Drug shortage: a public health problem

Descontinuação de medicamentos: um problema de saúde pública

Discontinuación de los medicamentos: un problema de salud pública

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Gaps in access to medicines due to drug shortages create a serious public health problem [1]. In Brazil, such gaps are commonly reported as "lack of medicines". Some research articles refer to the problem as "drug supply failure", specifying flaws in the complex system of measures to support the consumer chain for medicines [2]. Health surveillance refers to the problem as "drug shortage" [3]. This definition offers a more comprehensive idea that the supply failure, whether occasional or permanent for the given product, jeopardizes the chain of care despite policy and logistic improvements in the organization of pharmaceutical assistance.

Drug shortage is a global problem [4] that has increased in Brazil in the last decade, interfering in all levels of care, both public and private, from primary to specialized care. As a complex and multifactorial phenomenon, it is influenced by elements of pharmaceutical logistics and diverse political factors, from broad definitions for the health and science and technology sectors to quality of action in the customs, fiscal, and health regulatory agencies [1,2]. During a shortage, the drug's duality becomes evident: as a health product, subject to health regulation in its production, marketing, and consumption, and as merchandise, or part of the international financial system as high added-value commodities with high economic risk. In either situation, shortages involve high political interests, since health infringements or problems with expected profits can jeopardize the supply chain, limiting or even entirely impeding the drug's availability to patients.

In the complex determination of drug shortages, production involves technical and economic issues that interlink in a network of factors. Technical factors include irregularity in the supply and quality of inputs and the inadequacy of good practices [5,6,7,8]. Such factors can lead to the interruption of production or recall of drugs from health services, a problem aggravated when there are only one or a few suppliers of a given drug [6]. Countries that are heavily dependent on technology from the international market are more vulnerable to supply problems [2]. Although Brazil is one of the world's largest markets and currently has advanced regulatory and regulation instruments for production, importation, and guaranteed access, the country is still dependent on technology and the supply of inputs from abroad. Only systematic linkage of research and development policies for production throughout the chain and guaranteed access can reduce this vulnerability. This linkage is especially important for protecting supply against economic factors, including stoppages or cutbacks in production due to low financial returns, new economic plans in pharmaceutical companies, or production line changes due to mergers of laboratories [2,9].

All these factors come under government control in one way or another, and specific sector policies offer more complex explanations

for shortages and the factors in which government is better able to provide more effective solutions. In technical or economic problems in production and distribution, governments have limited forecasting capacity but can establish focused, short-term measures. Thus, pressured by drug shortages, in 2014 the Brazilian Health Regulatory Agency (Anvisa) published a ruling for dealing with temporary and definitive drug shortages [3]. However, due to weaknesses in the health and science and technology sector policies, shortages are an ever-present risk. Well-linked policies in these areas are essential for Brazil to develop its technological base for the production and absorption of new technologies.

Another fundamental requirement is information. A link on the Anvisa website concerning specific drug shortages helps health services and professionals identify the problem, thereby facilitating the elaboration of intervention strategies. However, this Anvisa link still operates passively, and the agency needs to improve its communication strategies, actively reaching health services, patients' associations, representative organizations of service providers, health professionals' technical and scientific societies, and consumer defense bodies.

Given the negative impact of drug shortages on the health system, Anvisa has acknowledged the importance of monitoring links in the supply chain and establishing short and long-term plans to mitigate the problem. Anvisa's role is increasingly important in regulating drug manufacturing conditions and managing conflicts in the pharmaceutical industry. Such conflict management involves definitions concerning the essential nature of the drug in strategic planning for supply maintenance, signaling opportunities for the contribution by the public and private pharmaceutical industry to develop its production plans to simultaneously guarantee and maintain its economic return and growth and responsible action to meet its social role.

As for consequences, drug shortages jeopardize quality of health care, patients' treatment outcomes and safety, and adherence to clinical protocols, besides increasing treatment costs [1,10,11,12,13,14,15]. For example, the control of gestational and congenital syphilis in Brazil has been affected negatively in recent years by the shortage of benzathine benzylpenicillin and benzylpenicillin potassium [12,13]. In early 2016, epidemiological surveillance measures for communicable diseases were also jeopardized by the shortage of immunobiologicals. Hospital infection control programs were affected by the lack of antimicrobials. All these problems could have been avoided or mitigated by government measures allowing effective linkage between more accurate forecasts of drug supply and immediate interventions, whether through directing production by government laboratories or linkage with the private system, or in the final analysis in planning substitutions or importing the products.

Importantly, substitution during a drug shortage is a complex process that involve risks to patient safety, since medication errors and adverse drug reactions are more likely when a treatment approach is replaced for reasons other than clinical needs [11,16]. In this complex scenario, a shortage increases patient care costs, given that the alternative treatments are usually more expensive; during low supply or reduced competition, prices tend to increase [17,18,19].

Contributors

All the authors participated equally in the manuscript's production.

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