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Tackling medicine shortages during and after the COVID-19 pandemic: Compilation of governmental policy measures and developments in 38 countries

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ABSTRACT

In response to increasing shortages of medicines, governments have implemented legislative and non-legislative policy measures. This study aimed to map these policies across high-income countries in Europe and beyond as of 2023 and to analyse developments in governmental approaches since the beginning of the pandemic. Information was collated from 38 countries (33 European countries, Australia, Brazil, Canada, Israel and Saudi Arabia) based on a survey conducted with public authorities involved in the Pharmaceutical Pricing and Reimbursement Information (PPRI) network in 2023. 34 countries requested pharmaceutical companies to notify national registers of upcoming shortages and 20 countries obliged manufacturers and/or wholesalers to stock supply reserves of critically needed medicines. Further common measures included export bans for defined medicines (18 countries), regulatory measures to facilitate import and use of alternative medicines (35 countries) and multi-stakeholder coordination (28 countries). While the legislation of 26 countries allows imposing sanctions, particularly for non-compliance to reporting requirements, fines were rather rarely imposed. Since 2022, at least 18 countries provided financial incentives, usually in the form of price increases of some off-patent medicines. Overall, several policies to address medicine shortages were taken in recent years, in some countries as part of a comprehensive package (e.g., Australia, Germany). Further initiatives to secure medicine supply in a sustainable manner were being prepared or discussed.

1. Introduction

Countries all over the world, including high-income countries in Europe, have been experiencing increases in temporary and permanent non-availability of medicines, commonly referred to as shortages [1–9]. Already before the COVID-19 pandemic, the number of medicine shortages reported had reached unprecedented levels in several high-income countries in the last decade (e.g., Canada [10], Finland [11], France [12], Switzerland [13]). For 2019, a European Commission study surveyed more than 6633 shortage notifications (relating to nearly 3000 medicines) in Portugal and over 4800 notifications (1630 products) in the Netherlands [7]. In COVID-19 times, in particular in the early months of the pandemic, increases in shortages of medicines, including those needed to treat COVID-19 symptoms, were reported [14–20]. The extent of medicine shortages remained high in the course of the years: for instance, in the Northern hemisphere winter 2022/2023, several countries faced shortages of "basic medicines" for the treatment of respiratory tract infections, including paediatric formulations, over several months [21–23].

Data agree in documenting substantial increases in notified shortages over the last decade (however, with a decrease in 2021 compared to the previous year but resulting in another increase in 2022 at higher levels than in 2020) [24–27], which may also be attributable to stricter reporting requirements [1,7,12,13]. However, the magnitude of shortages (and increases in shortages) cannot be compared across countries. This is due to a lack of a harmonised definition and counting methodology for reporting shortages (see Acosta et al. 2019 [28], a 2022 OECD study [1] and the annex in Vogler and Fischer 2020 [29] for an overview

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of national definitions for a medicine shortage).

In some cases, therapeutic alternatives might be identified for the medicine in short supply, so that a supply chain disruption does not compromise patient access to medicines. The German language provides for a distinction between a "Lieferengpass" (interruption in the normal volume of supply over a defined period of time) and a "Versorgungsengpass" (a treatment shortage resulting from a shortage in supply) [30]. Such treatment shortages pose risks which endanger patient health [31–33]. Adding to negative impacts on clinical health outcomes for patients, medicine shortages also have economic implications, since they were found to increase costs, due to the need to purchase more expensive alternatives or due to additional costs incurred for health professionals and the health system to manage medicine shortages [13,34,35]. Evidence shows that health care providers have been investing relevant parts of their working time to secure needed medications for patients, e.g., by identifying and procuring alternatives [2,36]. Most recent data of the annual survey of European community pharmacy association with responses from 29 countries indicated that in 2022 community pharmacy staff spent on average 6.68 h per week on dealing with medicine shortages, and these figures had increased compared to previous years [37].

A variety of supply-side and demand-side related root causes, which may occur simultaneously, are responsible for the non-availability of medicines. They include quality problems in the production, global concentration of production sites for active pharmaceutical ingredients (API), disruptions in the transportation and business strategies by suppliers as well as increased demand due to higher incidence of some diseases as observed during the COVID-19 pandemic and in the winter season 2022/2023 when other infections had increased [1,7,13,32,38].

In light of the urgency for action, policy-makers, staff in public administration, health care providers and further experts are interested in learning about policies that other countries have been applying. Some studies provided cross-country overviews of policy measures to address medicine shortages [1,7,28,29,39]. However, these publications took stock of policies which were in place before or at the beginning of the COVID-19 pandemic. A systematic update on more recent measures is, to our best knowledge, not available.

Against this backdrop, this article maps governmental policy measures to manage and mitigate medicine shortages in mostly high-income countries in 2023. Additionally, it explores the developments and changes in national policy approaches during the years of the COVID-19 pandemic. The study investigates a larger number of countries, including those European countries which are less in the focus of public attention and less covered in scientific research (e.g., smaller and/or less resourced countries).

2. Methods

This article builds on methodological approaches applied in the research of Vogler and Fischer 2020 [29], which studied policies to address medicine shortages that were place in 24 countries in 2020.

2.1. Scope of the survey

The study investigated governmental policy measures, i.e., those which were prepared, piloted or implemented by governmental institutions such as ministries of health or medicines agencies. While acknowledging that further health care providers and stakeholders (e.g., supply chain actors) may play an important role in the management and avoidance of medicine shortages, their activities were not in the scope of this study. Multi-stakeholder cooperation was included if initiated and coordinated by governmental institutions.

2.2. Survey with competent authorities

To gain most updated information from several countries, including those rarely mentioned in the literature, a primary survey with public authorities was conducted.

We developed a questionnaire, which was an extended version of the survey tool used by Vogler and Fischer 2020 [29]. A question on financial incentives (e.g., price increases, higher reimbursement amounts) was added to complement five other building blocks of policy interventions, relating to the obligation to notify upcoming and ongoing shortages (national registers), supply reserves (including stocking requirements for suppliers), export bans for medicines at risk of short supply, measures related to regulatory requirements (e.g., regarding imports) and multi-stakeholder coordination. Open space for further input was provided. Data was collected for the year 2023. Additionally, respondents were requested to report on developments (recently adopted measures, policies under preparation or being discussed) in the period between 2020 and 2023 (see the questionnaire in S1 in the Supplementary Materials).

To ease the workload for respondents, we pre-filled in the questionnaire for those 24 countries which had participated in the 2020 survey on measures to address medicine shortages.

We approached public authorities for pharmaceutical policy that were involved in the Pharmaceutical Pricing and Reimbursement Information (PPRI) network. Members of the PPRI network had also responded in the previous survey. At the time of the launch of the survey (Q1/2023), the PPRI network for competent authorities comprised 50 member countries, compared to 47 countries in 2020 (five non-European countries had meanwhile joined and the membership of Belarus and the Russian Federation was suspended in 2022) [40].

While PPRI network institutions tend to be focused on pharmaceutical pricing and reimbursement policies (e.g., pricing authorities, public payers) and are usually not directly involved in the management of shortages, PPRI delegates have been committed to respond to queries launched in the network. In case of requests addressing topics beyond their areas of expertise, they have been coordinating with institutions in their country to collect the needed information [41].

2.3. Data collection, analysis and validation

We sent the questionnaire to the members of the PPRI network at the beginning of March 2023, with the request to respond within two weeks. We had two rounds of reminders to those network members that had not responded in March and April 2023 as well as another call for participation during a face-to-face meeting in March 2023. In May and June 2023, we followed up in personalised messages to remind some member countries, which resulted in a few additional responses (latest filled questionnaire was received end of June 2023).

