GHMC

Global Insights:

Patient Advocacy Trends

Foreword

Patient advocacy and engagement is increasingly influential in shaping decision-making in life science companies across the medicines development lifecycle. Across the markets represented by GHMC's network of independent healthcare partners, a clear direction of travel is emerging, even if the pace varies by region.

Engagement between pharma and patient organizations is broadly shifting from transactional to strategic. Regulatory recognition of patient experience data is gathering momentum worldwide, from NICE in the UK to IETS in Colombia to the FDA's Patient-Focused Drug Development initiative and the EMA's PED reflection paper, giving patients a more recognised role in regulatory and reimbursement processes than ever before.

Yet common constraints persist and the landscape is complex and often contradictory For example, life science companies often champion patient-centricity in mission statements and speeches but the resources and urgency surrounding patient-focused initiatives do not always match the rhetoric. Furthermore, while regulators and payors are increasingly supportive of patient involvement in regulatory and reimbursement, transparency on the weighting of the patient voice in decision making is not always forthcoming.

At GHMC, we believe the key to real progress lies in pairing a deep understanding of patient experience with strategic acumen to create shared value for all stakeholders. By combining deep cross-lifecycle expertise with advanced capabilities in patient research, stakeholder collaboration and evidence-based storytelling, we help organisations make patient advocacy and engagement not just a principle but a powerful driver of strategic and cultural change.

The insights that follow, contributed by GHMC partners across Asia-Pacific, Europe, North America, and Latin America, offer a closer look at how barriers to and opportunities for patient advocacy and engagement present market by market.

