices in LMICs</td>
<td>UNICEF, WHO, WB</td>
</tr>
<tr>
<td>Develop a self-assessment framework for LMIC procurement practices</td>
<td>UNICEF, WHO</td>
</tr>
<tr>
<td>Model the global implications of allowing LMICs to benefit from the GAVI price for new vaccines, while financing them from government funds</td>
<td>UNICEF, WHO, GAVI partners</td>
</tr>
</tbody>
</table>

#### 5.2 Financing of partner inputs

Once there is general agreement on the roles of the different partners in implementation of the agreed prioritized activities, the assurance of funding support for these activities will be critical. The need for extra funding is one reason that some already ongoing and funded activities in the previous workplan have not been identified as of highest priority. It is understood that all activities proposed here in Table 4 will need to be funded. Some funding might be assured if the activities to be supported under VISI will be expanded to include LMIC countries.

WHO in particular will need additional funding support to implement these activities. The options for support through WHO could be:

- Devote a percentage of GAVI funds to WHO for activities to LMICs
- Include LMIC representatives on most of GAVI advocacy and capacity building activities
- Give greater prioritization to LMICs in WHO workplans
- Encourage and facilitate peer review and intercountry communication between LMICs to generate group learning, information exchange, capacity building, and benefiting from the experiences of other countries.

#### 6. Conclusions and areas for further exploration

The current paper has tried to synthesize inputs from a number of stakeholders representing the point of view of LMICs (but note that no LMIC representatives have actually been interviewed for this paper). This has led to the identification of activities that need to be launched as a priority for a LMIC strategy, and the provisional assignment of lead agencies for each of these activities. A need for funding support has been identified.

The next steps include:

1. A partners meeting including all GAVI partners, plus strong representation from LMICs to focus and specifically define the next steps. Key agenda items will include:
   - Agreement on the countries to be included
   - Agreement on the objectives of a LMIC strategy
- Agreement on the optimal mechanism to target countries
- Agreement on priority topics and activities
- Agreement on a mechanism to perform needs assessments in key countries or for the group as a whole
- Agreement on the roles and responsibilities of each of the partners
- Agreement on advocacy and resource mobilization for priorities.

It is suggested that WHO convene this meeting on behalf of partners and countries.

2. Consider the market and financial impact of:
   a. allowing LMIC access to the GAVI global prices for HepB and Hib containing vaccines and newer vaccines Pneumococcal and rotavirus, with funding coming from own government sources and technical assistance provided by UN agencies; and
   b. providing financial support to LMIC for the same vaccines, currently supported by GAVI, in low income countries. (HepB and Hib containing vaccines and newer vaccines Pneumococcal and rotavirus) including at differing levels of co-payment.
Annex 1. List of partners consulted

PAHO:
Jon Andrus
Monica Perreira
Maria de los Angeles Cortes Castillo

EMRO:
Ezzedine Mohsni
Additional team members, including Irtaza Chaudhri

EURO
Andrei Lobanov
Additional team members

WPRO
Manju Rani

GAVI Alliance
Anshu Banjeree
Craig Burgess

Rotavirus Vaccine Program/PATH
John Wecker

Pneumo ADIP
Orin Levine
Angeline Nanni

Hib Initiative
Rana Hajjeh

UNICEF
Patience Kuruneri

ABT Associates
Marty Makinen

WHO HQ
Patrick Zuber
Patrick Lydon
Miloud Kaddar
Lidija Kamara
Sarah Schmitt
Peter Strebel

Vaccine Industry
Mahima Datla, Biological E
Annex 2. Questionnaire

NUVI Strategy Questionnaire

1. Do you agree with the strategies proposed during the NUVI June 2007 meeting for MI countries (see recommendations attached)? Why or why not?

