WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Glossary of Pharmaceutical Terms

Update: 2016

Gesundheit Österreich GmbH

PPRI Pharmaceutical Pricing and Reimbursement Information

MINISTERIUM FRAUEN GESUNDHEIT

Glossary

of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Update: July 2016

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Vienna, July 2016

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WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

MINISTERIUM FRAUEN GESUNDHEIT

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Introduction

When communicating in any field, a common understanding is of major importance. All people involved in providing and/or addressed with information –no matter if they are experts or lay persons– need to understand the underlying concepts and notions in that field.

This is a major lesson learned from the PPRI (Pharmaceutical Pricing and Reimbursement Information) project (for further information on PPRI see below). Based on the observations about misunderstandings among the PPRI network members, all of them experts, the PPRI secretariat decided to establish a glossary which was mandatory for the PPRI network members when they wrote the PPRI Pharma Profiles. The first version of the PPRI Glossary was drafted, revised after a consultation process with the PPRI network and published in 2006.

Since terminology is constantly changing, the authors of the PPRI glossary invited experts and the public to provide feed-back on the glossary, make suggestions for changes and propose new terms. A major revision was done via the PHIS Glossary in the course of the EC co-funded project PHIS (Pharmaceutical Health Information System, see below). The PHIS Glossary was produced under the lead of the Italian Medicines Agency AIFA together with Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (Austrian Health Institute) and after feed-back of the PHIS network (European competent authorities for pharmaceutical pricing and reimbursement, hospital pharmacists) and the PHIS Advisory Board. This PHIS Glossary particularly aimed to incorporate pharmaceutical policy-related terms with regard to the in-patient sector.

Further revisions followed in April 2011, in October 2012 and November 2013 which resulted in new versions of the glossary.

In addition to regular updates and revision of the glossary, the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies is committed to disseminating the glossary: We believe that the tool of a glossary can contribute to an improved joint understanding. Furthermore, to support clarity on terminology, glossaries in national languages are being produced; a German and a Spanish glossary are already available.

The current Glossary on Pharmaceutical Terms of the WHO Collaborating Centre of Pharmaceutical Pricing and Reimbursement Policies is available as a full text document and in an online searchable version, both of them accessible at the website http://whocc.goeg.at → Glossary.

PPRI, PHIS, and WHO Collaborating Centre

Pharmaceutical Pricing and Reimbursement Information (PPRI) started as a research project, co-funded by the European Commission, Directorate-General Public Health and Consumers. It was carried out from 2005 till early 2008. In the course of the project the PPRI network was established, and a set of pharmaceutical indicators, filled with real data from 27 PPRI countries, as well as more than 20 country reports (PPRI Pharma Profiles) and brief overviews on the pharmaceutical systems (country information) were produced.

Today, Pharmaceutical Pricing and Reimbursement Information (PPRI) is a networking and information-sharing initiative on urgent issues of pharmaceutical policies from a public health perspective. The PPRI network involves representatives from around 90 institutions: These are public authorities and third party payers from 46 countries (mainly European countries, including all 28 EU Member States) as well as European and international institutions such as European Commission services and agencies, OECD, WHO (HQ and Regional Office for Europe) and the World Bank.

In the on-going PPRI initiative, the networking of the public authorities continues via regular networking meetings and continuous sharing of relevant information for decision-making, including up-dates of country-specific information. The PPRI secretariat is hosted at the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.

The PPRI project was selected by the Executive Agency for Health and Consumers, in collaboration with the Health Programme's National Focal Points (NFP) and the Directorate General for Health and Consumers (DG SANCO), as a good practice example of EU Public Health projects with an important impact for EU Member States.

The Pharmaceutical Health Information System (PHIS) was a European Commission co-funded project which ran from September 2008 to April 2011. The project aimed to increase knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the EU Member States, covering both the out-patient and the in-patient sectors. A special focus of the project was on medicines in the in-patient sector, with a European survey of medicines management in hospitals in the EU Member States and an investigation and analysis of official and actual prices of medicines in hospitals in selected countries. Methodology tools, in particular with regard to terminology, indicators and reporting tools, have been further developed based on work started in PPRI.

The Health Economics Department of the Austrian Health Institute was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in the summer of 2010. The Centre has been continuing methodology work started under

the framework of the PPRI and PHIS projects: One of the Centre's explicit tasks is to develop a tool for describing and analyzing national pharmaceutical pricing and reimbursement systems ('Pharma Profiles'). WHO Collaborating Centre staff were also involved as experts in the development of the revised WHO Pharmaceutical Country Profiles by helping to expand the current tool of the PPRI/PHIS Pharma Profiles for the European countries, and adapting it so that it can describe the pharmaceutical sector in other health system arrangements.

Within the PPRI and PHIS projects, websites were established. Policy makers, researchers and the interested public are offered free access to our findings and the methodological tools developed. Though the PPRI and PHIS project websites are no longer maintained all relevant PPRI and PHIS information was integrated into the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies established in 2010: http://whocc.goeg.at. The website of the Centre is designed to serve as an information platform about pharmaceutical policies, and it provides published profiles, indicators of the PHIS database, glossaries and templates for reporting of pharmaceutical pricing and reimbursement information.

Contact

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Recommended citation:

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. Glossary of pharmaceutical terms. Update July 2016. Accessible at http://whocc.goeg.at/Glossary

ABC Analysis
Method by which medicines are divided, according to their annual usage (unit cost times annual consumption) into class A items (the 10 to 20 percent of items that account for 75 to 80 percent of the funds spent), class B items (with intermediate usage rates), and class C items (the vast majority of items with low individual usage, the total of which accounts for 5 to 10 percent of the funds spent).

ABC analysis can be used to give priority to Class A items in procurement, inventory control, and port clearing.

[Source: Quick et al. Managing Drug Supply, 2nd ed. Kumerian Press: 1997; 181]

Access (Accessibility)
The patient's ability to obtain medical care, including medicines, and a measure of the proportion of a population that reaches appropriate health services, including medication.

The ease of access is determined by such components as the availability of medical services and their acceptability to the patient, the location of health care facilities, transportation, hours of operation and cost of care.

Barriers to access can be financial (insufficient monetary resources), geographic (distance to providers), organisational (lack of available providers) and sociological (e.g., discrimination, language barriers).

Efforts to improve access often focus on providing/improving health coverage.

[Source: adapted from WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Access with Evidence Development (AED)
Initiative in which a payer provides temporary or interim funding for a particular technology or service to facilitate the collection of information needed to reduce specific uncertainties around a coverage decision.

See also: ➲ managed entry agreement

[Source: Stafinski T, McCabe C, Menon D: Funding the unfundable – mechanisms for managing uncertainty in decisions on the introduction o new and innovative technologies into healthcare systems. Pharmacoeconomics 2010;28:113-42.]

Accreditation
An evaluative process in which a health care organisation undergoes an examination of its policies, procedures and performance by an external organisation (accrediting body) to ensure that it is meeting predetermined standards.

For facilities, accreditation standards are usually defined in terms of physical plant, governing body, administration, and medical and other staff. Accreditation is often carried out by organisations created for the purpose of assuring the public of the quality of the accredited institution or program.

The State can recognise accreditation in lieu of, or as the basis for mandatory approvals.

Public or private payment programs often require accreditation as a condition of payment for covered services.

Accreditation may either be permanent or may be given for a specified period of time.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Active Ingredient (Active Substance, Compound, Active Pharmaceutical Ingredient)
Ingredient that alone or in combination with one or more other ingredients is considered to fulfil the intended activity of a medicine.

[Source: European Committee for Standardisation. ENV 12610 – Medical informatics– Medicinal product identification]

Actor
Umbrella term for persons and entities which comprises authorities, market players and stakeholders.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Acute Care
A type of health care in which a patient is treated for an acute (immediate and severe) episode of illness, for the subsequent treatment of injuries related to an accident or other trauma, or during recovery from surgery.

Acute care is usually given in a hospital by specialised personnel, using complex and sophisticated technical equipment and materials.

Unlike chronic care, acute care is often necessary for only a short time.

[Source: NHS Quality Improvement Scotland – Raising Health care standards]

Acute Care Beds

Acute care beds are beds accommodating patients where the principal clinical intent is to do one or more of the following:

» manage labour (obstetric)
» cure illness or provide definitive treatment of injury
» perform surgery
» relieve symptoms of illness or injury (excluding palliative care)
» reduce severity of illness or injury
» protect against exacerbation and/or complication of an illness and/or injury which could threaten life or normal functions
» perform diagnostic or therapeutic procedures.

See also: ➲ Hospital beds

[Source: 2001 Data Collection on Education Systems: Definitions, Explanations and Instructions, UNESCO, OECD, Eurostat, page 45]

Adaptive Licensing (Progressive Licensing, Staggered Approval)

A prospectively planned process, starting with the early authorization of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorization to expand access to the medicine to broader patient populations.

As a holistic approach, adaptive licensing requires the involvement of all stakeholders who have a role in determining patient access, including the European Medicines Agency, the industry, ➲ health technology assessment (HTA) bodies, organisations issuing clinical treatment guidelines and patient organisations

[Source: European Medicines Agency]

Adherence

Adherence to long term therapy is defined as the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.

[Source: WHO. Adherence to long term therapies – evidence for action.2003]

Advanced Therapy Medicine

Advanced therapy medicines are based on manufacturing processes focussed on various gene transfer-produced bio-molecules, and/or biologically advanced therapeutic modified cells as active substances or part of active substances. They include:

Gene therapy medicine: a product obtained through a set of manufacturing processes aimed at the transfer, to be performed either in vivo or ex vivo, of a prophylactic, diagnostic or therapeutic gene (i.e. a piece of nucleic acid), to human/animal cells and its subsequent expression in vivo. The gene transfer involves an expression system contained in a delivery system known as a vector, which can be of viral, as well as non-viral origin. The vector can also be included in a human or animal cell.

Somatic cell therapy medicine: it means the use in humans of autologous (emanating from the patient himself), allogeneic (coming from another human being) or xenogeneic (coming from animals) somatic living cells, the biological characteristics of which have been substantially altered as a result of their manipulation to obtain a therapeutic, diagnostic or preventive effect through metabolic, pharmacological and immunological means.

Somatic cell therapy medicines include:

» Cells manipulated to modify their immunological, metabolic or other functional properties in qualitative or quantitative aspects;

» Cells sorted, selected and manipulated and subsequently undergoing a manufacturing process in order to obtain the finished medicines;

» Cells manipulated and combined with non-cellular components (e.g. biological or inert matrixes or medical devices) and exerting the principle intended action in the finished product;

» Autologous cell derivatives expressed in vitro under specific culture conditions;

» Cells genetically modified or otherwise manipulated to express previously unexpressed homologous or non-homologous functional properties.

Tissue engineered product means a product that contains or consists of engineered cells or tissues, and is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue.

A tissue engineered product may contain cells or tissues of human or animal origin, or both. The cells or tissues may be viable or non-viable. It may also contain additional substances, such as cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices.

Products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action, shall be excluded from this definition.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007, adapted]

Adverse Reaction (Adverse Drug Reaction, ADR)
A response to a medicine which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

Serious adverse reaction: An adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

Unexpected adverse reaction: An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

Type A adverse reactions are those that are the result of an exaggerated but otherwise predictable pharmacological effect of the medicine. They tend to be common, dose-related, and less serious than Type B reactions

Type B adverse reactions are those that are aberrant effects of the medicine. They tend to be uncommon, not dose-related, and unpredictable.

[Source: Strom, Kimmel. Textbook of pharmacoepidemiology]

Affordability
The extent to which medicines and further health care products are available to the people who need them at a price they / their health system can pay.

[Source: adapted from WHO. A model quality assurance system for procurement agencies]

Analogous Substitution
Dispensation of a medicine (often generic) by the pharmacist with a different ➲ active ingredient (or combination product) but the same therapeutic effect instead of the product prescribed by the physician.

See also ➲ generic substitution.

[Source: PPRI Glossary]

Anatomical, Therapeutic, Chemical classification (ATC Classification)
A classification system of medicines where the ➲ active ingredients are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.

Medicines are divided into fourteen main groups (1st level, ATC 1 level), with pharmacological/therapeutic subgroups (2nd level – ATC 2 level). The 3rd and 4th levels (ATC 3 and ATC 4 level) are chemical/pharmacological/therapeutic subgroups and the 5th level (ATC 5) is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups.

See also: ➲ reference group, reference price system

[Source: WHO Collaborating Centre for Drug Statistics Methodology – Guidelines for ATC classification and DDD assignment]

Auction-like Policies (Auction-like Systems)
In such processes, the price is determined through competitive bidding: the pharmaceutical company that offers the lowest, or best, price for a specific medicine / group of medicines will be awarded the ➲ tender. The tendered medicines will be

included in reimbursement (often a ➲ reference product, impacting the prices/reimbursement status of similar medicines); the tendered price is likely to serve as reimbursement price.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement]

Authority
Government entities responsible for designing the regulatory framework and implementing policies (e.g. ministries, public agencies). In the European context the term 'competent authority' is frequently used.

[Source: adoptef from PPRI Glossary]

Batch (Lot)
A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

[Source: EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use]

Benchmark
A measure or standard to which an activity, performance, service or result can be compared. Benchmarking is the term given to the process of measuring standards of actual performance against those achieved by others with broadly similar characteristics. The aim is to improve quality so that all organisations or services can raise their own performance to that of the best.

[Source: NICE Glossary]

Bioavailability
Bioavailability means the rate and extent to which the active substance or active moiety is absorbed from a pharmaceutical form and becomes available at the site of action.

In the majority of cases substances are intended to exhibit a systematic therapeutic effect, and a more practical definition can then be given, taking into consideration that the substance in the general circulation is in exchange with the substance at the site of action:

Bioavailability is understood to be the extent and the rate to which a substance or its active moiety is delivered from a pharmaceutical form and becomes available in the general circulation.

It may be useful to distinguish between the absolute bioavailability of a given dosage form as compared with that (100%) following intravenous administration (e.g. oral solution vs. iv.). and the relative bioavailability as compared with another form administered by the same or another non intravenous route (e.g. tablets vs. oral solution).

[Source: EMEA. Note for guidance on the investigation on bioavailability and bioequivalence]

Bioequivalence

Two medicines are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and if their bioavailabilities after administration in the same molar dose are similar to such degree that their effects, with respect to both efficacy and safety, will be essentially the same.

[Source: EMEA. Note for guidance on the investigation on bioavailability and bioequivalence]

Biological Marker (Biomarker)

A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

Biomarkers may have the greatest value in early efficacy and safety evaluations such as in vitro studies in tissue samples, in vivo studies in animal models, and early-phase clinical trials to establish 'proof of concept'.

Biomarkers have many other valuable applications in disease detection and monitoring of health status. These applications include the following:

» use as a diagnostic tool for the identification of those patients with a disease or abnormal condition (e.g., elevated blood glucose concentration for the diagnosis of diabetes mellitus)

» use as a tool for staging of disease (e.g., measurements of carcinoembryonic antigen-125 for various cancers) or classification of the extent of disease (e.g., prostate-specific antigen concentration in blood used to reflect extent of tumour growth and metastasis)

» use as an indicator of disease prognosis (e.g., anatomic measurement of tumour shrinkage of certain cancers)

» use for prediction and monitoring of clinical response to an intervention (e.g., blood cholesterol concentrations for determination of the risk of heart disease).

[Source: Biomarkers Definitions Working Group]

Biological Medicinal Product (Biological Medicine, Biopharmaceutical)

A medicine that contains one or more active biological substances. A biological substance is produced by or extracted from a biological source and needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control.

The following shall be considered as biological medicines

» immunological medicines and medicines derived from human blood and human plasma

» products developed by means of one of the following biotechnological processes: recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, hybridoma and monoclonal antibody methods

» advanced therapy medicines.

