Boryana Marinkova

PhD of UNWE

CEO of the Bulgarian Association for Medicines Parallel Trade Development (BAMPTD), Sofia, Bulgaria

Corresponding author:

e-mail: b.marinkova@parallel-trade-development.org

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PUBLIC HEALTH CRISIS MANAGEMENT THROUGH PUBLIC COMMUNICATIONS

ABSTRACT

The Covid-19 pandemic has put public health systems in all countries to the test, escalating endemic health policy problems of access to treatment and medications. This article presents an overview and typology of public health crises caused by drug shortages and presents an approach to mitigate and resolve them through the public communications. Based on an empirical study conducted by the author on 1,477 patient alerts collected through an online platform developed by the author, data on the causes of shortages and the possibilities of solving them through improved public communications are summarised.

Keywords: public management; public communications; public health crisis

JEL: H42, I18, M38

INTRODUCTION

Crises in public health have been a matter of concern within scientific communities for decades due to their high impact on large populations and the severe consequences for the economy and the public sphere. The past three years have been dominated by a global pandemic, which has been a test for the public health system in every country worldwide, resulting in millions of casualties, significantly more disabled and severely ill patients, and enormous damage to various sectors of the economy, with serious psychological consequences for contemporary society. One of the priorities of public health is access to therapy, and the pandemic has led to a widespread shortage of medications, which has left a significant imprint on efforts to control the spread of the virus. Considering that the majority of participants in the pharmaceutical supply process are private entities regulated by public authorities, we will seek solutions in public communications to manage the crisis in public health caused by the shortage of medicinal products.

The focus is placed on the drug shortage examined comparatively by interpreting data before and during the spread of the coronavirus, for which the author has conducted own research. The methodology is based on an in-depth analysis of contemporary literary sources on public health, involving health policies, public authorities, healthcare providers, the pharmaceutical sector, and society. The study examines the effectiveness of Public communications methods in identifying, managing, and preventing potential crises from the perspective of drug shortages in Bulgaria.

The scope of the "drug shortage" phenomenon, based on data from Bulgaria, the European Economic Area, and the United States, is concerning. According to the study by the author, analysing 1,447 reports of missing drugs among users in Bulgaria between 9 June 2018 and

January 13, 2022, nearly 70% of them cannot be resolved without changes in the regulation of public health and active interventions in the marketing mix of companies. Data from the latest survey among pharmacists in the EU indicate that 60% of shortage cases can be overcome through improved distribution, and the findings of the study among wholesale traders in Europe suggest the implementation of approaches to publoc communications policies in the pharmaceutical sector.

1. Literature review

1.1. Extent of Research on the Issue

On an international level, the problem of drug shortage has gained widespread attention since the beginning of the new millennium. Between 2000 and 2018, cases of drug shortage in the EU increased by 20 times. The increased global scientific and public interest in the topic can be seen from the number of citations on the subject of "drug shortage" in the established PubMed database: 430 articles for the entire period from 1946 to 2000, exponentially increasing to 1,026 for 2001-2010, and 3,383 articles from 2011 to March 11, 2022. The highest number of results is observed in the period 2020-2022, totalling 1,086, which corresponds to the relevance of the topic during the COVID-19 pandemic. At the national level, there are currently individual publications and analyses, often within the scope of public communications by institutions and the nongovernmental sector.

Significant portions of national and supranational public policies, regulations, and forms of public communication have focused on the phenomenon since 2000. Regulators such as the European Commission, the Council of Europe, the European Medicines Agency, the U.S. Food and Drug Administration, and others have shown interest in addressing the issue.

A leading scholar and analyst of the problem is A. Serbezova (Serbezova, 2021). The concept of shortage was defined for the first time in the Law Amending the Human Medicinal Products Act in 2016. Since June 2018, data on the reasons for medication shortages have been provided, which the author collects and analyses, regularly informing institutions and users through the media in the spirit of proactive public communication to improve understanding of the crisis and seek effective management methods.

