



COUNTRY PROFILE: CANCER MEDICINES SHORTAGES

FINLAND

Introduction

| EIU indicators | 2018 ratings |
|---|--------------|
| Political environment rating (10=high) | 8.6 |
| Effectiveness of system in policy implementation (5=high) | 4.0 |
| Infrastructure rating (10=good) | 9.3 |
| Level of corruption (5=low) | 4.4 |

In 2016, a report on access to and quality of healthcare, published by The Lancet Global Health, ranked Finland's healthcare system as one of the best in the world.¹ Health expenditure per capita in Finland has been increasing since 2005 and in 2015 it reached 2891 EUR, which is above the European Union (EU) average.² Health spending as a percentage of the country's Gross Domestic Product (GDP) is slightly below the

EU average—9.4% compared to 9.9%.² Nearly all of the population is covered by health insurance, however, the level of out-of-pocket payments (OOP) as a percentage of total healthcare expenditure (20%) is higher than in other Western European countries. More than one-third of OOP is spent on medicines and co-payments can be a financial burden for some patients.²

The wholesale distribution of medicines in Finland is based on a single-channel system, where a wholesaler holds an exclusive distribution contract with a pharmaceutical manufacturer covering all its products, and pharmacies or hospitals can acquire a certain pharmaceutical product only through this wholesaler. The country is divided into 24 hospital districts each of which is allocated to one of five expert responsibility areas (ERAs) for specialised care. Hospital medicines procurement is managed at the ERA level through competitive tendering.³ The company winning the bid is obliged to supply the medicines that are needed to cover the actual patients' needs over the specific tender period.³

Finland has a system of mandatory reserve supply for medicines with "critical medical significance" based on the national legislation.^{4,5} The Finnish Medicines Agency (Fimea) is responsible for compiling the list of medicines with mandatory reserve supply which, in May 2018, included 1425 products.⁵ Depending on the type of product, medicines are kept in stock by manufacturers and wholesalers in quantities necessary to cover the demand from three to ten months. Hospital pharmacies are also obliged to keep certain medicines in stock from two weeks to six months.⁴ Nevertheless, our interviews with the Finnish health professionals clarified that the emergency reserve stocks are not intended to be used in case of medicines shortages, but are reserved for situations of national emergency.

According to the definition of the European Medicines Agency (EMA), a medicine shortage "occurs when supply cannot meet demand at a national level."⁶ Over the last decade the number of medicines in short supply in Finland, as reported by Fimea, has increased tenfold—from 67 products in 2010 to 696 in 2018.^{7,8} According to the 2018 European Association of Hospital Pharmacists (EAHP) survey, nearly 80% of Finnish hospital pharmacists reported that medicines shortages were a current problem in their hospital, and about two-thirds stated that shortages occurred on a daily or weekly basis, with a typical shortage lasting up to two months.⁹ The 2018 EAHP survey reported that cancer medicines are the third most common class of medicines to experience shortages, after antimicrobials and vaccines.⁹

As cancer is the second leading cause of deaths in Finland, after cardiovascular diseases, accountable for 25% of deaths in men and 21% of deaths in women, the shortages of cancer medicines might represent a concern in the country.²

What is happening on the ground?

Ensuring access to and availability of safe, effective medicines to patients at all times is a priority in Finland’s Medicines Policy 2020.¹⁰ Nevertheless, this policy document does not discuss the issue of medicines shortages specifically. The ‘ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe’ is one of the few published studies on the availability of cancer medicines that provides shortages data for Finland.¹¹ This study reported that most of the medicines (both generic and innovative) used to treat melanoma, renal cancer, lung cancer, colorectal and prostate cancer were “usually” but not “always” available. During the survey period (April to June 2014), the eleven cancer medicines of the WHO Model List of Essential Medicines included in the study did not have any availability issues.¹¹

Although shortages of cancer medicines are not very common in Finland, they do not cease to be a concern for health professionals and patients, as they tend to affect older, inexpensive, essential medicines which still have clinically meaningful benefits. In fact, the analysis of the data for medicines shortages notified by marketing authorisation holders (MAHs) to Fimea shows that cancer medicines shortages account for nearly 5% of the total number of shortages —34 occurrences out of 696 in 2018 (Table 1).⁷ Interviewed physicians state that cancer medicines shortages are less frequent at the moment although they have been around for decades. A patient organisation representative also perceived that cancer medicines shortages are not a current problem in the country. (Personal communication) However, from the hospital pharmacist’s perspective, it seems that cancer medicines shortages are becoming more common and may occur at least once a week.* This implies that the shortages are occurring with varying frequency in different parts of the country.

