

Supplementary Material 1: OECD analysis of national shortage monitoring systems

This document presents material that supplements:

Chapman, S, Dedet, G, and Lopert, R (2022), "Shortages of medicines in OECD countries", *OECD Health Working Papers*, No. 137, OECD Publishing, Paris, <https://doi.org/10.1787/b5d9e15d-en>.

As noted in Sections 2 and 3 of the paper, *Shortages of medicines in OECD countries*, a comprehensive analysis and comparison of national shortage monitoring mechanisms in OECD countries was undertaken with the objectives of 1) providing a general overview of shortage monitoring systems in OECD countries and 2) trying to understand similarities and differences in terms of products notified in shortage across countries. The following sections describe the methods used and show some results that are not present, but are referred to, in the main body of text. Since the data were originally collected in March/April 2020, with updates for some countries drawing on information collected by Vogler and Fischer (2020_[1]) in August 2020, there may have been some changes that are not reflected in the below tables, such as the introduction of new databases or the modification of existing ones. This is especially important to recognise in light of the impact of COVID-19.

Overview of shortage monitoring systems in OECD countries

Table 1 below provides an overview of national (government-based) notification reporting for actual or expected shortages in OECD countries, including the presence of an online database displaying shortages at product-level (current as of March / April 2020, with updates for some countries based on information collated by Vogler and Fischer (2020_[1]) in August 2020). The list was compiled based on a search of national health authority websites for databases as well as prior information presented in a number of published sources, as well as on opportunistic consultations with various authorities. For European countries, the European Medicines Agency (EMA) website contains a list of national medicine shortages registers¹, as does the Heads of Medicines Agencies (HMA) website². The below list may be incomplete in some cases. In some countries, there may be additional reporting on shortages in online databases held by non-government entities, such as pharmacists' associations (e.g. in Australia, France, Ireland, the Netherlands, Portugal, Spain, Switzerland, the United Kingdom and the United States).

¹See <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines/shortages-catalogue>, consulted on 30 November 2019, updated 13 January 2021.

²See <https://www.hma.eu/598.html>, consulted on 27 February 2020, updated 13 January 2021.

Table 1. National registers for online reporting of medicine shortages in OECD countries

Held by national government entities (as of March/April 2020, updated with information from August 2020 for some countries)

Country	Institution managing register for national shortages ¹	Web link	Online database ²
Australia	Therapeutic Goods Administration (TGA)	https://apps.tga.gov.au/prod/MSI/search	√
Austria	The Austrian Federal Office for Safety in Health Care (BASG)	https://medicineshortage.basg.gv.at/vertriebseinschraenkungen	√ ³
Belgium	Federal Agency for Medicines in Health Products (FAMPH)	https://banquededonneesmedicaments.afmps-fagg.be/#/query/supply-problem/human or https://pharmastatus.be/human	√
Canada	Bell Canada under contract of Health Canada	www.drugshortagescanada.ca/	√
Chile	None found	N/A	N/A
Czech Republic	State Institute for Drug Control (SÚKL)	https://www.sukl.cz/vypadky-leku	√
Denmark	The Danish Medicines Agency (DKMA)	https://laegemiddelstyrelsen.dk/da/godkendelse/kontrol-og-inspektion/mangel-paa-medicin/meddelelser-om-forsyning-af-medicin/	√ ⁴
Estonia	The Estonian State Agency of Medicines (SAM)	https://www.ravimiregister.ee/en/publichomepage.aspx	√
Finland	The Finnish Medicines Agency (FIMEA)	https://www.fimea.fi/web/en/databases_and_registers/shortages	√
France	French National Agency for Medicines and Health Products Safety (ANSM)	http://ansm.sante.fr/S-informer/Informations-de-securite-Ruptures-de-stock-des-medicaments	√ ³
Germany	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM); Paul-Ehrlich-Institut (PEI) for vaccines	BfArM: https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/Arzneimittelinformationen/Lieferengpaesse/functions/Filtersuche_Formular.html?nn=11296612 PEI: https://www.pei.de/EN/medicinal-products/vaccines-human/supply-shortages/supply-shortages-node.html?cms_tabcounter=0	√
Greece	National Organization for Medicines (EOF)	http://www.eof.gr/web/quest/eparkeia	√
Hungary	National Institute of Pharmacy and Nutrition (OGYEI)	https://www.ogyei.gov.hu/gyogyszeradatbazis/	√
Iceland	Icelandic Health Insurance; The Icelandic Medicine Pricing and Reimbursement Committee; The Icelandic Medicines Agency	Icelandic Health Insurance: https://gg.sjukra.is/bidlistilyfja Icelandic Medicines Agency: https://www.ima.is/	√ ⁵
Ireland	Health Products Regulatory Authority (HPRA)	http://www.hpra.ie/homepage/medicines/medicines-information/medicines-shortages	√
Israel ⁶	Ministry of Health of Israel	http://www.health.gov.il/NewsAndEvents/Recall_drugs/Pages/drugstop.aspx	√
Italy	The Italian Medicines Agency (AIFA)	https://www.aifa.gov.it/farmacaci-carenti	√
Japan	None found ⁷	N/A	N/A
Korea	None found	N/A	N/A
Latvia	The State Agency of Medicines of Latvia (SAMLV)	https://www.zva.gov.lv/en/medicines-shortages-management-latvia	√

Country	Institution managing register for national shortages ¹	Web link	Online database ²
Lithuania	The State Medicines Control Agency (SMCA)	https://www.vvkt.lt/index.php?2644926549	√
Luxembourg	None found	N/A	N/A
Mexico	None found	N/A	N/A
Netherlands	Medicine shortages and defects notification centre, coordinated by the Medicines Evaluation Board (MEB) and the Health Care Inspectorate (IGZ). The notification centre is commissioned by the Ministry of Health, Welfare and Sport (VWS).	https://www.medicineshortagesdefects.nl/	X ⁸
New Zealand	None found ⁹	N/A	N/A
Norway	Norwegian Medicines Agency (NoMA)	https://legemiddelverket.no/legemiddelmangel/legemiddelmangel-og-avregistreringer-rad-til-apotek-og-helsepersonell-inneverende-ar	√
Poland	None found	N/A	N/A
Portugal	The Portuguese National Authority on Medicines and Health Products (INFARMED)	Not public. Internal database of restricted access.	√ ³
Slovak Republic	The State Institute for Drug Control (SUKL)	https://portal.sukl.sk/PreruscheniePublic/?act=PreruschenieOznList&mld=2	√
Slovenia	Agency for Medicinal Products and Medical Devices (JAZMP)	https://www.jazmp.si/humana-zdravila/podatki-o-zdravilih/zdravila-na-trgu/	√
Spain	Spanish Agency of Medicines and Health Products (AEMPS)	https://www.aemps.gob.es/distribucion-de-medicamentos/problemas-de-suministro-de-medicamentos/	√
Sweden	Swedish Medical Products Agency (MPA)	https://www.lakemedelsverket.se/sv/behandling-och-forskrivning/forskrivning/restsituationer	√
Switzerland	Federal Office for National Economic Supply (FONES)	https://www.bwl.admin.ch/bwl/de/home/themen/heilmitel/meldestelle.html	√
Turkey	Turkish Medicines and Medical Devices Agency	http://www.titck.gov.tr/	√
United Kingdom	Department of Health and Social Care (DHSC)	https://www.gov.uk/government/publications/reporting-requirements-for-medicine-shortages-and-discontinuations	X
United States	Food and Drug Administration (FDA)	https://www.accessdata.fda.gov/scripts/drugshortages/	√

