Executive Board, 140th Session, 2017
Agenda Item: 7.1
Heath Emergencies and WHO Reform: A reality check

Two years have passed since the peak of the West Africa Ebola epidemic that revealed the deficiencies and limitations of the global health system in the face of a virulent, lethal disease. While some actions have been taken towards the reform of WHO in emergencies – in particular the creation of the WHO Health Emergencies Program and the strengthening of the International Health Regulations and the establishment of a new blueprint to coordinate research and development for emerging infectious diseases – demonstrable improvements have not yet materialised in practice. There remains an imbalance in the system, with an overreliance on surveillance mechanisms and insufficient emphasis on response capacity. To achieve concrete change, Member States must overcome their lack of political will, dedicate sufficient and sustainable financing for emergency response, and push for change in the internal organisational culture of WHO.

Furthermore, four main challenges MSF witnessed in Ebola have yet to be properly addressed:

- Lack of positive incentives to declare health emergencies;
- Insufficient or inappropriate medical leadership in emergencies;
- Lack of responders with appropriate surge capabilities and technical expertise;
- Failure to meet real time needs for diagnostics and treatments with the assurance that emerging products are affordable and available to all in need.

Reality check

If the current response to emergencies is taken as the indicator of progress, then the reality is that we still have a long way to go. We are collectively still struggling to respond to outbreaks and other health emergencies on the ground. From MSF's point of view from the field, two emergencies last year highlighted the ongoing difficulties to meet these challenges, both of which brought to bear serious consequences on the health of the affected populations.

Epidemics: Yellow fever in Angola and Democratic Republic of Congo (DRC)

On the heels of the Ebola outbreak came the resurgence of yellow fever in Angola in December 2015. The outbreak spread from the urban capital, Luanda, throughout the country and then internationally, to neighbouring DRC. Yellow fever is a well-known disease for which an efficacious and affordable vaccine has existed for the past 80 years, and is since used in the prevention and control strategy launched in 2007. In theory, no one should be dying from yellow fever today. Yet the disease spread across two countries and required huge vaccination campaigns to be halted, in part by stretching supplies with diluted doses of the limited vaccines available.

The risk of re-emergence of yellow fever has been a red flag for more than a decade. With limited vaccine supplies and producers, catch-up vaccination campaigns could not happen simultaneously, nor at scale, across sub-Saharan African countries at risk, leaving large swathes of people unprotected from the disease.

It took six weeks for the identification and confirmation of cases in Angola, demonstrating yet again that **weak diagnostic capacity** in the region remains a key challenge. The ability to conduct polymerase chain reaction (PCR) or plaque reduction neutralisation (PRN) tests is only possible in a few reference labs in Africa. Mobile labs should be dispatched much more quickly in an emergency when it is clear diagnostic capacity is limited or risk struggling against the epidemic in the dark.

The delay in recognising the disease, coupled with the inability to quickly diagnose cases and then reactively vaccinate, allowed yellow fever to take hold in the capital city and then spread. Once cases were confirmed and the outbreak was declared, it took more than eight weeks to launch the first phases of mass vaccination campaigns and more than three months since the initial cases to implement full outbreak control measures. The delay was partially linked to the **limited global stockpile of vaccines**, but not only. It is important to note the role of a failure to immunise within the Expanded Program on Immunization in this outbreak, despite the introduction of routine infant yellow fever vaccination in Angola and DRC, coverage have been so low that a large proportion of the birth cohort remained susceptible and at high risk for epidemics.

The incident management system (IMS), under the new WHO Emergency Programme, was activated only in April once two countries were already affected. The outbreak was ongoing for nearly five months before the Emergency Committee under the International Health Regulations was convened in May. International attention focused on the Zika epidemic also meant that the yellow fever outbreak went largely unnoticed in the first months. This outbreak again lay bare that **leadership roles still must be clarified** between national and international health authorities.

