Life Sciences Glossary

Term	Abbrev.	Definition
340B		Requires drug discounts for hospitals serving low-income people.
510(k)	510(k)	FDA clearance for devices similar to existing devices.
Abbreviated New Drug Application	ANDA	Application for a generic drug approval.
Accelerated Approval		Conditional approval based on a surrogate endpoint.
Accountable Care Organization	ACO	Network of providers paid per head rather than fee for service.
Active Pharmaceutical Ingredient	API	Substance used in a finished pharmaceutical product.
Affordable Care Act	ACA	Law passed under President Obama expanding health insurance.
Average Sales Price	ASP	The average price of a drug net of most rebates.
Biologic		A medical product derived from living organisms.
Biologics License Application	BLA	Application to FDA for marketing a biologic product.
Biosimilar		Generic biologic.
Black box warning		Warning of serious or life-threatening risks.
Breakthrough status		A program that gives the developer special access to FDA staff.
Buy-and-bill reimbursement		Providers purchase products and are reimbursed by insurers.
Center for Biologics Evaluation and Research	CBER	FDA center overseeing tissues and vaccines.
Center for Devices and Radiological Health	CDRH	FDA center overseeing medical devices.
Center for Drug Evaluation and Research	CDER	FDA center overseeing drugs.
Centers for Disease Control and Prevention	CDC	US agency focused on public health.
Children's Health Insurance Program	CHIP	The government program for children in low-income families.
Class I device		Low-risk medical device.
Class II device		Moderate-risk medical device.
Class III device		High-risk medical device requiring premarket approval.
Contract Manufacturing Organization	CMO	Company that manufactures products for other companies.
Contract Research Organization	CRO	Company providing clinical trials for other companies.

Copayment		Amount paid by a patient with the remainder paid by insurance.
Corporate Integrity Agreement	CIA	Agreement as part of a civil settlement with the Inspector General.
De novo		New but low or moderate-risk device.
European Medicines Agency	EMA	European agency responsible for drug evaluation and supervision.
Fast Track		FDA process to expedite drug development.
Food and Drug Administration	FDA	US agency regulating cosmetics, devices, drugs, food, and tobacco.
Generic		A product intended to be equivalent to a branded product.
Good Manufacturing Practices	GMP	Standards for manufacturing processes.
Health Care Provider	HCP	A person providing medical services.
Health Technology Assessment	HTA	Evaluation of the cost effectiveness of a product or service.
Incremental Cost Effectiveness Ratio	ICER	Added cost per additional health outcome achieved.
Inflation Reduction Act	IRA	US law that created new Medicare price controls.
Institute for Clinical and Economic Review	ICER	Non-profit organization evaluating clinical and economic value.
Intellectual Property	IP	Legal rights protecting inventions.
ISO 13485		International standard for quality management systems.
Medicaid		US health insurance program for low-income people.
Medicare		US health insurance program for seniors and disabled people.
Monoclonal Antibody	mAb	Antibody from cloned cells which is used to neutralize antigens
National Institute for Health and Care Excellence	NICE	Agency that evaluates health technologies for the United Kingdom.
National Institutes of Health	NIH	US agency that funds medical research.
New Chemical Entity	NCE	Newly developed active ingredient in a drug.
New Drug Application	NDA	Application for approval to market a new drug.
New Molecular Entity	NME	Newly approved drug with no prior equivalents.
Orphan drug		Drug for a rare disease.
Over the Counter	OTC	Drugs available without a prescription.
Paragraph IV challenge		Legal challenge stating that a patent is infringed by a generic.
Patent		Exclusive right granted for an invention.

Pharmacy Benefit Manager	PBM	Manages which drugs are covered and negotiates prices.
Phase I trial		Initial clinical trials assessing safety.
Phase II trial		Clinical trials assessing efficacy and side effects.
Phase III trial		Large-scale trials confirming effectiveness.
Phase IV trial		Post-marketing studies on long-term effects.
Premarket Approval	PMA	FDA clearance for devices different from existing devices.
Prescription	Rx	A doctor's authorization for medication.
Prescription Drug User Fee Act	PDUFA	Law allowing FDA to collect fees from drug manufacturers.
Priority Review		Expedited review for drugs addressing unmet needs.
Priority Review Voucher	PRV	Reward for treatments for neglected and rare diseases.
Risk Evaluation and Mitigation Strategy	REMS	Strategy to manage a drug's risks.
Substantial Equivalence	SE	FDA criterion based on similarity to an existing device.
Vaccines for Children Program	VFC	US program providing vaccines to children.
Warning Letter		FDA notice of regulatory non-compliance.
Wholesale Acquisition Cost	WAC	Manufacturer's list price for a drug.

By David Ridley. Please feel free to suggest edits, but stay within a 60-character limit for the definition.