

Shortage of essential pediatric medications puts children's health at risk. Results from a European Confederation of Primary Care Paediatricians (ECPCP) Survey 2023

Christine Magendie^{a,*}, Gottfried Huss^a, Laura Realì^a, Stephen Reingold^b

^a European Confederation of Primary Care Paediatricians, Lyon, France

^b Meheudet Health Services, Tel Aviv, Israel

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ABSTRACT

Unparalleled drug shortages during the winter of 2022/2023 had a profound impact on paediatric primary care across Europe. A survey conducted by the European Confederation of Primary Care Paediatricians (ECPCP) evaluated the availability of essential pediatric drugs and the resulting challenges. The survey was conducted between January and March 2023 and included responses from 640 paediatricians from 18 countries. The results of the survey indicated that there were substantial shortages, particularly of child friendly formulations of commonly prescribed medicines. Paediatricians in the survey feared that the use of less appropriate alternatives could potentially compromise the efficacy and safety of treatment. The survey findings highlight the urgent need for coordinated actions at multiple levels to ensure the availability of essential pediatric medications and safeguard children's health in future crises.

During the winter of 2022/2023 drug shortages of unprecedented proportions were experienced in Europe, significantly and adversely affecting healthcare across the continent. Primary pediatric healthcare was particularly affected due to a shortage of essential medications, as well as limited availability of pediatric formulations.¹ In contradistinction to the adult population, pediatric care relies on a relatively fewer number of approved drugs available in formulations suitable for pediatric use. The crisis was further aggravated by an unexpected surge in respiratory illnesses after rescinding COVID restrictions,² resulting in an increased demand for antipyretics and antibiotics.¹ The European Union (EU) has become increasingly dependent upon third-world countries, India and China in particular, for active pharmaceutical ingredients, chemical raw materials and finished drugs. Measures adopted by the EU to enhance self-sufficiency in healthcare³ have not yet succeeded in mitigating the effect of foreign dependence upon drug shortages. Though the European Parliament had called for strengthening drug production in Europe, adopting best practices on stockpile management, increasing joint purchasing of medicines, and simplifying the transfer of medicines between member states, the benefits of such legislation has yet to be realized.

A brief survey was issued by the ECPCP to ascertain the effect of this shortage as experienced by primary care pediatricians. The responses

from various European countries should call public attention and discuss specific actions to overcome the shortage and prevent future supply problems.

Methods

The survey was conducted using an online questionnaire, which was distributed to primary care pediatricians across Europe between January 31st and March 31st 2023. The questionnaire focused on the availability of selected essential drugs and pediatric preparations during the winter of 2022/2023. The survey also addressed the perceived consequences of medicine shortages on the quality of care, as well as strategies to prevent future crises.

Results

A total of 640 pediatricians from 18 European countries responded to the survey. The distribution of answers was uneven with more than half (52.5 %) of the answers originating from Austria and Switzerland (Table 1). 10 participants didn't indicate their country of work. The distribution may reflect particular concern in central European countries with usually rather robust health systems.

* Corresponding author.

E-mail address: christinemagendie@gmail.com (C. Magendie).

Table 1
Answers to the survey from 18 European countries.

Country	Number of responses
Austria	219
Croatia	16
Czechia	1
Finland	1
France	42
Germany	51
Hungary	32
Israel	7
Italy	24
Liechtenstein	1
Lithuania	1
Portugal	9
Slovakia	19
Slovenia	42
Spain	8
Turkey	23
Ukraine	17
Switzerland	117

89 % (563) of the respondents to our survey work in pediatric primary care, 84 % (524) in a practice setting. 98 % (620) indicated that they write prescriptions for pharmacies, 27 % (170) dispense medicines to patients in a practice dispensary.

We found that the availability and supply of essential drugs and preparations for children varied significantly among the countries but also regionally, within the countries surveyed. Almost all countries reported significant shortages for Amoxicillin syrups for the use in young children (Table 2).

Children's formulations of commonly prescribed medications were more greatly affected than adult preparations (Table 2) and children were likely to be treated with less appropriate preparations, (such as tablets and capsules) and reduced compliance.

Two-thirds of the respondents (66 %) agree that the shortage of pediatric preparations places children's health at risk. (Fig. 1) Of particular concern are children requiring specific medications that are not easily substituted.

