Reporting medicines shortages

Models and tactical options

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Colophon

Contents

1 Introduction

Medicines shortages have become a complex global issue, creating ever more difficulties for health care professionals, and compromising patient safety. People's lives are being put at risk because of medicines shortages. There is evidence that these shortages are worsening with time; in some countries, medicines shortages tripled between 2005 and 2010.[1] The causes of these shortages are several and multidimensional in the context of a complex global supply chain. As a result, there is a growing concern among health care professionals about the future of medicines supplies worldwide.

1.1 Objectives

This report aims to provide an overview of some of the models used to report medicines shortages. It can be used to:

1. Guide the development of a reporting system (or the improvement of an existing system) through the sharing of best practices;
2. Inform and support the implementation of the World Health Assembly Resolution 69.25 "Addressing the global shortage of medicines and vaccines" and, in particular, point 1(f), which calls on Member States to "*advance, gradually, regional and international cooperation in support of national notification systems including, but not limited to, sharing of best practices, training for human capacity building through regional and sub-regional structures where necessary*";, and point 3 (3), which calls on the WHO Secretariat to "*support Member States in addressing the global challenges of medicines and vaccines shortages by developing a global medicine shortage notification system that would include information to better detect and understand the causes of medicines shortages.*"[2]

1.2 Methodology

The methodology used in this report is a survey of publicly accessible reporting systems, based on previous references in International Pharmaceutical Federation (FIP) publications, knowledge of the country's systems, and publicly inaccessible reporting systems.

The selection of the countries and reporting systems does not aim to be exhaustive, but rather to consider a diversity of approaches and considerations for such reporting systems.

Eight information management systems on medicines shortages have been considered for this report:

Name	Country	Managed by
Drug Shortages Database	USA	US Food and Drug Administration (FDA)
ASHP Drug Shortages Resource Center	USA	American Society of Health-System Pharmacists (ASHP)
Canadian Drug Shortage Database	Canada	Coalition of stakeholders
KNMP Farmanco	Netherlands	KNMP (Royal Dutch Pharmacists Association)
The Medicines Shortages Information Initiative	Australia	Therapeutic Goods Administration
Stop Stock Outs Project	South Africa	Coalition of stakeholders
Medicines in Shortage Project	Slovakia	Slovak Chamber of Pharmacists
Medicines shortage internal database	Slovakia	Slovak Medicines Agency (ŠÚKL)

2 What medicines shortages reporting systems tell us

A medicines shortage reporting system aims to:

- Support evidence-based and informed public health decisions (e.g. from medicines regulatory agencies or ministries of health);
- Provide guidance and information to enable health care professionals (such as pharmacists) to limit the impact of medicines shortages;

  In the USA, South Africa and the Netherlands the medicines shortages reporting systems provide guidance to health care professionals and patients.[3-7] Both the Dutch system and ASHP provide suggestions for alternative therapies.[5, 7] In some cases, the FDA provides "Dear health care provider" letters to give more information about a particular shortage. These letters are created by pharmaceutical companies, but approved by the agency.[3, 4] The South African Stop Stock Out Project guides patients to health care facilities that have stock by listing the ones which do not have the medicines of interest (such as antiretrovirals and medicines for tuberculosis). From time to time, they mention if neighbouring facilities have stock.[6]

- Offer data on medicines shortages (e.g. evolution over the past few years) and monitor the impact of public health policies.

  Medicines shortages reporting systems can be used as a tool to raise awareness of shortages. The Stop Stock Outs Project aims not only to understand and identify the causes of shortages but also to raise awareness about the impact of shortages on the struggling health system.[6, 8] The Stop Stock Outs Project seeks to advance transparency in the management of medicines shortages. Since 2013, the initiative has published annual reports assessing the impact of shortages.[6] One of the methods they have used is a "stockout map", which shows the geographical locations of recent shortages (clusters) and offers country-relevant categories such as shortages of tuberculosis medicines and HIV medicines (other categories are: vaccines, others and all categories) to highlight the shortages of these particular medicines.[9]

It is crucial to define clearly the objectives of a medicines shortages reporting system and to determine how it fits with the broader strategy on access to medicines information.[10]

3 Commonalities and options for reporting systems

Based on the analysis of the eight reporting systems (summarised in the Appendix), five major considerations have been identified, and are outlined below.

