

An abstract geometric composition on a dark navy blue background. On the left, a vertical cream-colored rectangle is divided by a thin teal line, with two horizontal teal lines intersecting it at points marked by small teal dots. To the right, a large teal shape is composed of a rectangle and a triangle. A thin white line extends from a small teal circle at the top of the teal triangle's vertical edge. The word "France" is centered in the upper half of the image in a white, sans-serif font.

France

France

Understanding the applicable framework

French collaboration combines legislation, applicable Leem ethical provisions and organisational responsibilities. Leem revised its framework to include individual patients as well as associations. Most changes applied from January 2026; the restriction concerning commercial or promotional functions of company interlocutors applied from 1 July 2026 (Leem, 2025, 2026).

Check the operative provision and effective date rather than rely on a general announcement. Record the version used and any transition affecting the activity.

What companies need to understand

Legal existence and health-system accreditation are different matters. Public Health Code Article L.1114-1 establishes accreditation for associations representing users in specified hospital and public-health bodies, including independence, representativeness and transparent management. Not every association holds or needs this status for every collaboration (Code de la santé publique, n.d.).

Ask which role the association is undertaking. Company-workshop participation differs from nominating an official user representative. Check statutes and approval arrangements without requesting accreditation irrelevant to the activity.

What patient organisations need to understand

The revised Leem framework restricts patient and association interaction by personnel performing commercial or promotional activities. It recognises patient expertise remuneration and expenses within applicable legal and ethical requirements (Leem, 2025, 2026).

Identify a suitable company contact and distinguish organisational services from individual engagements. These provisions do not permit every payment automatically: the recipient, service and contractual arrangement still require assessment.

Transparency and payments

Transparence-Santé covers relevant agreements, remuneration and benefits involving specified recipients, including health-system user associations. Companies make the declarations. Explain publication before signing, confirm legal names and descriptions, and provide a correction route (French Ministry responsible for Health, n.d.).

Transparency and controls on benefits are separate frameworks. Assess payments according to the recipient's status, including whether an individual is also a healthcare professional, rather than assuming identical treatment for associations and individuals.

Regulatory and access participation

HAS invites associations and user groups to contribute collective experience to medicine reimbursement and early-access assessments using the relevant questionnaire and deadline. Published questionnaires should not contain nominative personal information (Haute Autorité de Santé [HAS], 2026).

Plan this as the association's own evidence activity, with time for differing experiences. Check interests and eligibility for the specific role; an organisational contribution and an individual expert appointment may have different conditions.

Practical example and local checks

For an information-needs workshop, establish whether the association and individual patients are engaged separately, who receives payment and whether the company contact meets Leem requirements. Agree publication of relationship information, privacy, stories and safety responsibilities. Check official representative roles separately.