Examples include proteins such as hormones (growth hormones, insulins, erythropoietins), enzymes that are naturally produced in the human body, or monoclonal antibodies, but also blood products, immunological medicinal products such as sera and vaccines, allergens, and advanced technology products such as gene and cell therapy products. Like all medicines, biological medicines work by interacting with the body to produce a therapeutic outcome, but the mechanisms by which they do this may vary from product to product and across indications. Biopharmaceuticals can be tailor-made to fit the desired target. Therefore the role of the physicians in treatment of patients with these complex medicinal products is particularly important. This definition only refers to biotechnology-derived medicines which, since 1995, must be assessed centrally by the European Medicines Agency (EMA) and in case of a positive scientific opinion adopted by the scientific committee, are subject to a formal decision process for marketing by the European Commission.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, adapted; European Commission. Entreprise and Industry Directorate-General. Consensus Information Document: 'What you need to know about Biosimilar Medicinal

Products'. Brussels: Process on Corporate Responsibility in the Field of Pharmaceuticals. Access to Medicines in Europe, 2013]

Biosimilar (Similar Biological Medicinal product, Biosimilar Medicinal Product, Biosimilar Medicine)

A ➲ biological medicine that is developed to be similar to an existing biological medicine (the 'reference medicine'). Biosimilar medicines can only be marketed following the ➲ patent expiry of the reference medicine.

Biosimilars are not the same as ➲ generics, which have simpler chemical structures and are considered to be identical to their reference medicines.

The active substance of a biosimilar and its reference medicine is essentially the same biological substance, though there may be minor differences due to their complex nature and production methods. Like the reference medicine, the biosimilar has a degree of natural variability. When approved, its variability and any differences between it and its reference medicine will have been shown not to affect safety or effectiveness.

An authorised biosimilar is generally used at the same dose to treat the same conditions. If there are specific precautions to be considered when taking the reference medicine, the same will generally apply to the biosimilar. Biosimilars can only be authorized for use once the period of data exclusivity on the original 'reference' biological medicine has expired. In general, this means that the ➲ biological reference medicine must have been authorized for at least 10 years before a similar biological medicine can be made available by another company.

[Source: European Commission. Entreprise and Industry Directorate-General. Consensus Information Document: 'What you need to know about Biosimilar Medicinal Products'. Brussels: Process on Corporate Responsibility in the Field of Pharmaceuticals. Access to Medicines in Europe, 2013; European Medicines Agency (EMA). 'Questions and answers on biosimilar medicines (similar biological medicinal products). London, 2012]

Biosimilar price link

Practice of setting the price of a biosimilar medicine, in relationship to the reference medicine price, usually at a certain percentage lower than the reference medicine price. The design of the price link policy may vary, with different percentages for the different following biosimilar products (first follower coming to the market, second follower, etc.), and in some cases the prices of reference medicines might also be part of the policy, i.e. that they will also be required to decrease.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement]

Biosimilar substitution
Practice of dispensing a biosimilar medicine instead of another equivalent and interchangeable biosimilar or biotechnological originator medicine at the pharmacy level without consulting the prescriber.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement]

Blood Establishment
Any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and ➲ distribution when intended for transfusion. This does not include hospital blood banks.

[Source: Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003]

Branch Pharmacy
A branch pharmacy is attached to a pharmacy and is operated under its supervision. The branch pharmacy has its own independent premises and professionally qualified staff. Branch pharmacies may retail the same products as the pharmacy and may also dispense prescription medicines. Branch pharmacies (or a limited number of branch pharmacies) may be allowed even in countries where pharmacy chains are forbidden.

[Source: adapted from Association of Danish Pharmacies website]

Brand Name (Innovator`s Name, Proprietary Product Name, Medicine Speciality Product Name, Medicinal Product Speciality Name)
Name given for marketing purposes to any ready-prepared medicine placed on the market under a special name and in a special pack. A brand name may be a protected trademark.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Budget Impact
A budget is an estimate of revenue and expenditure for a specified period.

Budget impact refers to the total costs that pharmaceutical reimbursement and use entail with respect to one part of the health care system, pharmaceutical care, or to the entire health care system, taking into account the possible reallocation of resources across budgets or sectors of the health care system.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Budget Impact Analysis (BIA)
Budget Impact Analysis is an essential part of a comprehensive economic assessment of a health care technology and is increasingly required, along with cost-effectiveness analysis (CEA), prior to formulary approval or reimbursement.

The purpose of a BIA is to estimate the financial consequences of adoption and diffusion of a new health care intervention within a specific health care setting or system context given inevitable resource constraints. In particular, a BIA predicts how a change in the mix of medicines and other therapies used to treat a particular health condition will impact the trajectory of spending on that condition.

Users of BIA include those who manage and plan for health care budgets such as administrators of national or regional health care programs, administrators of private insurance plans, administrators of health care delivery organisations and employers who pay for employee health benefits.

BIA should be viewed as complementary to cost-effectiveness analysis (CEA), not as a variant or replacement. Whereas, CEA evaluates the costs and outcomes of alternative technologies over a specified time horizon to estimate their economic efficiency, BIA addresses the financial stream of consequences related to the uptake and diffusion of technologies to assess their affordability.

[Source: Report of the ISPOR Task Force on Good Research Practices – Budget Impact Analysis]

Bulk Product
Any product that has completed all processing stages up to, but not including, final packaging.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Bundling
Bundling is a marketing strategy that involves offering several products for sale as one combined product.

[Source: Developed by PHIS group in the framework of PHIS Hospital Pharma]

Burden of Disease

The burden of disease is a measurement of the gap between a population's current health and the optimal state where all people attain full life expectancy without suffering major ill-health.

Burden of disease analysis enables decision makers to identify the most serious health problems facing a population.

Loss of health in populations is measured in disability-adjusted life years (DALYs), which is the sum of years of life lost due to premature death and years lived with disability.

[Source: WHO. Health Promotion Glossary: new terms]

Cancer

A group of over a hundred diseases that occur when malignant forms of abnormal cell growth develop in one or more body organs.

Cancer arises after a series of genetic mutations remove the normal checks on cell growth. These cancer cells continue to divide and grow to produce tumours. Cancer cells can invade adjacent structures and spread via the lymph or blood to distant organs.

It is estimated that about 80 percent of cancers are due to environment or lifestyle, and therefore are potentially preventable. The risk factors for some cancers have been clearly identified, but for others further research is needed.

The cancer treatment that a patient receives is determined by the stage of cancer at diagnosis, the type and location of the cancer, the standard medical practices in the patient's country, and the ability of the patient to pay for treatment (through national or private insurance or otherwise).

Cancer treatment is a challenge to the sustainability of health care system.

[Source: WHO. Priority medicines for Europe and the world. 2003]

Capitation

Strictly speaking, the term 'capitation' refers only to a payment mechanism – paying a provider a specific sum of money for the ongoing care of a person or group of people for a particular period of time.

The sum is set in advance of the actual period of service, and it therefore represents a prediction, or at least an agreed-on estimate, of the amount of money that will be required to provide that care.

Technically, a contract based on capitation can include or exclude almost any medical service. One can provide payment on a capitated basis, for example, for only primary care visits, for primary care visits and associated laboratory tests, or for only referrals to specialists. Mental health care can be covered. So can specialty services or surgery, whether or not primary care is included.

The rate may be adjusted for the age, gender and other health characteristics of the population, based on actuarial projections of medical utilisation (Risk-adjusted capitation).

[Source: adapted from: Berwick, D.M. Payment by Capitation and the Quality of Care. Part Five of Six. NEJM 1996]

Carriage and Insurance Packaging (CIP)
A type of price quotation, indicating the delivery of goods including cargo insurance to the named place of destination at seller's expense. In an export the quotation indicates the place of destination (discharge) after the acronym CIP, for example CIP Athens.

[Source: PPRI Glossary]

Case-mix
A measure of the mix of cases being treated by a particular health care provider that is intended to reflect the patients' different needs for resources.

Case-mix is generally established by estimating the relative frequency of various types of patients seen by the provider in during a given time period, and may be measured by factors such as diagnosis, severity of illness, utilisation of services, and provider characteristics.

[Source: Office of Technology Assessment. Compilation of Abbreviations and Terms]

Catchment Area
A geographic area defined and served by a health program or institution such as a hospital or community mental health centre, which is delineated on the basis of such factors as population distribution, natural geographic boundaries, and transportation accessibility.

By definition all residents of the area needing the services of the program are usually eligible for them, although eligibility may also depend on additional criteria.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Chronic Care
The ongoing provision of medical, functional, psychological, social, environmental and spiritual care services that enable people with serious and persistent health and/or mental conditions to optimise their functional independence and well-being, from the time of condition onset until problem resolution or death.

Chronic care conditions are multidimensional, interdependent, complex and ongoing.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Chronic Condition (Chronic Disease)
A disease which has one or more of the following characteristics: is permanent; leaves residual disability; is caused by no reversible pathological alteration; requires special training of the patient for rehabilitation; or may be expected to require a long period of supervision, observation or care.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Claw-back
A funding element in a reimbursement system allowing ➲ third party payers to recoup (part of the) ➲ discounts/ ➲ rebates granted by various stakeholders, e.g. ➲ wholesalers and ➲ pharmacists.

[Source: adapted from PPRI Glossary]

Clinical Endpoint
A characteristic or variable that reflects how a patient feels, functions, or survives.

Clinical endpoints are distinct measurements or analyses of disease characteristics observed in a study or a clinical trial that reflect the effect of a therapeutic intervention. Clinical endpoints are the most credible characteristics used in the assessment of the benefits and risks of a therapeutic intervention in randomised clinical trials.

[Source: Biomarkers Definitions Working Group]

Clinical Paths (Hospital Pathways)
A clinical path is a key tool for managing treatment processes. It is a network of multidisciplinary diagnostic treatment measures founded on evidence-based clinical practice guidelines, which takes patient expectations, quality and cost-effectiveness into consideration and creates process-related lists of all services and resources used during a patient's hospital stay from admission to discharge.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Clinical Pharmacology
The study of the effects of the pharmaceuticals in humans.

[Source: Strom, Kimmel. Textbook of pharmacoepidemiology]

Clinical Trial (Clinical Study)
Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

The terms clinical trial and clinical study are synonymous.

Clinical trials are generally divided into Phases I-IV. It is not possible to draw clear distinctions between these phases, and different opinions about details and methodology do exist. However, the individual phases, based on their purposes as related to the clinical development of pharmaceutical products, can be briefly defined as follows:

Phase I. These are the first trials of a new active ingredient or new formulations in humans, often carried out in healthy volunteers. Their purpose is to make a preliminary evaluation of safety, and an initial pharmacokinetic/ pharmacodynamic profile of the active ingredient.

Phase II. The purpose of these therapeutic pilot studies is to determine activity and to assess the short-term safety of the active ingredient in patients suffering from a disease or condition for which it is intended. The trials are preformed in a limited number of subjects and are often, at a later stage, of a comparative (e.g. placebo-controlled) design. This phase is also concerned with the determination of appropriate dose ranges/ regimens and (if possible) the clarification of dose-response relationships in order to provide an optimal background for the design of extensive therapeutic trials.

Phase III. This phase involves trials in large (and possibly varied) patient groups for the purpose of determining the short- and long-term safety-efficacy balance of formulation(s) of the active ingredient, and assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated, and special features of the product must be explored (e.g. clinically relevant medicine interactions, factors leading to differences in effect, such as age). The trials should preferably be randomized double-blind, but other designs may be acceptable, e.g. long-term safety studies. In general, the conditions under which the trials are conducted should be as close as possible to the normal conditions of use.

Phase IV. In this phase studies are performed after the pharmaceutical product has been marketed. They are based on the product characteristics on which the marketing authorization was granted and normally take the form of post-marketing surveillance, and assessment of therapeutic value or treatment strategies. Although methods may differ, the same scientific and ethical standards should apply to Phase IV studies as are applied in premarketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc., are normally regarded as trials of new pharmaceutical products.

[Source: ICH Guideline for Good Clinical Practice]

Co-insurance
Cost-sharing in the form of a set proportion of the cost of a service.

See also: ➲ out-of pocket payments

[Source: OECD. A System of Health Accounts]

Combination Product
A medicine that contains more than one ➲ active ingredient.

See also: ➲ fixed dose combination (FDC) product

[Source: PPRI Glossary]

Community Care
Services and support to help people with care needs to live as independently as possible in their communities.
Sometimes considered as synonym for the out-patient (ambulatory) health care sector, in contract to the hospital sector.

See also: ➲ out-patient

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Community Pharmacy
Health care facility dispensing ➲ medicines (➲ prescription-only medicines/POM and ➲ Over-the-Counter/OTC medicines), ➲ reimbursable and non-reimbursable medicines) to ➲ out-patients. Community pharmacies offer also further services apart from ➲ dispensing.

Pharmacies are subject to pharmacy legislation (e.g. national legislation regarding establishment and ownership of pharmacies). In many countries, community pharmacies are private facilities, but public pharmacies (i.e. in public ownership) also exist. Pharmaceutical provision for inpatients is provided for by ➲hospital pharmacies or p➲ harmaceutical depots; in some cases hospital pharmacies also act as community pharmacies.

See also: ➲ pharmaceutical services, ➲ hospital pharmacy

[Source: adapted from PPRI Glossary]

Co-morbid Condition (Co-morbidity)
Conditions that exist at the same time as the primary condition in the same patient (e.g. hypertension is a co-morbidity of many conditions, such as diabetes, ischemic heart disease, end-stage renal disease, etc.).

Two or more conditions may interact in such a way as to prolong a stay in hospital or hinder successful rehabilitation.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Complication
A medical condition that arises during a course of treatment and is expected to increase the length of stay by at least one day for most patients.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Compounding
The preparation and supply of a single unit of a product intended for immediate use by a specific consumer. Compounding may provide a solution to the individual's needs, when a medicine is not available, or is unavailable in a form suitable for a particular patient. The reasons why compounding might be needed comprise: different dosage form required, for example liquid form required but only tablets available, ointment required instead of cream; sensitivity/allergy to excipients and preservatives; discontinued or unavailable medicine; different dose or concentration required; different route of administration required; compliance problems, for example palatability. Compounding is also known as extemporaneous dispensing.

See also: ➲ extemporaneous dispensing, magistral formula (extemporaneous preparation), officinal formula

[Source: Feldschuh, Mark. 'Compounding in community pharmacy'. (2008): 30-31. http://www.australianprescriber.com/magazine/31/2/30/1]

Compulsory Health Insurance
Health Insurance under an obligatory scheme basing on a legal act, usually with income-related contributions.

See also: ➲ social health insurance and voluntary health insurance

[Source: PPRI Glossary]

Conditional Coverage
Schemes where coverage is granted conditional on the initiation of a program of data collection.

See also: ➲ managed entry agreement

[Source: Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010 Aug. 96(3):179-90.]

Conditional Marketing Authorisation (Conditional Approval)
In case of conditional approval, marketing authorization is granted based on a smaller package of clinical data, with follow-up obligations to submit additional clinical efficacy and safety evidence of the product.

A conditional marketing authorisation may be granted where, although comprehensive clinical data referring to the safety and efficacy of the medicine have not been supplied, all the following requirements are met:

a) the risk-benefit balance of the medicine is positive;
b) it is likely that the applicant will be in a position to provide the comprehensive clinical data;
c) unmet medical needs will be fulfilled;
d) the benefit to public health of the immediate availability on the market of the medicine concerned outweighs the risk inherent in the fact that additional data are still required.

In emergency situations, a conditional marketing authorisation may be granted, also where comprehensive pre-clinical or pharmaceutical data have not been supplied.

In the context of conditional marketing authorisation 'unmet medical needs' means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in the Community or, even if such a method exists, in relation to which the medicine concerned will be of major therapeutic advantage to those affected.

By way of specific obligations, the holder of a conditional marketing authorisation shall be required to complete ongoing studies, or to conduct new studies, with a view to confirming that the risk-benefit balance is positive and providing the additional data.

In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

The specific obligations referred and the timeframe for their completion shall be clearly specified in the conditional marketing authorisation and made publicly available.

After its period of validity of one year the conditional marketing authorisation may be renewed annually.

Once a renewal application has been submitted in accordance with paragraph 2, the conditional marketing authorisation shall remain valid until a decision is adopted by the Commission in accordance with Article 10 of Regulation (EC) No 726/2004.

See also: ➲ marketing authorisation

[Source: Commission Regulation (EC) No 507/2006 of 29 March 2006]

Conditional Treatment Continuation (CTC)
Continuation of coverage for individual patients is conditioned upon meeting short-term treatment goals.

See also: ➲ managed entry agreement

[Source: Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010 Aug. 96(3):179-90.]