2. For MI countries with which you work (see complete list attached), what are their most important characteristics related to new vaccine introduction (e.g. population, prospects for increased income, donor support, ability to profit from an international intervention such as GAVI, innovation in vaccine and other health interventions, % government financing of immunization and vaccine, coverage, vaccine production or procurement)?

3. For the countries mentioned in Question 2, what are the main constraints to new vaccine introduction?

4. If there were to be an approach to MI countries, what should be the basis for grouping/targeting countries?
   a. None – all should be treated the same
   b. Infrastructure, using coverage for example
   c. % government financing
   d. History of NUVI
   e. Vaccine source (production, procurement, etc)
   f. Level of income (WB classification,..)
   g. Membership in regional or sub regional entity
   h. % of population below the poverty line

5. Potential types of interventions by WHO, GAVI and partners might include financial support, technical advice (through consultations or meetings), capacity building, supply (such as group procurement), and/or advocacy (provision of materials and data). What approach would you favor, and why? Or can you suggest other types of interventions?

6. Are there types of interventions that GAVI and its partners might consider that you would find totally unacceptable? Please describe these and the reasons for their unacceptability.
Annex 3. WHO plan of action for new and under-utilized vaccines implementation: 2007-2010

Work Area II.2. Develop an approach to assist middle income countries with new vaccines implementation

In the past, WHO efforts in vaccine introduction have prioritized assistance to the poorest countries, in particular 72 countries eligible for financial and program assistance from the GAVI Alliance. An additional focus on middle income (MI) countries is required for a number of reasons.

First, these countries represent a large market. For fiscal year 2007, the World Bank classifies 79 countries as MI countries; this is a very diverse group of countries having a per capita income ranging between US$ 876 and US$ 6,055. This qualifies them to borrow from the International Bank for Reconstruction and Development (IBRD). This group includes a number of populous countries, including Brazil, China, Korea, Russian Federation, South Africa, the Philippines, and Thailand, with a total population of 3.1B, representing over half of the 5.1B total combined population of low and middle income countries. The World Bank classification of MI countries is divided into two categories "upper" and "lower" MI economies. This workplan focuses on the 58 lower MI countries (see attached list Annex 1) not eligible for IBRD funding (with a GNI per capita between US$ 876 and US$ 1025). The total population of the low MI group is 2.4 B and includes 5/9 NRA members of the DCVRN and 4/12 emerging suppliers with pre-qualified products.

Historically, MI countries have financed their own vaccines paying higher prices than low income countries. In addition, in some instances the private sectors in MI countries were early adopters of new vaccines acting as an instrument for wider update of new vaccines. Moreover, MI countries maybe more likely to have better developed infrastructure to quantify disease burden and thus measure vaccine impact. Finally, this group accounts for six of the nine regulatory authorities included in the Developing Country Vaccine Regulators Network (DCVRN) and five of the 12 emerging manufacturers producing WHO-prequalified products (the rest are in India, Korea, and Senegal). Thus, their actions impact on vaccine development and licensing decisions in the developing world.

The potential benefits of greater attention to MI countries needs includes the following: 1/ as a potentially large and attractive market for manufacturers, these countries impact on supply issues, tiered pricing, and forecasting demand, as a step-down from a pure high-end market strategy; 2/ vaccine presentation issues, serious and unexpected adverse events following immunization (AEFI), and impact on disease surveillance figures can be followed readily in some of these countries, and the experience gained can better inform WHO strategies as well as low income countries; and 3/ these countries provide regulatory directions with strong relevance for the poorest
countries. According to the World Bank, these economies have grown at an average 5.8% over the last four years. They tend to be vital contributors in the creation of global public goods, e.g., fighting the spread of communicable diseases. Rather than traditional development assistance they want inputs into their national process based on knowledge services and access to technologies. Therefore, activities could be considered in the following areas: 1/ developing support to strengthen the decision making process; 2/ including the private health sector in vaccine delivery issues; 3/ developing potential supply strategies, not necessarily limited to multinational suppliers; 4/ addressing the challenge of vaccine procurement systems; 5/ strengthening regulatory systems; and 6/ identifying financing opportunities.