Northeast Nigeria: Mass displacement, high crude mortality rates, and a late response

Seven years of violent conflict in northeast Nigeria has left at least 20,000 people dead and has displaced more than 2.6 million people from their homes. The severity of the crisis in Borno State reached a catastrophic peak in the summer and autumn of 2016. In June an MSF team in Bama undertook a rapid nutritional screening of more than 800 children and found that 19 percent were suffering from severe acute malnutrition (SAM). In July, MSF teams working in Banki undertook a similar survey to find that one in twelve children had died and that one in fifteen children had severe acute malnutrition. In September, an MSF team in Ngala found that one in ten children had SAM.

Recently humanitarian assistance has increased and fragile gains have been made in reducing mortality in accessible areas. However, international recognition of the scale of the crisis came much too late. The WHO supports a polio programme in the region that it states is able to reach communities that others could not due to the high insecurity. Yet the single-minded focus on polio eradication in the early days of the response was a missed opportunity to raise attention early on and tackle the increasingly dire nutrition and health crisis affecting the region. While outbreak risks such as polio certainly must be addressed, attention to other major morbidities like malaria and vaccine preventable diseases in malnourished children as measles, pneumonia and cholera should run in parallel, especially when access is extremely

restricted. Recognition of all needs and proper prioritisation require **strong and unbiased medical leadership.** Response should be adapted and adjusted in a timely manner as doing otherwise leads to wasted resources and opportunities that cause more lives lost than necessary.

The way forward

1. *Effective WHO coordination and leadership in responding to emergencies*
   The WHO must be first in line to demonstrate leadership in health. However, leadership cannot be imposed – it must be earned. The normative role of WHO has never been in question, but WHO must prove its leadership ability in epidemics. This requires sustained political and financial support. Without the strong buy-in and ownership of Member States and their recognition that WHO should be able to confront Member States when necessary to assure timely and effective emergency interventions, the programme will fail.

   - The success of the new WHO Health Emergencies Program also relies on WHO representatives and country offices and their responsibility to implement and facilitate its activities. Strong representatives at all levels with solid experience should be at the helm. MSF urges that concrete and rapid response to emergencies is prioritised and not given a backseat to the *en vogue* discourse of preparedness and IHR implementation. In cannot be stated enough that while having posts properly filled at central or headquarter or even regional levels is important, effective and timely response demands the right personnel on the ground. MSF strongly agrees with the Independent Oversight and Advisory Committee that recruitment at country levels should be expedited and prioritised.
   - The inclusion of infectious diseases events leading to IASC Level 3 activation may be a positive initiative to ensure a more effective response. However medical leadership must remain with an organisation with a health mandate. MSF will remain attentive and flag any negative consequences.

2. *Optimal partnerships and quality response*
   A number of steps have been taken thus far to implement the Health Emergencies Program through the prioritisation of platforms such as the Global Health Cluster and the Global Outbreak Alert and Response Network (GOARN), as well initiatives on specialised responders such as the Emergency Medical Teams (EMT). The primary focus of these mechanisms is to ensure a proper and effective response to health emergencies. Faced with a variety and multiplication of potential coordination and surge bodies, the right balance will have to be found between enabling the intervention of responders while not adding coordination layers of organisational burden. Teams deployed must meet the needs on the ground of the people directly affected. The Incident Management System has to be customised and adjusted according to the needs of the communities and should be inclusive in harnessing the active contribution of the community and its local capacity. Ultimately, specific attention should be paid to ensuring that there is space for independent assessment and action to fill potential gaps.

3. *Research and Development in epidemic response*
   MSF supports the efforts of WHO to establish the WHO Blueprint for Research and Development for potentially epidemic diseases and its affiliated activities. At present, MSF would like to highlight four areas for additional clarification from the Secretariat as implementation of the Blueprint continues:

i. Coherence with the Consultative Expert Working Group (CEWG) and the Nagoya Protocol: MSF would like to ensure that principles included within the reports and resolutions related to the CEWG are integrated into the WHO Blueprint. In particular, it is critical that R&D under the Blueprint is 'de-linked, needs-driven, evidence-based, considered a shared responsibility' and thereby ensures affordability, efficacy and equity of developed products. In particular, WHO should clarify two particular aspects of the Blueprint:

- To what extent are platform technologies selected under the WHO Blueprint applying standards established under the CEWG (in particular as it relates to intellectual property and affordability)?
- What are the relevant access standards that are being integrated into disease roadmaps for priority pathogens for the Blueprint? In particular, how will the Blueprint ensure new technologies will be made widely affordable and available to populations in need?

