ACCESSPILOT · WHITE PAPER · 2026

From hurdles to access

A practical map of European market access risks for lean biotech teams, and how to address them before launch

Emmanuel Lacharme, PharmD, MSc · Independent market access specialist

Executive summary

Marketing authorisation is only the first gate. Between approval and the patient sit dozens of hurdles: evidence that does not match what assessors compare against, prices that travel through international referencing, budget ceilings, guideline delays and operational gaps between headquarters and affiliates. Large companies absorb these with dedicated teams. Lean biotechs usually cannot.

This paper groups the most common hurdles into six risk families, shows when each one should be addressed in the product lifecycle, and describes a proportionate response: a structured European Launch Assessment, targeted consulting, and, where a task recurs, an AI companion that drafts while people decide.

Key messages

- Most access failures are visible 18–36 months before launch, in trial design, comparator choice and evidence plans.
- The EU HTA Regulation and Joint Clinical Assessment (JCA) make early PICO scoping essential for oncology and ATMPs now, and for more products from 2028 and 2030.
- Launch sequence and price corridor are one decision: international reference pricing links them.
- Recurring work (HTA monitoring, literature screening, dossier updates) is where AI saves time, always with a named human reviewer.

Six families of access hurdles

The hurdles below are condensed from a broader overview of over 30 market access challenge areas, from regulatory approval to post-launch reassessment (see source note A). Time from approval to availability varies widely across Europe [6]; reference pricing links national prices [7, 8].

Risk family	Typical hurdles	When to act
1. Evidence	Wrong comparator or standard of care; immature OS; surrogate endpoints not accepted; missing PRO/QoL; no real-world data	Phase II – pivotal design
2. HTA & value	No or minor added benefit; ICER above threshold; weak model assumptions; poor indirect comparisons; high uncertainty	24–12 months pre-filing
3. Pricing	External reference pricing; price spillover; launch sequencing; parallel trade; mandatory discounts and price cuts	Before first launch decision
4. Reimbursement & budget	Restricted listing; step therapy; hospital-only funding; budget caps; high budget impact for large populations	Dossier & negotiation
5. Adoption & system	Guideline inclusion delays; diagnostic and biomarker testing; procurement and tenders; regional variation	12 months pre-launch onward
6. Operations & lifecycle	HQ–affiliate alignment; data availability; forecast accuracy; reassessment; new comparators; label expansion	Continuous

What changes in Europe now

- **EU HTA Regulation.** Since January 2025, new oncology medicines and ATMPs undergo a Joint Clinical Assessment. Member States submit PICOs, and a single dossier must answer many of them at once. Orphan medicines follow in 2028 and all new medicines in 2030 [1, 2].
- **National appraisal remains.** JCA covers relative clinical effectiveness only. Pricing, economic evaluation and reimbursement stay national: G-BA/AMNOG in Germany, HAS/CEESP in France, AIFA in Italy, and NICE and SMC in the UK, outside the EU process [3–5].
- **Switzerland and the UK** keep their own timelines, reference baskets and evidence expectations, and are often part of an early launch wave.

A proportionate response

Risk family	European Launch Assessment	Consulting	AI companion
Evidence	Gap review against payer and HTA questions	Evidence generation plan, PRO/RWE strategy	RWE / PRO evidence mapping; literature monitoring
HTA & value	Comparator and PICO expectations per market	Value story, GVD, objection handling	EU JCA PICO scoping; health economic model support
Pricing	Price corridor and launch sequence options	Pricing and IRP analysis	Pricing scenarios
Reimbursement & budget	Route and managed entry options by market	Dossier and negotiation preparation	Payer objection handler
Adoption & system	Early flags on guidelines, diagnostics, tenders	Stakeholder and pathway mapping	HTA intelligence brief
Operations & lifecycle	Prioritised roadmap and owners	Affiliate coordination, interim support	Executive access briefing; advisory-board follow-up

Using AI safely in market access

AI is useful for recurring, source-heavy tasks. It should never make pricing or reimbursement decisions, generate unsupported claims, or handle confidential data without access controls. Every companion is built on approved sources, cites them, keeps an audit trail and has a named human reviewer. It is judged on two measures: review time saved and accuracy against expert review [9, 10].

Ten questions to ask before a European launch

1. Which comparator will each HTA body expect, and does the trial support it?
2. Which PICOs are likely in the Joint Clinical Assessment?
3. Are endpoints and follow-up mature enough for assessors?
4. Which evidence gaps can still be closed before submission?
5. What added benefit rating is realistic in Germany and France?
6. What price corridor holds across referencing markets?
7. Which launch sequence protects that corridor?
8. Which reimbursement routes or managed entry agreements are realistic?
9. Will guidelines, diagnostics or tenders slow uptake?
10. Who owns each access decision, at headquarters and in affiliates?

Start with one conversation. The European Launch Assessment turns these questions into a prioritised, market-by-market roadmap. Contact: lacharme_emmanuel@hotmail.fr

References and source notes

This paper combines two kinds of material. They are kept apart so readers can judge each claim on its own basis.

A. Poster-derived insights (practitioner synthesis)

- The six risk families, the hurdle lists and the "when to act" timing on page 1 are condensed from the author's own overview posters of market access hurdles and AI agents for market access and HEOR. They reflect professional experience, not a systematic review.
- The mapping of risks to the Launch Assessment, consulting and AI companions, the ten questions and the 18–36 month window are the author's judgement and should be read as guidance.

B. Cited evidence (numbered in text)

[1] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment. Official Journal of the EU, L 458, 22.12.2021.

[2] Commission Implementing Regulation (EU) 2024/1381 laying down procedural rules for joint clinical assessments of medicinal products for human use. Official Journal of the EU, 2024.

[3] Gemeinsamer Bundesausschuss (G-BA). Benefit assessment of medicinal products according to §35a SGB V (AMNOG). g-ba.de.

[4] Haute Autorité de Santé (HAS). Transparency Committee doctrine and economic evaluation guidance (CEESP). has-sante.fr.

[5] National Institute for Health and Care Excellence. NICE health technology evaluations: the manual (PMG36). London: NICE; 2022, updated.

[6] EFPIA / IQVIA. EFPIA Patients W.A.I.T. Indicator Survey (latest annual edition). Brussels: EFPIA.

[7] Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products and their inclusion in national health insurance systems.

[8] OECD. Pharmaceutical Pricing and Reimbursement Policies; Health Policy Studies. Paris: OECD Publishing.

[9] European Medicines Agency. Reflection paper on the use of artificial intelligence (AI) in the medicinal product lifecycle. EMA/CHMP/CVMP/83833/2023; 2024.

[10] Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act). Official Journal of the EU, 2024.

Rules and timelines summarised as of November 2026. Check the current version of each source before relying on it for a submission.