3.1 Data source, accessibility and ownership

3.1.1 Source of information

There are multiple options for the source of information:

- Manufacturers and distributors (Slovakia)
- Manufacturers and importers (Canada)
- Manufacturers, exporters and importers (Australia)
- Patients (and health care professionals) (South Africa)
- Pharmacists (Slovakia)
- A combination of the above, including manufacturers, importers, distributors, patients, and health care professionals (USA, Netherlands)

The selection of the source of information can be guided by the objectives of the reporting systems. Some aim to inform public policies, such as those issued by medicines regulatory authorities within their scope of action. In such cases, the status of the shortage will be measured at the manufacturer level (e.g. FDA in the USA). Other systems aim to reflect the status at the health provider level (e.g. ASHP in the USA).[3] In South Africa, the Stop Stock Outs Project focuses on the health care facility level, by listing facilities that have experienced a stock out causing patients to go without treatment.[6]

In spring 2017, Canada is planning to make reporting of medicines and vaccines shortages mandatory for manufacturers and importers.[11] In Slovakia, manufacturers and distributors are already obliged to report stock outs to the Slovak Medicines Agency (ŠÚKL).[12]

Some reporting of medicines shortages has been integrated into dispensing software used by all community pharmacies. [13] For example, In France, the report is sent to the database of the National Council of the Chamber of Pharmacists of France where the information is processed and sent to the health authorities. The information on medicines shortages is then made publicly accessible on the website of the French Medicines Agency.

3.1.2 Accessibility of information

Most of the systems looked at in this review provided a public internet page or database where anyone can access information on medicines shortages. Nevertheless, the sample in this report is not a representative sample and different countries have adopted different systems to share information about medicines shortages. One deciding factor is provided by the identity of the target group for the medicines shortage information.

For instance, the Slovak Chamber of Pharmacists has integrated its internal database into the pharmacy software used by pharmacists because they are the target group for the medicines shortage information gathered.

Similarly, some of the data has been made available through a dedicated application. In the USA, there are two apps reporting shortages.[14, 15] One of them has been created by the FDA and the other by an individual pharmacist, drawing on the publicly-accessible information on the FDA and ASHP websites.[14, 15]

It should be noted that the public accessibility of information supports transparency. However, some commercial players may misuse such data to optimise their revenues through stockpiling medicines, especially in countries where medicines prices are not regulated.[1]

3.1.3 Data ownership and management

There is no universal medicines shortage reporting system in place and different countries have adopted different practices. In some countries, such as the USA and Slovakia, there can be different entities (pharmacists' associations and medicines agencies) collecting, owning and publishing the data.

The data can be owned (collected and processed) by:

- A national medicines regulatory agency, such as in the USA (US Food and Drug Administration [FDA]),[3] Slovakia (Slovak Medicines Agency [ŠÚKL])[12] or Australia (Therapeutic Goods Administration);[16]
- A national pharmacy association, as in the Netherlands (Royal Dutch Pharmacists Association [KNMP])[17], USA (American Society of Health-System Pharmacists [ASHP]) [18] and Slovakia (Slovak Chamber of Pharmacists);[19]
- A coalition of stakeholders or organisations, such as in Canada and South Africa.[6, 20]

3.2 Scope

3.2.1 Medicines

The World Health Organization's draft definition of a medicines shortage concerns essential medicines only.[21] This has not been the approach of existing medicines shortage reporting systems; in fact, most of the medicines shortage reporting systems observed for this report have covered a wider scope. The exception is the Stop Stock Outs Project in South Africa, which reports on public sector facilities and only provides information on medicines included on the national Essential Medicines List (EML). The medicines monitored are a sub-set of that EML. The FDA database in the USA reports on shortages of medically-necessary products (excluding products such as weight loss, fertility or sexual dysfunction medicines).[7, 22] The Australian system reports only on prescription medicines,[16] whereas the systems in Slovakia[19] and Canada[23] include all authorised medicines for human use (only excluding veterinary medicines). In the Netherlands, the KNMP lists orphan medicines and raw materials (primarily used for compounding) as well.[17]