Table 1. Examples of cancer medicines affected by shortages in 2018

| Cancer Medicine | Indication |
|-----------------|--|
| Anastrozole | Breast cancer |
| Cytarabine | Acute non-lymphoblastic leukaemia; Acute lymphoblastic leukaemia; Acute myeloblastic leukaemia; other cancers |
| Letrozole | Breast cancer |
| Methotrexate | Acute lymphoblastic leukaemia; Breast cancer; Head and neck cancer; Lung cancer; Non-Hodgkin’s lymphoma; Osteosarcoma; other cancers |
| Temozolomide | Melanoma; Glioma |
| Zoledronic acid | Breast cancer; Myeloma; Prostate cancer; Renal cancer (Hypercalcaemia of malignancy) |

Source: Finnish Medicines Agency (Fimea)⁷

* Expert interviews

Medicines shortages have an impact on the quality and safety of patient care. The shortages may cause delays of treatment, use of substandard alternative product, or medication and dosing errors. In Finland, some of the oncology products most commonly affected by shortages include etoposide and methotrexate. However, often oncologists have been able to minimise the impact of shortages by using different medicinal forms. For example, during the shortage of etoposide phosphate or zoledronic acid, oncologists were able to use respectively the old soluble format and other compounds. Moreover, although methotrexate was on shortage, it did not affect patients care and treatment. However, the shortage of etoposide phosphate has been challenging in the treatment of children as alternative products require the use of more diluent and therefore larger volume of infusions which can be invasive for children.*

The impact of shortages on health professionals is mostly related to the time spent in solving the shortage situation—time that can be used for taking care of the patients. It should be mentioned that in Finland, when a wholesaler cannot deliver a certain product, it is the MAH's responsibility to procure the product from another supplier to fulfil its contractual obligation and cover the extra costs in case of need.*

Why do inexpensive cancer medicines go missing?

Although the supply of cancer medicines has not been extensively compromised in Finland in recent years, shortages do occur and the reasons behind these shortages are often undetermined.

Case study: Oriola's distribution problems, 2017

In September 2017, one of the two main pharmaceutical wholesalers in Finland, Oriola, experienced problems with the introduction of a new Enterprise Resource Planning system.¹³ As Oriola is responsible for nearly half of the deliveries in the country, for an entire week medicines were either being incorrectly delivered to healthcare units or not delivered at all, which led to a number of medicines shortages, including certain cancer medicines. The Association of Finnish Pharmacies reported that a quarter of all pharmacies had not had their urgent orders filled. Although there were no critical events reported, in part because most pharmacies keep a supply of the most common products correspondent to the average sales of a two to three weeks' period, it took about a month to stabilise the situation and some less commonly used medicines were not available for a longer time. The fact that each medicine is distributed by a single wholesaler aggravated this event and showed some of the vulnerabilities of the current distribution model.

Main reasons for cancer medicines shortages in Finland

A 2017 study on the reasons behind medicines shortages from the perspective of pharmaceutical companies and wholesalers in Finland found that the causes of shortages are often complex and interrelated.³ According to the study participants the causes for medicines shortages in Finland are mostly supply-related.³

Structure of the pharmaceutical market

The size of the market in Finland is small compared with many other countries, and small sales volumes are often associated with low profitability for the manufacturers leading to more delisted

* Expert interviews

products in the market and thus to medicines shortages. Finland is highly dependent on foreign manufacturing, which can lead to long-delivery times and eventually to shortages.³ Experts interviewed for this report agreed that long production chains and the small number of manufacturers for certain medicines may be key drivers for shortages.

Economic reasons

The lower prices for some of the essential cancer medicines in Finland in comparison with other markets¹² can also contribute to the lack of interest of manufacturers and thus to product withdrawals.

Wholesale distribution system

As distribution is based on a single-channel system, where each pharmaceutical company is represented by a single wholesaler, the system might be subject to shortages as demonstrated in the Oriola case.

Manufacturing issues

These can be caused by complex production chains, raw material shortages for the production of active ingredients, production quality issues, or issues related to the malfunction of a packaging line.³

Table 2. Who is involved in tackling shortages in Finland and what are the current initiatives?

| Competent Authority | Responsibilities and current initiatives |
|---|--|
| Finnish Medicines Agency (Fimea) ⁷ | <ul style="list-style-type: none"> • Receives and manages notifications for medicines shortages or withdrawals from MAHs. • Manages an online public platform about temporary shortages with up-to-date information from MAHs. • In exceptional situations, such as when no substitute for the medicine in shortage is available, releases complementary information about the procedure to follow. • Grants parallel importation licenses for the medicine in shortage or, in exceptional circumstances, a special use permission for importing a medicine that does not have marketing authorisation in Finland. |

According to the national legislation, MAHs must ensure that the products registered in the country are continuously available to wholesalers and pharmacies to meet patients’ needs.⁷ In case of potential problems, MAHs are obliged to notify Fimea at least two months in advance of an expected shortage. The MAHs’ notification forms are included on Fimea’s shortages website.⁷ If a medicine remains unavailable for one year, the event is no longer considered to be a shortage and the MAHs must submit a notification for withdrawal of the product from the market.⁷

While the Fimea website enhances the transparency of shortages, it does not provide information about the causes. Moreover, only 57% of the Finnish pharmacists who took part in the 2018 EAHP survey were aware of the existence of a reporting system in the country and only 29% of them considered it to be “effective, working or functional.”⁹ The main reported issue is that the website is not a searchable database which makes it difficult for any user to find if a specific product is in short

supply. The other issue is linked to the fact that the website only reports notifications from MAHs, while those that are directly affected by the shortages, such as pharmacists, clinicians and patients, are not able to submit information about missing medicines. This highlights that in the country there is a lack of awareness regarding the systems in place to tackle medicines shortages.