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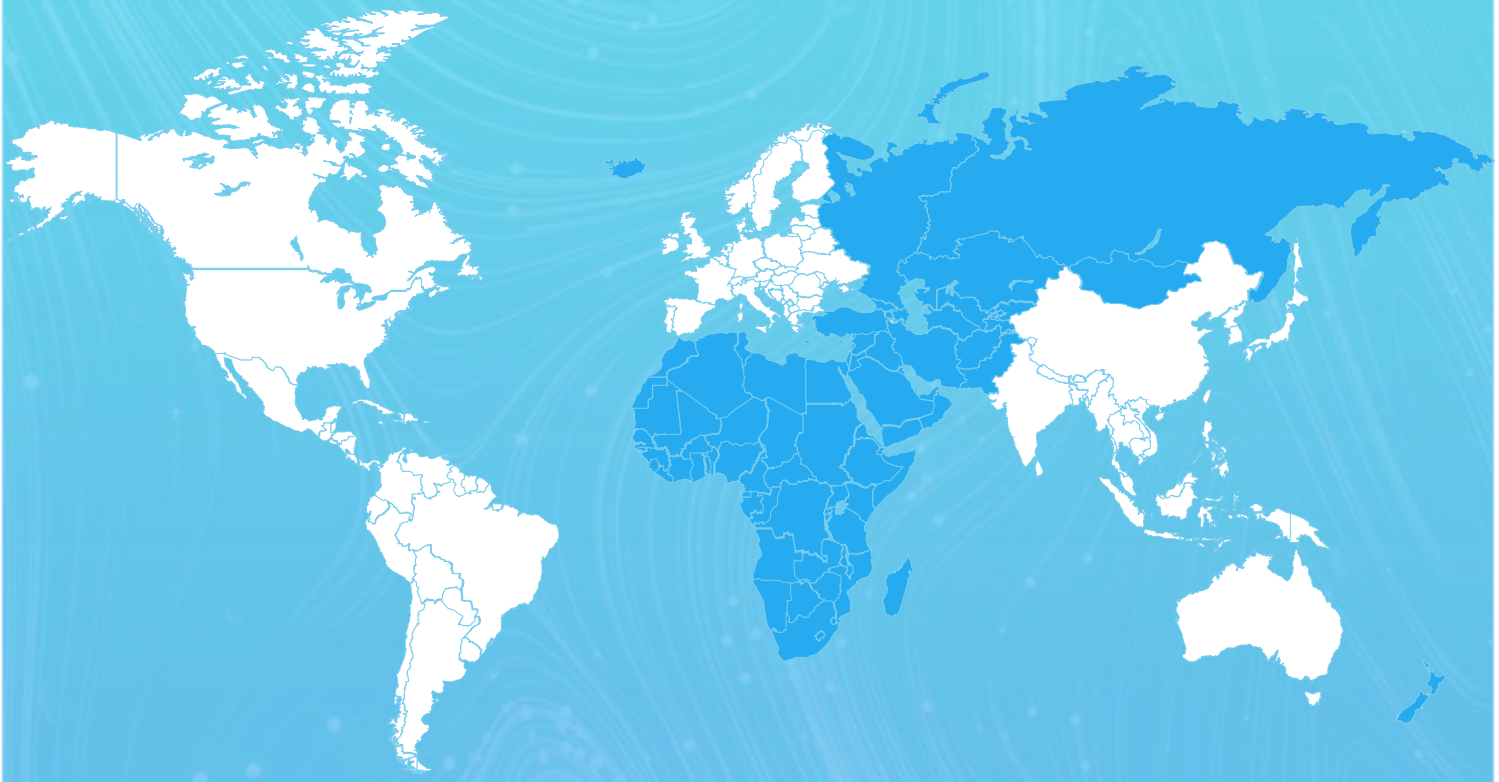
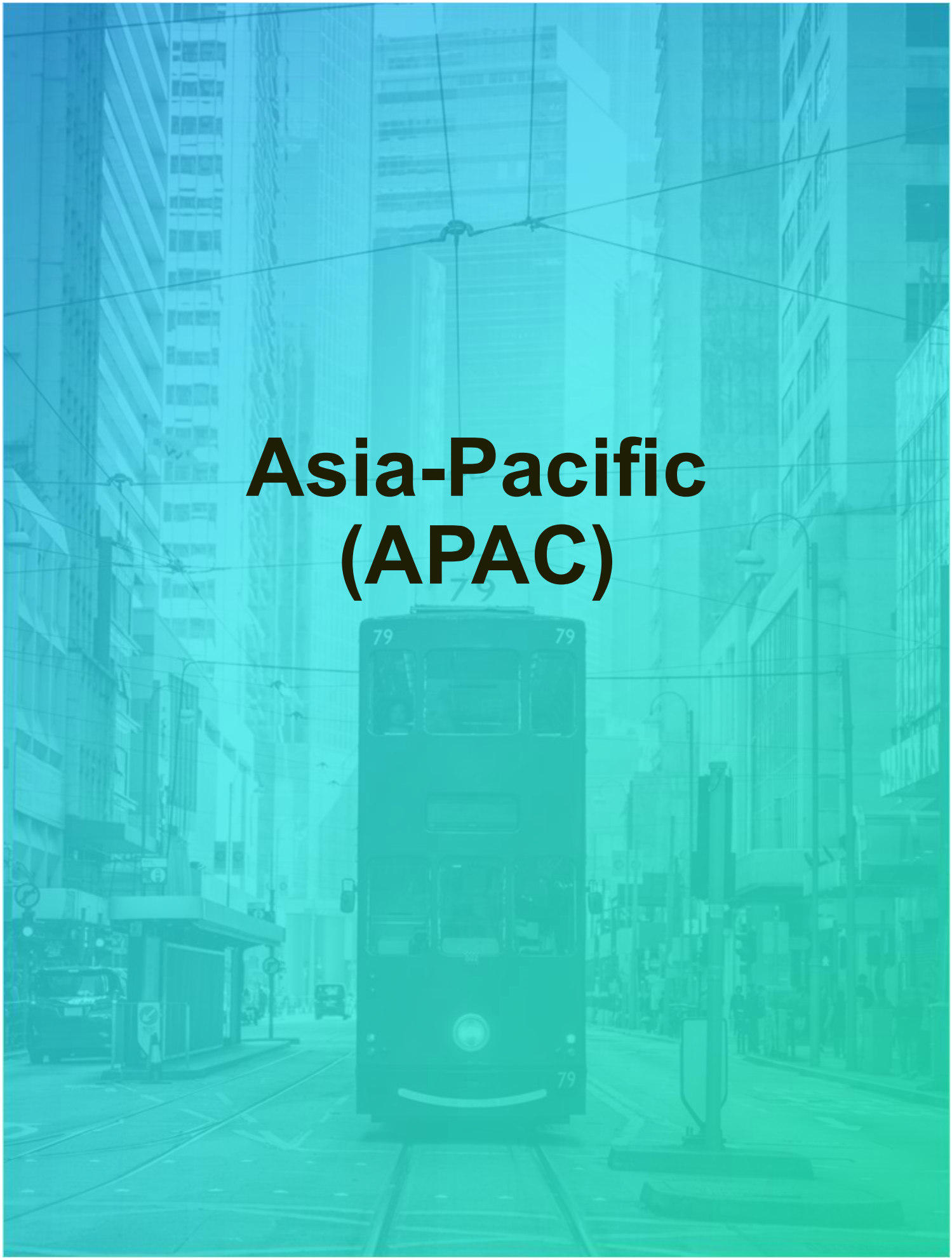




Asia-Pacific (APAC)

Australia

Partnering with PAGs is standard practice: Patient organizations are embedded across pharma, medtech, and healthcare communications, carrying significant credibility and influence, particularly in a small market where a handful of leading groups dominate most disease areas.

