



## Review

## Global support for new vaccine implementation in middle-income countries

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## ABSTRACT

Middle-income countries (MICs) as a group are not only characterized by a wide range of gross national income (GNI) per capita (US \$1026 to \$12,475), but also by diversity in size, geography, governance, and infrastructure. They include the largest and smallest countries of the world—including 16 landlocked developing countries, 27 small island developing states, and 17 least developed countries—and have a significant diversity in burden of vaccine-preventable diseases. Given the growth in the number of MICs and their considerable domestic income disparities, they are now home to the greatest proportion of the world's poor, having more inhabitants below the poverty line than low-income countries (LICs). However, they have little or no access to external funding for the implementation of new vaccines, nor are they benefiting from an enabling global environment. The MICs are thus not sustainably introducing new life-saving vaccines at the same rate as donor-funded LICs or wealthier countries. The global community, through World Health Assembly resolutions and the inclusion of MIC issues in several recent studies and important documents—including the Global Vaccine Action Plan (GVAP) for the Decade of Vaccines—has acknowledged the sub-optimal situations in some MICs and is actively seeking to enhance the situation by expanding support to these countries. This report documents some of the activities already going on in a subset of MICs, including strengthening of national regulatory authorities and national immunization technical advisory groups, and development of comprehensive multi-year plans. However, some additional tools developed for LICs could prove useful to MICs and thus should be adapted for use by them. In addition, new approaches need to be developed to support MIC-specific needs. It is clear that no one solution will address the needs of this diverse group. We suggest tailored interventions in the four categories of evidence and capacity-building, policy and advocacy, financing, and procurement and supply chain. For MICs to have comparable rates of introduction as other wealthier countries and to contribute to the global fight against vaccine-preventable diseases, global partners must implement a coordinated and pragmatic intervention strategy in accord with their competitive advantage. This will require political will, joint planning, and additional modest funding.

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**Abbreviations:** cMYP, comprehensive, multi-year plan for immunization; EMRO, WHO Eastern Mediterranean Regional Office; GNI, gross national income; GVAP, Global Vaccine Action Plan; Hib, *Haemophilus influenzae* type B; HPV, human papillomavirus; LIC, low-income country; LMIC, lower-middle-income country; MIC, middle-income country; NRA, national regulatory agency; ODA, official development assistance; PAHO, Pan American Health Organization; PCV, pneumococcal conjugate vaccine; R4D, Results for Development Institute; RF, revolving fund; RV, rotavirus vaccine; SAGE, strategic advisory group of experts on immunization; SIVAC, Supporting National Independent Immunization and Vaccine Advisory Committees; UMIC, upper-middle-income country; UNICEF SD, United Nations Children's Fund Supply Division; V3P, Vaccine Product, Price, and Procurement Project; WHA, World Health Assembly; WHO, World Health Organization.

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## 1. Introduction

Middle-income countries (MICs) determined by the World Bank classification based on gross national income (GNI) per capita, are more than ever on the global public health agenda because (1) the number of low-income countries (LICs) is declining, (2) most of those living in poverty now reside in the 111 MICs, (3) these countries have a slower uptake of new and priority vaccines against diseases of public health importance, and (4) the prices available to MICs for new vaccines differ significantly and may affect the rate of new vaccine introduction in some cases.

Since 2000, the GAVI Alliance has provided effective support to poorer countries, including 40 of the 111 MICs, to assist them with improving immunization infrastructure and introduce these new vaccines. Eligible countries pay only a fraction of the GAVI price for new vaccines obtained by the UNICEF Supply Division (SD) as a co-financing amount to complement GAVI's support.

Countries with a per capita GNI less than \$1000 were eligible for GAVI support from its start to 2011, when the threshold was raised to \$1500. Countries with a per capita GNI that rises above the threshold lose eligibility for additional GAVI support (and are referred to as "graduates"). Of the 111 MICs, 3 MICs have already graduated and 16 more are graduating in 2015 and will need continued assistance in the transition phase to immunization self-sufficiency. Nevertheless, these GAVI-graduating countries still have the opportunity to buy some priority vaccines at special GAVI prices. Prior to graduation they pay an increasing percentage of this price (co-financing). Post-graduation they will have access to pay the full GAVI price, while some of the 71 MICs that have never been eligible for GAVI but have similar per capita incomes must pay higher prices (i.e., market prices).

Some of the GAVI graduates that have had rapid economic growth have higher per capita GNI than a number of countries that were never eligible for GAVI support. Twenty-eight countries that have never been eligible for GAVI support have a GNI lower than the highest GNI graduating country (Azerbaijan had a \$5290 per capita GNI in 2011).

The focus of donors and activities of global partners on the poorest countries with little extension to the MICs poses equity and

ethical questions. There are several additional reasons why it makes good public health sense to address the uptake of new vaccines in MICs:

1. *Public health impact*: failure to introduce priority vaccines leaves these countries vulnerable to infectious diseases which can then threaten neighboring countries even if they have been able to begin immunization.
2. *Immunization equity*: with the changes in economic growth rates and levels leading to the emergence of a "new bottom billion" [1] in MICs, the poorest populations are again losing out.
3. *A healthy vaccine market*: MICs could provide a large stable demand volume for vaccine supply promoting competition and a healthy vaccine market to the benefit of both recipient countries and suppliers. Because of the competing priorities, MICs are burdened fiscally by the vaccine prices paid by high-income countries and do not have the access to the lower prices paid by LICs and donors. A more rapid uptake of new vaccines in MICs will increase the predictability of demand and level of funding available and, in the case of pooled procurement, reduce transaction costs to suppliers. In combination, these two factors could make the production investment less risky.
4. *The threat of inappropriate decision-making*: because of inadequate information, capacity, or support, MICs may (1) wait to adopt and put their populations at avoidable risk or (2) choose to adopt but pay unsustainably high prices to access these new vaccines and then could be forced to discontinue or reconsider their use, with deleterious consequences for the vaccine market and the health of their populations.

Many partners are now beginning to intervene, but the vision so far has been limited. A coordinated effort is needed to accelerate sustainable new vaccine implementation by MICs.

The objective of this paper, one of the companion papers to the Global Vaccine Action Plan (GVAP) [2], is to bring attention to this issue. Section 2 deals with the MICs, who they are, and why they are important; Section 3 considers actions taken to date at the global level as part of this focus on MICs; Section 4 describes new vaccine

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