Let’s talk early access schemes & share your experience?

Impact on access for 50 medicines in 5 UE countries *- England, France, Germany, Italy, Spain*

PPRI network meeting 9th April – « hot potatoes » session

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LET'S TALK EARLY ACCESS SCHEMES (EAS)

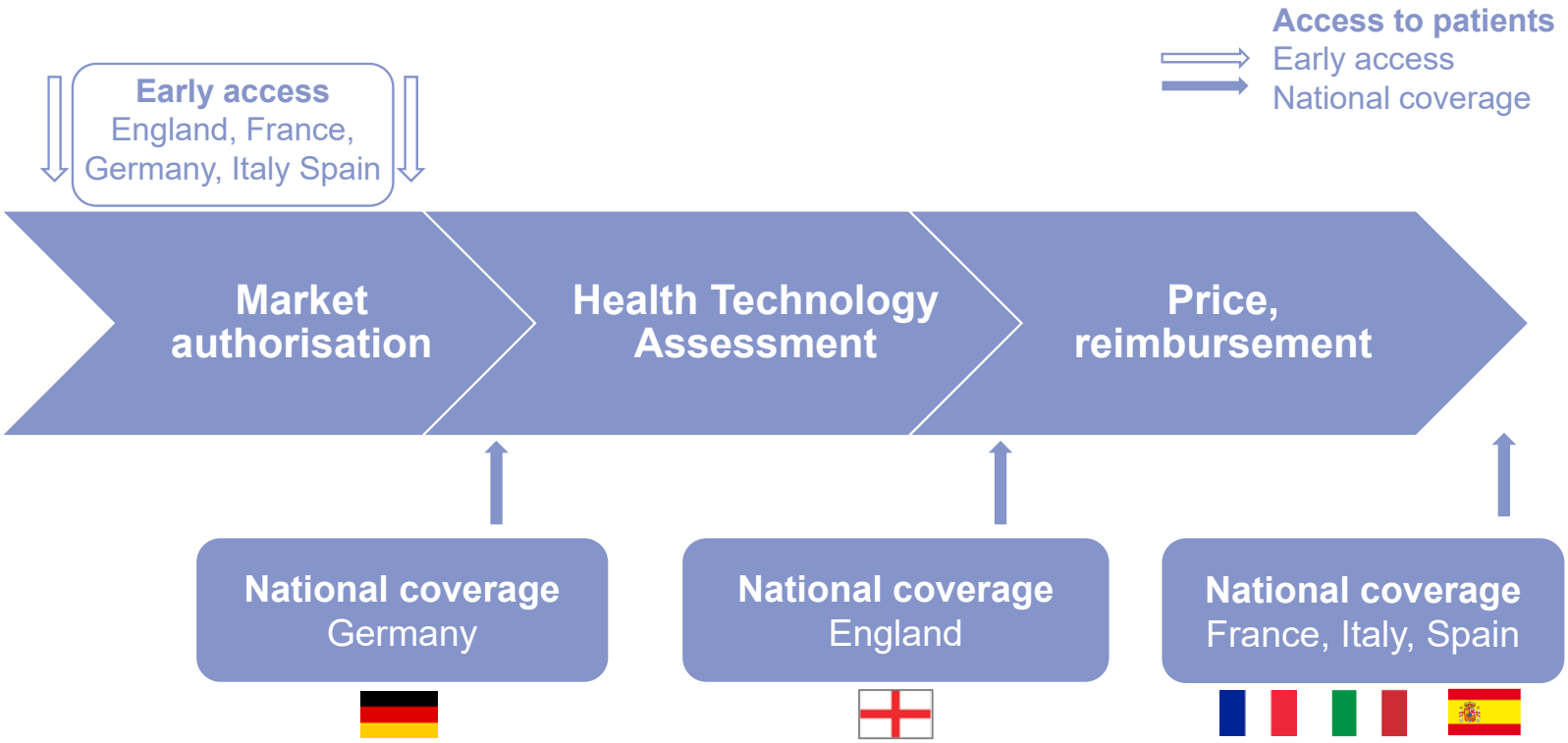
- **Impact on access times in 5 countries : 2024 monitor - 50 medicines**
  - ✓ Focus on **medicines with medical improvement and address medical need** (HAS rating)
  - ✓ **8 -11% of pharmaceutical market across the 5 countries** (reimbursed at manufacturer prices excl. VAT)

