Reference Pricing as a Deterrent to Entry

Evidence from the European Pharmaceutical Market

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Price regulation can affect access to drugs

Drug prices are strictly regulated in most countries

- US: prices are benchmarked to private market
- UK: prices tied to therapeutic value
- EU: gov't negotiates using external reference pricing (ERP)
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- Linking prices across countries limits price-discrimination
- Firm may respond by delaying entry in low-income countries

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How does ERP affect access to newly approved drugs?

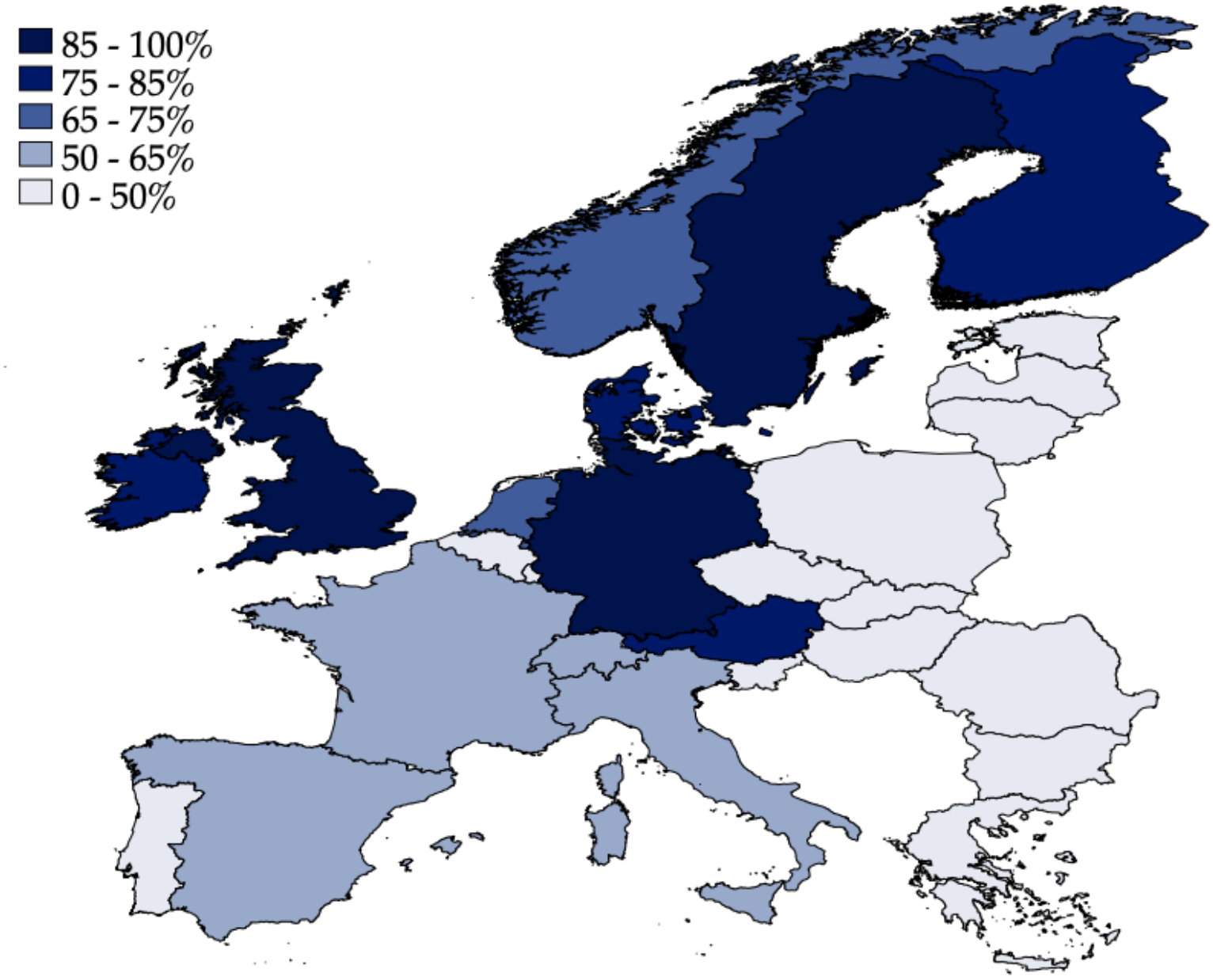
This paper quantifies the impact of ERP in Europe

Overview of today's presentation

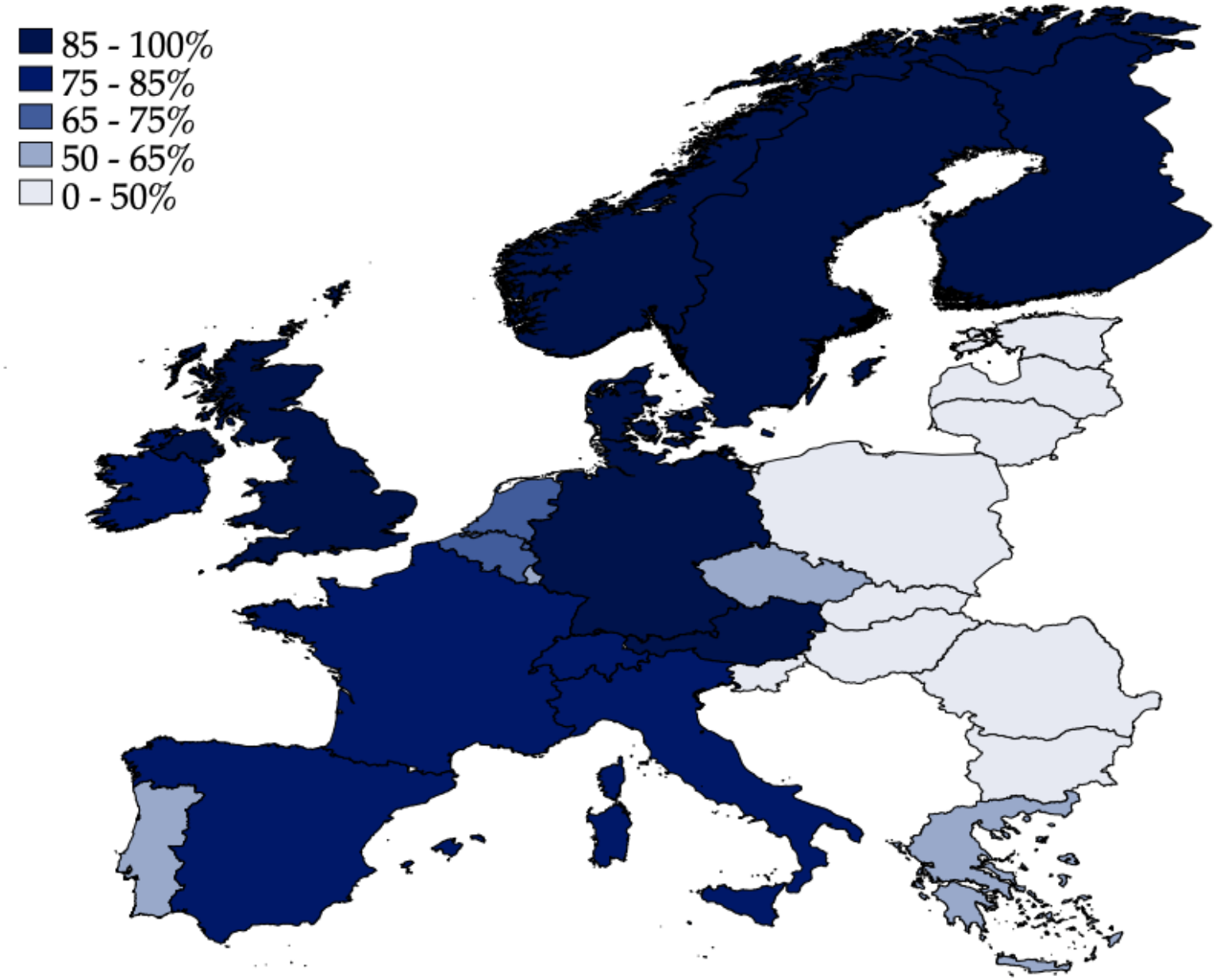
1. Launch delays in Europe: what models (don't) justify them?
2. ERP as a deterrent to entry: theory
3. Estimation of the impact of ERP in three parts:
   - Do countries actually follow ERP guidelines?
   - Are firms better off with delays?
   - How much would delays fall if ERP were removed?