1.2. Essence and Typology of Crises in Public Healthcare

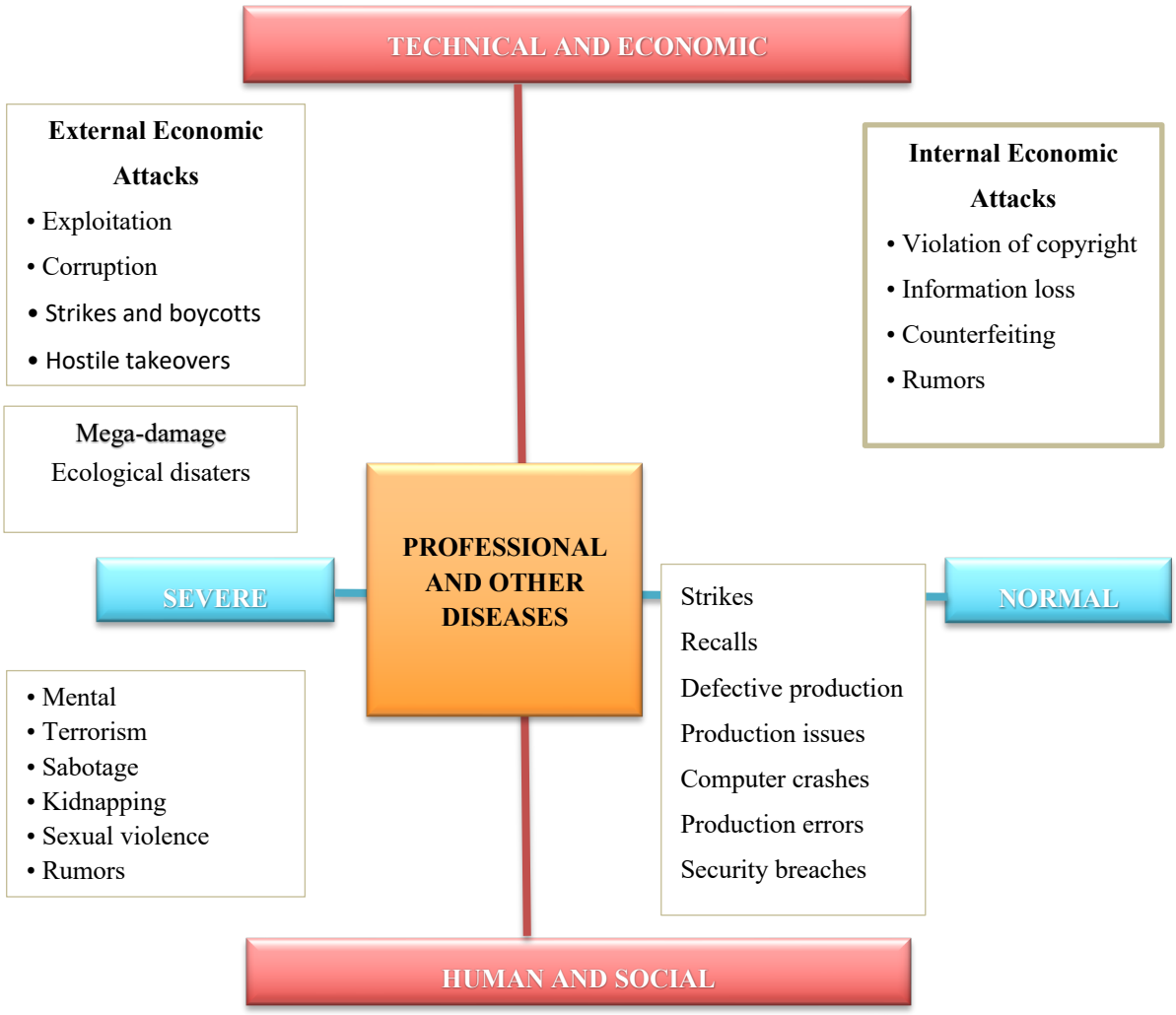
The first study on crises from a management perspective began with a publication in 1963, focusing on their impact on organizational viability (Hermann, 1963). In the past two years, the scientific community has focused on the unprecedented pandemic, which has highlighted the role of science in global public healthcare crises. Lessons learnt from the pandemic provide a broad basis for discussing how public health, with its regulations and the marketing efforts of the business sector, contributes to identifying and adequately responding to crises. Due to its uniqueness and heterogeneity, there is no consensus, both in recent years and half a century ago, regarding the phenomenon of "crisis."

In public healthcare, the term "crisis" has been used for decades to encompass a wide range of complex events such as COVID-19, HIV/AIDS, childhood tobacco smoking, and obesity. Crises in the sector can result from diseases, industrial processes, or poor policies, and their severity can be measured by the number of people affected within a geographical area, morbidity, or mortality caused by pathogenic or nonpathogenic processes.

There is a wide spectrum of approaches to typologizing potential crisis situations. Internal-external and intentional-unintentional are two dimensions of crisis types. They are grouped

within a "crisis family" (Pauchant & Mitroff, 1992), encompassing external information attacks, external economic attacks, mega-damage, disruptions, psychological and occupational illnesses (Fig. 1). These are differentiated in two dimensions: severity (horizontal axis) and cause (vertical axis). The crises on the left fall outside the realm of normal and rational human behaviour, while those on the right are more easily understood and controlled by institutions. The vertical typology distinguishes those caused or influenced by economic or technical factors from crises caused by human factors, such as insufficient or incorrect communication, sabotage, etc.