- **Early access in France – key figures**

- **What about early access in your countries?**

2024 MONITOR

P&R TIMELINES : COMMON LAW VS EARLY ACCESS IN 5 EU COUNTRIES



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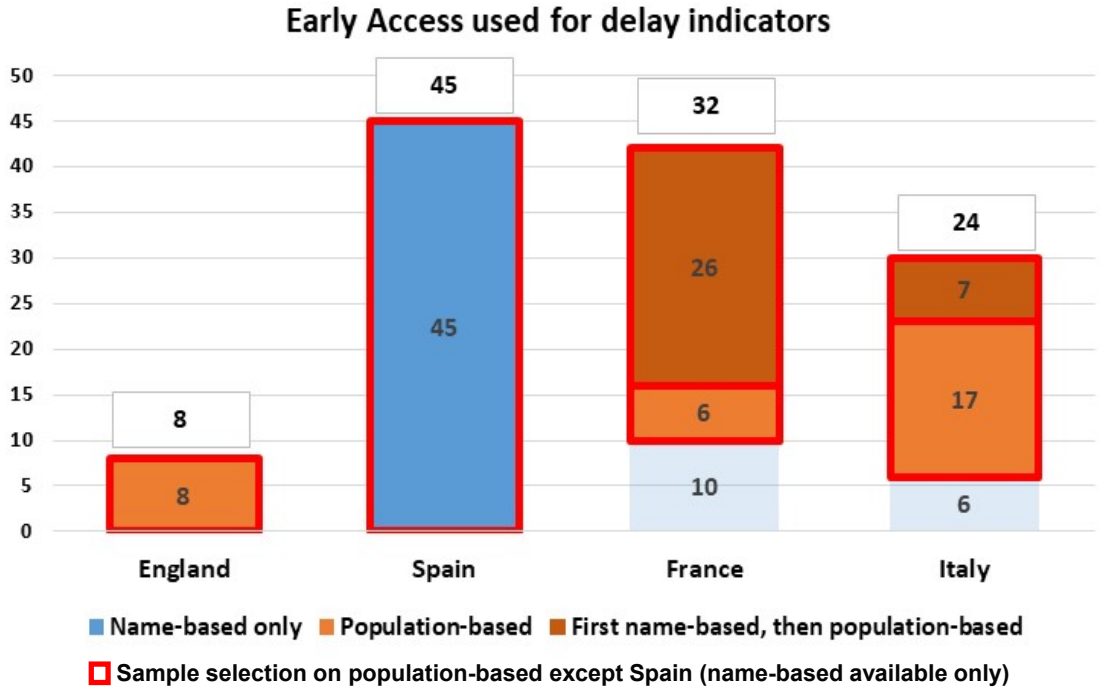
FRANCE & SPAIN WITH HIGHEST NUMBER OF PRODUCTS WITH EAS

➢ **Population-based EAS prioritized** over **named-based** ones when applicable (except Spain)



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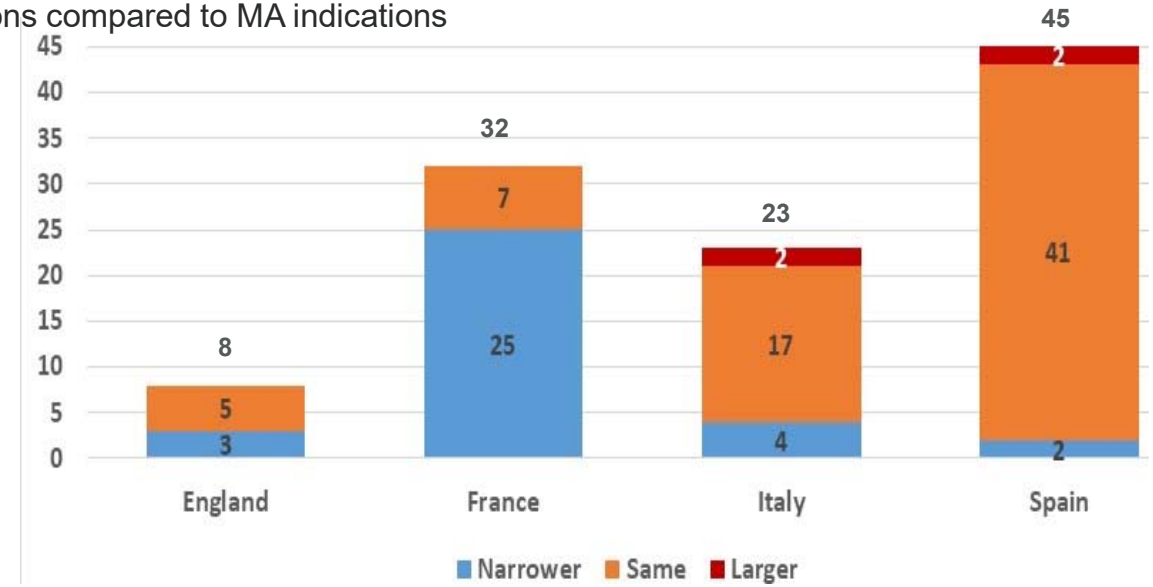
MOSTLY THE MA INDICATION SCOPE, NARROWER IN FRANCE BY DESIGN