Consignment (Delivery)
The quantity of a pharmaceutical(s), made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Consumption (Utilisation)
Use of services and supplies.

Consumption in health care is commonly examined in terms of pattern of use of a single service (e.g. number of visits to a doctor per person per year) or type of care (e.g. admissions to the hospital per 1,000 persons in total or over age 65 per year).

Consumption of medicines can be measured either in packages (or other units) or in DDD (Defined Daily Doses) within a given time period.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Consumption-based Reimbursement
The level of reimbursement depends on the expenses for medicines of a patient within a certain period of time (increasing reimbursement with rising consumption).

[Source: PPRI Glossary]

Container
The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers.

Containers are referred to as **primary** if they are intended to be in direct contact with the product. **Secondary** containers are not intended to be in direct contact with the product.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Continuity of care
Defined as the degree to which a series of discrete healthcare events is experienced as coherent and connected and consistent with the patient's medical needs and personal context.

See also: ➲ interface management, integrated care (comprehensive care, transmural care), seamless care

[Source: Haggerty JL, Reid RJ, Freeman GK, Starfield BH, Adair CE, McKendry R. Continuity of care: a multidisciplinary review. BMJ. 2003;327(7425):1219-21]

Co-payment
Insured patient's contribution towards the cost of a medical service covered by the insurer. Can be expressed as a percentage of the total cost of the service or as a fixed amount. Co-payment is a form of ➲ out-of pocket payment.

Co-payments might be designed in different formats. With regard to co-payment applied to the medicines, commonly applied variants in European countries are

prescription fees, percentage reimbursement / co-payment rates and, but to a less extent, deductibles.

See also: ➲ out-of pocket payments, prescription fee, percentage co-payment, deductible

[Source: adapted from OECD – Pharmaceutical Pricing Policies in a Global Market]

Cost-benefit Analysis
Compares the cost of a medicinal intervention to its benefit. Both costs and benefits must be measured in the same monetary units (e.g. euro, dollars)

[Source: Strom, Kimmel. Textbook of pharmacoepidemiology]

Cost-containment
Policies, interventions and activites aiming to reduce expenditure and/or the growth rate of expenditure, or the unit cost of services.

Cost-containment measures may be targeted to control inefficiencies in consumption, allocation, or production of health care services that contribute to higher than necessary costs.

Cost-containment is a word used freely in health care to describe most cost reduction activities by providers. This includes a broad range of cost control mechanisms e.g. limiting budgets, cost-sharing, regulation of supply of services and staff, patients' waiting lists, exclusion of certain groups from entitlement to services, privatisation, and managed competition.

Regarding medicines, it may concern the framework of the pricing and reimbursement systems (e.g. price control, ➲ reimbursement lists) and subsequent changes (e.g. ➲ price freezes/ ➲ price cuts, ➲ de-listings).

[Source: adapted from PPRI Glossary]

Cost-effectiveness
Value for money.

A specific health care treatment is said to be 'cost-effective' if it gives a greater health gain than could be achieved by using the resources in other ways.

[Source: NICE Glossary]

Cost-effectiveness Analysis (CEA)
Cost-effectiveness analysis (CEA) is an economic analysis that assesses both the costs and the effects of a health intervention.

Costs are measured in monetary units. Effects are measured in units of outcomes experienced such as life year gained (LYG), quality adjusted life of years (QALY) or cases of disease prevented. Whether the outcome of an analysis is cost-effective depends on the cost-effectiveness threshold value.

CEA can identify the alternative that, for a given output level, minimises the actual value of costs, or, alternatively, for a given cost, maximises the outcome level.

Cost-free Medicines
Cost-free medicines are products which are given to hospitals/hospital pharmacies in the course of the delivery without need for payment (e.g. from ➲ wholesaler to ➲ hospitals / ➲hospital pharmacies or pharmaceutical company to hospitals/hospital pharmacies.

[Source: Developed by PHIS group in the framework of PHIS Hospital Pharma]

Cost, Insurance and Freight (CIF)
The cargo insurance and delivery of goods to the named port of destination (discharge) at the seller's expense. Buyer is responsible for the import customs clearance and other costs and risks. In the export quotation, indicate the port of destination (discharge) after the acronym CIF, for example CIF Athens.

[Source: PPRI Glossary]

Cost-plus Pricing
Pricing procedure which calculates a 'reasonable' price for a product based on the production costs, promotional expenses, research & development, administration costs, overheads and profit.

[Source: adapted from PPRI Glossary]

Cost-sharing
A provision of health insurance or third party payment that requires the individual who is covered to pay part of the cost of health care received. This is distinct from the payment of a health insurance premium, contribution or tax which is paid whether health care is received or not.

See also: ➲ out-of pocket payments

[Source: OECD – A System of Health Accounts]

Counterfeit Medicine

The term counterfeit medicine describes a product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic medicines.

Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without ➲ active ingredients, with incorrect amounts of active ingredients, or with fake packaging. Violations or disputes concerning patents must not be confused with counterfeiting of medical products.

Medicines (whether generic or branded) that are not authorised for marketing in a given country but authorised elsewhere are not considered counterfeit.

Substandard batches of or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

[Source: WHO. International Medical Products Anti-Counterfeiting Taskforce — IMPACT. 2008]

Coverage

A measure of the extent to which the services rendered cover the potential need for those services in the community.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Coverage with Evidence Development (CED)

A binary coverage decision is conditioned upon the collection of additional population level evidence to support continues, expanded, or withdrawal of coverage.

See also: ➲ managed entry agreement

[Source: Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010 Aug. 96(3):179-90.]

Day Care

Day care comprises medical and paramedical services delivered to patients that are formally admitted for diagnosis, treatment or other types of health care with the intention of discharging the patient on the same day. An episode of care for a patient who is admitted as a day care patient and subsequently stays overnight is classified as an overnight stay or other in-patient case. Services for non-admitted patients that are extended to formal admission for day care are considered as day care. A day patient (or 'same-day patient') is usually admitted and then discharged after staying between 3 and 8 hours on the same day. Day care is usually performed in institutions or wards specialised for this kind of care (for example elective surgery).

[Source: OECD. A System of Health Accounts]

Deductible

Initial expense up to a fixed amount which must be paid out-of pocket for a service or over a defined period of time by an insured person; then all or a percentage of the rest of the cost is covered by a ➲ third party payer.

See also: ➲ out-of pocket payments

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Defined Daily Dose (DDD)

The DDD is a unit of measurement defined as the assumed average maintenance dose per day for a pharmaceutical used for its main indication in the adult. A DDD will normally not be assigned for a substance before a product is approved and marketed in at least one country. The basic principle is to assign only one DDD per route of administration within an ATC code. DDDs for plain substances are normally based on monotherapy. Doses for individual patients and patients groups will often differ from the DDD. DDD does not necessarily reflect the recommended or Prescribed Daily Dose.

DDDs are not established for topical products, sera, vaccines, antineoplastic agents, allergen extracts, general and local anaesthetics and contrast media.

[Source: WHO Collaborating Centre for Drug Statistics Methodology – Guidelines for ATC classification and DDD assignment]

De-listing (Delisting)

Exclusion of a medicine from a ➲ reimbursement list (e.g. ➲ positive list), often resulting in exclusion from ➲ reimbursement.

[Source: PPRI Glossary]

Delivery Chain (Supply Chain)
A delivery chain is the system of organisations, people, technology, activities, information and resources involved in moving a product or service from supplier to customer. Delivery chain activities in the pharmaceutical sector involve transformation of natural resources, raw materials and components into a finished pharmaceutical that is delivered to the patient or customer.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Demand
Schedule of quantities of a product (good/service) that potential buyer are willing and able to purchase at a given price during a certain period and at a certain location.

[Source:adapted from economics textbooks such as Samuelson & Nordhaus, Microeconomics]

Demand side Measures (Demand-side measures)
Policies that are directed at ➲ stakeholders such as health care professionals prescribing medicines (usually physicians), pharmacies and patients/consumers who prescribe, dispense and ask for medicines.

[Source: King DR, Kanavos P. Encouraging the Use of Generic Medicines: Implications for Transition Economies. Croatian Medical Journal. 2002;43(4):462-469]

Diagnosis Related Groups (DRG)
A classification system of hospital cases used to pay hospital services, regardless of the cost to the hospital to provide services.

The system is based not on the severity of the disease but on the amount of resources consumed.

It categorises illness by diagnosis and treatment. A specific software ('grouper') groups patients into 'homogeneous groups' on the basis of diagnosis at discharge (coded by the International Classification of Diseases) and modified by the presence of a surgical procedure, patient age, presence or absence of significant comorbidities or complications, and other relevant criteria.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Differential pricing
Differential pricing is the strategy of selling the same product to different customers at different prices. In the case of (reimbursable) medicine prices would vary among the countries according to their ability to pay. It was not introduced in the European countries due to the wide-spread practice of ➲ external price reference and the existence of parallel trade.

[Source: adapted from Bouvy J, Vogler S. Background Paper '8.3 Pricing and Reimbursement Policies: Impacts on Innovation' to the Priority Medicines for Europe and the World. 'A Public Health Approach to Innovation' Update 2013]

Direct Payments
Payments for goods and services which are not covered by a ➲ third party payer (including self-medication).

[Source: adapted from PPRI Glossary]

Disability-adjusted Life Years (DALYs)
A measure of the burden of disease on a defined population and the effectiveness of the intervention. DALYs are advocates as an alternative to QALY and claimed to be a valid indicator of population health.

They are based on adjustment of life expectancy to allow for long term disability as estimated from official statistics. However their use as currently expressed and calculated may be limited because the necessary data are not available or do not exist. Moreover, the concept postulates a continuum from disease to disability to death that is not universally accepted.

[Source: Last. A dictionary of epidemiology edited for the International Epidemiological Association]

Discount
A price reduction granted to specified purchasers under specific conditions prior to purchase.

See also: ➲ rebate

[Source: adapted from OECD. Pharmaceutical Pricing Policies in a Global Market]

Disease
A failure of the adaptive mechanisms of an organism to counteract adequately, normally or appropriately to stimuli and stresses to which the organism is subjected, resulting in a disturbance in the function or structure of some part of the organism. This definition emphasises that disease is multifactorial and may be prevented or treated by changing any or a combination of the factors.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Disease-specific Reimbursement
Eligibility for reimbursement is linked to the underlying disease which shall be treated.

[Source: PPRI Glossary]

Disinvestment
Disinvestment relates to the process of withdrawing health resources, either partially or completely, from existing healthcare practices (including procedures, devices, diagnostics, programs and pharmaceuticals) that are deemed to deliver no or low health gain for their cost, and are thus not efficient health resource allocations. Released resources can then be reinvested in clinical practices and technologies that deliver safe and effective healthcare for all patients, therefore representing efficient health resource allocation.

The term disinvestment is generally disliked by clinicians and consumers alike due to its negative connotations around funding withdrawal. While other, more acceptable terms include prioritisation, reappraisal, reprioritisation, optimisation, substitutional reinvestment and evidence-based reassessment, the term 'disinvestment' is currently used internationally.

It is distinguished between 'passive disinvestment' (interventions once common which get outmoded, e.g. surgical interventions) and 'active disinvestment': Active disinvestment strategies use a more directed approach to reduce the practice of unnecessary, ineffective, inefficient or harmful interventions. Nationally and internationally, ➲ health technology assessment (HTA) programs are now looking to incorporate processes for disinvestment where it is generally understood to mean that low- or no-value healthcare will cease to be funded where there is a lack of safety, clinical and cost effectiveness evidence to support its continued use.

See also: ➲ de-listing

[Source: Health Policy Advisory Committee on Technology. Disinvestment in Australia and New Zealand 2013]

Dispensing
To supply a clinically appropriate medicine to a patient or care giver, usually against a written prescription, for self-administration or administration by another professional, and to advise on safe and effective use.

[Source: Global Conference on the Future of Hospital Pharmacy]

Dispensing Doctors
Physicians who have been granted the right to dispense medicines to their patients.

[Source: PPRI Glossary]

Dispensing Fee
A type of ➲ remuneration to reward pharmacies for their service of filling prescriptions. Normally it is a fixed fee that pharmacies are allowed to charge per prescribed item, independent from the price of the medicine.

See also: ➲ mark-up, margins

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Distance Selling
Dispensing of pharmaceuticals via internet or posting services.

[Source: PPRI Glossary]

Distribution (Pharmaceutical Distribution)
The division and movement of pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Distribution Actors
Persons or entities involved in the supply, delivery and logistics management of medicines (e.g. ➲ wholesalers, importers).

Some distribution actors are also allowed to dispense medicines (e.g. ➲ pharmacists, ➲ dispensing doctors).

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Drug Utilisation Research
Research on marketing, distribution, prescription, and use of medicines in a society, with special emphasis on the resulting medical, social and economic consequences

[Source: World Health Organisation]

Early Awareness and Alert (EAA) System (Early Warning System)
A system that aims to identify, filter and prioritise new and emerging health technologies, or new uses of existing interventions; to assess or predict their impact on health, health services and/or society; and to disseminate information.

» Filter: a process to remove technologies that are not relevant to the early awareness and alert system from a list of technologies originating from the identification process.
» Prioritise: a process to determine the significance of, or order for dealing with, filtered technologies according to their relative importance to the aims of the early awareness and alert system.

See also: ➲ horizon scanning

[Source: International Information Network on New and Emerging Health Technologies (EuroScan International Network)]

Effectiveness
Effectiveness is the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice.

Relative effectiveness can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice.

[Source: European Union Pharmaceutical Forum. Core principles on relative effectiveness]

Efficacy
Efficacy is the extent to which an intervention does more good than harm under ideal circumstances.

Relative efficacy: can be defined as the extent to which an intervention does more good than harm, under ideal circumstances, compared to one or more alternative interventions.

[Source: European Union Pharmaceutical Forum. Core principles on relative effectiveness]

Efficiency
An ability to perform well or achieve a result without wasted energy, resources, effort, time or money thus the extent to which objectives are achieved by minimising the use of resources (i.e. obtaining the best possible value for the resources used).

Greater efficiency is achieved where the same amount and standard of services are produced for a lower cost, if a more useful activity is substituted for a less useful one at the same cost or if needless activities are eliminated.

Efficiency can be measured in physical terms (technical efficiency) or terms of cost (economic efficiency).

Technical efficiency means producing the maximum possible sustained output from a given set of inputs.

Allocative efficiency is when resources are allocated in such a way that any change to the amounts or types of outputs currently being produced (which might make someone better off) would make someone worse off.

[Source: World Bank]

Eligibility Scheme(s)
There are, in general, 4 types of eligibility schemes:

» product-specific reimbursement
» disease-specific reimbursement,
» population-group-specific reimbursement,
» consumption-based reimbursement

[Source: PPRI Glossary]

Emergency
Sudden unexpected onset of illness or injury which requires the immediate care and attention of a qualified physician, and which, if not treated immediately, would jeopardise or impair the health of the individual.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Emergency Unit
The section of a health care facility for providing rapid treatment to victims of sudden illness or trauma.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

End Users of medicine (End Users)
End users can be patients, consumers, or professional who directly use the pharmaceutical product on patients/consumers.

[Source: WHO. IMPACT. Principles and elements for national legislation against counterfeit medical product]

Equitable access to medicines
Equitable access to medicines involves:

a. a fair and non-discriminating access to needed medicines for all citizens; fair in the sense of being distributed at a price the individual and the community can afford
b. making sure that the essential medicines (those that satisfy the priority health care needs of the population) are available
c. affordability for all citizens, especially regarding vulnerable groups (e.g. with increased needs for medicines, low socio-economic status)

Access to health care and therefore to essential medicines is part of the fulfilment of the fundamental right to health. All countries have to work towards the fulfilment of equitable access to health services and commodities, including essential medicines necessary for the prevention and treatment of prevalent diseases.

See also: ➲ access to medicine, essential medicines

[Source: developed by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies based on WHO. Equitable Access to Essential Medicines: A Framework for Collective Action – WHO Policy Perspectives on Medicines, No. 008, March 2004]

Essential Medicines

Essential medicines are those that satisfy the priority health care needs of the population.

They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

The concept of essential medicines is forward-looking. It incorporates the need to regularly update medicines selections to reflect new therapeutic options and changing therapeutic needs; the need to ensure medicine quality; and the need for continued development of better medicines, medicines for emerging diseases, and medicines to meet changing resistance patterns.