An analysis of preliminary results was presented in a PPRI network webinar in May 2023. Holding this event offered an opportunity to invite participants to comment on their country input, which was presented in a compilation, and to encourage some non-responders. In July 2023, the PPRI Secretariat presented the findings of the mapping exercise to EMA's Medicine Shortages Single Point of Contact (SPOC) Working Party [42]. In addition to dissemination purposes, this talk served as an additional quality assurance activity for the validation of data given the expertise of the SPOC members.

In early October 2023, we contacted once again all those network members who had provided 2023 information on their country for a final validation. They were invited to check the information on their country as presented in the tables of this paper. This contact was also used to consult if any relevant updates related to policies to address medicine shortages had taken place since the initial response to the questionnaire provided a few months earlier. 27 countries responded, several of them by offering updates on more recent developments since the first or second quarter of 2023. This allowed capturing the situation as of October 2023.

2.4. Included countries and key information sources

The article contains information of 38 countries, which were all members of the PPRI network in 2023: These are 24 EU Member States (all EU countries except Luxembourg, Poland and Slovakia), ten further countries in the WHO European Region (Albania, Armenia, Iceland, Israel, Moldova, North Macedonia, Norway, Switzerland, Türkiye and the United Kingdom) and four PPRI countries in other regions (Australia, Brazil, Canada and Saudi Arabia). Apart from the United Kingdom, all countries participated in the above-mentioned 2023 survey. Despite its non-response, we decided to keep the United Kingdom, which had provided input to the 2020 survey, and updated information retrieved from the literature [43–47].

In addition to the survey data, we also used published materials as background information for some countries to gain a more comprehensive understanding (e.g., details of the measures stipulated in the legislation). We benefited from references to websites and publications indicated by the respondents when filling the questionnaire, and we also considered additional evidence identified in a targeted literature review. S2 in the Supplementary Materials summarises the sources (survey data and published materials) which informed this paper.

3. Results

3.1. Updated compilation of measures to manage and mitigate shortages

Common measures to address or mitigate shortages include obligations on suppliers to notify existing and upcoming shortages to national registers, medicine supply reserves, export bans, regulatory measures to facilitate imports, multi-stakeholder coordination and financial measures, both incentives and sanctions (Table 1).

As of 2023, 34 of the 38 investigated countries reported to have a national shortage register in place. Apart from Malta and Ireland, all remaining countries implemented this register in a mandatory manner, obliging the marketing authorisation holders to report a shortage. Some countries (e.g., Bulgaria, Germany, Latvia) also request notifications about shortages from wholesalers. The official registers are usually managed by the countries' medicines agencies (except for Cyprus, Israel and the United Kingdom, where shortages are notified to the Ministry of Health). 25 countries do not limit the notification requirements to specific medicines groups, whereas some countries request reporting for prescription-only medicines (Austria, Sweden), publicly funded medicines (Bulgaria, United Kingdom) or defined essential medicines (Switzerland). It is requested to report as soon as the suppliers have become aware of an upcoming shortage, and most countries have reporting deadlines of minimum two months before the occurrence of the shortage. Australia, Canada, Saudi Arabia and the United Kingdom have imposed notification requirements of six months in advance and Brazil of 12 months. The shortage register is publicly accessible in most countries (one of the few exceptions is the Netherlands, where the notifications of the pharmaceutical companies to the medicines agency are not publicly accessible, but the pharmacy association publishes a register of shortages experienced in community pharmacy). Detailed information on specifications in medicine shortage registers and reporting requirements in the studied countries are provided in S3 in the Supplementary Materials.

To ensure a supply reserve for needed medicines, 20 countries impose stockpiling obligations on manufacturers or wholesalers, and in a few further countries (e.g., Czech Republic, Iceland) this measure is being discussed or prepared. The Netherlands introduced a medicine supply reserve at the beginning of 2023, allowing safety stocks of shorter time periods in the beginning that gradually increased. This measure had been prepared since 2018, with earlier plans of five months' stocking, which were subsequently changed to reduced stocking periods in response to stakeholder concerns and environmental considerations. As part of a large reform package to address shortages, Australia introduced the obligation to stockpile medicines listed in the Pharmaceutical Benefits Scheme (PBS), i.e., publicly funded medicines, and requested stocking of four months as a rule and six months for medicines which had been granted a price increase. Comprehensive legislation to address medicine shortages, which was passed in July 2023, provided the legal basis in Germany to request six months' stockpiling for medicines tendered by the health insurance funds. As shown in Table 1, the policy measure of a medicine supply reserve can be designed in different ways. As a result, country variation exists, among others, regarding the period for which the stocks are to be held and the types of medicines, and in some countries (e.g., Finland, France) different stockpiling periods have been defined for medicine groups. During the pandemic, longer periods were requested for medicines needed to treat COVID-19 medicines and larger samples of medicines were put under a supply reserve (e.g., in Estonia and Norway). Instead of stockpiling obligations targeted at suppliers, seven countries (e.g., Canada, Hungary, Slovenia) manage a national strategic, or emergency, stock of defined medicines. Moreover, a few countries (e.g., Denmark, North Macedonia) have imposed stocking requirements for suppliers and additionally keep a national reserve.

To manage medicine shortages, regulatory measures have been implemented, which comprise restrictions regarding exports of medicines in short supply (18 countries reported to have the legal possibility to impose export bans, and during COVID-19 times, they made use of this mandate in several cases) as well as facilitation of importation, supply and/or sale of alternative medicines (35 countries). For example, several countries allowed for accelerated imports with lower administrative requirements, including permitting use of medicines with patient information leaflets in a language different than the official country's language. A few countries (e.g., Australia, Belgium, United Kingdom) allowed, or facilitated (e.g., without consultation of the prescribing doctor), generic substitution in community pharmacies in case of (serious) shortages. Linked to accelerated and eased regulatory processes for actors in the supply chain, reimbursement processes for magistral preparations produced in community pharmacies, to replace medicines under serious shortages, were changed in Austria and Switzerland to enable easier access for patients.

Financial incentives were granted to manufacturers in at least 18 countries, mainly by allowing higher prices for defined medicines or higher reimbursement amounts. While several countries reported to have been confronted with ad-hoc requests for price increases, which they assess on a case-by-case basis, a few countries (e.g., Australia, France, and Germany, see also Table 2) systematically introduced price increases for some medicines. Brazil exempted a limited number of medicines from price regulation between June 2022 and June 2023. As another though different financial mechanism, the legislation of 26 countries provided the mandate to impose sanctions, in the form of fines, mainly for failing to comply with reporting requirements (20 countries). Some countries, in which medicines were tendered, included penalties for non-supply in the contracts (e.g., Denmark, Estonia, the Netherlands).

In all countries public authorities are in constant contact with manufacturers and wholesalers when they deal with specific cases of medicines in short supply. A more systematic approach of multi-stakeholder coordination was identified in 28 countries, where a task force or working group, usually coordinated by the medicines agency and with representatives of public authorities and of all relevant actors in the supply chain, explored sustainable, non-case-specific solutions. Additionally, some countries reported about their involvement in European and international initiatives, such as the CHESSMEN (Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network) Joint Action for EU Member States [48] or the Global Regulatory Working Group on Drug Shortages (GRWG).

Table 1
Measures to address medicine shortages in the study countries, 2023.