Note:

1. This list includes databases by official national government entities and may be incomplete for some countries. In some countries, there is additional reporting on shortages in online databases held by non-government entities such as pharmacists' associations (e.g. in Australia, France, Ireland, the Netherlands, Portugal, Spain, Switzerland, the United Kingdom and the United States).
2. Refers to the availability of a comprehensive, public, online database displaying expected or real medicine shortages at product-level. This database may only be accessible in an online format, or available for download as PDF, XML, CSV etc.
3. Data for subsequent OECD analyses provided under a confidentiality agreement.
4. Publicly accessible database for selected shortages since 24 June 2020. At the time of initial review, information was published on some medicine shortages, but not all, and was not technically a database and could not be used as a complete overview of shortages in Denmark.
5. Data for Iceland include those products on the market which may temporarily not be in pharmacy stores (based on data compiled by the Icelandic Health Insurance). This may differ to what is available on the Icelandic Medicines Agency website, for which data were not extractable.
6. The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

7. In Japan, reporting of current or expected shortages is not mandatory for companies, however, companies report voluntarily to the health authority. Generally 50 to 60 cases are reported every year.

8. No publicly accessible register of the regulatory authorities but the register of the Dutch Pharmacy Association (KNMP) is publicly accessible at: <https://farmanco.knmp.nl>.

9. Reporting of shortages was not mandatory for companies under legislation in New Zealand at the time of review, however companies are still requested to notify the relevant authorities. Medsafe (New Zealand Medicines and Medical Devices Safety Authority), which registers pharmaceuticals for use in New Zealand, have collected basic information on shortages since the implementation of a new stock shortage form for companies in 2019. PHARMAC (Pharmaceutical Management Agency), which decides which medicines and related products are subsidised, collects basic data on shortages only where the medicine is funded by the New Zealand government, where there is also a supply contract in place with a specific supplier.

Source: Authors based on search of national authority websites and information from (Acosta et al., 2019^[2]), the European Medicines Agency's website <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines/shortages-catalogue>, and the Heads of Medicines Agency's website <https://www.hma.eu/598.html> and provided by national authorities in March/April 2020. Updated for some countries with information collected by (Vogler and Fischer, 2020^[1]) in August 2020.

Using data gathered from the sources mentioned in Table 1 above, as well as additional data from existing literature and/or discussed with relevant national authorities, comparability of shortage notification processes in countries was assessed across a number of parameters:

- Definition of a shortage;
- Who notifies and whether it is mandatory;
- When a shortage or expected shortage is to be notified;
- What types of shortages are notified in the database (i.e. current shortages, resolved shortages, drugs that have been discontinued, vaccines, human and veterinary medicines);
- Frequency of update of publicly available data; and
- Whether a notification form is available.

Table 2 below provides an overview of **national definitions** of a medicine shortage in OECD countries.³ As described in Box 2 in the main text, formal definitions, or related terms used to describe medicine shortages, vary from country to country. In 2017, the World Health Organization proposed a draft definition of shortages, considering both demand and supply (World Health Assembly, 2017^[3]):

On the supply side: a “shortage” occurs when the supply of medicines, health products or vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs. This definition refers only to products that have already been approved and marketed, in order to avoid conflicts with research and development agendas.

On the demand side: a “shortage” will occur when demand exceeds supply at any point in the supply chain and may ultimately create a “stock out” at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient.

At the EU level, the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) and stakeholders from all Member States agreed on a broad definition in 2019 (EMA, 2019, p. 2^[4]):

A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level.

³ As formal definitions vary significantly from country to country, the term “medicine shortage” in the paper refers to any supply disruption or sudden change in the supply-demand equilibrium of a marketed pharmaceutical product that leads to an actual or anticipated lack of stock on the shelf for patients. An anticipated shortage may be preventable. Shortages include both temporary and permanent supply discontinuations (i.e. withdrawal from the market); the latter are sometimes referred to as “availability issues”. For the scope of the report, the specific case of when companies do not launch a product in a given market is excluded from the definition of a shortage.

The definition further defines the terms (EMA, 2019, p. 2₍₄₎):

A “shortage” as defined, allows for identification of current, impeding or anticipated disruption of supply of a medicinal product.

“supply” refers to the total volume of stock of the individual medicinal product that is placed on the market by the Marketing Authorisation Holder.

“demand” relates to the request for a medicinal product by a healthcare professional, veterinarian or patient in response to a clinical need. For demand to be satisfactorily met, the medicinal product will need to be acquired in time and sufficient quantity to allow continuity of best care of patients/animals. Wholesalers are usually a key supply link between MAHs and the users of medicines, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered.

“national level” refers to the situation in a specific country, i.e. if there is insufficient supply of a medicine to meet the demands of the country overall. Logistic -related issues leading to regional supply disruption of a medicinal product e.g. delivery difficulties, national redistribution of stock, are a short term and localised problem and should not be taken into account.

Table 2. National definitions of a medicine shortage in OECD countries

As of March/April 2020, updated with information from August 2020 for some countries