Launch delays in Europe: what models (don’t) justify them?

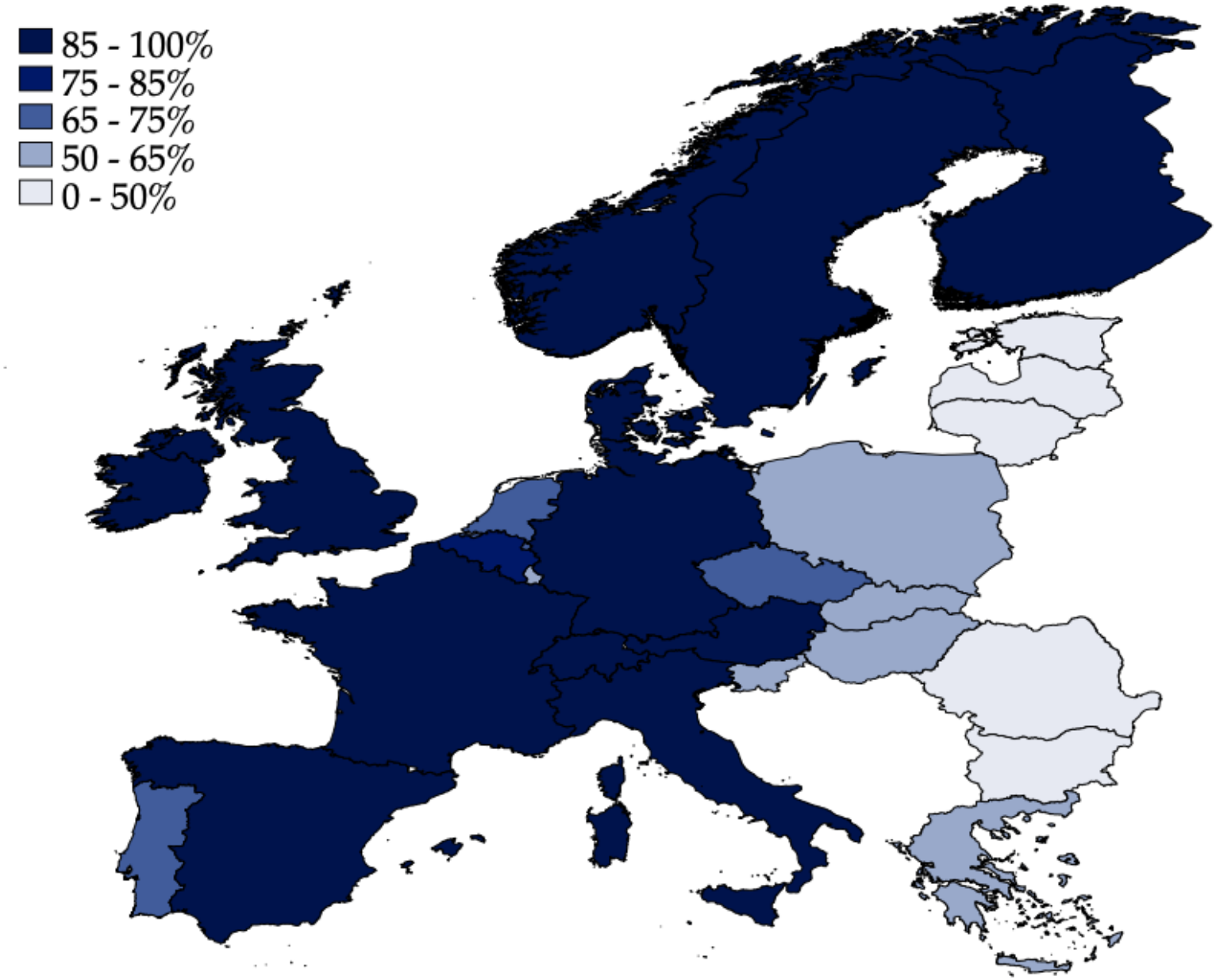
Drug diffusion across Europe: 1 year after approval



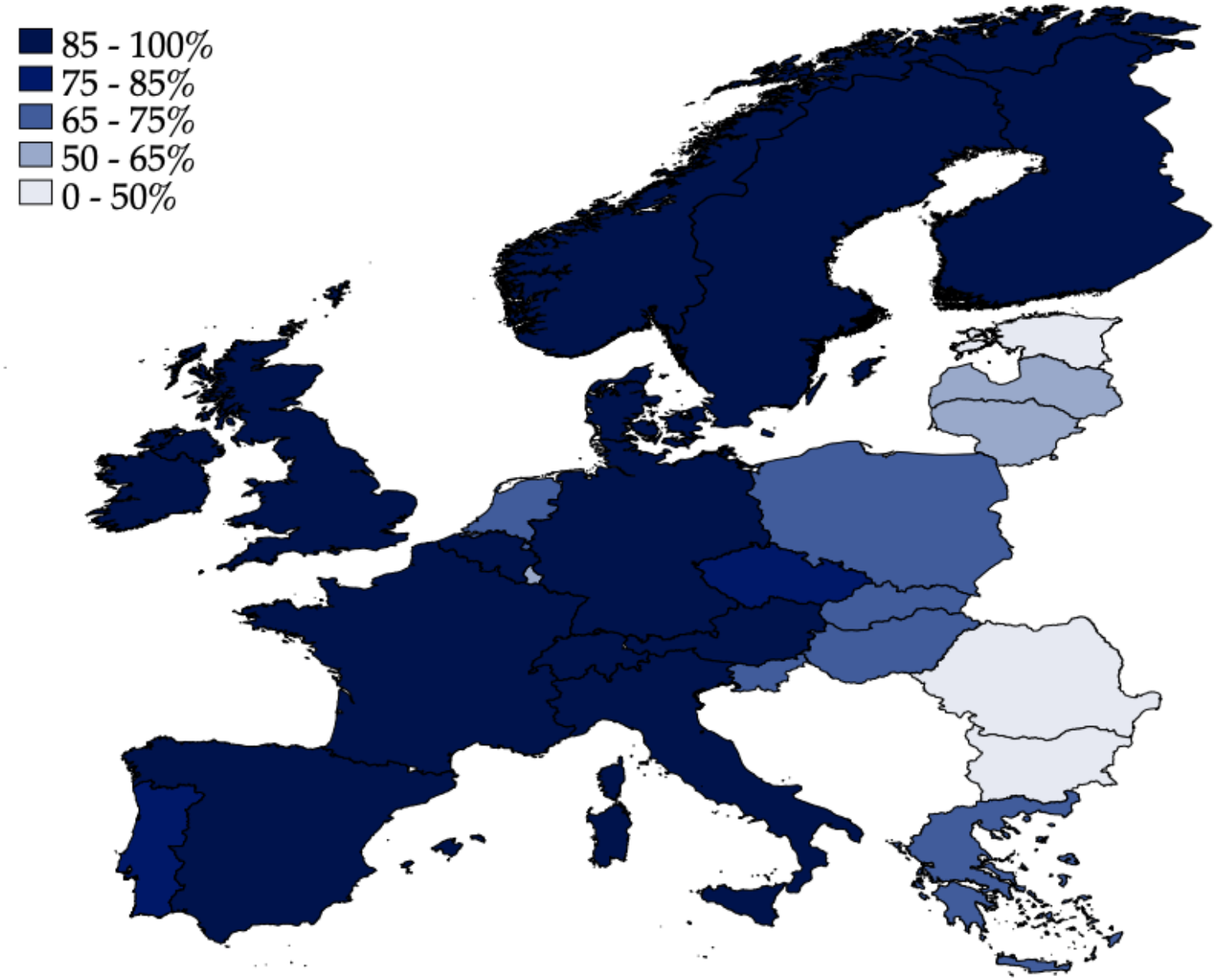
Drug diffusion across Europe: 2 years after approval



