



International
Hospital
Federation

ACCESS TO AND AVAILABILITY OF DRUGS

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Introduction

It is globally recognized that access to medicines is critical for healthcare provision. Unfortunately, shortage of medicines is an increasing global concern, impacting low-, middle- and high-income countries.

Limited availability and the high price of medicines directly impact the health and wellness of the population, causing health risks for patients. Shortage of medicines is also a burden for healthcare organizations, which are forced to find alternative solutions that are expensive and time consuming. In addition, this may increase the out-of-pocket expenditure and the recourse to a parallel (and frequently illegal) drug market.

Medicine shortage can be ascribed to different causes such as access to raw materials and regulatory, manufactory and supply chain issues (C. Lee Ventola, 2011).

According to the resolution WHA69.25 (WHO, 2016), “Addressing the Global Shortage of Medicines and Vaccines”, in 2016 the World Health Organization (WHO) organized an informal consultation of experts (WHO, 2017) to work on the definition of shortages and stockouts of medicines and vaccines. This consultation led to two draft definitions:

1. The first definition is from the supply perspective: “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.”
2. The second definition provides the demand perspective: “A “shortage” will occur when demand exceeds supply at any point in the supply chain and may ultimately create a “stockout” 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. “

During the 71st World Health Assembly held in May 2018, the issue of “global shortage of, and access to, medicines and vaccines” (WHO, 2018) was addressed. With Decision WHA71(8) (WHO, 2018), the WHO will work on developing a road map report for the period 2019-2023 to present the work program.

The International Pharmaceutical Federation (FIP) defines medicine shortage as “A drug supply issue requiring a change. It impacts patient care and requires the use of an alternative agent” (International Pharmaceutical Federation (FIP)).

Through Universal Health Coverage (WHO) and the Sustainable Development Goals (United Nations), countries have committed to improving access to drugs. Many international organizations are also strongly advocating for the accessibility of drugs. However, medias echo increased global difficulties for access to drugs.

In November 2016, the IHF General Assembly adopted the resolution, “Access to and availability of drugs for health care providers” (IHF, 2016) to raise global awareness of the challenges that health service providers are facing with medicine prices and availability,

especially for new treatments.

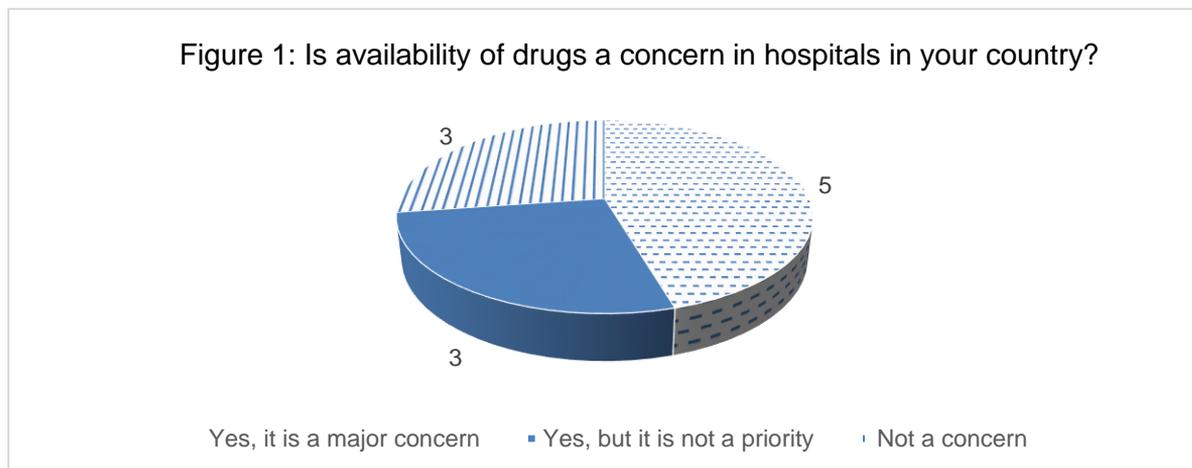
To assess how much this topic is a concern among IHF Members, the IHF Secretariat launched a short survey in June 2018.

