EU support to SMEs

EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation

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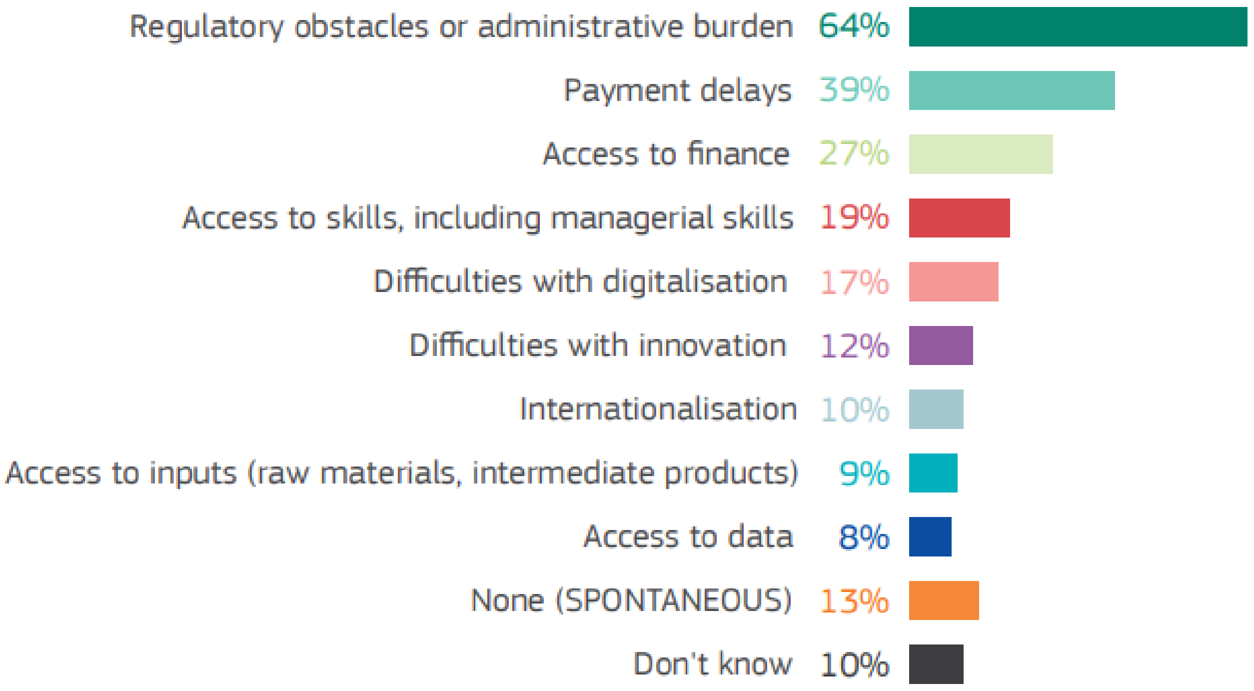
European Commission

"Europe's pharmaceutical resilience depends on a strong and diverse industrial base — from large research leaders to agile SMEs driving innovation, production capacity, and security of supply."

European Commission, Structured Dialogue on Security of Medicines Supply, Final Report, 2023