As noted in the report to the Executive Board, the Secretariat is in the process of developing material transfer agreement (MTA) templates for use in subsequent emergencies. Overall, MSF supports pragmatic efforts to template MTA. However, it is critical that WHO prioritises and accelerates discussions on the implementation and use of the Nagoya Protocol to govern such material transfer agreements and ensures that developing countries have the ability to ensure such template MTAs are consistent with evolving laws and standards related to the use and transfer of biological samples.

ii. Developing country and civil society representation: MSF hopes that as the Blueprint continues to evolve, there will be greater efforts by the Secretariat to expand and encourage representation from affected countries, civil society organisations and other developing countries for all activities under the WHO Blueprint, including the development of the Global Coordination Mechanism and various forms of standard-setting.

iii. Coalition for Epidemic Preparedness Innovations (CEPI): WHO is currently an Observer of CEPI – a new vaccine R&D partnership that seeks to finance and facilitate the development of vaccines to address emerging infectious diseases included in the Blueprint (MSF is an interim Board Member). At present, the precise relationship between the Blueprint and CEPI has not been defined. More urgently, MSF has two particular concerns:

- CEPI access standards: CEPI is in the process of finalising access standards that will apply to all R&D grants that CEPI awards. MSF is concerned that the final standards established by CEPI will not meet the goals and expectations of the CEWG – including in particular the possibility that CEPI will encourage tiered prices for developing countries, and that CEPI will not ensure that intellectual property is available on a non-exclusive basis for use by third parties to ensure the affordable and appropriate development of target vaccines.

- Role and influence of the pharmaceutical industry: At present, multiple pharmaceutical companies are on the Board of CEPI and are also actively playing a role in various decision-making and technical bodies run by CEPI.

While a balanced presence of these companies might be necessary, their current involvement in setting rules even when conflicts of interest are openly acknowledged, undermines the ability of CEPI to uphold public health standards and results in difficulties in adopting acceptable access terms. It should also lead WHO to carefully evaluate its role as an Observer and to consider the ramifications of any close link between CEPI and the WHO Blueprint.

iv. Regulatory capacity: Introducing a regulatory pathway to develop and approve medical tools for infectious diseases remains a critical challenge. MSF hopes that WHO, through the Blueprint, will continue to build upon and expand the use of the Emergency Use Assessment and Listing (EUAL) as a means to provide during outbreaks conditional use of medical tools that are not fully approved. Yet beyond the EUAL and the WHO Prequalification Program (PQP), WHO should seek to develop its own independent capacity to provide conditional approvals for medical tools. Furthermore, WHO should be allowed to exercise such regulatory capacity even when a public health emergency of international concern has not been declared. Such measures can help to safeguard the independence of WHO while also ensuring that tool development progresses in a timely fashion so that they are available for use during emergency and outbreak response.

In conclusion, in an age of complex emergencies that are becoming more and more severe and frequent, the one-size-fits-all model no longer works. Response must be tailored, customised and adapted according to the needs at hand. This requires not only the unwavering commitment of all actors and responders on the ground but also, and most critically, it demands the strong political will of the Member States, without which the system is doomed to fail.

WHO Executive Board, 140th Session 2017
Agenda Item: 7.2 (EB 140/11)
Antimicrobial Resistance (AMR)

Two years ago at the Sixty-Eight World Health Assembly (WHA), Member States agreed to the Global Action Plan (GAP) on antimicrobial resistance (AMR) that contains the blueprint for Member States and the WHO to address the public health challenges caused by AMR. Last year, in September 2016 at a United Nations High Level Meeting, Member States reiterated these commitments and deepened them by adopting a High Level Political Declaration on AMR that MSF welcomed.

