

## DRUG SHORTAGES AS A CONSTANT PUBLIC HEALTHCARE CRISIS - CAUSES, CONSEQUENCES, SOLUTIONS

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### Abstract

*Publications on drug shortages have examined the extent, causes, nature and consequences of the triggers to public healthcare crises that have adverse effects on healthcare systems and patients. The shortage of medicines is investigated in different countries and is found to be due to a complex of reasons, putting to a serious test not only the drug supply chain but also the entire public healthcare systems, with high potential for serious impact on human health. It is becoming a worldwide issue that has deepened in recent years, especially in the context of a global pandemic, affecting both developed and developing countries. Prior the pandemic the United States reports an increase in shortages of newly registered products from 70 to 267 drugs over the five-year period from 2006 to 2011. The European Commission alarms that between 2000 and 2018 the shortage of widely used drugs has increased. Covid – 19 pandemic led to unprecedented lack of medicines due to manufacturing problems, stockpiling and overconsumption. The shortage of medicines puts the branches and structures of public healthcare in a situation of inability to fulfill their legal and moral obligations and responsibilities to consumers - from patients to specialists, pharmacies, and medical facilities. Being not only market deficiency but also regulatory challenge. Being a global phenomenon it still lacks common knowledge and common regulatory actions of different countries obvious in the fact that there are 25 definitions in the world of what constitutes a "drug shortage". This article is based on a study of the author of the consumer implications of drug shortages, conducted in Bulgaria in the period June 2018 - December 2021, covering 1460 signals for drugs in short supply before and during the pandemic. The article is also supported by a literature review on drug shortages. The author discusses the thesis that in-depth study of the causes and consequences of this ongoing crisis in public health would provide scientific and expert circles with tools to find sustainable solutions through which it can be foreseen, managed, and overcome with timely and effective measures.*

**Key words:** public healthcare, crisis management, drugs, shortage, supply chain

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## INTRODUCTION

Publications on drug shortages have examined the extent, causes, and nature of triggers to public healthcare crises that have adverse effects on health systems and patients. The shortage of medicines is investigated in different countries and is due to a complex of reasons, putting to a serious test not only the drug supply chain but also the entire public healthcare systems, with high potential for serious impact on human health as Burinskiene states in his work *The Concept of Medicines Shortage: Identifying and Resolving Shortage* (2019). Drug shortage is becoming a global phenomenon that has deepened in recent years, especially in the context of a global pandemic, affecting both developed and developing countries – a fact that is profoundly examined in Ireland by Costelloe et al. (2015) in 2015 and later in 2019 by Sarnola and Linnolahti in their article dedicated on EU member-state Finland “A regulatory perspective on the availability of medicines and medicine shortages in outpatient care” (2019). In Bulgaria drug shortages are recently examined in their regulatory and market aspects by Serbezova in her pre-print “Drug shortages: causes and solutions” (2021). The specific regulatory framework puts medicinal products in the status of strictly regulated, not ordinary goods. For their distribution and use, respectively, the standard principles of the economy of supply and demand, the classic marketing mix and positioning strategies cannot be applied and the influence of consumers over the product is almost completely absent. The shortage of medicines puts the branches and structures of public healthcare in a situation of inability to fulfill their legal and moral obligations and responsibilities to consumers - from patients to specialists, pharmacies, and medical facilities. It can occur at the production level when there is a shortage of raw materials and especially active substances (APIs) and go in the direction of the entire supply chain to wholesalers (distributors of pharmaceuticals), retailers and medical establishments for hospital care) up to the consumer level. At the same time, it is possible for production, marketing, or regulatory reasons to localize the shortage at only one level of the legal supply chain. Due to the complex and multifaceted nature of the phenomenon, in the world there are over 25 definitions of what constitutes a "drug shortage".

## THEORETICAL OBSERVATION

Shortage of medicines is becoming a worldwide issue that has deepened in recent years, especially in the context of a global pandemic, affecting both developed and developing countries. Prior the pandemic the United States reports an increase in shortages of newly registered products from 70 to 267 drugs over the five-year period from 2006 to 2011<sup>2</sup>. The European Commission alarms that between 2000 and 2018 the shortage of widely used drugs has increased<sup>3</sup>. Covid – 19 pandemics led

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<sup>2</sup> American Hospital Association, American Society of Anesthesiologists, American Society of Clinical Oncology, American Society of Hospital Pharmacists, Institute for Safe Medication Practices, The PEW Charitable Trusts. 2014 Drug Shortages Summit. 1 August 2014 [meeting report]

<sup>3</sup> <https://www.europarl.europa.eu/news/bg/headlines/society/20200709STO83006/nedostigh-na-lekarstva-v-es-prichini-i-resheniia>

to unprecedented lack of medicines due to manufacturing problems, stockpiling and overconsumption.