[Source: WHO. Equitable Access to Essential Medicines: A Framework for Collective Action – WHO Policy Perspectives on Medicines, No. 008, March 2004]

Evidence Based Medicine (EBM)

The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.

[Source: Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312(7023):71-2]

Excipient
A substance, other than the ➲ active ingredient, which has been appropriately evaluated for safety and is included in a medicine delivery system to:

» aid in the processing of the medicine delivery system during its manufacture;
» protect, support or enhance stability, bioavailability, or patient acceptability;
» assist in product identification; or
» enhance any other attribute of the overall safety and effectiveness of the medicine during storage or use.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Ex-factory Price
The manufacturer's posted price. ➲ Discounts or other incentives offered by manufacturers result in an actual price that is lower than the ex-factory price.

[Source: adapted from OECD. Pharmaceutical Pricing Policies in a Global Market]

Extemporaneous Dispensing
The manipulation by pharmacists of various medicine and chemical ingredients using traditional compounding techniques to produce suitable medicines when no commercial form is available.

See also: ➲ compounding, magistral formula (extemporaneous preparation), officinal formula

[Source: Brion F, Nunn AJ, Rieutord A. Extemporaneous (magistral) preparation of oral medicines for children in European Hospitals. Acta Paediatr. 2003; (294): 486-496, cited in: http://www.who.int/childmedicines/partners/Nunn_Extemp_Partners.pdf]

External Price Referencing (International Price Comparison, External Reference Pricing, EPR, ERP, IPR)
The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.

[Source: adapted from PPRI Glossary]

Fee-for Service (Fee-for Service Remuneration)
Payments to a provider (for example a general practitioner) for each act or service rendered. Pharmacy ➲ remuneration might also be organised as fee-for service

remuneration; in this case, pharmacists get remunerated for different types of services, e.g. for the filling of prescriptions, counselling, administrative tasks, etc.).

See also: ➲ dispensing fee, margin, mark-up

[Source: PPRI Glossary]

Fixed Co-payment
An out-of pocket payment in the form of a fixed amount (like for example a prescription fee) to be paid for a service, a ➲ medicine or a ➲ medical device.

See also: ➲ deductible and percentage co-payment

[Source: PPRI Glossary]

Fixed Dose Combination (FDC) Product
A combination of two or more active substances in a fixed ratio of doses. This term is used generically to mean a particular combination of active substances irrespective of the formulation or brand. It may be administered as single entity products given concurrently or as a finished pharmaceutical product.

[Source: WHO expert committee on specifications on pharmaceutical preparations]

Forecasting
Evidence-based expections on sales, budget requirements, demand, projected health gain/outcome and similar.

See also: ➲ pre-launch activity

[Source: WHO Regional Office for Europe. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. 2015]

Free Pricing
Pricing ➲ policy, where pharmaceutical companies determine the price of the medicine they launch.

See also: ➲ price control, pricing policies

[Source: PPRI Glossary]

Full-line Wholesale (Full-line Wholesaling, Full-liner)
All activities consisting of the purchase and sale, warehousing, order preparation and delivery / distribution of the full assortment of medicines (in range and depth) on a defined market.

[Source: adapted from GIRP website]

Gatekeeper
A health professional, who may be a medical practitioner, nurse or other professional, who has the first encounter with an individual and controls the individual's entry into the health care system.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

General Sales List (GSL) Medicines
Specific OTC medicines allowed for general sale might be sold by any ➲ retailer with the respective license. Usually, these are food shops, super- and minimarkets, grocery stores, para-pharmacies and petrol stations.

See also: ➲ Pharmacy-only medicine

[Source: EMINet: OTC medicines - Distribution]

General Practitioner (GP)
A physician (medical doctor) who does not limit his/her practice to certain disease categories and assumes the responsibility for the provision of continuing and comprehensive medical care or referring to another health care professional.

In all EU countries, GP is treated as a specialisation.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Generic (Generic Medicine)
A pharmaceutical product (medicine) which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicine, and whose bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies.

According to European Community legislation, different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in

properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form.

Generics can be classified in **branded generics** (generics with a specific 'invented' trade name) and **unbranded generics** (which use the International Non-proprietary name and the name of the company).

The above mentioned definition refers to European legislation. However, it should be noted that there is a variety of different, sometimes overlapping, definitions of the term 'generics' due to differences in the requirements for registration of generics between countries the world over, especially differences related to the degree and proof of therapeutic equivalence and the fact that they can be sold under brand (branded generics) or International Nonproprietary Name (unbranded generics).

The World Health Organization (WHO) defines generics as multi-source pharmaceutical products that are therapeutically equivalent are interchangeable, not taking into consideration of whether or not the 'originator' molecule is, or was, under patent protection.

See also: ➲ Biosimilar, multi-source medicine, off-patent medicine, on-patent medicine

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; WHO. Report 40. Annex 7. Technical Report No. 937. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Geneva: World Health Organization; 2006]

Generic Policies (Generics Policies, Generic Promotion Policies, Generic Promotion)
Regulation, measures and initiatives, typically undertaken by the government authorities, to promote the use of ➲ generics and/or (licensed) ➲ off-patent medicines. It includes ➲ generic substitution, ➲ international non-proprietary name (INN) prescribing and campaigns to raise awareness and inform the public. Generic policies may be targeted at prescribers, ➲ pharmacists, patients/consumers and other stakeholders.

[Source: adapted from PPRI Glossary]

Generic Price Link (Generic Price Linkage)
Practice of ➲ setting the price of a ➲ generic in relationship to the ➲ original product medicine, usually at a certain percentage lower than the original medicine price. The design of this generic price link policy may vary, with different percentages for the different generics (first generic coming to the market, second generic, etc.), and in some cases the prices of orignal medicines might also be part of the policy, i.e. that they will also be required to decrease.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement]

Generic Substitution
Practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same ➲ active ingredient(s). Generic substitution may be allowed (indicative generic substitution) or required (mandatory/obligatory generic substitution).

See also: ➲ INN prescribing

[Source: adapted from WHO. A model quality assurance system for procurement agencies]

Global Budgeting
A method of hospital funding in which participating hospitals must share a prospectively set budget.

Method for allocating funds among hospitals may vary but the key is that the participating hospitals agree to an aggregate cap on revenues that they will receive each year.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

[Source: ICH Guideline for Good Clinical Practice]

Good Distribution Practices (GDP)
Good distribution practices are that part of quality assurance that ensure that the quality of a pharmaceutical products is maintained through adequate control throughout the numerous activities which occur during the distribution process.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Good Manufacturing Practices (GMP)
That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation.

[Source: WHO. Quality assurance of pharmaceuticals. A compendium of guidelines and related materials, 1999]

Gross Domestic Product (GDP)
The gross domestic product (GDP) is defined as the gross expenditure on the final uses of the domestic supply of goods and services valued at purchasers values less imports of goods and services. Comparisons of gross domestic products are arguably best based on purchasing power parities (PPP) and not on market exchange rates.

[Source: OECD. Society at a glance, 2001]

Group Purchasing
Formation of an alliance of several purchasers to negotiate product price based on increased volume. This includes bulk procurement through a tender system, at a national or regional level.

[Source: Global Conference on the Future of Hospital Pharmacy]

Guideline
A systematically developed tool which describes aspects of a patient's condition and the care to be given. A good guideline makes recommendations about treatment and care, based on the best research available, rather than opinion. It is used to assist clinician and patient decision-making about appropriate health care for specific clinical conditions.

[Source: NICE Glossary]

Haemovigilance
A set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients of blood products, and the epidemiological follow-up of donors.

[Source: Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003]

Health
A state of complete physical, social and mental well-being, and not merely the absence of disease or infirmity.

Health is a resource for everyday life, not the object of living. It is a positive concept emphasising social and personal resources as well as physical capabilities.

It is recognised, however, that health has many dimensions (anatomical, physiological, and mental) and is largely culturally defined.

[Source: WHOTERM WHO Terminology Information System]

Health care Provider
A health care provider or health professional is an organisation or person who delivers proper health care in a systematic way professionally to any individual in need of health care services.

[Source: Global Conference on the Future of Hospital Pharmacy]

Health Economics
The study of how scarce resources are allocated among alternative uses for the care of sickness and the promotion, maintenance and improvement of health, including the study of how health care and health related services, their costs and benefits, and health itself are distributed among individuals and groups in society.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Health Establishment
A health establishment is the whole or part of a public or private facility, building or place, whether operated for profit or not, that is operated or designed to provide health care services including the supply of pharmaceutical products to the end user.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Health Expenditure (HE, Total Health Expenditure, THE)

Health expenditure is defined as the sum of expenditure on activities that – through application of medical, paramedical, and nursing knowledge and technology – has the goals of:

» Promoting health and preventing disease;
» Curing illness and reducing premature mortality
» Caring for persons affected by chronic illness who require nursing care;
» Caring for persons with health-related impairments, disability, and handicaps who require nursing care;
» Assisting patients to die with dignity;
» Providing and administering public health;
» Providing and administering health programmes, health insurance and other funding arrangements.

Health expenditure includes expenditure on:

Personal health (curative care, rehabilitative care, long term nursing care, ancillary services to health care, medical goods dispensed to ➲ out-patients) and expenditure on

Collective health (prevention and public health, administration and insurance).

Health expenditure can be separated in:

Public expenditure*:* health expenditure incurred by public funds (state, regional and local government bodies and social security schemes).

Private expenditure*:* privately funded part of total health expenditure. Private sources of funds include out-of pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care.

[Source: OECD. A System of Health Accounts]

Health Information

Health information is information and data that relates to the past, present or future health or condition of an individual or the provision, organisation and funding of health care.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Health Status
The state of health of a specified individual, group, or population.

It may be measured by obtaining proxies such as people's subjective assessments of their health; by one or more indicators of mortality and morbidity in the population, such as longevity or maternal and infant mortality; or by using the incidence or prevalence of major diseases.

Conceptually, health status is the proper outcome measure for the effectiveness of a specific population's medical care system, although attempts to relate effects of available medical care to variations in health status have proved difficult.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Health Technology
Health technologies include ➲ medicines, ➲ medical devices such as artificial hip joints, diagnostic techniques, surgical procedures, health promotion activities (e.g. the role of diet versus medicines in disease management) and other therapeutic interventions.

[Source: NICE Glossary]

Health Technology Assessment (HTA)
Health technology is the application of scientific knowledge in health care and prevention.

Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.

Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

[Source: EUnetHTA]

Herbal Medicine
Any medicine, exclusively containing as ➲ active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Herbal substances
All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances.

Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Herbal preparations
Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

High-Cost Medicine (High-priced Medicine, Premium-priced Medicine)
The concept of 'high-cost', 'high-priced' or 'premium-priced' medicines has not yet been clearly defined internationally. In principle, high cost (expenditure) of medicines can also be attributable to high prices. The high price itself might not be the decisive criterion: other determining factors may include use of or demand for the product, resulting in high costs for the treatment of the patient. A broad definition of a new premium-priced medicine is one whose acquisition cost is greater than €10 000 per patient for a yearly therapy for the public payer and which is replacing an existing medicine (whose costs public payers were already paying). Few countries in Europe seem to have a country-specific definition of what is a high-cost medicine.

[Source: adapted from WHO Regional Office for Europe. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. 2015]

High-cost Patient
A patient whose condition requires large financial expenditures or significant human and technological resources.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

High-risk Patient
A patient who has a complex or catastrophic illness or injury or who requires extensive medical interventions or treatment plans.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

High-risk Procedures
Generic procedures involving the preparation and administration of products (e.g. medicines) that have been identified by risk assessment as most likely to pose a significant risk to patients.

[Source: National Patient Safety Agency. Patient Safety Alert No. 20]

High-risk Products
Those products (e.g. medicines) whose preparation and/or administration have been identified by risk assessment as most likely to pose a significant risk to patients.

[Source: National Patient Safety Agency. Patient Safety Alert No. 20]

Home Care
This item comprises medical and paramedical services delivered to patients at home. Included are obstetric services at home, home dialysis, telematic services and the like.

It excludes the consumption of medical goods (pharmaceuticals, other medical goods) dispensed to ➲ out-patients as part of private household consumption.

[Source: OECD. A System of Health Accounts]

Homeopathic Medicines
Any medicine prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or,

in the absence thereof, by the pharmacopoeias currently used officially in the Member States.

A homeopathic medicinal product medicine may contain a number of principles.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

Horizon Scanning
The systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to effect health, health services and/or society.

An emerging health technology in this context is a health technology that has not yet been adopted within the healthcare system. Pharmaceuticals are in the Phase II or III clinical trial, or pre-launch stage; medical devices are in the pre-marketing stage.

A new health technology is a health technology that is in the launch, early post-marketing, or early diffusion stages.

Horizon scanning systems (e.g. early awareness and alert (EAA) systems) aim to support decision-making and the adoption and use of innovative technologies to the benefit of patients and health services.

See also: ➲ pre-launch activity, ➲ Early awareness and alert (EAA) system

[Source: International Information Network on New and Emerging Health Technologies (EuroScan International Network)]

Hospice (Hospice Care)
Facility or program providing care for the terminally ill.

Hospice care involves a team-oriented approach that addresses the medical, physical, social, emotional and spiritual needs of the patient.

Hospice also provides support to the patient's family or caregiver as well.

[Source: Medicare Glossary]

Hospital

Licensed establishment primarily engaged in providing medical, diagnostic, and treatment services that include physician, nursing, and other health services to in-patients and the specialised accommodation services required by in-patients. Hospital provides in-patient health services, many of which can only be provided using the specialised facilities and equipment that form a significant and integral part of the production process. In some countries, health facilities need in addition a minimum size (such as number of beds) in order to be registered as a hospital.

Hospitals may also provide out-patient services as a secondary activity.

Hospitals can be classified in general hospitals, mental health and substance abuse hospitals and speciality (other than mental health and substance abuse) hospitals.

A **general hospital** is a licensed establishments primarily engaged in providing diagnostic and medical treatment (both surgical and non-surgical) to in-patients with a wide variety of medical conditions. These establishments may provide other services, such as out-patient services, anatomical pathology services, diagnostic X-ray services, clinical laboratory services, operating room services for a variety of procedures, and pharmacy services.

A **mental health and substance abuse hospital** is a licensed establishment primarily engaged in providing diagnostic and medical treatment, and monitoring services to in-patients who suffer from mental illness or substance abuse disorders. The treatment often requires an extended stay in an in-patient setting including hostelling and nutritional facilities. Psychiatric, psychological, and social work services are available at the facility. These hospitals usually provide other services, such as out-patient care, clinical laboratory tests, diagnostic X-rays, and electroencephalography services.

A **speciality hospital** is a licensed establishment primarily engaged in providing diagnostic and medical treatment to in-patients with a specific type of disease or medical condition (other than mental health or substance abuse). Hospitals providing long term care for the chronically ill and hospitals providing rehabilitation, and related services to physically challenged or disabled people are included in this item. These hospitals may provide other services, such as out-patient services, diagnostic X-ray services, clinical laboratory services, operating room services, physical therapy services, educational and vocational services, and psychological and social work services.

Regarding ownership hospitals can be divided into public, non-profit and for-profit hospitals. **Public hospitals** are owned and funded by the state (e.g. federal state, regions, municipalities), whereas **non-profit hospitals** are privately owned (e.g. by religious orders). However, non-profit hospitals often function in the public sector.

Private for-profit hospitals are owned by non-public stakeholders and act on a commercial basis.

[Source: OECD. A System of Health Accounts; adaption/further definitions by PHIS group in the framework of PHIS Hospital Pharma]

Hospital Admission (Hospitalisation)
The initiation of care, usually referring to in-patient care, although the term may be used for day or community care as well.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Hospital Association
Is a union of two or more hospitals e.g. within a certain geographic area or of the same owner that medically and operationally collaborate (e.g. with regard to purchase of medicines) in order to benefit from synergy effects.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Hospital Beds
Beds which are regularly maintained and staffed in a hospital and immediately available for the care of admitted patients.