Médecins Sans Frontières (MSF) witnesses, first-hand, the emergence of antimicrobial resistance in a wide range of its operational contexts.

The adoption of the GAP and the Political Declaration were important political steps towards recognizing the systemic challenges causing and resulting from AMR. Success now depends on the full and timely implementation by WHO and Member States of these commitments with appropriate resources and accountability. The response must recognize the multifactorial nature of AMR with a public health driven agenda that puts the needs of patients and health workers at the core of the AMR response.

During the 2017 140th session of the Executive Board and 70th World Health Assembly, MSF calls WHO and Member States to transform words into action. Now the focus has to turn to urgently and fully implementing these commitments through the development, funding and execution of national action plans as well as normative and regulatory frameworks, including a global framework for development and stewardship to ensure needs-driven innovation, affordable and sustainable access to existing and new health technologies.

Specifically, MSF recommends Member States and WHO to:

1. Provide increased monitoring and surveillance to bridge the gap in knowledge regarding the extent, types and burden of antibiotic resistance, especially in countries and areas with limited resources or poor health infrastructure.

2. Recognize and address the multiple reasons for the development of AMR, including the inappropriate use of medicines, the lack of access to diagnostics and other health technologies, and inadequate medical strategies in under-resourced health systems.
    - Policies and regulations to promote optimal use of antimicrobials must be tailored to the diversity of country contexts. In developing countries where MSF mostly works there is an overall need to:
        a) increase microbiology laboratory capacity and context-adapted diagnostics in order to target antibacterial therapy and to document types and rates of resistance,
        b) improve infection prevention and control in medical settings to reduce burden of infection and transmission, and

c) provide training and support for healthcare workers in the appropriate prescription and use of antibiotics.

- Recognize that high prices and barriers to access are an inappropriate way to achieve stewardship and rational use of antibiotics as it impacts patient care. Countries need to increase access to suitable, affordable and effective medical tools to facilitate effective prevention, diagnosis and treatment strategies. Recommendations and measures included in the Global Vaccine Action Plan should be taken into account both by the Secretariat and Member States. As an example, increasing affordable access and therefore coverage of both Pneumococcal Conjugate Vaccine (PCV) and rotavirus vaccine are essential tools to reduce mortality and prevent the unnecessary use of antibiotics. It has been estimated that universal PCV coverage would avert up to 11.4 million days of antibiotic use for pneumonia in <5 year old children per year. MSF welcomes the GSK/Pfizer commitment to reduce the price of PCV to MSF and NGOs working in humanitarian contexts and asks for price reductions to be extended to all governments.

- Prioritise the implementation of strategies agreed within the WHO Global Plan of Action on Public Health, Innovation, and Intellectual Property and the WHO resolutions on the Follow up to the CEWG report in ensuring innovation, affordability and access to existing and new diagnostics, drugs and vaccines.

3. Acknowledge that a global and comprehensive AMR response must ensure that the needs of neglected patients are not further forgotten. MSF welcomes the special recognition of drug-resistant tuberculosis (DR-TB) in the UN political declaration and the Member States decision to host a UN High Level Meeting on TB in 2018. As the largest non-governmental provider of DR-TB treatment worldwide, MSF data shows that countries need to step up in the prevention, diagnosis and treatment of DR-TB by updating national policies and practices, while pharmaceutical companies must take clear and concrete steps to increase affordable access to newer drugs.

4. After two decades of private sector under-investment and withdrawal from research and development to address AMR, Member States should recognize that the current research and development (R&D) model has failed to deliver the necessary tools to combat AMR. As a result, medical treatment providers, like MSF, do not have the medical tools needed to diagnose, prevent and provide appropriate treatment for our patients and the pipeline of new drugs is nearly empty. MSF is encouraged to see that the UN Political Declaration on AMR builds on the recommendations of the recent report of the UN Secretary General High Level Panel on Access to Medicines in recognizing the failures of the current medical research and development system and commits Member States to incorporate strong R&D and public health commitments to try to ensure that the new antibiotics, vaccines and diagnostics we urgently need to curb bacterial resistance are available and affordable for all who need them. Governments now need to ensure that any new incentive and funding for innovation coming from public or philanthropic sources fully delinks R & D costs from prices and sales, and start negotiating a global framework on biomedical innovation to ensure that research priorities will be driven by patient and public health needs and that public investment on R&D achieve optimal public health outcomes.

