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Medicine Scarcities in the European Union

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Key points

Although the European Union has a competent authority in “E.M.A”¹ about drug shortages reports across Europe, it seems like national reporting systems are functioning independently of one another and also of the European Medicines Agency. Despite the efforts that have been made to mitigate the problem, medicines shortages have been augmented over the past four years (EAHP, 2018)². Medicine shortages affect a wide scope of stakeholders such as patients, pharmacists, doctors and medicine suppliers. National reporting systems are particularly complicated and lengthy (“web based but considered by many not user friendly, which may hinder the reporting system”, EAHP 2018 1). Also, reporting systems in a national level often are absent, or, when existent, not always accurate and updated. Dysfunctional communication and economic causes, such as price-based tendering procedures, and heterogeneity in drug storage among European countries, add to the problem. This policy brief suggests three possible recommendations:

- Thorough cooperation, in order to have accurate and daily updated notifications about medicine shortages in a national and Pan-European level.
- More than one winner in tenders, in order to have multiple medicine suppliers.
- Parallel trade restrictions when a country is facing medicine shortages

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Introduction

Medicine scarcity is a threatening problem that in extreme cases can lead to the paralysis of the public health system. Drug shortages is a phenomenon that includes both innovative medicines and generic medicines. The “2018 Medicines Shortages Survey by EAHP”² indicates that the situation of medicine shortages in Europe has deteriorated over the past 4 years (in comparison to the 2014 EAHP report³ for drug shortages). It is crucial to underline the necessity that the problem is dealt through not only a national, but also, through a PanEuropean level. Although the most directly affected by the problem are the patients, medicine shortages concern a wide scope of stakeholders such as pharmacists, doctors and wholesalers. In 2018, the supply chain actors adopted a joint declaration⁴ in order to improve supply chain actor’s communication about medicine shortages. That was a step forward, but, it’s not enough. A trustworthy and clear list of the shortages in Europe is essential for the problem to mitigate.

Repercussions of medicine shortages

Medicine shortages in Europe have increased by 5% in just four years, according to the EAHP (currently 91, 8%). EAHP addressed questions to European hospital employees, about the problems they come across with reference to drug scarcity.

- 35% of 1666 respondents reported that, the pharmacy of the hospital, they work in, faces drug shortages daily, and,
- 38% of them stated that medicine shortages occur weekly in their working space. (2018, EAHP)²

Medicine shortages affect adversely the patients’ treatments; they lead to protracted hospital stays (which also means additional costs), “delays and cancellations of medical procedures” (Economist, 2017)⁵. They can also cause degradation of the patients’ health. According to 8 % of the EAHP 1.666 respondents, medicine shortages resulted in adverse events. A small percentage (1%) reported that medicine shortages lead to patient’s death. Also, medicines deficits are most commonly reported in crucial (“oncology medicines”) and wide spectrum drugs (“antimicrobial agents, vaccinations”).

Non- availability of medicines also affects pharmacists and doctors. In their case, medicine shortages result in them working overtime, trying to find alternative therapies for patients. Surely, their anxious efforts to find a solution can subvert the care that patients should enjoy in a hospital. Also, their attempts may turn out to be pointless, resulting to medical errors. The time and effort that that pharmacists put in to find an alternative solution has increased over the past 4 years. Over 5 hours a week are spent on average trying to find a substitute treatment (EAHP, 2018).³ In addition, alternative medications are often more expensive. Doctors should, also, deal with the psychological

