THE NEW LITMUS TEST FOR EARLY ACCESS IN FRANCE: IS YOUR PRODUCT REALLY INNOVATIVE?

FIRST INSIGHTS INTO HOW HAS EVALUATES ELIGIBILITY TO EARLY ACCESS UNDER THE NEW RULES

Since 1st July 2021 the decision power for early access programs in France (accès précoce, previously known as ATU) has shifted to the French National Authority for Health (Haute Autorité de Santé, HAS).

A pharmaceutical product is eligible to the reformed early access program if it is intended to treat a serious, rare, or debilitating disease and all of? the following conditions are met:

1. There is no appropriate treatment available to patients
2. The treatment with the new product cannot be deferred
3. The efficacy and safety of the product is strongly presumed
4. **The product if presumed to be innovative, particularly versus a possible clinically relevant comparator** NEW

When the new conditions came into effect, it was unclear how HAS would define or quantify innovation, and whether the new conditions would negatively affect the number of products eligible for early access. This ambiguity is the core concern of access planners vis-à-vis impact to France, and indeed the rest of Europe and other international markets that refer to France.

So, what has happened since? Is HAS now stricter than ANSM has been?

First insights are now available seven months after the new rules came into effect. HAS has already evaluated 32 products for early access. Fourteen of those decisions involved products that had previously been granted an ATU by ANSM prior to July 2021. Six products had a cohort ATU authorized by ANSM prior to July 2021 and eight products were available through a nominative program. Ten out of these 14 products have had their early access re-authorized by HAS and will continue to be reimbursed in the transition phase between marketing authorization and reimbursement (previously known as Post-ATU funding).

The early access of four products has been refused by HAS after having been granted by ANSM (3 nominative and 1 cohort ATU). HAS did not perceive those products as innovative and considered that treatment with these products could be deferred because appropriate treatment options are currently available to patients.

For most of these 14 products, HTA is still ongoing. Four products who continue to be available via early access have been assessed so far and have been awarded ASMR III (1), ASMR IV (1) and ASMR V (2). Of the products who were refused early access by HAS, one has been assessed so far and has been awarded ASMR V (no added benefit).

From the decision HAS has made so far, we conclude that early access has indeed become more restrictive. To be considered innovative, a product must provide (1) significant progress, or (2) a substantial added benefit versus a clinically relevant comparator or the current therapeutic strategy. In absence of such proof - or if a clinical development plan is not considered adapted to create such evidence, a new product - even if it has a new mode of action - will not be considered innovative by HAS and not be eligible for early access.

What does that mean for your clinical development and early market access plans?

While pricing and reimbursement in many EU countries have traditionally relied on a new product providing an added benefit versus current standard of care, the added benefit concept now also becomes more and more incorporated in early access programs and in the regulatory process.

Of note, the added benefit concept also decides whether a new product designated for a rare disease can its orphan drug designation at time of EMA approval (see also our recent blogpost on this subject: “How safe is your orphan drug designation? - Implications for pricing and market access in Europe?”).

This highlights again the need to define your pricing and reimbursement strategy early in the clinical development process. Now more than ever, planning for market access needs to go hand in hand with your regulatory access strategy to ensure that your product is available to patients as early as possible.

About LatticePoint Consulting:

LatticePoint is a boutique consulting firm that focuses on pricing and market access for innovative medicines and medical devices. LatticePoint is led by former industry market access leaders who understand how to plan for the political, scientific, and financial realities that will be pivotal in negotiating product access. We work with biopharma companies and investors to help define, negotiate, and defend the value of their products in key markets around the world. The LatticePoint team has over 40 years of pharmaceutical and biotechnology industry experience. Led by former industry market access leaders and a high-caliber team with significant experience in the sciences, licensing, M&A due diligence and integration, venture capital and international affiliate operations, we have a depth of experience, both at the global and regional levels. Our multilingual staff of native German, French, Italian, Spanish, Portuguese and English speakers is experienced at handling negotiations in many key countries while keeping an eye on cross-border implications. We engage with payers, providers, hospitals, HTA bodies and EMA for early access, give feedback on clinical program design, and create and execute in-country reimbursement strategy negotiations in key markets around the world. We retain a Global Payer Panel for market research interviews.

About the author:

Karin Steinbach

Senior Consultant
Market Access and Pricing

Karin joined LatticePoint in August 2019. She holds a PhD in Biology obtained from the University of Hamburg, Germany. Karin develops early access and launch strategies, and value-based communication tools for innovative orphan medicines entering European and North American markets.

contact: karin.steinbach@latticepointconsulting.com

www.linkedin.com/company/latticepoint

https://www.latticepointconsulting.com

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