Number of medicines granted early access
indications compared to MA indications



➢ **EAS are considered regardless of their funding** (public or pharma-sponsored), as it is neutral from a patient's perspective

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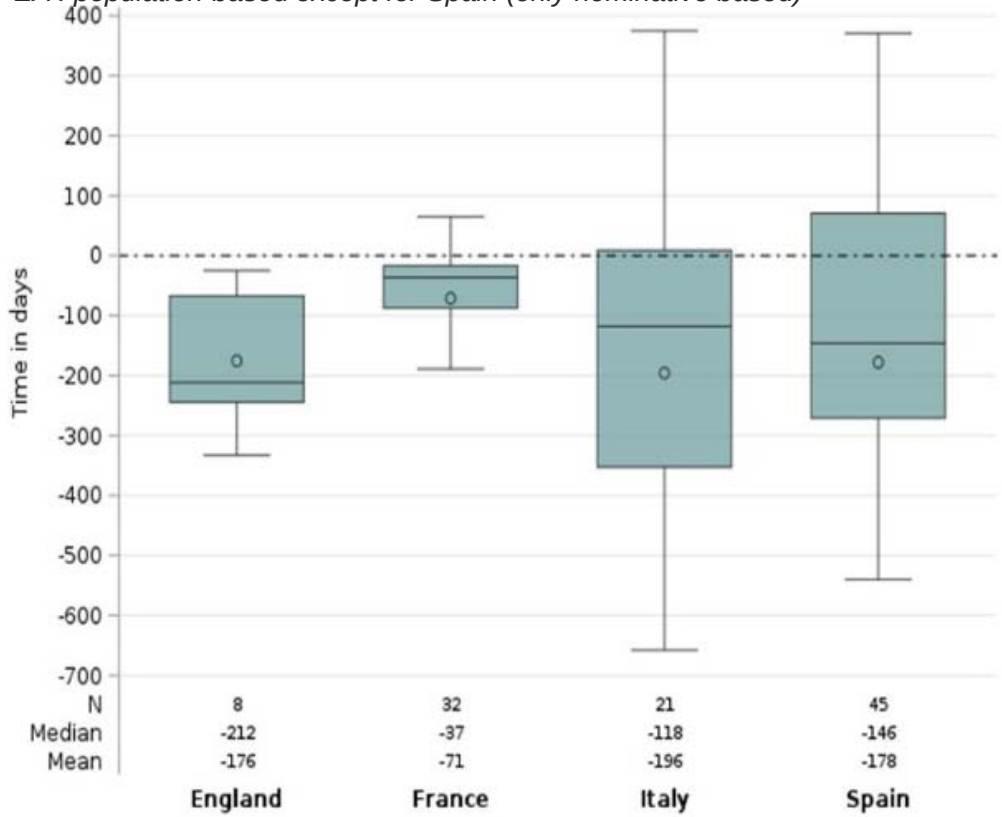
Early access variability across countries

Number of days from early access to MA

** EA : population-based except for Spain (only nominative based)*



- **Most of EA delivered before MA**
- **Comparable average EA times in England, Italy and Spain**
- **Wider distribution of EA times in Italy and Spain**

Source : Assessing medicines access time: a cross-country comparison in Europe - insights from England, France, Germany, Italy and Spain. 2024 edition. Comparaisons internationales n° 6. Février 2025. Sophie Delcroix-Lopes, Nadia Amer, Christophe Chaignot, Charlotte Pelletan.