Funding competition is the primary barrier: Most PAGs rely on government grants and donations. Where multiple groups represent the same condition, competition for the same funding pools creates internal politics that can complicate joint initiatives.

Significant Pharmaceutical Benefits Scheme (PBS) advocacy role: PAGs play an active and influential role in PBS reimbursement processes through government submissions, public campaigns, and media activity, though their involvement in Therapeutic Goods Administration (TGA) safety approvals is more limited.

India

Engagement is growing but not yet standardized: Many companies are making patient-centric commitments, but the advocacy ecosystem remains immature. Most groups are informal, small, and disease-specific, with no consolidated cross-condition network.

Capacity and trust are the central barriers: Conflict-of-interest concerns on both sides, compliance uncertainty, and significant capability gaps within PAGs limit the depth of partnership. Geographic and socioeconomic diversity means urban voices dominate while rural and lower-income patients remain under-heard.

Regulatory momentum is building: The Digital Personal Data Protection (DPDP) Act, digital health IDs, and strengthened pharmacovigilance mechanisms with patient participation are reshaping the data and engagement landscape, even without dedicated patient experience guidance for drug approvals.

HTA involvement is consultative and uneven: Health Technology Assessment India (HTAIn) formally recognizes patients but late-stage engagement, absent standardized submission formats, and low technical capacity limit meaningful impact.

Singapore

Patient organizations as key partners: Engagement with patient groups is becoming essential for credibility and impactful communication, particularly in a tightly regulated and competitive market, but the practice is not as formalized when compared to the US or EU.

A structured but cautious environment: The Singapore Association of Pharmaceutical Industries' 2024 guidelines and Health Sciences Authority (HSA) anti-promotion rules create clear guardrails for pharma-PAG collaboration, reinforcing non-promotional conduct. This creates a structured but cautious environment where partnering with patient groups is standard practice but tightly governed.

Institutionalization of patient input is underway: The Agency for Care Effectiveness (ACE) has introduced clearer processes for PAG contributions on unmet need and lived experience, and national strategies on cancer, mental health, and rare diseases are embedding patient advocacy into policymaking, even without formal mandates.

South Korea

Engagement is strengthening, led by global companies: Many multinational pharma companies are now running patient-focused programs and involving patient groups in reimbursement discussions, driven in part by budget constraints within Korea's universal insurance system that give PAG voices influence over coverage decisions.

Formal inclusion exists but influence is limited: Some representative PAGs hold seats in reimbursement processes, though their role is not decisive. Ensuring groups receive accurate, balanced information remains a priority.

