



**70<sup>th</sup> WHO World Health Assembly (WHA) – 22-31<sup>st</sup> May 2017**  
**Médecins Sans Frontières (MSF) briefing on provisional agenda item 14.1,**  
**Global Vaccine Action Plan (GVAP)**  
**Document A70/25**

**Background**

**At the 2015 WHO World Health Assembly, more than 50 countries raised their concern about high vaccine prices and adopted a landmark resolution (WHA68.6) calling for improved vaccine price transparency and greater vaccine affordability.** The resolution, which was largely led by governments that are struggling to afford new vaccines because they don't benefit from donor financial support (such as from Gavi, the Vaccine Alliance), nor do they have access to affordable prices, was a direct reaction to the rising cost to immunize a child: between 2001-2014, the cost of the minimum WHO-recommended package of vaccines (including 6 vaccines in 2001 and 12 in 2014<sup>1</sup>) increased from US\$ 0.67 to US\$ 32.09 - US\$ 45.59<sup>2</sup>. The significant cost increase is mainly due to the inclusion of new and expensive vaccines such as Rotavirus, Human Papillomavirus (HPV) and Pneumococcal Conjugate vaccines (PCV); these three vaccines accounted for 86% of the total cost of the vaccines package in 2014 (The Right Shot report, MSF 2015<sup>3</sup>).

**In reaction to rising vaccine prices, the 2015 resolution (WHA68.6 – see annex) was introduced by Libya, eventually co-sponsored by 17 governments, and ultimately adopted by all member states of the WHO.** The resolution called on the WHO and other global health partners to improve vaccine affordability through a variety of interventions, including:

- 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 robust competition.

Following the adoption of resolution 68.6, MSF has been working closely with global health actors and a number of governments to specifically try to reduce the price of pneumococcal conjugate vaccines (PCVs) for both humanitarian organizations as well as governments. This collective effort has had an impact: in late 2016, the two manufacturers of PCV (Pfizer and GlaxoSmithKline) committed to offer the lowest global price for the vaccine (the Gavi price) to humanitarian organizations working to vaccinate children caught in humanitarian crises. **This is good news but a lot remains to be done in order to secure the lowest global price for PCV for all low- and middle-income countries.**

We have reached the mid-point of the Decade of Vaccines (2011-2020) and progress towards the objectives of the Global Vaccine Action Plan (GVAP) is greatly off track. At this year's 70<sup>th</sup> WHA, member states are

<sup>1</sup> Tuberculosis, measles, diphtheria, tetanus, pertussis and poliomyelitis in 2011 / + rubella, hepatitis B, *Haemophilus Influenzae* type B, pneumococcal diseases, rotavirus and, for adolescent girls, human papillomavirus (HPV).

<sup>2</sup> US\$ 45.59 when three doses of HPV are included for girls.

<sup>3</sup> <https://www.msfacecess.org/content/right-shot-bringing-down-barriers-affordable-and-adapted-vaccines>

invited to note the GVAP progress report and to consider the recommendations for action.<sup>4</sup> **Additionally, a resolution was introduced at the 140<sup>th</sup> Executive Board in January 2017 by Australia, Brazil and Colombia<sup>5</sup> by that is currently under discussion by member states. MSF recommends member states work to ensure this draft resolution includes language that will continue to advance measures to bring vaccine prices down.**

### **Global Vaccine Action Plan (GVAP) draft resolution – MSF’s recommendations for its improvement**

As we have reached the mid-way point of the Decade of Vaccines, the draft resolution circulated at the 140<sup>th</sup> Executive Board is intended to reinvigorate progress towards the GVAP targets. The draft resolution has thus far focused on the role of member states in improving their work to advance towards the GVAP objectives, and centered largely on calling for member states to increase domestic resources for immunization, improve accountability for immunization programmes and data, and improve surveillance systems. While these are important elements, MSF believes that we must not lose sight of a key barrier to improving access to vaccines: price. Language that calls on the global community to improve vaccine affordability has thus far essentially been left out of the draft resolution.

MSF therefore suggests that in lead up to the 2017 WHA, member states work to incorporate language in the draft resolution that will address the need for more affordable vaccines.

**1. Member states can highlight the different concerns expressed in 2015 regarding high vaccine prices which unfortunately have not yet been addressed:** limited access to newer and improved vaccines due to their high price, lack of vaccine price transparency (now especially at vaccine manufacturer level), and lack of competition (which is proven to lower vaccine prices).

**2. More specifically, 3 areas of work should be included in the new 2017 resolution with clear requested actions:**

- **Vaccine price transparency**

#### **Action requested:**

Members states should acknowledge the success of the WHO’s global database on vaccine prices (Vaccine Product, Price and Procurement - V3P) and **request the WHO Secretariat to maintain its role as facilitating and administering this database.** Member states should also commit to sharing their vaccine price data with V3P if not doing so already, and using the tool more widely.