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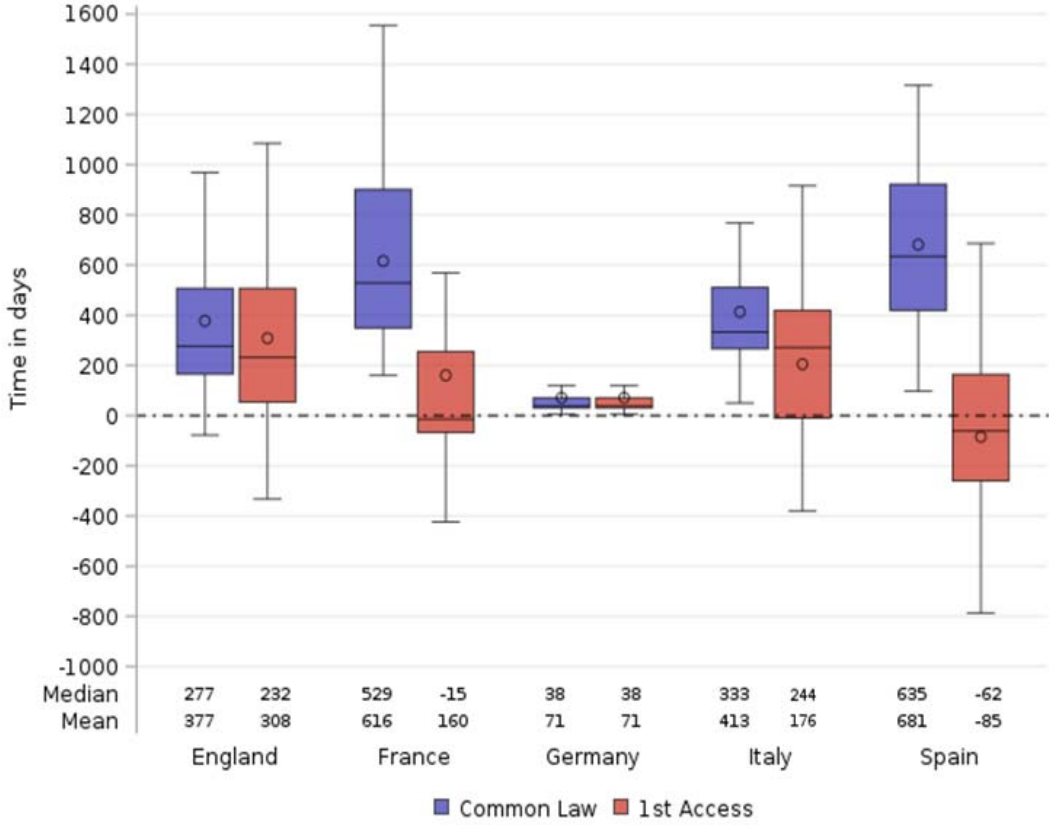
EARLY ACCESS CUTS AVERAGE ACCESS TIMES

Number of days from MA to coverage (national coverage or early access)

50 medicines



- **Germany:** shortest times, with direct market entry after MA
- **England:** access after HTA (including health economic assessment)
- **France, Spain, Italy**: EAS enable rapid patient access while ensuring the completion of HTA and price negotiations before national coverage

Source : Assessing medicines access time: a cross-country comparison in Europe - insights from England, France, Germany, Italy and Spain. 2024 edition. Comparaisons internationales n° 6. Février 2025. Sophie Delcroix-Lopes, Nadia Amer, Christophe Chaignot, Charlotte Pelletan.

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EARLY ACCESS IN FRANCE IN A NUTSHELL

- Progressively implemented since 1992 (HIV context)

- Reformed in July 2021 : simplified and strengthened
  - **Early access : population-based, *transition to common law***
    - address unmet medical needs, for patients with severe, rare or disabling diseases whose treatment cannot be postponed, presumed innovative, presumed efficacy and safety
  - **Compassionate use : mainly nominative-based, *medicines without marketing purpose***
  - ***Data collection funded by the company***

- After 3 years
  - **Better targeted medicines : 80% with added benefit**
  - **Increased :**
    - **Nb of patients :** times 2 in 3 years (126 000 patients since 2021)
    - **Nb of indications** : 122 indications approved (71% applications)
    - **Increased expenditures** : +35% in 2023 (640 M€), estimated 5% of total drugs expenditures (net prices)

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OPEN DISCUSSION : HOW IS IT IMPLEMENTED IN YOUR COUNTRY?

