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Impacting the future

October 2025 - SME Round Table

The SME status is very beneficial for life sciences companies

Financial incentives for SMEs

1. 90% fee reduction for EMA Scientific Advice
2. Even 100% reduction for orphan-designated products
3. 40 – 100% reductions for Scientific Advice after approval as well

Operational support services

- User Guides
- Newsletters
- Public Register
- Training Events
- Regulatory Assistance
- Clinical Data publications

The SME questionnaire lays out the key concerns for entrepreneurs

Companies need access to more funding

- While the availability of capital has increased in recent years, there remains a large gap for investments in later stage biotech developments.
- Financing instruments for PoC studies, regulatory and launch preparation and commercial execution are still largely missing.

There is a key need for less red tape

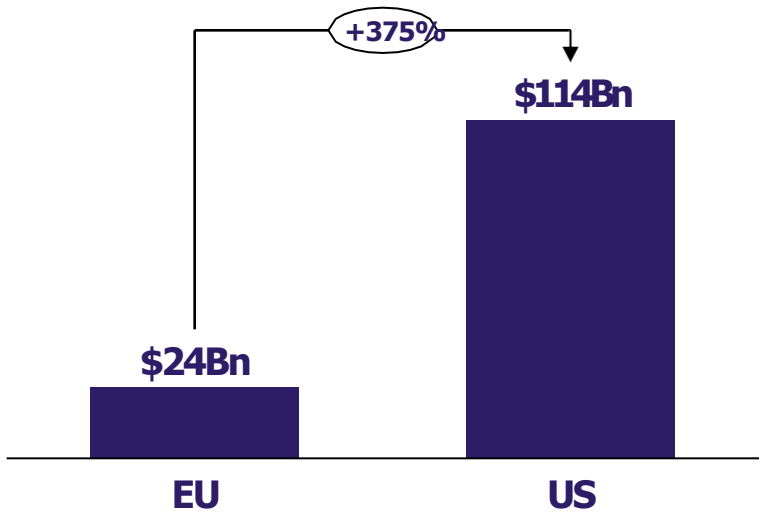
- The regulatory framework is too complex and inconsistent across Member States of the EU.
- Reimbursement considerations vary widely across countries
- Waiting times in Europe for decision making are long (especially in NL).

A clear need for better and faster market access

- There is a clear need for a better interconnected market, that accelerates the entry of drugs across the EU.
- Geopolitical independence in Biotech can only be assured in a level European playing field.

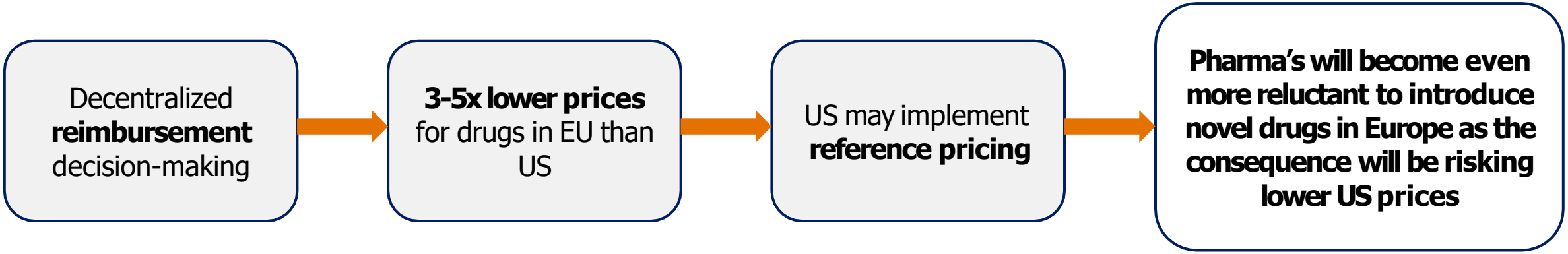
The existing capital availability gap between EU and US must be addressed

Biopharma VC investments in 2024



- Nasdaq is the **only well-functioning public market** for life science companies
- **Required critical mass** of specialized investors, stock analysts and bankers is only present there