Furthermore, a very significant portion of the primary care pediatricians (76 %) expressed concern that drug shortages may result in less appropriate drug substitutions (Fig. 2).

A comprehensive review of medicine shortages in the examined period is beyond the limited scope of our survey. When asked about other essential drugs with significant shortages the respondents described difficulties in securing anti-epileptics, adrenalin pens, oral steroids, metered dose inhalers of bronchodilators and steroids, a broad range of antibiotics not itemized in our survey, analgesics, anti-inflammatories, local anesthetics, certain vaccines, and even oral rehydration solutions.

The last part of the survey explored ways to address these shortages and improve the availability of essential medicines for the pediatric population (Table 3). Interestingly, respondents considered reasonable

Table 2
Availability of generics and child appropriate preparations.

Substance	Preparation	Not available %	Short %	Available %
Amoxicilline	Syrup	38	47	13
Amox/Clav	Syrup	25	45	29
Penicilline V	Syrup	45	20	15
Paracetamol	Syrup	12	35	52
Ibuprofen	Syrup	31	37	29
Paracetamol	Suppositories	12	30	55
Ibuprofen	Suppositories	21	24	37
Amoxicilline	Tablets	15	40	36
Amox/ Clav	Tablets	10	33	48
Penicilline V	Tablets	26	24	24
Paracetamol	Tablets	4	16	74
Ibuprofen	Tablets	4	19	68

practice and the judicious use of antibiotics as a key factor to avoid these shortages in the future. In some countries antibiotic prescriptions skyrocketed during the RSV wave in early fall, despite limited indications for antibiotic use.¹

Reallocation of pharmaceutical production to Europe, monitoring of stockpiles, coercion of pharmaceutical industry to ensure sufficient stocks of essential medicines for children, distribution of tailored volumes and education of parents and caregivers were also deemed necessary.

Discussion

During the winter of 2022/2023 pediatricians and other primary care healthcare providers had to cope with an early and particularly high wave of respiratory tract infections, possibly caused by an altered population immunity after the COVID pandemic. The exceptional occurrence of early and very intense bronchiolitis and flu waves in children had placed an unexpected burden on pediatric primary care and increased the demand for commonly used children's medicines. In this context primary care providers experienced an exceptional shortage of drugs tailored to children.

The shortage of first-line antibiotics for common infections was of concern, and in particular, that of Amoxicillin which accounts for 80 % of all pediatric antibiotic use.¹ Narrow spectrum antibiotic use is a critical issue in pediatric health in the fight against bacterial resistance and in protecting the gut flora. Unnecessary use of wide-spectrum antibiotics can have drastic effects on public health. Such over-prescribing is likely to increase the risk of bacterial resistance and may cause iatrogenic harm and unnecessary costs.

Research indicates that pediatricians are more likely to follow clinical practice guidelines for child infectious diseases when compared to other primary care providers, thus mitigating the aforementioned deleterious public health effects.⁴ Therefore, and all the more so, health authorities must enable pediatricians by ensuring the availability of appropriate antibiotics. Improved vaccination against common viruses, such as influenza, RSV and rotavirus may prevent the need for medications and alleviate pressure on medicine supplies and the healthcare system overall.

Supply shortages of antipyretics and analgesics have significant public health effects as well. Parental concern of their children's fever and pain increases when they lack the medications to help relieve those symptoms, resulting in increased office visits and parental demands for antibiotics. Pediatricians and other primary care providers need to inform parents and caregivers about the physiological role of fever in fighting common viral infections to avoid unnecessary prescriptions. With proper counseling caregivers can be empowered to manage the symptoms of minor illnesses without resorting to unnecessary drug treatments.

Mitigation measures include the availability of various pediatric formulations for the same drug, including syrups, chewables, dispersibles and suppositories. The quantity of medication dispensed should be tailored to dosage and treatment duration to avoid unnecessary waste. Improved communication with prescribers and providers about available medications can help to spare families' unnecessary trips from one pharmacy to another and repeat trips to the pediatrician.

The scope of medication shortages extended far beyond the limited examples in our survey. Shortages disproportionately affected pediatric formulations and child-friendly medicines used to treat various pediatric conditions. Healthcare providers need to be aware of the potential risks from these shortages and support appropriate actions to mitigate them. A significant majority (three out of four) pediatricians in our survey fear that drug shortages may lead to inappropriate treatment such as regrettable substitutions, dosage errors and compliance issues. Two-thirds affirmed that these shortages could present a risk to children's health making it a public health concern.