3.2.2 Vaccines and biological medicines

In Canada,[23, 24] Australia,[25] USA (ASHP),[3, 18] Slovakia[12] and the Netherlands[5], the reporting systems list shortages of vaccines and biological medicines. The US FDA has a separate system where it lists shortages of vaccines and some biological medicines.[3]

3.2.3 Medical devices and other non-medical products

Shortage reporting systems can, in addition, include data on shortages of medical devices and *in vitro* diagnostics. In South Africa, for example, the database includes syringes, HIV test kits and gloves.[8, 9] In the USA, the ASHP's website includes products such as sterile empty vials.[18] In the Netherlands, the system specifies if the shortage originates from shortage of packaging materials, rather than the finished pharmaceutical product.[17]

Medicines shortage reporting systems can additionally include products related to the administration of a medicine. For example, in Canada the register includes products such as empty capsules.[24]

3.3 Inclusion criteria

3.3.1 Marketing authorisation

Reporting systems may require medicines to have a marketing authorisation within the country, as in Canada,[26] the USA,[7] Slovakia and Australia.[16] Although not explicit, this is also true of the South African system.

3.3.2 Duration and geographical impact

The Dutch shortage reporting system states that they aim to list shortages that are likely to last more than two weeks.[17] Similar requirements have been set in the Canadian system, which recommends reporting of a shortage that is likely to take more than 20 days to meet expected volumes.[26] The Slovak medicines shortage reporting system requires manufacturers and distributors to report if the medicine is unavailable for more than 60 days.[12] Several systems such as the Australian,[16] Dutch[17] and American (ASHP)[3] require that the shortage is nationwide and not localised.

3.3.3 Past, present and future shortages

All of the chosen countries list current medicines shortages but the Australian system also lists anticipated shortages.[16, 25] Some databases also cover discontinued products, such as in the USA,[7, 27] Canada[24] and Australia.[25]

All systems listed recently resolved medicines shortages. The availability of past and resolved shortages allows the different stakeholders to determine whether some shortages are recurrent and allows researchers to access retrospective data.

In addition, the ASHP lists products where there are "no commercially available drug preparations", which is a list of products that no manufacturer can provide in any form leading to a severe shortage.[28]

3.3.4 Verification of the shortage

Systems accepting medicines shortage reports from the public or health care professionals are under additional pressure to verify the information received. The ASHP Drug Shortages Resource Center in the USA encourages anyone to report a new shortage and it aims to verify the shortage by contacting manufacturers; thus it usually takes 24 to 72 hours before a shortage is listed.[3, 28] In the Netherlands, medicines shortage reports are verified by escalating them through the supply chain as a part of their normal process.[17] The South African Stop Stock Outs Project verifies medicines shortage reports from patients, health care workers and sentinel surveyors, mapping the reported cases and tracking specific issues. All reports are then escalated through the supply chain and resolution is sought through the direct engagement of civil society with accountable government individuals and entities.[6]

3.4 Information on medicines shortages

3.4.1 Overview of shortages

When entering a database or website, the menu view can already give key data on shortages as shown in Figure 1.

Figure 1. Shortages displayed in Canadian medicines shortage reporting system[24]

Certain data are frequently made available as part of the first information available on the website:

- Identification of the medicine
    o Active ingredient or generic name[4, 5, 8, 18, 24, 25]
    o Brand name[5, 22, 24]
    o Medicine's identification number[25]
    o Strength[25]
    o Dosage form[25]
    o Name of the supplier (manufacturer or importer)[24]
- Classification of the product
    o Type (medicine, raw material, packing or orphan medicine)[5]
    o Category of the medical product[8]
- Shortage updates and duration
    o Start date[8, 24]
    o Expected supply[8, 25]
    o Shortage status (e.g. currently in shortage, resolved or discontinuation)[4, 8]
    o Revision date[5, 8, 18, 24, 25]
- Effect, actions and location
    o Facility and province (name and location of the facility suffering from the shortage)[8]
    o Effect (substitution possible, limited availability, alternatives available, solved, impending shortage, import possible)[5]
    o The impact and actions on facility level[8]

3.4.2 Detailed information on shortages

In addition to information available in the overview of current shortages, additional information may be accessed when clicking on a specific shortage. Figure 2 illustrates this extended information, from the Canadian example.