In the last year, the causes of the shortage and the increased consumption of medicines under the shadow of the pandemic and the pressure caused by it on the drug supply chain have been thoroughly studied. Reasons for shortages include supply problems, demand problems and regulatory issues, and affect all other areas of life and business. Review of the current scientific literature, conducted by Serbezova (2021) shows that the problems with the supply of medicines are due to production problems, lack of raw materials, logistics and business problems. They distinguish that demand problems include overconsumption, seasonal demand, and unpredictable drug demand. Regarding regulatory cases, the essential factor is the lack of a uniform definition of drug shortages. The definition of the European Medicines Agency (EMA), "shortages of medicinal products for human or veterinary use are observed when, at national level, supply does not meet demand"<sup>4</sup>. Bulgaria has adopted more conservative definition has been adopted in the Law on Medicinal Products in Human Medicine (LMPHM), which is narrowed down to the medicinal products included in the Positive Drug List or the medicines that the National Health Insurance Fund (NHIF) partially or fully pays for. A shortage is registered for them when "it is established that the quantities of the respective medicinal product available on the territory of the Republic of Bulgaria are less than 65 per cent of the quantities necessary to meet the health needs of the population for a period of one month. of the average monthly consumption of the medicinal product concerned for the previous 6 months from the day of the analysis"<sup>5</sup>.

#### **DATA COLLECTION. OBJECT OF STUDY**

This article is based on a study of the author of the consumer implications of drug shortages, conducted in Bulgaria in the period June 2018 - December 2021, covering 1460 signals for drugs in short supply before and during the pandemic. Data is collected on the online platform of the Bulgarian Association for Medicines Parallel Trade Development (BAMPTD) where it is operated by the author of the article. For the creation and maintenance of this first online platform for signaling of drug shortages in Bulgaria the author and Federation Bulgarian Patient Forum were awarded the prize for Innovation and good practice in the health sector in the second competition organized by Capital and AbbVie in 2019<sup>6</sup>. Signals are gathered over the platform and are stored in a registry for drugs in deficiency with the following attributes: date of signaling, date of signal solving, type of signaling person or institution – patient, relative, physician, pharmacist, patient organization, media; drug trade name, dosage, active substance, indication for usage, marketing authorization holder (MAH), export status – positive or negative; reason for signaling, drug market status – available in the supply chain, hospital product, not permitted drug, deregistered drug,

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<sup>4</sup> Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA), 01 July 2019, EMA/674304/2018

<sup>5</sup> Law On Medicinal Products In Human Medicine, SG. No. 31 of April 13, 2007, last ed. and ext. SG. No. 103 of December 4, 2020, as amended. and ext. SG. issue 105 of December 11, 2020.

<sup>6</sup>[https://www.capital.bg/politika\\_i\\_ikonomika/zdraveopazvane/2019/12/06/4004936\\_boriana\\_marinkova\\_tursihme\\_leka\\_rstvata\\_na\\_702\\_pacienti/](https://www.capital.bg/politika_i_ikonomika/zdraveopazvane/2019/12/06/4004936_boriana_marinkova_tursihme_leka_rstvata_na_702_pacienti/)

temporarily ceased supply, permanently ceased supply; solution of the signal – drug found and information provided about drug location, in case of hospital products, not permitted or deregistered drug – recommendation for consultation with a physician; signaling person's or institution contact details.

The object of the study is the individual implication of drug shortages. The subjective factor in determining the shortage of drugs has been studied and a solution to each one has been sought. The data collection, their analysis and conclusions were performed by the author through an online platform created by him for signals for shortages of medicinal products in human medicine. Electronic messages for shortage of intermediate and end users of health services have been processed.

## RESEARCH METHODS

In order to differentiate the problem of drug shortage as a public healthcare crisis in Bulgaria and its subjective implication on each end user based on author's research conducted in 30 months and collected 1460 signals for deficient medicinal products. The data is registered and statistical analysis is aided by SPSS, version 20.0. Continuous variables are directly expressed as a range. The categorical variables are expressed as a number (%). A regulatory review of the market specifics leading to lack pharmaceutical products in Bulgaria and EU was conducted, based on the applicable law for public health in our country - LLPHM and related EU regulatory framework.