Country	Register	Supply reserve via stocking obligations	Export bans	Regulatory measures	Financial sanctions	Financial incentives	Multi-stakeholder coordination	Further initiatives
Austria	Yes, obligatory reporting for POM	No, but under discussion	Yes, export ban for POM included in a list	None reported, but reimbursement facilitation for magistral preparation (see "further initiatives")	No	No	Yes, a working group of stakeholders	Reimbursement of 2 active ingredients (amoxicillin and cefaclor) if produced as magistral preparation in the pharmacy upon prescription (before, patients had to seek approval from Social Insurance for these 2 magistral preparations)
Albania	No	Yes, MAH and wholesalers are obliged to stock reimbursed medicines	No	Yes, special permits for the import of medicines (simplified process in shortage situations)	Yes, for non-compliance to stocking requirements (in contracts)	No	Yes, a working group of stakeholders	None reported
Armenia	No	No	No	Yes, permits for the import of non-authorised medicines	No	No	Yes, stakeholder dialogues and consultations	None reported
Australia	Yes, obligatory reporting for POM and some NPM	Yes, obligatory for PBS listed medicines that meet the legislated criteria (6 months' stocking for medicines with price increase granted, otherwise 4 months)	No	Yes, temporary approval of import or supply of a non-authorised alternative medicine	Yes, for non-compliance to reporting requirements and the legislative power to delist in response to stocking requirements	Yes, one-off price increases for low-priced medicines (10/2022) and introduction of minimum floor price for medicines under supply reserve	Yes	In case of serious shortages community pharmacists are allowed to substitute specific medicines without prior approval from the prescribing doctor
Belgium	Yes, obligatory reporting for any medicine	No	Yes	Yes, derogation may be granted to import and supply non-authorised medicines, less strict requirements for PIL for alternatives	Yes, for non-compliance to reporting requirements Under preparation: legislation to oblige companies to cover additional costs due to shortages	Yes, ad-hoc price increases are possible, no structured process	Yes, a working group of stakeholders	Pharmacists are allowed to substitute a medicine in case of notified non-availability without previous agreement of the prescriber (exemptions for some medicines)
Brazil	Yes, obligatory reporting for any medicine	Yes, obligatory for medicines that may cause shortages	No	Yes, special permits to import (alternative) medicines	Yes, for non-compliance to reporting requirements	Yes, temporary suspension of price control (maximum price) for restricted number of medicines	No	Technical commission to address shortages in the Medicines Agency
Bulgaria	Yes, obligatory reporting for publicly paid POM	No	Yes, for reimbursable POM included in a shortage list	No	Yes, for non-compliance to reporting requirements	No	Yes, a working group of stakeholders	None reported
Canada	Yes, obligatory reporting for any POM and NPM administered under practitioner's supervision	No stocking obligations for suppliers, but the National Emergency Strategic Stockpile maintained by the Public Health Agency of Canada contains medicines (e.g., antibiotics, antivirals, analgesics, anaesthetics) for use in case of	Yes, export ban for defined medicines intended for the Canadian market for use outside if doing so could cause or worsen a shortage	Yes, special permits for import and sale of medicines	Yes, for non-compliance to reporting requirements	No	Yes, a multi-stakeholder steering committee and further task forces	2021 mandate letter to the Minister of Health to strengthen the security of the medical supply chains

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Table 1 (*continued*)

Country	Register	Supply reserve via stocking obligations	Export bans	Regulatory measures	Financial sanctions	Financial incentives	Multi-stakeholder coordination	Further initiatives
		emergency events. Temporary COVID-19 related measure (2020–2022) of a Critical Drug Reserve: commitment of the Federal Provincial Territorial governments to create a reserve of 12 medicines critical for the treatment of COVID-19						
Croatia	Yes, obligatory reporting for any medicine	No stocking requirements for suppliers, but a national reserve of defined medicines held by the MoH	No	Yes, special permits for the import of medicines with PIL not in Croatian language	Yes, for non-compliance to reporting requirements	Yes, higher reimbursement prices may be granted	No	None reported
Cyprus	Yes, obligatory reporting for any medicine	No	No	Yes, special permits for the import of medicines in non-registered packages (as a rule, PIL must be in English and Greek)	Yes, for non-compliance to reporting requirements and for breach of contractual obligations to supply	No	Yes, regular meetings with stakeholders	Possibility for non-prescribing of out-of-stock medicines
Czech Republic	Yes, obligatory reporting for any medicine	No, but under negotiation	Yes, export ban for critical medicines and export notification for medicines included in a list	Yes, special permits for the import of medicines with PIL not in national language	Yes, for non-compliance to reporting requirements and non-supply	Yes, full reimbursement for medicines in emergency supply (those for which maximum prices are set by the MoH for public health reasons, a 1-year temporary measure)	Yes, a shortage task force	None reported
Denmark	Yes, obligatory reporting for any medicine whose shortage is expected to influence the treatment of patients	Yes, 3 months stocking requirements on certain critical inpatient medicines in a shortlist (e.g., antibiotics and anaesthetics) for MAH as part of tender obligations; for vaccines (e.g., for the Danish Childhood Vaccination Programme) by the Statens Serum Institut under MoH	No	Yes, exemptions by the Medicines Agency for sale and dispensing of medicines (e.g., related to labelling) in cases of shortages	Yes, for non-compliance to reporting requirements and in inpatient tender contracts for non-compliance of stocking requirements	No	Yes, a national task force	Implementation of suggestions of stakeholder meetings (e.g., notifying doctors of shortage of a medicine s/he aims to prescribe) are being explored
Estonia	Yes, obligatory reporting for any medicine	Yes, obligation for wholesalers to stock medicines (approx. 800 medicines in 2020, approx. 170 medicines since 2021) as defined in contracts by the Estonian Stockpiling Agency	Yes, export ban for any medicine whose shortage may impose a risk and obligation to notify exports for all medicines	Yes, special permit for importation with fewer regulatory requirements (e.g., related to language)	Yes, for non-compliance to reporting requirements, – in tender contracts and price volume agreements between health insurance fund and MAH – for non-supply at appropriate pricing, for non-	No, not for MAH of medicines under shortages, but special reimbursement procedures for non-authorised alternative medicines	No	Establishment of the Estonian Stockpiling Agency which is tasked to manage the emergency supplies of essential medicines, including a 1-month supply of medicines sold in the community. Supplies were procured through tenders. See also

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Table 1 (*continued*)

Country	Register	Supply reserve via stocking obligations	Export bans	Regulatory measures	Financial sanctions	Financial incentives	Multi-stakeholder coordination	Further initiatives
					compliance of wholesalers in stocking (as defined in contracts)			Latvia on the ePIL pilot project
Finland	Yes, obligatory reporting for any medicine	Yes, 3–10 months stocking obligation for MAH, importers, health care units (e.g., hospitals) and National Institute for Health and Welfare regarding defined medicines (2023: 1457 medicines; list is updated once a year) and 2 weeks stock for community pharmacies	Yes, export ban for medicines in the supply reserve	Yes, special permits for the import of medicines with PIL not in national language and possibility of standardised PIL for Nordic countries	Yes, for non-compliance to stocking requirements	No	Yes, cooperation of all stakeholders, including the public	None reported
France	Yes, obligatory reporting for any medicine	Yes, stocking obligation for MAH of at least 1 month for all medicines and 2–4 months for medicines of therapeutic interest. Obligation for wholesalers to hold at least 90 % of the presentations of the medicines marketed in France and be able to deliver them within the 8 h	Yes, export ban for critical medicines	No	Yes, for non-compliance to reporting and stocking requirements	Yes, price increases may be granted for defined medicines (public health threat, price increases of the raw material) and suspension for price reduction for generics on list of essential medicines whose manufacturing chain is fragile	Yes, a multi-stakeholder steering committee	Yes, obligation for MAH for a shortage management plan
Germany	Yes, obligatory reporting for POM that are relevant or critical for supply as defined by the German Medicines Agency (BfArM)	Yes, mandatory 6 months stocking requirement for medicines under newly concluded "discount agreements" (i.e. off-patent medicines tendered by health insurers)	No	Yes, waiving the obligation to label in national language in case of shortages (for defined medicines)	Yes, for non-compliance to stocking requirements	Yes, defined medicines for children exempt from internal price referencing (maximum reimbursement amount) since 2022, made permanent in 7/2023 legislation. Additional mark-ups for pharmacies for generic substitution in case of shortages. Possibility of relaxed co-payment rules to decrease price competition (based on 7/2023 legislation, implementation under way). Local production as award criterion in tendering contracts (applied for antibiotics in the beginning, to be extended).	Yes, a multi-stakeholder advisory board at the Medicines Agency working on shortages	Lists of critical shortages to be established (based on 7/2023 legislation)
Greece	Yes, obligatory reporting for any medicine	Yes, stocking requirements for all POM targeted at MAH and	Yes, export bans for critical medicines	Yes, special permits for the import of medicines in	Not known	Yes, price increases for public health reasons (3/2020); exclusion of defined	Yes, a multi-stakeholder committee (MoH, Medicines	Manufacturers are requested to increase production, import and stocks of