Outcomes

The survey was sent to 39 national healthcare organizations and more than 135 hospitals. We have received a total of 11 answers from the following countries: Belgium, Japan, Mongolia, Oman, Philippines, Portugal (3), South Africa, Spain, United Arab Emirates. The survey was launched in June and reminders (3) were sent until early August.

All respondents are hospitals, out of which one fully private and two public-private partnership.

When asked if availability of drugs is a concern in hospitals in their countries, respondents provided the following answers:



It is a major concern in Belgium, Mongolia, Philippines, South Africa and for one of the three respondents from Portugal. Those who responded that it is a major concern are all from the public sector, except the one from the Philippines.

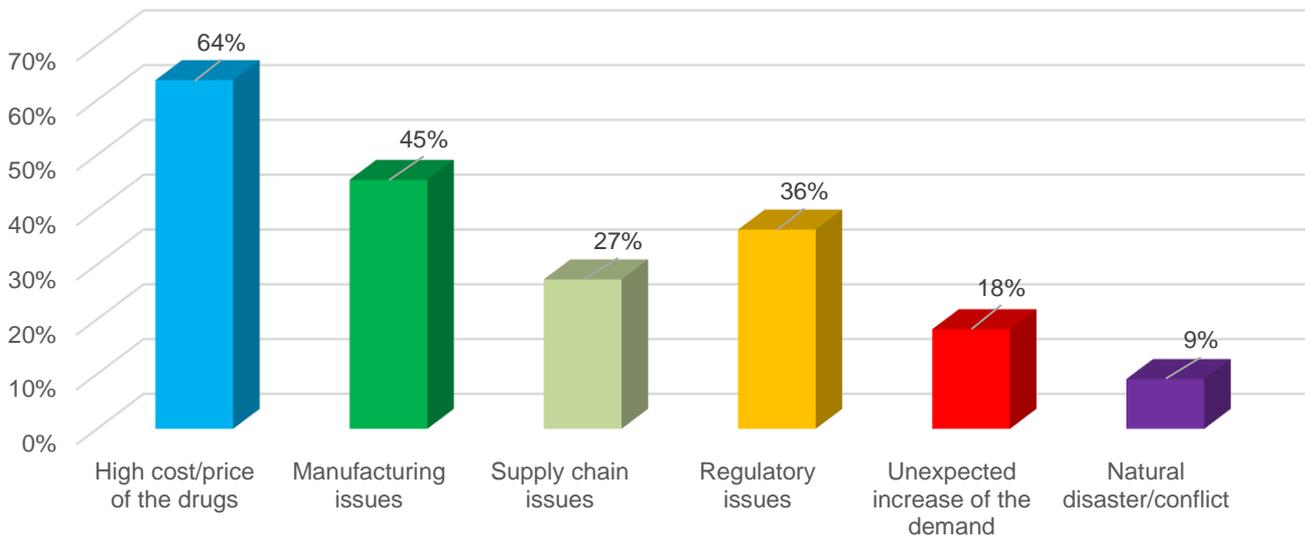
Those who responded that availability of drugs is somehow a concern, reported that the following are the less available types of drugs:

- Anti-infective drugs;
- Cancer drugs;
- Heart and circulatory drugs
- Rare disease drugs

In almost 70% of the cases, this includes both brand and generic drugs. The issue is related only to brand drugs in Oman, United Arab Emirates and one respondent from Portugal.

In the survey, we provided a list of possible reasons for drug unavailability. This list is non-exhaustive, but the objective was to have an overview of the possible explanation for the shortage of medicines and to understand the major trends.

