
NOTIFICATION SYSTEMS FOR SHORTAGES AND STOCKOUTS OF MEDICINES AND VACCINES



Technical Consultation

MEETING REPORT

July 2017



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List of Acronyms

ACAME	African Association of Central Medical Stores for Essential Medicines
API	Active Pharmaceutical Ingredient
ART	Antiretroviral Therapy
CMS	Central Medical Stores
DOH	Department of Health
EML	WHO Model List of Essential Medicines
FIP	International Pharmaceutical Federation
GDF	Global Drug Facility
GSMS	Global Surveillance and Monitoring System
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
ICH	International Council for Harmonisation
IFPMA	International Federation of Pharmaceutical Manufacturers
MSF	Médecins sans Frontiers
MOH	Ministry of Health
NEML	National List of Essential Medicines
NMRA	National Medicines Regulatory Agency
PAHO	Pan American Health Organization
PQ	WHO Prequalification
PSM	Procurement and Supply Management
SF	Spurious and Falsified
SRA	Stringent Regulatory Authority
USFDA	United States Food and Drug Administration
VEN	Vital, Essential and Necessary
VEN	Vital, Essential and Non-Essential
WHO	World Health Organization

**Technical consultation on notification systems for
shortages and stockouts of medicines and vaccines
Geneva, Switzerland
26-27 July 2017**

Executive summary

In May 2016, WHO Member States adopted Resolution WHA69.25 *Addressing global shortages of medicines and vaccines*¹. The resolution highlights the problems that occur when essential medicines and vaccines are not sufficiently available in national health systems. Shortages and stockouts affect public health systems of countries of all income levels. Shortages are reported on the supply side as well as the demand side of medicines markets. Supply shortages, or insufficient supply at manufacturing levels, have been increasing in recent years. Demand side shortages remain a persistent problem and disproportionately affect countries with limited capacity in their procurement and supply chain management systems. The impact is increasingly serious, including higher medicine costs and poorer patient outcomes. Shortages and stockouts can also put patients in danger from inappropriate medication substitution as well as heighten risks for the infiltration of substandard and falsified products into the supply chain².

Resolution WHA69.25 calls for specific actions by stakeholders, including WHO to develop a “global medicine shortage notification system that would include information to better detect and understand the causes of medicines shortages.” National level reporting systems exist for shortages and stockouts, but only in a limited number of countries. A shortage in one country or region may predict or have a connection to problems elsewhere, highlighting the need for a global approach to manage this multi-faceted problem.

A technical consultation was hosted by WHO in July of 2017 at its Geneva headquarters offices to gather expert information on key components that should be included in a global notification system for shortages and stockouts of medicines and vaccines. The meeting was preceded by consultations in October of 2016 and December of 2015 to harmonize definitions of shortages and review the details of existing approaches^{3,4}.

Aligned with the objectives of the consultation, key points regarding the content and structure, definitions, key audiences and uptake options used in a reporting mechanism are summarized below.

The structure should account for existing systems and consolidate information to identify trends and problems earlier. A global reporting mechanism would not supplant existing national systems. It

¹ Addressing the global shortage of medicines and vaccines;
<http://apps.who.int/medicinedocs/documents/s22423en/s22423en.pdf>

² Blackstone, A; Fuhr, J; Pociask, S, The Health and Economic Effects of Counterfeit Drugs; *Am Health Drug Benefits*; 2014 June; 7(4)

³ Technical Consultation on Preventing and Managing Global Stockouts of Medicines.
http://www.who.int/medicines/areas/access/Medicines_Shortages.pdf

⁴ Meeting Report: Technical Definitions of Shortages and Stockouts of Medicines and Vaccines.
http://www.who.int/medicines/areas/access/Meeting_report_October_Shortages.pdf

would provide an option for countries that do not have reporting systems, as well as a mechanism to consolidate information from existing systems.

The content should focus on monitoring Essential Medicines as a first priority. A global reporting mechanism would initially encourage reporting of medicines currently on the WHO Model List of Essential Medicines (EML), national EMLs (NEML), or their prioritized subsets such as medicines and vaccines identified in Vital, Essential and Non-essential (VEN) analyses⁵.

Content management features should include clear inclusion criteria. In addition to the above criteria that discuss which medicines should be included, stockout and shortage reports should include the type, cause, and expected duration in order to facilitate appropriate solutions and responses. For example, challenges with Active Pharmaceutical Ingredients (API), regulatory decisions to withhold products from market for quality reasons, or insufficient manufacturing capacity all require different solutions. Similarly, demand side shortages have multiple root causes that may be related to sudden peaks in demand, forecast management challenges, or failures of procurement and supply management systems to secure adequate supply.

Target audiences should be those with access to national level information. The entities that participate in a reporting system should be trained and access should be limited to those recognized as having an official, national or international capacity to report, validate and respond. Entities would include regulatory and procurement authorities in countries, WHO, manufacturers and others as designated. It would not necessarily provide an open reporting platform for individuals, the value and interest in such reporting systems notwithstanding.

Engagement should include both incentives as well as adequate security and safeguards. To avoid abuse of the information, such as hoarding and price increases of medicines in shortage, the system should reserve certain details for approved participants and only make more general information visible publicly. This follows the practice of existing reporting mechanisms. For example, there could be a publically accessible “dashboard” with basic information, while data and analytics sections could be restricted to authorized users.