WHO country activities for new vaccines implementation to date have focused on strengthening national decision making processes, including providing information packages, promoting national decision making bodies, and providing models and data on cost-effectiveness for prioritization purposes. These activities are important for a MI strategy as well, though they should be carefully tailored to meet the different needs of the individual members of this group of countries. MI countries are attractive as clinical trial and pilot introduction sites; this could spearhead accelerated introduction activities. Because private sector vaccine delivery plays an important role in these countries, any MI strategy must include efforts to involve this sector, such as training in vaccine handling and other field issues, and in capturing reports of AEFI.

Key issues relate to vaccine supply and demand. A major lesson learned from the Hib vaccine introduction experience was the need for both national demand and a supply strategy in advance of introduction. Currently the pneumococcus and rotavirus ADIPs and agencies partnering with WHO are addressing this for the vaccines relevant to them. MI countries can play a major role since they are an attractive market allowing firm demand forecasts to be developed on which capacity expansion can be based. In addition, they are potential sources of new vaccine supply, through partnerships, licensing agreements, or through their own research activities. The Developing Country Vaccine Manufacturer Network (DCVMN) would be a good entry point for this kind of intervention.

Many of these countries either buy their own vaccines directly, or through a procurement agent, or produce their vaccines locally. WHO has developed a procurement support strategy that includes a standardized assessment tool, a manual, and training activities, though recent activities have been limited by lack of staff resources. In addition, WHO and its collaborators (PATH, the PAHO Revolving Fund, and the Gulf Cooperation Council Group Purchasing Program) have developed an analysis of regional group purchasing activities for vaccines, which identifies several common features considered to have contributed to accelerated immunization achievements, including the introduction of new vaccines. While these countries normally cannot count on direct donor support for vaccine purchase, and have generally financed their own vaccines, they can expect to receive collaborative support for some of the ancillary activities. IBRD loans may be one place to start. WHO has a
history of developing advocacy tools and of working with national
government officials in ways that can support new vaccine uptake.

WHO already has a well-developed strategy for developing regulatory
pathways for new vaccines, which heavily involves the DCVRN, mostly
composed of MI countries. These MI country regulatory agencies could thus
serve as leaders in addressing issues related to the regulation of these new
products. A related WHO initiative strengthens national abilities to oversee
and evaluate clinical trials. Again, this work is most advanced in MI
countries.

<table>
<thead>
<tr>
<th>Strategies</th>
<th>Activities</th>
</tr>
</thead>
</table>
| **Strategy 1**
Provide support to decision making in MI countries. | • Provide support to MI countries in prioritization of health interventions in broad context (not just NVI).
• Support MI countries with the development and implementation of cMYP, including a budget line for vaccine purchase.
• Provide training and capacity building for evidence-informed decision making for new vaccine introduction.
• Ensure that each MI country has an Immunization Advisory Committee that meets a certain level of norms/standards and that pool of regional expertise is exchanged to strengthen Committees, and to facilitate sharing of experiences. |
| **Strategy 2**
Enhance participation of the private health sector in provision of immunization services. | • Map the role the different segments of the private sector are playing in immunization services.
• Develop a framework to support countries in analysis of their vaccine delivery characteristics.
• Develop training on introduction of specific new vaccines meeting the needs of the private sector as well as of public sector staff.
• Develop training guidelines for private sector providers in vaccine handling and management and reporting of potential vaccine AEFI’s.
• Define collaborative mechanisms with the private sector for provision of immunization services. |
| **Strategy 3**
Develop potential vaccine supply strategies. | • Establish a group of partners to explore the areas where work needs to be done to ensure a sustained and uninterrupted supply of affordable new vaccines of ensured quality.
• Key role of a supply strategy would be to get clear demand forecast from MI countries as a group and passing this information onto industry. This would result in a comprehensive demand forecast which could have positive benefits.
• Promote and facilitate the environment for technology transfer (particularly for the vaccine manufacturers within the lower middle income group); mapping the risks for key vaccine products (examples YF, Meningococcus A, measles aerosol). |
| **Strategy 4**
Develop a process to address the challenge of vaccine procurement. | • Undertake a mapping of procurement strategies and practices in MI countries, including import taxes and freight costs.
• Provide information, capacity building, and sharing of best procurement practices/processes (provide an options package analyzing procurement |
| **Strategy 5**  
Strengthen regulatory systems. | • HQ to collaborate with Regions to understand procurement challenges and opportunities (pros/cons). Where feasible help leverage more rational procurement mechanisms and longer group contracts that might reduce prices.  
• Develop a structural framework for the use of MI countries to assess their own procurement systems, including procurement for private sector providers, if centralized, and procurement from local suppliers.  
• Explore intercountry and pooled procurement mechanisms in at least 2 regions. 

