REPORT PREVIEW

DTO
B2B Research & Strategies

PHARMACEUTICAL MARKET OUTLOOK

Opinion Monitor Pharmaceutical Market

Assessments, expectations and
pressure points in the pharmaceutical industry

The monitor combines current European market, research, and supply data with documented industry developments and editorially synthesized perspectives along the pharmaceutical value chain.

REVIEW PERIOD

As of: 13 July 2026
Outlook: 2026–2030

MARKET COVERAGE

Pharmaceuticals | Biotechnology
Generics & Biosimilars |
Manufacturing
Market Access

OPINION MONITOR 2026

Strategic perspective for decision-makers

RESEARCH, DEVELOPMENT AND INNOVATION

THE PIPELINE IS PRODUCTIVE - DEVELOPMENT SPEED IS THE BOTTLENECK

Strong scientific momentum - the bottleneck increasingly lies in development speed, capital and scaling.

Pipeline remains productive

In 2025, EMA recommended a total of 104 human medicines for authorization, including 38 new active substances and 41 biosimilars. At the same time, CTIS has received almost 13,000 initial applications since 2022; more than 10,600 clinical trials were authorized by EU Member States. Activity is high, but Europe is competing on study speed, talent, data access and capital.

Where momentum is particularly strong

- Oncology and immunology: strong pipelines, intense competition and rising requirements for comparative evidence.
- Metabolism, diabetes and obesity: exceptional demand, combined with major manufacturing and reimbursement implications.
- Rare diseases and ATMPs: high medical value, but complex scaling and small evidence bases.
- RNA, ADCs and precision medicine: platform opportunities, but demanding development, biomarker and manufacturing logic.

Data and AI are becoming part of the development model

By February 2026, DARWIN EU had reached around 40 data partners in 18 European countries and access to data from approximately 250 million patients. AI can support target identification, study design, documentation and pharmacovigilance - but economic value arises only from validated data, transparent governance and clear integration into regulated processes.

> *"AI does not automatically shorten development. It creates value when it makes a decision more robust or genuinely replaces an experimental cycle."*
> - Head of Preclinical Development at a biotechnology company

> *"In cell and gene therapies, manufacturing is not a downstream step. Manufacturability, logistics and reimbursement must be part of the product concept from the outset."*
> - Head of Clinical Development at an ATMP company

DEVELOPMENT FILTER

1 Medical benefit

Clarify unmet need, differentiation and patient-relevant endpoints early.

2 Evidence & data

Combine HTA, RWE, biomarkers and comparator therapy in the development plan from the outset.

3 Scalability

Secure manufacturing, costs, the supply chain and launch volumes before late phases.

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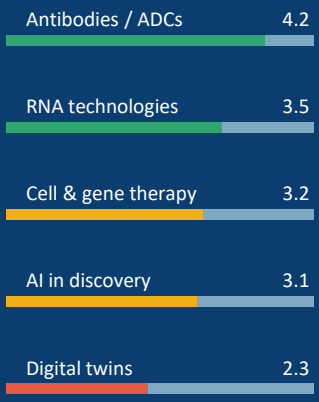
EMA 2025

104
Recommendations for human medicines.

38
Medicines with a new active substance

41
Recommendations for biosimilars.

INNOVATION MATURITY



EU STUDY WINDOW

113 days
average authorization time for multinational EU studies according to the EC comparison; Biotech Act target: 47 days.

Sources: [2] EMA Human Medicines 2025; [3] EMA Annual Report 2025; [8] EMA RWE Report 2026; [10] EC Biotechnology / Clinical Trials. | Qualitative classification: DTO.