

Reading List | Medicine Shortages

Contents

1

Causes and solutions for medicine shortages

1.2

Economic causes driving medicine shortages

2

Information on medicine shortages

1 – Causes and solutions for medicine shortages

Medicines for Europe position paper on medicine shortages

Causes & recommendations to tackle medicine shortages

Causes of generic medicine shortages

- **Pressure of costly regulatory/quality procedures and cost-containment measures on generic medicines industry**

Members of Medicines for Europe are highly committed to quality. To achieve this quality, manufacturers comply with important and stringent regulatory/quality procedures. These procedures are costly and experience has proven that there is an inability of the market to reward the investment on these procedures. Additionally, the **extreme pressure on prices due to short-term cost containment measures** such as tendering, external reference pricing and payback mechanisms challenge the sustainability of our industry forcing the **withdrawal of generic medicines from the market and increasing the risk of medicines shortages**.

In order to tackle medicines shortages in a multi-source context, Medicines for Europe believes in an approach that addresses both the **root causes of medicines shortages (preventing medicines shortages)** and **mitigates medicine shortages** once they occur.

Recommendations to prevent medicine shortages (addressing the root causes)

- **Ensure market predictability**
 - A predictable and sustainable pricing & reimbursement environment will increase the number of manufacturers in the market guaranteeing that in case one of the manufacturers cannot supply other manufacturers in the market are able to supply the medicine

- Revision and prevention of the application of short-term cost containment measures (e.g. mandated price reductions, internal and external reference pricing, tendering and payback mechanisms) to generic medicines that are undermining the long-term sustainability of manufacturers while increasing the risk of medicines shortages which ultimately affects patient health
- Prevent disproportionate sanctions that can increase the risk of medicine shortages
- **Improve regulatory efficiency to reduce administrative and cost burden of keeping medicines in the market**
 - Implement flat fee structure for variations
 - Optimise the use of Centralised and Decentralised procedures for generic medicines
 - Increase flexibility to accept different pack sizes or multi-country packs to address market needs
 - Increase use of telematics tool (e.g. FMD, ISO-IDMP, Art. 57, etc.) for communication of changes currently requiring variation submission in large portfolios
 - Lower fees/costs for older molecules that still serve a healthcare need
- **Manage available market stock information with non-coercive systems**
 - Use systems such as European Medicines Verification System that will be in place in 2019 to manage information on medicine shortages throughout the supply chain

Recommendations to mitigate medicine shortages

- **Specific regulatory measures to mitigate imminent medicine shortages**
 - Flexibility to accept different pack sizes at national level based on Marketing Authorization
 - Flexibility to accept multilingual packages (e.g. eLeaflet as a solution)
 - Efficient Repeat Use Procedure
 - Incentives for medically essential low price products (e.g. lower variation fees/flat fee)

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1.2 Economic causes driving medicine shortages

- **An Evaluation of Medicines Shortages in Europe with a more in-depth review of these in France, Greece, Poland, Spain, and the United Kingdom.**

Birgli. 2013.

Full text available [here](#)

- **The Impact of Shortages on Medication Prices: Implications for Shortage Prevention.**

Alevizakos M, Detsis M, Grigoras CA, et al. Published in Drugs. 2016; 76(16):1551-8.

Full text available [here](#)

- **FDA strategies to prevent and respond to drug shortages: finding a better way to predict and prevent company closures.**

Barlas S. Published in P & T: a peer-reviewed journal for formulary management. 2013; 38(5):261-3.

Full text available [here](#)

- **Causes of drug shortages in the legal pharmaceutical framework.**

De Weerd E, Simoens S, Hombroeckx L, et al. Published in Regulatory toxicology and pharmacology. 2015; 71(2):251-8.

Full text available [here](#)

- **Drug Shortages: Searching for a Cure.**

Gagnon 2012. Published in Healthcare policy Vol.7 No.4, 2012

Full text available [here](#)

- **The impact of anti-infective drug shortages on hospitals in the United States: trends and causes.**

Griffith MM, Gross AE, Sutton SH, et al. Published in Clinical infectious diseases: an official publication of the Infectious Diseases Society of America. 2012; 54(5):684-91.

Full text available [here](#)

- **Drug shortages in Europe and the USA: The underlying reasons and consequences.**

Holtorf AP, Rinde H, Maniadakis N. Published in ISPOR 15th Annual European Congress; 10th February 2017; Berlin. Germany: Presented at the ISPOR 15th Annual European Congress (Berlin, 5 November 2012); 2012.

Full text available [here](#)

- **Medicine shortages: a commentary on causes and mitigation strategies.**

Iyengar S, Hedman L, Forte G, et al. Published in BMC medicine. 2016; 14(1):124.

Full text available [here](#)

- **Drugs, money, and power: the Canadian drug shortage.**

Kaposy C. Published in Journal of bioethical inquiry. 2014; 11(1):85-9.

Full text available [here](#)

- **Drug shortages: the cycle of quantity and quality.**

Kweder SL, Dill S. Published in Clinical pharmacology and therapeutics. 2013; 93(3):245-51.

Full text available [here](#)

- **Drug Shortages: The Problem of Inadequate Profits.**

Markowski ME. Published in Cambridge, MA: Harvard Law School, 2012.

Full text available [here](#)

- **Drug shortages and the burden of access to care: a critical issue affecting patients with cancer**

McKeever AE, Bloch JR, Bratic A. Published in Clinical journal of oncology nursing. 2013; 17(5):490-5.

Full text available [here](#)

- **Drug shortages in European countries: a trade-off between market attractiveness and cost containment?**

Pauwels K, Huys I, Casteels M, et al. BMC health services research. 2014; 14:438.

Full text available [here](#)

- **Insights into European drug shortages: a survey of hospital pharmacists.**

Pauwels K, Simoens S, Casteels M, et al. Published in PloS one. 2015; 10(3):e0119322.

Full text available [here](#)

- **The impact of drug shortages on patients with cardiovascular disease: causes, consequences, and a call to action.**

Reed BN, Fox ER, Konig M, et al. Published in American heart journal. 2016; 175:130-41.

Full text available [here](#)

- **Clinical dilemmas and a review of strategies to manage drug shortages.**

Rider AE, Templet DJ, Daley MJ, et al. Published in Journal of pharmacy practice. 2013; 26(3):183-91.

Full text available [here](#)

- **Economic and technological drivers of generic sterile injectable drug shortages.**

Woodcock J, Wosinska M. Published in Clinical pharmacology and therapeutics. 2013; 93(2):170-6.

Full text available [here](#)

- **The Role of Government Reimbursement in Drug Shortages.**

Yurukoglu AL, E. Ridley D.B. Published in US: Stanford University. 2016.

Full text available [here](#)

2 – Information on medicine shortages

Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages

The European associations representing manufacturers of medicinal products, parallel distributors, pharmaceutical wholesalers and pharmacists have announced a series of recommendations on the provision of information, designed to help tackle medicines shortages.

This statement builds on existing good practices and recommends some specific features of ideal medicines shortages information systems. The European associations representing manufacturers of medicinal products, parallel distributors, pharmaceutical wholesalers and pharmacists hope that, taking into consideration the national specificities of each country, these recommendations can help enhance information systems at a national level, and potentially form the basis of future European level action.

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