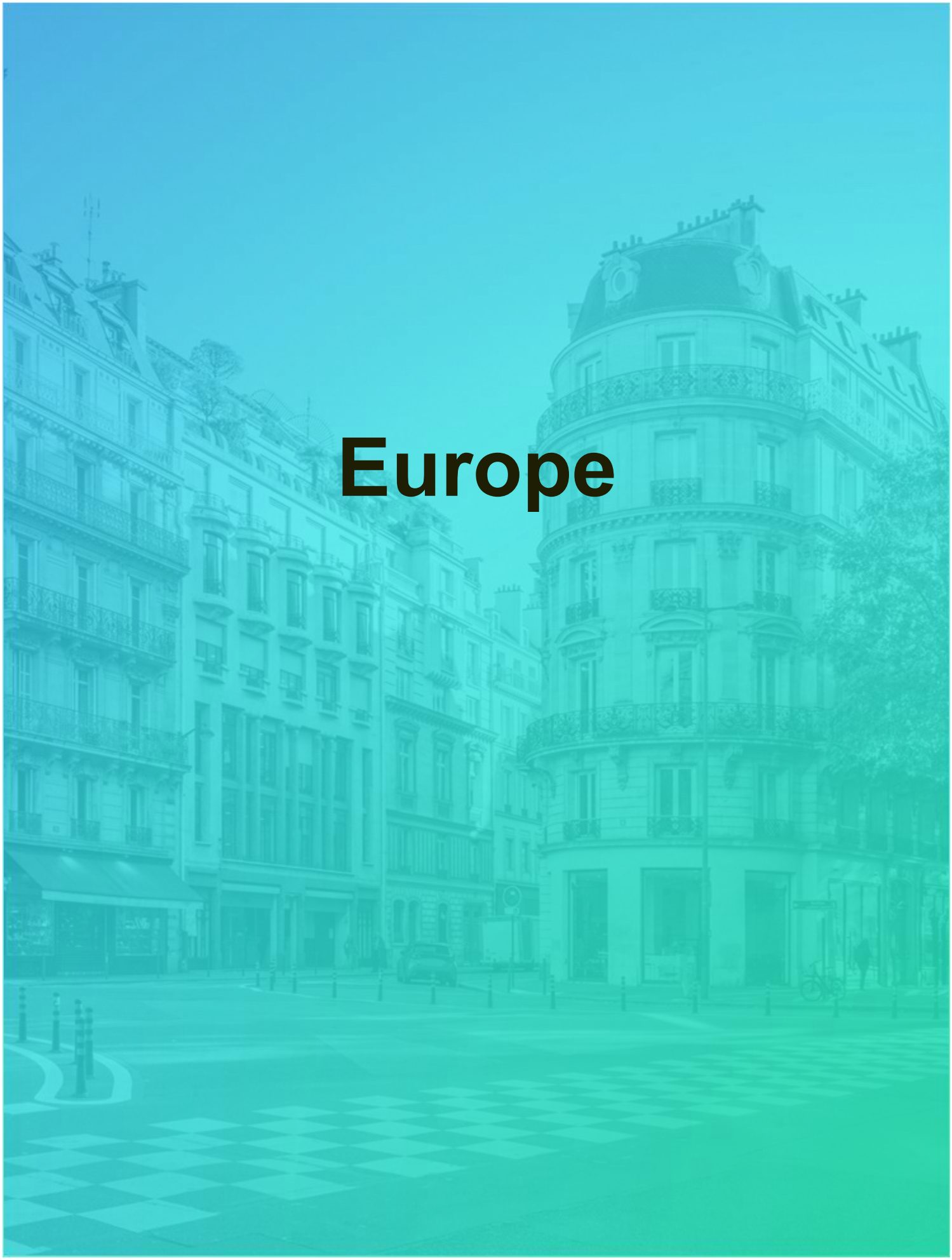
Taiwan

Advocacy is maturing from mere attendance to substantial partnership: Taiwanese PAGs play a crucial role in disease education and actively drive social initiatives like cancer patients' workplace rights. Under the National Health Insurance (NHI) system, PAGs voice perspectives via the "Patient Opinion Sharing Platform" and attend drug reimbursement meetings, making Taiwan a highly organized advocacy market in Asia.

Striving for early and formal HTA participation: Taiwanese PAGs face the risk of tokenism. Currently, patient representatives mostly serve in an observational capacity during key NHI reimbursement decisions without stable representation. Consequently, PAGs are strongly advocating for permanent, formal seats to ensure patients' lived experiences are integrated into Health Technology Assessments (HTA) and expert consultations earlier.

Policy influence expands beyond single diseases: The impact of PAGs is crossing disease-specific boundaries to drive national legislation. A prominent recent example is the collaborative push by patient groups and multiple stakeholders to institutionalize a multi-billion NTD "Cancer New Drug Fund." This aims to secure sustainable financing and accelerate patient access to innovative treatments.

Collaboration focuses on empowering "patient experts": To bridge the professional gap when communicating with medical authorities and the government, cross-disease coalitions are actively promoting educational training. These initiatives transform patients into knowledgeable "patient experts" equipped with a solid understanding of health policy, drug development, and health economics, enabling genuine, effective collaboration.


Europe

United Kingdom

Patient engagement and advocacy is widespread but cross-functional integration is still maturing: Pharma works closely with PAGs on panels, advisory boards, disease awareness campaigns, and patient-facing materials as standard practice. Companies are also beginning to integrate patient perspectives earlier, including clinical trial protocol design, though this still lags behind engagement at later stages in the development lifecycle. Embedding patient engagement as a true strategic discipline across clinical, medical, commercial, and communications functions remains a work in progress.