They can be divided in:

***Curative care (acute care) beds**:* are hospital beds that are available for curative care and where the principal clinical intent is to do one or more of the following: manage labour (obstetric), cure non-mental illness or provide definitive treatment of injury, perform surgery, relieve symptoms of non-mental illness or injury (excluding palliative care), reduce severity of non-mental illness or injury, protect against exacerbation and/or complication of an non-mental illness and/or injury which could threaten life or normal functions, perform diagnostic or therapeutic procedures.

***Psychiatric care beds**:* are hospital beds accommodating patients with mental health problems.

***Long term care beds**:* are hospital beds accommodating patients requiring long term care due to chronic impairments and a reduced degree of independence in activities of daily living (including beds in long term care departments of general hospitals, beds for long term care in specialty (other than mental health and substance abuse), beds for palliative care).

***Other beds**:* All other beds in hospitals not elsewhere classified (including beds for rehabilitation).

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Hospital Blood Bank
A hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities.

[Source: Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003)

Hospital Day (Bed-day, In-patient Day)
A day during which a person admitted as an in-patient is confined to a bed and in which the patient stays overnight in a hospital.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Hospital Discharge
A (hospital) discharge is the formal release of a patient from a hospital after a procedure or course of treatment (episode of care).

A discharge occurs anytime a patient leaves because of finalisation of treatment, signs out against medical advice, transfers to another health care institution or because of death.

A discharge can refer to in-patients or day care patients.

Transfers to another department within the same institution are not considered discharges.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Hospital-only Medicines (HOM)
Type of classification; medicines that may only be administered in hospitals.

[Source: PPRI Glossary]

Hospital Pharmaceutical Formulary (Hospital Formulary, HPF)
A list of medicines that may be prescribed and applied by physicians in a hospital.

Please note that the term 'hospital formulary', used here as synonym, may also be applied.

Hospital Pharmacists
Health care professionals who provide services to patients and health care professionals in hospitals.

[Source: adapted from European Association of Hospital Pharmacists]

Hospital Pharmacy
Hospital pharmacy is the health care service, which comprises the art, practice, and profession of choosing, preparing, storing, compounding, and dispensing pharmaceuticals and ➲ medical devices, advising health care professionals and patients on their safe, effective and efficient use.

Hospital pharmacy is a specialised field of pharmacy which forms an integrated part of patient health care in a health facility.

Hospital pharmacy is the profession that strives to continuously maintain and improve the medication management and pharmaceutical care of patients to the highest standards in a hospital setting.

[Source: European Association of Hospital Pharmacists]

Hospital Pharmacy Specialist
A pharmacist who has completed an additional training program after completing the pharmacist degree in order to gain more specific and in-depth knowledge about hospital pharmacy.

This definition does not describe pharmacists that work in hospitals who have not completed additional training.

[Source: Global Conference on the Future of Hospital Pharmacy]

Hospital Price (Average Selling Price to Hospitals)
The price or amount paid by a hospital (or hospital pharmacy) in order to take delivery of certain unit of medicines. Often, the hospital list price corresponds to the ex-factory

price, in some cases to the pharmacy purchasing price. It may or may not include ➲ value-added tax/VAT. In addition, ➲ discounts and/or➲ rebates may be granted to the ➲ hospitals by the ➲ suppliers.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Hospital Purchasing Body (Hospital Procurement Body, Hospital Purchasing Committee, Hospital Procurement Committee)

The hospital purchasing body is responsible for buying medicines used in their hospital(s) via direct negotiations with medicine companies or the process of public procurement. A hospital purchasing body can either be a single person (e.g. the hospital head pharmacist), a joint committee (e.g. ➲ hospital pharmacists of more hospitals), a designated purchasing department established at the management of a hospital or a hospital owner organisation.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Hospitalisation Rate

The number of hospital cases in a given population on an established period of time.

Statistics on hospitalisation rate can be disaggregated by reasons for hospitalisation (according to Major Diagnostic categories or at lower level) and/or by age.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Human Medicine

1. Any ➲ active ingredient or combination of active ingredients presented as having properties for treating or preventing disease in human beings.
2. Any ➲ active ingredient or combination of active ingredients which may be used in human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions.

[Source: PPRI Glossary]

Illness

A person's own perceptions, experience and evaluation of a disease or condition, or how he or she feels. For example, an individual may feel pain, discomfort, weakness, depression or anxiety, but a disease may or may not be present.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Indicators

A parameter that aims to describe, in a few numbers as much detail as possible about a system, to help understand, compare, predict, improve, and innovate. .Indicators serve two major functions: They reduce the number of measurements and parameters that normally would be required to give a accurate picture of a situation, and they facilitate the communication process for providing the reader with the results of measurement.

[Source: adapted from NHS – the good indicators guide]

Structural, process and outcome indicators can be distinguished. Indicator data can either be quantitative or qualitative.

Structural indicators: These indicators provide qualitative information to assess the pharmaceutical system's capacity to achieve its policy objectives. They are intended to check whether the key structures/systems/mechanisms necessary to implement a pharmaceutical policy exist in the country (e.g. POM dispensaries)

Process indicators: Process indicators assess the degree to which activities necessary to attain the objectives are carried out and their progress over time (e.g. pricing policies).

Outcome indicators: These indicators measure the results achieved and the changes that can be attributed to the implementation of a policy (e.g. life expectancy).

[Source: adapted from WHO. Indicators for Monitoring National Drug Policies]

Infusion

Administration, from a syringe or other rigid or collapsible container e.g. plastic bag, of a volume of sterile solution of an injectable medicine directly into a tissue, organ, vein or artery, at a constant rate, under gravity or by means of an electronic or mechanical pump or other means of rate control, over a defined period usually of at least 10 minutes.

[Source: National Patient Safety Agency. Patient Safety Alert No. 20]

Informal Payments
Informal payments are payments to health care professionals in cash or in kind made outside official remuneration for these services by ➲ third party payers. They are usually provided by patients.

[Source: PPRI Glossary]

Injectable Medicines
Sterile medicines intended for administration by bolus injection, perfusion or infusion by any of the following routes: intravenous, intramuscular, intrathecal, intra-arterial, subcutaneous, intradermal, intraventricular, epidural, intravesicular, intravitreal, intrapleural and intraocular.

An injectable medicine is **Ready-to-administer** when it requires no further dilution or reconstitution and is presented in the final container or device, ready for administration or connection to a needle or administration set. For example, an infusion in a bag with no additive required.

An injectable medicine is **Ready-to-use** when it requires no further dilution or reconstitution before transfer to an administration device. For example, a liquid with an ampoule, of the required concentration, that only needs to be drawn up into a syringe.

[Source: National Patient Safety Agency. Patient Safety Alert No. 20]

In-patient Care
An in-patient is a patient who is formally admitted (or 'hospitalised') to an institution for treatment and/or care and stays for a minimum of one night in the hospital or other institution providing in-patient care.

In-patient care is mainly delivered in hospitals, but partially also in nursing and residential care facilities or in establishments that are classified according to their focus of care under the ambulatory-care industry but perform in-patient care as a secondary activity.

It should be noted that the term 'in-patient' used in the OECD-SHA has a wider meaning compared to some national reporting systems where this term is limited to in-patient care in hospitals. Included are services delivered to in-patients in prison and army hospitals, tuberculosis hospitals, and sanatoriums.

In-patient care includes accommodation provided in combination with medical treatment when the latter is the predominant activity provided during the stay as an in-patient.

On the other hand, accommodation in institutions providing social services, where health care is an important but not predominant component should not be included in the health function. Examples might include institutions such as homes for disabled persons, nursing homes, and residential care for substance abuse patients.

[Source: OECD. A System of Health Accounts]

Integrated Care (Comprehensive Care, Transmural Care)

Is a concept bringing together inputs, delivery, management and organization of services related to diagnosis, treatment, care, rehabilitation and health promotion. Integration is a means to improve services in relation to access, quality, user satisfaction and efficiency.

See also: ➲ continuity of care, ➲ interface management, ➲ seamless care

[Source: Gröne O, Garcia-Barbero M. Trends in Integrated Care – Reflections on Conceptual Issues. Copenhagen: World Health Organization, 2002]

Interchangeable Medicine (Interchangable Pharmaceutical Product)
An interchangeable medicine is one which is therapeutically equivalent to a comparator product and can be interchanged with the comparator in clinical practice.

See also: ➲ generic, ➲ multi-source medicine, ➲ off-patent medicine, ➲ on-patent medicine

[Source: WHO. MultiSource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability]

Interface Management
Mechanisms of cooperation between the hospital and the out-patient sectors.

In the pharmaceutical system of several countries, the provision of medicines in the out- and the in-patient sectors is realised by different actors and following different pharmaceutical policies. Interface management measures increase a seamless treatment with medicines, continuation of care according to the patient's needs and ensure an efficient use of resources in health care systems.

See also: ➲ continuity of care, ➲ seamless care, ➲ integrated care (comprehensive care, transmural care)

[Source: adapted from PHIS Glossary]

Internal Price Referencing
The practice of using the price(s) of identical medicines (➲ ATC 5 level) or similar products (➲ ATC 4 level) or even with ➲ therapeutically equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.

[Source: adapted from PPRI Glossary]

International Classification of Diseases (ICD)
The WHO (World Health Organization) international standard diagnostic classification coding system used for all general epidemiological and many health management purposes.

The purpose of the ICD is to permit the systematic recording, analysis, interpretation and comparison of mortality and morbidity data collected in different countries or areas and at different times.

[Source: PPRI Glossary]

International Classification of Functioning, Disability and Health (ICF)
A classification of health and health-related domains that describe body functions and structures, activities and participation. The domains are classified from body, individual and societal perspectives. Since an individual's functioning and disability occurs in a context, this classification includes a list of environmental factors.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

International Classification of Health Problems in Primary Care (ICHPPC)
A classification of diseases, conditions and other reasons for attendance for primary care. This classification is an adaptation of the ICD but makes allowance for the diagnostic uncertainty that prevails in primary care.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

International Classification of Primary Care (ICPC)
The official classification of the World Health Organisation of Family Doctors. It includes three elements of the doctor-patient encounter: the reason for the encounter; the diagnosis; and the treatment or other action or intervention.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

International Non-proprietary Name (INN, Generic Name)
The shortened scientific name based on the active ingredient. WHO is responsible for assigning INNs to pharmaceutical substances.

INN is a unique name that is globally recognised and is public property.

Since its inception, the aim of the INN system has been to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance. The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide.

As unique names, INN have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INN universally available they are formally placed by WHO in the public domain, hence their designation as 'non-proprietary'. They can be used without any restriction whatsoever to identify pharmaceutical substances.

Another important feature of the INN system is that the names of pharmacologically-related substances demonstrate their relationship by using a common 'stem'. By the use of common stems the medical practitioner, the ➲ pharmacist, or anyone dealing with pharmaceutical products can recognise that the substance belongs to a group of substances having similar pharmacological activity.

Non-proprietary names are intended for use in pharmacopoeias, labelling, product information, advertising and other promotional material, medicine regulation and scientific literature, and as a basis for product names, e.g. for generics. Their use is normally required by national or, as in the case of the European Community, by international legislation.

As a result of ongoing collaboration, national names such as British Approved Names (BAN), Dénominations Communes Françaises (DCF), Japanese Adopted Names (JAN) and United States Adopted Names (USAN) are nowadays, with rare exceptions, identical to the INN.

To avoid confusion, which could jeopardise the safety of patients, trade-marks cannot be derived from INN and, in particular, must not include their common stems.

[Source: WHO. Guidance on INN. Available at:
http://www.who.int/medicines/services/inn/innguidance/en/index.html*]*

International Non-proprietary Name Prescribing (INN Prescribing)
Requirements for prescribers (e.g. physicians) to prescribe medicines by its ➲ INN, i.e. the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory/obligatory INN prescribing).

See also: ➲ generic substitution

[Source: PPRI Glossary]

Internet Pharmacy (Online Pharmacy)
Umbrella term for ➲ retailers of ➲ prescription-only medicines (POM) and ➲ Over-the-Counter (OTC= medicines who sell their products via the World Wide Web.

[Source: PPRI Glossary]

Joint Procurement
The procurement of certain products or services is done by a single purchasing body for several healthcare providers (e.g. hospitals, regions, countries).

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Length of Stay (LOS)
The number of days an individual stays in a hospital or in-patient facility.

The **average length of stay (ALOS)** is computed by dividing the number of hospital days (or bed-days or in-patient days) from the date of admission in an in-patient institution (date of discharge minus date of admission) by the number of discharges (including deaths) during the year.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Life Expectancy
A statistical abstraction based on existing age-specific death rates.

The average number of years an individual of age x is expected to live if current mortality rates continue to apply.

***Disability-free life expectancy**:* It is the number of healthy years of life that can be expected on average in a given population. It is generally calculated at birth, but estimates can also be prepared at other ages. It adjusts the expectation of years of life for the loss on account of disability, using explicit weights for different health states.

[Source: European Health Expectancy Monitoring Unit. Glossary & WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Line-item Budgeting
A general term used to describe a relatively unsystematic budgetary chart of accounts.

In addition to standard votes or 'lines' for items such as 'salaries and wages', separate lines for new requirements are introduced as they arise, thus giving rise to lengthy, ad hoc forms for appropriating and accounting for spending.

[Source: OECD. Glossary of Statistical Terms]

List Price
The prices that purchasers display as the prices at which they are prepared to sell their products and/or regulated by legislation. The prices of products as quoted in the purchaser's price list, catalogue, internet site, advertisements, in a national price list/formulary etc. They are not necessarily actual transaction prices. Depending on the country and/or the product, they may or may not include delivery and installation costs, ➲ VAT and other indirect taxes on products, ➲ discounts, surcharges and ➲ rebates, invoiced service charges and voluntary gratuities. Certain pharmaceutical transactions, such as setting payment rates to pharmacies, may be based on list prices.

Also referred to as 'Offer price'.

[Source: EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)]

Lifecylce Management

The practice of brand-name manufacturers seeking to further extend the market exclusivity periods for their medicines to maintain revenue streams. Market exclusivity extensions may be achieved through a number of different strategies, often called 'evergreening strategies'

[Source: Kesselheim AS (2013) Rising Health Care Costs and Life-Cycle Management in the Pharmaceutical Market. PLoS Med 10(6): e1001461. doi:10.1371/journal.pmed.1001461]

Long Term Care (LTC, Long Term Aged Care)

A range of health care, personal care and social services provided to individuals who, due to frailty or level of physical or intellectual disability, are no longer able to live independently. Services may be for varying periods of time and may be provided in a person's home, in the community or in residential facilities (e.g. nursing homes or assisted living facilities). These people have relatively stable medical conditions and are unlikely to greatly improve their level of functioning through medical intervention.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Long Term Care Beds in Hospital

Hospital beds accommodating patients requiring long term care due to chronic impairments and a reduced degree of independence in activities of daily living.

They include: Beds in long term care departments of general hospitals, beds for long term care in specialty (other than mental health and substance abuse) hospitals, beds for palliative care.

They do not include: beds in mental health and substance abuse hospitals, beds for rehabilitation.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Long Term Care Beds in Nursing and Residential Care Facilities
Beds, dedicated to long term nursing care or used for palliative care, for people requiring ongoing health and nursing care due to chronic impairments and a reduced degree of independence in activities of daily living (ADL).

Can be divided in:

Beds in nursing and residential care facilities when the establishments are primarily engaged in providing residential care combined with either nursing, supervision or other types of care as required by the residents.

Beds in nursing care facilities when the establishments are primarily engaged in providing in-patient nursing and rehabilitative services.

In both cases the care provided can be a mix of health and social services.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Magistral Formula (Extemporaneous Preparation)
Any medicine prepared in a pharmacy in accordance with a medical prescription for an individual patient.

See also: ➲ compounding, extemporaneous dispensing, officinal formula

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

Major Diagnostic Category (MDC)
A clinically coherent group of ➲ International Classification of Diseases (ICD) diagnoses by major organ system or etiology that is used as the first step in assignment of most diagnosis related groups (DRGs). MDCs are commonly used for aggregated DRG reporting.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Managed Entry Agreement (MEA; Managed-Entry Agreement)
An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize their effective use, or limit their budget impact.

