

Why Are Some Drugs in Short Supply?

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Abstract:

Traditional market theory says that efficient markets will supply the quantity of a good or service demanded at a satisfactory price that clears the market by assuring that the quality demanded is equal to the quantity supplied. Markets are sometimes inefficient when supply does not meet demand, as is the current case with certain cancer medications and other frequently ordered pharmaceuticals.

Introduction

Private markets produce a significant portion of the world's pharmaceuticals. Drug manufacturers make use of their expertise to provide the pharmaceuticals patients require for their medical treatment.

Economic theory would say that markets are behaving efficiently when the quantity supplied to the market is equal to the quantity demand-

ed and the market is said to have cleared. But markets do experience inefficiency on some occasions when the available supply of medication does not meet the demand for that drug.

Discussion

Although such inefficiencies in the supply of medications are known to occur, when cancer medications fall victim to such supply shortages,

the results can be problematic for treating practitioners and can have deadly consequences for cancer patients.

As of May 23, 2023, the US Food and Drug Administration listed 15 cancer drugs on its drug shortage list (Llamas, 2023). Among the cancer drugs in short supply are Carboplatin and Cisplatin. A late May survey by the National Comprehensive Cancer Network (NCCN) indicated that 93% of surveyed US cancer centers reported a shortage of Carboplatin and 70% reported a shortage of Cisplatin (Horvath, August 8, 2023).

In an interesting demonstration of international drug diplomacy, two Chinese pharmaceutical firms are coordinating with the US Food and Drug Administration (FDA) to increase the availability of the injectable drug due to the shortage (Qilu Pharmaceutical, May 24, 2023).

Medical oncologists claim that these shortages are affecting patient treatment and could shorten the lives of some cancer patients (Yong, 2023). Substituting other medications is not always a workable solution, especially if the medications in short supply have proven their effectiveness over time. Other complicating factors include the stage of the patient's cancer, the side effects of substituted medicines and the clinical effectiveness of the originally prescribed medications.

The inadequate supply of certain cancer medications is only part of a larger issue. How is it that established medications are found to be in short supply in this day and age? If private markets are heralded as the most efficient means of meeting patient needs, why are needed medicines so difficult to obtain?

According to Marta Wosinska, a health economist at the Brookings Institution:

“...shortages are caused by internally generated problems, created within the market because of its structure. In other words, ‘they’re self-inflicted wounds’.” (Yong, *ibid.*)

Reasons for shortages in medicine supplies

Shortages in drug supplies for patients are both a health and social problem. They can be caused by increased consumption, production problems, distribution issues and problematic laws and regulations. The Slovak minister of

health, Michal Palkovič, stated that approximately 27% of Slovak patients over the age of 65 have unnecessary and excessive prescriptions for medications (Rezort zdravotníctva, 2023).

The world recently experienced the increased consumption of certain drugs during the COVID-19 pandemics such as inhalation corticoids, which were used in support therapy, as well as other drugs that were considered effective against the disease. Production problems may include shortages in supplies of precursors or chemicals necessary in the production process, detected contamination and temporary retraction from the market. Distribution of drugs and other goods was hampered during the COVID-19 measures, bringing about negative impacts on transportation, and this is commonly seen in areas where there are natural catastrophes and military conflicts.

Regulations to decrease the cost of medicines as a reason for shortages in drug supplies in the Slovak Republic

Sometimes drug shortages are caused or aggravated by laws and regulations. In the Slovak Republic, the cost of medicines is responsible for almost 30% of all costs for healthcare (Rážova, 2017). Therefore, there have been several attempts to decrease their cost. One of them was a law stating the price of drugs in Slovakia has to be among the lowest prices in the European Union.

Until December 2011, the price of medicines was set at a maximum of the average of the six lowest prices in the European Union. From December 2011, the maximum manufacturer's price was set at the second lowest price in the EU. This measure caused a significant increase in the re-export of medicines from Slovakia, causing a shortage of medicines for Slovak patients.

The subsequent modification of the law after January 2013 brought about two changes. The manufacturer's maximum price was set as the average of the 3 lowest prices in the EU Member States, and additionally, distributors were obliged to report planned re-exports of medicines to the State Institute for the Control of Medicinal Products (ŠÚKL) (Novák, 2016). Under Act No 363/2011 Coll., all categorized medicinal products are subject to referencing,

and their price is approved at the level of the European reference price, meaning the average of the three lowest prices of a given medicinal product in other European countries (Zákon č. 363/2011 Z. z.).

This law, which aimed to decrease the cost of medicines in Slovakia, had a negative effect on their availability for Slovak patients. It led some speculators to re-export cheaper drugs from Slovakia and sell them for higher prices in other countries. Re-export means that medications that are usually produced in a different country and are exported from there to Slovakia are subsequently re-exported to yet another country. The missing medications were mostly from the generally more expensive groups: cytostatics, immunosuppressants, immunoglobulins and antidepressants. At the same time, they were medications that were often irreplaceable by other medicines. For instance, oncological therapies are often taken long term, and they are based on verified protocols with specific combinations of certain medicines. Such shortages harmed groups of very vulnerable patients.