Tokenism and diversity gaps remain: Many companies are still in the habit of engaging patients for validation rather than genuine collaboration. Hard-to-reach and harder-to-treat voices are still underrepresented, and PAG capacity is under increasing pressure as funding becomes more competitive and AI summaries of health conditions drive traffic away from their trusted information.

Regulatory recognition of value is advancing: The Medicines and Healthcare products Regulatory Agency (MHRA) Patient Involvement Strategy has embedded patients across scientific advice, benefit-risk assessments, and post-market monitoring. A 2026-2030 plan is in development. The potential parallel MHRA-NICE review pathway creates new opportunities for earlier PAG contribution, with potential to reduce time to patient access by three to six months.

NICE and the Scottish Medicines Consortium (SMC) embed patient evidence formally: Lived experience, disease burden, and treatment acceptability are considered alongside clinical and economic data. The SMC's Patient and Clinician Engagement (PACE) meetings offer additional depth for rare and end-of-life conditions.

Switzerland

Patient-partnering is increasingly standard: The shift from passive patient roles to active co-creation is well underway, supported by Swissmedic's dedicated patient organization working group and the Pharma Cooperation Code's disclosure requirements.

Incremental formalization is underway: The International Council for Harmonisation (ICH) Guideline E22 consultation, concluding April 2026, will harmonize Patient Preference Study frameworks. The federal DigiSanté program is building patient-centered data infrastructure. Revisions to the Therapeutic Products Act (TPA) are strengthening digital traceability and safety monitoring.

HTA involvement is structured but constrained: Patient organizations feed into Federal Commission processes, specifically the Federal Medicines Commission (EAK) and the Federal Commission for Medical Benefits and Principles (ELGK), and the Federal Office of Public Health (FOPH) HTA program, though they face resource, technical, and multilingual barriers to consistent cross-regional representation.

Spain

Engagement is common but not yet fully standardized: Pharma companies regularly partner with PAGs for disease awareness, education, and support programs, though compliance concerns and uneven PAG maturity remain barriers.

A landmark legislative moment is approaching: The Draft Bill on Patient Organizations (Anteproyecto de Ley de Organizaciones de Pacientes) will formally define patient groups' roles, representativeness, and transparency obligations within the Spanish health system, a significant step toward structured, EU-aligned patient participation.

HTA involvement remains indirect: There are no fully standardized national mechanisms for patient input into reimbursement decisions. Engagement occurs mainly through advisory councils and public consultations.

ESG collaboration is broadening: Partnerships are increasingly extending beyond disease-specific topics to encompass health equity, patient access, and patient empowerment.

Romania

Strategic engagement is standard for multinationals, but fragmentation is a structural challenge: Members of the Romanian Association of International Medicine Manufacturers (ARPIM) have moved beyond transactional sponsorships, but the PAG landscape is fragmented and under-resourced, often requiring significant capacity-building investment before meaningful collaboration is possible.

The Cancer Plan set an important precedent: Law 293/2022 formally integrated PAGs into its design and technical working groups, the most significant policy development shaping patient engagement in Romania.

HTA involvement is consultative, not technical: Patient representatives hold seats on the Board of the National Health Insurance House (CNAS) but lack a voting role in clinical and economic scoring. A technical knowledge gap is still the primary barrier to more influential participation.

Portugal

Patient perspectives are increasingly recognized, but engagement remains cautious: In Portugal, pharma companies are increasingly engaging with patient organizations, mainly around disease awareness, education, and access. However, patient engagement is not yet standardized across the product lifecycle, and strict promotion rules continue to limit direct interaction with patients and PAGs.

Policy and regulation prioritize transparency over formal participation: Patient advocacy and engagement are shaped primarily by national oversight from INFARMED which tightly regulates pharma–PAG interactions, with a strong focus on transparency and non-promotional conduct. While patient involvement is expanding in areas such as research and policy dialogue, Portugal lacks a national framework to formally integrate patient-experience data into regulatory decision-making. Progress remains measured and EU-driven.

Patient involvement in HTA is present but not systematically embedded: HTA and reimbursement decisions are led by INFARMED, with patient input typically confined to consultations or broader advocacy efforts. Patient perspectives are not systematically embedded in HTA, and their impact on final decisions is often indirect, constrained by limited PAG resources and the complexity of HTA processes.

Engagement beyond therapy areas is emerging, particularly within ESG-related priorities: Partnerships beyond therapy areas are developing, particularly around social ESG priorities such as health equity, patient empowerment, and health literacy. These collaborations are still small-scale and short-term, reflecting regulatory caution and the absence of clear long-term engagement frameworks.