[Source: Klemp M, Frønsdal KB, Facey K. What principles should govern the use of Managed Entry Agreements? International Journal of Technology Assessment in Health Care. 2011 Jan;27(1):77-83]

Types of managed entry agreements:

» ➲ Access with evidence development (AED)
» ➲ Conditional coverage
» ➲ Conditional treatment continuation (CTC)
» ➲ Coverage with evidence development (CED)
» ➲ Only in research (OIR)
» ➲ Only with research
» ➲ Outcome guarantees
» ➲ Patient access scheme (PAS)
» ➲ Pattern or process care
» ➲ Performance based agreement
» ➲ Performance based health outcome reimbursement schemes
» ➲ Performance-linked reimbursement
» ➲ Price volume agreement
» ➲ Risk sharing schemes (RSS)

Please consult definitions in this Glossary in alphabetical order.

Manufacturer
Natural or legal person with responsibility for the manufacturing of a product.

Manufacturing includes all operations of receipt of materials, production, packaging, repackaging, labelling, relabeling, quality control, release, storage, and distribution of ➲ active pharmaceutical ingredients (APIs) and related controls.

[Source: EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use]

Margin (Distribution Margin)
The percentage of the selling price that is profit.

In the case of the ➲ pharmaceutical distribution, a wholesale or pharmacy margin is one type of remuneration awarded to ➲ distribution actors such as ➲ wholesalers and ➲ pharmacies for handling their services.

The **wholesale margin** is the gross profit of wholesalers, expressed as a percentage of the wholesale price (pharmacy purchasing price).

The **pharmacy margin** is the gross profit of pharmacies expressed as a percentage of the pharmacy retail price.

See also: ➲ mark-up

[Source: adapted from PPRI Glossary]

Marginal Cost (Incremental Cost, Differential Cost)
Increase or decrease in costs as the result of one more or one less unit of output.

Determining marginal cost is important in deciding whether or not to vary a rate of production.

[Source: J.P. Friedmann. Dictionary of business terms]

Mark-up (Distribution Mark-up)
A defined (linear or percentage) amount is added on to the cost of a good to create a profit (either linear or regressive at the wholesale and/or retail levels). In the case of the ➲ pharmaceutical distribution, it is one type of remuneration awarded to ➲ distribution actors such as ➲ wholesalers and ➲ pharmacies for handling their services.

The **wholesale mark-up** is the gross profit of wholesalers, expressed as a fixed or percentage add-on to the ex-factory price.

The **pharmacy mark-up** is the gross profit of pharmacies expressed as a fixed or percentage add-on to the ➲ wholesale price (or pharmacy purchasing price).

See also: ➲ margin

[Source: adapted from PPRI Glossary]

Marketing Authorisation (Licencing)
A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment. There are four application procedures possible in the European Union:

Centralised procedure (CP): Way of approval of medicines valid in all Member States. The CP is administered by the European Medicines Agency (EMEA) in London. It consists of a single application which, when approved, grants marketing authorisation for all markets within the European Union. This procedure is available to all new, innovative medicines, and is obligatory for 1. biotechnology-derived products, 2. new

active ingredients for treating AIDS, cancer, diabetes and 'neuro-degenerative illnesses' as well as 3. orphan medicines. Under certain conditions the CP can be limited for one year. If the medicine is important for public health (especially therapeutic innovations) the appraisal period can be abbreviated.

Decentralised procedure: The decentralised procedure came into operation in late 2005. It is applicable in cases where a marketing authorisation does not yet exist in any of the EU Member States. Identical dossiers are submitted to all Member States where a marketing authorisation is sought. A Reference Member State, selected by the applicant, will prepare draft assessment documents within 120 days and send them to the Concerned Member States. They, in turn, will either approve the assessment or the application will continue into arbitration procedures. The new decentralised procedure will involve concerned Member States at an earlier stage of the evaluation than under the MRP in an effort to minimise disagreements and to facilitate the application for marketing authorisation in as many markets as possible.

Mutual recognition procedure (MRP): The MRP is the most common marketing authorisation procedure in the EU. It states that the marketing authorisation granted in one EU Member State (the so-called 'Reference Member State') being 'mutually recognised' as valid in other Member State (the 'Concerned Member State') upon request. The legal basis is Directive 2001/83/EC, as amended by Directive 2004/27/EC, and further guidance is given in the Notice to Applicants, which forms Chapter 2 of the Rules Governing Medicinal Products in the EU.

National procedure: Independent national marketing authorisation procedures are still applicable during the initial stage of the mutual recognition procedure in the country that is to act as Reference Member State. They are also applicable in situations in which the mutual recognition procedure is not compulsory, namely: 1. Bibliographical applications for medicines with a well-established medicinal use for which no reference product is available in the EU. 2. Line extensions of nationally registered medicines for which no harmonised product information is available within the EU. Although some changes to dossiers for nationally registered medicines (such as a change in the strength, pharmaceutical form or route of administration) require the submission of a new marketing authorisation application, these changes are considered as variations to a nationally issued marketing authorisation.

Registration: For herbal medicines, homeopathic medicines and medical devices no authorisation but a registration procedure is necessary.

[Source: PPRI Glossary]

Paediatric use marketing authorisation (PUMA): the paediatric use marketing authorisation (PUMA) is a dedicated marketing authorisation for medicines indicated exclusively for use in the paediatric population, or subsets thereof, with, if necessary,

an age-appropriate formulation. It has been designed to promote paediatric development of already authorised products which are no longer covered by a ➲ supplementary protection certificate (SPC) or a patent qualifying for a SPC.

[Source: Article 30 of Regulation (EC) No 1901/2006 ('Paediatric Regulation')],

Marketing Authorisation Holder
The Marketing Authorisation Holder holds the authorisation to place a medicine on the market and is responsible for marketing it. The marketing authorisation holder may be a natural or legal person.

[Source: European Commission, Directorate-General Enterprise]

Marketing Authorisation under Exceptional Circumstances
In exceptional circumstances and following consultation with the applicant, a marketing authorisation may be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning the safety of the medicine, notification to the competent authorities of any incident relating to its use, and action to be taken.

This authorisation may be granted only for objective, verifiable reasons and must be based on one of the assumption that the applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because:

» The indications for which the product in question is intended are encountered so rarely that the

» applicant cannot reasonably be expected to provide comprehensive evidence, or

» In the present state of scientific knowledge, comprehensive information cannot be provided, or

» It would be contrary to generally accepted principles of medical ethics to collect such information.

In these cases a marketing authorisation may be granted subject to certain specific obligations.

These obligations may include the following:

» The applicant shall complete an identified programme of studies within a time period specified by the competent authority, the results of which shall form the basis of a reassessment of the benefit/risk profile,

» The medicine, in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radio-pharmaceutical, by an authorised person,

» The package leaflet and any medical information shall draw the attention of the medical practitioner to the fact that the particulars available concerning the medicine in question are as yet inadequate in certain specified respects.

See also: ➲ marketing authorisation, conditional marketing authorisation

[Source: CHMP Guideline on procedures for the granting of a marketing authorisation under exceptional circumstances]

Market Player
Actors with a commercial interest in the pharmaceutical system. Market players include pharmaceutical ➲ manufacturers, ➲ distribution actors and equipment ➲ suppliers.

[Source: PPRI Glossary]

Maximum Price
This term is used in a different way in different countries: e.g. in some countries it is the maximum amount which is reimbursed (cf. ➲ reference price system), in others it is the maximum share that is refunded by ➲ third party payers expressed as percentage of the reimbursement basis.

[Source: PPRI Glossary]

Medical Device
A medical device is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

» -diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

» investigation, replacement or modification of the anatomy or of a physiological process,

» control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

A distinction is made between device and 'accessory', which is an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

[Source: Council Directive 93/42/EEC of 14 June 1993concerning medical devices]

Medical Record
Documentation of treatment of the patient.

[Source: Global Conference on the Future of Hospital Pharmacy]

Medical Services
Services provided by a health care system to a population. They include:

» **Hospital medical services** aimed at curing, restoring and/or maintaining the health of a patient: surgical services, medical services, gynaecological and obstetrical services, rehabilitation services, psychiatric services, other hospital services (medical, pharmaceutical and paramedical services, nursing services, laboratory and technical services including radiological and anaesthesiological services, etc), military hospital services; prison hospital services

» **General medical services**: services consisting of the prevention, diagnosis and treatment by doctors of medicine of physical and/or mental diseases of a general nature, such as consultations, – physical check-ups, etc. These services are not limited to specified or particular conditions, diseases or anatomical regions. They can be provided in general practitioners' practices and also delivered by out-patient clinics, clinics attached to firms, schools, etc.

» **Specialised medical services**: consultation services in paediatrics, gynaecology-obstetrics, neurology and psychiatry, and various medical services; surgical consultation services; treatment services in out-patients clinics, such as dialysis, chemotherapy, insulin therapy, respirator treatment, X-ray treatment and the like; • functional exploration and interpreting of medical images (X-ray photographs, electrocardiograms, endoscopies and the like).

» **Dental services**: orthodontic services, e.g. treatment of protruding teeth, crossbite, overbite, etc., including dental surgery even when given in hospitals to in-patients; services in the field of oral surgery; other specialised dental services, e.g. in the field of periodontics, paedondontics, endodontics and reconstruction; diagnosis and treatment services of diseases affecting the patient or aberrations in the cavity of the mouth, and services aimed at the prevention of dental diseases.

» **Deliveries and related services, nursing services, physiotherapeutic and para-medical services**: services such as supervision during pregnancy and childbirth;

supervision of the mother after birth; services in a field of nursing care (without admission), advice and prevention for patients at home, the provision of maternity care, children's hygiene, etc.; services provided by physiotherapists and other para-medical persons (including homeopathological and similar services); physiotherapy and para-medical services are services in the field of physiotherapy, ergo therapy, occupational therapy, speech therapy, homeopathy, acupuncture, nutrition, etc. These services are provided by authorised persons, other than medical doctors.

» **Ambulance services**: services involving transport of patients by ambulance, with or without resuscitation equipment or medical personnel.

» **Residential health facilities services other than hospital services**: combined lodging and medical services provided without the supervision of a medical doctor located on the premises.

» **Other human health services n.e.c.**: services provided by medical laboratories; services provided by blood, sperm and transplant organ banks; dental testing services; medical analysis and testing services; other human health services not elsewhere classified.

[Source: OECD. A System of Health Accounts]

Medication Error
Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

[Source: PPRI Glossary]

Medication Order (Order)
Written directions provided by a prescribing practitioner for a specific medication to be administered to an individual.

Specific term in hospital context: see ➲ order

[Source: Bureau of Developmental Services (BDS) of the New Hampshire Department of Health and Human Services BDS Medication Administration Curriculum, http://www.dhhs.nh.gov/dcbcs/bds/nurses/documents/sectionIII.pdf]

Medication Persistence
Medication persistence may be defined as 'the duration of time from initiation to discontinuation of therapy'. Continuing to take any amount of the medication is consistent with the definition of persistence.

This definition can be operationalised in both prospective and retrospective assessments by determining the initiation of treatment, or a point in time during chronic treatment, to a point in time defined as the end of the observation period.

By definition, persistence is reported as a continuous variable in terms of number of days for which therapy was available. Persistence may also be reported as a dichotomous variable measured at the end of a predefined time period (e.g. 12 months), considering patients as being 'persistent' or 'non persistent'.

[Source: ISPOR. Medication Compliance and Persistence: Terminology and Definitions]

Medication Reconciliation
The process of comparing a patient's ➲ medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or medicine interactions.

[Source: Global Conference on the Future of Hospital Pharmacy]

Medication Shortages (Drugs Shortages, Medicines Shortages)
Lack and/or gaps in the availability of medicines, usually due to problems in the supply chain. This supply issue affects how the pharmacy prepares or dispenses a medicine or influences patient care when prescribers must use an alternative.

[Source: adapted from the American Society of Health-System Pharmacists, ASHP)]

Medicine (Pharmaceutical, Pharmaceutical Product, Medication, Medicinal Product)
A) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

or

B) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

See also: ➲ advanced therapy medicine, biological medicine, herbal medicine, homeopathic medicine

The term 'drug' should be avoided, unless in well established terms like ADR.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

Me-too Medicine
A me-too medicine is approved after a pioneering product and is defined as comparable or similar but not clinically superior product.

[Source: PPRI Glossary]

Mortality Rate
An estimate of the proportion of a population that dies during a specified period. The numerator is the number of persons dying during the period; the denominator is the number in the population exposed to the risk of dying, usually estimated as the midyear population.

[Source: European Health Expectancy Monitoring Unit. Glossary]

Multi-channel System
Distribution system at wholesale level. Medicines of a ➲ manufacturer are distributed and supplied in parallel via different ➲ wholesalers.

[Source: PPRI Glossary]

Multi-source Medicine
A medicine that can be purchased under any of several trademarks from different manufacturers or distributors. When the patent of a medicine expires, a ➲ single-source medicine becomes multi-source.

Multi-source medicines are intended to be pharmaceutically equivalent or pharmaceutical alternatives that are bioequivalent and hence are therapeutically equivalent and interchangeable.

See also: ➲ generic, single-source medicine

[Source: adapted from WHO. MultiSource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability]

National Health Service (NHS)
The system of social security and health services arising out of the Beveridge report (1943) in England and Wales, and set in place in 1948.

A NHS System is financed through general taxation (central or regional) usually covering all inhabitants/residents. The scope of services rendered is identical for every person covered and most services are offered by public institutions. In some countries people may opt for a complementary voluntary health insurance for services, which are not covered through the NHS.

[Source: PPRI Glossary]

Negative List
List of medicines that cannot be prescribed at the expense of a ➲ third party payer.

[Source: PPRI Glossary]

New Molecular Entity (NME)
A new molecular entity (NME) includes new chemical entities (NCE) and biological entities.

A new chemical entity (NCE) is a ➲ pharmaceutical that contains no active moiety, i.e. without any molecule or ion, but including those appended portions of the molecule that cause the medicine to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the pharmaceutical substance. It is a chemical molecule developed by the innovator company in the early discovery stage, which after undergoing clinical trials could translate into a pharmaceutical that could be a cure for some disease.

[Source: adapted from Food and Drug Administration Website]

Non-Reimbursable Medicines
Medicines which are not eligible for ➲ reimbursement. Their costs are not covered by ➲ third party payers, but they have to be fully paid out of pocket by the patient.

See also: ➲ direct payments

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Nurse
A nurse is a person who has completed a programme of basic nursing education and is qualified and authorised in his/her country to practise nursing in all settings. Nursing professionals assist medical doctors in their tasks, deal with emergencies in their absence, and provide professional nursing care for the sick, injured, physically and mentally disabled, and others in need of such care, or they deliver or assist in the delivery of babies, provide antenatal and post-natal care and instruct parents in baby care.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Occupancy Rate
A measure of in-patient health facility use, determined by dividing available bed days by patient days. It measures the average percentage of a hospital's beds occupied and may be institution-wide or specific for one department or service.

[Source: PHIS Glossary]

Officinal Formula
Any medicine which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question.

See also: ➲ compounding, magistral formula (extemporaneous preparation)

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

Off-label Prescribing
When a ➲ medicine or ➲ medical device is prescribed outside its licensed indication, to treat a condition or disease for which it is not specifically authorised.

[Source: adapted from NICE Glossary]

Off-patent Medicine
A medicine gets off-patent once the right of making, using and selling an invention protected by a grant for a set period of time expires.

See also: ➲ generic, multi-source medicine, on-patent medicine

[Source: PPRI Glossary]

Only in Research (OIR)
Coverage conditional on individual participation in research (i.e. only patients participating in the scientific study are covered).

See also: ➲ managed entry agreement

[Source: Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010; 96(3):179-90.]

Only with Research
Coverage conditional on a scheme to conduct a study that informs the use of the medical product in the payer patient population.

See also: ➲ managed entry agreement

[Source: Carlson JJ , Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010; 96(3):179-90.]

On-patent Medicine
A branded medicine protected by a grant for a set period of time allowing the manufacturer the sole right to make, use and sell that medicine.

See also: ➲ generic, multi-source medicine, off-patent medicine

[Source: PPRI Glossary]

Order
In the context of hospitals: Statement in the patient's permanent medical record describing actions, including medication administration, that an authorised individual wish to be undertaken during a hospital visit.

In general health care context: see ➲ medication order (order)

[Source: Global Conference on the Future of Hospital Pharmacy]

Order Entry
Process by which a ➲ medication order is reviewed and processed in preparation for dispensing; may include manual or electronic processes.

