



Index of regulations and laws

4 Index of laws regulations and related frameworks

This index identifies principal instruments for organisational governance, funding, medicines communications, information and research. It is not an exhaustive legal catalogue. Columns indicate main relevance, not exclusive responsibility. Medicines rules may affect patient organisations; privacy, anticorruption and contract requirements may affect both partners. Legal form, charitable status, tax relief, fundraising permission and donation receipts are separate matters.

4.1 EU framework

The EU has no single charity law governing patient organisations across Member States. National governance and tax rules remain important. The following instruments provide a shared layer for relevant activities.

Instrument	Relevance
Directive 2001/83/EC (2001)	Human medicines, advertising and pharmacovigilance; read with national implementation.
Regulation (EC) No. 726/2004 (2004)	Centralised authorisation and EMA responsibilities.
Regulation (EU) 2016/679 (2016)	GDPR, including health information, responsibilities and transfers.
Regulation (EU) No. 536/2014 (2014)	Clinical trials; patient engagement is not automatically a trial.
Regulation (EU) 2021/2282 (2021)	EU HTA processes and relevant participation arrangements.

Separate frameworks include the EFPIA Code, EMA eligibility and interests policies and Commission HTA participation procedures. Establish applicability independently of legislation.

4.2 Europe

United Kingdom

Area	Instruments and checks
Governance	Charities Act 2011, as amended, England and Wales; Charities and Trustee Investment (Scotland) Act 2005; Charities Act (Northern Ireland) 2008; legal-form-specific company, trust and association law.
Pharmaceutical	Human Medicines Regulations 2012; applicable clinical-trial legislation.
Both partners	UK GDPR; Data Protection Act 2018, as amended; Bribery Act 2010.
Separate frameworks	ABPI Code, PMCPA guidance, MHRA and relevant HTA procedures.

Check territorial extent, amendments and commencement for the specific activity (Charities Act 2011, 2011; Human Medicines Regulations 2012, 2012).

France

Area	Instruments and checks
Governance	Law of 1 July 1901 on associations and implementing decree; Alsace-Moselle local association law where applicable; relevant tax provisions.
Pharmaceutical	Public Health Code, including Articles L.5122-1 onward on advertising.
Funding and representation	Public Health Code Article L.1114-1 on accreditation; L.1453-1 on transparency; L.1453-3 onward on benefits controls according to scope.
Both partners	GDPR; Law No. 78-17, as amended; relevant anticorruption provisions.
Separate frameworks	Leem provisions and Q&A; ANSM and HAS procedures.

Transparency, benefits controls and accreditation are distinct assessments (Code de la santé publique, n.d.).

Germany

Area	Instruments and checks
Governance and tax	BGB; applicable foundation laws; Abgabenordnung, particularly public-benefit provisions.
Pharmaceutical	Arzneimittelgesetz; Heilmittelwerbe-gesetz.
Self-help and participation	Social Code Book V, §§ 20h and 140f; Patient Participation Ordinance.
Both partners	GDPR; Bundesdatenschutzgesetz; applicable criminal and anticorruption provisions.
Separate frameworks	FSA Code; current GKV funding guidance; G-BA procedures.

Public-benefit tax status and self-help funding eligibility require separate checks (Abgabenordnung, 1976; Heilmittelwerbe-gesetz, 1965).

Netherlands

Area	Instruments and checks
Governance	Civil Code Book 2; governance provisions introduced through the Wet bestuur en toezicht rechtspersonen.
Tax	Applicable tax laws and ANBI requirements; ANBI is not a legal form.
Pharmaceutical	Geneesmiddelenwet and implementing advertising and inducement rules.
Both partners	GDPR and its Dutch implementing Act.

Area	Instruments and checks
Separate frameworks	Current CGR Code, transparency register rules, CBG-MEB and Zorginstituut procedures.

Association, foundation and ANBI status are different categories (Netherlands Enterprise Agency, n.d.).