Country / Region	EU-wide definition applied and from what effective date	National definition [source]
European Economic Area	Yes – 1 July 2019	A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level. [(EMA, 2019, p. 2 ₍₄₎)]
Australia	N/A	When supply of a medicine in Australia will not, or will not be likely to, meet the demand for that product in Australia any time within the next six months. Reported medicines include prescription medicines, controlled substances, and certain non-prescription medicines considered critical and listed in the relevant legislative instrument. [https://apps.tga.gov.au/prod/MSI/search]
Austria	Yes – 1 April 2020	The marketing authorization holder must immediately notify the Federal Office for Safety in Health Care of any restriction in the marketability of a prescription-only medicinal product in Austria. A limitation of the marketability is a non-availability (i.e. product can no longer be dispensed by pharmacies in Austria) that is expected to extend beyond two weeks or a partial availability (i.e. the product can no longer be supplied continuously and in sufficient quantities by pharmacies in Austria) that is expected to extend beyond four weeks to cover the needs of patients domestically [national authorities and https://www.ris.bka.gv.at/eli/bqbl/II/2020/30]
Belgium	Yes – unknown effective date	A medicine is considered to be unavailable when the marketing authorisation holder is not able to deliver the totality of an ordered quantity for public service obligations within 3 working days [national authorities and http://www.ejustice.just.fgov.be/cgi/article_body.pl?language=fr&pub_date=2020-02-03&caller=summary&numac=2020020147]
Canada	N/A	A shortage means, in respect of a drug, a situation in which the manufacturer that sets out the drug identification number assigned for the drug is unable to meet the demand for the drug. Drug shortages can include temporary or permanent discontinuances in the production and supply of a drug [national authorities and https://www.drugshortagescanada.ca/]
Chile	N/A	No official national definition available. [(Bochenek et al., 2018 ₍₅₎)]
Czech Republic	Yes – unknown effective date	No official national definition available [national authorities]
Denmark	Yes – unknown effective date	No official national definition available [national authorities]
Estonia	Yes – unknown effective date	
Finland		Marketing authorisation holders are required to report temporary disruption of medicines, i.e. lack of availability for a period of one year or less. If the disruption lasts more than one year, marketing authorization holders should report the withdrawal from the market. [https://www.fimea.fi/laakehaut_ja_luettelot/saatavuushairio-uusi]

Country / Region	EU-wide definition applied and from what effective date	National definition [source]
France	Yes – unknown effective date	A supply disruption of a medicine for human use is defined by law in France as the inability of a dispensing pharmacy or a pharmacy within an establishment (e.g. hospital) to dispense a drug to a patient within 72 hours, or within a shorter period depending on the optimal continuation of the patient's treatment. [per Le Décret n° 2012-1096 du 28 septembre 2012, https://www.legifrance.gouv.fr/loda/id/JORFTEXT000026426883/]
Germany	Yes – unknown effective date	A delivery bottleneck is an interruption of delivery that is likely to last more than 2 weeks or a significantly increased demand that cannot be adequately met. [national authorities]
Greece		No official national definition available. [National Organization for Medicines (EOF) website and (Bochenek et al., 2018 ^[5])]
Hungary		No official national definition available. [National Institute of Pharmacy and Nutrition (OGYEI) website and (Bochenek et al., 2018 ^[5])]
Iceland [Icelandic Medicines Agency website]	Yes – unknown effective date	
Ireland		When the supply of a medicinal product is inadequate to meet the needs of patients. [national authorities]
Israel	N/A	No official national definition available [(Vogler and Fischer, 2020 ^[11])]
Italy	Yes – unknown effective date	The term 'deficient medicinal product' refers to a medicinal product that is not available nationwide and for which the Marketing Authorisation Holder (MAH) cannot temporarily ensure a continuous supply. [Italian Medicines Agency (AIFA) website https://www.aifa.gov.it/farmaci-carenti]
Japan	N/A	No official definition of medicine shortage in health system [national authorities]
Korea	N/A	
Latvia	Yes – unknown effective date	The actual unavailability of a medicinal product is a situation when none of the medicinal product manufacturers or wholesalers actually has the possibility to supply the medicinal product (there is no medicinal product in stock) to a pharmacy, medical institution, social care institution, as well as practicing veterinarians and veterinary care institutions upon their request. In the case of medicinal products which are included in regulatory enactments regarding the procedure for reimbursement of expenses for the purchase of medicinal products and medical devices intended for outpatient treatment, the said list of reimbursable medicinal products (hereinafter - list of reimbursable medicinal products) may not be delivered within 24 hours. [national authorities and Regulation No. 416 Adopted 26 June 2007 https://likumi.lv/ta/id/159645-zalu-izplatisanas-un-kvalitates-kontroles-kartiba article 5. 5.12]
Lithuania	Yes – unknown effective date	No official national definition available [national authorities]
Luxembourg		
Mexico	N/A	
Netherlands		
New Zealand	N/A	
Norway	Yes- unknown effective date	No official national definition available [national authorities]
Poland		
Portugal	Yes – unknown effective date	No official national definition available [national authorities]
Slovak Republic		
Slovenia	Yes – unknown effective date	No official national definition available [national authorities]
Spain		A supply problem is a situation where the available units of a drug in the pharmaceutical channel are less than the needs for national or local consumption. [https://www.aemps.gob.es/distribucion-de-medicamentos/problemas-de-suministro-de-medicamentos/]
Sweden	Yes – 1 July 2019	According to the Medicinal Products Act (SFS 2015:315 Läkemedelslagen, 4 kap. 18 § first paragraph (2015:315) the marketing authorisation holder (MAH) of a pharmaceutical drug should, at least two months in advance notify the Swedish Medical Products Agency (MPA) if the sales of the medicinal product temporarily or permanently ceases. The notifications can be made later if there are special reasons for it (for example it was not a known issue, thus the company cannot report it). The notification obligation applies to virtually all approved drugs sold in Sweden and all shortages that are expected to last for at least three weeks. The company shall also notify the national authorities in cases where the company is aware of a shortage expected to last less than three

Country / Region	EU-wide definition applied and from what effective date	National definition [source]
		weeks, but which are still expected to pose patient safety risks. The company, MAH of the drug or its legal representative, must make the notification via MPAs e-service for shortages. Parallel importers are not currently covered by the notification obligation as they are not considered MAH. MPA encourages voluntary notification from parallel importers as well [national authorities and https://www.lakemedelsverket.se/en/treatment-and-prescription/prescription/medicinal-shortages]
Switzerland	N/A	A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level. Federal Office for National Economic Supply (FONES) only come into action if the duration is more than 14 days and for certain (lifesaving) products [national authorities and https://www.admin.ch/opc/fr/classified-compilation/20141823/index.html]
Turkey	Yes – unknown effective date	When supply of a medicinal product doesn't meet demand, a shortage in that medicine occurs. According to our regulation, we call the situation a "medicine supply problem". There is a unit named "Medicine Supply Problem" in the Turkish Medicine and Medical Device Agency. That means a shortage in medicine is a general term. Medicines which are more critical for patients have a privilege when evaluating the situation. Necessary measurements are taken by focusing on the root causes of shortage.[national authorities]
United Kingdom	N/A	A supply shortage of a presentation of health service medicine occurs when supply does not meet patient demand at national level. A discontinuation of a health service medicine occurs when a manufacturer or importer of the presentation intends to permanently stop supplying a product to the UK market. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/783659/dhsc-reporting-requirements-for-medicine-shortages-and-discontinuations.pdf]
United States	N/A	A period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug. In general, the focus is on shortages of medically necessary products that have a significant effect on public health. (Center for Drug Evaluation and Research, 2018 ^[6])

Note: Cells are left empty when the information is not available or could not be retrieved.

Source: Authors based on sources as cited, current as of March/April 2020, updated for some countries with information collected by (Vogler and Fischer, 2020^[11]) in August 2020.