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Table 1 (*continued*)

Country	Register	Supply reserve via stocking obligations	Export bans	Regulatory measures	Financial sanctions	Financial incentives	Multi-stakeholder coordination	Further initiatives
		wholesalers / distributors		foreign packaging with PIL not in national language and special permit for essential medicines		medicines from annual price review and review of price requests	Agency, Social Insurance, hospital pharmacies, etc., and industry as observer)	alternative medicines and monitoring of parallel exports by wholesalers (to assess necessity for export bans)
Hungary	Yes, obligatory reporting for any medicine	No stocking requirements but an emergency stock of essential medicines for managing catastrophic events held by the public sector (National Directorate General for Hospitals)	No	Yes, special procedures for the import of medicines needed in large quantities	No	No	No	None reported
Iceland	Yes, obligatory reporting for any medicine	No, not yet, but implementation of supply reserve (stocking requirements) is in process, plus a national hospital reserve	No	Yes, exemptions from package labelling on a temporary basis, and special procedures for the import of medicines. ePIL project for hospital medicines	Yes, for non-compliance to stocking requirements	Yes, higher prices granted in case of serious supply shortages (+15 %)	No task force but continuous dialogue with supply chain actors	None reported
Ireland	Yes, but not obligatory. Voluntary reporting for any medicine	No	No	Yes, a range of regulatory flexibilities subject to needs on a case-by-case basis (e.g., expediting controlled medicine licences, expedited inspections or assessments, and authorising a batch of medicines from one jurisdiction to supply to Ireland)	No	No	Yes, continuous dialogue between the stakeholders both on a case-by-case basis and on a broader higher level, as part of the "Medicine Shortages Framework"	None reported but constant refinement of the "Medicine Shortages Framework" which is the main tool to coordinate multi–stakeholder response, based on a review of 2022 and further learning during the pandemic and in winter 2022/2023
Israel	Yes, obligatory reporting for any medicine	Yes, obligation for MAH and wholesalers of at least 30 days stock of all medicines	No	Yes, special permits for the import of medicines from certain countries on a case-by-case basis	No	No	Yes, cooperation of all stakeholders, including public	None reported
Italy	Yes, obligatory reporting for any medicine	No	Yes, export bans for defined medicines and obligation to notify export for all medicines	Yes, special permits for the import of defined medicines affected by a shortage	Yes, for non-compliance to reporting requirements	No	Yes, a special task force	Possibility to use national federal production sites (e.g. military) to produce medicines
Latvia	Yes, obligatory reporting for any medicine	Yes, obligatory stocking by wholesalers for defined medicines for emergency situations and recommended for hospitals	Yes, list of medicines for which export is restricted (list first established in July 2020, updated bi-weekly) – Medicine Agency may	Yes, special permits for the import of medicines in foreign packaging with PIL not in national language and special permits for non-	Yes, for non-compliance to export bans	No	Yes, a working group of stakeholders (MAH, wholesalers, hospitals)	Launch of the ePIL pilot project in the 3 Baltic states, within the framework of which medicines for inpatient use can be distributed without paper instructions for use, thus facilitating the registration of

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Table 1 (*continued*)

Country	Register	Supply reserve via stocking obligations	Export bans	Regulatory measures	Financial sanctions	Financial incentives	Multi-stakeholder coordination	Further initiatives
			allow export in certain cases	authorised medicines				claims for license holders
Lithuania	Yes, obligatory reporting for any medicine	No stocking obligation for suppliers but a national reserve for emergency situations	No	Yes, special permits for import of medicines with PIL not in national language to be dispensed by community pharmacies. No special permit for medicines without PIL in national language required for supply to hospitals	No	No	No	None reported but see also Latvia on the ePIL pilot project
Malta	Yes, but not obligatory. Voluntary reporting for any medicine	Yes, voluntary request to MAH and wholesalers to keep a 6-months stock of all authorised medicines	No	Yes, regulatory measures to mitigate shortages on a case-by-case basis	No	No	No working group, bilateral dialogue with wholesalers	None reported
Moldova	No	No	Yes, exports ban can be imposed for medicines with stock of less than 3 months	Yes, a special commission for unregistered medicines to grant authorisation for import of needed medicines	No	No	Yes, a stakeholder working group	Medicine law revision (including chapters on shortage register and export bans) under preparation
Netherlands	Yes, obligatory reporting for any medicine	Yes, stocking obligations for all POM (6 weeks of safety stock for MAH and 4 weeks for wholesalers)	No, but gentleman's agreement that wholesalers do not export medicines targeted by a shortage	Yes, special permits for the import of medicines (simplified process in shortage situations)	Yes, for non-compliance to reporting and stocking requirements and – for winners of tenders – for non-supply	Yes, increase by 15 % of maximum prices for groups of pharmaceutically comparable medicines with relatively low sales	Yes, a working group of stakeholders	Coordination centre to support mapping supply and demand, coordinating distribution of stock and working with medical specialists in prioritising patients
North Macedonia	No	Yes, 2 months stocking obligation for MAH and wholesalers in exceptional situations when MA is withdrawn, and a national reserve for emergency situations (defined medicines and medical supplies) managed by an Agency	No	Yes, special permits for import of non-registered medicines	Yes, for non-compliance to stocking requirements	Yes, granting price increases requested by MAH	No	None reported
Norway	Yes, obligatory reporting for any medicine	Yes, 2 months stocking obligation for wholesalers (outpatient: for defined therapeutic groups, inpatient: defined by procurement agency)	Yes, export ban for pneumococcal vaccines since March 2020 (COVID-19 related legislation), ceased in 5/2023 (end of pandemic)	Yes, prioritisation of applications according to urgency / medical need	No	Yes, higher prices granted for 15 active ingredients, mainly antibiotics, in 9/2023. Wholesalers are compensated for costs of increased stocks	Yes, active dialogue with stakeholders	None reported
Portugal	Yes, obligatory reporting for any medicine	Yes, 2 months stocking obligation on all medicines for MAH and wholesalers	Yes, export ban for defined medicines included in the "Ex Ante	Yes, special permits for MAH, wholesalers, hospitals and pharmacies to	Yes, for non-compliance to reporting requirements (non-reporting	Yes, price increases of 5 % for medicines priced up to € 10 and of 2 % for medicines	Yes, meetings with representatives of national associations of	Issuance of therapeutic guidelines, controlled distribution

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Table 1 (*continued*)

