

Addressing the global shortage of medicines and vaccines

Report by the Secretariat

1. In May 2016, the Sixty-ninth World Health Assembly adopted resolution WHA69.25, which was intended to address global shortages of medicines and vaccines. In the resolution, the Secretariat was requested “to develop technical definitions, as needed, for medicines and vaccines shortages and stock outs, 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”.
2. WHO commissioned a systematic review of the available definitions used in the management of medicines and vaccines shortages and stock outs. The preliminary results revealed, among other things, that functional definitions vary broadly depending on the context in which they are used, underscoring the need to harmonize and develop well-understood definitions. The review also showed that terms are used interchangeably to refer to different aspects of shortages.
3. The preliminary results of the systematic review and informal consultations with experts in supply chain and programme management for medicines and vaccines show that:
 - (i) On the supply side, existing definitions and indicators are found mainly in reporting mechanisms established by national medicines regulatory authorities – which therefore vary from country to country – and which require timely advance notice of potential shortages by market authorization holders. The advance notification mechanisms use these definitions as part of a system to detect shortages at the manufacturing level and to plan approaches to mitigate the potential negative impact of a shortage or stock out on the public health system, such as the rapid deployment of other supply sources or the temporary use of other clinically appropriate medicines. These systems and the related definitions were developed with a view to providing public health solutions at the national level.
 - (ii) On the demand side, existing definitions are used mainly in reference to procurement, planning and supply chain management related problems. These definitions most frequently describe and define various types of disruptions at various levels in medicines and vaccines supply systems, ranging from the absence of a physical inventory to failures to meet the needs of individual patients. In the case of a stock out, the demand side definitions are generally also linked to the duration of the stock out; however, it is interesting to note that the time-bound aspects of the demand-side definitions are measured only in terms of hours and days and not in terms of consequences to the patient of delayed treatment.

(iii) The existing definitions used in relation to both the supply and the demand sides include references to reporting mechanisms and to the availability of data related to shortages and stock outs. In the case of supply-side shortages and stock outs, summary information on specific products is generally made available to the public by the responsible agencies, usually a national medicines regulatory authority. In the case of demand-side shortages, it is noted that data come from multiple sources and are not systematically validated or provided to a central entity. Also on the demand side, information is limited regarding the management of data from the various reporting mechanisms, and there is an absence of systems to manage the quality, reliability and appropriate use of these data across multiple potential data sources. Immunization programmes frequently have separate monitoring and reporting mechanisms.

4. Based on the preliminary results of the systematic review and the informal expert consultations, the Secretariat has developed an overarching draft technical definition of medicines and vaccines shortages and stock outs. In addition, a framework is under development for the purpose of articulating more detailed considerations, such as variables for implementation and indicators for measurement. The overarching draft technical definition is divided into supply-side and demand-side definitions, in accordance with the outcome of the systematic review and informal expert consultations.

5. The overarching draft definition, which refers to shortages on the supply side and shortages and stock outs on the demand side, reads as follows:

- On the supply side: A “shortage” occurs when the supply of medicines, health products and vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs. This definition refers only to products that have already been approved and marketed, in order to avoid conflicts with research and development agendas.
- On the demand side: A “shortage” will occur when demand exceeds supply at any point in the supply chain and may ultimately create a “stock out” at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient.

6. It is noted that all definitions must have a clear purpose and that guidance on the appropriate context is needed in order for them to be useful and also to avoid unintended consequences. Examples of unintended consequences include instances of reporting of shortages at the wholesale level contributing to hoarding behaviours and price increases. In addition, the reporting of shortages at lower levels of the supply chain is considered to be a sensitive area, as health care workers could face reprisals for shortages or stock outs and may therefore avoid reporting them. A report of a facility stock out is a useful indicator of the overall status of a facility or system, but is not diagnostic in nature, underscoring the need for guidance on the use of such reports. National medicines regulatory authorities that monitor shortages and stock outs among their market authorization holders have specific requirements and use reported data to react with multiple mitigation responses; however, the capacity to implement a reporting and response system is dependent on resources. Furthermore, the impact of shortages in one region of the world may be limited to a single region, or may be global, depending on the manufacturing base of the medicine or vaccine. Final definitions will be accompanied by guidance on how to use the definitions in various contexts, including on how best to use the definitions in appropriate strategies in order to mitigate or avoid a shortage or stock out.

7. The Secretariat will conduct a broader Member State consultation in 2017 in order to expand the involvement of stakeholders in the development of these definitions and to provide appropriate guidance and will work further on strategic efforts to develop a medicine and vaccine shortage notification system for medicines and vaccines at risk of shortage.

8. Pursuant to the other provisions of resolution WHA69.25, WHO has embarked on collaborative work on health data management, notably as part of the Health Data Collaborative, to promote the availability of reliable data on shortages and stock outs and data for improved planning and management. In addition, WHO's programme on the prequalification of medicines and vaccines aims to include medicines at risk of shortage and stock outs in order to provide efficient regulatory pathways and contribute to improved market stability. In this regard, the programme's fee structures have been revised to ensure its sustainability. In recognition of the fact that most medicine and vaccine markets serve multiple countries, WHO is also supporting collaboration at high levels across supply chain programmes and will serve as the secretariat for the Interagency Supply Chain Group in 2017.

ACTION BY THE EXECUTIVE BOARD

9. The Board is invited to note the report.

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