The following tables provide a summary of national shortage notification processes and requirements in OECD countries. Table 3 provides an overview of who notifies (and whether or not it is mandatory); when to notify; how to notify; and on what to notify. Table 4 provides an overview of the type of information notified that is present in existing databases, as well as frequency of update. To inform comparability between countries, indicators present in shortage notification databases were also reviewed (see Table 5.). The most relevant variables for comparative analysis were identified as:

- Brand name
- Strength
- Pharmaceutical form
- Pack size
- Anatomical Therapeutic Chemical (ATC) classification⁴
- Active substance
- Cause of shortage
- Actual (or anticipated) start date
- Actual (or expected) end date
- Pharmaceutical company name (i.e marketing authorisation holder)

⁴ See the ATC classification system developed by the World Health Organization Collaborating Centre for Drug Statistics Methodology (WHOCC) available at https://www.whooc.no/atc_ddd_index/. Further details on the classification system can also be found at https://www.whooc.no/atc/structure_and_principles/ (accessed June 2020).

Table 3. National reporting of medicine shortages in OECD countries

As of March/April 2020, updated with information from August 2020 for some countries

Country [source]	Mandatory notification [sanctions]	Voluntary notification	When to notify expected shortage	Minimum duration of shortage requiring notification
Australia [TGA website]	MAH (since 1 January 2019)		Within 2 working days (critical shortages) to 10 working days (non-critical shortages) after they know or ought to have reasonably known of the shortage; where shortage refers to interruption expected anytime within the next 6 months	
Austria [national authorities & (Vogler and Fischer, 2020 ^[1])]	MAH (for POM), manufacturers (for shortages connected to quality defects); obligatory since April 2020, voluntary prior [no sanctions]	MAH (for NPM)	Not less than 2 months prior; and “immediately” for unforeseen shortages	At least 2 weeks if not available and at least 4 weeks if partially available
Belgium [national authorities]	MAH	None ¹	Not less than 2 months prior, and 6 months for reimbursed medicines ¹	3 working days
Canada [national authorities & (Vogler and Fischer, 2020 ^[1])]	MAH, manufacturers (for POM and NPM under practitioner’s supervision) [sanctions possible]	None	Up to 6 months in advance if it is anticipated or within 5 days of becoming aware of the shortage if it was not anticipated	None. All shortages must be reported
Chile				
Czech Republic [national authorities & (Vogler and Fischer, 2020 ^[1])]	MAH (for any medicine) [sanctions possible]	None	Not less than 2 months prior	
Denmark [national authorities & (Vogler and Fischer, 2020 ^[1])]	MAH (for any medicine expected to influence treatment of patients in Denmark) [sanctions possible]	Wholesalers, pharmacies, patients, doctors	Not less than 2 months prior	None. Notified shortages include only those expected to influence the treatment of patients in Denmark
Estonia [(Acosta et al., 2019 ^[2])]	MAH			
Finland [FIMEA website & (Vogler and Fischer, 2020 ^[1])]	MAH (for any medicine) [no sanctions but their introduction under discussion]		Not less than 2 months prior	No minimum. If more than one year, MAH should report market withdrawal.
France [national authorities]	MAH ² , manufacturer	None	Immediately when a shortage is happening or anticipated	No minimum. Must notify of shortage longer than 72 hours
Germany [national authorities & (Vogler and Fischer, 2020 ^[1])]	MAH (for POM that are relevant or for critical supply); obligatory since April 2020, voluntary prior [sanctions possible],	Manufacturers, wholesalers, community pharmacists, hospital pharmacists, other health care professionals, patients	Not less than 2 months prior - but the desired lead time is ideally 6 months	14 days
Greece [(Acosta et al., 2019 ^[2])]	MAH			

Country [source]	Mandatory notification [sanctions]	Voluntary notification	When to notify expected shortage	Minimum duration of shortage requiring notification
Hungary [(Acosta et al., 2019 ^[2]) and OGYEI website]	MAH			
Iceland [Icelandic Medicines Agency website]	MAH	Public	Not less than 2 months prior, or as soon as possible in special circumstances	None. Report products that have been unreliable in the market for a long or short time and will be lacking in pharmacies
Ireland [national authorities]	MAH	From anyone e.g. Wholesaler, patient, healthcare professional		
Israel [Ministry of Health website & (Vogler and Fischer, 2020 ^[11])]	MAH (for any medicine) [sanctions possible]		3 or 6 months in advance (or “immediately” in case of an immediate shortage)	
Italy [(Acosta et al., 2019 ^[2]) & AIFA & (Vogler and Fischer, 2020 ^[11])]	MAH (for any medicine) [sanctions possible]		Not less than 4 months prior	
Japan ³	None	MAH		
Korea				
Latvia [national authorities & (Vogler and Fischer, 2020 ^[11])]	MAH (for any medicine) [sanctions possible]	Manufacturers, wholesalers, community pharmacists, hospital pharmacists, other health care professionals, patients	Not less than 2 months prior	None
Lithuania [national authorities & (Vogler and Fischer, 2020 ^[11])]	MAH (for any medicine)	None	Not less than 2 months prior	None
Luxembourg				
Mexico				
Netherlands [MEB website & (Vogler and Fischer, 2020 ^[11])]	MAH (for any medicine) [sanctions possible]		Not less than 2 months prior	
New Zealand [national authorities]	None	MAH		
Norway [national authorities & (Vogler and Fischer, 2020 ^[11])]	MAH (for any medicine) [no sanctions]	Hospitals, pharmacies, patients	Not less than 2 months prior	None ⁴
Poland				
Portugal [national authorities & (Vogler and Fischer, 2020 ^[11])]	MAH (for any medicine) [sanctions possible in cases of non-reporting or delayed reporting without justification]	None	Not less than 2 months prior	None
Slovak Republic [(Acosta et al., 2019 ^[2])]	MAH			
Slovenia [national authorities & (Vogler and Fischer, 2020 ^[11])]	MAH (for any medicine) [sanctions possible]	Wholesalers, pharmacies	Not less than 2 months prior	None

Country [source]	Mandatory notification [sanctions]	Voluntary notification	When to notify expected shortage	Minimum duration of shortage requiring notification
Spain [AEMPS website]	MAH			
Sweden [national authorities & (Vogler and Fischer, 2020 ^[1])]	MAH (for POM) [no sanctions]	Parallel importers	Not less than 2 months prior	Lasting at least 3 weeks, or shorter if there are special reasons for it.
Switzerland [national authorities & (Vogler and Fischer, 2020 ^[1])]	MAH (only drugs defined as essential), manufacturers (if they are based in Switzerland) [no sanctions]	Wholesalers, hospital pharmacists	5 days after knowledge of the shortage	14 days (only those over 14 days notified prior to October 2016)
Turkey [national authorities and (Acosta et al., 2019 ^[2])]	MAH	Wholesalers, pharmacies, hospitals other health care professionals, patients	As soon as possible (1 month prior) discontinuation or disruption	
United Kingdom [DHSC website & (Vogler and Fischer, 2020 ^[1])]	MAH (if also UK producer who manufactures the product), manufacturers or importers (if based in the UK) [sanctions possible]		At least 6 months in advance, or as soon as reasonably practicable	None
United States [FDA website]	Manufacturers	Health care professionals, patients/individuals, professional organisations	At least 6 months in advance or as soon as possible, but no later than 5 business days after the start of discontinuation or interruption	

Note: TGA Therapeutic Goods Administration (Australia), MAH marketing authorisation holder, POM prescription-only medicine, NPM non-prescription medicine, FIMEA The Finish Medicines Agency, OGYEI National Institute of Pharmacy and Nutrition (Hungary), AIFA Italian Medicines Agency, MEB Medicines Evaluation Board (the Netherlands), DHSC Department of Health and Social Care (the United Kingdom), FDA Food and Drug Administration (the United States). Cells are left empty when the information is not available or could not be retrieved.

