Reference Pricing and Access to Pharmaceuticals: A Structural Approach

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Research Question

Innovation policy can affect the welfare impact of innovation in two ways. It can increase incentives to invest in R&D, or it can promote the diffusion of already available innovative products. In the pharmaceutical market, considerable attention is devoted to policies that increase incentives to invest in R&D. However, a considerable body of evidence has highlighted an "access gap" for innovative drugs across countries, which is imputable to both bureaucratic delays as well as strategic behavior of pharmaceutical companies in response to various government policies (Cockburn et al., 2016). Of these two components, the latter one poses an important economic problem: can we understand the incentives motivating launch strategies, and, if so, can we propose policy changes to accelerate the diffusion of innovative drugs?

In this project I propose to study how external reference pricing (ERP) affect strategic launch delays. ERP is a widely used policy that governments use to impose price ceilings based on prices charged in other countries. This practice does not only erode profit margins, but, crucially, also limits a firm's ability to price-discriminate across different national markets, which in turn can reduce the incentive to introduce a new drug and generate launch delays. This effect is best understood as an externality imposed by high-income countries on the low-income countries that they reference. For example, if the Italian governments imposes a price cap that is affected by the Polish price a low price in Poland could decrease a firm's profits in Italy. As a result of this externality, manufacturers might try to bargain for a higher price in Poland, or possibly even delay entry to avoid a costly reference. In either case, Italy imposes an externality on Poland, and as a result Poland will either have to accept a higher price or be denied access to a potentially valuable drug for a number of years.

Empirical Strategy

I plan to analyze the impact of these policies on launch delays by building a structural model of entry that incorporates spillover effects from reference pricing. I then estimate the model using data from IMS Health on sales of pharmaceutical products between 2002 and 2012 in countries

that participate in the European Economic Area (EEA).[1] In the model, firms maximize profits over the life cycle of the drug by choosing which countries to enter and when. Firms might optimally decide to initially launch in a more restricted set of high-income countries in order to secure a greater price. Strategic delays will then occurr as firms expand the original launch set when products approach loss of exclusivity, or when new competitors enter and reduce market shares in high-income countries (thus decreasing the magnitude of the ERP externality).

The empirical strategy I propose has several advantages. First, by recovering model primitives, the structural approach allows me to perform counterfactual analysis and examine welfare under a host of alternative pricing policies, such as centralized pricing, or a more limited reference pricing regime (as suggested, among others, by Towse et al., 2015). This is important because even though reduced-form evidence has already established a correlation between stricter price regulation and longer delays (Danzon et al., 2005; Kyle, 2007), I will be able to to quantify it, both in terms of years of delay, as well as using a money metric derived from demand estimates. Second, because EEA members have relatively homogeneous patent laws, I can separate the impact of pricing regulation from that of patent regulation. Third, my model specifically allows for bureaucratic delays, which would otherwise be unobservable in the data. Thus, I can isolate the impact of strategic delays due to reference pricing, from that of other factors such as the time required to process the application, or to run additional Health Technology Assessments, which many countries in Europe require.

References

Cockburn, Iain M., Jean O. Lanjouw, and Mark Schankerman, "Patents and the global diffusion of new drugs," *American Economic Review*, 2016, *106* (1), 136–164.

Danzon, Patricia M., Y. Richard Wang, and Liang Wang, "The impact of price regulation on the launch delay of new drugs - Evidence from twenty-five major markets in the 1990s," *Health Economics*, 2005, *14* (September 2004), 269–292.

Kyle, Margaret K., "Pharmaceutical Price Controls and Entry Strategies," *Review of Economics and Statistics*, 2007, *89* (February), 88–99.

Towse, Adrian, Michele Pistollato, Jorge Mestre-Ferrandiz, Zeba Khan, Satyin Kaura, and Louis Garrison, "European Union Pharmaceutical Markets: A Case for Differential Pricing?," *International Journal of the Economics of Business*, 2015, *22* (2), 263–275.

[1] The EEA includes all EU countries as well as members of the European Free Trade Area (currently Iceland, , Lichtenstein, Norway, and Switzerland). The data is available through Fabio Pammolli at IMT Lucca in Italy, who is a coauthor on the project.

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Reference Pricing and Drug Launches in the EU: A Structural Approach (with Fabio Pammolli and Armando Rungi)

Prescription Drug Spending in the US: Is the Era of Slow Growth Over? (with Murray Aitken, Ernie Berndt, David Cutler, and Michael Kleinrock)

The Impact of Health Coaching on Compliance with Prescription Drugs (with Jason Block)