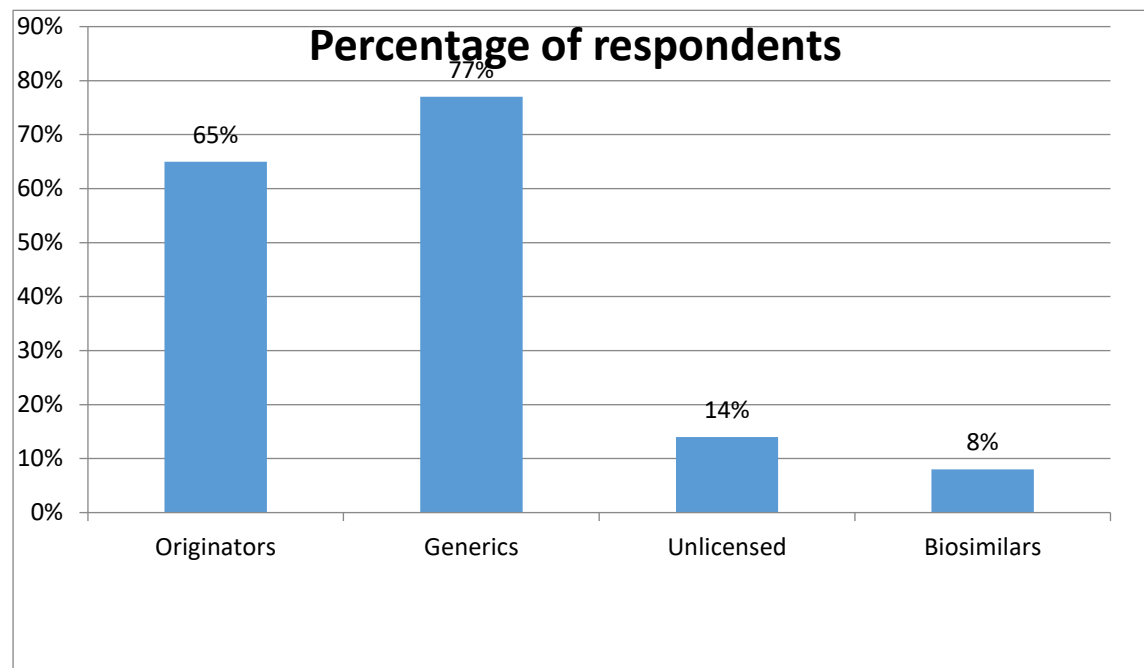


distress of them being accused for malpractice, as the alternatives they may find could cause adverse events to the patient’s health. Non availability of medicines is an issue that involves both patented medicines (originators) and generics (off-patent drugs). According to the 2018 EAHP survey, generics are most commonly in scarcity. Given the significance of generics for the E.U. (-they are the majority of pharmaceuticals in Europe, -with generic competition the E.U. saves approximately 100 billion dollars per year. Source: Medicines for Europe⁷), it is essential that they E.U. tackles shortages especially on generics.

*“Percentage of participants in the survey who identified this type of medicine to be most commonly in short supply. (N=1,347) (Note that this was a tick all that apply question)”
(Source: EAHP *12)*

Factors of medicine shortages

- Economic factors contribute to the worsening of the problem. Parallel trade often leads to excessive medicine shortages in non-wealthy countries. Traders often buy large amounts of medicines for cheap in countries that the prices are low and sell them in wealthy countries, in an effort to multiply their profits. In this manner, low-price countries are experiencing larger medicine shortages. Especially in the domain of generic medicines, competitive bidding systems (“tendering”) decrease the competition .Tendering aims to withhold the cost of medicines but in such manner, the market is



restricted to a few suppliers. Tendering with the solely concern to reduce costs, leads to a limited number of manufacturers. In this way, the risk of drug shortages isn’t spreaded out and if the risk occurs it would result in even larger scarcities. Also, “payback



policies” (The Economist, 2017)⁵, “claw-back tax⁶ and external reference pricing” (Medicines for Europe, 2016)⁶ add to the (generic) drug shortages’ issue.

- Communication factors/Reporting of shortages: Most European countries have a reporting system in a national level. The reporting system is responsible for informing about the possible upcoming shortages in medicines. Although, in some countries the detection of medicine shortages is up-to date, that isn’t the case for the majority of the countries in the E.U. Even in the countries that a reporting system exists, usually it’s not convenient and facile to understand. Also, hospital employees, often, aren’t aware of the national reporting system. Due to lack of time and to the fact that in some countries reporting is not obligatory, the system is not up to date with the current drug shortages. In addition, in some countries, reporting systems are not accessible to pharmacies. According to EAHP almost “70% of the interviewees responded that their country has a reporting system but only half of them consider it to be efficient”. (EAHP,2018)³

Recommendations

- The challenge of efficient cooperation:

Communication is the biggest challenge the European Union is facing, concerning drug scarcities. As said, current national systems haven’t met the expectations for valid and up to date information about drug shortages. This policy brief suggests thorough communication between the E.U. and its members. The current European Medicines Agency list for medicines shortages should be revised, in order to be easily accessible and comprehended by all actors of medicine supply-chain and also by the hospital’s pharmacists. At the same time, an up-to-date catalogue of medicine shortages in a national level is required. For it to be accurate, daily medicine shortages reports should be mandatory. It is needed that manufacturers inform pharmacies about future medicine shortages. Also, the E.U. can make annual reviews on the functioning of the national reporting systems of the member-States.

- Tendering procedure with a view to patients’ health:

The main stakeholders of medicine shortages are patients. Bidding procedures shouldn’t be based only economic factors. Often, tenders have only one winner. This leads to fewer suppliers, which means that shortages of medicines aren’t easily restored. If tender winners were multiple, based (not only on price but also) “on the type of the medicine and the needs of the market” (Medicines for Europe, 2018), more manufacturers would be able “to meet the demand of the market” (The Economist, 2017⁵). In order to ensure patients’ treatment, supply exclusivity needs to be sacrificed.

- Restrictions on parallel trade: As mentioned, parallel trade permits to traders to buy medicines in countries that the prices are low such as Greece, and sell them in high prices in countries like Germany(Art.34 and 35 of Treaty on the Functioning of the European Union⁷). This tactic often leads to higher percentages of drug shortages in



countries with low prices. Quantity restrictions on parallel trade of medicines and even export bans in times with extreme medicine shortages may be the best way to tackle the depletion of the market.



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