Figure 1. Typology of Crises in Public Health



Source: *Own*

1.3.Aetiology of the Causes of Crisis in Public Healthcare

In recent years, there has been a significant increase in crises, including ecological disasters, terrorist acts, employee sabotage, and regional and global health crises. Cause often influences the level of support an organisation receives. The public tends to react more favourably to crises caused by natural disasters than to crises caused by human intervention or inaction (Dinkin, 2007).

Crises in public healthcare can arise from the simultaneous disruption of technical, organisational, and human systems within an organisation or due to a mismatch between the

organization and its environment. However, these are not isolated phenomena, but the result of complex systemic interactions among various variables, and one crisis can give rise to other crises. The activation of multiple crises is more likely if the initial crisis is poorly managed or if the affected system is highly dependent. The speed of this interactive cascade is determined by the degree of interconnection and dependence within the system.

1.4. Impact of Crises on Public Health

Crises can significantly affect and cause substantial losses for public healthcare and its participants, such as reduced revenue, loss of personnel, reputation damage, stress among employees, and the community. Crises, as subjects of effective public communication, contribute to drawing lessons and future prevention.

- Human and social impacts: The risk of loss of life is one of the most severe risks associated with public health crises. Psychological and emotional effects can lead to severe trauma, stress, depression, withdrawal from social interaction, inability to concentrate, fear, anxiety, and insomnia, including burnout syndrome among public health teams.

- Managerial and communication impacts: High-quality and timely information is part of effective crisis management and its absence leads to the generation of dangerous rumours. In the first hours following the onset of a crisis, public opinion begins to form, and in the absence of official information, individuals draw their own conclusions. An organisation that promptly discloses a crisis establishes trust, conveys responsibility, instils a sense of control, and serves as a criterion for honesty and transparency (Mallozzi, 1994).

- Technological impacts: Public health is increasingly dependent on advanced technologies. Electronic health, information systems, registries, cloud solutions, mRNA vaccines, biotechnologies, telemedicine, big data, etc. are so complex that it is difficult to predict all possible problems. Crises that could affect the technological dimension in the sector can be caused by natural disasters, intentional or unintentional human actions, including errors or sabotage.

1.5. Crisis Management in Public Healthcare Through Public Communications

Crisis management through public communication is considered a complex set of regulatory and public policies aimed at preventing, responding to, and learning from crises. Prevention is the proactive component that aims to reduce the likelihood of the emergence of a new or recurring crisis. The reactive component is associated with swiftly containing and minimising the consequences, followed by active communication to raise awareness. The learning component involves continuous improvement in the crisis management process. Developing comprehensive crisis plans that anticipate and plan for worst-case scenarios is an essential process for timely public communications.

Contemporary views of researchers indicate that the true measure of success lies in preestablished and approved procedures that prevent crises, facilitate their swift recognition and containment, address the communication and management consequences, and quickly draw lessons from the crisis.

1.6.Phases of Crisis Management in Public Healthcare through Public Communications

The phases can be grouped as follows:

(a) Pre-crisis phase: a process of identifying, analysing, and responding to risks. It involves assessing the likelihood, expected scope, and potential impact of a specific crisis;

(b) Crisis response phase: limit and minimizing the consequences of the crisis, followed by active communication to inform the public after identifying the causes;

(c) Post-crisis behaviour: fulfil and disclosing the commitments made during the crisis phase and repair the damages caused.

1.7.Tools of Public Communications

The need for a systematic communication approach is supported by the following facts and trends: a) the increase in disaster, accident, and emergency cases in recent years, and b) investments in crisis preparedness can be justified by the significant costs to public health in terms of human and financial losses, fatalities, and damaged trust and reputation.

Social marketing, linked to public communications in the field of public health, is a primary function in providing community services, and the healthcare sector plays a critical role in providing a service that is measured by lives saved. Organisations that fail to communicate quickly and honestly with their internal and external audiences during a crisis can suffer serious damage to their reputation, relationships, and ongoing activities (Rubel, Naik, and Srinivasan, 2011). Social marketing allows an organisation to recover, and public communications are important tools for providing information to key audiences, the community, or the entire global population, such as during the COVID-19 pandemic.

2. Methodology

The comprehensive literature review encompasses publications describing public healthcare as subjects of public communication, covering the past 40 years, including crises caused by shortages of medicinal products at the international, regional, and national levels. The selection was performed using specific keywords in MEDLINE, Embase, Web of Science, and Google Scholar. Normative regulations were reviewed and official websites of health institutions, both domestic and foreign, were consulted. An analysis of the pharmaceutical market, its specificities, regulations and participants was conducted, utilizing content analysis, synthesis, induction, and other methods, in addition to proprietary research. The study was carried out between June 2018 and January 2022, and included 1,477 patient signals. The collection, processing, analysis, and conclusions were carried out by the author through an online platform developed by them. This online platform has been recognized as an innovative solution in the field, winning first place in the "Innovation for Patients" category at the Innovation and Good Practices in Healthcare Competition organized by "Capital" weekly.