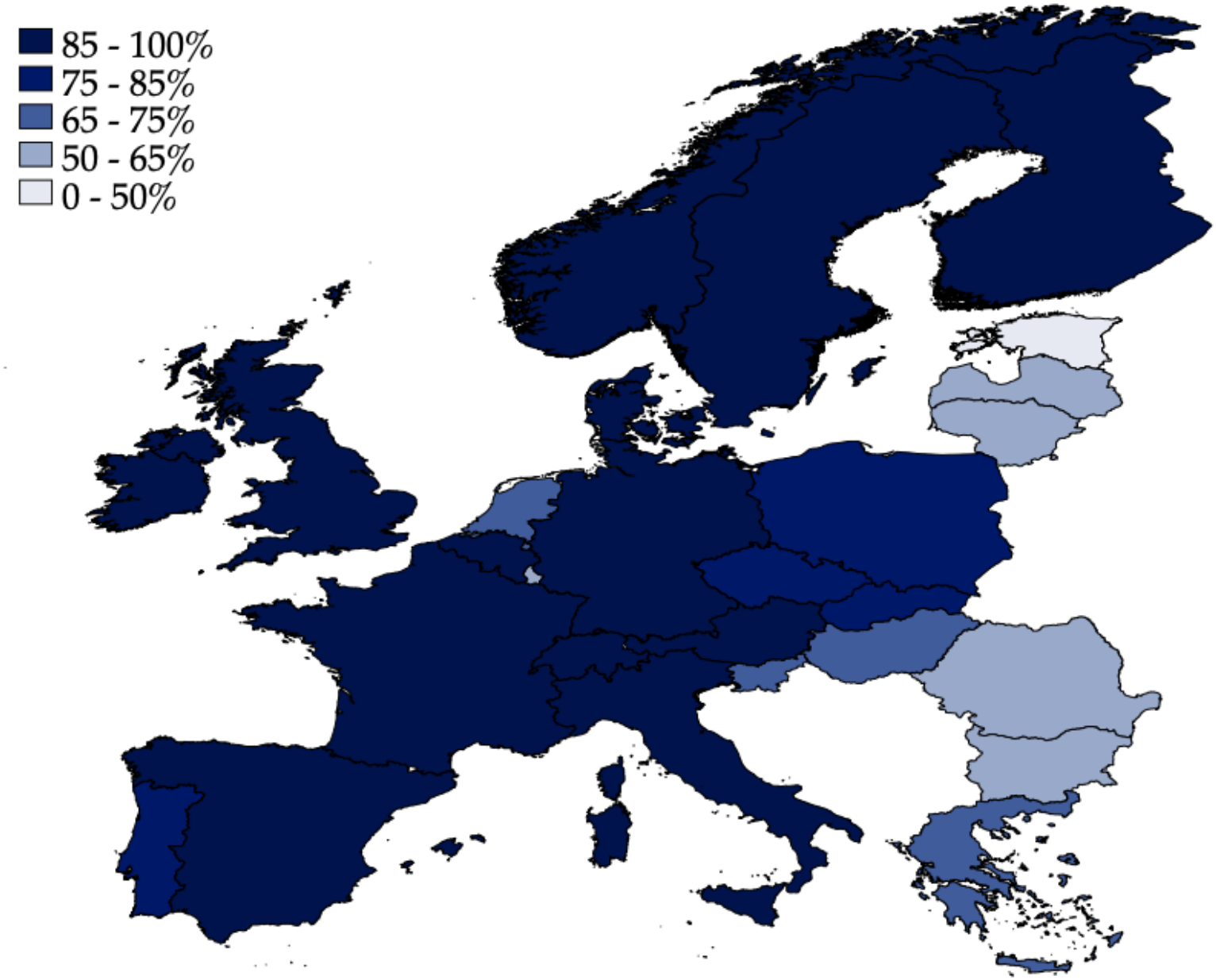
Drug diffusion across Europe: 3 years after approval



Drug diffusion across Europe: 4 years after approval



Drug diffusion across Europe: 5 years after approval



Many models predict delays...

1. Limited number of entry applications at the same time

2. Fixed costs of entry

3. Capacity constraints

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...but data patterns don't quite fit any of them

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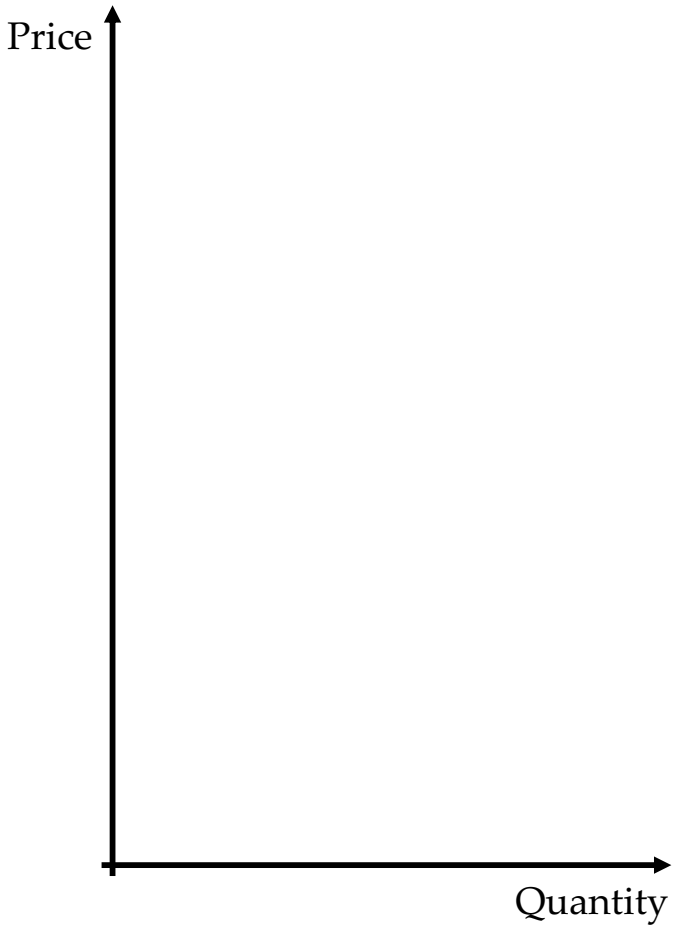
   - ~~No more entry once firm hits full capacity~~
   - > 10% of launches occur after the firm has reached peak output

ERP as a deterrent to entry: theory

ERP generates delays by limiting price discrimination

Toy model: 1 firm, 2 countries, 2 periods



At the end of each period countries adjust prices to match minimum available price.

Period 1: price p_j
quantity q_j

Period 2: price $\min_{k \in (1,2)} (p_k)$
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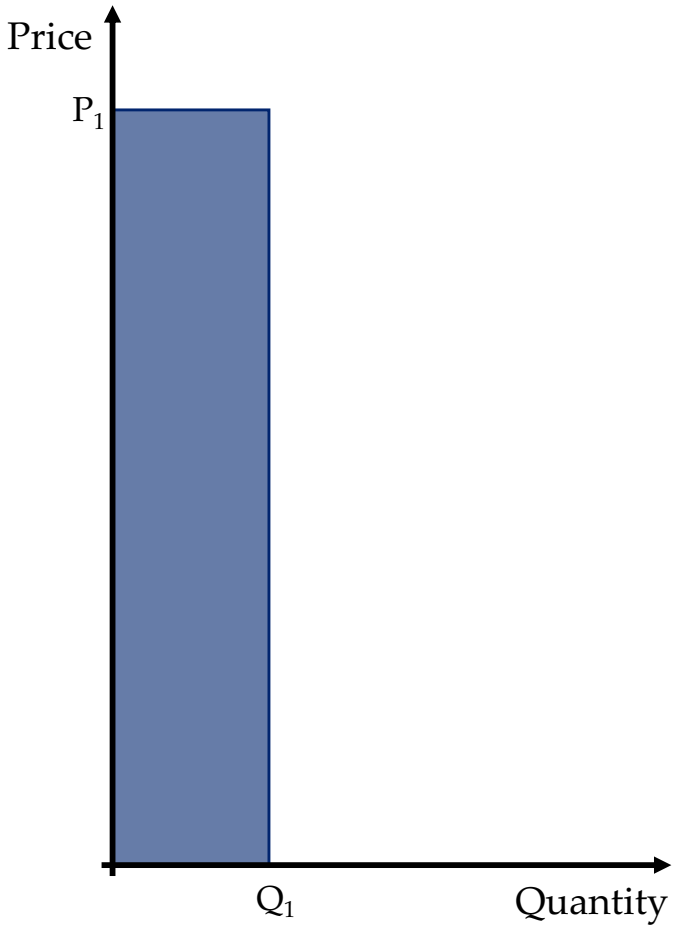

