Background

Five years ago at the 2012 World Health Assembly (WHA), Member States endorsed the Global Vaccine Action Plan (GVAP), the 2011-2020 Decade of Vaccines framework for improving vaccination for all.\(^1\) The following year, WHA delegates adopted the GVAP Monitoring, Evaluation and Accountability framework, asking for additional indicators – such as vaccine price information – to be tracked over the course of the decade.

Each year, the WHO Strategic Advisory Group of Experts (SAGE) – WHO’s immunization policy-setting body – reviews progress against the GVAP targets (as reported by the Decade of Vaccines Secretariat\(^2\)), and issues an *Assessment Report of the Global Vaccine Action Plan*.\(^3\) The recommendations in the SAGE *Assessment Report* aim to outline corrective actions that the Decade of Vaccines partners and Member States can take towards improving progress against the GVAP targets.

This year’s GVAP report is particularly important as it marks the mid-way point of the Decade of Vaccines (2012-2020). Progress towards the GVAP targets has been very poor: the GVAP targets for 2015 were missed in all but one category. More generally, and still alarmingly, global average immunization coverage has increased by only 1% since 2010.

At this year’s Executive Board, Member States are invited to note the nine (9) recommendations outlined in the SAGE *Assessment Report*.

This MSF briefing paper highlights areas of the SAGE *Assessment Report* where we recommend Member States take particular note, as well as omissions in the SAGE *Assessment Report* that warrant Member State action.

Vaccine pricing: a persistent obstacle for Member States & humanitarian actors

One area of particular concern that has been repeatedly highlighted by Member States is the challenge of expensive new vaccines. Newer, more expensive vaccines – such as vaccines against pneumococcal disease, diarrhoea and cervical cancer – are often priced out of reach for countries that do not receive donor support, and these countries often do not receive any other assistance to access affordable prices. Countries that are losing financial support through *Gavi, the Vaccine Alliance* (>30% of the Gavi cohort by 2020), so-called “transitioning countries,” also face a significant affordability challenge; they will have to fully self-finance the cost of new vaccines and will be challenged with unpredictable prices once they lose access to lower Gavi-negotiated prices.

One reason why vaccine prices remain high is due to a lack of competition, particularly in the new vaccines market. For example, there are only two WHO prequalified manufacturers each for the newest vaccines: Pfizer and GlaxoSmithKline for pneumococcal conjugate vaccines (PCV); GlaxoSmithKline and Merck for rotavirus vaccines; and GlaxoSmithKline and Merck for human papillomavirus vaccines (HPV). The accelerated introduction of new products on the market to increase competition would lower the price of vaccines and help to make vaccines more affordable for countries and humanitarian organizations. One way to accelerate competition is for the WHO to

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\(^1\) Resolution 65.17 - [http://www.who.int/immunization/global_vaccine_action_plan/en/](http://www.who.int/immunization/global_vaccine_action_plan/en/)


proactively engage with manufacturers of promising PCV and HPV candidates and their respective regulatory authorities during the clinical development process. An early collaboration reduces the risks of regulatory shortcomings and paves the way for a streamlined prequalification resulting in considerable reductions in licensing and prequalification timelines.

The 2015 WHA was a watershed moment for Member States when a resolution by the World Health Assembly (WHA 68.6) on vaccine pricing was adopted.\(^4\) The resolution, originally introduced by Libya, was ultimately co-sponsored by 17 other Member States\(^5\); and 54 Member States voiced strong support for the resolution, highlighting their challenges in introducing new vaccines due to the price.

Tenets of the 2015 WHA resolution on vaccine pricing include:

- Increasing publicly-available vaccine price data through transparency measures;
- Monitoring vaccine prices through annual reporting;
- Pursuing strategies such as pooling vaccine procurement in regional and interregional or other groupings, as appropriate, to leverage economies of scale;
- Promoting competition by expanding the number of manufacturers, particularly in developing countries, that can produce WHO-prequalified vaccines; and
- Reporting upon technical, procedural and legal barriers that may undermine the robust competition.

Resolution 68.6 concluded with a request to the Director-General to report on progress in implementing the resolution. While some reporting towards resolution 68.6 is included in the GVAP Secretariat’s report, it is minimal.

Unfortunately, other initiatives in progress to improve vaccine affordability have been curtailed. For example, WHO has recently closed a Middle Income Countries (MIC) Task Force that was constituted in 2014 with the purpose of improving vaccine access specifically for MICs. While the Task Force developed a strategy, the lack of resources for its implementation has resulted in premature cessation of this critical MICs work stream.