Country	Register	Supply reserve via stocking obligations	Export bans	Regulatory measures	Financial sanctions	Financial incentives	Multi-stakeholder coordination	Further initiatives
			notification list" (those with high numbers of shortages)	import and dispense medicines with PIL not in national language	or delayed reporting)	with a price between € 10 to € 15 (pharmacy retail price levels). The essential medicines list foresees the possibility to authorise specific benefits (such as fees exemptions and price reviews) in return for new obligations like holding permanently 4 months stock.	MAH, wholesalers, pharmacies	
Romania	Yes, obligatory reporting for any medicine	No	Yes, 3-months export ban for defined antibiotics (Q1//2023)	Yes, special permits for the import of medicines (simplified process in shortage situations)	Yes, for non-compliance to reporting requirements	No	Yes, a working group of stakeholders	None reported
Saudi Arabia	Yes, obligatory reporting for any medicine	Yes, obligatory stocking requirements of six months for MAH and hospitals	No	Yes, e.g., fee exemption to register alternatives, accelerated registration for alternatives, simplified importation procedures, import of unregistered medicines or medicines packs in foreign language, extension of expiry date	Yes, for non-compliance to reporting and stocking requirements, for non-supply and for lack of cooperation	Yes, price increases for certain medicines at request of MAH	Yes, regular stakeholder exchange	None reported
Slovenia	Yes, obligatory reporting for any medicine	No, but a national strategic reserve for emergency situations	No	Yes, special permits for the import of medicines under shortage if on the list of essential medicines (around 3000 items)	Yes, for non-compliance to reporting requirements (MAH) and for non-supply of medicine within 24 h on weekdays or 72 h over weekend (wholesalers, public service obligation) but execution is difficult	No	No	None reported
Spain	Yes, obligatory reporting for any medicine	No but reserve for COVID-related medicines was established (stocking by government), in addition to a national reserve for medical countermeasures against specific threats (including vaccines, antivirals, etc.).	Yes, in case of supply disruptions of the concerned medicine	Yes, special permits for the import of non-authorised medicines, exceptional MA for medicines in packs of different languages and with an expiry date of less than 6 months, expedition of variations	Yes, for non-compliance to reporting requirements and management of shortages of critical medicines	Yes, for certain medicines: suspension of the reduction of (internal) reference price, establishment of a weighted reference manufacturer price and price increases granted	No, but ad-hoc communication with MAH and wholesalers	A list of strategic medicines for which industry has to present prevention and mitigation plans

(*continued on next page*)

Table 1 (*continued*)

Country	Register	Supply reserve via stocking obligations	Export bans	Regulatory measures	Financial sanctions	Financial incentives	Multi-stakeholder coordination	Further initiatives
Sweden	Yes, obligatory reporting for POM	No, but medicine reserve stocks are in preparation, and a national reserve for emergency situations exists	No, but export bans are under discussion	Yes, special permits for MAH and pharmacies to import and dispense medicines with PIL not in national language	Yes, for non-compliance to reporting requirements (since 7/2023) and – for winners of tenders – for non-supply (previous law)	No	Yes, a working group of stakeholders	None reported
Switzerland	Yes, obligatory reporting for defined essential medicines and vaccines	Yes, obligation of 3 months stock of defined medicines (e.g. (antibiotics, neuraminidase inhibitors, opiates, haemostatics, insulins) for MAH	No	Yes, enabling to dispense (and reimburse) only the needed amounts of medicines in short supply	No	Yes, special regulation for the reimbursement of officinal preparations and imported medicines for pharmacies in case to cover for non-available medicines and exemption from price decreases for critical medicines, granting of price increases in exceptional cases	Yes, several working groups of stakeholders	None reported
Türkiye	Yes, obligatory reporting for any medicine	Yes, stocking obligation for few medicines	Yes, temporary export ban for some medicines in short supply, e.g., antibiotics	Yes, special permit to import alternative medicines	No	Yes, price increases may be considered	Yes, a multi-stakeholder working group	Increase of production capacity
United Kingdom	Yes, obligatory reporting for any NHS (i.e. reimbursed) medicine	Yes, as part of contractual obligation for suppliers who were commissioned to store the Essential Medicines Buffer Stock (i.e. essential medicines to treat (1) conditions that are exacerbated by flu and (2) conditions that would lead to hospitalisations and deaths in case of major supply disruptions) for 4 years	Yes, export ban for defined medicines	Yes, specific regulation to facilitate import and supply of unlicensed medicines ("specials") in case of shortages, temporary exemptions to labelling requirements, and permission to community pharmacists to supply small quantities to other pharmacies without wholesale license	Yes, for non-compliance to reporting requirements	Yes, price concessions for imported medicines	Yes, a working group of stakeholders	Pharmacists are allowed to substitute the patient's prescribed order in case of an active "serious shortage protocol" issued by the DoH (legislation in place since 2/2019)

DoH: Department of Health, ePIL: electronic patient information leaflet, MA: marketing authorisation, MAH: marketing authorisation holder, MoH: Ministry of Health, NHS: National Health Service, NPM: non-prescription medicine(s), PBS: Pharmaceutical Benefits Scheme, PIL: patient information leaflet, POM: prescription-only medicine(s).

3.2. Developments 2020–2023

In COVID-19 and post-pandemic times, studied countries took several measures to mitigate medicine shortages, either through introduction of new policies or changes in the design of an existing measure (e.g., electronic portals to facilitate reporting to shortage registers, implementation policies to make the legal possibility to charge financial penalties effective). Financial incentives to suppliers (mainly implemented in 2022 and 2023), stocking requirements and systematic multi-stakeholder coordination rank among most common actions taken in the years from 2020 to 2023. A visual overview is provided in Fig. 1, with details presented in S4 in the Supplementary Materials.

Given the continuity of and (expected) increases in medicine shortages in 2022 and 2023, some countries (e.g., Australia, Germany, France) prepared larger legislative packages, which contained a set of measures, sometimes with staggered implementation dates for the planned policy options. Table 2 presents some country case study examples.

In addition, numerous measures were discussed, negotiated with stakeholders and prepared for implementation. For instance, some countries were working on identifying critical medicines which would be subsequently subject to stocking requirements or export bans. As of October 2023, it was not clear if policies under discussion would be implemented, and whether, or not, one-off measures (e.g., price increases which Portugal exceptionally applied in the 2023 annual price review) would be repeated in the future.

Table 2
Reform packages to address medicine shortages in selected countries, 2020–2023.