3. Results

3.1.Drug Shortages in Bulgaria and the World as a Phenomenon Requiring Active Management through Public Communications

The shortage of medicines is observed in various countries and is attributed to a complex set of reasons. This phenomenon severely challenges the public health system and has a significant potential impact on people's health. The problem is global and has been exacerbated in the context of the pandemic, affecting both developed and developing countries. The shortage

hampers the ability of public health to fulfil its obligations and responsibilities toward patients, healthcare professionals, pharmacies, and healthcare facilities. It can manifest itself in the scarcity of raw materials, particularly active substances, and can be replicated throughout the supply chain, from manufacturers to wholesalers, retailers and patients. It can also occur at a specific level of the supply chain for production, marketing, or regulatory reasons.

The complex and multi-layered nature of drug shortages has resulted in over 25 different definitions of the phenomenon worldwide. According to the European Medicines Agency (EMA), a "drug shortage for human use is observed when the supply at the national level does not meet the demand" (EMA, 2019). The PGEU 2021 Drug Shortages Survey (PGEU, 2021) defines "medicine shortage" as any (temporary) inability of a pharmacy to supply a requested product due to factors beyond their control. The definition provided by Bulgarian legislation in Article 217b(5) of the Law on Medicinal Products for Human Use (LMPHU) is limited to medicines included in the Positive Drug List when "the available quantities of the respective medicinal product are less than 65% of the necessary quantities to meet the healthcare needs of the population for a period of one month, calculated based on the average monthly consumption of the respective medicinal product for the previous six months from the day of analysis" (LMPHU). To facilitate the calculation, a Specialized Electronic System for Tracking and Analysing Medicinal Products has been developed, administered and maintained by the Bulgarian Drug Agency (BDA).

In healthcare systems where the supply is analysed over a longer period, an exacerbation of medicine shortages is observed. The United States reported an increase from 70 to 267 drug shortages between 2006 and 2011. The European Commission reported an increase in supply between 2000 and 2018 due to manufacturing issues, unexpected increases in demand during epidemics or disasters, price disparities, and dependence on imports of active ingredients from India and China.

In 2016, the EMA and the medicines agencies in the European Union established the HMA/EMA Task Force on the Availability of Authorized Medicines to provide strategic support to member states in addressing supply disruptions by reducing administrative deadlines, providing reporting guidelines for manufacturers, promoting collaboration between stakeholders, and communicating with patients.

A comprehensive study in 2014 found that 21% of hospital pharmacists face drug shortages every day, and 45% experience shortages on a weekly basis. European pharmacists (PGEU, 2020) report that in 96% of countries surveyed, shortages cause stress, in 81% they result in treatment interruptions, and in 23% they lead to medication errors, among other consequences.

During a shortage, the public healthcare system enters a crisis, risking patients' access to comprehensive, timely, and quality healthcare services, and raising questions about its own functions and purpose (Acosta, Vanegas, Rovira, Godman, Bochenek, 2019). The pandemic has constituted the shortage as a secondary crisis, escalating to extreme levels and complete unavailability of products from the therapeutic regimen for COVID-19 treatment. Causes include reduced production, overconsumption, export restrictions, and stockpiling. Coupled with barriers at the borders of producing countries and transit countries, the shortage affects not only patients with COVID-19, but also those who depend on these medications for chronic or temporary conditions.

The Bulgarian pharmaceutical market is among the smallest in the EU but has experienced significant growth in the past 20 years, with a 11% growth in 2020. The total sales of prescription and over-the-counter medications amounted to 2.286 billion euros, according to

IQVIA. Sales in pharmacies account for two thirds of the market and reached a total value of 1.48 billion euros in 2020. Hospital medicines were the main driver in 2020, growing by 23% and reaching 479 million euros. The expenses covered by the National Health Insurance Fund (NHIF), the Ministry of Health and hospitals amount to 663 million euros, with 66% being paid by patients. The NHIF covers 25%, 50%, 75% or 100% of medicines for 1,953,697 patients in 2018. Each patient pays an average of 150 BGN per year, making Bulgaria the country with the highest patient co-payment percentage in the EU.

The top ten pharmaceutical corporations account for 40% of medicine sales in 2020. The highest sales growth was observed in oncology due to innovative products introduced into reimbursement. Three of the top ten best-selling medications have antirheumatic indications. COVID-19 has led to increased demand for new anticoagulants, the best-selling one experiencing a 30% growth compared to 2019.