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Two possible strategies:

1. Wait until period 2 to launch in country 2

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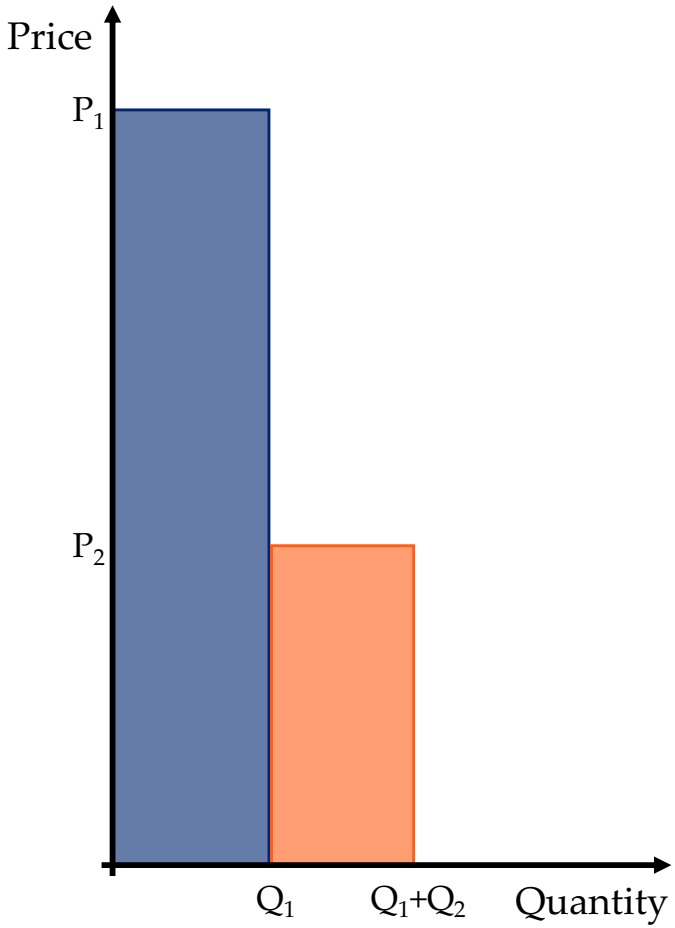

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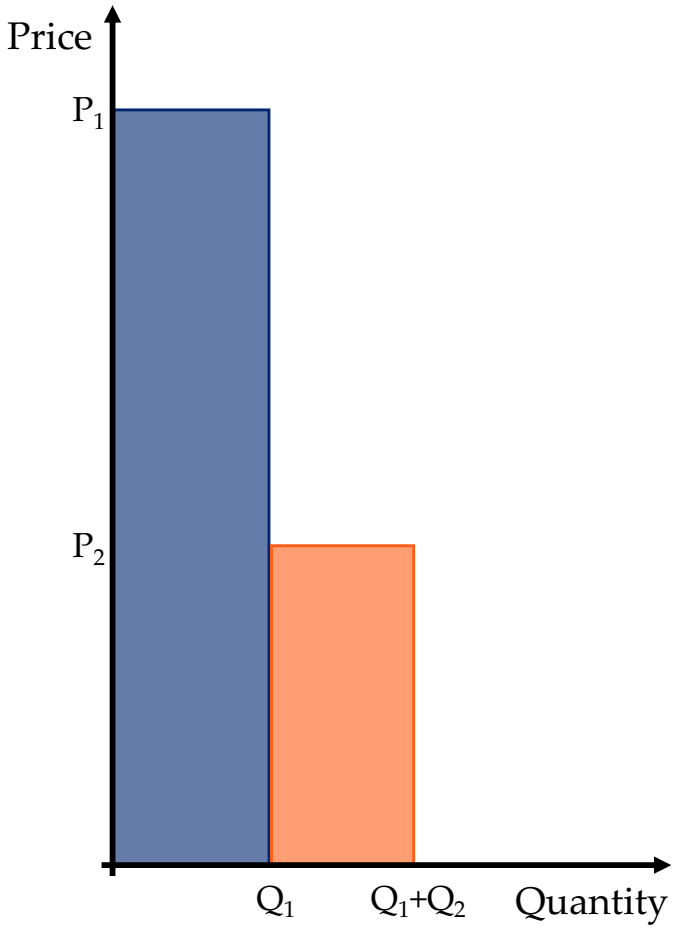

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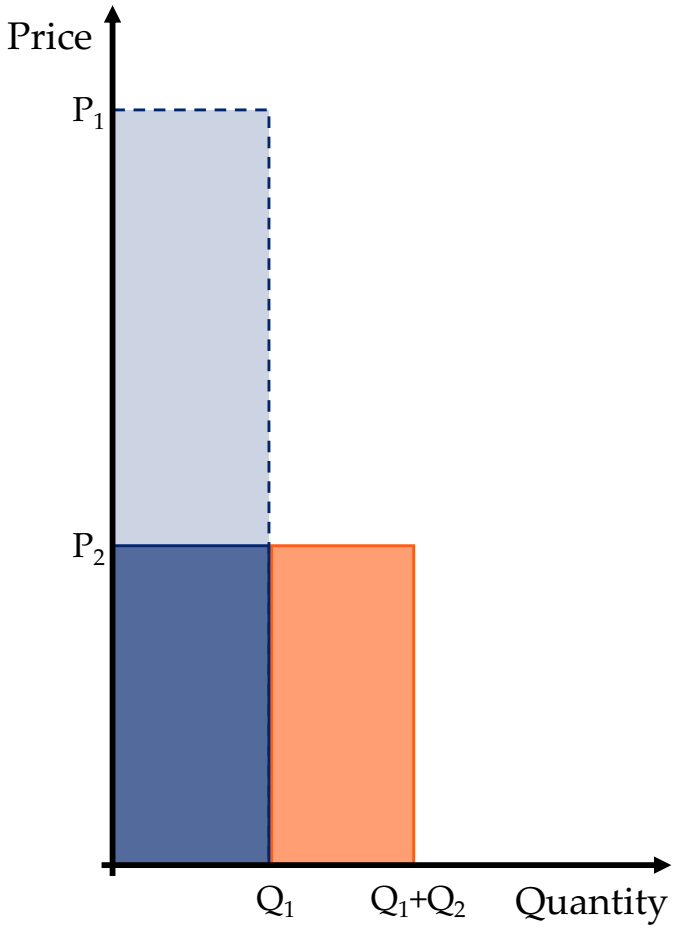

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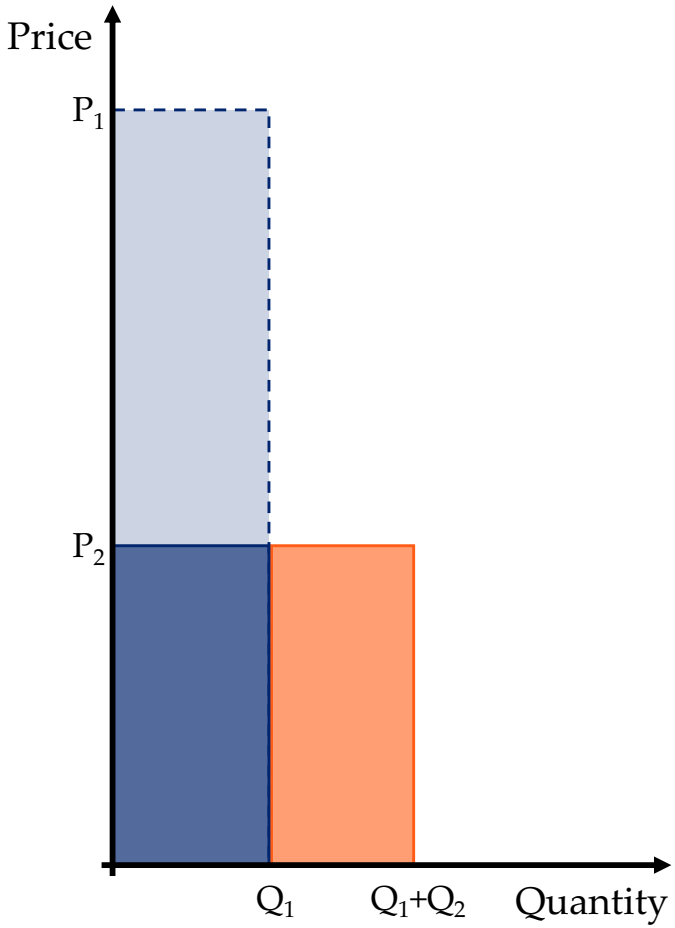