The article is also supported by a literature review on drug shortages. The author discusses the thesis that in-depth study of the causes and consequences of this ongoing crisis in public health would provide scientific and expert circles with tools to find sustainable solutions through which it can be foreseen, managed, and overcome with timely and effective measures.

## FINDINGS

Shortage of medicines became a worldwide phenomenon accelerating its significance and implications in recent years in the context of a global pandemic. Nevertheless, the problem has been in the focus of the US and EU authorities since 2014. A literature review reveals numerous articles and regulatory actions to reveal causes of shortages and decision for its mitigation prior and during the COVID-19 pandemic.

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) network set up the HMA / EMA Task Force on the Availability of Authorized Medicines for Human and Veterinary Use in 2016, with the main aim of providing strategic support and advice to cope with drug shortages of EU Member States in the event of interruptions in the regular supply of medicinal products for human and veterinary use<sup>7</sup>, and one of the key priorities of this working group is to find regulatory approaches to reduce interruptions in the regular supply of medicinal products (e.g. by sharing work between regulators, reducing administrative deadlines, etc.), developing guidelines for pharmaceutical companies to report drug shortages, encouraging the sharing of good practices

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<sup>7</sup> <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines>

and information between Member States, strengthening cooperation between stakeholders and communication with patients about drug shortages, which is part of the integrated communications of the participants in the pharmaceutical market.

According to the European Parliament statement in 2020<sup>8</sup>, the geopolitical dimensions of drug shortages in the EU are:

- Dependence of 80% of the active substances on India and China;
- Dependence of 40% of finished medicinal products sold in the EU by India and China;
- China and India produce about 60% of global paracetamol use, 90% of penicillin and 50% of ibuprofen.

The same data from the European Parliament shows that more than 50% of the drugs in short supply are medicines for treatment of cancer, infections and neurological diseases (epilepsy, Parkinson's disease), etc.

A large-scale study in Europe in 2014 (EAHP, 2014) found that 21% of hospital pharmacists reported experiencing a shortage of medicines every day, and 45% every week. One in five pharmacists said they could not cope with many of these situations and said the drug shortage was causing the patient inconvenience from stopping treatment.

The problem of shortages has received significant public and political attention in the EU. The scale of the public healthcare crisis called "shortage of medicines" is proven also by the fact that the European Commission (EC) considered it necessary to coordinate the efforts of EU member states to overcome it at European level in 2016<sup>9</sup>.

In the latest Pharmaceutical Group of the European Union (PGEU) survey from 2020<sup>10</sup>, 96.15% of countries surveyed said drug shortages caused stress and anxiety, 80.77% discontinued treatment, 57.69% increased patient co-payments, 23.07% made medical errors, and so on. The shortage of certain medicinal products (anti-infective agents, vaccines, etc.) has consequences that exceed the consequences for the individual.

The COVID-19 pandemic has further spotlighted shortages of medicines and interruption in pharmaceutical supply chains. In March 2020 the Commission, together with the EMA and Member States set up an EU Executive Steering Group on Shortages of Medicines Caused by Major Events to effectively respond to and prevent the escalation of shortages<sup>11</sup>.

In April 2020, EU university hospitals warned of the danger of depletion of certain drugs - anesthetics, antibiotics, muscle relaxants and others. The reasons are reduced production, restrictions on exports from other countries and the desire to accumulate reserves during the health

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<sup>8</sup> <https://www.europarl.europa.eu/news/bg/headlines/society/20200709STO83006/nedostigh-na-lekarstva-v-es-prichini-i-resheniia>

<sup>9</sup> 13. Criteria for classification of critical medicinal products for human and veterinary use, 2016, EMA/24304/2016, [https://www.ema.europa.eu/en/documents/other/criteria-classification-critical-medicinal-products\\_en.pdf](https://www.ema.europa.eu/en/documents/other/criteria-classification-critical-medicinal-products_en.pdf)

<sup>10</sup> PGEU Medicine Shortages Survey Results, 2020 <https://www.pgeu.eu/wp-content/uploads/2019/03/2020-PGEU-Medicine-Shortages-Survey-Results-v2.pdf>

<sup>11</sup> European Medicines Agency (Press release 10 April 2020) Update on EU actions to support availability of medicines during COVID-19 pandemic. Available at <https://www.ema.europa.eu/en/news/update-eu-actions-support-availability-medicines-during-covid-19-pandemic>.

crisis<sup>12</sup>. According to this analysis of the growing shortage of essential medicines and the reasons for this, on 17 September 2020, Parliament adopted a resolution calling on Europe to guarantee its independence in the field of health by securing supplies, restoring local production and improving coordination within the EU.