| **Strategy 6**  
Define financing opportunities. | • Working through WHO’s regulatory pathways initiative, strengthen the ability of DCVRN members and other MI regulatory authorities for decision making on marketing authorization of these new vaccines.  
• Design a strategy to support regulatory network initiatives to strengthen clinical trial oversight activities in MI countries.  
• Promote awareness of the “expedited” marketing authorization based on prequalification status of a product.  

|  | • Explore how GAVI could support new vaccine introduction in MI countries including higher co-financing levels, contribution to revolving fund, etc.  
• WHO to undertake a critical analysis with GAVI and other funding entities on the use and implications of establishing revolving funds for procuring vaccines for MI countries and some GAVI-eligible countries.  
• Revisit and re-analyze, in light of MI country practices, the WHO policy on user fees and see if it is still relevant.  
• Develop new vaccines financing options and opportunities for MI countries.  
• Support countries in advocacy and resource mobilization at all national policy levels.  
• Support countries in identifying and initiating discussions with local organizations that might support vaccine purchase, disease surveillance, and immunization delivery activities.  
• Work with the regional and international finance institutions including the World Bank to identify the role of IBRD loans in this area. |
## Annex 4. Draft partial WHO work plan for NUVI

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Activity</th>
<th>Priority</th>
<th>Partner Inputs</th>
<th>Focal Point</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strategy #1</strong></td>
<td>1. Provide support to MI countries in prioritization of health interventions in broad context (not just NVI)</td>
<td>B</td>
<td>UNICEF</td>
<td>NVI</td>
</tr>
<tr>
<td></td>
<td>2. Support MI countries with the development and implementation of cMYP, including a budget line for vaccine purchase.</td>
<td></td>
<td>Hib Initiative to provide technical support UNICEF</td>
<td>RO</td>
</tr>
<tr>
<td></td>
<td>3. Provide training and capacity building for evidence-informed decision making for new vaccine introduction.</td>
<td></td>
<td>PATH HVP vaccine focus on generating data for decision making - Peru UNICEF</td>
<td>RO</td>
</tr>
<tr>
<td></td>
<td>4. Ensure that each MI country has an Immunization Advisory Committee that meets a certain level of norms/standards and that pool of regional expertise is exchanged to strengthen Committees, and to facilitate sharing of experiences.</td>
<td></td>
<td>UNICEF</td>
<td>RO</td>
</tr>
<tr>
<td><strong>Strategy #2</strong></td>
<td>1. Map the role of different segments of the private sector are playing in immunization services.</td>
<td>C</td>
<td></td>
<td>PFP</td>
</tr>
<tr>
<td></td>
<td>2. Develop a framework to support countries in analysis of their vaccine delivery characteristics.</td>
<td>B</td>
<td>UNICEF</td>
<td>IMS</td>
</tr>
<tr>
<td></td>
<td>3. Develop training on introduction of specific new vaccines, meeting the needs of the private sector as well as of public sector staff.</td>
<td>B</td>
<td>PATH has developed training material and provided training on many vaccines, including HPV</td>
<td>NVI</td>
</tr>
<tr>
<td></td>
<td>4. Develop training guidelines for private sector providers in vaccine handling and management and reporting of potential vaccine AEFIs.</td>
<td>A</td>
<td>UNICEF</td>
<td>IMS</td>
</tr>
<tr>
<td></td>
<td>5. Define collaborative mechanisms with the private sector for provision of immunization services.</td>
<td>C</td>
<td></td>
<td>IMS</td>
</tr>
<tr>
<td><strong>Strategy #3</strong></td>
<td>1. Establish a group of partners to explore the areas where work needs to be done to ensure a sustained and uninterrupted supply of affordable new vaccines of ensured quality.</td>
<td>B</td>
<td>All PATH vaccine projects UNICEF PneumoADIP</td>
<td>PFP</td>
</tr>
<tr>
<td></td>
<td>2. Key role of a supply strategy would be to get clear demand forecast from MI countries as a group and passing this information onto industry. This would result in a comprehensive demand forecast which could have positive benefits.</td>
<td>A</td>
<td>UNICEF PneumoADIP</td>
<td>NVI</td>
</tr>
</tbody>
</table>
### Strategy #4