1. At the time of review, voluntary notification by wholesalers, community pharmacists, hospital pharmacists was foreseen for the next release of the Belgian notification website. 2. Mandatory notification only for effective and predicted shortages of major therapeutic interest (i.e. drugs whose shortage would be life-threatening or representing a loss of treatment opportunity for patients with a severe disease). 3. Japan has no national mandatory reporting system. Pharmaceutical companies voluntarily report what they consider important or necessary information on current or expected medicine shortages. There is no official guidance on the content of what to report. 4. While shortages of any duration are reported to the Norwegian Medicines Agency, only those lasting longer than two weeks are mentioned in the extractable online database.

Source: Authors based on sources cited, current as of March/April 2020, updated for some countries with information collected by (Vogler and Fischer, 2020^[1]) in August 2020. See Table 1, for a source list of government institutions reporting on national shortages in OECD countries.

Table 4. Type of information notified in existing shortage databases in OECD countries

As of March/April 2020, updated with information from August 2020 for some countries

Country [source]	Current (or anticipated) shortages	Resolved shortages	Products that have been discontinued (withdrawn from the market)	Vaccines	Human medicines	Veterinary medicines	Frequency of database update
Australia [TGA website]	√	√	√	√	√		Daily
Austria [national authorities]	√	√	X	√	√	√	Daily
Belgium [national authorities]	√	√	√	√	√	√	Daily
Canada [national authorities]	√	√	√	√	√	X	Daily
Chile	<i>No online database found</i>						
Czech Republic [national authorities]	√	√	√	√	√	X	Daily
Denmark [Danish Medicines Agency website]	√				√		Not regularly
Estonia [(Acosta et al., 2019 ^[2]) and SAM website]	√		√	√	√	√	After each notification
Finland [(Acosta et al., 2019 ^[2])]	√			√	√		As required
France [national authorities]	√	√	√	√	√		
Germany ¹ [national authorities]	√	√	√	X	√	X	After each notification and whenever data changes or is outdated
Greece [(Acosta et al., 2019 ^[2]) and website]	√				√		Monthly
Hungary [OGYEI website]	√	√	√	√	√		
Iceland [website]	√	√		√	√		Weekly
Ireland [website]	√	√ ²		√	√		
Israel [Ministry of Health website]	√	√	√	√	√		Weekly
Italy [(Acosta et al., 2019 ^[2])]	√		√	√	√		Weekly
Japan	<i>No online database found</i>						
Korea	<i>No online database found</i>						
Latvia [national authorities]	√	√	√	√	√	X	Daily (every hour)

Country [source]	Current (or anticipated) shortages	Resolved shortages	Products that have been discontinued (withdrawn from the market)	Vaccines	Human medicines	Veterinary medicines	Frequency of database update
Lithuania [national authorities]	√	X	√	√	√	X	After each notification, up to once a day
Luxembourg	<i>No online database found</i>						
Mexico	<i>No online database found</i>						
Netherlands	<i>Not known due to lack of accessibility to the database</i>						
New Zealand	<i>No online database found</i>						
Norway [national authorities]	√	√	√	√	√	X	Weekly
Poland							
Portugal [national authorities]	√	√	√	√	√	X	Daily
Slovak Republic [(Acosta et al., 2019 ^[2]) and website]	√	√	√	√	√		Weekly
Slovenia [national authorities]	√	√	√	√	√	X	Weekly
Spain [(Acosta et al., 2019 ^[2]) and website]	√	√		√	√		As required
Sweden ³ [national authorities]	√	√	X	√	√	√	Daily
Switzerland [national authorities]	√	√	√	√	√	X	After each notification
Turkey [national authorities]	√	√	√	√	√		Monthly
United Kingdom	<i>No online database found</i>						
United States [FDA website]	√	√ ²	√		√		Daily

Note: TGA Therapeutic Goods Administration (Australia), SAM The Estonian State Agency of Medicines, OGYEI National Institute of Pharmacy and Nutrition (Hungary), FDA Food and Drug Administration (the United States). Cells are left empty when the information is not available, could not be retrieved, or when no formal database exists. Some institutions may hold this information across multiple databases / registers, rather than in one central repository.

1. In Germany, discontinued products are located in a different database than current and resolved shortages, hosted by the same institution, while vaccines and veterinary shortages are located in databases hosted by different institutions.
2. Only display resolved shortages for the preceding six-month period. For Ireland, this is in a separate database. For the United States, this is a recent update. At the time of data extraction for the cross-country analysis, resolved shortages greater than six months old were still included.
3. In Sweden, current and resolved shortages are located in different databases. These data were combined for analysis.

Source: Authors based on sources cited, current as of March/April 2020, checked against information collected by (Vogler and Fischer, 2020^[11]) in August 2020 for some countries. See Table 1, for a source list of government institutions reporting on national shortages in OECD countries.

Table 5. Indicators present in shortage notification databases in OECD countries

As of March/April 2020, updated with information from August 2020 for some countries

Country	AUS	AUT	BEL	CAN	CHE	CZE	DEU	DNK	ESP	EST	FIN	FRA	GRC	HUN	IRL	ISL	ISR	ITA	LTU	LVA	NOR	PRT	SVK	SVN	SWE	USA
Brand name	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Strength	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√ ¹	√
Form	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Pack size			√	√		√		√	√		√	√		√		√		√	√	√	√ ²		√	√	√ ¹	√
ATC code		√	√	√ ³	√		√	√		√	√	√ ³		√		√				√	√	√			√	
Active Substance	√	√	√	√			√	√		√	√	√	√	√	√			√	√	√	√	√			√	√
Cause of Shortage	√	√ ⁴	√	√		√		√				√		√	√		√	√			√	√				√
Anticipated Start Date				√				√	√			√													√	
Actual Start Date	√	√	√	√	√		√			√ ⁵	√	√	√	√	√	√	√	√		√	√	√	√	√	√	√
Expected End Date	√	√	√	√		√	√	√	√	√ ⁵		√	√	√	√		√	√	√	√		√		√	√	
Actual End Date		√	√	√	√						√	√				√					√	√		√		
Company Name	√	√ ⁴	√	√	√			√	√	√	√	√	√	√			√	√		√	√	√	√	√	√	√
Alternatives/ substitution			√ ⁴			√			√	√ ⁵		√	√	√				√			√				√	

Note: ATC Anatomical Chemical Classification. Presents information for those countries with a comprehensive, publicly available, online database displaying expected or real medicine shortages at product-level. This database may only be accessible in an online format, or available for download as PDF, XML, CSV etc. In some cases, detailed information on notifications can only be found by clicking on certain products. Cells are left empty when the information is not available or could not be retrieved.