Sweden

Area	Instruments and checks
Governance and tax	Applicable association principles and statutes; Foundations Act (1994:1220); Income Tax Act (1999:1229).
Pharmaceutical	Medicines Act (2015:315); Medicines Ordinance (2015:458); agency regulations; Marketing Act (2008:486).
Both partners	GDPR; supplementary Act (2018:218).
Separate frameworks	Lif rules effective February 2026; funding conditions; TLV and medicines-authority procedures.

Check actual form and funding conditions rather than assume a UK-style charity model (Läkemedelslag, 2015).

Switzerland

Area	Instruments and checks
Governance and tax	Civil Code, arts. 60–79 on associations and 80 onward on foundations; federal and cantonal tax rules.
Pharmaceutical	Therapeutic Products Act, SR 812.21; Advertising Ordinance, SR 812.212.5; relevant integrity/transparency instruments.
Both partners	Federal Act on Data Protection and ordinance; relevant research and anticorruption law.
Separate frameworks	Pharma Cooperation Code, Pharma Code, Swissmedic and access procedures.

Assess Swiss law independently of EU implementation (Federal Office of Public Health, n.d.).

Poland

Area	Instruments and checks
Governance	Law on Associations (1989); Foundations Act (1984); Public Benefit Activity and Volunteer Work Act (2003).
Pharmaceutical	Pharmaceutical Law (2001), implementing advertising rules; Reimbursement Act (2011).
Both partners	GDPR; Personal Data Protection Act (2018).
Separate frameworks	INFARMA September 2026 Code; Ombudsman listing; AOTMiT procedures.

Check amendments after the 2026 consolidated pharmaceutical text (Pharmaceutical Law, 2001).

Italy

Area	Instruments and checks
Governance	Civil Code; Legislative Decree 117/2017, Third Sector Code, where applicable; RUNTS rules.
Pharmaceutical	Legislative Decree 219/2006.
Both partners	GDPR; Legislative Decree 196/2003, as amended; Legislative Decree 231/2001 where applicable.
Transparency check	Law 62/2022, including implementing and commencement arrangements.
Separate frameworks	Farindustria September 2026 Code; AIFA procedures.

Spain

Area	Instruments and checks
Governance and tax	Organic Law 1/2002; Foundations Law 50/2002; Law 49/2002 on nonprofit taxation and patronage; applicable regional laws.
Pharmaceutical	Royal Legislative Decree 1/2015; Royal Decree 1416/1994 on advertising, as amended.
HTA	Royal Decree 415/2026 and transitional arrangements.
Both partners	GDPR; Organic Law 3/2018.
Separate frameworks	Farindustria Code; national and regional participation.

Check regional governance and staged HTA implementation (Ley 50/2002, 2002; Real Decreto Legislativo 1/2015, 2015).

Belgium

Area	Instruments and checks
Governance	Companies and Associations Code (2019).
Pharmaceutical	Medicines Law of 25 March 1964; Royal Decree of 7 April 1995 on information and advertising; implementing rules.
Transparency	Law of 18 December 2016, relevant Sunshine provisions; Royal Decree of 14 June 2017.
Both partners	GDPR; Law of 30 July 2018.
Separate frameworks	pharma.be Code; beTransparent procedures; INAMI/RIZIV participation.

Governance and statutory disclosure are separate responsibilities (Belgian Federal Public Service Justice.).

Türkiye

Area	Instruments and checks
Governance and funding	Civil Code 4721; Associations Law 5253; Foundations Law 5737; Collection of Aid Law 2860 where applicable.
Pharmaceutical	Law 1262; 2015 Regulation on Promotional Activities for Human Medicinal Products, as amended.
Both partners	Personal Data Protection Law 6698, including amended sensitive-data and transfer provisions.
Separate frameworks	Applicable AIFD Code; TİTCK and reimbursement procedures.

Check amended privacy provisions (KVKK, n.d.-a).

4.3 Americas

United States

Area	Instruments and checks
Governance and tax	State nonprofit corporation, charitable trust and solicitation laws; Internal Revenue Code, including § 501(c)(3) where applicable.
Pharmaceutical	Federal Food, Drug, and Cosmetic Act; relevant Title 21 CFR advertising, research and safety rules.
Assistance and funding	Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); False Claims Act and beneficiary-inducement provisions where applicable.
Privacy and transparency	HIPAA and implementing rules where applicable; state privacy laws; Open Payments, 42 U.S.C. § 1320a-7h and 42 CFR Part 403, where applicable.
Separate frameworks	PhRMA principles; OIG assistance guidance; FDA procedures.