Table 1. Comparison of the Top 10 Pharmaceutical Corporations for 2020 and 2019

Top 10 Pharmaceutical corporations (2020)	Top 10 pharmaceutical corporations (2019)
1. Novartis	1. Novartis
2. Roche	2. Roche
3. Teva	3. Actavis/Teva
4. Merck Sharp & Dohme	4. Pfizer
5. AbbVie	5. GlaxoSmithKline
6. Pfizer	6. Merck Sharp & Dohme
7. GlaxoSmithKline	7. AbbVie
8. Sopharma	8. Sanofi
9. Sanofi	9. Sopharma
10. Bayer	10. Bayer

Source: IQVIA, 2021

3.2. Analysis of the Causes and Extraction of Qualitative and Quantitative Parameters of Drug Shortages across the Supply Chain

3.2.1. Study of Drug Shortages from the Patients' Perspective

To assess the context in Bulgaria, an author-conducted study has been carried out since June 2018, and is ongoing. The author has developed and administered the first online platform in Bulgaria to report drug shortages. The platform is aimed at patients to examine the customers' aspect of the phenomenon, as well as to group and analyse individual signals in search of appropriate communication and communication approaches to address drug shortages at both the individual and general consumer levels.

A total of 1,477 signals have been received, processed, and analysed for the period between June 9, 2018, and January 13, 2022, from 39 locations across the country. Of these, 49% of the signals originate from the capital city, which can be attributed to the high population density in Sofia and the established customers' habits of seeking electronic solutions for various issues and enquiries. Among the 1,477 signals, almost two-thirds pertain to different pharmaceutical products, while one-third of the signals duplicate previously reported drug shortages.

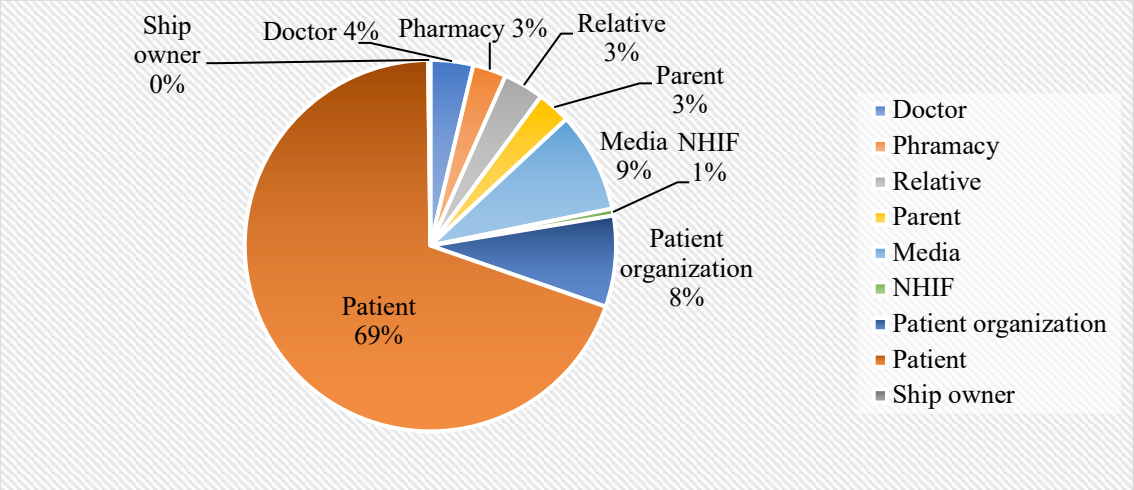
Table 2. Number of Signals and Repetitive Medicinal Products

Number of signals	1477	100%
Number of product	972	65,81%
Repeated products across various signals	505	34,19%

Source: Own

Most signals are submitted directly by the patients themselves, without seeking the assistance from other individuals or organisations. Others are supported by their treating physician, pharmacist, patient organisation, media representatives, after the patients have reached out to journalists for help or to raise awareness about their issue, as well as the National Health Insurance Fund. In rare cases, the signal is submitted by close relatives of the patient, usually due to advanced age, or by a parent seeking medication for their child.

Figure 2. Distribution of Signals by their Senders



Source: Own

The distribution of signals according to the type of reported product indicates that the platform has been communicated effectively, as over 92% of the signals are related to the absence of medications.