**MSF requests that the work of Member States in forging resolution 68.6 be maintained and Executive Board members request the WHO Secretariat to improve upon implementation of resolution 68.6 as well as its reporting.**

**Completing the immunization schedule for children with interrupted or delayed vaccination, and vaccinating crisis-affected populations: the need to provide immunization services to the most vulnerable**

People living in fragile states and crisis contexts are often the most vulnerable, often missed by health services, or fleeing conflict zones or natural disasters. Average vaccination coverage levels declined between 2010 and 2015 in 25 countries, many of which are experiencing war (Iraq, Yemen, Somalia, Syria) or considered fragile states (Mali, Guinea, Liberia).

The chance for children who may not have completed their vaccination schedule and are now over 1 year of age (>1yr) to receive their needed doses is still critical. While WHO recommends that children still receive their missed doses\(^6\) even after their first birthday, this is typically not implemented.

The negative effect of war and conflict on immunization has also been well documented with UNICEF noting that two-thirds of the world’s unimmunized children live in conflict-affected

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\(^5\) Countries co-sponsoring the 2015 World Health Assembly resolution on vaccine pricing: Algeria, Bahrain, Brazil, Egypt, Iran, Lebanon, Morocco, Nigeria, Pakistan, Qatar, Saudi Arabia, Sudan, Thailand, Togo, Tunisia, Venezuela, Zimbabwe.

countries. While progress has been made towards improving vaccination services for crisis-affect populations – including recent commitments by two manufacturers (GSK and Pfizer) to offer the lowest global price for their pneumococcal conjugate vaccines (PCV) to humanitarian organizations working to vaccinate children in crisis – barriers remain to expanding immunization for these highly vulnerable populations. Governments hosting refugees do not have systematic access to affordable prices, often finding their immunization budgets strained with population influxes – a doubly difficult challenge on top of already high vaccine prices.

**MSF recommendations:**

During the upcoming Executive Board, MSF wishes to direct Member States to the SAGE recommendations that can help advance towards more affordable vaccines and increase vaccination coverage amongst children over 1 year of age, as well as populations in crises and humanitarian emergencies.

Specifically, MSF encourages member states to:

- Note the SAGE recommendations below, drawing particular attention to the need for WHO to reinforce its recommendation on completing the immunization schedule even for children who are delayed in their primary vaccination schedule (children >1 year).
- Highlight the need to rapidly advance the work on affordable access to vaccines for people affected by humanitarian emergencies, including access to the lowest global prices for both humanitarian organizations and governments providing vaccination services to crisis-affected people.
- Further to the above, request WHO to ensure that its existing frameworks on ‘Vaccination in Acute Humanitarian Emergencies’ and ‘Recommendations for Interrupted or Delayed Routine Immunization’ are implemented by all global immunization partners; and
- Require the WHO Secretariat to report back on progress.

Additionally, MSF requests Member States to:

- Remind the WHO Secretariat of the 2015 World Health Assembly resolution (68.6) on vaccine affordability, and the request to the Director-General to improve upon activities to implement the requests of Members States in this resolution.
- Highlight that transitioning countries and Middle Income Countries still need special attention to ensure sustainability of their immunization programmes. For example, following the unfortunate dissolution of the MICs Task Force, WHO should do this by: reconstituting a group to work specifically towards increasing vaccine affordability for MICs; working on advancing pooled procurement mechanisms; and coordinating member states and other donors to resource this area of work.
- Request the WHO Secretariat to take the necessary measures to ensure that promising Pneumococcal Conjugate Vaccine (PCV) candidates from developing country vaccine manufacturers are being prioritized in the technical and regulatory support provided by WHO to both manufacturers and their respective regulatory authorities in view of their timely licensing and prequalification. In addition, partners such as Gavi and other donors should facilitate the resources and support needed to accelerate these candidate vaccines to market.
- Acknowledge the success of WHO’s global database on vaccine prices (V3P) and request the WHO Secretariat to maintain its role as facilitating and administering this database.
Select SAGE Assessment Report Recommendations

**Recommendation: Prioritize immunization system strengthening.**
a) Countries should expand immunization services beyond infants and children to the whole life course, and determine the most effective and efficient means of reaching other age groups within integrated health service provision. New platforms are urgently needed to reach people during the second-year-of-life, childhood, adolescence, pregnancy, and into later adulthood. (report page 21)

**Recommendation: Resolve barriers to timely supply of affordable vaccines in humanitarian crisis situations.**
International agencies, donors, vaccine manufacturers and national governments must work together to alleviate the financial burden placed on countries to buy and deliver vaccines for displaced populations at high risk of vaccine-preventable diseases and ensure a timely supply of affordable vaccines in humanitarian crisis situations (report page 23)