Federal exemption does not replace state registration; HIPAA and Open Payments have defined scopes (IRS, n.d.-a; HHS, n.d.; CMS, n.d.).

Canada

Area	Instruments and checks
Governance and tax	Income Tax Act; Canada Not-for-profit Corporations Act where federally incorporated; provincial charity, incorporation and trust laws.
Pharmaceutical	Food and Drugs Act; Food and Drug Regulations.
Both partners	PIPEDA where applicable; provincial privacy and health-information laws; relevant lobbying and election laws.
Separate frameworks	IMC Code; Health Canada guidance; national and provincial assessment, including Québec-specific arrangements.

Check federal and provincial responsibilities and uncommenced amendments (Food and Drugs Act, 1985; Food and Drug Regulations, 1978).

Brazil

Area	Instruments and checks
Governance	Civil Code, Law 10.406/2002; Law 13.019/2014 for covered public partnerships.
Pharmaceutical	Law 6.360/1976; Law 9.294/1996; applicable ANVISA rules.
Both partners	LGPD, Law 13.709/2018; Anticorruption Law 12.846/2013 where applicable.
Separate frameworks	INTERFARMA Code; Conitec participation and interests procedures.

Governance and health-data requirements need separate assessment (Código Civil, 2002; ANPD, 2026).

Mexico

Area	Instruments and checks
Governance and tax	Applicable civil codes and state private-assistance law; Federal Civil Society Activities Promotion Law; income-tax provisions.
Pharmaceutical	General Health Law; Health Supplies Regulation; health advertising regulation.
Both partners	Private-sector Personal Data Protection Law (2025); applicable anticorruption law.
Separate frameworks	CIETEMIS; COFEPRIS and institutional access procedures.

Incorporation, civil-society registration and tax treatment are distinct (Ley Federal de Fomento a las Actividades Realizadas por Organizaciones de la Sociedad Civil, 2004).

Argentina

Area	Instruments and checks
Governance	Civil and Commercial Code, Law 26.994; provincial or Buenos Aires registration rules.
Pharmaceutical	Medicines Law 16.463; Decree 150/1992; operative ANMAT provisions.
Both partners	Personal Data Protection Law 25.326 and Decree 1558/2001; organisational-liability Law 27.401 where applicable.
Separate frameworks	Applicable CAEMe Code; ANMAT and current assessment-body procedures.

The Code distinguishes civil associations, simple associations and foundations (Código Civil y Comercial, 2014).

4.4 Asia and Middle East

China mainland

Area	Instruments and checks
Domestic organisations	Civil Code; Charity Law revised 2023, effective September 2024; applicable organisation and foundation regulations.
Fundraising and overseas NGOs	Public Fundraising Measures (2024); Overseas NGO Law (2016).
Pharmaceutical	Drug Administration Law revised 2019; implementing regulations; Advertising Law.
Both partners	PIPL; Data Security Law; cybersecurity and transfer requirements.
Separate frameworks	Applicable industry commitments and confirmed RDPAC succession; CDE/NMPA guidance.

Registration, public fundraising and overseas activity are distinct (Drug Administration Law, 2019; Overseas NGO Law, 2016).

Japan

Area	Instruments and checks
Governance	Act on Promotion of Specified Non-profit Activities; General Incorporated Associations and Foundations Act; public-interest authorisation legislation.
Pharmaceutical	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, Act 145/1960, as amended.
Both partners	Act on Protection of Personal Information; relevant clinical-research laws.
Separate frameworks	JPMA and company implementation guidelines; PMDA procedures.

Singapore

Area	Instruments and checks
Governance	Charities Act 1994 and relevant registration, accounts, IPC and fundraising regulations; Societies or Companies Act according to form.
Pharmaceutical	Health Products Act 2007; Therapeutic Products Regulations; Advertisement of Specified Health Products Regulations.
Both partners	Personal Data Protection Act 2012; Prevention of Corruption Act.
Separate frameworks	SAPI Code and guidance; HSA and ACE procedures.

