



How should drug shortages be defined? A review

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BACKGROUND

Drug shortages are currently on the rise. In-depth investigation of the problem of drug shortages is necessary, however, a variety of definitions for 'drug shortages' are adopted by different organisations, e.g. Italian Medicines Agency, Belgian law, German reporting system. For international comparison, it is important to clearly denote which definition is used by the national authorities or by (inter)national organisations.

OBJECTIVE

Identifying and comparing different definitions of drug shortages and analyze the overlap and missing information in each definition

METHODS

A literature review was performed searching scientific databases MEDLINE and Embase for definitions of drug shortages. Grey literature, such as websites and documents governmental and professional organisations were also incorporated. Definitions were read and analyzed and topics which returned frequently were identified.

RESULTS – GENERAL

Over 20 different definitions were found. Different sources are acknowledged, including:

- national laws
- governmental and professional organisations
- scientific articles

The results will be discussed according to different topics.

RESULTS – WHEN

Source	Definition
Health Canada	... when the drug supply cannot meet the actual or projected demand ...
EFPIA (European Federation of Pharmaceutical Industries and Associations)	... an interruption of supplies of a drug ...
FIP (Fédération International Pharmaceutique)	A drug supply issue requiring a change (impact patient care or use of alternative agent)
Italian Medicine Agency	... when a product is not available or commercially available ...

RESULTS – TIME FRAME

Source	Definition
Belgian law	A drug is unavailable when enterprises ... are unable to deliver that drug for an uninterrupted period of 4 days
France law	When a drug is undeliverable within 72 hours
Canadian Drug Shortage Databank	That it will take longer than 20 days to supply a drug to meet expected patient volumes
ISPE (International Society of Pharmaceutical Engineering)	A situation in which the total supply of an approved drug is inadequate to meet the current or projected demand at the user level

RESULTS – TYPOLOGY

Source	Definition
FDA	... the total supply of all clinically interchangeable versions of an FDA-regulated drug is ...
German reporting system – BFARM	Prescription drugs intended primarily for the treatment of life-threatening or serious diseases for which no alternative preparations are available
Spanish reporting system – AEMPS	All drugs which experience supply problems are reported, except for those for which a quick fix is expected

DISCUSSION

- **When** is a supply problem is classified as drug shortage? A decision should be made between at patient level ("not meeting the demand") or at pharmacy level (an interruption of supply).
- Is a **time frame** important in a definition (varies from 1 day till 20 days)? The delay of treatment for infectious diseases for 20 days can have serious impact for patients.
- Is a distinction in **typology** necessary? Definitions only mentioning prescription drugs or interchangeable drugs, cover only partially the offer. Still patients may encounter some difficulties by switching to a less familiar (generic) product.

CONCLUSIONS

The ultimate goal is to formulate a general European definition for drug shortages, which is based on inputs of all different stakeholders. Many decisions should be made before this definition can be generated.

1. Determination of when a supply problem is as well a drug shortage
2. Indicating a time limit is an essential element for the comparison of national reported drug shortages
3. Decision about which types of drugs are considered. All type of drugs should be covered in the general definition to acknowledge the size of the problem.