Table 3. Distribution of Signals by Type of Pharmaceutical Product

Product type	**Count**	**%**
Medicinal product	1365	92,42%
Food supplement	82	5,55%
Medical device	27	1,83%
Other- Cosmetics, Homeopathy	3	0,20%
Total	**1477**	**100%**

Source: Own

The aggregated data from the platform, classified according to the market status (available or in shortage) due to temporary or permanent disruptions in imports and sales in Bulgaria, indicate that the reported medications may be lacking due to the following reasons (Table 4):

Table 4. Distribution of Signals by Market Availability Status and Reason for Shortage of the Signalled Pharmaceutical Product

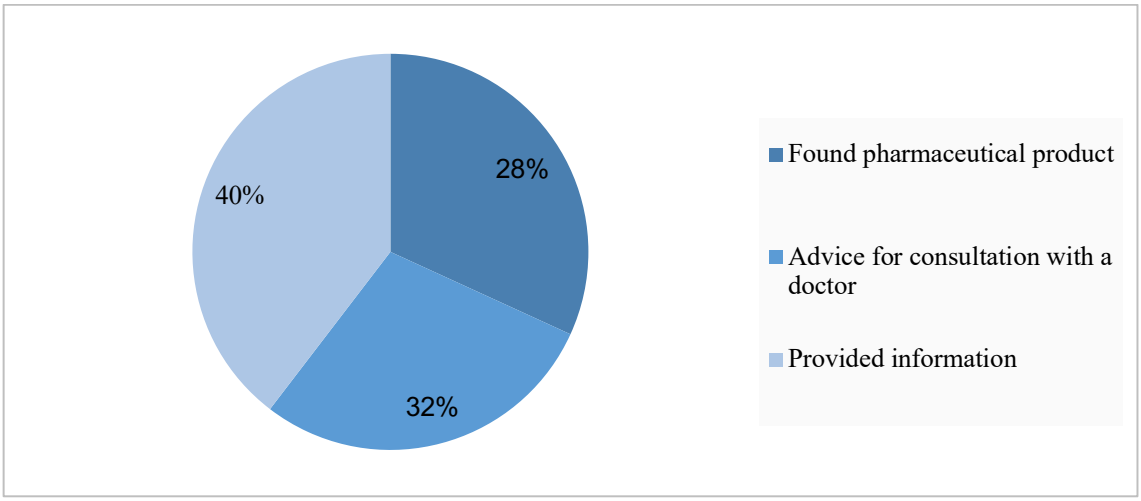
Status of availability on the market or reason for shortage	**Count**	%
Available in the pharmacy network	408	27,62%
Hospital product	23	1,56%
Permanently discontinued import or sale	394	26,68%
Temporarily discontinued import	298	20,18%
Deregistered and suspended from import products	313	21,19%
Not registered in Bulgaria	41	2,78%
Total	**1477**	**100%**

Source: Own

According to the patent protection status of the reported medications, 38% are under patent protection and do not have competing products on the market with the same active ingredient. Slightly more than half of the signals are related to generic drugs. As of January 13, 2022, based on 1,477 signals collected and processed from patients, doctors, and pharmacists, the following general observations can be made:

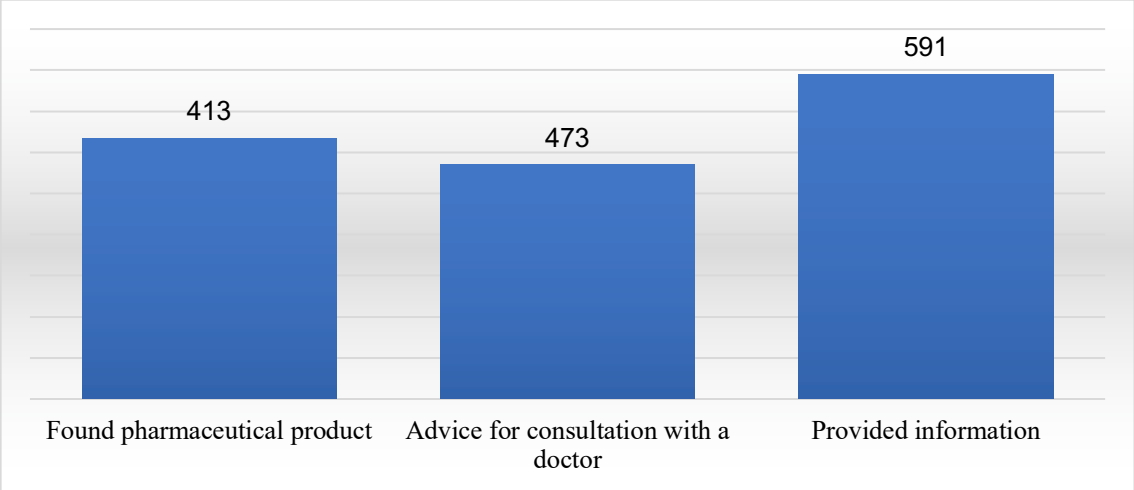
- 70% of the shortage signals could be resolved through imports, including medications with temporarily suspended imports, medications subject to excessive demand, deregistered and unapproved products prescribed in Bulgaria.
- 29% of the signals are related to medications registered in Bulgaria, and 90% of them being available in the pharmacy network.
- 46% of the signals originate in Sofia, with over 80% coming from major cities.
- 28% of the submitters direct their enquiries to the pharmacy to obtain their medication, while 72% receive information and recommendations for consultation with a doctor and customised therapy.