[Source: Global Conference on the Future of Hospital Pharmacy]

Original Product (Originator, Original Medicine)
The first version of a medicine, developed and patented by an originator pharmaceutical company which has exclusive rights to marketing the product in the European Union for 20 years.

An original product has a unique trade name for marketing purposes, the so called brand name.

[Source: PPRI Glossary]

Orphan Medicine (Orphan Medicinal Product, OMP)
A product that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the European Community, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the product in the Community would generate sufficient return to justify the necessary investment and that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the product will be of significant benefit to those affected by that condition.

[Source: Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products]

Outcome
The end result of care and treatment and / or rehabilitation.

In other words, the change in health, functional ability, symptoms or situation of a person, which can be used to measure the effectiveness of care / treatment / rehabilitation.

Researchers should decide what outcomes to measure before a study begins; outcomes are then assessed at the end of the study.

[Source: NICE Glossary]

Outcomes Guarantees
An agreement where the manufacturer provides ➲ rebates, refunds, or price adjustments if the product fails to meet the agreed outcome target.

See also: ➲ managed entry agreement

[Source: Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010; 96(3):179-90]

Outlier
Usually an outlier in mathematics is a data point that is distinctly separate from the rest of the data. In the context of hospital care an outlier is a hospital admission requiring either substantially more expenses or a much longer length of stay than average.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, adapted from PHIS Glossary]

Out-of Pocket Maximum (Annual Ceiling)
The maximum amount (e.g. a certain percentage of income) that an insured person has to pay for all covered health care services for a defined period (often a year).

[Source: PPRI Glossary]

Out-of Pocket Payments (OPP) (1)
Payments made by a health care consumer that are not reimbursed by a ➲ third party payer.

They include cost-sharing and informal payments to health care providers.

Cost-sharing: a provision of health insurance or ➲ third party payment that requires the individual who is covered to pay part of the cost of health care received. This is distinct from the payment of a health insurance premium, contribution or tax which is paid whether health care is received or not.

Cost-sharing can be in the form of ➲ deductibles, ➲ co-insurance or ➲ co-payments.

[Source: OECD. A System of Health Accounts]

Out-of Pocket Payments (OPP) (2)

The expenses of a person for medical care or medicines that are not covered by ➲ reimbursement of a ➲ third party payer – often for a defined period (e.g a year).
It includes:

» Expenses for ➲ non-reimbursable medicines, ➲ direct payments
» Any form of co-payment:

Fixed co-payment: A out-of pocket payment in the form of a fixed amount (like for example a prescription fee) to be paid for a service, a ➲ medicine or a ➲ medical device.

Percentage co-payment: Cost-sharing in the form of a set proportion of the cost of a service or product. The patient pays a certain fixed proportion of the cost of a service or product, with the ➲ third party payer paying the remaining proportion.

Deductible: Initial expense up to a fixed amount which must be paid out-of pocket for a service or over a defined period of time by an insured person; then all or a percentage of the rest of the cost is covered by a ➲ third party payer.

See also: ➲ private pharmaceutical expenses, ➲ co-payments

[Source: adapted from PPRI Glossary]

Out-patient (out patient)

An out-patient is not formally admitted to the facility (e.g. physician's private office) and does not stay overnight. An out-patient is thus a person who goes to a health care facility for a consultation/treatment, and who leaves the facility within several hours of the start of the consultation without being 'admitted' to the facility as a patient.

[Source: adapted from OECD. A System of Health Accounts]

Out-patient Care (Ambulatory Care, Community Care)

This item comprises medical and paramedical services delivered to ➲ out-patients.

Out-patient (ambulatory) care is provided in the ➲ out-patient sector, as opposed to ➲ hospital care and the ➲ hospital sector.

Hospital ➲ out-patient departments are usually not part of the out-patient sector.

It should be noted that the term 'out-patient' used in the OECD System of Health Accounts (SHA) has a wider meaning compared to some national reporting systems where this term is limited to care in out-patient wards of hospitals. In the SHA, all visitors to ambulatory care facilities that are not day cases or over-the-night cases, are considered out-patients.

[Source: OECD. A System of Health Accounts, adapted]

Out-patient Clinics (Out-patient Care Centres, Ambulatory Care Centre, Independent Health care Centres, Out-patient Clinic, Independent Out-patient Health Clinic)
Out-patient clinics offer facilities for the out-patient treatment of a patient except hospital out-patient departments or doctors' offices e.g. medical laboratories, physical therapy institutes, radiological facilities, sports medical institutions.

[Source: PHIS Glossary]

Out-patient Facilities
Out-patient facilities include all possibilities of care which do not require an overnight stay. Those facilities can range from simple doctors' offices that provide primary care, to large, independent hospitals without beds.

See also: ➲ out-patient care and out-patient clinics

[Source: PHIS Glossary]

Out-patient Department (Hospital Out-patient Department, Hospital Out-patient Ward, OPD)
Out-patient departments are specialised and/or general units that may be located within all kinds of hospitals, which, however, serve ➲ out-patients. Hospital out-patient departments are available for emergency services and for acute specialist care, as well as for after-care and preventive medical check-ups. They may be open 24 hours.

[Source: PPRI Glossary]

Out-patient Physician (Out-Patient Doctor)
Health care provider e.g. in a physician's office, clinic, or day surgery center in the ambulatory sector (not in-patient, not in hospital).

[Source: adapted from PPRI Glossary]

Out-patient Sector
The type of the health care sector in which ➲ out-patient care is provided, in contrast to the hospital (in-patient sector)

See also: ➲ out-patient care

[Source: PPRI Glossary]

Overhead
The general costs of operating an entity which are allocated to all the producing operations of the entity but which are not directly attributable to a single activity.

For a hospital, these costs normally include maintenance of the facility, occupancy costs, housekeeping, administration, and others.

[Source: PHIS Glossary]

Over Prescribing
If a physician prescribes more medicines than physicians whose prescription pattern is believed to be comparable (e.g. with a patient of similar indication). Over prescribing is one form of irrational use of medicines (see also ➲ rational use of medicines).

[Source: adapted from PPRI Glossary]

Over-the-counter (OTC) Medicine (Over-the-counter Product, Non-Prescription Medicines (NPM))
Medicines which may be dispensed without a prescription. In some countries they are available via self-service in pharmacies and/or other retail outlets (e.g. drugstores). Selected OTC medicines may be reimbursed for certain indications in some countries.

See also: ➲ prescription-only medicine, switch

[Source: PPRI Glossary]

Palliative Care
The active total care offered to a person and that person's family when it is recognised that the illness is no longer curable, in order to concentrate on the person's quality of life and the alleviation of distressing symptoms. The focus of palliative care is neither to hasten nor postpone death. It provides relief from pain and other distressing symptoms and integrates the psychological and spiritual aspects of care. It offers a support system to help relatives and friends cope during an individual's illness and with their bereavement.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Parallel Trade
Parallel trade in medicines within the EU is a form of arbitrage in which medicine are purchased in one Member State, typically where income levels are relatively low, and sold into other Member States, where income levels and hence prices are higher (although there are exceptions to this, when high prices are being charged in lower income Member States). About 100 parallel trade enterprises are involved, between them employing about 12,000 people (5,000 in the UK), some on a part-time or casual basis.

The major companies are represented at EU level by the trade association European Association of Euro-Pharmaceutical Companies (EAEPC), but there are a relatively large number of others holding licences about whom less is known.

[Source: Europe Economics. Safe Medicines Through Parallel Trade Contribution to an Impact Assessment]

Paramedicines (Parapharmaceuticals)
Paramedicines are substances or compounds which do not correspond to the legal definition of a medicine. They are in any event products which, by virtue of their composition, utilisation or presentation, are compatible with the dignity of the profession of ➲ pharmacist.

[Source: PPRI Glossary]

Patent
A patent is a set of exclusive rights granted by a state (national government) to an inventor or their assignee for a limited period of time in exchange for public disclosure of its invention. Typically, however, a patent application must include one or more claims defining the invention which must be new, non-obvious, and useful or industrially applicable.

[Source: European Commission. Entreprise and Industry Directorate-General. Consensus Information Document: 'What you need to know about Biosimilar Medicinal Products'. Brussels: Process on Corporate Responsibility in the Field of Pharmaceuticals. Access to Medicines in Europe, 2013.]

Patent Expiry

After a defined period of time the ➲ patent is no longer valid and subsequent medicines (i.e. ➲ generics, ➲ biosimilar) may come on the market.

See also: ➲ patent

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Patient Access Scheme (PAS)

Patient access schemes are special ways pharmaceutical companies can propose to enable patients to gain access to high costs medicines. PAS is the name for ➲ managed entry agreements in the United Kingdom. They are proposed by a pharmaceutical company and agreed between the Department of Health and the pharmaceutical company; as other managed entry agreements they can take different forms (e.g. financial or performance based agreement).

See also: ➲ managed entry agreement

[Source: Patient Access Scheme Liaison Unit at NICE, adapted]

Patient Registry

Collections of secondary (clinical) data on diagnosis, follow-up and treatment related to patients with a specific diagnosis, condition, or procedure. Patient registries are relevant for quality assurance, documentation and for future analyses, and are a post-launch policy option to optimise the entry of new medicines.

See also: ➲ post-launch activity

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Pattern or Process Care

Schemes where the reimbursement level is tied to the impact on clinical decision making or practice patterns. They are a type of ➲ managed entry agreement.

See also: ➲ managed entry agreement

[Source: Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy 2010: 96(3):179-90]

Pay-back (Payback)
A financial mechanism that requires manufacturers, or other health care stakeholders, to refund a part of their revenue to a payer (i.e. ➲ third party payer) if sales exceed a previously determined or agreed target budget.

[Source: adapted from PPRI Glossary]

Percentage Co-payment
One type of ➲ co-payment asking patients to cost-share in the form of a set proportion of the cost of a service or product. The patient pays a defined share of the cost of a service or product, with the ➲ third party payer paying the remainder. Percentage co-payments for ➲ reimbursable medicines are in place in several European countries.

[Source: adapted from PPRI Glossary]

Performance Based Agreement
Agreement between a payer and a pharmaceutical, device or diagnostic manufacturer where the price level and/or revenue received is related to the future performance of the product in either a research or a real world environment.
One category of managed-entry agreements, in contrast to the financial agreements.

See also: ➲ managed entry agreement, ➲ Performance Based Health Outcome Reimbursement Schemes and Performance-Linked Reimbursement

[Source: Towse A, Garrison L. Can't get no satisfaction? Will pay for performance help? Toward an economic framework for understanding performance-based risk sharing agreements for innovative medical products. Pharmacoeconomics 2010, 28:93-102.]

Performance Based Health Outcome Reimbursement Schemes
Schemes between healthcare payers and medical product manufacturers in which the price, level, or nature of reimbursement are tied to future measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life, appear to have arisen out of a desire to provide patients with access to novel and potentially

beneficial healthcare technologies under conditions of significant uncertainty and cost pressures.

See also: ➲ managed entry agreement, ➲ Performance Based Agreement and Performance-Linked Reimbursement

[Source: Carlson JJ , Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy: 2010: 96(3):179-90]

Performance-Linked Reimbursement
Schemes where the reimbursement level for covered products is tied to the measure of clinical outcomes in the real world.

See also: ➲ managed entry agreement, ➲ Performance Based Agreement and Performance Based Health Outcome Reimbursement Schemes

[Source: Carlson JJ , Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010: 96(3):179-90]

Peri-Launch Activity
Policy undertaken around the launch of a medicine on the market. Related to the entry of new medicines, this might be specific arrangements (e.g. managed-entry agreements, HTA) during the pricing and reimbursement decision process. Peri-launch activities address, among other things, issues of access and affordability.

See also: ➲ pre-launch activity, post-launch activity

[Source: WHO Regional Office for Europe. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. 2015]

Pharmaceutical Alternatives
Medicines are pharmaceutical alternatives if they contain the same active moiety but differ in chemical form (salt, ester, etc) of that moiety or in the dosage form or strength.

[Source: EMEA. Note for guidance on the investigation on bioavailability and bioequivalence]

Pharmaceutical and Therapeutics Committee (Pharmaceutical Commission, Pharmaceutical Committee, PTC)

A Pharmaceutical and Therapeutics Committee is assigned to develop a list of medicines (➲ hospital pharmaceutical formulary) that is authorised for hospital use. This committee can either be established within a hospital (e.g. Austria, Belgium) or by government (e.g. Cyprus). Members of a PTC may be the head of the hospital pharmacy, the chief physician, the chief nurse, the administrative director, and specialist physicians.

Note: The term 'Pharmaceutical and Therapeutics Committee' is also used in other contexts (e.g. development of medicine plans in Canada).

[Source: PHIS Glossary]

Pharmaceutical Budget

Pharmaceutical budgets define ex-ante the maximum amount of money to be spent on medicines during a period of time. Pharmaceutical budgets may be addressed to payers, health care professionals (e.g. physicians) and companies. They may be designed in different forms and may include financial incentives or sanctions.

[Source: adapted from PPRI Glossary]

Pharmaceutical Care

Pharmaceutical care is the responsible provision of medicine therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are:

» cure of a disease;
» elimination or reduction of a patients' symptomatology;
» arresting or slowing of a disease process; or
» preventing a disease or symptomatology.

Pharmaceutical care involves the process that a pharmacist co-operates with the patient and healthcare professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This in turn involves three major functions:

» identifying potential and actual medicine-related problems;
» resolving actual medicine-related problems; and
» preventing medicine-related problems.

Pharmaceutical care is a necessary element of health care, and should be integrated with other elements. Pharmaceutical care is, however, provided for the direct benefit to

the patient, and the pharmacist is responsible directly to the patient for the quality of that care. The fundamental relationship in pharmaceutical care is a mutually beneficial exchange in which the patient grants authority to the provider and the provider gives competence and commitment (accept responsibility) to the patient. These fundamental goals, processes, and relationships of pharmaceutical care exist regardless of practice setting and of professional background.

[Source: Hepler, D.D. & Strand, L.M. Opportunities and Responsibilities in Pharmaceutical Care, Am.J. Pharm. Educ. 1989:53;7S-15S]

Pharmaceutical Depot (Medicines Depot, Pharmaceutical Supply Facility)
A unit within a hospital for the internal supply of the hospital with medicines. It usually has fewer tasks, competences and responsibilities than a hospital pharmacy, and it might be run by a hospital pharmacy of another hospital.

Note: The term 'pharmaceutical depot' might also be used for other facilities than hospitals (e.g. public health agency).

[Source: PHIS Glossary]

Pharmaceutical Equivalence
Medicines are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage forms that meet the same or comparable standards.

Pharmaceutical equivalence does not necessarily imply bioequivalence as differences in the excipients and/or the manufacturing process can lead to faster or slower dissolution and absorption.

[Source: EMEA. Note for guidance on the investigation on bioavailability and bioequivalence]

Pharmaceutical Expenditure (PE, Total Pharmaceutical Expenditure, TPE)
It is defined as total expenditure on pharmaceutical and other medical nondurables.

This comprises medicinal preparations, branded and generic medicines, on-patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives.

Other medical nondurables comprise wide range of medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices.

Pharmaceutical expenditure can be separated in:

***Public expenditure**:* pharmaceutical expenditure incurred by public funds (state, regional and local government bodies and social security schemes).

***Private expenditure**:* privately funded part of total pharmaceutical expenditure. Private Sources of funds include out-of pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care.

***Out-patient expenditure**:* pharmaceutical expenditure incurred in the out-patient (ambulatory setting). Due to data availability limitations in several countries, what is listed as total pharmaceutical expenditure only refers to the out-patient expenditure.

***In-patient expenditure**:* pharmaceutical expenditure incurred in the hospital setting.

Pharmaceutical expenditure data reported in the OECD System of Health Accounts encompass expenditure by both private and public sectors. Pharmaceutical expenditure may or may not include the value of pharmaceuticals dispensed in hospitals, depending on the country.

[Source: adapted from OECD. A System of Health Accounts]

Pharmaceutical Form
Way in which a medicine is presented, e.g. a film coated tablet, an ointment, a vial, a spray.

