De-Risking international revenue whichever way you are planning to commercialise

The European Market Access Checklist for Innovative Biotech

From Protocol to Profitable Reimbursement

Apersy

Value | Market Access | Commercialisation

Market & payer insights must shape development programmes

Whether or not you are planning to commercialise yourself across European markets, in today's turbulent geopolitical dynamics, changing European regulations and highly competitive environment, market and payer considerations are no longer a *nice-to-have* but a crucial element of your strategic clinical development:
Strategic access and price considerations are getting more complex and urgent; fund raising, partnering and licensing deals are harder to come by, favouring the best prepared companies.

Indicators of lacking Market Access preparedness

In Europe, industry bodies and patient associations have long since highlighted that the lack of relevant market access data is the key reason for patient access delays and restrictions.

Internationally, findings from industry surveys indicate that **75%** of **biotech** first-time launches considered Market Access too late in development, with management noting a **negative effect on launch performance and commercial KPIs.***

81% of pharma companies now initiate their market **access planning earlier** than five years ago, many already involved in market access research by phase 1.**

*McKinsey Survey of first-time launch leaders 2022
**MMIT 2024 State of Patient Access survey

What has changed?

European Market Access procedures now start before marketing authorisation and launch; evidence and strategy preparations need to be developed earlier. The new EU Joint Clinical Assessment (JCA) requires companies to prepare for and submit a full dossier of access evidence at the same time as their EMA Marketing Authorisation Application.

With US price pressure increasing (MFN, IRA), international pricing and access need additional attention. Putting go-to-market preparedness for Europe on hold is not a solution, potentially distorting global strategies, creating delays and endangering overall product value. **Biotechs cannot afford to miss out on European revenue, nor to lose investor confidence** through negative bias in price potential and revenue forecasts.

Being able to choose the **best option for European commercialisation** in tight financial markets and a **tough partnering environment**, requires companies to present evidence packages that will either **ease the launch burden for licensees** or allow financing of “go-alone”-options.

EUROPEAN MARKET ACCESS CHECKLIST

European reimbursement: Do you get the bigger picture?

This checklist, derived from specialist knowledge of the European Health Technology Assessment (HTA) systems and pricing environments, is designed to help biotechs in Phase 1-2 to identify and close critical strategic knowledge gaps and related evidence gaps that can cause costly delays and suboptimal reimbursement.

Your ability to execute this checklist is a direct measure of your "Market Access preparedness" at this stage of development. This type of readiness can provide valuable commercial insights and a strategy foundation to presented to a partner or lincensee.

A "No" on any item below may represent a critical risk to your European partnering and commercial success or indicate what needs more consideration in your development roadmap, further evaluation in the context of the global product strategy.

Henrike Granzow, MSc
Market Access consultant,
health economist

My Role:

I provide early-stage, European-specific market access intelligence, price strategy and payer evidence alignment in an international strategy context. Based on over 15 years of experience in global CROs, Life Sciences Consulting and investment management, I support innovation reach European patients.

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About Apersy

Apersy is an independent strategy consultancy for Life Sciences companies, supporting them to create valuable assets that meet the expectations of investors, partners and healthcare payers, ultimately de-risking revenue, reimbursement and market access.

We see that care environments and payer realities are changing, so we make it our mission to help rethink product value and to support continuous commercial adaptation and optimisation.

Section 1: Market Context and Opportunity

Europe is not one market, but 27 individual healthcare systems with different stakeholders, treatment guidelines and standards of care, and of course with different payer systems.
While the FDA and EMA ask, "Is it safe and effective?", European healthcare systems ask:

"Is it worth the money compared to what we already use?" - “Does this fit with and serve our patient pathways”? and “How can it be adopted?”

Strategic Questions: Market understanding and value proposition

Question	Status
1. Market need: Have you conducted a thorough market analysis to understand the potential **patient population(s)** and **unmet need** in key European markets?	□ Yes / □ No
2. Local standard of care: Have you identified **patient management, the main competitors** and their market shares in each key country?	□ Yes / □ No
3. Value/Price Ambition: Have you formulated an aspirational value proposition for these markets and a high-level initial price/ reimbursement potential?	□ Yes / □ No

Pricing, reimbursement and access assumptions remain the main point of disagreement in valuations when talking to pharma partners!