Executive Board, 140th Session, 2017
Agenda Item:8.3
Addressing the global shortage of medicines and vaccines

Background

Shortages and stock outs of medicines, vaccines and diagnostics continue to be a challenge that MSF encounters every day in our operational settings. Shortages and stock outs have an unacceptable and preventable impact on patients around the world, as they lead to delays in treatment initiation, use of inferior treatment choices and treatment interruptions resulting in poor health outcomes. Stock outs also have broader public health implications. For treatment of HIV, TB and other infectious diseases stock outs lead to antimicrobial resistance and the spread of these resistant strains. Furthermore, patients confronted with stock outs are likely to lose trust in the health system and could turn to less appropriate or less affordable sources of medicines. For health care workers already challenged in difficult settings, stock outs and shortages create additional workload and are a source of frustration.

In an environment where donors are transitioning low and middle income countries (wherein donors and global health funds have played a critical role managing supply), and with the increased focus of drug companies – branded and generic – on more lucrative products without any plan to ensure sustainability of product lines and transitioning strategies for treatment of HIV to new products, supply chains will continue to be pressured and affected, requiring the support of the Secretariat and donors to accelerate and expand on the aims of the resolution.

Feedback on Secretariat Report and progress to date

MSF welcomes the resolution passed during last year's World Health Assembly (WHA) on addressing the global shortage of medicines and vaccines[1].

Based on the Secretariat report, there has been little to no progress on resolution and the requests to the Director General from last year's resolution. Thus far, WHO has commissioned a systematic review and held a preliminary consultation that provided draft technical definitions and committed to further consultation in 2017. From this report, any progress in the area of vaccines is unclear.

MSF also has the following concerns with last year's Resolution and actions taken since last year:

[1] Requests of WHA Resolution: to develop technical definitions, as needed, for medicines and vaccines shortages and stockouts, taking due account of access and affordability in consultation with Member State experts in keeping with WHO-established processes, and to submit a report on the definitions to the Seventieth World Health Assembly, through the Executive Board;

1. to develop an assessment of the magnitude and nature of the problem of shortages of medicines and vaccines;
2. to support Member States in addressing the global challenges of medicines and vaccines shortages by developing a global medicine shortage notification system that would include information to better detect and understand the causes of medicines shortages;
3. to report on progress on, and outcomes of, the implementation of this resolution to the Seventy-first World Health Assembly.

Reference: http://apps.who.int/medicinedocs/en/d/Js22423en/

1. Few tangible interventions have been implemented in countries where MSF works to create national early warning mechanisms to prevent stock outs or shortages. As opposed to manufacturing shortages causing stock outs in developed countries with efficient supply networks, MSF experience shows that most stock outs affecting patients in low resource settings are resulting from logistical challenges in country and funding to improve those, lack of reliable data and limited accountability[2].
2. The unbalanced focus of the resolution on global manufacturing issues presents an inaccurate picture to public health agencies and policy makers. In addition, patients in the countries that are most affected seem to have been left out of the discussions. While global supply chain actors, such as the Global Fund, are showing increasing interest to ensure end-to-end delivery of medicines, implementation has been slow and countries like Guinea, Mozambique and DRC still do not have regular delivery of medicines to health centres. Inevitably, when in-country consumption data management and supply planning improve, there is a substantial impact on national and global forecast planning and thus a reduction of shortages.
3. MSF is also concerned that the draft definitions of stockouts and shortages in the Secretariat report are already too complex. The final definitions of each should be simple and applicable to any part of the supply chain system, regardless of being related to manufacturer, distribution or in-country supply chain difficulties. Situation-specific variables are part of the root cause analysis and solution implementation, and should not be included in the definitions as they will impede progress if too complicated from the outset. The most critical definitions, i.e. stock outs at patient level and the impact on individuals and health outcomes have been given little mention. Similarly, while global and national notification systems form part of the ambitions of the resolution, patient level notification is not included.
4. The resolution falls short of including a mechanism for a rapid response that would coordinate actors at the global, regional, national, and end-user level during critical periods to avoid global or end-user shortages. It should also be noted that the global shortage notification system does not include vaccines or diagnostics, both of which should be added.
5. The role of patients remains unclear or ignored in the resolution and follow up. Patients play a critical role in these notification systems. With simple technology, they can alert when stockouts are occurring, and provide the necessary data to inform the supply actors. Experience of civil society in Southern Africa with the Stop StockOuts[3] program and in Central Africa shows that patients as independent observers, are essential to highlight failures in the supply system, that are otherwise not reported through the regular paths, and hence trigger the solutions.