Figure 3. Distribution according to the patient's decision for the signalled pharmaceutical product



Source: Own

Figure 4. Distribution according to the patient's decision regarding the signalled product



Source: Own

The reported medications are primarily not subject to exports; 1,119 cases involve medications that are supplied and traded only in the domestic market, while 136 medications are subject to export to other EU member states. There are 112 signals that are not applicable to this criterion.

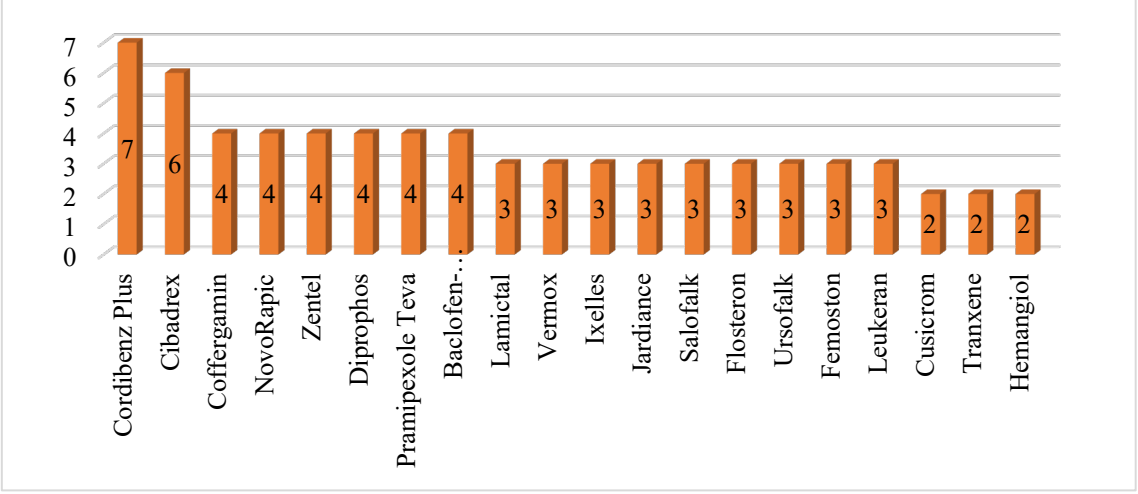
Table 5. Distribution of signals according to their status on the international market

Status	**Count**	**%**
Not subject to export	1199	82,86%
Subject to export	136	9,40%
Non applicable	112	7,74%
Total products	**1447**	**100%**

Source: Own

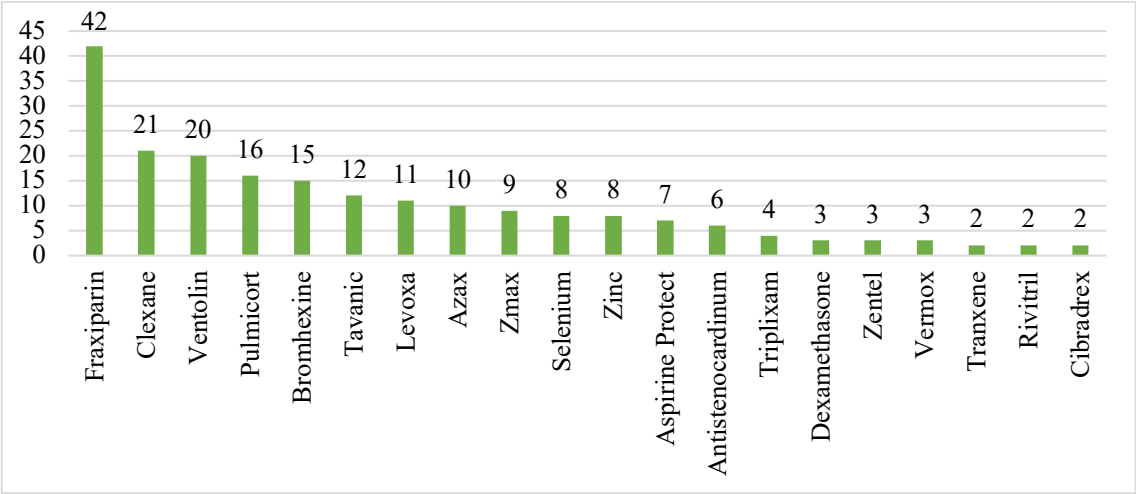
Prior to the pandemic, the reported medications were primarily those that were deregistered or in the process of deregistration. Generic products and those with low prices predominated. During the pandemic, there was a predominance of medications associated with excessive demand, linked to current protocols for hospital or home treatment in different periods.