Figure 2: The limited availability of drugs is due to



As we can see in Figure 2, the high cost of drugs and manufacturing issues are the major reasons for the shortage. Respondents also provided the following additional answers:

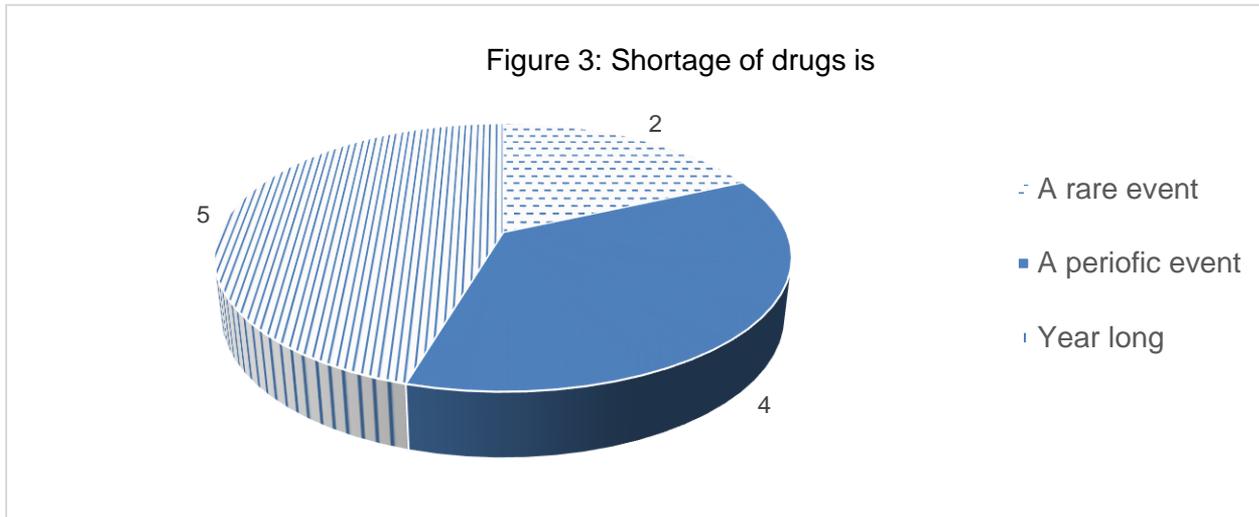
- Parallel imports;
- Pharmaceutical Companies dropping out of the national market

According to the responses, in most cases, shortage of drugs is connected to any pharmaceutical specialties. Only one respondent from Portugal indicated that the shortage is mostly connected to one specific pharmaceutical specialty.