Registration, reporting and fundraising have distinct subsidiary requirements (Commissioner of Charities, n.d.-b).

India

Area	Instruments and checks
Governance	Applicable society laws, state public-trust law or Companies Act 2013, § 8.
Funding and tax	FCRA 2010 and Rules; tax provisions; Companies Act § 135 and CSR Rules where relevant.
Pharmaceutical	Drugs and Cosmetics Act 1940 and Rules; Drugs and Magic Remedies Act 1954; New Drugs and Clinical Trials Rules 2019.
Privacy	Applicable IT/privacy provisions and DPDP Act 2023 framework, subject to operative commencement.
Separate government framework	UCPMP 2024, as amended; not an ordinary voluntary industry code.

South Korea

Area	Instruments and checks
Governance	Civil Act nonprofit provisions; applicable public-interest, nonprofit and donation-collection legislation.
Pharmaceutical	Pharmaceutical Affairs Act and implementing rules.
Both partners	Personal Information Protection Act; applicable anticorruption and improper-solicitation legislation.
Separate frameworks	Current KRPIA/KPBMA fair-competition arrangements; MFDS, HIRA and NHIS procedures.

Taiwan

Area	Instruments and checks
Governance	Civil Code; Civil Associations Act; Foundations Act; applicable public-benefit fundraising law.
Pharmaceutical	Pharmaceutical Affairs Act and implementing and advertising rules.
Both partners	Personal Data Protection Act; applicable research and anticorruption law.
Separate frameworks	IRPMA Code; TFDA and NHIA/CDE procedures.

Check commencement separately from adoption dates (Civil Associations Act, 1989, as amended; Pharmaceutical Affairs Act, 1970, as amended).

Saudi Arabia

Area	Instruments and checks
Governance and funding	Civil Society Associations and Organisations Law and implementing regulations; NCNP fundraising and foreign-funding requirements; banking rules.
Pharmaceutical	Current Pharmaceutical and Herbal Establishments and Preparations Law, implementing regulations and SFDA advertising requirements.
Both partners	PDPL and implementing/transfer regulations; applicable anticorruption law.
Authority frameworks	SFDA promotional Code and patient guidance, not private association codes.

4.5 Oceania and Africa

Australia

Area	Instruments and checks
Governance and tax	ACNC Act 2012 and Regulations; Charities Act 2013; legal-form incorporation law; income-tax/DGR provisions.
Fundraising	Applicable state and territory legislation and arrangements.
Pharmaceutical	Therapeutic Goods Act 1989; Regulations 1990; applicable advertising instruments.
Both partners	Privacy Act 1988; relevant state/territory health-records and research requirements.
Separate frameworks	Medicines Australia Edition 20; TGA and PBAC procedures.

New Zealand

Area	Instruments and checks
Governance	Charities Act 2005; Incorporated Societies Act 2022; Charitable Trusts Act 1957 according to form.
Pharmaceutical	Medicines Act 1981; Medicines Regulations 1984.
Both partners	Privacy Act 2020; Health Information Privacy Code 2020 where applicable; research requirements.
Separate frameworks	Edition 17 plus operative replacement and supplementary guidance; Medsafe and Pharmac procedures.

South Africa

Area	Instruments and checks
Governance	NPO Act 71/1997; Companies Act 71/2008 for NPCs; Trust Property Control Act 57/1988 for trusts.
Tax and donations	Income Tax Act 58/1962, including §§ 30 and 18A where applicable.
Pharmaceutical	Medicines and Related Substances Act 101/1965 and General Regulations.
Both partners	POPIA 4/2013; National Health Act 61/2003 for relevant research; applicable anticorruption law.
Separate frameworks	MCA Version 19; SAHPRA and EML procedures.

NPO registration, PBO approval and section 18A eligibility require separate checks (SARS, n.d.).