Looking into the future

Cancer medicines shortages are occurring with varying frequency in different regions of the country. Although they are a small proportion of the overall number of products experiencing shortages, they still have an impact on patient care and can be particularly challenging when the patients are children. Our analysis highlights that the collaborative way of working between pharmacies in a given district or between districts has been a crucial factor contributing to the prevention and mitigation of cancer medicines shortages in the country.

Some recent initiatives and proposals that have been discussed in Finland to address the issue of medicines shortages include:^{13,14}

- The flow of information between health professionals and patients can be improved. Pharmacists and clinicians should be able to provide more feedback to patients about the causes and duration of medicines shortages.
- Physicians should be aware if a medicine is not available before prescribing it. This could be done by linking a database of temporary availability disruptions to an electronic prescription system.
- The Baltic Partnership Agreement, which includes Estonia, Latvia and Lithuania, is a model for collaboration that could be explored in Finland. While the focus of this partnership originally was on joint procurement for vaccines, since 2014 there have been several instances of lending of centrally procured medicines to enable countries to prevent or mitigate shortages.¹⁵ Interviewed experts mentioned that the process resembles the internal collaboration among hospital districts within Finland.
- As Finland has two official languages the regulatory requirements for the information included in the medicine package currently makes it difficult to resolve some shortages. The Nordic co-operation initiative, involving Denmark, Finland, Iceland, Norway and Sweden, aims to promote the use of multilingual packages.⁴ If the two official languages in Finland are included, this could help to mitigate shortages through a fast exchange of medicines.
- The mandatory reserve supply system could be re-evaluated in the context of shortages affecting essential cancer medicines.
- Causes of medicines shortages should be further investigated. Specific measures should be considered to prevent withdrawals of inexpensive, essential cancer medicines from the market due to economic causes.

There is a lack of awareness regarding the systems in place to tackle medicines shortages.

Possible solutions

Solution 1

Develop a list of essential cancer medicines

- This initiative should involve national competent authorities, policymakers, as well as professional organisations of oncologists and oncology pharmacists. The list should include all essential medicines required for the treatment of cancer patients, including those on the WHO Model List of Essential Medicines.
- Keeping essential cancer medicines on the list of medicines with marketing authorisation should be a priority.

Solution 2

Create a task force and update the legal framework to address medicines shortages

- The task force should include representatives of national regulatory authorities, policymakers, healthcare professionals, patients, and the pharmaceutical industry.
- Develop a national strategy for the prevention and mitigation of shortages. The legal framework should recognise wholesalers as potential originators of shortages. The current distribution system in Finland should be re-evaluated, to ensure that unpredicted events that affect one supplier do not increase the risk of shortages.

Solution 3

Improve the reporting system for shortages

- Pharmacists are a key agent in providing insights of day-to-day performance of the medicines' supply chain. Pharmacies should be able to provide information on shortages.
- Clinicians and patients should also be able to submit information to Fimea about medicines shortages.

Solution 4

Establish procurement models designed to prevent shortages

- Based on the list of essential cancer medicines and the number of patients in the country, the procurement model should be redesigned to prevent shortages or product withdrawals from the market.
- Consider shortening the supply chain to allow hospital pharmacies to purchase missing essential medicines directly from MAHs in situations of shortages.

Solution 5

Join international collaborations to facilitate the exchange of products in short supply

- The Baltic Partnership Agreement (2012) and the Nordic Pharmaceuticals Forum (2015) which includes Denmark, Iceland, Norway and Sweden, were established to explore opportunities for joint tendering as well as lending medicines to other countries in shortage situations.
- By joining such initiatives Finland would ensure better access to medicines which are temporarily unavailable in the country. Additionally, by being part of a group for joint negotiations and purchases, Finland would be less susceptible to shortages related to its small market size.

Acknowledgements

- Dr Wilppu Terhi, Hospital Pharmacist, Turku University Central Hospital, European Society of Oncology Pharmacy (ESOP)
- Dr Vesa Kataja, Chief Medical Officer, Central Finland Health Care District (KSSHP), Adjunct Professor of Clinical Oncology, Jyväskylä, Finland
- Dr Liisa Sailas, Head of Oncology, North Karelia Central Hospital, North Karelia Social and Health Care Services (Siun Sote), Joensuu, Finland

The Economist Intelligence Unit bears sole responsibility for the content of this document. The findings of the report and the views expressed do not necessarily reflect the views of all the experts involved. We thank the ESMO Public Policy Steering Committee and the ESMO Cancer Medicines Committee's Inexpensive, Essential, Cancer Medicines Working Group for their input.

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