1. In Sweden, there is one notification row for multiple strengths of a product (i.e. one notification per combination of brand/form). 2. In Norway, the database structure changed over 2017-2019; in some cases there may be one notification row for brand/strength/form/pack size, and in others, per brand/form. 3. Only partial ATC code available. 4. Information available, but in a separate database. 5. Information only available by clicking on certain products, and not available in the structure of the extracted database.

Source: Authors based on national databases, current as of March/April 2020, updated with information collected by (Vogler and Fischer, 2020^[1]) in August 2020 for some countries. See Table 1, for a source list of government institutions reporting on national shortages in OECD countries.

OECD analysis of medicine shortage notifications across 14 OECD countries

The second objective of the OECD data collection on notification data was a comparative, retrospective analysis, to identify 1) the main therapeutic areas affected by shortages (see Section 3.2, main text), 2) whether shortages were predominantly country-specific or cross-national (Section 3.3) and 3) the type of active substance concerned (e.g. older, off-patent or more recent products) (Section 3.3). Although shortage data should generally be regarded as of poor or low quality, a group of databases were identified for which data could be compared across 14 OECD countries to provide a high-level assessment of the situation in OECD countries: Austria, Belgium, Canada, Estonia, France, Germany, Hungary, Iceland, Latvia, Norway, Portugal, Sweden, Switzerland and the United States. These 14 databases were chosen for analysis as they contained comprehensive data that was either publicly available or shared with the OECD by national authorities, and included either the active substance or Anatomical Therapeutic Chemical (ATC) classification⁵ for each notification. All notifications of actual or expected shortages with an actual (or anticipated) start date between 1 January 2017 and 31 December 2019 were included. Notifications with an unknown date were excluded from the analysis. Despite lack of date information, data for Estonia were included given the overall limited number of notifications and the time of extraction of the data (February 2020). A three-year period was selected, assuming that a single problem in the supply chain, likely to impact several countries, could affect these countries at different points in time. During the review process, it was also noticed that data prior to 2016 was patchy and likely to be unreliable.

Although not the primary objective of the data collection, the total number of notifications was compared between countries for the period 2017-2019. One notification row in the database constituted one shortage episode, and this varied across countries. For example, in Iceland one shortage episode refers to brand/strength/form/pack size, where as in Germany it refers to one notification per brand/strength/form. Caveats are noted in Box 3.1 of the paper, and Table 6 below summarises the comparison of the shortage notification data and associated caveats for the 14 analysed databases.

Further analyses focused on the pharmaco-therapeutic areas covered by shortage notifications for the whole time period, as identified by the ATC classification. Active substances in each notification in each database over the time period were matched to their respective ATC level-5 classification. In some cases, ATC-level 5 information was already available in the database (e.g. Austria, Belgium, Estonia, Germany, Hungary, Iceland, Latvia, Portugal, Sweden, and Switzerland). In other databases, either no ATC codes or only partial ATC codes were available (e.g. Canada, France, United States). For the latter, active substances were matched with their respective codes using the World Health Organizations Collaborating Centre for Drug Statistics Methodology (WHOCC) 2020 ATC index. In some cases, one active substance may have multiple ATC-level 5 codes (based on strength, route of administration, therapeutic use, use in combination etc), in which case the code for the predominant indication or the otherwise most appropriate code was assigned manually. Notifications for the whole period were then compared across countries according to different levels of ATC classification.

A total of 2112 active substances received at least one shortage notification in any of the 14 analysed countries over the three-year time period. This was further analysed by looking at the:

- number of active substances according to the number of countries with at least one shortage notification (Figure 3.3, main text)
- number of active substances with at least one shortage notification in one country only (Table 7)
- list of active substances with shortage notifications in the majority of countries analysed (Table 8).
- list of 20 active substances subject to the highest number of shortage notifications (Table 9).

⁵ See the ATC classification system developed by the World Health Organization Collaborating Centre for Drug Statistics Methodology (WHOCC) available at https://www.whocc.no/atc_dd_index/ (accessed June 2020).

Table 6. Summary comparison of shortage notification data for 14 OECD countries included in 2017-2019 OECD analysis

Country	Institution managing the online register	Notification by MAH	Current or expected	Resolved shortages	Discontinued products	Vaccines	Frequency of database update	Unit (i.e. one notification row per...)	Other comments	Data and information sources
Austria	The Austrian Federal Office for Safety in Health Care (BASG)	Mandatory for POM since April 2020 (voluntary prior); not less than 2 months prior; and for shortage lasting at least 2 weeks if not available and at least 4 weeks if partially available	√	√	X	√	Daily	Combination of brand/ strength/ form		https://medicineshortage.basg.gv.at/v-ertriebseinschraenkungen (full dataset provided to OECD under confidentiality agreement); email survey received 30 March 2020; (Vogler and Fischer, 2020 ₍₁₎)
Belgium	Federal Agency for Medicines in Health Products (FAMPH)	Mandatory; not less than 2 months prior, and for 6 months for reimbursed medicines; and for shortage lasting 3 working days	√	√	√	√	Daily	Pack size		https://banquededonneesmedicaments.afmps-fagg.be/#/query/supply-problem/human or https://pharmastatus.be/human ; email survey received 12 April 2020
Canada	Bell Canada under contract of Health Canada	Mandatory for POM and NPM under practitioner's supervision; Up to 6 months in advance if it is anticipated or within 5 days of becoming aware of the shortage if it was not anticipated	√	√	√	√	Daily	Pack size		www.drugshortagescanada.ca/ ; email survey received 15 April 2020; (Vogler and Fischer, 2020 ₍₁₎)
Estonia	The Estonian State Agency of Medicines (SAM)	Mandatory	√		√	√	After each notification	Combination of brand/ strength/ form	No dates specified – extraction date 21 February 2020	https://www.ravimiregister.ee/en/publichomepage.aspx ² ; (Acosta et al., 2019 ₍₂₎) and SAM website April 2020
France	French National Agency for Medicines and Health Products Safety (ANSM)	Mandatory; immediately when shortage is happening or anticipated; must notify shortage longer than 72 hours	√	√	√	√		Combination of brand/ strength/ form	Only includes medicines for which there is major therapeutic interest i.e. drugs whose shortage would be life-threatening or representing a loss of treatment opportunity for patients with a severe disease	http://ansm.sante.fr/S-informer/Informations-de-securite-Ruptures-de-stock-des-medicaments ;
Germany ¹	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	Mandatory for POM since April 2020 (voluntary prior); Not less than 2 months prior - but the desired lead time is ideally 6 months; and for	√	√	X	X	After each notification and whenever	Combination of brand/ strength/ form		http://lieferungpass.bfarm.de/ords/f?p=30274:2:609130577714::NO ; email survey received 25 March 2020; (Vogler and Fischer, 2020 ₍₁₎)