Country	Description of the package of measures
Australia	**Supply reserve obligation for manufacturers, in combination with financial compensation for low-priced medicines** Following up on the Medicine Shortages Information Initiative (MSII), which started in 2014 and was voluntary, reporting of medicine shortages has become mandatory since 1 January 2019. The Medicines Supply Security Guarantee (MSSG) legislation entered into force iteratively from 1 July 2022 to support pharmaceutical industry to implement minimum stockholding requirements for selected medicines from 1 July 2023. As first part of the measures, the package provided for one-off price increases on 1 October 2022 for medicines priced at less than Australian dollar (AUD) 3.50 / € 2.10, retention of thresholds which protect medicines against price reductions under Australia's legislative pricing regime, and a floor price to prevent the price dropping below AUD 4.- / € 2.40 for medicines which are subject to stockholding. As second part of MSSG, manufacturers are required to hold a minimum stock in Australia for certain listed medicines from 1 July 2023. The stockpiling requirements addressed medicines listed on the Pharmaceutical Benefits Scheme (PBS), thus publicly funded, that received a price increase on or after 1 July 2022, medicines priced at AUD 4.- / € 2.40 or less, and older, multi-branded medicines subject to the 30 % price disclosure threshold (the latter being a measure for generic medicines). Manufacturers are required to hold a 4- or 6- month minimum stock (4 months of stock for medicines that have not received a price increase or 6 months of stock for medicines that have received a price increase). The list of medicines subject to stockholding requirements is published at the PBS's website and updated bi-annually. The current framework agreement between the government and industry associations 2022–2027 includes the new minimum stockholding requirements within the MSSG package.
Canada	**Several measures, some of them started as temporary and were then made permanent** Canada has been working on measures to mitigate shortages for more than a decade: In 2012, the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) was established, and in 2017, mandatory reporting for manufacturers about upcoming and new shortages to the register was introduced. The 2019 Minister of Health mandate letter prioritised access to needed medicines. In the Prime Minister's December 2021 mandate letter to the Minister of Health, the commitment of "strengthening the security of medical supply chains" was stipulated. During the COVID-19 pandemic, some further measures were taken, through a temporary 1-year regulatory framework (Interim Order) and were subsequently made permanent through regulations in 2021 and 2022. For instance, Canada introduced a prohibition on distributing certain medicines intended for the Canadian market for use outside Canada, if doing so could cause or worsen a shortage. In these cases, the drug establishment licence holder who plans to do so must conduct an analysis showing that doing so will not cause or worsen a medicine shortage within Canada (Interim Order introduced in November 2020, and then made permanent in the Food and Drug Regulations in November 2021). The drug establishment licence holder must maintain the record of the analysis, which is to be provided to Health Canada upon request. Second, Canada made an Interim Order permitting exceptional imports and sale for medicines that were not licensed for sale in Canada (i.e. not fully compliant with Canadian regulations but were manufactured according to similar standards). The original 2020 Interim Order was re-issued in 2021, and the regulatory provisions were transitioned into permanent amendments to the Food and Drug Regulations, which came into force in March 2022. The permanent regulations no longer require a medicine shortage to be related to the COVID-19 pandemic to be eligible for exceptional importation and sale. The Interim Order also provided authority for the Minister of Health to require a company to provide information related to a medicine shortage. This provision has also been transitioned into permanent regulations. The Public Health Agency of Canada maintains the National Emergency Strategic Stockpile (NESS) of medical assets, including medicines. In direct response to the COVID-19 pandemic, the Government of Canada established in 2020 a time limited COVID-19 Critical Drug Reserve, working with provinces and territories. It contained 12 medicines critical for the treatment of COVID-19, and the measure came to an end in 2022.
France	**New measures and requirements for manufacturers and wholesalers, including financial sanctions and incentives** Given an increase in shortages, a set of measures, which was legally prepared (Social Security Budget Law 2020, follow-up implementation decree of March 2021) and entered in force in October 2021, provided for stronger financial penalties for manufacturers in cases of not reporting and not stocking. This legal package introduced the obligation for manufacturers to develop a shortage management plan for all medicines brought on the market in France and introduced safety stocks of at least two months for critical medicines (médicaments d'intérêt thérapeutique majeur (MITM)). The Medicines Agency was granted the right to extend the stocking period to up to four months, where needed. For non-critical medicines the stocking requirements were prolonged from one week to one month. The regulation on financial sanctions was updated in 2022, with new guidelines by the French National Agency for the Safety of Medicines and Health Products (ANSM) entered in force in October 2022. Changes included specifications and additions (new non-compliance cases which caused financial penalties, increases in the amount of the penalties and procedural issues). During 2022 and 2023, financial incentives were introduced to address shortages. The 4-year Framework Agreement between the Pricing Committee (CEPS) and the industry association (LEEM) signed in March 2021 provided the basis for granting price increases in case of critical medicines, risk of unmet public health need if the company leaves the market and price increases "mainly based on the increase of the raw material". Furthermore, in 2023, generics that appear on a list of essential medicines whose manufacturing chain is fragile were exempted from price reductions.
Germany	**Comprehensive legislation with several measures, with staggered implementation** At the end of July 2023 a comprehensive legislation called „Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz" (ALBVVG), which contained several measures for improved management and mitigation of medicine shortages was passed. The Medicines Agency was tasked to establish an early warning system for upcoming medicine shortages and to draw a list of "critical shortages" (i.e. relating to active substances that are relevant or critical for the supply) and a list of medicines for which regular reporting by the manufacturers is necessary. The law also contained financial incentives. To enhance practical rules for substitution in case of non-availability in the community pharmacy, pharmacists receive a mark-up of € 0.50 for each prescribed medicine that needs to be substituted due to a shortage. Patients are not charged higher co-payments if the co-payment increases were caused by a shortage-related substitution of the prescribed medicine. Wholesalers are granted an additional compensation of € 0.03 for all transactions to compensate for higher efforts due to shortages. In case of tendering for outpatient off-patent medicines by health insurance funds (so-called "discount agreements"), the suppliers are requested to stock the medicines for six months. In principle, the legal possibility to stockpile was established in April 2020, but the ALBVVG strengthened and developed further these obligations. In future, in the tendering, bids by suppliers with production of active pharmaceutical ingredients in Europe will be prioritised. The immediate implementation on the award criterion of local production is limited to antibiotics in the short run. To avoid a dramatic situation regarding medicines, including antibiotics, for children as observed in the 2022/2023 winter season, it was decided to exempt medicines for children (relevant pharmaceutical forms) from being included in the reference groups of the internal reference price system. The Medicines Agency was tasked to develop a list of defined medicines. This measure followed up on previous steps taken in December 2022 and January 2023 when some medicines for children had already been exempt from internal price referencing, which defines a maximum reimbursement amount for substitutable medicines. Manufacturers had been allowed to increase the price by up to 50 % above the previous reimbursement amount. A change in the co-payment regulation (possibility to exempt medicines from co-payment in case of a price 20 % below the reimbursement amount, compared to previously 30 %) aims to reduce price competition. The measures of the legislation regarding financial aspects were defined to enter into force in February 2024, whereas the other measures became valid with immediate effect.
Netherlands	**Discussion and implementation of measures in response to the COVID-19 pandemic and beyond** A milestone regarding measures to address shortages was the quantification of the obligation to hold sufficient stock. This measure, which had been planned prior to the COVID-19 pandemic and was defined in a legislation of June 2022, provided for the implementation of obligatory supply stocks of all prescription-only medicines from 1 January 2023. Stocking obligations target marking authorisation holders (six weeks of stock) and wholesalers. For sake of practicability, a gradual

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Table 2 (*continued*)

Country	Description of the package of measures
	implementation approach was scheduled for wholesalers, with two weeks of stock from January 2023 and eventually four weeks from July 2023. An evaluation of the supply reserves took in place in 2023. Changes based on learnings from this evaluation are planned for January 2024. During the COVID-19 pandemic, a coordination centre for medicines was established, which continues to play a role for severe shortages in post-COVID times, e.g., by mapping supply and demand, coordinating distribution of stock and working with medical specialists in prioritising patients. In pandemic times, medicines under shortage (e.g., Visudyne®) were subject to rationing. In earlier pandemic times, the Dutch government provided temporary financial incentives, including increases by 15 % for maximum prices of groups of pharmaceutically comparable medicines with relatively low sales (below € 500.000 annually). Export bans were discussed when the pandemic emerged but were eventually not implemented. However, according to a gentlemen's agreement wholesalers are committed to refraining from exporting medicines targeted by a shortage.
Sweden	**2023: a year of implementation and preparation** In mid-April 2023, a law was passed to introduce fines to be imposed on companies when they fail to notify temporary or permanent non-availability of medicines. The law became effective on 1 July 2023. The extent of the fines may range between Swedish krona (SEK) 25,000 / € 2150 and SEK 100,000,000 / € 8600; the exact amount will be determined for each case based on an assessment of the seriousness of the violation and general circumstances. As of October 2023, no fine has yet been imposed but the number of notifications was reported to have substantially increased upon implementation of the new law. The new financial sanctions add to existing penalties for the non-supply of medicines which have been selected as winners in the tenders for off-patent outpatient medicines (i.e., so-called "products of the month" which must be dispensed in pharmacies through mandatory generic substitution when medicines of the same active substance are prescribed).