- **Middle Income Countries (MICs) support**

The 2015 resolution (68.6) had a clear request to the WHO Director General: “(1): to explore ways to mobilize funding to fully support collaborative efforts with international partners, donors and vaccine manufacturers in order to support low- and middle-income countries in accessing affordable vaccines of assured quality in adequate supply.”

Unfortunately, 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.

Furthermore, many MICs in the world are also facing additional pressure to their public health expenditure related to the large influx of refugees. Global institutions are not actively engaging in ensuring more affordable prices, despite this additional pressure on government vaccine budgets.

<sup>4</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/WHA70/A70\\_25-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_25-en.pdf)

<sup>5</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/EB140/B140\\_CONF2-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_CONF2-en.pdf)

**Action requested:**

Member states should call on the WHO Secretariat to reconstitute a group to work specifically towards increasing vaccine affordability for Middle Income Countries; working on advancing pooled procurement mechanisms (that can lower vaccine prices through economies of scale); and coordinating member states and other donors to resource this area of work.

- **Accelerate competition for PCV vaccine**

The 2015 resolution (68.6) included two (2) requests to the WHO Director General:

(5): “to strengthen the WHO prequalification programme and provide technical assistance to support developing countries in capacity building for research and development, technology transfer, and other upstream to downstream vaccine development and manufacturing strategies that foster proper competition for a healthy vaccine market”; and

(6): “to report upon technical, procedural and legal barriers that may undermine robust competition that can enable price reductions for new vaccines, and address other factors that can adversely affect the availability of vaccines.”

**Action requested:**

Member states should call on the WHO (Regulation of Medicines and other Health Technologies Unit) to take the necessary measures to **ensure that promising Pneumococcal Conjugate Vaccine (PCV) candidates from developing country manufacturers are being prioritized** in the technical and regulatory support provided by WHO to 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’ entry to market.

Furthermore, the **WHO Collaborative Registration Procedure**<sup>6</sup> for vaccines needs to be further advertised and promoted by WHO as an effective means to accelerate national registrations of vaccines subsequent to their WHO prequalification at national level. Member states, through their National Regulatory Authorities, should consider joining this collaborative procedure and sign the corresponding agreement with the WHO.

Finally, WHO should examine relevant intellectual property barriers that may hinder competition for new vaccines, including generating patent landscapes of relevant vaccines and introducing recommendations for strategies to address such intellectual property barriers that are consistent with the WHO Global Strategy and Plan of Action on Public Health under Resolution 61.21 and Resolution 62.16.

**MSF believes that these clear asks should be added to the resolution under development, through an official request from individual governments or a working group on behalf of their respective region. We appeal to your honorable government representatives to advance the work on vaccine affordability by working to include the above points in the 2017 GVAP resolution.**

**For further information and support on both the upcoming WHA resolution and the PCV Price Negotiation Toolkit, please contact:**

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<sup>6</sup> <http://apps.who.int/medicinedocs/en/m/abstract/Js22405en/>

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## **Resolution WHA68.6 Global vaccine action plan<sup>7</sup>**

### SIXTY-EIGHTH WORLD HEALTH ASSEMBLY

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The Sixty-eighth World Health Assembly,

Having considered the report on the global vaccine action plan;<sup>8</sup>

Emphasizing the importance of immunization as one of the most effective interventions in public health and access to immunization as a key step towards access to health and universal health coverage;

Acknowledging the progress made in global immunization and the commitment under the Decade of Vaccines (2011–2020) to achieve immunization goals and milestones;

Recalling resolutions WHA58.15 and WHA61.15 on the global immunization strategy, resolution WHA65.17 on the global vaccine action plan, resolution WHA61.21 on the global strategy and plan of action on public health, innovation and intellectual property, resolution WHA54.11 on the WHO medicines strategy, and resolution WHA67.20 on regulatory system strengthening for medical products;

Noting with concern that, globally, immunization coverage has increased only marginally since the late 2000s, and that in 2013 more than 21 million children under one year of age did not complete the three-dose schedule of diphtheria-tetanus-pertussis vaccination;

Recognizing that the availability of new vaccines against important causes of vaccine-preventable diseases such as pneumonia, diarrhoea and cervical cancer can prevent leading causes of childhood or women's death;

Acknowledging that successful national immunization programmes require sustainable political and financial support of Member States;

Appreciating the contributions of WHO, UNICEF, The Gavi Alliance and all partners in their efforts to support the introduction of new vaccines in developing countries and strengthen immunization services;

Concerned that inequities between Member States are growing, inter alia, owing to the increased financial burden of new vaccines and the status of eligibility or ineligibility for financial and technical support from global partners;

Concerned that many low- and middle-income countries may not have the opportunity to access newer and improved vaccines, particularly because of the costs related to the procurement and introduction of these vaccines; and concerned at the increase of costs of overall immunization programmes because of the increase in price of the WHO-recommended vaccines;

Recognizing that publicly available data on vaccine prices are scarce, and that the availability of price information is important for facilitating Member States' efforts towards the introduction of new vaccines;

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<sup>7</sup> See Annex 8 for the financial and administrative implications for the Secretariat of this resolution.