6 References

- Abgabenordnung [Fiscal Code] (Germany). (1976, as amended).
- Administración Nacional de Medicamentos, Alimentos y Tecnología Médica. (n.d.-a). *Formulario de comunicación con las asociaciones de pacientes sobre estudios de farmacología clínica regulados por ANMAT* [Patient-association communication form concerning regulated clinical pharmacology studies].
- Administración Nacional de Medicamentos, Alimentos y Tecnología Médica. (n.d.-b). *Opinión pública* [Public opinion].
- Agency for Care Effectiveness. (n.d.). *Opportunities for patient involvement*.
- Agenzia Italiana del Farmaco. (n.d.). *AIFA Ascolta*.
- Argentine Ministry of Health. (2026). *Participación ciudadana* [Citizen participation].
- Association of Research-Based Pharmaceutical Companies. (2023). *Code of good promotional practice (Edition 8.01)*.
- Association of the British Pharmaceutical Industry. (2024). *ABPI code of practice for the pharmaceutical industry 2024*.
- Australian Charities and Not-for-profits Commission. (n.d.). *Deductible gift recipients (DGR) and the ACNC*.
- Australian Government Department of Health, Disability and Ageing. (2026). *Public consultation on items to be considered by the PBAC: March 2026*.
- Autoridade Nacional de Proteção de Dados. (2026, September 9). *Perguntas frequentes* [Frequently asked questions].
- Belgian Federal Public Service Justice. (n.d.). *ASBL* [Nonprofit associations].
- beTransparent. (n.d.). *Frequently asked questions*.
- Cámara Argentina de Especialidades Medicinales. (2018, December). *Código de buenas prácticas* [Code of good practice].
- Canada Revenue Agency. (2020, November 27). *Public policy dialogue and development activities by charities (Guidance CG-027)*.
- Canada Revenue Agency. (n.d.). *Differences between a registered charity and a non-profit organization*.
- Center for Drug Evaluation [China]. (2022, November 21). *() [General considerations for organising patient participation in drug development (trial)]*.
- Center for Drug Evaluation [Taiwan]. (2025). *Annual report 2024*.
- Centers for Medicare & Medicaid Services. (n.d.). *Open Payments program participants*.
- Charities Act 2011, c. 25 (UK). (2011, as amended).
- Charity Commission for England and Wales. (2026, April 22). *Identifying and managing conflicts of interest in a charity*.
- Civil Associations Act (Taiwan). (1989, as amended).
- Code de la santé publique [Public Health Code] (France). (n.d., as amended).
- Código Civil, Lei No. 10.406 [Civil Code] (Brazil). (2002, as amended).
- Código Civil y Comercial de la Nación, Ley No. 26.994 [Civil and Commercial Code] (Argentina). (2014, as amended).
- Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde. (2026, April 30). *Orientações: Perspectiva do paciente* [Guidance: Patient perspective].
- Commissioner of Charities. (n.d.-a). *About IPCs*.
- Commissioner of Charities. (n.d.-b). *Legislations governing charities and IPCs*.
- Companies Office. (n.d.). *How recent law changes affect incorporated societies*.
- Consejo de Ética y Transparencia de la Industria Farmacéutica. (2021). *Código de integridad, ética y transparencia de empresas de insumos para la salud* [Code of integrity, ethics and transparency for companies providing healthcare products].

Council for International Organizations of Medical Sciences. (2022). *Patient involvement in the development, regulation and safe use of medicines*.

Decreto Legislativo No. 117, Codice del Terzo settore [Third Sector Code] (Italy). (2017, as amended).

Decreto Legislativo No. 219, Human medicines legislation (Italy). (2006, as amended).

Department of Pharmaceuticals. (n.d.). *Portal for Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024*.

Drug Administration Law of the People's Republic of China. (2019 revision).

European Federation of Pharmaceutical Industries and Associations. (n.d.). *Patient organisations*.

European Medicines Agency. (n.d.). *Handling competing interests*.

European Parliament & Council of the European Union. (2001). *Directive 2001/83/EC on the Community code relating to medicinal products for human use. Official Journal of the European Communities, L 311, 67–128*.

European Parliament & Council of the European Union. (2004). *Regulation (EC) No. 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products and establishing a European Medicines Agency. Official Journal of the European Union, L 136, 1–33*.