While the work on this resolution has been off to a slow start, likely due to insufficient funding and resourcing, there are areas where WHO could facilitate measures to support Member States who are interested in beginning in-country work to improve the stockout and shortages situations in their countries. Thus, MSF would like to offer some specific recommendations on some immediate measures that can be taken forward:

1. The pending assessment by WHO of the magnitude and nature of the problem of shortages of medicines and vaccines should assess the intellectual property barriers that restrict market access for multiple suppliers worldwide or suppliers for any particular country. In South Africa in 2015, for example, lopinavir/ritonavir (LPV/r) was supplied by only one company, Abbvie, which holds a patent on the drug. In 2015, demand for LPV/r exceeded forecasted amounts in South Africa, and for over six months, Abbvie

[2] SSP report + Empty Shelves :
1. https://www.doctorswithoutborders.org/sites/usa/files/msf_out_of_stocks_low_per_pages.pdf
2. http://www.stockouts.org/uploads/3/3/1/1/3311088/2015_stock_outs_national_survey.pdf

[3] http://www.stockouts.org/uploads/3/3/1/1/3311088/2015_stock_outs_national_survey.pdf

was unable to supply adequate quantities, leaving patients to return home without medicines in South Africa and reportedly in other countries. Shortages were also reported in other countries using Abbvie's LPV/r product. While cutting supplies to South Africa and other countries in the region, supplies to non-African markets, presenting a larger profit margin, continued. Generic suppliers registered locally in South Africa were unable to supply due to the patent barrier, and had limited stocks on hand to supply and support other countries facing LPV/r shortages. Countries should be supported to improve their intellectual property laws, including laws related to compulsory licensing and parallel importation, to take steps to alleviate shortages.

2. WHO could easily connect Member States with experience in implementing global medicine shortages notification systems with other countries prepared to work on this, in a bilateral manner that would require minimum effort and funds by WHO.
3. While the resolution calls upon manufacturers, wholesalers, global and regional procurement agencies and other stakeholders to contribute by participation in notification systems, it seems to be voluntary and stops short of holding them accountable for their responsibilities to patients. Further work in this area should include empowering countries and National Drug Regulatory Authorities to implement regulations to require reporting of shortages and stockouts by manufacturers to allow time for mitigation strategies. These exceptional measures could include fast-track registration procedures, compulsory licensing and collaborative registration programs.

Executive Board, 140th Session, 2017
Agenda Item 9.1 (EB140/25) – Global Vaccine Action Plan

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

[1] Resolution 65.17 - http://www.who.int/immunization/global_vaccine_action_plan/en/
[2] http://www.who.int/immunization/global_vaccine_action_plan/gvap_secretariat_report_2016.pdf?ua=1
The report is based upon data from 2015, the latest year for which data is available.
[3] http://www.who.int/immunization/global_vaccine_action_plan/SAGE_GVAP_Assessment_Report_2016_EN.pdf

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

[4] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R6-en.pdf
[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.
[6] WHO Recommendations on Delayed or Interrupted Immunization http://www.who.int/immunization/policy/Immunization_routine_table3.pdf

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

http://www.who.int/immunization/global_vaccine_action_plan/SAGE_GVAP_Assessment_Report_2016_EN.pdf

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)**