Country	Institution managing the online register	Notification by MAH	Current or expected	Resolved shortages	Discontinued products	Vaccines	Frequency of database update	Unit (i.e. one notification row per...)	Other comments	Data and information sources
		shortage lasting more than 14 days					data changes or is outdated			
Hungary	National Institute of Pharmacy and Nutrition (OGYEI)	Mandatory	√	√	√	√		Pack size		https://www.ogyei.gov.hu/gyogyszera-datbazis/ ; (Bochenek et al., 2018 ^[6]), (Acosta et al., 2019 ^[2]), OGYEI website April 2020
Iceland	Icelandic Health Insurance	Mandatory; not less than 2 months, or as soon as possible in special circumstances; no minimum shortage duration	√	√		√	Weekly	Pack size	Not MAH reported data; includes notifications by wholesalers/distributors for those products on the market which may temporarily not be in pharmacy stores (based on data compiled by the Icelandic Health Insurance).	https://gg.sjukra.is/bidlistilyfja (database used); https://www.ima.is/ Icelandic Medicines Agency website
Latvia	The State Agency of Medicines of Latvia (SAMLV)	Mandatory for any medicine; not less than 2 months prior; no minimum shortage duration	√	√	√	√	Daily (every hour)	Pack size		https://www.zva.gov.lv/en/medicines-shortages-management-latvia ; email survey received 07 April 2020; (Vogler and Fischer, 2020 ^[11])
Norway	Norwegian Medicines Agency (NoMA)	Mandatory for any medicine; not less than 2 months prior; no minimum shortage duration	√	√	√	√	Weekly	In some cases, combination of brand/strength/form/pack size, and in others, per brand/form.	Statistical 'unit' not the same across years	https://legemiddelverket.no/legemiddelmangel/legemiddelmangel-og-avregistreringer-2017-rad-til-apotek-og-helsepersonell ; email survey received 25 March 2020; (Vogler and Fischer, 2020 ^[11])
Portugal	The Portuguese National Authority on Medicines and Health Products (INFARMED)	Mandatory for any medicine; not less than 2 months prior; no minimum shortage duration	√	√	√	√	Daily	Combination of brand/ strength/ form		Internal database of restricted access (not public) and provided to OECD under a confidentiality agreement; email survey received 10 March 2020; (Vogler and Fischer, 2020 ^[11])
Sweden	Swedish Medical Products Agency (MPA)	Mandatory for POM; not less than 2 months prior; and for a shortage lasting at least 3 weeks, or shorter if there are special reasons for it	√	√	X	√	Daily	Combination of brand/ form	Current and resolved shortages located in different databases but these data were combined for analysis.	https://www.lakemedelsverket.se/sv/behandling-och-forskrivning/forskrivning/restsituationer ; email survey received 02 April 2020

Country	Institution managing the online register	Notification by MAH	Current or expected	Resolved shortages	Discontinued products	Vaccines	Frequency of database update	Unit (i.e. one notification row per...)	Other comments	Data and information sources
Switzerland	Federal Office for National Economic Supply (FONES)	Mandatory; 5 days after knowledge of the shortage; and for a shortage lasting 14 days (only those over 14 days notified prior to October 2016)	√	√	√	√	After each notification	Combination of brand/ strength/ form	Only includes those medicines considered essential by the health care system.	https://www.bwl.admin.ch/bwl/de/home.html ; email survey received 13 April 2020
United States	Food and Drug Administration (FDA)	Mandatory; at least 6 months in advance or as soon as possible	√	√	√		Daily	Pack size	Only includes those medicines that are life -supporting; life-sustaining; or intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery. Resolved shortages greater than 6 months included.	https://www.accessdata.fda.gov/scripts/drugshortages/ ; FDA website April 2020

Note: POM prescription-only medicine, NPM non-prescription medicine, MAH Marketing Authorisation Holder. Cells are left empty when the information is not available or could not be retrieved. 1. In Germany, data analysis included current or expected shortages and resolved shortages only. Discontinued products are located in a different database than current and resolved shortages, hosted by the same institution, while vaccines and veterinary shortages are located in databases hosted by different institutions. 2. Updated website. Link to original database from which data were downloaded no longer available.

Source: Authors based on sources as cited. Summary information current as of March/April 2020, updated for some countries with information collected by (Vogler and Fischer, 2020^[1]) in August 2020.

Table 7. Number of active substances with at least one shortage notification in one country only (2017-2019)

Country	Total number of active substances for which there was at least one notification	Number of active substances for which there was a notification in this country only (% of total)
Austria	308	28 (9)
Belgium	759	72 (9)
Canada	814	135 (17)
Estonia	180	6 (3)
France	704	97 (14)
Germany	74	10 (14)
Hungary	312	20 (6)
Iceland	843	107 (13)
Latvia	602	76 (13)
Norway	543	74 (14)
Portugal	883	101 (11)
Sweden	540	29 (5)
Switzerland	121	6 (5)
United States	263	43 (16)

Note: Data definition and comparability (including caveats) is summarised in Box 3.1 of the main text and in Table 6, Supplementary Material 1. Source: Authors based on national data. See Table 6 for country data sources.