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quantities (q_1, q_2)

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quantities (q_1, q_2)

Optimal solution: delay if

$$(p_1 - p_2) \times q_1 > p_2 \times q_2$$

We estimate an extended version of this toy model

Model components

1. Demand
   - Data: **quantity** sold for each drug i, year t, country j
   - Goal: **predict quantity** in years prior to entry

2. Price
   - Data**:** average yearly drug **prices**, **reference pricing functions**
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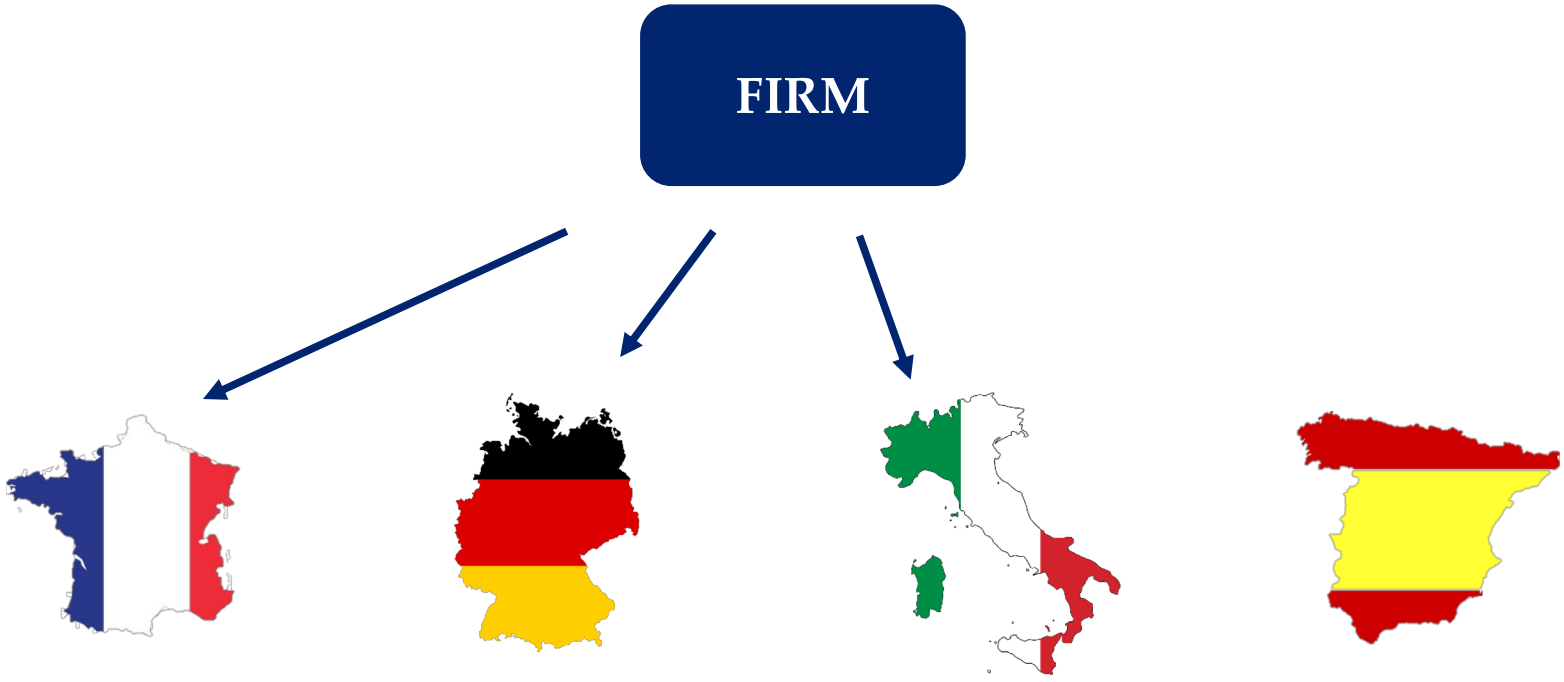
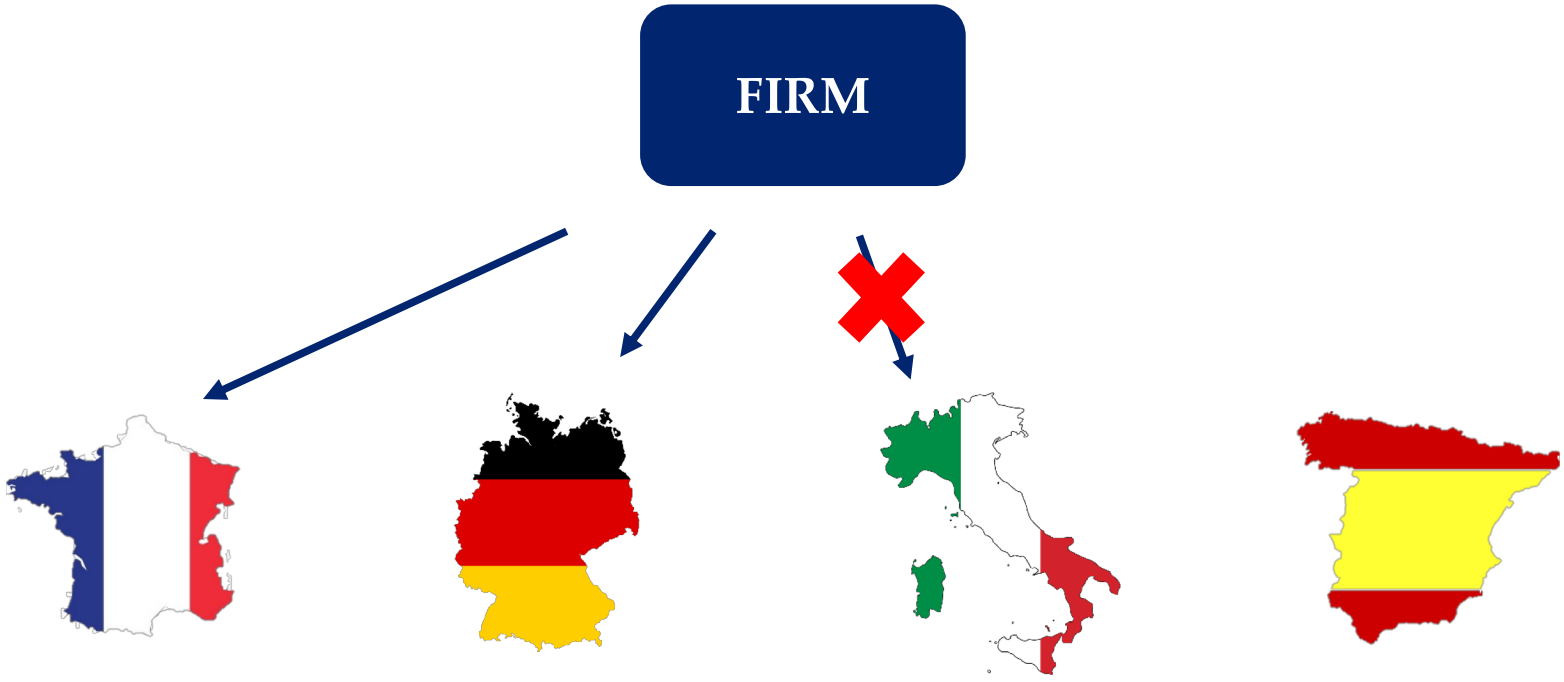
3. Firm **dynamic** entry decision model
   - Firms apply for entry, but may experience **stochastic** delays
   - Goal: link 1. & 2. to compute revenue of any entry sequence

