The Costs of Pharmaceutical Safety

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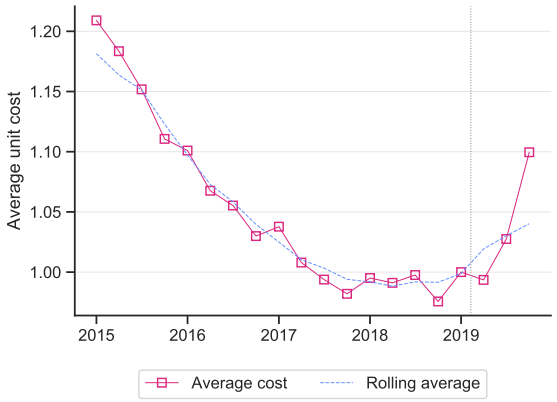
In this project, we propose to study the competitive effects of a 2019 change in EU safety regulation of pharmaceuticals, generated by the implementation of the Falsified Medicines Directive (Directive 2011/62/EU). The purpose of the reform was to eliminate counterfeit medicine from the European market, in order to avoid health risks for consumers receiving falsified medication. The reform took effect in February of 2019 and immediately following this, a rapid and unprecedented rise in average prices of generic pharmaceuticals began. Figure 1 shows a very unpolished first look at the publicly available price data. The reform also likely affected availability of products, with supply shortages being a recurring topic in the media throughout 2019. In this project, we propose to empirically estimate the effect of the reform on firm exit rates, pharmaceutical prices, and consumption of pharmaceuticals. Thus, we will provide policy makers with estimates of the costs of the safety regulation.

Motivation: Pharmaceutical markets are often characterized by relatively weak competition between only a few firms with significant market power. An often cited reason is the high cost of entering the market with a product due to stringent regulatory requirements, which are in place to ensure the safety of medicine to consumers. However, the costs of burdensome regulation may come indirectly through firm exit weakening competition and resulting in higher prices, or even increased prevalence of stockouts. The indirect nature of the costs make them extremely hard to assess ex ante with the obvious risk of policy makers overemphasizing the very salient health benefits of safety and ignoring the indirect costs. We aim to remedy this, providing estimates of the cost of the EU regulation in terms of pharmaceutical prices, consumption, and supply shortages. These insights furthermore come at an opportune moment where the Danish market design for generic pharmaceuticals is under close scrutiny. In earlier work, Hauschultz and Munk-Nielsen (2017; 2019; also funded by EPRN) uncovered large recurring price cycles in the markets. This has lead policy makers to demand changes to the system. The insights derived from this project will be an invaluable input into this debate. From a research perspective, we contribute to measuring the effect of market structure on the price equilibrium in a procurement auction. The unique

transparency and large number of markets in Denmark it an ideal setting for this type of study.

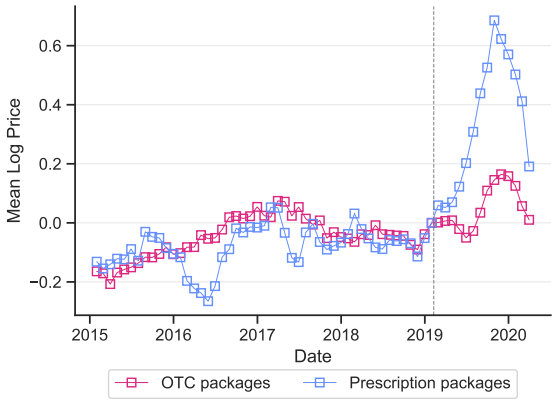
The reform: The reform is a an implementation of a EU directive, and thus directly affects pharmaceutical markets serving a population of 445 million EU residents. The directive was motivated by an increase in detected counterfeit medicinal products across the EU and introduced as solution an electronic tracking system, which would add an additional layer of safety by requiring that each individual package be tracked in a central EU repository.

Figure 1: Generic drug transaction prices



Note: The graph is constructed using publicly available revenue and sales data from esundhed.dk for generic products where the patent expired before 2015. The vertical line marks the reform.

Figure 2: Prescription and OTC prices



Note: The plot compares the price development for the subset of off-patent drugs which are sold both OTC (typically for small, low-dose packages) and on prescription (for stronger- and larger packages).

Empirical strategy: Our primary empirical strategy is a simple before-and-after evaluation of the reform in 2019 using the full market data (Figure 1). We plan to supplement this wiht a Difference-in-Difference (DiD) analysis using the fact that over-the-counter (OTC) medicine was not affected by the reform. Figure 2 shows a very preliminary and simple example of this with simple raw averages for both groups. Additionally, there is the possibility of using veterinary medicine or markets outside the EU such as the US as comparison groups. A large part of the analysis will be determining what constitues a good comparison group. The goal is to study the changes following the reform in the number of active firms per market, firm revenue, and pharmaceutical consumption of individuals using register data. Furthermore, we have data on supply shortages, which is another outcome of interest.

Having documented the effects of the reform, we want to dive furhter into the firm-level responses to safety regulation. For example, if compliance with the regulation takes the form of a fixed cost investment – e.g. in IT infrastructure – then exit decisions may be

at the firm rather than merely product-level. This question has important rammifications for competition policy, but requires precise historical data on firm ownership structures and accounting data. Such data is available publicly e.g. from annual repots but very time-consuming to collect into a useful form for empirical work, which is why we require extra research assistance.

Literature: We relate to a literature on pharmaceutical prices. Most closely related, Kaiser et al. [2014] evaluated a Danish reform of the reimbursement system in 2005, which improved competition in the markets for statins and resulting in lower prices. That reform affected demand through the reimbursement system while our reform affects firm costs. Other related work has explored how pharmaceutical prices are affected by the doctor's prescription decision [Hauschultz and Munk-Nielsen, 2020], consumer switching costs [Janssen, 2019, Ericson, 2014, Ho et al., 2017], trade barriers [Ganapati and McKibbin, 2019], and insurance contract design [Duggan and Scott Morton, 2011]. We have previously documented the presence of so-called "price-cycles" in the Danish markets [Hauschultz and Munk-Nielsen, 2017, 2020, Janssen, 2018]. This project will contribute to a strand of literature that emphasizes the role of competition [Berndt et al., 2017].

Timeline: The reform affects all pharmaceutical markets in the EU, so the risk that other researchers start working on the same idea is real. Therefore, our planned timeline is:

2020: Purchase data immediately, and hire research assistant to start collecting data on the ownership structures of all pharmaceutical companies in Europe. **2021:** Primary analysis done in the spring, working paper ready for circulation and presentation by summer. **2022:** Purchase updated data to have more time post-reform for the analysis. Revise analysis and draft based on comments received. Submission late 2022. **2023:** Revisions. We cautiuosly hope for publication ultimo 2023.

Publication: We aim to publish in a top field journal in health economics, IO or public economics, like the Journal of Health Economics, Journal of Industrial Economics, or the Journal of Public Economics.

Budget: We require funding for data in the form of the most recent pharmaceutical and demograhic data (*lægemiddelstatistikregistret*). We need to buy the data immediately, but we want to update the data after the first round of presentations to have more data post-reform. Additionally, we require detailed data on pharmaceutical companies, including entry, exit, mergers, and ownership structure. The data for this is publicly available but time-consuming to collect, which is why we require more research assistance than usual.

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