Figure 6. Top 20 signalled pharmaceutical products



Source: Own

Figure 7. Top 20 signalled pharmaceutical products



Source: Own

The interim results of our national online survey revealed that in 70% of cases, the solution to the drug shortage lies in imports and rapid intracommunity deliveries that need to be properly communicated in the societyby the institutions. The signals from patients are related to deregistered medications, products with permanently or temporarily suspended imports, as well as excessive demand in the context of the pandemic.

4. Discussion

How effective is communication with the public and stakeholders? This question was analysed by public health authorities in 2018, revealing that 87% of regulatory authorities in the EU publish information about shortages on their websites, while 13% do not. Only a few member states have criteria that distinguish the duration and criticality of drug shortages. In the United States, the Pharmaceutical Association and the Food and Drug Administration publish a web list of medicines in shortage, providing brief information about them, the reasons for the shortage, suitable alternatives, and the expected resolution date.

Numerous elements of the public communications arsenal can be used for prevention and crisis management in public health. National Medicines Agencies (NMAs) publish regulatory reports with recommendations that closely follow the principles and tools of public relations: issuing press releases and holding press conferences, providing comprehensive information coverage on official websites, etc. Notification should occur once the shortage information has been confirmed by the NMA. Early communication with the public is encouraged as it is critically important to allow adequate planning and ensure continuity of patient treatment. Communication from national authorities should be targeted towards patients and healthcare professionals, while other participants in the supply chain, particularly wholesalers and pharmacies, should be addressed. The language used should be expert, yet understandable, with a calm tone. Public communication is achieved through the channels of stakeholders, scientific societies, media outlets (print, television, online, radio), and potentially through electronic systems in healthcare.

Regulatory affairs in the pharmaceutical sector are considered part of the communication mix. It serves as a channel for institutional communication with public authorities and for participation in public discussions on legislation and decisions related to public health.

Regulatory affairs are the key to overcoming and mitigating the impact of drug shortages. A flexible regulatory approach could include adapted strategies regarding Brexit and the status of UK companies in the EU, incentives for implementing medication verification systems, intra-community emergency supplies, procedures for "re-use," incentives for the production and trade of pharmaceutical products at low cost, etc.

CONCLUSION

(1) *Public healthcare requires immediate and strategic management with a focus on their impacts and the affected parties*. They are a pressing issue for public authorities and subject to investigation by the scientific and academic communities, especially in the context of the COVID-19 pandemic. The need for a systematic communication approach to crisis management in public healthcare is justified by the fact that disaster, accident, and emergency cases have been increasing in recent years. Additionally, investments in crisis preparedness led to prevention of human and financial losses, fatalities, and erosion of trust. A strong response from public communications can help quell public discontent, while a comprehensive communications toolkit can accelerate the recovery period after a crisis. Crises that have been timely and properly managed have a positive impact on individuals, stakeholders, and public authorities.

(2) *The Bulgarian pharmaceutical market chronically experiences drug shortages and is vulnerable to crises*. Limited purchasing power and low health literacy contribute to distorted consumption patterns. The regulatory framework, characterised by heavy price regulation of medicines, leads to the deregistration of 300 products annually, bans on generic substitution, and significant administrative burdens on parallel imports. These factors hinder economic and marketing opportunities to address the shortage.

(3) *The regulatory environment in Bulgaria does not adequately address the causes and impacts of drug shortages.* The COVID-19 pandemic exacerbated the existing shortage, but no regulatory actions have been taken in Bulgaria to initiate normative changes toward contemporary crisis management approaches and the promotion of the adoption of marketing methods to address the problem.

(4) *The leading causes of drug shortages are related to production and price regulation.* Aggregated data from consumer surveys, pharmacist surveys, and wholesalers outline the high risks associated with production, including disrupted supply chains due to logistics and raw material quality issues, batch recalls, pricing pressures, and withdrawal from low-volume national markets. Accordingly, product and pricing policies from the marketing mix are the means of influence, emphasizing the need to pay attention to integrated marketing communications. Logistic reasons are addressed through distribution policies, while regulatory reasons are again within the purview of the communication mix. They follow the local specifics in full synergy with the spirit of strategic marketing.

(5) *Public communications serve as a tool for timely interaction with the public.* Informing and engaging the public is a successful approach to mitigating the consequences of shortages and, in many cases, preventing them. Public health in Bulgaria has numerous untapped communication territories that could improve interactions with stakeholders through public relations, content marketing, digital marketing, etc.

(6) Legislative and institutional initiatives are necessary to establish mechanisms for the prevention and management of drug shortages, including the promotion of parallel imports, generic substitution, price flexibility, and incentives for manufacturers to invest in quality and sustainable production and still need to be properly communicated by the institutions to society.

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