The root cause of drug shortages for essential pediatric drugs and

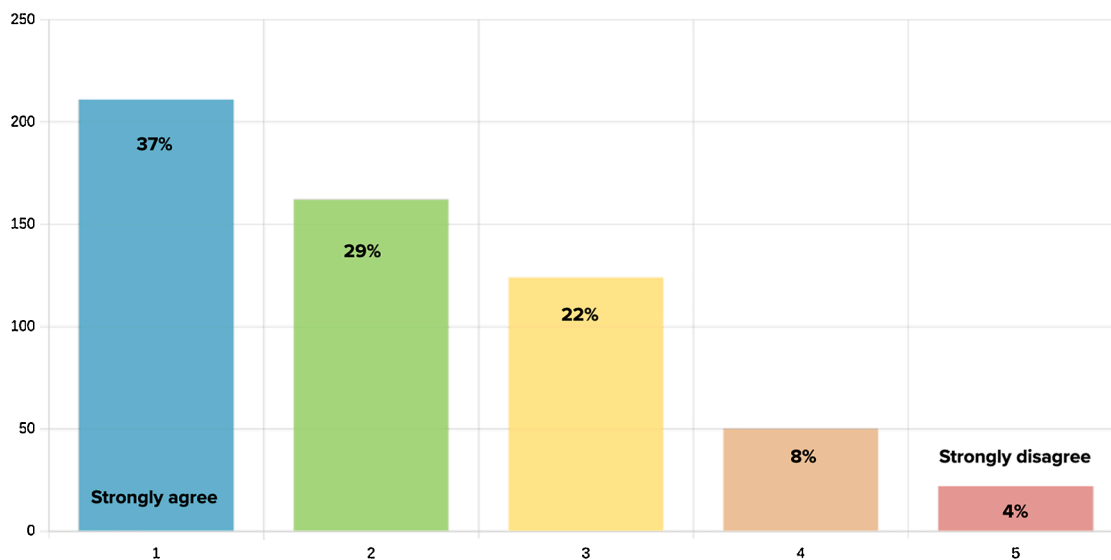


Fig. 1. Does the shortage of children's medicines put children's health at risk?

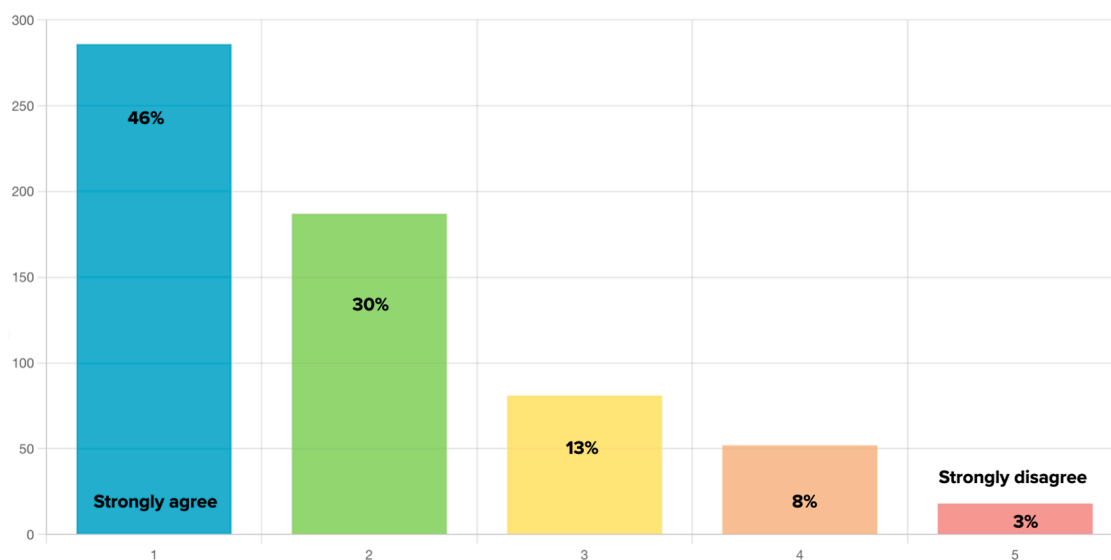


Fig. 2. Do you think that drug shortages pose a risk to the appropriateness of your prescriptions?

preparations for children is multifactorial including epidemiological seasonality, prescription patterns, supply chain and production issues, distribution, demand, pricing, and procurement challenges.