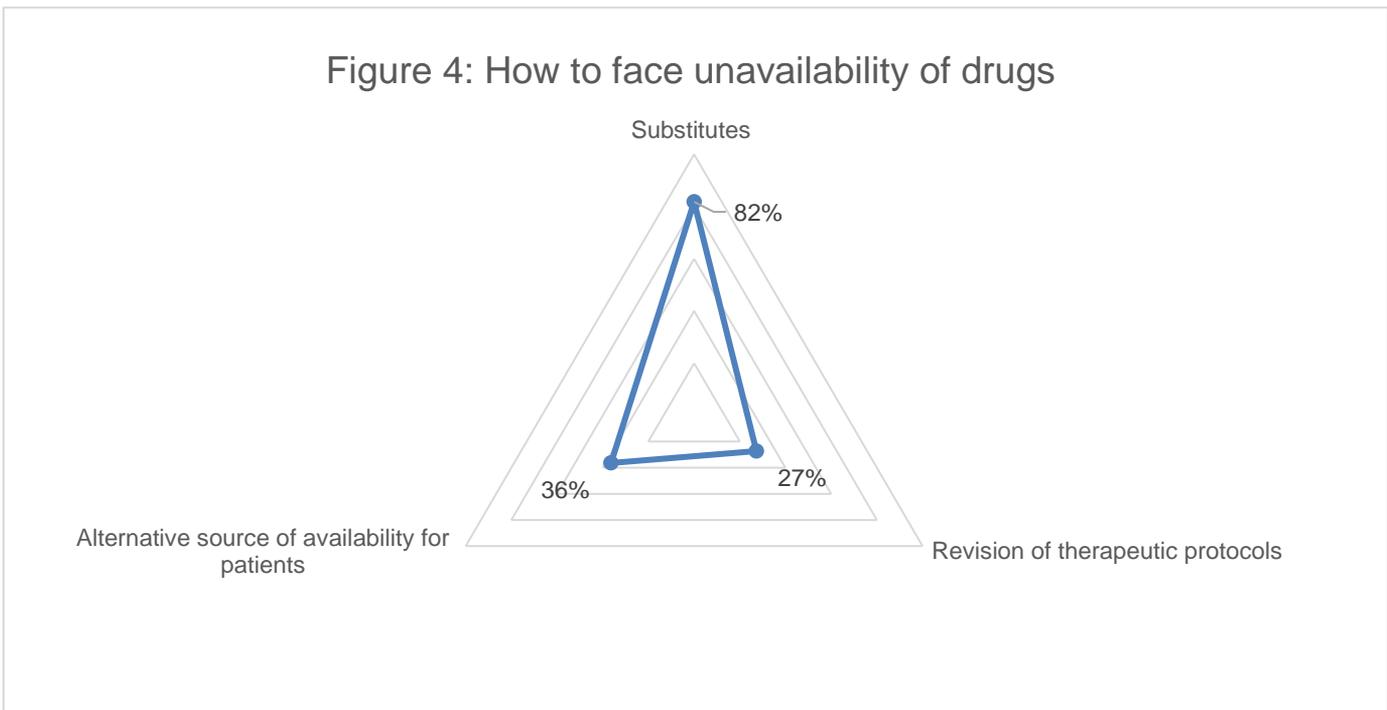
Respondents were invited to comment on the reasons for pharmaceutical companies not to supply drugs:

- Production problems, quality problems;
- The shortage of a brand causes stock breakages in other;
- Low prices of old medicines;
- Technical reasons (production, transportation, etc.);
- People cannot afford to buy the medications, especially in the provinces;
- Country is too small a market.

As shown in the chart below (Figure 3), shortage of drugs is mostly a year-long event and all respondents agree that it happens at any time of the year.



Among the local measures adopted/implemented to face shortage of medicines, almost all respondents indicated the use of substitutes.



We asked respondents to indicate the measures adopted to influence relevant stakeholders responsible for the shortage, and we collected the following answers:

- Importing medicines from other countries, derogations. This is organized with the association of hospital pharmacists and the federal agency of medicines;
- High prices of innovative cancer drugs delay the approval of such drugs in the country, obliging hospitals to import them directly from abroad, with the authorization of the National Drugs Agency. This fact determines inequities in patient treatments, depending on the hospital where patients are being treated;
- The Spanish drug agency manages alternative imports;



- Finding another supplier;
- We have established a forum which includes all stakeholders (manufacturers, health professionals, health facility managers, patient groups, etc.) that meet regularly to discuss risks and mitigation strategies;
- Generic drug law passed by Congress and Senate.

We asked respondents about their perception on how the availability of drugs is affecting care provision in hospitals. On a scale from 1 (low) to 10 (high), the average was 4. We can therefore deduce that availability of drugs has a low impact on care provision in the countries that participated in the survey.

Conclusion

The literature review shows that the concern about medicine shortage is spread worldwide. International organizations and national and regional agencies are on the alert about the need to prevent and find solutions to this growing issue with a strong impact on quality of care and patient safety.

From this short survey, we can assume that there is a lack of uniformity and that shortage of drugs is a major issue in some countries, mostly due to the high price of medicines, manufacturing process issues and inefficiencies in the purchasing/delivering system. However, due to the low response rate, we cannot consider this topic a major concern for IHF Members.

Unless specifically requested by IHF Members, the IHF Secretariat will not invest additional efforts into exploring the issue of medicine shortage.



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