- **Name-based versus population-based**
- **Funding types : public, industry, mix**
- **Submission process** (eg industry or prescriber based)
- **Scope, therapeutic areas**
- **EAS figures (eg. share of expenses), possible to share?**
- **Other fast-track process in place or considered**

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2022-2024 MONITORS DISSEMINATION

- **Cnam strategic report** (French only) Yearly monitor since 2022

- **PPRI conference April 2024 : presentation + poster**
  WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

- **Cnam « working papers » 2023 and 2024 editions** (english)
  https://www.assurance-maladie.ameli.fr/etudes-et-donnees/2025-comparaisons-internationales-delai-acces-medicaments

- **Health Policy** : publication by April 28th

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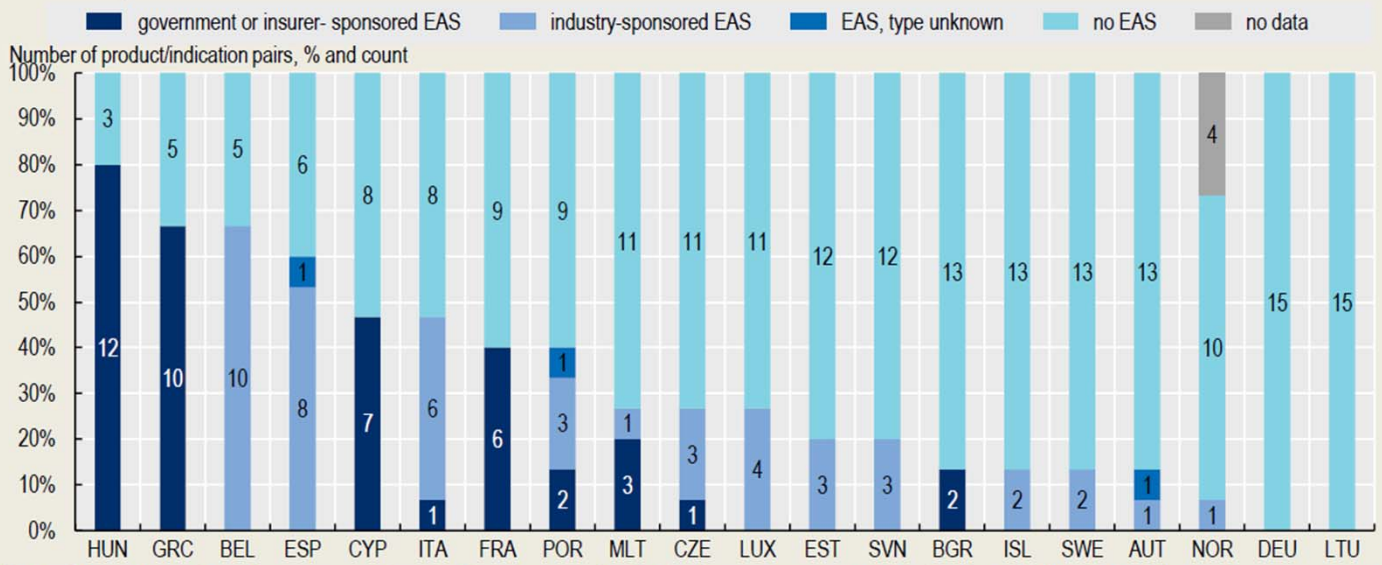
OECD 2021 SAMPLE OF 12 MEDICINES : FUNDING TYPES

Figure 2.3. Proportion of sample product/indication pairs by early access scheme across countries

Use of early access schemes varied across countries



Note: Proportions based on a sample of 15 index product/indication pairs, as at 01 October 2021. Data labels show counts of product/indication pairs. In Finland, some pharmaceutical companies may use EAS, but there is no public data. Germany may have EAS under special circumstances whereby the pharmaceutical company provides the medicinal product prior to marketing authorisation on a voluntary basis. Source: OECD survey on access to novel medicines 2021.

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