Stage I: Firm choose where to send entry applications



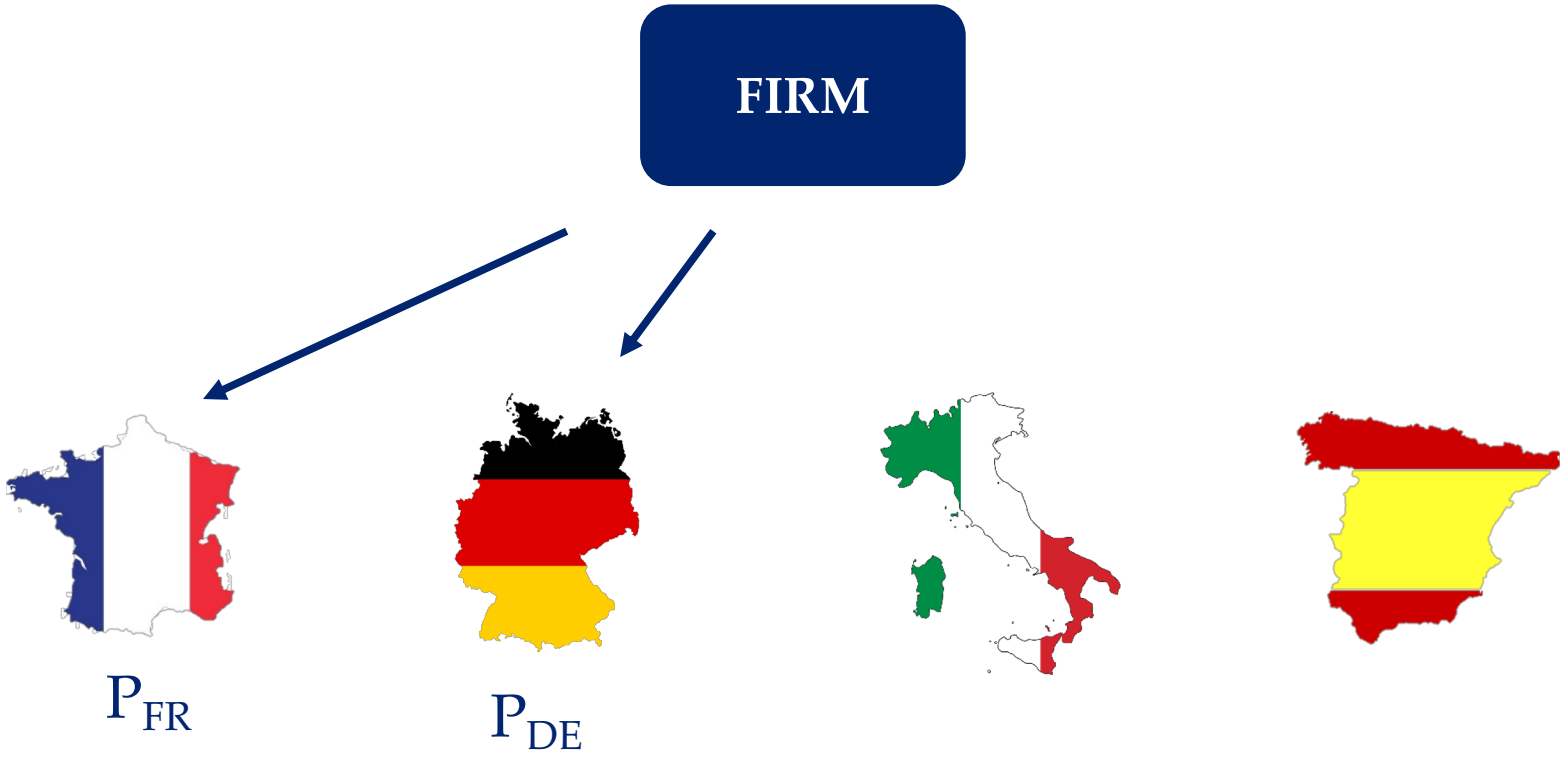
Strategic delays:
firm only sends applications to some countries

