



German terminology and acronyms: AMNOG and Market Access of drugs

A

AMNOG-Verfahren	AMNOG process
Analyseplan	Analysis plan
Anwendungsbegleitende	Routine practice data collection
Datenerhebung (AbD)	
Arzneimittel	Drug
Arzneimittelanwendung	Drug use
Arzneimittelbewertung	Drug evaluation
Arzneimittelgesetz (AMG)	Medicinal Products Act in Germany
Arzneimittel-Lieferengpassbekämpfungsgesetz und Versorgungsverbesserungsgesetz (ALBVVG)	German law from 2023 aimed at addressing drug supply shortages and improving the availability of medicines.
Arzneimittelkommission der deutschen Ärzteschaft (AkdÄ)	Drug Commission of the German Doctors
Arzneimittelmarkt-Neuordnungsgesetz (AMNOG)	Act on the Reform of the Market for Medicinal Products
Arzneimittel-Nutzenbewertungsverordnung (AM-NutzenV)	Regulation of the Benefit assessment of Medicinal Products
Arzneimittel-Richtlinie (AM-RL)	Medicines Directive
Apothekenverkaufspreis (AVP)	Pharmacy retail price
Aut idem	In the context of prescriptions in Germany, “aut idem” refers to the regulation that allows pharmacists to substitute a prescribed medicinal product with a therapeutically equivalent one - unless the prescribing doctor explicitly excludes substitution

B

Behandlungsmethode	Treatment method
Beschlussvorlage	Draft resolution
Bewertungsbericht	Assessment report
Bewertungsprozess	Assessment process / evaluation process
Bewertungsschritt	Assessment step / evaluation step
BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte)	Federal Institute for Drugs and Medical Devices
Bluthochdruck	High blood pressure
Bundesministerium für Gesundheit (BMG)	Federal Ministry of Health
Brückenkomparator	Bridging comparator
Bundesärztekammer (BÄK)	General Medical Council

D

Daten aus der realen Versorgung – „Evidenz aus der Praxis“	Real-World Evidence (RWE)
Deutsche Krankenhausgesellschaft	German Hospital Federation
Differenzbetrag	Differential amount
Digitale Gesundheitsanwendungen (DiGA)	Digital health applications
Direktmarketing an Endverbraucher	Direct-to-Consumer (DTC)
Dossier	Dossier
Dossiererstellung	Dossier preparation

E

Effektmodifikation

Effect modification

Erstatten (Kosten)

To reimburse

Erstattungsfähig

Reimbursable

Erstattungsbetrag

Reimbursement price

Erstattungshöchstbetrag

Maximum reimbursement price

Erstattungsregelung

Reimbursement regulation

Europäische Arzneimittelbehörde (EMA)

European Medicines Agency

Evidenz

Evidence

Evidenzbasiert

Evidence-based

F

Fachgesellschaften

Medical professional societies

Fachkräfte im Gesundheitswesen, z. B.

Healthcare Professionals (HCP)

Ärzt*innen oder Pflegepersonal

Festbeträge

Reference price

Festbetragsgruppe

Reference price group

G

G-BA (Gemeinsamer Bundesausschuss)

Federal Joint Committee

gesetzlichen Krankenversicherung (GKV)

statutory health insurance (SHI)

Gesundheitsleistung

Health care benefit

Gesundheitsministerium (BMG)

Federal Ministry of Health

Gesundheitssystem

Healthcare system

Gesundheitstechnologiefolgeabschätzung

Health technology assessment (HTA)

GKVS (GKV-Spitzenverband)

The National Association of Statutory Health

Insurance Funds

Goldstandard

Gold standard

H

Heilmittelwerbegesetz (HWG)

German Act on Advertising of Medicinal Products

Herstellerabschlag

Mandatory rebate

Herstellerabgabepreis (ApU)

Ex-factory price

I

IQWiG

Institute for Quality and Efficiency in Health Care

Indikationsgebiet

Therapeutic area

Indikationsstellung

Establishing the indication

Inverkehrbringen

Market launch

K

Kasse

Health insurance fund

Kassenärztliche Bundesvereinigung (KBV)

The National Association of Statutory Health

Insurance Physicians in Germany

Kassenärztliche Vereinigung (KV)

Regional association of statutory health insurance

physicians in Germany.

L

Laborparameter

Laboratory parameter

Lauertaxe

Comprehensive German drug database used for pricing and reimbursement

Leistungskatalog

Statutory health insurance benefits

Leistungspunkt (EBM)

Service point according to the Uniform Value Scale

M

Markt

Market

Markteinführung

Market launch / market introduction

Medizinproduktegesetz (MPG)

German Medical Devices Act, which regulates the marketing, clinical trials, and surveillance of medical devices in Germany.

Morbidität

Morbidity

Mortalität

Mortality

N

Neue Untersuchungs- und
Behandlungsmethoden (NUB)

New diagnosis/treatment method introduced in the inpatient healthcare sector in Germany

Nutzenbasierte Preisbildung

Value-Based Pricing

Nutzenbewertung

Benefit assessment

Nutzendossier

Benefit dossier

Nutzenkategorien

Benefit categories

P

Packungsgrößenverordnung

Ordinance on Package Sizes

Paul-Ehrlich-Institut (PEI)

Germany's Federal Institute for Vaccines and Biomedicines

Patientenvertreter

Patient representative

Pharmahersteller

Pharmaceutical manufacturer

Pharmazentralnummer (PZN)

Unique identification number assigned to medicinal products, medical devices, and other pharmacy-related items in Germany

PICO

Widely used framework in evidence-based medicine: patient-intervention-comparison-outcome

Verband der privaten Krankenversicherung e.V. (PKV)

Association of private health insurers in Germany

Population

Population

Preisbildung

Price setting

Preisreduktion

Price reduction

Preisverhandlung

Price negotiation

Q

Qualitätssicherung

Quality assurance

R

Randomisierung

Randomisation

Risikoreduktion

Risk reduction

Robert Koch-Institut (RKI)

One of the most important bodies for the safeguarding of public health in Germany

Rx

Prescription-only medicine

S

Schiedsstelle

Arbitration board

Schiedsstellenverfahren

Arbitration procedure

Sozialgesetzbuch V

Book V of the Social Code

Studienpopulation

Study population

Surrogate

Surrogate

U

Unterausschuss

Subcommittee

V

Verfahrensordnung

Rules of procedure

Vergleichsgruppe

Control group

Vergleichsprodukt

Comparator product

Vergleichstherapie

Comparative treatment

Verordnung

Prescription

Versorgungskontext

Healthcare context

Vierte Hürde

Fourth hurdle

Vollständigkeitsprüfung

Validation of completeness

Z

Zulassung (Arzneimittel)

Marketing authorisation

Zulassungsbehörde

Regulatory authority

Zulassungsunterlagen

Marketing authorisation documents

Zweckmäßige Vergleichstherapie (ZVT)

Appropriate comparator therapy within the
AMNOG process

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