Country	Register	Supply reserves	Export bans	Regulatory measures	Sanctions	Financial incentives	Multi-stakeholder coordination	Others
Austria	2020	2023	2020					2023
Albania								
Armenia								
Australia		2023				2022		
Belgium			2023		2023			7/2022
Brazil						Q3/2022-Q2/2023		11/2022
Bulgaria	8/2020		2020-2023				2020	
Canada		2020 - 2022	2020 & 2021	2020, 2021 & 2022	2020			
Croatia								
Cyprus	2022						Date not known	2023
Czech Republic		2023				2022	2022	
Denmark		2020-2023					2021	2023
Estonia		2020-2023						
Finland		2022		2020				
France		2021-2022			2020, 2021 & 2022	2021-2023		2020
Germany	4/2020	2023			12/2022 & 7/2023	2023	4/2020	4/2020 & 7/2023
Greece						2020-2023	2023	
Hungary								
Iceland	2020 & 2023	2022 & 2023		2021		2022		
Ireland							2022-2023	
Israel			Discontinued				2022	
Italy	11/2020							
Lativia			7/2020	1/2022				2023
Lithuania	2023			11/2023				
Malta	2023							
Moldova	2023		2023					
Netherlands		1/2023				2020	10(2023	2020
North Macedonia								
Norway		3/2020	3/2020, ceased 5/2023			9/2023		2020
Portugal						1/2023	2023	
Romania			Q1/2023					
Saudi Arabia	2021			2020				2023
Slovenia	2023	2023		2023				
Spain				2020 & 2021		Over the last years		2020, 2021 & 2022
Sweden		2020-2023	2020-2023		7/2023			
Switzerland	2023	2023		1/2023	2023	2023	2022	2023
Türkiye			2023			2023		
United Kingdom	10/2020					2022 & 6/2023	5/2022	

Fig. 1. Changes in policies to manage medicine shortages in the study countries, 2020–2023
Black box: a measure that was implemented; grey box: measure under discussion or preparation; white box: no change (a measure may be in place or not)
The figure visualises developments, which may comprise introduction of new measures, changes in the design or discontinuation, and indicates – where available – the month of the change. It is acknowledged that the extent of the measure may vary. Details are provided in S4 in the Supplementary Materials.

4. Discussion

The survey showed that the 38 investigated countries had a variety of governmental policy measures in place to manage and mitigate medicine shortages. In the course of the studied three years new policies were introduced and existing policies were changed.

Some measures appear to be part of the standard policy toolbox to manage medicine shortages. These include shortage registers (usually with mandatory reporting requirements), regulatory mechanisms to facilitate use of alternative medicines (e.g., special permits for importation, waivers from language requirements for patient information leaflets) and, to a certain extent, also multi-stakeholder coordination to explore long-term solutions. A minority of the studied countries did not apply these measures; for instance, Albania, Armenia, Moldova and North Macedonia were the sole countries in 2023 that did not run a shortage register. Some countries introduced such standard measures in or after 2020 (e.g., mandatory shortage registers in Austria, Bulgaria, Germany and multi-stakeholder coordination in Bulgaria, Czech Republic, Germany and Greece). These policies have apparently come to stay: in none of the countries shortage registers and multi-stakeholder

coordination processes were canceled and regulatory mechanisms, if changed, were rather extended or made permanent in cases of temporary solutions.

Measures to tackle medicine shortages may, among others, be differentiated into those which can be taken in the short run (e.g., to respond to an emergency such as a pandemic) and those which require longer preparation. Export bans constitute an example of the first, under the condition that their legal mandate has been established. Export bans were frequently used in the early times of the pandemic, sometimes based on a COVID-19 related legislation (e.g., Norway). They were also imposed in the winter season 2022/2023 (e.g., on antibiotics, by Romania and Türkiye). Expanding stocking requirements, or enlarging a strategic supply reserve, may also be implemented on short notice and may thus serve as crisis response – provided that the legal mandate exists. The Netherlands, which introduced stocking obligations in 2023, reported to have worked on its implementation for years.

This differentiation between short-term and long-term measures is also reflected in the two major time periods in which a concentration of governmental measures was observed: the early months of the COVID-19 pandemic in 2020 and the months of and after the (European) autumn 2022 to prepare for and respond to (expected) shortages of the winter seasons.

In the early times of the COVID-19 pandemic, therapeutics which were needed to treat COVID-19 symptoms (increase in demand) as well as other medicines were subject to shortages due to vulnerabilities in the supply chains [14,17,18]. Typical crisis management measures taken in these months included those which could be implemented rather smoothly and quickly, as described above. However, some measures of that period (e.g., reporting obligations which entered in force in Austria and in Germany in April 2020) coincided with the pandemic but the underlying legislation had been passed months earlier in response to the growing number of shortages in the previous years [29]. As another preparedness measure, the United Kingdom passed a legislation in 2019 to allow pharmacists to dispense a different dosage in case of "serious shortage protocols", to support the management of medicine shortages which were expected to increase after the Brexit (i.e. the United Kingdom leaving the EU in February 2020) [49].

Measures taken in the years 2022 and 2023 were different since they tended to require longer-term preparation, both in technical terms (e.g., drawing up lists of critical medicines) as well as regarding stakeholder consultation (i.e., to mitigate opposition). In addition, financially-based measures gained momentum. On the one hand, a few countries worked on ensuring that penalties, which were stipulated in the legislation but rarely charged, would be imposed in practice. Sweden, for instance, introduced a new law which regulated financial fines. As of October 2023, Belgium was considering obliging companies to pay for the additional costs caused by the shortages. On the other hand, financial incentives, such as higher prices, were granted to suppliers. This move was guided by the concern that the own market might not be sufficiently attractive to suppliers, who might subsequently decide to withdraw medicines or prioritise other markets in cases of vulnerabilities. Shortages typically concern the off-patent markets [1,7,13,50,51], and granting higher prices and similar financial incentives can be understood as governments' responses to industry's claim of low and unprofitable prices.

While that statement of low profitability of prices can neither be confirmed nor refuted due to lack of access to data, the topic of low generic medicine prices, and their potential cause for unavailability of medicines, has been dominating the public debate in many European countries in 2022 and 2023 (e.g. [52]). Some large markets (e.g., Brazil, Germany, France) increased medicine prices (or reimbursement amounts) without linking this reward to obligations. It is yet to see whether other countries will follow this route.

One of the longer-term governmental approaches to security of supply is fostering local API production [53]. Some government-sponsored initiatives to enhance API production in Europe through public-private partnership initiatives, e.g. in France, have been launched [54]. Encouraging local production, however, is not the mandate of the health authorities but of the ministries responsible for the economy that manage financial support for establishing and maintaining production sites. This division of responsibilities necessitates multi-sectoral coordination. Health authorities will play a role when they reward national or European production through higher prices or reimbursement amounts (such as France and Germany do as part of their policy toolbox to mitigate medicine shortages).

During later phases of the COVID-19 pandemic and in post-pandemic times, some governments strengthened and expanded existing measures (e.g., defining additional details of reporting requirements in Iceland). In some countries (e.g., Canada, Demark, the Netherlands), measures which had initially been introduced as interim in the emergency state, were prolonged or made permanent. This change into permanent provisions particularly concerned measures which were not restricted to COVID-19 therapeutics, whereas critical supply reserves of COVID-19 related medicines tended to be suspended or downscaled at the end of the pandemic. However, some countries decided to maintain at least parts of the activities and structures which had been established during the pandemic (e.g., a national supply reserve in Spain, a coordination centre in the Netherlands).

