



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 vaccines¹.

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 accountability².
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 StockOuts³ 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.