Stage II: delay shocks are realized

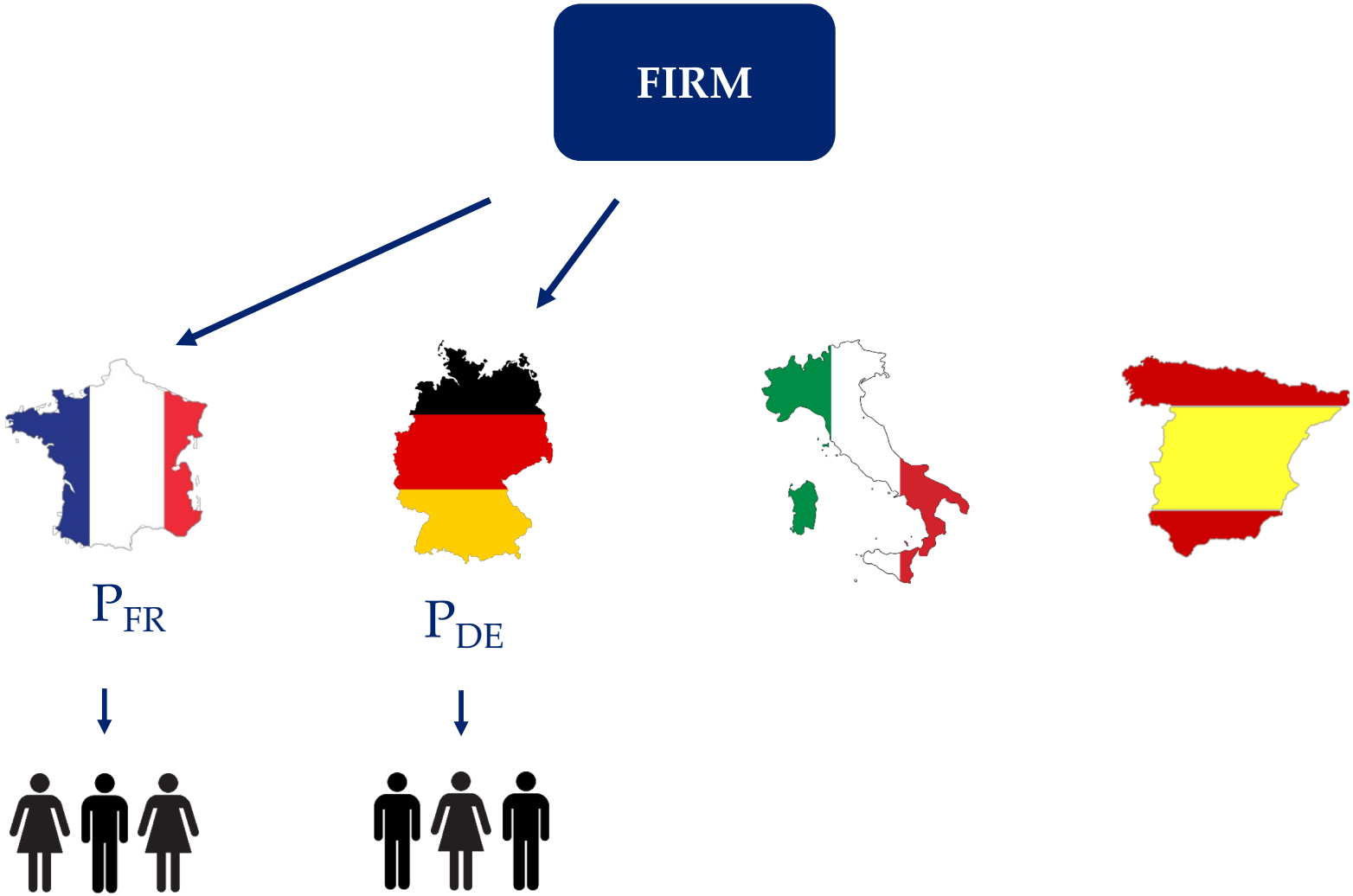


Idiosyncratic delays:
some applications are randomly delayed

Stage III: prices are set



Stage IV: products are sold and profits realized



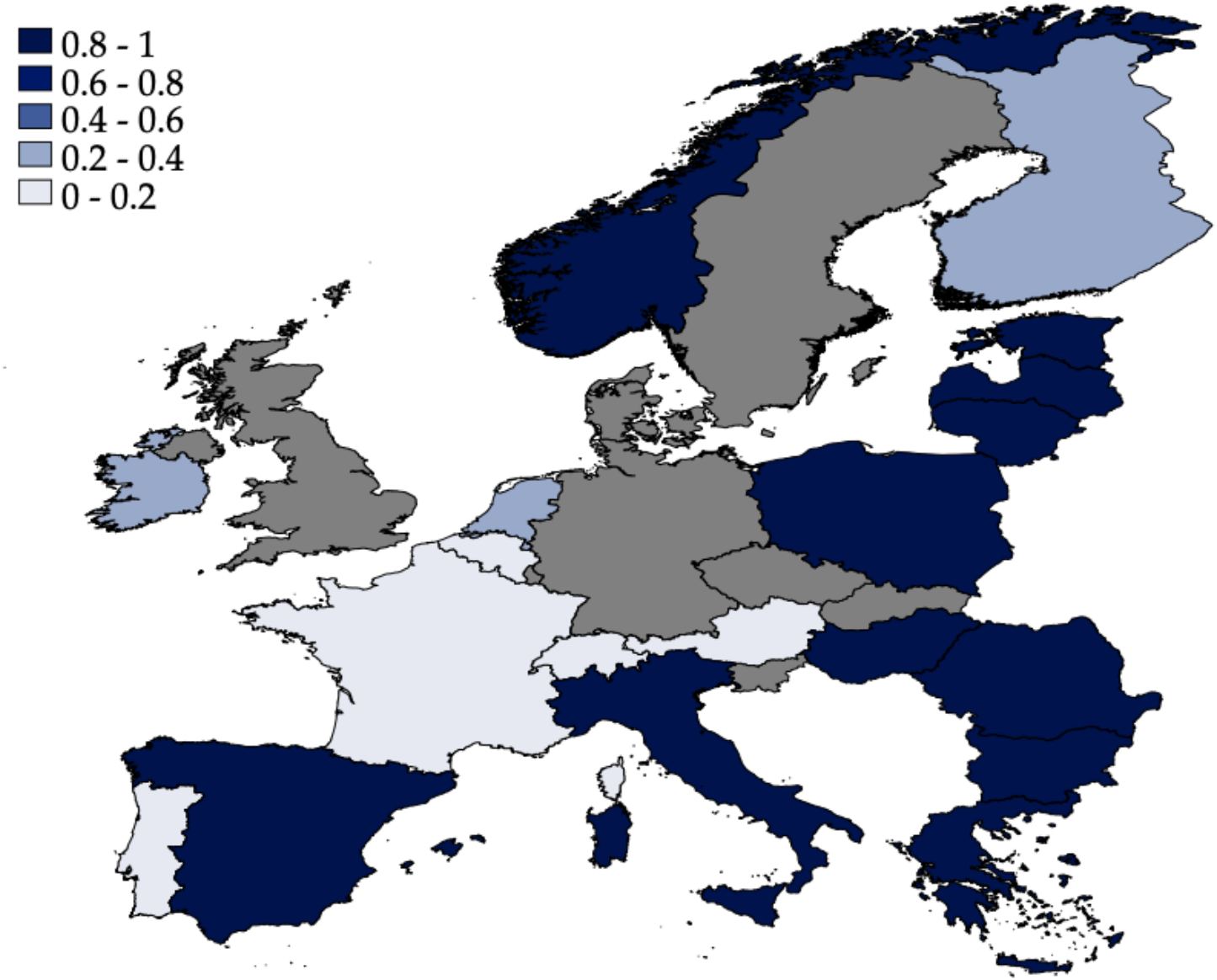
Estimation of the impact of ERP in three parts

What we need to estimate

1. Do countries actually follow ERP guidelines?
   - μ_j needs to be close to 1 for at least some countries

Do countries actually follow ERP guidelines?

Estimates of μ_j



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1. Do countries actually follow ERP guidelines?
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   - **Spain and Italy follow ERP, their prices are affected by EU10**

2. Are firms better off with delays?
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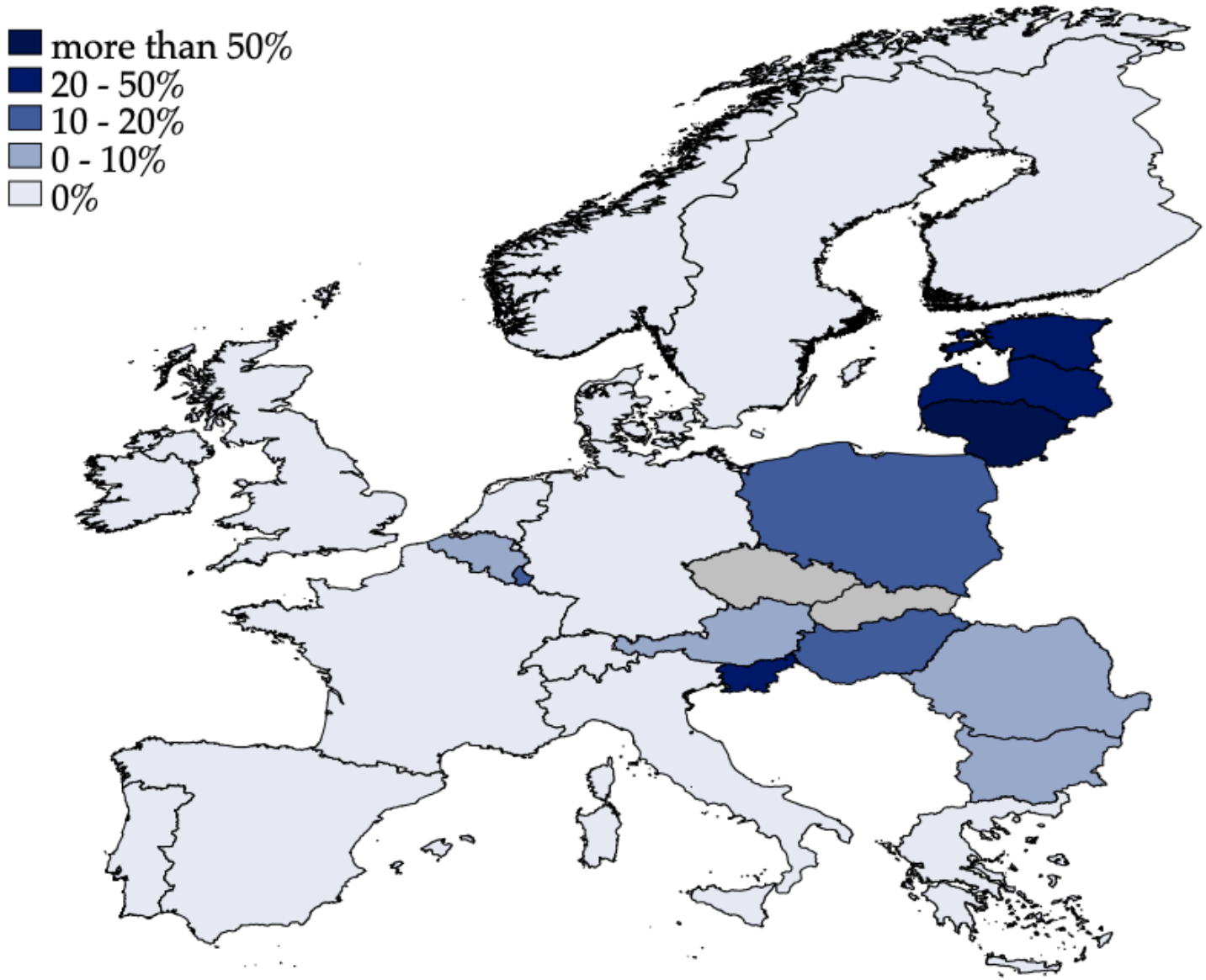
Are firms better off with delays?