Uptake options should recognize training and resource implications. Training and access to information were recognized as the most useful incentives to promote uptake and use of the system. A desirable feature would include the ability to transfer information directly from other, existing systems to reduce any redundant activity for countries that already have formal reporting mechanisms.

Definitions used in the system should address data interoperability. Considering that a medicine might be reported in multiple countries and might also be subject of other reporting mechanisms, the reporting mechanism for shortages should be structured to allow for data to be easily combined and analysed. In addition, definitions of the type of shortage should correspond to definitions developed through earlier consultations.

⁵ Drugs and Therapeutic Committees: a practical guide. WHO Press 2003. Accessed August 2017.
<http://apps.who.int/medicinedocs/en/d/Js4882e/8.2.html#Js4882e.8.2>

Background on medicine shortages

The continuous supply of quality, safe, effective and affordable medicines is one of the building blocks of every well-functioning health system. Reports of shortages and stockouts at the manufacturing level have been increasing and have negative effects on health systems, such as increased costs, poorer patient outcomes and medication errors when other medicines are inappropriately substituted. Reported shortages include but are by no means limited to cancer medicines, important antibiotics as well as generic medicines for treating chronic conditions and several vaccines. The problem affects countries of all income levels.

The root causes of shortages and stockouts are complex and there can be multiple causes affecting the same medicine. For example, sudden increases in demand from an outbreak can create acute short-term shortages; however, if a production problem occurs at the same time, the problem could quickly become a stockout across multiple markets. Other examples of complicated situations include decisions around quality failures. If a National Medicine Regulatory Agencies (NMRA) detects a quality concern with a product, weighing the risks could include withholding a product and managing a temporary shortage.

Market dynamics are frequently an issue, such as the higher costs of maintaining supply channels in complex or fragmented markets. Prices that have been driven too low by excessive focus on low price, or factors such as competition for API, can also lead to manufacturers discontinuing production for financial reasons. Systemic problems with rigid procurement systems and poor supply chain data only exacerbate the market dynamics challenges. Even in cases where a shortage can be resolved, it may not be possible to do so in time to avoid a complete stockout and the resulting negative public health impact.

Solutions are available, such as consolidating procurement for small markets, promoting systems and policies that support longer term procurement contracts and the utilization of TRIPS flexibilities⁶ in cases of patented medicines. Specific programs have also succeeded in normalizing availability of medicines for the priority diseases of HIV, malaria and tuberculosis. However, these solutions take time, financial and technical resources as well as optimal market conditions to implement⁷.

National mechanisms exist for reporting shortages at the manufacturing, wholesale and distribution levels of the value chain. Systems that capture information on shortages at the manufacturing level exist in only a limited number of countries, mainly in those with Stringent Regulatory Authorities (SRA) or NMRAs with relatively advanced capacities. In those cases, manufacturers report anticipated shortages to the NMRA and participate in the development of strategies to avoid potential negative impact. It is important to recognize that these mechanisms are nationally focused

⁶ Trade, Intellectual Property rights and Access to Medicines addresses international trade agreements and impact on access to medicines. Additional information can be accessed on <http://www.who.int/medicines/areas/policy/globtrade/en/>

⁷ A WHO presentation in the meeting provided case studies situations where the efforts did not succeed due to competitive practices in the market.

and not necessarily intended to provide support to global or regional markets. They may not contain sufficient information on the scope, nature and other conditions about the shortage to predict indicate impact on other countries. An example is the report of asparaginase reported to the United States Food and Drug Administration (USFDA) ⁸, where it was reported in one country but was ultimately a shortage in countries throughout the Americas. If the shortage involved a multi-national manufacturer, it could be unclear whether they (or their competitors) had production capacity and market authorizations that would be sufficient to continue supplying to other countries.

Other mechanisms include information exchanges across wholesale and distribution levels. Examples include web sites where pharmacists and medicines wholesalers post information on shortages in their location. These systems provide valuable solutions, especially for short term problems, where pharmacies and distributors can facilitate inventory transfers; however, they tend to be informal and voluntary in nature, and information is not always validated or complete. In limited cases, they have also been associated with inappropriate use of the information, such as hoarding and price increases.

There is currently no facility or system at the global level to report anticipated or actual shortages, which limits options to identify solutions that would reduce potential negative impact. A global reporting mechanism, as requested in Resolution WHA69.25, will be critical in understanding root causes and developing adapted solutions for the increasing global problem of shortages and stockouts of medicines and vaccines.

Meeting Objectives

At the Sixty-ninth World Health Assembly, resolution WHA69.25 on addressing the global shortage of medicine and vaccines calls on WHO to develop strategies to improve global capacity to understand and respond to the problem of shortages. One of the specific requests is to develop a global notification system to better detect and understand the causes of shortages of medicines and vaccines⁹.

A technical consultation was hosted by WHO in July of 2017. The overall objectives of this meeting were to identify and review examples of existing systems, understand challenges from countries without reporting systems and identify areas critical to the development of a global notification system. The objectives of this consultation included:

1. Review proposed structure and content of a global reporting mechanism;

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