The latest report on shortages in EU, published in December 2021 emphasizes that Member States and many stakeholders, including pharmacy organisations, have signalled a rise in shortages of medicinal products in the EU (Jough, 2021). The report reveals that shortages present a major problem for the quality and continuity of patient care and “at best, patients can be provided with an equivalent medicine, but if no such equivalent is available, pharmacists may have to resort to therapeutic substitution”. The authors assess that this could increase the risk of reduced treatment compliance or incorrect use of the medicine, leading to lower treatment effectiveness and disease progression. Medicine shortages also have important economic consequences, show the authors of Future-proofing pharmaceutical legislation — study on medicine shortages and spotlight that pharmacists spend several hours per week on conferring with prescribers about suitable alternatives and patients may face higher costs when prescribed alternatives are more expensive or if they must pay for additional visits with their healthcare provider to discuss alternatives.

The authors research in Bulgaria assesses namely patients’ experience related to shortage of medicines based on 1,462 patient signals. After they have been collected and processed, the following is derived as results:

- 70% of the signals for shortage would be solved by import – these are drugs with temporarily suspended import, drugs subject to overuse, deregistered drugs, unauthorized products that are prescribed in Bulgaria
- 29% of the signals are for the medicinal products registered in Bulgaria, as 96% of them are available in the pharmacy network
- 46% of the signals come from Sofia, over 80% are from big cities
- 28% are people referred to a pharmacy nearby to get their medicine
- 71% are referred to their doctors for consultation due to suspended import or search for deregistered / unregistered products in our country or in 1% of cases due to search in pharmacies for hospital medicinal products.

## DISCUSSION

The literature review reveals that predominant reasons are reduced production, restrictions on exports from other countries and the desire to accumulate reserves during the health crisis. According to this analysis of the deep shortage of essential medicines and the reasons for this, on 17 September 2020 the European Parliament adopted a resolution calling on Europe to guarantee its independence in the field of health by securing supplies, restoring local production, and improving coordination within EU. At the same time, the European Commission called in two of its guides on Member States, "to preserve the free movement of all goods and, above all, to ensure the supply

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<sup>12</sup> <https://www.europarl.europa.eu/news/bg/press-room/20200910IPR86823/covid-19-es-triabva-da-velichi-usilliata-za-spraviane-s-nedostigha-na-lekarstva>

chain of essential products such as medicines" and stressed that there should be no restrictions on the movement of goods. the single market, especially when they relate to health.

On the other hand, the interim results of authors' national online survey showed that in 70% of the cases the reason for shortage is related to supply, and the offered solution to these shortage is in imports and fast intra-community supplies. The signals from the patients concern deregistered medicines, products with permanently or temporarily suspended import in Bulgaria, medicines subject to overconsumption within the pandemic, for which not enough supplies have been provided.

The author discusses that liberal policies and regulatory changes to promote the non-interruption of supply and encouraging fast import of medicines in an adequate and effective regulatory framework will ensure the availability of medicines in Bulgaria as a EU MS. The respective regulatory infrastructure would largely solve the situations of shortage and shortage of medicines in Bulgaria and will ensure the access of patients to a variety of medicines in all European countries, not just those registered in the local market by fast delivery, parallel imports and flexible regulation of not registered in Bulgaria but registered in EU drugs.

The EC in its latest report on shortages quoted above assessed stakeholders' perspectives on the introduction of measures to create an economic and regulatory framework incentivising the local production of APIs, raw materials and medicines to better protect continuity of supply and reduce Europe's dependence on pharmaceutical manufacturing elsewhere and to focus not only on innovative but also on most often involving older, off-patent and generic medicines and also on regulatory issues as to national pricing and procurement practices. Further dialogue between authorities and manufacturers, such as that currently taking place in the EU structured dialogue, may deepen the understanding of what measures are most appropriate to improve supply chain resilience and what role reshoring of pharmaceutical production can play in this" discuss the authors of the report (Jough, 2021). A series of 16 policy measures are presented for action at EU and national level that are to be discussed by politicians and stakeholders.

## CONCLUSION

Medicine shortages present a growing problem for EU and globally. Consequences of shortages as a permanent public healthcare crisis include a decreased quality of treatment received by patients and an increased burden on healthcare professionals, and on health systems. In recognition of the problem and of the need for concerted action at the European level, the European Commission requested an analysis of medicines in shortage in the EU and their root causes, as well as an assessment of the current regulatory framework, to devise potential legislative and non-legislative solutions. While the comprehensive comparative analysis is severely hampered by a lack of high-quality, standardised information about shortage monitoring at national levels. Notwithstanding data limitations, this article by discussion confirms that medicine shortages occur frequently across the world, most often involving older, off-patent and generic medicines. The causes are multifactorial affecting all stakeholders along the pharmaceutical value and supply chain, from manufacturing of raw materials to national pricing and procurement practices.