ENOXAPARIN SODIUM - Drug Shortages

Market Authorization Holders adopt various measures to appropriately and reliably supply Canadians with innovative medicines approved by Health Canada. Despite these efforts, situations may arise that cause a drug shortage in Canada.

On this website, users will be able to view Current and Resolved drug shortages in our Drug Shortage database. As we have only just launched this website, we expect that information in each of these categories will change somewhat in the first few months of operation.

Drug Shortage Details

Company Name	Sanofi Canada
Product Name	LOVENOX HP
Product Number	50088917
Drug Ingredient	ENOXAPARIN SODIUM
Strength	120MG
Dosage Form	SOLUTION
Package Size	10
Drug identification number	02242692
UPC/GTIN	065914111334
Reason for Shortage	Supply delay
Estimated Resupply Date	April 14, 2017
Updated	March 3, 2017

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Figure 2. Profile of a medicines shortage displayed in Canadian medicines shortage reporting system[24]

Extended information on a specific shortage may include:

- About the medicine in shortage
  - Active ingredient or generic name[4, 5, 18, 24, 25]
  - Brand name[5, 18, 24, 25]
  - Medicine's identification number[4, 18, 24, 25]
  - Manufacturer/supplier[4, 5, 18, 24, 25]
  - Dosage form[4, 5, 18, 24, 25]
  - Strength[4, 5, 18, 24, 25]
  - Pack size[4, 5, 18, 24]
  - Therapeutic category[4]
- About the shortage
  - Reason for shortage[4, 5, 18, 25]
  - Availability of alternative medicines[4, 5, 18, 24]
  - Estimated duration of shortage/resupply date[4, 5, 18, 24, 25]
  - History of updates/last update[5, 18, 24]
  - Status (e.g. currently in shortage, resolved or discontinuation)[4, 25]
  - Related information (e.g. "Dear consumer" letter, link to supplier's website)[4, 5, 25]
  - Related shortages[18]

3.4.3 Reason for the medicines shortage

In Australia and the Netherlands, the reason for shortage is always listed.[5, 25] The Dutch system aims to be transparent by listing the references for the reasons.[5] In Canada, the reason for shortage is not always listed in the database, but manufacturers are requested to provide this information.[23, 24] In the USA, the FDA and ASHP systems have different practices in listing the reasons for medicines shortages.[3]

The FDA database must follow the terminology specified in the Food and Drug Administration Safety and Innovation Act, and thus lists one or more of the following reasons for a shortage:

- Shortage of an active ingredient,
- Demand increase for the drug,

- Requirements related to complying with good manufacturing practices,
- Shortage of an inactive ingredient component,
- Delay in shipping of the drug,
- Regulatory delay,
- Discontinuation of the manufacture of the drug.[7]

The ASHP database uses different terminology from that used by the FDA and lists the reason only if the manufacturer is willing to reveal it.[3]

3.5 Criteria for resolving the medicines shortage

There are some subtle differences between the reporting systems, as to when the system considers shortages to be resolved. These are:

- One or more companies can fill the market demand for that product (USA, FDA)[3]
- When the medical product is available again (the Netherlands); [5]
- All manufacturers of the medicine have restored all dosage sizes in all formulations.[3] Despite partial or restricted availability, products may be listed by the ASHP system because there can be disruptions at provider or patient level and their aim is to reflect the availability at provider-level (USA);
- When contacted, the health care facility confirms they have stock again (South Africa).[8]

4 Conclusions

This report intends to guide countries as they develop a national reporting system, or improve an existing system. Such actions would facilitate the implementation of Resolution 69.25 on "Addressing the global shortage of medicines and vaccines."

