

An abstract geometric composition on a dark navy blue background. On the left, a vertical cream-colored bar is divided into four equal segments by three thin teal horizontal lines. Two teal dots are positioned at the intersections of the first and second, and second and third horizontal lines. To the right of this bar, a large teal shape is composed of a trapezoid at the bottom, a rectangle in the middle, and a triangle at the top. A thin white vertical line runs down the center of the teal trapezoid, ending in a small teal circle. The word "Germany" is written in a white, sans-serif font, centered horizontally and partially overlapping the cream bar and the teal shape.

Germany

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Understanding the applicable framework

The FSA patient-organisation Code provides a dedicated framework for companies within scope, alongside medicines, privacy and organisational law. It seeks to preserve neutrality and independence and should be identified as an industry code (Freiwillige Selbstkontrolle für die Arzneimittelindustrie [FSA], n.d.).

Establish company commitments and the organisation's governing, umbrella-body and funding conditions at intake. Compliance with one framework does not settle all other responsibilities.

What companies need to understand

Statutory health-insurance self-help funding has its own conditions. GKV-Spitzenverband revised its guidance in June 2025 for application from January 2026. Check the operative guidance and specific award conditions when assessing industry collaboration (GKV-Spitzenverband, 2025).

Ask whether expenditure is already funded, whether notification is needed and how neutrality is protected. Allow the organisation time to consult its funding contact. A company grant should be assessed in the context of existing commitments.

What patient organisations need to understand

The FSA Code restricts recommendations for prescription medicines or groups and addresses acknowledgements, promotional rights and public reporting. Agree wording and logo use, and obtain a specific assessment for links, shared digital activity or other promotional arrangements (FSA, n.d., §§ 9, 15).

A company should explain whether a request arises from the Code, law or policy. Acknowledging support should not be treated as recommending treatment.

Funding and workload

Describe support and commissioned services separately, even when the same organisation undertakes both. Define their purposes, responsibilities, budgets and outputs so classification and disclosure can be assessed accurately.

Recognise consultation, preparation and approval time. Explain covered costs and restrictions with their source. A budget used in another country should not be assumed suitable for Germany.

Regulatory and access participation

Formal G-BA patient participation follows Social Code Book V and the Patient Participation Ordinance. Recognised organisations have specified consultation and application rights; patient representatives do not vote. Nomination follows prescribed arrangements (Gemeinsamer Bundesausschuss [G-BA], n.d.; Patientenbeteiligungsverordnung, 2003, § 4).

Company collaboration creates no automatic G-BA entitlement. Separate company and representative roles and check relevant independence, appointment and disclosure requirements.

Practical example and local checks

Before accepting a company-supported information project, a publicly funded self-help group should check existing funding conditions, overlapping costs and independence. Agree disclosure and editorial arrangements. Assess formal participation roles separately and retain the project decision, allocation and advice obtained.