Section 2: Clinical Trial Design for HTA Readiness

The overarching question here is “Have you designed your clinical trial(s) to meet the requirements of European regulators **and** HTA bodies?”

National HTA processes in each European healthcare system, as well as the new EU-level Joint Clinical Assessment (JCA) mean that a pivotal trial must satisfy highly specific data requirements.

Strategic Questions: Phase 2/3 HTA Readiness

Question	Status
4. HTA/JCA Scoping: Have you performed a **PICO (Population, Intervention, Comparator, Outcome) mapping** across key markets (e.g. Europe 5)?	□ Yes / □ No
5. Patient Reported Outcomes (PROs): Have you included **validated, HTA-preferred PROs** measures that demonstrate "Quality of Life" or "Functionality" improvement?	□ Yes / □ No
6. Subgroup Analysis: Is your statistical analysis plan designed to support subgroup claims that **may be required for reimbursement** ?	□ Yes / □ No
7. Study design adequacy: Have you evaluated the trial [programme] as a whole in light of **payer / HTA requirements** (duration, endpoint hirarchy, blinding, etc)	□ Yes / □ No

Section 3: National Pricing, Access Rules, and Policy Environment

National access processes in Europe contiune to determine the price, conditions and speed of reimbursement together with other access details. A global asset strategy requires at least some understanding of local payers and stakeholders, political, and policy landscapes in key markets.

Strategic Questions: Stakeholders and pharmaceutical policies

Question	Status
8. Route to revenue: Have you identified **national reimbursement paths and access landscapes** - at least for the major markets: What are your **access scenarios**?	□ Yes / □ No
9. Payer Stakeholder Mapping: Have you identified the key political/payer **decision-makers** for the Europe 5 who influence access, and assessed their likely stance on your therapeutic area?	□ Yes / □ No
10. Global pricing: Have you developed a **pricing strategy that reflects the value of your product** and the competitive landscape in key markets? (and the broader international (reference pricing) context).	□ Yes / □ No

Section 4: Operational and Commercial Preparedness

Market Access requires local expert knowledge and is a cross-functional effort. Integrating access thinking seemlessly in daily operations and R&D can help avoid inefficiencies and delays. Even if you are a small organisation, you want to make sure that everybody is on the same page and to find neccessary external expertise to support.

Strategic Questions: Operations and go-to-market thinking

Question	Status
11. Market Access expertise: Do you have a clear understanding of the capabilities needed for Market Access?	□ Yes / □ No
12. Team Alignment: Do you have processes to align **Clinical, Regulatory, and Commercial** teams?	□ Yes / □ No
13. TPP alignment: Do you have a **"reimbursable" [payer-informed] Targte Product Profile** (TPP) to translate your strategic insights and asset strategic during development	□ Yes / □ No
14. Business model/market entry strategy: Have you systematically evaluated different market entry strategies (e.g., "go-alone", licensing, distribution partnerships)? for the European markets?	□ Yes / □ No

Access excellence to de-risk reimbursement and revenue

Creating a valuable global asset today means staying on top of dynamic policy developments, to evaluate policy impact and incorporate new realities and scenarios instead of standing still, immobilised by market uncertainty. Questions of strategic positioning, patient need, launch and pricing need to be aligned with clinical and regulatory efforts to create opportunities in the tension between global and local.

Putting in place early activities to proactively follow and evaluate policies and competitor efforts, to understand opportunities more broadly than a list price will be the way forward as we are going through 2026. Coherent global Market Access Excellence will help to navigate conflicting international priorities strategically.

Actionable steps today:

1. Start with the check list as a guide. Tick the boxes and note your organisation's familiarity with each domain or question.

2. Identify your current priorities and needs in terms of Market Access knowledge: This might be your value story, a validation of first price assumptions for investors or the preparation of a new trial protocol ...

3. **Book a free consultation**: We will discuss each item on the check list, identify gaps and risks, and validate priorities. - The goal is to provide you with actionable next steps to bring your access readiness to the right level for your asset at this point of development.