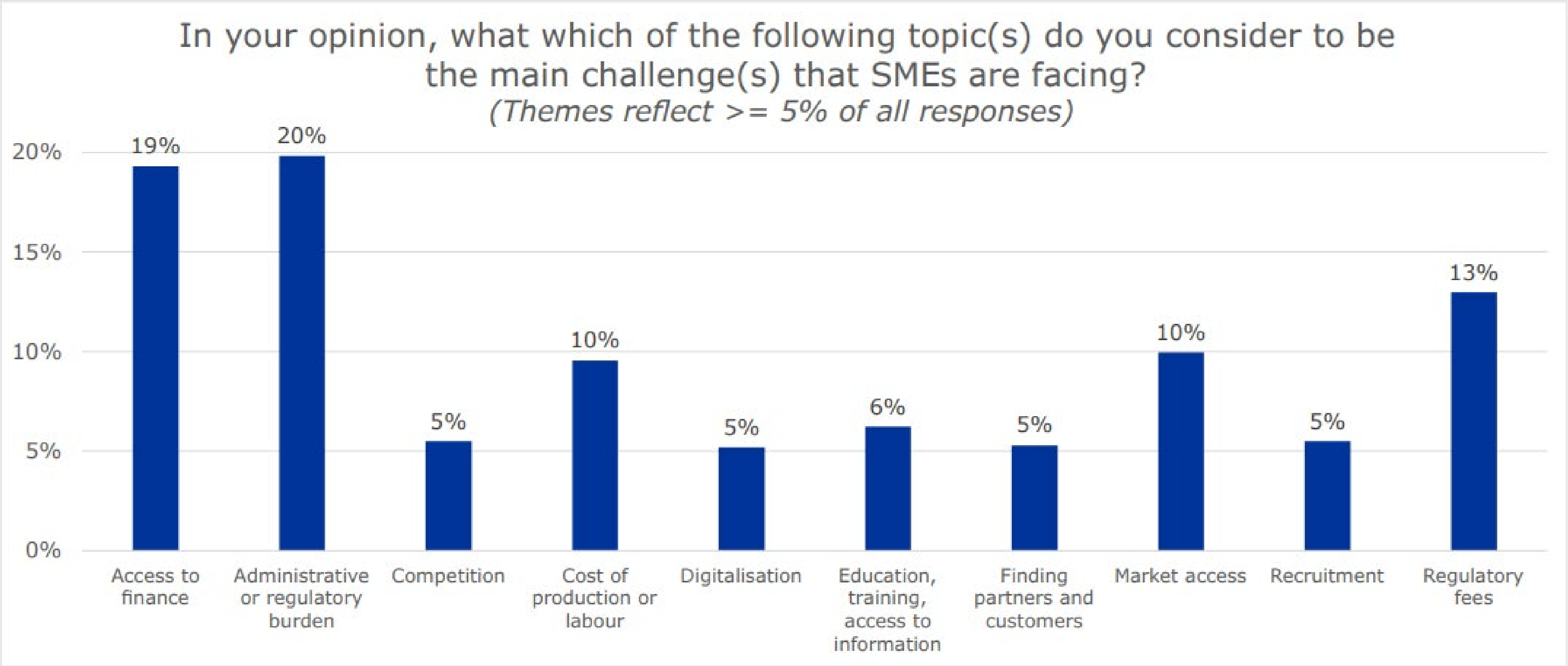
Challenges reported by EU SMEs - 2025

From the following list, indicate the area that poses the biggest problem by your enterprise in general



Source: Eurobarometer executive summary February - April 2025

Challenges faced by SMEs in the pharmaceutical sector - 2025



Source: Outcome of SME Office survey on the implementation of the SME regulation - Commission Regulation (EC) No 2049/2005 EMA/218450/2025)

Regulatory Simplification – how can SMEs benefit?

Prevention: SME test + SME-friendly provisions

- Thorough **assessment of impact of legislative proposals** on SMEs + mitigating measures
- **Standard legal clauses** that can be integrated into draft Commission proposals or used by co-legislators.
- These provisions address aspects of legislation that are commonly applicable across multiple legislative acts (e.g., guidance, phased implementation, simplified reporting, lighter requirements, etc.).
- They are designed to ease the practical application of EU legislation by SMEs.

Cure: Omnibus proposals

- Six omnibus proposals so far bringing over EUR 8.1 billion cost savings
    - Of which over EUR 2.7 billion for SMEs
- Simplification measures benefitting pharmaceutical sector:
    - **Sustainability** (VSME standard, value chain cap)
    - **Invest EU** (additional budget, simplification of SME definition and reporting)
    - **Digitalisation** (eliminate requirement for paper-based declarations)
    - **SMC** (GDPR threshold for mandatory record keeping is raised)
    - **Chemicals** (Simplified hazardous chemical labelling)

Upcoming Omnibuses e.g Digital, Environmental

Scaling-up and targeted support

Defining SMCs:

- Enterprises which are not SMEs, **employ fewer than 750 persons** and have an annual turnover not exceeding EUR 150 million or an annual balance sheet total not exceeding EUR 129 million
- Single Market Strategy supports SMCs:
  - introduce a new SMC category
  - SMC omnibus
  - + consideration in future proposals

SME targeted measures:

- SME ID
- Business transfers

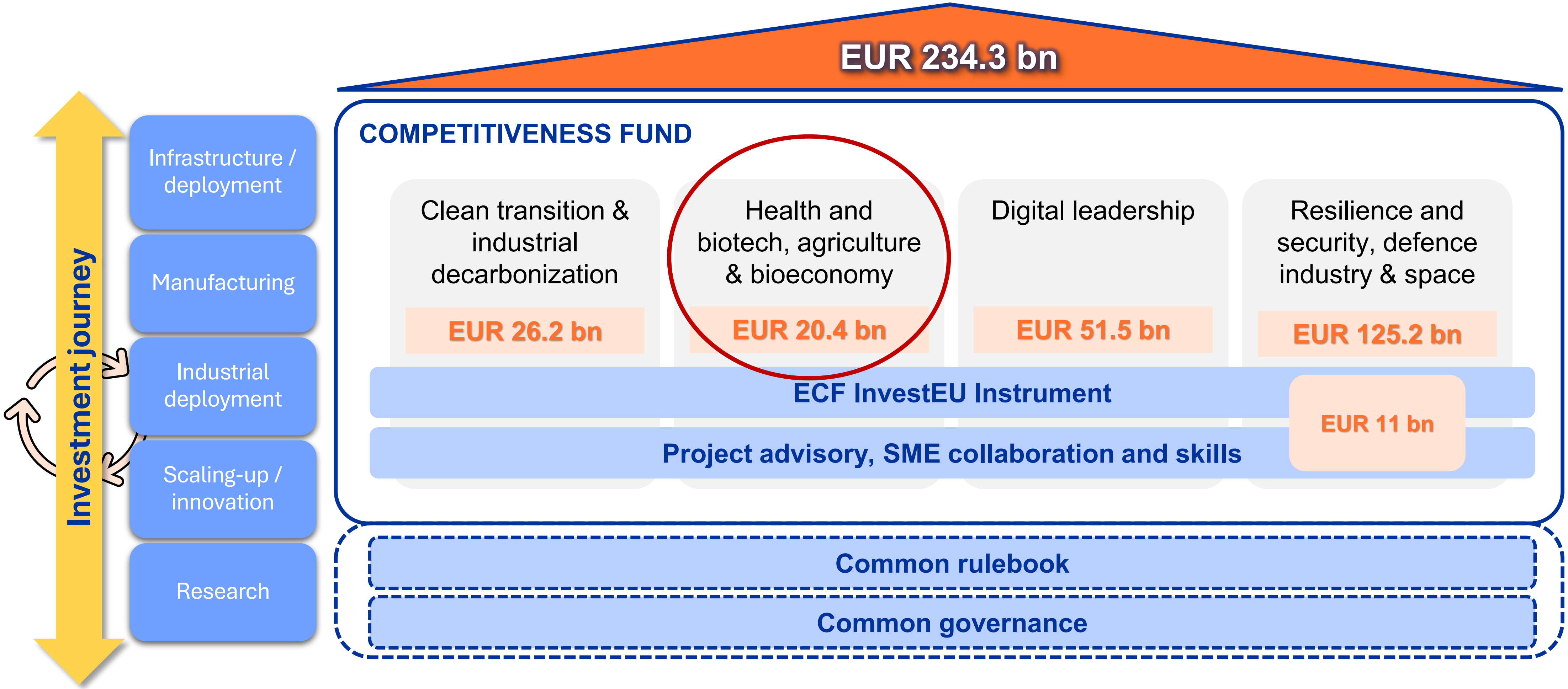
Access to finance:

- SME window within InvestEU (€ 6.9 bn in EU guarantee):
  - Facilitates access to debt and equity finance.
- Strategic Technologies for Europe Platform (STEP)
- HERA Invest fund

<u>Upcoming:</u>

- Scaleup Europe Fund
- European Competitiveness Fund

European Competitiveness Fund



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