European Parliament & Council of the European Union. (2014). *Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use. Official Journal of the European Union, L 158, 1–76*.

European Parliament & Council of the European Union. (2016). *Regulation (EU) 2016/679 (General Data Protection Regulation). Official Journal of the European Union, L 119, 1–88*.

European Parliament & Council of the European Union. (2021). *Regulation (EU) 2021/2282 on health technology assessment. Official Journal of the European Union, L 458, 1–32*.

Farmaindustria. (n.d.-a). *Collaborations with patient organisations*.

Farmaindustria. (n.d.-b). *Código de buenas prácticas: Interrelación con organizaciones de pacientes [Code of practice: Interactions with patient organisations]*.

Farmaindustria. (n.d.-c). *Código de buenas prácticas: Section 18.7, colaboraciones [Code of practice: Collaborations]*.

Farmaindustria. (2026, September 14). *Codice deontologico [Code of ethics]*.

Federal Data Protection and Information Commissioner. (n.d.). *Data protection in clubs and associations*.

Federal Office of Public Health. (n.d.). *Medicinal products and medical devices legislation*.

Food and Drug Regulations, C.R.C., c. 870 (Canada). (1978, as amended).

Food and Drugs Act, R.S.C., c. F-27 (Canada). (1985, as amended).

Freiwillige Selbstkontrolle für die Arzneimittelindustrie. (n.d.). *Kodex zur Zusammenarbeit mit Patientenorganisationen [Code on collaboration with patient organisations]*.

Gemeinsamer Bundesausschuss. (n.d.). *Patientenbeteiligung [Patient participation]*.

GKV-Spitzenverband. (2025, June 16). *Leitfaden zur Selbsthilfeförderung [Guidance on self-help funding; effective January 1, 2026]*.

Haute Autorité de Santé. (2026, April 3). *Contribuer à l'évaluation des médicaments en vue de leur remboursement ou d'une autorisation d'accès précoce [Contributing to medicine reimbursement or early-access assessment]*.

Health Canada. (2023). *Guidance on distinction between advertising and other activities for health products*.

Health Insurance Review and Assessment Service. (n.d.). *Medical treatment management procedure*.

Health Sciences Authority. (2026, October 29). *Advertisements and promotions of therapeutic products*.

Heilmittelwerbegesetz [Healthcare Advertising Act] (Germany). (1965, as amended).

Human Medicines Regulations 2012, SI 2012/1916 (UK). (2012, as amended).

Indian Ministry of Home Affairs. (n.d.). *Do not mix foreign contribution with domestic receipts*.

INFARMA. (2026). *Code of good practice [Effective September 1, 2026]*.

Inland Revenue Authority of Singapore. (n.d.). *Donations and tax deductions*.

Innovative Medicines Canada. (2022). *Code of ethical practices: Annotated version*.

INTERFARMA. (2021). *Código de conduta [Code of conduct]*.

Internal Revenue Service. (n.d.-a). *Charitable solicitation—State requirements*.

Internal Revenue Service. (n.d.-b). *Exemption requirements—501(c)(3) organizations*.

International Federation of Pharmaceutical Manufacturers and Associations. (2019). *IFPMA code of practice*.

International Federation of Pharmaceutical Manufacturers and Associations. (2020, March 16). *IFPMA note for guidance on patient and patient organization interactions*.

International Research-Based Pharmaceutical Manufacturers Association. (n.d.). *Code of practice*.

Italian Ministry of Labour and Social Policies. (n.d.). *Scopri il RUNTS [Discover RUNTS]*.

Japan Pharmaceutical Manufacturers Association. (2022, May 25). *Transparency guideline for the relationship between corporate activities and patient organizations*.

Japan Pharmaceutical Manufacturers Association. (n.d.). *The 40th patient organization seminar*.

Kamer van Koophandel. (n.d.). *De vereniging: Rechtsvorm met leden [The association: A legal form with members]*.

Kişisel Verileri Koruma Kurumu. (n.d.-a). *Özel nitelikli kişisel veriler [Special categories of personal data]*.