Attempts to solve the problem hampered by EU legislation

To solve the problem, Slovakia introduced the monitoring of medicine exports in 2013. If there was a shortage of a medicine, ŠÚKL (State Institute for Control of Medicinal Products) had the power to ban the export.

However, the European Commission considered this legislation to be in conflict with the free movement of persons and goods within the European Union. The Commission initiated infringement proceedings against Slovakia regarding the ban on the re-export of medicines in 2015.

The new legislation

This led to new legislation that permitted the re-export of medicines, but an attempt was made to regulate it through the stakeholders included in the process of production and different levels of distribution. The main stakeholders are **the holder of a categorized medicinal product registration**, wholesale distributors of categorized medicinal products and public pharmacies. The amended law that came into effect in 2017 stated that the **patient** has the right to get their

prescribed medicine within 24 hours from any pharmacy.

Pursuant to Section 9(1) of Act No 363/2011 Coll., the **holder of a categorized medicinal product registration** is obliged to ensure that the medicinal product is available on the market in sufficient quantities for the entire duration of the inclusion of the medicinal product in the list of categorized medicinal products. A sufficient quantity is an amount sufficient to cover the estimated monthly consumption of the medicinal product in the Slovak Republic (Slaný, 2017). Furthermore, the new law forbade the resale of medicines by pharmacies to any **wholesale distributor**, except the one that the pharmacy bought the medicine from. Previously when the pharmacies had resold medicines to wholesale distributors, some distributors re-exported them out of the country for profit. The legislation also obliged all stakeholders to keep records about the sale of medicines so it could be tracked. Exports of categorized medicinal products were only allowed to be made to the holder of a categorized medicinal product registration and the authorized manufacturer of the exported medicinal product (Slaný, 2017).

The legislators believed that these new regulations would make sure that there were no shortages of medicines in Slovakia.

The problem continues in 2023

Unfortunately, shortages of medicines caused by their re-export are a problem even today. In July 2023 there were 29 pharmacies involved in the illegal re-export of medicines. The director of ŠÚKL, Peter Potůček, said that most of them were biologics, the production of which is more expensive and thus the price abroad is higher than in Slovakia (ŠÚKL, 2023). The price of the medicines was above 7 million euro. There were several mechanisms used for illegal re-exports: falsified prescriptions, repeated use of the same prescriptions and the misuse of a form by which a distributor requests the removal of a medicinal product from the list of categorized medicinal products (Rezort zdravotníctva, 2023).

The problem with re-exporting also has impacts on shortages of certain medications in the Czech Republic, mainly medicines to treat high blood pressure, heart failure, breast cancer, diabetes, epilepsy, respiratory problems and blood

thinners. Some of it was happening directly from the Czech Republic to another country where the medication is more expensive, and some of the illegal trade was going through distributors from Slovakia. Pharmacies resold the medications despite the fact that they are not allowed to do so in the Czech Republic. Sometimes they bought the medications, did not register them in their electronic system and subsequently resold them (Janoušek et al., 2023).

Both the Czech Republic and the Slovak Republic are increasing the penalties for breaches of the laws and are considering further changes in regulations to prevent medicine shortages.

The appeal of churches to moral responsibility

The Bioethics Subcommittee of the Conference of Bishops of Slovakia, together with the Evangelical Church of the Augsburg Confession and the Ecumenical Council of Churches, created a common opinion that appeals to all those who deal with medicines at any level - manufacturers, registration holders, wholesale distributors, pharmacists and pharmacy care providers - to refuse to participate in any step that is part of the chain leading to the export of medicines and that deepens the unavailability of medicines for Slovak patients. Since such activities directly endanger the health and lives of very vulnerable patients, they are morally unacceptable (Stanovisko k problému reexportu liekov zo Slovenska, 2023).

Conclusion

If we assume that Wosinska is correct in her observation that drug shortages are a function of market structure, how might governmental and market forces influence the desired availability of medications in short supply? A few suggestions:

- Use government influence to improve the availability of ingredients required in pharmaceutical manufacturing and limit re-exportation to other nations. Manufacturers often cite the short supply of needed ingredients as a reason for being unable to meet market demand. When drugs are re-exported to other nations, domestic supply is limited, which may lead to increased prices for the drugs that remain available.

- Offer tax incentives to certain drug manufacturers and distributors who may be restraining supplies due to smaller margins on needed drugs.
- Seek to minimize the influence of pharmacy benefit managers in western nations. Such practices may be expected to impact the pricing of certain pharmaceuticals in international markets, thereby leading to shortages (Walker, 2023).

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