Germany

Patient focus meets strict regulations: In the German market, patient advocacy has evolved from a peripheral CSR activity into a core pharmaceutical strategy, heavily integrated into the development of (digital) health applications and clinical trials. However, a strong cultural commitment to patient rights clashes with stringent FSA regulations and strict advertising bans, making compliance highly complex.

Regulation is formalizing patient involvement: The 2026 regulatory landscape is rapidly shifting this dynamic. The Medical Research Act's focus on patient-reported outcomes, the national implementation of an electronic health record and the EU HTAR are forcing standardized, data-driven patient involvement.

Patient influence remains constrained in HTA: Within regulatory reimbursement processes, patients hold legal consultation rights but face an "influence ceiling." This is driven by a lack of formal voting power and an "expertise gap," as voluntary representatives must navigate highly technical data against well-resourced industry teams.

From disease focus to broader ESG impact: Collaborations are increasingly expanding into ESG priorities. Industry and advocacy groups now partner on "health equity" for diverse clinical trials, leverage strict transparency rules as a shared badge of credibility and address "green health" by focusing on the environmental footprint of pharmaceutical supply chains.

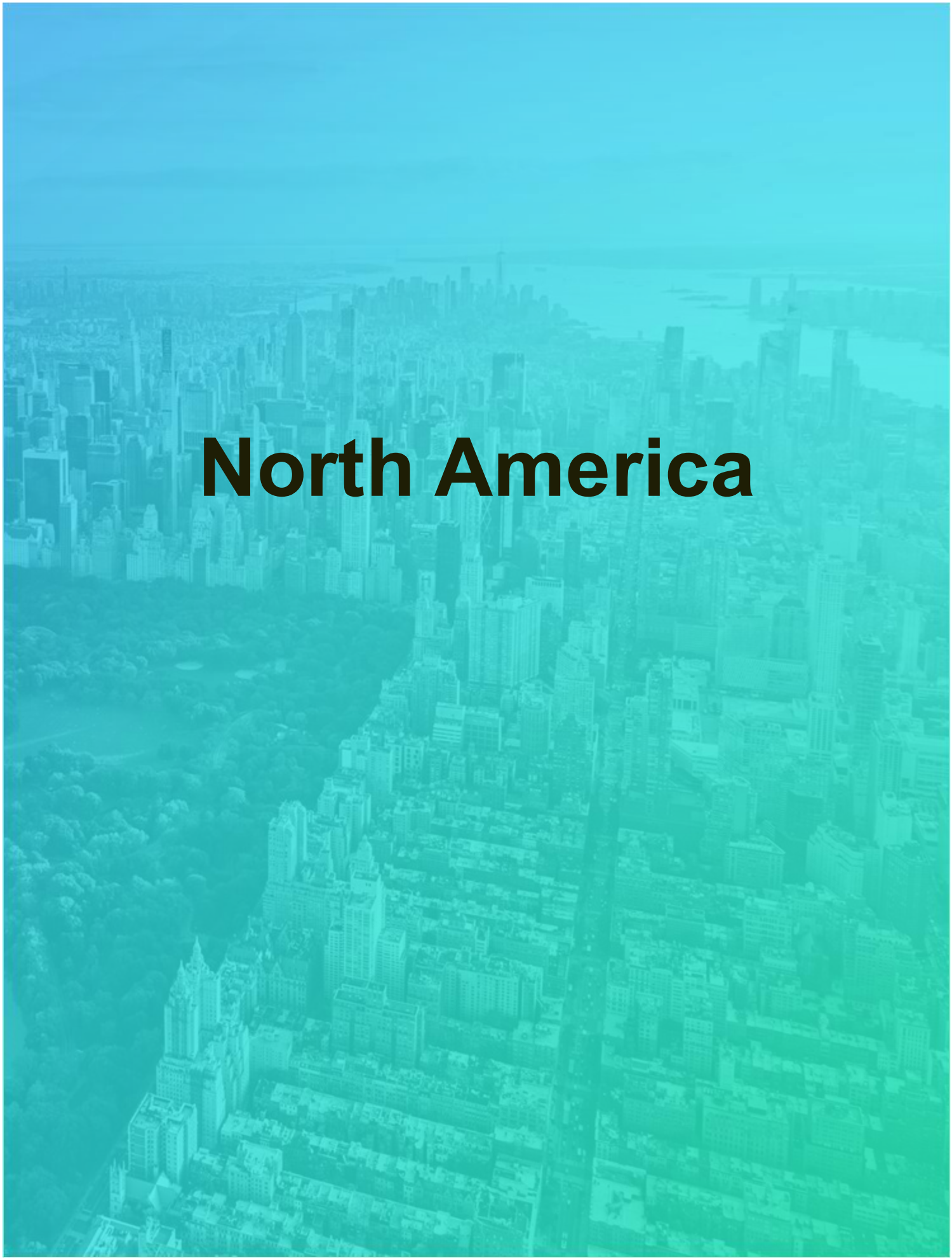
Italy

Patient engagement is well established but uneven in practice: Collaboration between pharmaceutical companies and patient organizations is increasingly common, particularly in oncology, rare diseases, and chronic conditions. Engagement typically includes disease awareness, patient support programs, advisory boards, and input into clinical or access strategies. However, activity remains highly compliance-driven and varies by company and therapy area, with patient involvement still largely consultative rather than co-decisional.

Regulatory and policy frameworks are strengthening formal recognition: The Farmindustria Code of Conduct provides a clear framework for pharma–PAG interactions, emphasizing transparency, written agreements, and non-promotional intent. Recent policy developments, including the Ministry of Health's 2022 Act of Guidance and the creation of the national patient organization registry (RUAS), have further institutionalized the role of patient groups. While these measures increase legitimacy and structure, participation remains primarily advisory.

Patient input in HTA is growing, but integration is limited: Patient organizations engage with AIFA and other stakeholders through consultations, dialogue initiatives, and the sharing of patient experience and real-world insights. The EU HTA Regulation, effective from 2025, is expected to elevate the role of patient evidence over time. However, patient input is not yet systematically embedded in HTA or reimbursement decisions, constrained by inconsistent methodologies, variable PAG expertise, limited resources, and unclear impact on final outcomes.