1. Undertake a mapping of procurement strategies and practices in MI countries, including import taxes and freight costs.  
   - **B** UNICEF  
   - **PFP**

2. Provide information, capacity building, and sharing of best procurement practices/processes (provide an options package analyzing procurement options).  
   - **B** UNICEF  
   - **PFP**

3. HQ to collaborate with Regions to understand procurement challenges and opportunities (pros/cons). Where feasible help leverage more rational procurement mechanisms and longer group contracts that might reduce prices.  
   - **B** UNICEF  
   - **PFP**

4. Develop a structural framework for the use of MI countries to assess their own procurement systems, including procurement for private sector providers, if centralized and procurement from local suppliers.  
   - **B** UNICEF  
   - **PFP**

5. Explore intercountry and pooled procurement mechanisms in at least 2 regions.  
   - **A** UNICEF  
   - **PFP**

### Strategy #5

1. Working through WHO’s regulatory pathways initiative, strengthen the ability of DCVRN members and other MI regulatory authorities for decision making on marketing authorization of these new vaccines.  
   - **A**  
   - **QSS**

2. Design a strategy to support regulatory network initiatives to strengthen clinical trial oversight activities in MI countries.  
   - **A**  
   - **QSS**

3. Promote awareness of the "expedited" marketing authorization based on prequalification status of a product.  
   - **A**  
   - **QSS**
<table>
<thead>
<tr>
<th>Strategy #6</th>
<th>1. Explore how GAVI could support new vaccine introduction in MI countries including higher co-financing levels, contribution to revolving fund, etc.</th>
<th>A</th>
<th>PFP</th>
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<tbody>
<tr>
<td></td>
<td>2. WHO to undertake a critical analysis with GAVI and other funding entities on the use and implications of establishing revolving funds for procuring vaccines for MI countries and some GAVI eligible countries.</td>
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<td>3. Revisit and re-analyze, in light of MI country practices, the WHO policy on user fees and see if it is still relevant.</td>
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<td>4. Develop new vaccines financing options and opportunities for MI countries.</td>
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<td>5. Support countries in advocacy and resource mobilization at all national policy levels.</td>
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<td>DO</td>
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<td>6. Support countries in identifying and initiating discussions with local organizations that might support vaccine purchase, disease surveillance, and immunization delivery activities.</td>
<td>A</td>
<td>NVI</td>
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<td>7. Work with the regional and international finance institutions including the World Bank to identify the role of IBRD loans in this area.</td>
<td>B</td>
<td>PFP</td>
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