Pediatric medications are often low-cost and not very profitable to pharmaceutical industries which may also explain why drug shortages disproportionately affect pediatric formulations and drugs.

Pediatricians in our survey supported a multi-stakeholder approach to address these shortages. This includes better monitoring of stockpiles, compelling the pharmaceutical industry to maintain sufficient stocks of essential medicines for children, relocating production to decrease reliance on unreliable international markets and dispensation of tailored volumes to avoid wasting medicines.

A recent survey⁵ has shown how governments throughout Europe have been responding to medicine shortages by imposing several short-term and long-term measures such as electronic-reporting and stocking obligations, financial incentives and sponsored initiatives to enhance local production including permission granted to pharmacies to produce magistral preparations that can help to mitigate drug shortages. These are crucial initial steps to preventing shortages in the future.

Conclusion

The results of this survey highlight the need for ensuring the availability of essential medicines for children. Causes for the drug shortage during the winter of 2022/2023 were multifactorial and included a rather exceptional epidemiological situation after the end of Covid restrictions and structural issues related to prescription, production, distribution, and procurement. Our survey confirmed that shortages of selected medicines disproportionately affected pediatric formulations and the scope of shortages of essential drugs and preparations for children reported in the survey is a cause for concern.

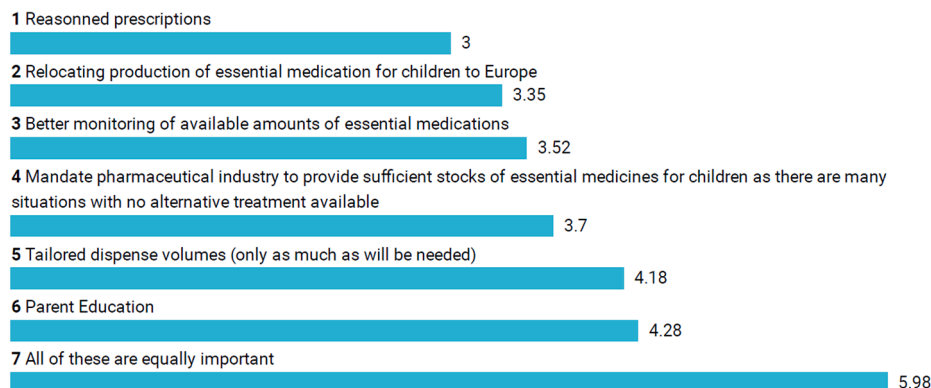
Although the survey's design prevents us from studying this particularity, the fact that more than half of the respondents are from Austria and Switzerland may suggest that primary care physicians in these countries are more responsive to the issue and aware of it, or that they have experienced more shortages.

Child-friendly medicines suffer disproportionately from economic pressure and the laws of the free market. Healthcare providers must be aware of the potential risks of drug shortages, and we must advocate to

Tab 3

Weighted answers about promising actions to improve availability of essential medicines.

What might be promising actions to avoid these kinds of shortages in the future ? Please sort with order of importance!



prevent this kind of crisis.

In a joint statement⁶, the ECPCP and EPA-UNEPSA underlined that all efforts should be made to ensure the availability of essential medicines for children and that any potential shortages are addressed promptly and effectively so as to mitigate their adverse effects. The ECPCP and EPA-UNEPSA have emphasized that drug shortages can pose health risks to the pediatric population, by undertreatment, medication errors, increased length of hospital stay, and adverse reactions due to attempts to replace unavailable drugs.

The survey demonstrates that these concerns are widely shared among primary care pediatricians in Europe and underscores the need for action at multiple levels including international organizations and agencies, national governments and health authorities, the pharmaceutical industries and local providers. Understanding and analyzing the roots and the scope of the problem can help to address the current emergency and strengthen the resilience of public health systems to deal with the next inevitable crisis.

CRediT authorship contribution statement

Christine Magendie: Conceptualization, Data curation, Investigation, Methodology, Writing – original draft. **Gottfried Huss:** Conceptualization, Formal analysis, Methodology, Supervision, Writing – review & editing. **Laura Reali:** Writing – review & editing. **Stephen Reingold:** Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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