Broader ESG collaboration is emerging, with a focus on social impact: Beyond therapy-specific engagement, companies and PAGs are increasingly collaborating on social ESG priorities such as health equity, health literacy, and access disparities. These initiatives remain largely project-based and early-stage. More advanced ESG partnerships—particularly in environmental or governance areas—are still limited, reflecting regulatory caution and the absence of fully scaled, long-term collaboration models.



North America

Canada

Patient engagement is now broadly expected in Canada:
Patient perspectives are routinely incorporated across the product lifecycle, particularly in rare disease, oncology, and chronic conditions. Partnerships with patient organizations are common in clinical development, HTA submissions, and access planning, though smaller or emerging groups continue to face capacity and funding constraints.

Canada's HTA landscape is evolving:
Since CADTH's transition to Canada's Drug Agency (CDA) in 2024, patient input remains a formal component of HTA reviews, with growing emphasis on patient-reported outcomes and real-world evidence. Despite increased recognition of lived experience, there is still no unified national mandate for patient engagement across the full drug lifecycle.

Patient input is structured but influence is uneven:
Patient organizations primarily contribute through formal submissions and advisory mechanisms within CDA-led HTA processes. Their impact is strongest in areas of high unmet need, but is limited by resourcing gaps, tight timelines, and limited transparency on how patient evidence affects final decisions—particularly beyond HTA into price negotiations and provincial reimbursement.

Collaboration beyond therapy areas is emerging:
Engagement on ESG-related priorities such as health equity, access disparities, and Indigenous health is growing but remains largely project-based. Regulatory caution, funding limitations, and unclear guardrails continue to restrict broader, long-term strategic partnerships in the Canadian market.

United States

Pharma-patient engagement is deeply embedded: Manufacturers routinely engage patient advocacy organizations across the development and commercialization lifecycle, though financial relationships require careful governance to manage real or perceived conflicts of interest.

Regulatory recognition of patient experience is established: The FDA's Patient-Focused Drug Development initiative formally embeds patient input across the regulatory lifecycle, supported by the Patient Engagement Advisory Committee, the Patient Representative Program, and structured listening sessions.

Transparency legislation is on the horizon: The proposed Open Payments Expansion Act would extend financial reporting requirements to cover patient advocacy organizations, reflecting growing congressional scrutiny of pharma-PAG relationships.

HTA and reimbursement involvement is informal and decentralized: Engagement occurs through the Institute for Clinical and Economic Review (ICER), Centers for Medicare and Medicaid Services (CMS) public comment processes, and Patient-Centered Outcomes Research Institute (PCORI)-funded research, but without formal mandates for systematic participation, impact on coverage decisions remains uneven.