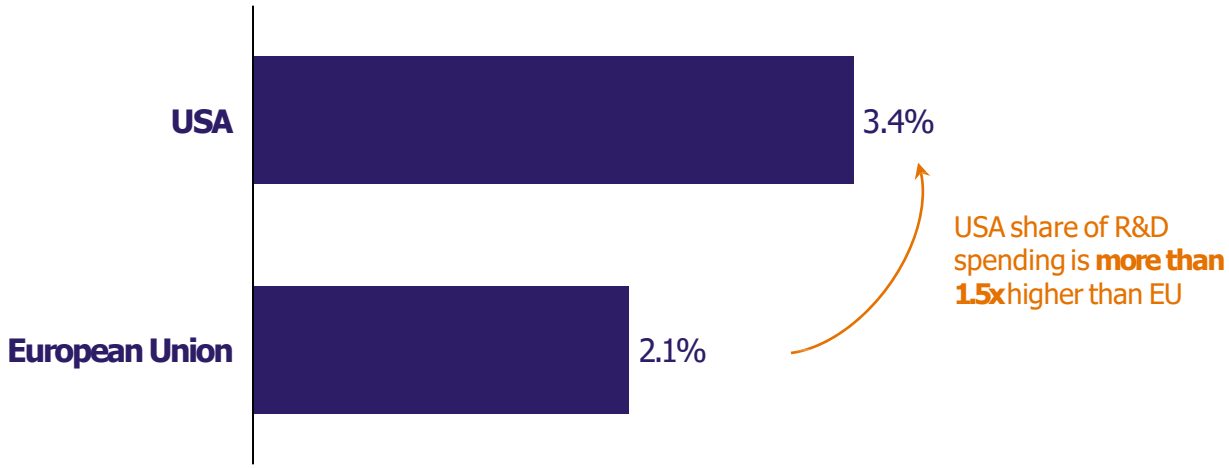
Drug prices are too low in Europe, risking further erosion of access to novel therapeutics



Catching up with the US will require a significant increase in R&D commitment

R&D Investment Gap: US vs. EU

Public – investments in R&D as share of GDP (2023)[1]



Private – Pharmaceutical company investments

- Pharma companies have further invested **$190Bn in R&D in 2024**
- With 50% of global pharmaceutical companies headquartered in the U.S., a large share of that capital remains there

This affects patient lives

Patients in the U.S. gain access to more drugs

- Past 5 years: 273 NAS launched in the U.S., compared to 204 in the EU4+UK

Americans also have earlier availability of novel medicines

- Past 5 years:, 110 novel drugs are available in the U.S. but not in Europe, while only 14 NAS are available in Europe but not in the U.S.

With Trump's reference pricing, this access gap could further increase!

Source: 1) OECD Data Explorer • Main Science and Technology Indicators (MSTI database)

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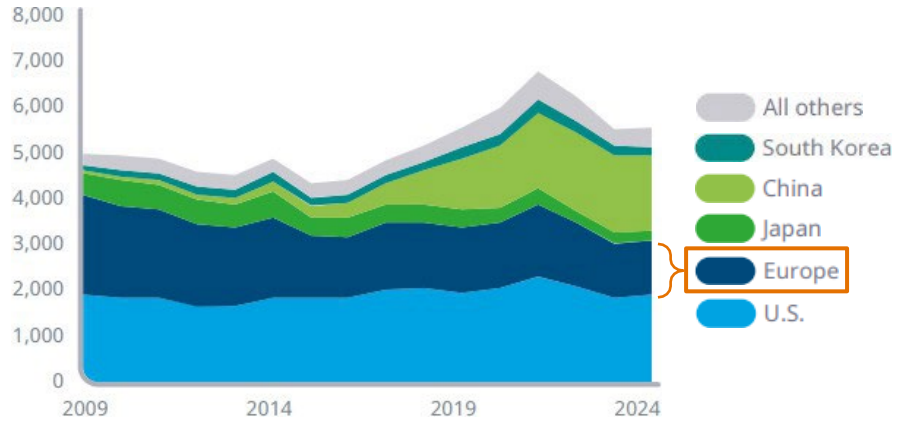
In a global healthcare market, more is needed from the EU

European Biotech presence has decreased



- In 2024, **Europe only started 21% of all trials**, down from 44% in 2009
- Trial starts from **China-headquartered companies are now 30%** of total trial starts, up from 1% over the same period
- The **US starts 35% of all trials**, remaining relatively stable over time

Drivers behind the Chinese force

1. Strong work ethic and strengthening quality standards
2. Great drug discovery capabilities
3. Fast clinical trial executions due to rapid recruitment & government support

Conclusions

SME regulation is favourable, but complexity slows EU Biotech
SME incentives lower barriers for life sciences companies, but regulatory and reimbursement process is still challenging

Europe can only lead in life sciences with a commercially attractive home market
Slower patient access and lower pricing make Europe less appealing for biotech and pharma

EU must strengthen Life Sciences funding with more private and public capital to bridge late-stage development funding gaps and reach maturity in Europe

Conclusion is that we need

Faster access

Fair prices

More capital

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