The analysis suggests that over the years newly introduced measures appear to have become more standardised (e.g., improvements in electronic reporting systems) and processes have been formalised. Additionally, it seems that in the beginning, with the first measures taken, the focus was rather on immediate management of shortages. In a study published in 2015, more than half of the respondents, who were hospital pharmacists in Belgium, argued that an obligation to the manufacturers to notify shortages could help solve the problem [5]. Meanwhile most countries have passed this stage, and policies to manage shortages (e.g., reporting requirements, regulatory mechanisms) have been supplemented by preventive measures. France, for instance, requests prevention plans from companies.

A lower number of changes reported does not necessarily imply that those countries apply overall fewer measures compared to others. It is possible that countries achieved a high level of policy implementation in earlier times and did not see a need for scaling up. Norway, for instance, had several policies in place to manage shortages before the outbreak of the pandemic and took further policy action in early 2020, but it did not introduce any new measures between 2021 and mid-2023.

It was beyond the scope of this paper to investigate a relationship between the magnitude of medicine shortages in a country and governments' responses to mitigate them. While our findings tend to suggest increased implementation levels of policy measures at the beginning of the COVID-19 pandemic and before the winter seasons 2022/2023 and 2023/2024 – periods of observed or expected higher number of shortages –, further research is needed to explore this in depth. However, those studies face the challenge of lack of comparable country data on shortage incidences.

Moreover, future analyses (e.g. impact assessments of measures to tackle shortages) would need to consider further measures which were not surveyed in this study. The latter include activities taken by non-governmental actors nationally and cross-country action, including initiatives at EU level.

Regarding the first, the role of health care providers and further actors involved in the management of medicine shortages has been widely acknowledged, including through financial rewards (e.g., additional compensation for wholesalers in Germany). Pharmacists, both in the community and hospitals, offer major contributions, such as by identifying and procuring alternative medicines as well as providing important information to patients and health professionals to facilitate potential changes of prescribed but unavailable medication [2,5]. They may also be tasked with documenting shortages, as in several countries pharmacists run in parallel shortage registers [18,29,55].

Some of the governmental measures identified in this study aim to

support the work of health care providers. For instance, in November 2023 (after the survey period), the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection announced that the Austrian pharmaceutical wholesale association was commissioned to establish a stock of active ingredients, supporting materials and packs which pharmacists may use to produce magistral ingredients for highly needed antibiotics and medicines to treat respiratory tract infections [56]. Another example in this context is permission of generic substitution in shortage situations in countries where it is not allowed (e.g., the United Kingdom) or to facilitate it (e.g., removal of the consultation of a doctor in Belgium). This is an illustration of an area where governments have built on existing cooperation structures between different health professionals and have benefited from legal frameworks, since generic substitution is in place in 35 of the studied countries, and it is implemented on a mandatory basis in 14 countries ([57], updated PPRI information for 2023). Finally, but not less importantly, governmental responses tend to acknowledge the importance of multi-stakeholder coordination through the establishment of institutionalised task forces and working groups, which allows reflecting on sustainable policy solutions beyond specific cases to ensure security of supply and resilient medicine delivery systems.

Furthermore, it is reasonable to assume that single-country solutions might not suffice. Thus, collaborative action at EU level was initiated, such as strengthening the mandate of the European Medicines Agency (EMA) in crisis preparedness and management for medicines and medical devices in 2022 [58] and stockpiling by the Health Emergency Preparedness and Response Authority (HERA) [59].

Further EU collaboration on the management of shortages can be expected. The proposal for the revision of the European pharmaceutical legislation, which was tabled in April 2023, includes several measures to support EU Member States to address medicine shortages [60,61]. A collaboration project of EU Member States, the CHESSMEN Joint Action [48], aims to address some of the challenges (e.g. lack of harmonised definitions for shortages and different reporting and counting methods in registers). In October 2023, a "voluntary solidarity mechanism for medicines" was launched in the EU through which countries would make stocks available to countries with medicines in short supply [62, 63]. Such support has been practiced in the Baltic Procurement Initiative since 2012, whose members (Estonia, Latvia and Lithuania) have been managing among themselves a lending mechanism for medicines and medical devices targeted by a shortage [64].

Despite these European collaborative moves, it is to note that some of the surveyed governmental measures (e.g., export bans, simplified importation, stockpiling) aim to protect the own national markets and they may contribute to worsening a vulnerable situation in other countries. Furthermore, systematic price increases, particularly if offered by large, economically strong markets, may convey a message to other countries to do similarly. This will likely increase the overall generic price levels in Europe and globally and may raise competition between countries, but it is yet to see whether it will be successful in improving the availability of medicines. While it was not the scope of this study and it would be too early to expect results on recently implemented policies, there is a need to evaluate the impact of these measures.

Impact assessments may show different results for the same policy measures across countries. Given country-specific contexts, a set of policy measures which works in one country can fail to reduce medicine shortages effectively and may trigger potential unintended effects in another country. Differences in the outcomes might also be attributable to differences in the design of the governmental policies and in the implementation (e.g. role of early consultation and involvement of stakeholders). In addition, since shortages may result from different root causes, different variants of policy measures may be needed to address the underlying causes.

This study has some limitations. As it presents information collected in a survey, we cannot exclude the possibility of underreporting or wrong reporting. We aimed to address this limitation by inviting the participants to review the information as presented in the manuscript, engaging in discussions with respondents to clarify ambiguous reporting and checking through other sources, where possible, e.g., for countries covered in the literature.

The respondents were predominantly experts in pharmaceutical pricing or reimbursement and, as such, only partially (e.g., when it came to financial incentives) or not involved in the management of shortages. However, in line with agreed commitments for PPRI membership, the primary recipients of the questionnaire addressed specialists for medicine shortages in their own authority or other relevant agencies in the public sector to help them to respond to the questionnaire.

While for the majority of the studied countries developments up till October 2023 were surveyed, the information relates to Q2/2023 in eleven countries that did not participate in the final validation round before submission of the manuscript.

We acknowledge that the information on the United Kingdom mainly refers to England and that reporting of the developments in the United Kingdom between 2020 and 2023 was based on a literature review.

5. Conclusions

The study has shown that governments have been responding to medicine shortages by imposing several measures. Policies were observed in all studied countries, independent of their income and market size, and no pattern of specific policies implemented by some countries was identified.

Actions have been taken during and after the COVID-19 pandemic, and to prepare for the next winter seasons, further measures are being discussed, negotiated and planned. Thus, while the pandemic highlighted the vulnerabilities in the supply chain, medicine shortages continue to remain a major public health threat in post-pandemic times. More recent policy responses that are rather focused on prevention and mitigation tend to complement existing measures for the management of shortages. Fostering API production in Europe is considered as one of the future approaches. Additionally, governments started to take measures, such as financial incentives for off-patent medicines, with the aim to prevent suppliers potentially leaving the markets. While the intended outcomes are yet to be demonstrated, financial compensation measures may, however, result in spill-over effects across countries and increased competition between countries for a "race to the top" on prices.

Since policy-makers, health professionals and the patients will continue to be confronted with the non-availability of medicines, further measures to manage and mitigate shortages can be expected. Continuous monitoring of future policy action is thus highly recommended, taking into consideration new developments. Furthermore, a follow-up study could investigate activities taken by health care professionals and other non-governmental actors as well as EU policy action.

Policy-makers can use the information provided in this study to develop further their policy toolbox for addressing medicine shortages. However, before implementing the policies they are advised to contact the countries which have these measures in place to benefit from their experience. Countries that have implemented policies are advised to ensure appropriate evaluation of these measures which will allow adapting their own strategy to mitigate medicine shortages as well as contribute to cross-learnings among countries.

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Visualization, Validation, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.healthpol.2024.105030.

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