Latin America (LATAM)

Brazil

PAG engagement is standard and strategically embedded: Particularly in oncology and rare diseases, dedicated Advocacy functions manage relationships with patient organizations in compliance with guidelines from Interfarma, the association representing research-based pharmaceutical companies in Brazil.

PAGs are influential in policy and reimbursement: Patient organizations are particularly influential in government decision-making, engaging in significant advocacy efforts with members of Congress and regularly meeting with local authorities and the Federal Government to discuss new technologies and public health policies. Some organizations have a strong and established presence within the National Health Council.

Colombia

Patient advocacy is gaining formal regulatory weight: The Institute for Health Technology Assessment (Instituto de Evaluación Tecnológica en Salud, or IETS) now mandates structured patient experience evidence, including Patient-Reported Outcomes and Experiences (PROMs/PREMs), caregiver input, and direct patient submissions, in technology assessments and reimbursement deliberations.

Formal but not yet fully influential: Clear frameworks for participation exist, but PAG impact on HTA decisions depends heavily on organizational capacity. Limited technical expertise, short timelines, digital access gaps, and the absence of standardized local PROMs/PREMs all constrain real-world influence.

A significant awareness gap remains: Despite the progress in regulatory frameworks, Colombia still lacks widespread public education about participatory mechanisms such as PROMs, PREMs, and patient submissions. Strengthening community knowledge about these tools is essential to ensure regulatory advances translate into meaningful and equitable patient involvement.

Big pharma community programs are filling system gaps: Amid a national medicines shortage and systemic financial pressure, companies have implemented targeted access, education, and support initiatives. These programs have strengthened the perceived value of the pharmaceutical industry and demonstrated that genuine engagement requires understanding what each community truly needs.

Argentina

Engagement is common but uneven: Multinational companies tend to have more structured PAG relationships than local companies. Oncology and rare disease organizations are generally the most developed, having built capacity largely with industry support.

No formal patient organizations law exists: PAGs must operate as registered non-profit civil associations. The Argentine Chamber of Specialized Medicines (Cámara Argentina de Especialidades Medicinales, or CAEME) Code of Good Practices governs industry interaction, though conflict-of-interest declaration requirements are not always consistently followed in practice.

Patient organization contributions are growing but remain non-binding: Argentina still largely operates under a physician-centered approach in its health system. Nevertheless, there have been advances in patient organization participation, including inclusion in discussion tables with health authorities, requests from industry for input on patient support programs, and acceptance of suggestions on communication design for clinical trials. These contributions are generally non-binding, however.

ANEFITS marks a significant structural shift: The new National Agency for the Evaluation of Financing of Health Technologies (Agencia Nacional de Evaluación del Financiamiento de Tecnologías en Salud, or ANEFITS) will assume the functions of the former National Commission for Health Technology Assessment and Clinical Excellence (CONETEC) and conduct comprehensive technology evaluation before commercialization. Still in implementation phase, its implications for formal patient organization participation are yet to be determined.

Mexico

Engagement is standard in high-cost therapy areas: PAG partnerships in oncology, rare diseases, and HIV are well-established, typically managed through Advocacy or Public Affairs to ensure compliance. Uneven PAG maturity and fragmented representation remain the main barriers.

Regulatory formalization is nascent but moving: The Ibero-Latin American Federation of the Pharmaceutical Industry (Federación Ibero-Latinoamericana de la Industria Farmacéutica, or FIFARMA) regional guidance is becoming a reference framework for governing pharma-PAG relationships. Formal recognition of patient voices is being discussed through public consultations and health system reform processes.

HTA involvement is informal: Mexico's HTA landscape is still evolving. PAGs participate primarily through submissions, public pressure, and legislative engagement rather than formal seats at the table with key barriers being lack of a standardized HTA processes, limited data access, and varying levels of technical capacity within PAGs.

Chile

Patient advocacy is embedded in public affairs strategy: Since approximately 2010, relations with patient organizations have been standard practice. The Ministry of Health now includes patient groups in round tables and public policy development, making joint working on public affairs, not just awareness campaigns, an expectation for pharma.

Patient organizations carry formal responsibilities: Groups are increasingly expected to collect patient data, map patient journeys, and serve as credible counterparts to health authorities and medical associations.

GHMC's global network of local and regional healthcare specialists translates these insights into strategies that help healthcare organizations engage patients and advocacy communities with clarity, relevance, and impact.

Discover more at ghmcnetwork.com