In particular, the report aims to help WHO member states to gradually advance regional and international cooperation in support of national notification systems, including, but not limited to, sharing of best practices, and training for human capacity building through regional and sub-regional structures where necessary. This report can also facilitate the development of a global medicines shortage notification system that would include information to better detect and understand the causes of medicines shortages.

This report provides an overview of some of the models used to report medicines shortages, describing a variety of approaches and considerations for such reporting systems. Eight information management systems on medicines shortages from six countries have been selected for this report.

The report is organised around the different areas of consideration. When determining the reporting, clear decisions about the ownership of the data (who owns the data and who manages them), availability (who is obliged/allowed to report and how) and accessibility of the data (with whom the data are shared) are needed. The scope of reporting may either be limited (or not) to items on the essential medicines list only, or also encompass vaccines, biological medicines, medical devices or non-medical products (such as syringes, gloves, sterile vials, packaging materials and products related to medicines administration).

Reporting may be limited to products with marketing authorisation. The minimal reporting requirements for shortage duration and geographical impacts differ. The availability of data on past and resolved shortages is a common practice. Listing the reasons for medicines shortages increases the transparency of the system, and listing if/ when the shortage would be resolved helps the health care professionals or patients to better consider interim solutions. Some countries offer guidance to pharmacists on alternative medicines.

Information on medicines shortages can be made available to the public via the Internet (websites, mobile apps), but some countries choose to limit availability to health care professionals only (for example, to pharmacists via their dispensing software). The data are organised around the product, duration of the shortage or effects. This report lists the different options for organising and detailing the information. Any reporting system should fit into a national strategy on access to medicines information.

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6 Appendix — Analysis of reporting systems

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Name of the initiative and link to the website)	The Medicines Shortages Information Initiative (http://apps.tga.gov.au/prod/MSI/search/)	Canadian Drug Shortage Database (http://drugshortages.ca/drugshortagehome.asp)	KNMP Farmanco (https://farmanco.knmp.nl/)	Project "Medicines in Shortage" [19] (www.slek.sk/nedostupnelieky)	Medicines shortage internal database	STOP Stock Outs Project (http://stockouts.org/)	ASHP Drug Shortages Resource Center (http://www.ashp.org/menu/DrugShortages.aspx)	Drug Shortages Database (http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm)
Purpose	To improve the management and communication of prescription medicines shortages in Australia.[16]	To make pivotal information about medicines shortages easily available to health care system and Canadians. [11]	To centralise information about medicines shortages in the Netherlands, so that adequate measures can be taken to solve the problem, incl. providing advice to pharmacists. [30]	To collect and provide information on the in-real-time medicines shortage information, suggest solutions, involve all supply chain actors, Ministry of Health and medicines agency. [19]	To collect and manage the data on medicines shortage towards measures resolving the shortage	To help people in a country with chronic stock outs on essential medicines. [6]	To collect and share timely, verified information about products in shortage with practitioners, administrators and regulators, and patients and caregivers.[27]	To provide information obtained from manufacturers about current shortages, estimated duration, and discontinuations and provides information about FDA's and other stakeholders' roles in addressing and preventing shortages. [3]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Who owns the data	Therapeutic Goods Administration (TGA) [16]	The Multi-Stakeholder Working Group, which is industry led. [20, 31]	Royal Dutch Pharmacists Association (KNMP)	Slovak Chamber of Pharmacists (SLeK) [19]	Slovak Medicines Agency (ŠÚKL) and Ministry of Health (MZ SR)[12]	STOP Stock Outs Project	American Society of Health System Pharmacists	US Food and Drug Administration
Co-owner of the data	Medicines Australia (organization representing pharmaceutical industry) and Generic and Biosimilar Medicines Association. [16]	As of September 2013, there were seven pharmaceutical industry associations: Canadian Pharmacists Association, Canadian Society of Hospital Pharmacists, Canadian Medical Association, Alberta Health, Health Canada and Canada's Agency for Drug and Technologies in Health. [23, 31]	Laboratorium Nederlandse Apothekers (LNA) [17]	The project was developed by Association of Innovative Pharmaceutical Industry (Asociácia inovatívneho farmaceutického priemyslu), Slovak Chamber of Pharmacists (SLeK) and Association of Patients' Rights Protection	None	The project was launched by MSF, the RHAP, RuDASA, SA HIV Clinician's Society, SECTION27 and the TAC [6]	The database is developed and updated by University of Utah Drug Information Service. [18]	None
Type of entity	Medicines agency in a multi-stakeholder coalition	Multi-stakeholder coalition, where one of the members is FIP member organisation	FIP member organisation	Pharmacists' organisation	Medicines agency and Ministry of Health[12]	Civil society coalition	FIP member organisation	Medicines agency