<sup>8</sup> Document A68/30.

Recalling many Member States' interventions on the Health Assembly's agenda item on immunization each year, in which they express concern over the unaffordable cost of new vaccines, and appealing to the global community to support strategies that will reduce prices;

Recalling the WHO global framework for expanding access to essential medicines, and its four components: the rational selection and use of medicines, reliable health and supply systems, sustainable financing, and affordable prices;

Taking into account the importance of competition to reduce prices and the need to expand the number of manufacturers, particularly in developing countries, that can produce WHO-prequalified vaccines and create a competitive market;

Stressing the crucial life-saving role of vaccines and immunization programmes and striving to make immunization available to all;

Noting with concern the global shortage of certain traditional routine vaccines, for example BCG vaccine and combined measles-rubella vaccine;

Acknowledging that shortages of vaccines are quite often an important cause of disruption of vaccination schedules and that therefore the establishment of effective and sustainable vaccine production, supply, procurement and delivery systems is essential to ensure access to all the necessary vaccines of assured quality at the right time;

Concerned that scepticism about vaccination is continuing to grow in society despite the proven efficacy and safety of modern vaccines, and that many children do not receive life-saving vaccines as a result of insufficient information to parents or health care workers or even of active anti-vaccination propaganda,

1. URGES Member States:<sup>9</sup>

- (1) to allocate adequate financial and human resources for the introduction of vaccines into national immunization schedules and for sustaining strong immunization programmes in accordance with national priorities;
- (2) to strengthen efforts, as and where appropriate, for pooling vaccine-procurement volumes in regional and interregional or other groupings, as appropriate, that will increase affordability by leveraging economies of scale;
- (3) to provide, where possible and available, timely vaccine price data to WHO for publication, with the goal of increasing affordability through improved price transparency, particularly for new vaccines;
- (4) to seek opportunities for establishing national and regional vaccine manufacturing capacity, in accordance with national priorities, that can produce vaccines to national regulatory standards, including WHO prequalification;
- (5) to create mechanisms to increase the availability of comparable information on government funding for vaccine development and work towards strategies that enhance public health benefit from government investments in vaccine development;
- (6) to support the ongoing efforts of various partners coordinated by WHO to design and implement the strategies to address the vaccine and immunization gaps faced by the low- and middle-income countries that request support;

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<sup>9</sup> And, where applicable, regional economic integration organizations.

(7) to improve and sustain vaccine purchasing and delivery systems in order to promote the uninterrupted and affordable safe supply of all the necessary vaccines and their availability to all immunization service providers;

(8) to strengthen immunization advocacy and provide training to health professionals and information to the public regarding immunization issues in order to achieve a clear understanding of the benefits and risks of immunization;

2. REQUESTS the Director-General:

(1) to explore ways to mobilize funding to fully support collaborative efforts with international partners, donors and vaccine manufacturers in order to support low- and middle-income countries in accessing affordable vaccines of assured quality in adequate supply;

(2) to continue developing and adequately managing publicly available databases on vaccine prices, such as that in WHO's Vaccine Product, Price and Procurement web platform, and working with Member States to increase availability of price information;

(3) to monitor vaccine prices through annual reporting of the global vaccine action plan;

(4) to provide technical support and facilitate financial resources for establishing pooled procurement mechanisms, where appropriate, for use by Member States;

(5) to strengthen the WHO prequalification programme and provide technical assistance to support developing countries in capacity building for research and development, technology transfer, and other upstream to downstream vaccine development and manufacturing strategies that foster proper competition for a healthy vaccine market;

(6) to report on technical, procedural and legal barriers that may undermine the robust competition that can enable price reductions for new vaccines, and address other factors that can adversely affect the availability of vaccines;

(7) to assist in mobilizing resources for countries that request support in the introduction of new vaccines in line with the global vaccine action plan and in accordance with national priorities;

(8) to continue to provide support to Member States to improve and sustain their vaccine delivery systems and to continue to provide technical support to Member States to strengthen the knowledge and skills of their health care professionals in vaccination programmes;

(9) to report on progress in implementing this resolution to the Health Assembly through the Executive Board in the annual report on the global vaccine action plan.

(Ninth plenary meeting, 26 May 2015 –  
Committee A, fifth report)