% of drugs for which delaying entry in country X only is optimal



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3. How much would delays fall if ERP were removed?
   - If we get rid of ERP, there should be faster entry

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Empirical problem: find ψ_j (prob. of random delay in country j)

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- Lower bound:
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  - Find these strategies $\rightarrow$ reject low values of ψ_j
- Upper bound:
  - Worst case scenario: all delays are idiosyncratic

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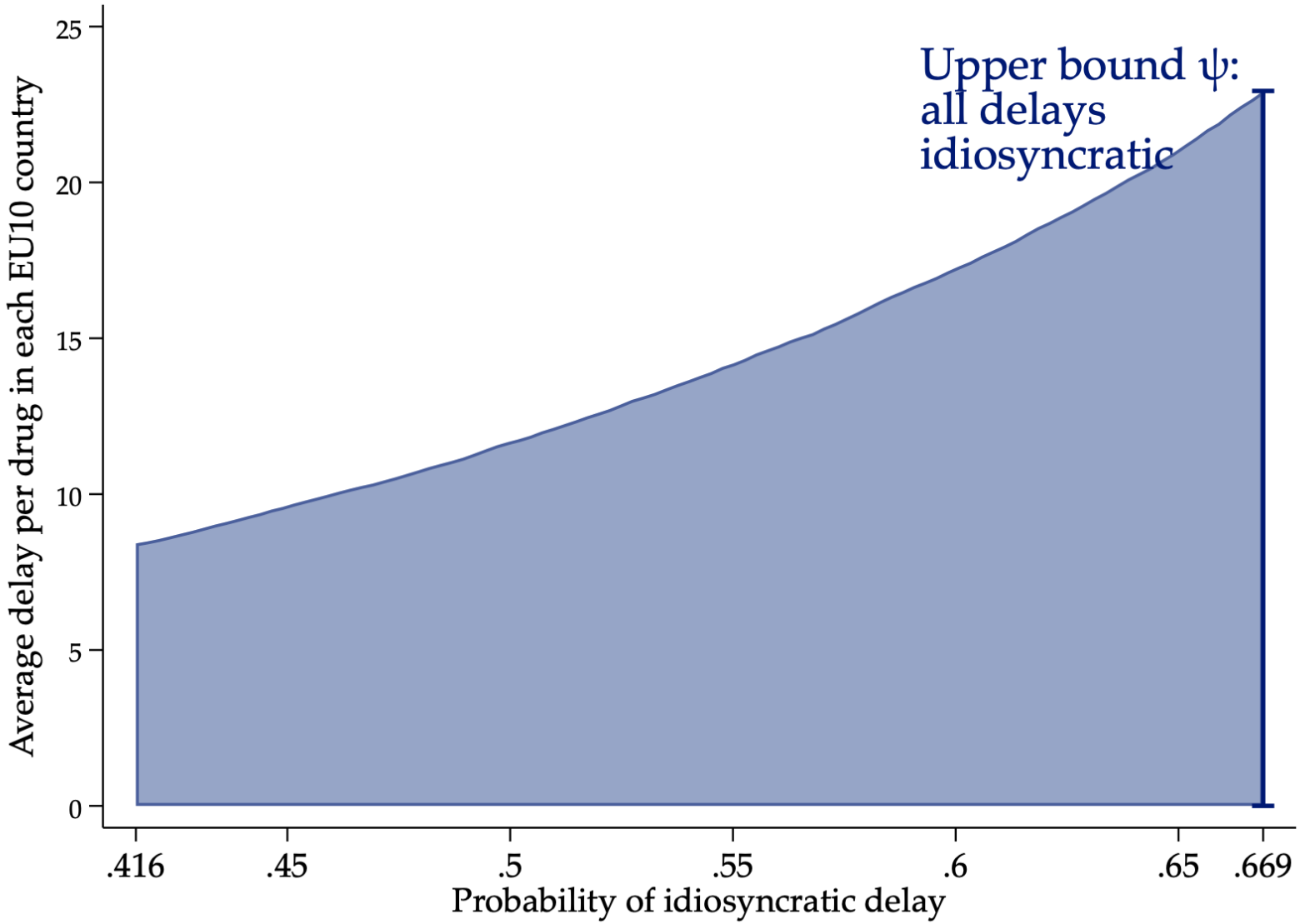
Output:

- Western Europe: assume away strategic delays
- Eastern Europe: estimate interval $\psi_{\mathbf{EU10}} \in [\mathbf{0.416}, \mathbf{0.669}]$

How much would delays fall if ERP were removed?

Simulated delays w/out ERP: only idiosyncratic delays remain



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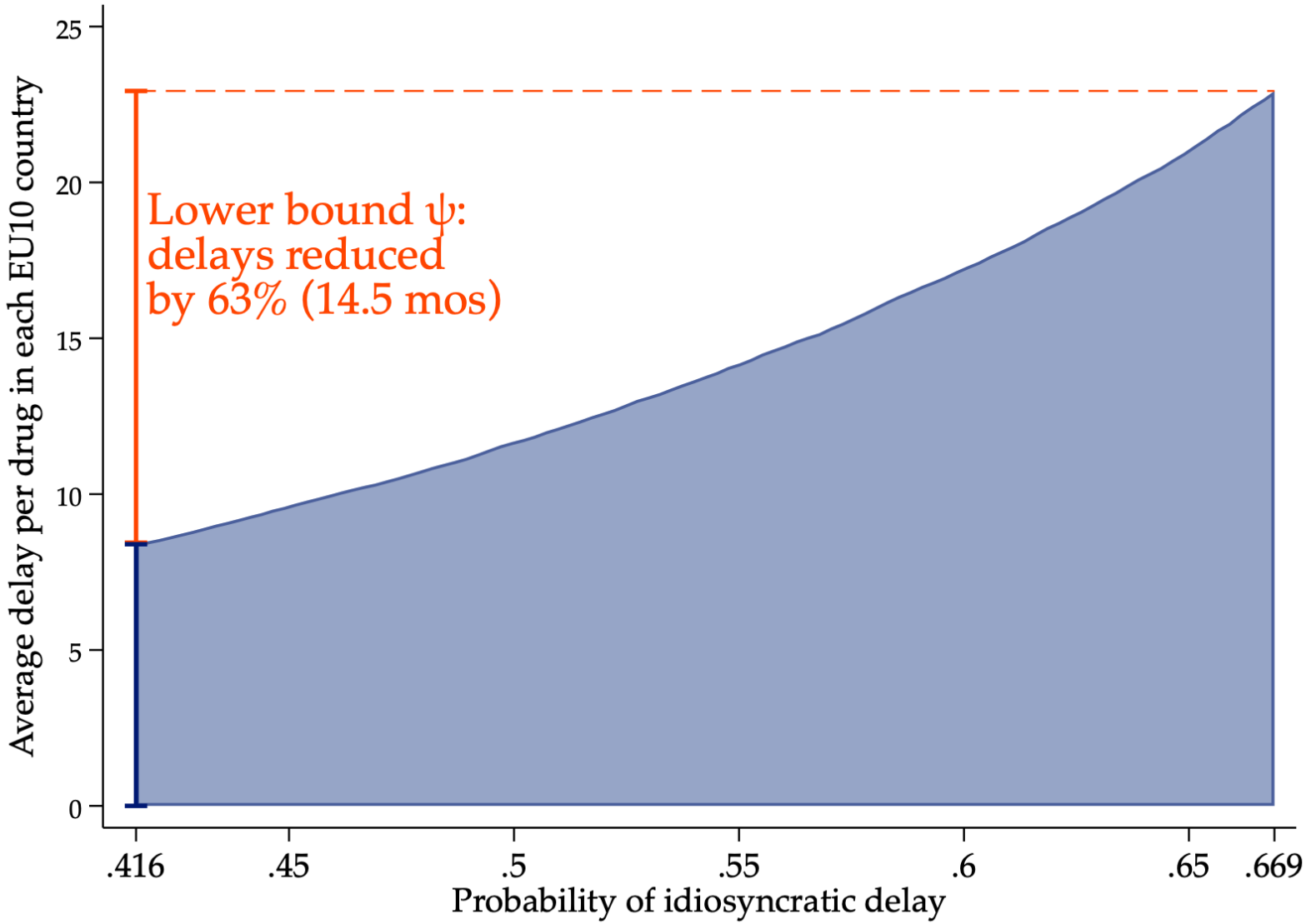

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   - **Up to 14.5 months earlier entry in EU10**

Conclusion: the bigger picture

Main takeaway:

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General implication: price-linked regulation causes spillovers

- Medicare/Medicaid reimbursement rules affect private prices
- Medicare Part B reform would introduce ERP to US
  - US prices are well above highest prices in Europe
  - US market is roughly 3x size of entire EU market

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What we still don't know

- W/out ERP would prices rise in West. EU or fall in East. EU?
- Would ERP reduce US prices, or raise foreign prices?

thank you