Kişisel Verileri Koruma Kurumu. (n.d.-b). *Özel nitelikli kişisel verilerin işlenmesine ilişkin rehber [Guidance on processing special categories of personal data]*.

Korea Research-based Pharma Industry Association. (n.d.). *[Ethical Business Practice Committee]*.

Läkemedelslag, SFS 2015:315 [Medicines Act] (Sweden). (2015, as amended).

Law on Administration of Activities of Overseas Nongovernmental Organizations in Mainland China. (2016).

Leem. (2025). *Q&A: Dispositions déontologiques professionnelles [Questions and answers: Professional ethical provisions]*.

Leem. (2026, January 20). *Les nouvelles règles déontologiques sectorielles applicables au 1er janvier 2026 [New sectoral ethical rules applicable from January 1, 2026]*.

Ley 25.326 de protección de los datos personales [Personal Data Protection Law] (Argentina). (2000, as amended).

Ley 50/2002, de Fundaciones [Foundations Law] (Spain). (2002).

Ley Federal de Fomento a las Actividades Realizadas por Organizaciones de la Sociedad Civil [Federal Civil Society Activities Promotion Law] (Mexico). (2004, as amended).

Ley Federal de Protección de Datos Personales en Posesión de los Particulares [Federal Private-sector Personal Data Protection Law] (Mexico). (2025, March 20).

Ley Orgánica 1/2002, reguladora del Derecho de Asociación [Organic Law on the right of association] (Spain). (2002).

Lif. (2026a). *Läkemedelsbranschens etiska regelverk [Ethical rules for the pharmaceutical industry; effective February 1, 2026]*.

Lif. (2026b). *Läkemedelsbranschens etiska regelverk: Kapitel 3 [Ethical rules: Chapter 3]*.

Marketing Code Authority. (2026). *Code of marketing practice and guidelines for interpretation (Version 19)*.

Medicines and Related Substances Act 101 (South Africa). (1965, as amended).

Medicines Australia. (2025). *Code of conduct (20th ed.)*.

Medicines Australia. (n.d.-a). *About the Code*.

Medicines Australia. (n.d.-b). *Code review*.

Medicines New Zealand. (n.d.). *Code of practice*.

Medicines and Healthcare products Regulatory Agency. (n.d.). *Opportunities for patients and the public to be involved in the work of the MHRA*.

Medsafe. (2023). *Guideline on the regulation of therapeutic products in New Zealand: Part 7—Advertising of therapeutic products*.

Ministry of Civil Affairs. (2024, September 5). *[Measures for administration of public fundraising by charitable organisations] (Order No. 74)*.

National Center for Non-Profit Sector Development. (n.d.). *Frequently asked questions*.

National Health Insurance Administration. (n.d.). *[Patient-opinion sharing for new medicines and medical devices]*.

National Institute for Health and Care Excellence. (n.d.). *Technology appraisal committees*.

National Institute for Health and Disability Insurance. (2025, April 1). *L'expérience des patients vient enrichir la Commission de Remboursement des Médicaments de l'INAMI [Patient experience enriches the Medicines Reimbursement Commission]*.

Netherlands Enterprise Agency. (n.d.). *Setting up a foundation in the Netherlands*.

New Zealand Ministry of Health. (n.d.). *Medicines Act*.

Nonprofit Organisations Act 71 (South Africa). (1997, as amended).

Office of Inspector General. (2014, May 21). *Supplemental special advisory bulletin: Independent charity patient assistance programs*.

Ondernemersplein. (n.d.). *Regel het bestuur en toezicht van uw organisatie [Arranging governance and supervision of your organisation]*.

Ontario Ministry of Health. (2026, October 27). *Patient input submissions for the drug funding review*.

Patient Rights Ombudsman. (n.d.). *Wykaz organizacji [List of organisations]*.

Patientenbeteiligungsverordnung [Patient Participation Ordinance] (Germany). (2003, as amended).

Personal Data Protection Act (Taiwan). (1995, as amended).

Personal Information Protection Act (Republic of Korea). (2011, as amended).