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Audience/ target group	Public and health care professionals [16, 25]	Health care professionals and patients [26]	Pharmacists, increasingly also being used by manufacturers and other stakeholders. [30]	Public and health care professionals	Relevant stakeholders in the supply chain	Patients and stakeholders [6]	Health care professionals[3]	Public[3]
Information about shortages publicly available	Yes [25]	Yes [24]	Yes [5]	No	No	Yes [8]	Yes [27]	Yes [4]
Scope of shortage list	Prescription medicines and biological medicines which have (or it is anticipated will have) a shortage in overall Australian market. [16]	Human pharmaceuticals, chemical pharmaceuticals, vaccines and biological medicines with market authorisation in Canada.[23]	Medicines, orphan medicines, raw materials or packing materials which have a nationwide shortage.[5, 17] Includes shortages which are impending. [5]	Medicines for human use and medical devices with market authorisation in Slovakia. [19]	Medicines for human use and medical devices with market authorisation in Slovakia. [12]	Any medicine, vaccine or treatment related product if there is a shortage[9]	All medicines and biologics shortages which have been confirmed by manufacturer and effect at national level. [3] The ASHP's scope is wider than the FDA's.	Medicines that are considered necessary to treat or diagnose a disease (excludes products such as fertility and weight loss medicines) which have a national shortage and have been confirmed by the FDA. [7, 22, 28]
Shortage list includes vaccines	Yes [25]	Yes [23, 24]	Yes [5]	Yes	Yes	Yes [8, 9]	Yes [18]	No [3]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Shortage list includes biological medicines	Yes [25]	Yes [23, 24]	Yes [5]	Yes	Yes	Yes [8]	Yes [3]	No [3]
Shortage list includes medical supplies, packing or compounding materials	No [16]	Yes (e.g. empty capsules)[24]	Yes (packing materials) [5]	Yes	Yes	Yes (e.g. syringes, HIV test kits, gloves) [8, 9]	Yes (e.g. sterile empty vials) [18]	No [3]
Verification of information	TGA has hired scientists and regulatory experts to coordinate and manage communication and activities that are related to medicines shortage activities. [16]	Information comes directly from manufacturers and importers. [11]	After receiving a report that there is a shortage, KNMP contacts the supplier to verify the information. [17]	Information is collected by pharmacists – they make a "notification of medicines in shortage" via a dedicated form.	Most information is received directly from manufacturers and distributors, patients and by internal monitoring.	The initiative tries to verify all information by escalating the reports through supply chain.[6]	All reports are verified with manufacturers and investigated (usually it takes 24-72 hours) before they are published. [3, 28] This process is done by the Drug Information Center of University of Utah.[18]	Most information is received directly from manufacturers. [7]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Source of shortage report	Information is based on voluntary notification from sponsors (manufacturers, importers and exporters [29]), which complements their ongoing communication activities while managing medicines shortages. [16]	Information is based on voluntary notification from pharmaceutical industry (manufacturers and importers). [11, 26]	The site allows anyone to report in theory, but KNMP requests that pharmacists, suppliers and wholesalers report.[17]	Information is based on voluntary notification from pharmacists.	Manufacturers and distributors are obliged to report the stock out to the Slovak Medicines Agency.[12]	Crowd sourced stock out reports from patients, health care workers and sentinel surveyors (i.e. person who reports regularly) [6] People can e-mail, call, text, whatsapp or report online.	Anyone can report a shortage via the website as it is based on voluntary reports from practitioners, pharmaceutical industry representatives, patients and others. [3, 27] Note: Reports reflect the shortage status at health care provider level [3]	Most reports come from manufacturers, but the FDA encourages other stakeholders and groups (e.g. patients and health care professionals) to inform it about shortages and supply issues.[7] In addition, the FDA receives reports from ASHP. [3] Note: Reports reflect the shortage status at manufacturer level [3]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Link to the reporting form	Reporting only available for sponsors. [16]	Reporting only available for manufacturers and importers[11, 23]	https://farmanco.knmp.nl/meldingsformulier	Pharmacy software	Unknown	http://stockouts.org/submit-report.html	http://ashp.az1.qualtrics.com/jfe/form/SV_25KOx5N9FJYhuyp	No form available online. [32] Reports should be done by contacting drugshortages@fda.hhs.gov or calling (240) 402-7770 Recently the FDA has established a direct platform for industry "CDER Direct NextGen" which can additionally be used to report shortages, but it requires credentials. [33]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Criteria for inclusion on list	-A notification from a sponsor that they cannot supply the wholesaler either temporarily or permanently. -Nationwide - Medicine is included in Australian Register of Therapeutic Goods (ARTG). [16]	-Medicine must have a market authorisation.