

CLIENT ALERT

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Hungary – Significant Changes Ahead for the Pharmaceutical Market

Hungary is preparing a potentially far-reaching reform of its pharmaceutical regulatory and reimbursement framework — with important implications for market access, regulatory strategy and evidence generation.

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- faster regulatory and authorization procedures;
- increasing clinical trial activity in Hungary;
- improving access to medicines;
- reducing administrative burdens.

At the same time, the government is preparing a broader reform of the pharmaceutical reimbursement system, with a stated objective of moving towards a more value-based and patient-centered approach within the next two years.

Under the proposed approach, reimbursement would not focus solely on the services or treatments provided, but increasingly on the health outcomes actually achieved. The proposed reform would also involve a review of Hungary's policy towards generic and biosimilar medicines.

What does this mean for pharmaceutical companies?

Although many elements of the reform remain at the policy and legislative preparation stage, the announcements point towards a potentially significant change in the Hungarian market access environment.

Companies operating in Hungary should closely monitor developments concerning:

1. Reimbursement and Health Technology Assessment: greater emphasis on real-world and patient-relevant outcomes could affect evidence-generation and market access strategies.
2. Transparency: publication of information underlying reimbursement decisions could materially change the level of visibility around the assessment of innovative medicines and health technologies.
3. Generics and biosimilars: future policy may seek to balance budgetary considerations with industrial and innovation objectives.
4. Regulatory procedures: the re-establishment of an independent medicines authority could lead to changes in authorization processes, clinical trial policy and administrative requirements.
5. Patient involvement: the increasing role of patient perspectives may become a relevant consideration in reimbursement and health technology assessment.

The proposed reforms are still developing, and their practical impact will depend on the implementing legislation and the detailed rules ultimately adopted. Further regulatory developments should therefore be monitored closely.

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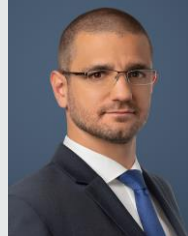


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