Personal Information Protection Commission. (n.d.). *[Is separate consent required when obtaining medical history and other special-care-required information directly from an individual?]*.

Personal Information Protection Law of the People's Republic of China. (2021).

Pharmaceutical Affairs Act (Republic of Korea). (1953, as amended).

Pharmaceutical Affairs Act (Taiwan). (1970, as amended).

Pharmaceutical Law (Poland). (2001, as amended).

Pharmaceutical Research and Manufacturers of America. (2012). *PhRMA principles on interactions with patient organizations*.

Pharmaceuticals and Medical Devices Act, Act No. 145 (Japan). (1960, as amended).

Pharmaceuticals and Medical Devices Agency. (n.d.). *Patient Centricity WG*.

Pharmac. (n.d.). *Having a say*.

Polish Ministry of Health. (2026). *Rola Agencji Oceny Technologii Medycznych i Taryfikacji w systemie ochrony zdrowia [The role of AOTMiT in the healthcare system]*.

R&D-based Pharmaceutical Association Committee. (2023). *RDPAC code of practice*.

Real Decreto 415/2026, por el que se regula la evaluación de tecnologías sanitarias [Royal Decree regulating HTA] (Spain). (2026).

Real Decreto Legislativo 1/2015, Ley de garantías y uso racional de los medicamentos y productos sanitarios [Consolidated law on medicines and health products] (Spain). (2015, as amended).

Reglamento de la Ley General de Salud en Materia de Publicidad [Regulation of the General Health Law on Advertising] (Mexico). (2000, as amended).

Saudi Central Bank. (n.d.). *300.1.5.2: Private associations*.

Saudi Data and Artificial Intelligence Authority. (n.d.). *Personal Data Protection Law: What is sensitive data?*

Saudi Food and Drug Authority. (2023). *Guidance on Saudi Food and Drug Authority policy for engagement with patients (MDS-G019)*.

scienceindustries. (2025). *Pharma cooperation code [Revised May 22, 2025; applicable October 1, 2025]*.

scienceindustries. (2026, September 3). *Disclosure of cooperation grants*.

Singapore Association of Pharmaceutical Industries. (2024, February). *Guidelines for interactions with patients, caregivers and patient organisations*.

Singapore Association of Pharmaceutical Industries. (2026, July). *Code of conduct 2026*.

South African National Department of Health. (2026). *National Essential Medicines List Committee bulletin for the meetings held on 30 July 2026*.

South African Revenue Service. (n.d.). *What is the difference between an NPO and a PBO?*

State Secretariat for Economic Affairs. (n.d.). *Associations: Another type of business structure*.

Stichting Code Geneesmiddelenreclame. (2024). *Gedragcode geneesmiddelenreclame [Code of conduct for pharmaceutical advertising; consolidated edition dated January 1, 2024]*.

Stichting Transparantieregister Zorg. (n.d.). *Welke financiële relaties maakt het register openbaar? [Which financial relationships does the register disclose?]*.

Swissmedic. (n.d.-a). *Collaboration with patient and consumer organisations*.

Swissmedic. (n.d.-b). *Control of advertising promoting medicinal products for the general public*.

Tandvårds- och läkemedelsförmånsverket. (n.d.). *Patientsamverkan [Patient involvement]*.

Therapeutic Goods Administration. (2026). *Complying with the restrictions on advertising prescription medicines to the public*.

U.S. Department of Health and Human Services. (n.d.). *Covered entities and business associates*.

U.S. Food and Drug Administration. (2023, December). *Direct-to-consumer prescription drug advertisements: Presentation of the major statement in a clear, conspicuous, and neutral manner in advertisements in television and radio format—Final rule questions and answers*.

U.S. Food and Drug Administration. (n.d.-a). *CDER patient-focused drug development*.

U.S. Food and Drug Administration. (n.d.-b). *FDA patient engagement opportunities*.

Zorginstituut Nederland. (n.d.-a). *Beoordeling van geneesmiddelen [Assessment of medicines]*.

Zorginstituut Nederland. (n.d.-b). *Vergoeding van extramurale geneesmiddelen (GVS) [Reimbursement of outpatient medicines]*.