[26] -Anticipated or actual shortage [23] -Likely to take more than 20 days to meet expected volumes [26]	- Nationwide - Likely to take more than two weeks.[17]	- Medicine for human use must have a market authorisation from Medicines Agency - When pharmacist cannot order the medicine for the patient.	-Medicine unavailable for 60 days - At least two months before the planned stock out, the manufacturer /distributor has to notify Medicines Agency	Any shortage or stock out which has resulted from altering the treatment, supply of insufficient amount of medicine, being referred to another place or turned away from the clinic/hospital. [6]	-Verified shortage[3] -Affects dispensing or preparation of the product or requires alternative medicines, which may affect patient care. [3] - National impact [3]	-Medicine must have a market authorisation from FDA [7] - Medicine is interchangeable [7] - Market demand is bigger than supply according to manufacturers and market sales research experts [3]
Criteria for resolving shortage	Product can meet normal customer demand. [29]	No criteria listed.	When the product is available again. [5]	No criteria listed.	No criteria listed.	Facility confirms they have stock again. [8]	All manufacturers of the medicine have restored all dosage sizes in all formulations. [3] Despite partial or restricted availability, products may be listed as there can be disruptions at provider or patient level	If one or more manufacturers are able to produce enough essential medicine to cover the market demand.[3]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Reason for shortage	Mentioned in the description of the shortage. [25]	Reason for shortage is not always listed in the database, but manufacturers are requested to inform it. [23, 24]	Website lists the explanations and references. [5]	No criteria listed.	No criteria listed.	No criteria listed. [8]	Manufacturers provide the reason if willing to disclose, however the reasons may be different from the FDA's, due to terminology needed to comply with legislation [3]	According to the Food and Drug Administration Safety and Innovation Act 2012 (FDASIA) -Shortage of an active ingredient -Demand increase for the drug, -Requirements related to complying with good manufacturing practices, -Shortage of an inactive ingredient component, -Delay in shipping of the drug, -Regulatory delay -Discontinuation of the manufacture of the drug. [7]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Information shared in the dataset: **Menu level**	- Generic name - Brand name -Active pharmaceutical ingredient - Strength - Dosage form -Identification number -Expected supply -Revision date [25]	- Product name - Generic name - Company name - Start date - Revision date [24]	-Type (medicine, material, packing or orphan) -Active pharmaceutical ingredient -Brand name -Dosage form -Revision date -Impact (substitution possible, limited availability, alternatives available, solved, impending shortage, import possible). [5]	Unknown	Unknown	- Stockout case (open/closed and if the case has been verified) - Generic name - Category the medicine belongs to -Facility (name of the facility suffering from the shortage) - Province -Date reported - Details (incl. impact, actions, update history) [8]	- Generic name - Revision date [18]	- Active ingredient or generic name - Status [4]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Information shared in the dataset: **Profile level**	-Product ›Generic name ›Brand name ›Active pharmaceutical ingredient ›Strength ›Dosage form ›Identification number - Dosage form - Sponsor ›Name ›Contact details - Shortage dates - Shortage details ›Shortage status ›Reason ›Related information [25]	- Company name - Product name - Active pharmaceutical ingredient - Dosage form - Strength - Package size - Estimated resupply date - Drug identification number - UPC/GTIN - Date of update.[24]	-Product description -Brand -Anticipated date of availability (if known) -Reason for non-availability -Pharmaceutical substitution (referring to other packet sizes or other generic producers) -Therapeutic alternatives - Revision date -Remark (if any). [5, 17]	Unknown	Unknown	No profiles available. [8] All information at menu-level.	-Description of the medicine (product name, active ingredient, dosage form, strength, package size, company name, medicine identification number) - Reason for the shortage - Estimated resupply dates -Available products -Related shortages -History of updates. [18, 27]	-Generic name and dosage form -Status (currently in shortage, resolved or discontinuation) - Date first posted - Therapeutic categories. [4, 7] All manufacturers (with all strengths) of the medicine listed separately with a contact number written accordingly. [4] The listing includes: -Presentation, -Availability and estimated shortage duration -Related information - Shortage reason (per FDASIA).