In Bulgaria liberal policies and regulatory changes to promote the non-interruption of supply and encouraging fast import of medicines in an adequate and effective regulatory framework will ensure the availability of medicines in Bulgaria as a EU MS are to be in the agenda of the new healthcare governance. The author suggests a respective regulatory infrastructure would largely solve the situations of shortage and shortage of medicines in Bulgaria and will ensure the access of patients to a variety of medicines in all European countries, not just those registered in the local market by fast delivery, parallel imports and flexible regulation of not registered in Bulgaria but registered in EU drugs.

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## НЕДОСТИГЪТ НА ЛЕКАРСТВА КАТО ХРОНИЧНА КРИЗА В ПУБЛИЧНОТО ЗДРАВЕОПАЗВАНЕ – ПРИЧИНИ, ПОСЛЕДСТВИЯ, РЕШЕНИЯ

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### Резюме

Публикациите, посветени на недостига на лекарства, изследват степента, причините, естеството и последствията от кризите в публичното здравеопазване, които имат неблагоприятно въздействие върху здравните системи и пациентите. Недостигът на лекарства са обект на проучване в различните държави, като се установява, че той се дължи на комплекс от причини, които поставят на сериозно изпитание не само веригата за доставки, но и цялата публична здравна система с висок риск за сериозен импакт върху човешкото здраве. Недостигът на лекарства се превръща в световен проблем, който се задълбочава през последните години, особено в контекста на глобална пандемия, засягаща както развитите, така и развиващите се страни. Преди пандемията Съединените щати отчитат нарастване на недостига на новорегистрирани продукти от 70 на 267 лекарства в периода 2006 - 2011 г. Европейската комисия алармира, че между 2000 и 2018 г. недостигът на широко използвани лекарства се е увеличил. Пандемията, предизвикана от Covid – 19, доведе до безпрецедентна липса на лекарства поради производствени проблеми, натрупване на запаси и свръхпотребление. Недостигът на лекарства поставя браншовете и структурите на публичното здравеопазване в ситуация на невъзможност да изпълняват своите законови и морални задължения и отговорности към потребителите – от пациенти до специалисти, аптеки и лечебни заведения. Това е не само пазарен дефицит, но и регулаторно предизвикателство. Бидейки е глобален феномен, за него все още няма изградени общи регулаторни действия на различните държави, което е очевидно от факта, че в света има 25 дефиниции за това какво представлява „недостигът на лекарствени продукти“. Тази статия е базирана на проучване на автора на потребителските последици от недостига на лекарства, проведено в България в периода юни 2018 - декември 2021 г., обхващащо 1460 сигнала за недостиг на лекарства преди и по време на пандемията. Статията е подкрепена и от преглед на литературата по отношение на недостига на лекарства. Авторът обсъжда тезата, че задълбоченото изследване на причините и последствията от настоящата криза в публичното здравеопазване би предоставило на научните и експертни среди инструменти за намиране на устойчиви решения, чрез които тя да бъде предвидена, управлявана и преодоляна с навременни и ефективни мерки.

**Ключови думи:** публично здравеопазване, управление на кризи, лекарства, недостиг, верига за доставки.

<sup>13</sup> Боряна Маринкова е докторант по Публична администрация в УНСС. Темата на нейната дисертация е Управление на кризите в публичното здравеопазване чрез маркетингови методи. Автор е на публикации, посветени на кризисните ситуации в здравеопазването, изследващи техния генезис, типология и протичане в търсене на ефективни методи за кризисен мениджмънт, навременно установяване и превенция. Маринкова е и хоноруван преподавател по Интегрирани маркетингови комуникации в УНСС. Към момента е изпълнителен директор на Българската асоциация за развитие на паралелна търговия с лекарства (БАРПТЛ). Има 11 години опит като маркетинг директор на "Токуда болница". В периода 2012 – 2017 година оглавява връзките с обществеността на Националното сдружение на частните болници. Завършила е магистратура по маркетинг в УНСС през 2004 след бакалавърска програма по Икономика на масмедиите отново в УНСС. Преминала е две сертификационни програми в BEIED - Professional Marketing Management и Professional Executive Management през 2015. b.marinkova@unwe.bg