Table 8. Active substances with shortage notifications in the majority of the countries analysed (2017-2019)

List of active substances with at least one shortage notification in 11 countries (n=27)		List of active substances with at least one shortage notification in 12 countries (n=12)		List of active substances with at least one shortage notification in 13 countries (n=5)	
ATC	Active ingredient	ATC	Active ingredient	ATC	Active ingredient
A02BC02	pantoprazole	A02BA02	ranitidine ^{1 a}	H02AB04	methylprednisolone
A09AA02	Multi-enzymes (lipase, protease etc.)	B02AA02	tranexamic acid ¹	J01DC02	cefuroxime ^{1 2}
C01CA24	epinephrine ¹	C08CA05	nifedipine ¹	L01BC01	cytarabine
G03CA03	estradiol	C09CA01	losartan ¹	L03AX03	BCG Live (intravesicle) ⁴
H03AA01	levothyroxine sodium ¹	C09CA03	valsartan	N04BA02	levodopa and decarboxylase inhibitor ¹
J01CA04	amoxicillin ¹	J01FA01	erythromycin ²		
J01CR02	amoxicillin and beta-lactamase inhibitor ¹	J01MA02	ciprofloxacin ^{1 2}		
J01CR05	piperacillin and beta-lactamase inhibitor ^{1 2}	J01XX08	linezolid ^{1 3}		
J01DD02	ceftazidime ^{1 2}	J02AC01	fluconazole ¹		
J01FA09	clarithromycin ^{1 2}	L01BB05	fludarabine		
J01FA10	azithromycin ^{1 2}	N01AX10	propofol ¹		
J01FF01	clindamycin ¹	R03DC03	montelukast		
J07BC01	hepatitis B, purified antigen ¹ (vaccine)				

List of active substances with at least one shortage notification in 11 countries (n=27)		List of active substances with at least one shortage notification in 12 countries (n=12)		List of active substances with at least one shortage notification in 13 countries (n=5)	
J07BC02	hepatitis A, inactivated, whole virus ¹				
L01AX03	temozolomide				
L01BA01	methotrexate				
L01CA02	vincristine				
L01DB03	epirubicin				
L01XA02	carboplatin				
L01XX19	irinotecan				
M01AE02	naproxen				
M05BA08	zoledronic acid				
N02AA01	morphine ¹				
N02AX02	tramadol				
N02BE01	paracetamol ¹				
N03AX12	gabapentin				
N03AX14	levetiracetam				

Note: Data definition and comparability (including caveats) is summarised in Box 3.1 of the main text and in Table 6, Supplementary Material 1.

1. Listed on the 2019 WHO 21st Model List of Essential Medicines

2. Listed as “watch” on the 2019 WHO AWaRE classification of antibiotics.

3. Listed as “reserve” on the 2019 WHO AWaRE classification of antibiotics.

4. Used as treatment for bladder cancer.

a. The special case of ranitidine and the regulatory suspension of marketing for the European Union impacted this value.

Source: Authors based on national data. See Table 6 for country data sources. WHO 21st Model List of Essential Medicines available at <https://www.who.int/medicines/publications/essentialmedicines/en/> (accessed June 2020)

WHO AWaRE classification of antibiotics available at <https://www.who.int/news/item/01-10-2019-who-releases-the-2019-aware-classification-antibiotics> (accessed June 2020).

Table 9. List of the 20 active substances subject to the highest number of shortage notifications in 14 OECD countries (2017-2019)

ATC5	Active ingredient (class)	Total number of notifications	Number of notifications in each country for each active ingredient (total number of notifications per country)													
			Austria (699)	Belgium (4 623)	Canada (8 508)	Estonia (306)	France (2 923)	Germany (195)	Hungary (982)	Iceland (8 863)	Latvia (1 720)	Norway (2 292)	Portugal (8 403)	Sweden (1 591)	Switzerland (339)	United States (1 819)
C09CA03	valsartan (antihypertensive)	411	23	26	53	0	53	26	11	24	12	27	98	1	0	57
N03AX16	pregabalin (antiepileptic)	385	1	34	91	1	15	0	0	97	21	1	122	2	0	0
N05AH04	quetiapine (antipsychotic)	385	0	50	114	5	3	0	1	58	8	30	116	0	0	0
C09DA03	valsartan and diuretics (antihypertensive)	302	28	24	13	0	43	28	14	24	6	26	96	0	0	0
N03AX14	levetiracetam (antiepileptic)	291	0	12	49	6	7	0	35	21	9	1	82	9	0	60
C09CA01	losartan (antihypertensive)	278	5	42	93	1	12	1	2	53	5	1	61	2	0	0
N05AH03	olanzapine (antipsychotic)	271	0	18	112	0	8	0	2	39	13	1	75	3	0	0
C09DA01	losartan and diuretics (antihypertensive)	259	5	36	79	1	19	0	3	26	1	0	89	0	0	0
N06AX16	venlafaxine (antidepressant)	259	0	45	87	0	3	17	0	40	8	0	56	3	0	0
A02BA02	ranitidine (antacid)	253	18	36	74	3	8	6	11	14	9	10	46	18	0	0
N05AX08	risperidone (antipsychotic)	251	0	16	59	3	19	0	0	38	16	2	76	0	0	22
N05BA12	alprazolam (anxiolytic)	240	0	25	29	1	7	0	0	50	10	7	96	15	0	0
C10AA07	rosuvastatin (statin)	238	0	28	118	4	4	0	0	26	22	2	30	4	0	0
M01AE01	ibuprofen (nsaid)	237	1	45	11	1	0	4	5	80	7	0	70	13	0	0
C09CA06	candesartan (antihypertensive)	232	5	16	100	2	19	4	1	22	8	0	55	0	0	0
N03AX12	gabapentin (antiepileptic)	232	0	25	85	3	8	1	2	38	10	4	49	7	0	0
N06AB06	sertraline (antidepressant)	227	0	22	64	0	6	0	0	43	4	7	71	10	0	0
V01AA20	various allergen extracts	224	0	0	0	0	0	0	224	0	0	0	0	0	0	0
C10AA05	atorvastatin (statin)	223	0	55	46	2	0	0	3	39	13	12	52	1	0	0
N06AX11	mirtazapine (antidepressant)	223	0	34	38	0	4	0	4	30	2	8	92	1	0	10

Note: Data definition and comparability (including caveats) is summarised in Box 3.1 of the main text and in Table 6, Supplementary Material 1. Source: Authors based on national data; see Table 6.

References

- Acosta, A. et al. (2019), “Medicine Shortages: Gaps Between Countries and Global Perspectives”, *Frontiers in Pharmacology*, Vol. 10, <http://dx.doi.org/10.3389/fphar.2019.00763>. [2]
- Bochenek, T. et al. (2018), “Systemic measures and legislative and organizational frameworks aimed at preventing or mitigating drug shortages in 28 European and Western Asian Countries”, *Frontiers in Pharmacology*, Vol. 8/JAN, <http://dx.doi.org/10.3389/fphar.2017.00942>. [5]
- Center for Drug Evaluation and Research (2018), *Manual of Policies and Procedures: Drug Shortage Management 4190.1 Rev.3*, <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp> (accessed on 29 April 2020). [6]
- EMA (2019), *Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)*, European Medicines Agency, <http://www.ema.europa.eu/contact> (accessed on 27 February 2020). [4]
- Vogler, S. and S. Fischer (2020), “How to address medicines shortages: Findings from a cross-sectional study of 24 countries”, *Health Policy*, Vol. 124/12, pp. 1287-1296, <http://dx.doi.org/10.1016/j.healthpol.2020.09.001>. [1]
- World Health Assembly (2017), *Addressing the global shortage of, and access to, medicines and vaccines: report by the Secretariat*, World Health Organization, Geneva, <https://apps.who.int/iris/handle/10665/274799> (accessed on December 2020). [3]