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Type of shortages covered by the dataset	-Anticipated -Current -Resolved (displayed for three months after the shortage has been resolved) -Discontinued medicines [16, 25]	-Current -Resolved -Discontinued medicines. [24]	-Current -Recently solved[5]	-Current -Resolved	-Current -Resolved	-Current -Resolved (marked as "closed" in the list) [8] The shortage map has categories: -HIV medicines, -Tuberculosis medicines, -Vaccines -Other [9]	-Current -Resolved -No commercially available products - Discontinued medicines [18, 27]	-Current, -Resolved -Discontinued medicines [7]
The guidance the dataset provides for health care professionals or patients	No[25]	No [24]	Provides suggestions for substitutes and alternative therapies. [5]	No	No	The information on the website guides patients to choose a facility with stock.[6]	Provides suggestions for alternative therapies [7]	FDA provides "Dear health care provider" letters in some cases. [3, 4]

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Anticipated changes	No	Mandatory reporting for manufacturers starting from spring 2017 [11] -Regulation that anticipated medicines shortages no less than six months in advance and unanticipated shortages within five days of learning about it (if shortage is expected to occur within the next half a year) [11] -Third-party owned public website for medicines shortages [11]	No	No	No	No	No	No

	Australia	Canada	Netherlands	Slovakia (SLek)	Slovakia (SUKL & MZ SR)	South Africa	USA (ASHP)	USA (FDA)
Format of the available data	Internet database [25]	Internet database [11]	Internet website [17]	Internal database	Internal database	Internet website [8] The website visualises, with the help of a map, where there are shortages, what type of shortages and the amount. [9]	Internet website [28]	Internet database and an app for smartphones. [7, 33]
Other information	The database includes food allergy tests and allergens (e.g. various pollens).[25]	Currently there is a public register listing those manufacturers and importers who have committed providing public information on shortages voluntarily.[11]				Because of the stockout map, the initiative highlights shortages of TB and HIV medicines,[9] although the map has not been updated since 2014.	A smartphone app called RxShortages, which is targeted to health care professionals who want to want to know more about medicines shortages. [7] The app accumulates its information automatically from the ASHP and FDA.	The FDA has a separate database which includes vaccines and certain biological medicines,[3] this is available from: www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/ucm351921.htm
Comments		The Canadian drug shortage database lists the menu level products separately if the strength is different. Yet the menu level does not show the strength. [24]						