[Source: UNI ENV 12610 Medical informatics. Medicinal product identification]

Pharmaceutical Promotion
Pharmaceutical promotion includes all kind of information and promotion activities to consumers, doctors or pharmacists that provide incentives with the aim of influence prescription, dispensing, sales or consumption of pharmaceuticals. Pharmaceutical promotion may be regulated.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Pharmaceutical Provision
Service of supplying the population with medicines.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Pharmaceutical Research
Pharmaceutical research includes scientific and policy studies in the pre-clinical, clinical and post-clinical phase of a medicine (e.g. basic and applied science; studies on the effectiveness, efficacy and safety of medicines, cost-benefit studies, HTA etc.).

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, based on input of PPRI (Pharmaceutical Pricing and Reimbursement Information) network]

Pharmaceutical Sample (Sample for Doctors, Free Sample)
Pharmaceutical samples are medicines which are given out for free to physicians mostly by pharmaceutical representatives. The purpose of a pharmaceutical sample is to promote new products among doctors. The provision of pharmaceutical samples is often regulated.

[Source: adapted from PPRI Glossary]

Pharmaceutical Service
All services rendered by pharmaceutical staff to support the provision of pharmaceutical care. Beyond the supply of pharmaceutical products, pharmaceutical services include information, education, and communication to promote public health, the provision of pharmaceutical information and counselling, regulatory services, education and training of staff.

[Source: Global Conference on the Future of Hospital Pharmacy]

Pharmaceutical System
A pharmaceutical system comprises the following elements: regulatory (marketing authorisation, market surveillance, vigilance), pricing, funding & reimbursement, supply chain / distribution and consumption of medicines.

[Source: PPRI Glossary]

Pharmacists
Persons who have completed studies in pharmacy at university level (granted by adequate diploma) and who are licensed to practise pharmacy. They may be either salaried or self-employed pharmacists delivering services irrespectively of the place of service provision.

Services provided by pharmacists include: preparing and directing the preparation of medicines according to prescriptions of medical and dental practitioners, or establish formulae; checking prescriptions to ensure that recommended dosages are not exceeded, and that instructions are understood by patients – or persons administering the medicines – and advising on possible medicine incompatibility; dispensing medicines in hospitals or selling them in pharmacies.

[Source: adapted from EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Pharmacoeconomic Evaluation (Pharmacoeconomics)

A discipline for economic evaluation of pharmaceutical products and services through determination, measurement and comparison of their costs and outcomes.

[Source: HTA Glossary]

Pharmacological Class
Group of ingredients according to their effects in human beings or animals.

[Source: UNI ENV 12610 Medical informatics. Medicinal product identification]

Pharmacopoeia
Pharmacopoeia (literally, the art of the medicine compounder), in its modern technical sense, is a book containing directions for the identification of samples and the preparation of combination products, and published by the authority of a government or a medical or pharmaceutical society.

[Source: PPRI Glossary]

Pharmacovigilance
Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce risks and increase benefits from medicines. It is a key public health function.

Pharmacovigilance comprises:

» Collecting and managing data on the safety of medicines
» Looking at the data to detect 'signals' (any new or changing safety issue) Evaluating the data and making decisions with regard to safety issues
» Acting to protect public health (including regulatory action) Communicating with stakeholders
» Audit, both of the outcomes of action taken and of the key processes involved.

Those directly involved in pharmacovigilance include:

» Patients as the users of medicines
» Doctors, pharmacists, nurses and all other health care professionals working with medicines
» Regulatory authorities including the EMEA and those in the Member States responsible for monitoring the safety of medicines
» Pharmaceutical companies, and companies importing or distributing medicines

[Source: European Commission, Entreprise and Industry Directorate-General: Pharmaceutical / Pharmacovigilance. Available at: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/pharmacovigilance_en.htm]

Pharmacy
See ➲ community pharmacy and ➲ hospital pharmacy.
[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Pharmacy Chain (Pharmacy Group)
A group of different pharmacies belonging to the same owner which may or may not be a pharmacist. Often, pharmacy chains are run by wholesale or manufacturing companies.

[Source: PPRI Glossary]

Pharmacy-only Medicine
A medicine which may only dispensed in a pharmacy (or another ➲ POM dispensary).

See also: ➲ General Sales List (GSL) medicines

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Pharmacy outlet
A pharmaceutical retail facility, often in place in rural and/or scarcely populated areas to guarantee pharmaceutical provision, e.g. Postos Farmacêuticos Móveis, PFM in Portugal. They are usually run and under the supervision of a ➲ community pharmacy and often only have a limited range of products.

[Source: PPRI Glossary]

Pharmacy Purchasing Price (Pharmacy Purchase Price, PPP, Wholesale Price)
The price charged by ➲ wholesalers to the ➲ retailers (usually ➲ community pharmacies). It includes any ➲ wholesale mark-up.

[Source: OECD. A System of Health Accounts]

Pharmacy Retail Price (PRP)
The price charged by community pharmacies to the general public. It includes any ➲ pharmacy ➲ remuneration such a pharmacy ➲ mark-up or ➲ dispensing fee.

It can be a **gross PRP** (including ➲ value-added tax/VAT) or a **net PRP** (excluding ➲ VAT).

[Source: adapted from PPRI Glossary]

Pharmacy Tax
A tax - other than the ➲ value-added tax/VAT - levied by a state or municipality on the ➲ pharmacy retail price of an item, collected from the ➲ retailer.

[Source: adapted from PPRI Glossary]

Physician
A person who has completed studies in medicine at the university level (granted by adequate diploma) and who is licensed to practise.

To be legally licensed for the independent practice of medicine, (s)he must, in most cases, undergo additional postgraduate training in a hospital.

Physicians may be either salaried or self-employed physicians delivering services irrespectively of the place of service provision.

Services provided by physicians include: conducting medical examination and making diagnosis, prescribing medication and giving treatment for diagnosed illnesses, disorders or injuries, giving specialised medical or surgical treatment for particular

types of illnesses, disorders or injuries, giving advice on and applying preventive medicine methods and treatments.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Policy Measures
Instruments, tools and approaches that allow ➲ policy makers to achieve defined objectives. Examples for pharmaceutical policy measures are ➲ price cuts or changes in the methodology of ➲ distribution remuneration (in the field of ➲ pricing), changes in ➲ co-payments or in the methodology of ➲ reference price systems (in the field of ➲ reimbursement), and ➲ pharmaceutical budgets and ➲ generic substitution.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Policy Maker
A person or institution that is involved in policy development and formulation (e.g. national governments, public authorities).

[Source: PPRI Glossary, adapted]

Polypharmacy
The administration of many medicines at the same time or the administration of an excessive number of medicines.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Polypill
A medication which contains a combination of multiple ➲ active ingredients. Originally the term was created to aim at prevention of cardiovascular disease. A polypill can also often be aimed to be consumed widespread in the population, even currently healthy ones, as a means of preventive medicine. It is intended to reduce the number of tablets or capsules that need to be taken, which in turn may facilitate handling and administration of the medicines. When used for preemptive use, the dosages are naturally relatively low compared to what is administered to people already having disease or significant risk factors.

[Source: Adapted from Wald, NJ, Law, MR. A strategy to reduce cardiovascular disease by more than 80%. BMJ 2003:326 (7404):1419]

Population-group-specific Reimbursement
Specific population groups (e.g. children, old-age pensioners) are eligible for medicines, while others are not.

[Source: PPRI Glossary]

Positive List (Formulary)
List of medicines that may be prescribed at the expense of a ➲ third party payer. This is one form of a ➲ reimbursement list.

See also: ➲ negative list

[Source: PPRI Glossary]

Post-Launch Activity
Policy undertaken after the launch of a medicine on the market. Related to the entry of new medicines, post-launch activities include monitoring the effectiveness and safety of new medicines in clinical practice and ensuring that patients with the greatest clinical need and those most likely to benefit from treatment can access the medicine, and include systematic detailed analysis of medicine usage data. Systems that facilitate data management include electronic accessible patient registries that collect key clinical data and e-prescription for reviewing prescribing practices to ensure these are consistent with agreed best practice outlines in guidelines and any prescribing restrictions. Standardizing data requirements and integration of different data sets across the health system, as well as close monitoring and evaluation, can allow for improvements in the use of medicines.

See also: ➲ pre-launch activity, peri-launch activity

[Source: WHO Regional Office for Europe. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. 2015]

Pre-Launch Activity
Policy undertaken before the launch of a medicine on the market. Pre-launch activities provide policy-makers with a forward-looking perspective on new medicines in development. This includes a review of their potential specific clinical and treatment outcomes and health system impact (in terms of cost and benefit to patients). Pre-launch activities also anticipate the budget impact of a treatment for its proposed indication, as well as understanding which patients stand to benefit most from the treatment. Governments and payers are thus directly involved as these activities assist them in taking a longer-term strategic approach in development of health care systems and facilitating access to interventions. Pre-launch activities further include

horizon scanning to identify potential new medicines meeting health care priorities and planning for their potential use
including physician and prescriber education; development of patient registries; and demand forecasting. An extensive evaluation of medicines prior to marketing (in some contexts broadly termed 'critical drug evaluation') is also part of the pre-launch activities.

See also: ➲ peri-launch activity, post-launch activity

[Source: WHO Regional Office for Europe. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. 2015]

Prescription
An order mostly in written form (~ receipt) by a qualified health care professional to a pharmacist or other therapist for a medicine or treatment to be provided to their patients. One prescription may contain several items. The maximum number of items on a prescription can be regulated.

[Source: adapted from PPRI Glossary]

Prescription Fee (Prescription Charge)
A fixed amount for each prescription item dispensed on the expense of a ➲ third party payer to be payable by the patient, i.e. a form of ➲ fixed co-payment.

[Source: PPRI Glossary]

Prescription Guidelines
Prescription guidelines ensure that the right medicine in the right dose is given to the right patient at the right time, all the time. These guidelines help improving the ➲ rational use of medicines.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Prescription Monitoring
The act of assessing/observing prescribing practices of physicians. It is sometimes accompanied by feedback to prescribers and in a few cases also sanctions in order to improve rational use of medicines are possible.

[Source: PPRI Glossary]

Prescription-only Medicines (POM)
Medicines that can be dispensed only on a health professional prescription.

Medicines are subject to medical prescription where they:

» are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision, or

» are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or

» are normally prescribed by a doctor to be administered parenterally.

» the medicine is intended for ➲ out-patients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

See also: ➲ Over-the counter medicines, switch

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

Prescription-only Medicines Dispensary (POM Dispensary)
Umbrella term for facilities that are allowed to sell POM/prescription-only medicines to ➲ out-patients, e.g. ➲ community pharmacies, ➲ dispensing doctors.

[Source: PPRI Glossary]

Prevalence
An indicator on how common a disease is.

Specifically, it is the number of existing cases of the disease in a defined population at a given point in time or over a defined time period divided by the number of people in that population.

[Source: Strom, Kimmel. Textbook of pharmacoepidemiology]. 2005

Price (Medicine Price)
Price is the value component of expenditure. The value of one unit of a product, for which the quantities are perfectly homogeneous not only in a physical sense but also in respect of a number of other characteristics.

The medicine price is the price related to one or more ➲ medicines. It may relate to different market segments (e.g. out-patient vs. in-patent market, reimbursement segment) and may be defined at different ➲ price types.

[Source: OECD Glossary of Statistical Terms, adapted]

Price Cap (Price Ceiling)
A cost-containment measure which fixes ex-ante the maximum price of medicine, e.g. taking into consideration inflation rates and production cost.

Pharmaceutical companies are allowed to choose any price below this threshold and in exchange authorities refrain from further control of company data (profit margins, sales etc.).

[Source: PPRI Glossary]

Price Control
Pricing policies where government authorities set the price of a medicine and/or indirectly influence it by different ➲ pricing procedures (e.g. ➲ statutory pricing, ➲ price negotiations, public ➲ procurement). Contrary to ➲ free pricing.

The bases on which regulated prices are set vary. These may be on prices in other countries, costs, return on investment, ➲ mark-ups, etc.

[Source: PPRI Glossary, adapted from OECD. Glossary of statistical terms]

Price Cut
A cost-containment measure during which the set price of a medicine is reduced by the authorities.

[Source: PPRI Glossary]

Price Freeze
A cost-containment measure during which the price of a medicine is fixed ('frozen') at a given level, mostly for a predetermined period of time. Price freezes are sometimes based on agreements between pharmaceutical industry and authorities but in most cases they are implemented by law.

[Source: PPRI Glossary]

Price Negotiation
A pricing procedure, where medicine prices are discussed/negotiated (e.g. between ➲ manufacturer and ➲ third party payer).

[Source: PPRI Glossary]

Price Notification
A form of ➲ pricing procedure where pharmaceutical companies can freely set the price of a medicine (➲ free pricing) but have to officially inform the authorities about the price of the medicine.

[Source: PPRI Glossary]

Price Review

Evaluation of the price of all, or groups of, medicines, typically in comparison to the prices of the same medicines in other countries, in order to account for developments such as the market entry of medicines and price changes in other countries and exchange rate evolutions. Price reviews may, or may not, be performed in combination with ➲ reimbursement reviews. Price reviews can be done systematically (e.g. once a year) or out-of-schedule.

See also: ➲ reimbursement review

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Price Type
The level at which the price of a medicine is set. The following price types exist:

» ex-factory price
» pharmacy purchasing price
» pharmacy retail price

[Source: PPRI Glossary]

Price Volume Agreement
Agreements which focus on controlling financial expenditure with pharmaceutical companies refunding over budget situations.

See also: ➲ managed entry agreement

[Source: Adamski J. Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. BMC Health Services Research:2010, 10:153]

Pricing (Price Setting)
The act of setting a price for a medicine.

[Source: PPRI Glossary]

Pricing Committee (Pricing Board)
A body responsible for recommending, setting or controlling/monitoring the price of a medicine. The PC may be composed of representatives of different government authorities (e.g. Ministry of Health, Ministry of Finance) in many countries also further stakeholders (e.g. doctors, patient interest groups) are involved.

[Source: PPRI Glossary]

Pricing Policies
Regulations and processes used by government authorities to set the price of medicine as part of exercising ➲ price control (e.g. ➲ statutory pricing, ➲ price negotiation). In the cases that other stakeholders are allowed to set medicine prices, their strategies can be also considered as pricing policies (e.g. ➲ free pricing by pharmaceutical companies).

See also: ➲ price control, ➲ pricing procedure

[Source: adapted from PPRI Glossary]

Pricing Procedure
There are several methods how government authorities can set the price of a medicine: ➲ internal price referencing, ➲ external price referencing, ➲ cost-plus pricing and ➲ profit control.

Sometimes pricing procedures and ➲ pricing policies are used as synonyms.

See also: ➲ price control, ➲ pricing policies

[Source: PPRI Glossary]

Primary Care
Basic or general health care focused on the point at which a patient ideally first seeks assistance from the medical care system. Primary care is considered comprehensive when the primary provider takes responsibility for the overall coordination of the care of the patient's health problems, be they biological, behavioural, or social.

Such care is generally provided by physicians (general practitioners, family practitioners, internists, obstetricians and paediatricians) but in some countries is increasingly provided by other personnel such as nurse practitioners or physician assistants.

[Source: PHIS Glossary]

Prioritisation
As a principle, it means doing 'first things first;' as a process, it means evaluating a group of items and ranking them in their order of importance or urgency. Priority setting in health care involves a process of choice among alternative health care programmes, medicines and services, and patients or groups of patients who are to receive health care. Priority setting is also a process by which the alternatives are ranked in accordance with different criteria, leading to the definition of a minimum or basic package of health care services (incl. medicines).

[Source: adapted from Business Dictionary; and Tragakes E. Key issues in rationing and priority setting for health care services. WHO Regional Office for Europe. 1998]

Private Pharmaceutical Expenses (Household Expenses)
This term includes all forms of out-of pocket payments:

» ➲ co-payments:
  * ➲ percentage co-payment,
  *➲ fixed co-payment,
  * ➲ deductibles

as well as

» ➲ direct payments.

See also: ➲ out-of pocket payments

[Source: adapted from PPRI Glossary]

Procurement
Pharmaceutical procurement is a complex process that involves many steps and many stakeholders. It is also conducted within national and institutional policies, rules, regulations, and structures that may hinder or support the overall efficiency of the procurement process. An effective procurement process at any level must ensure that four strategic objectives are achieved:

» the procurement of the most cost effective medicines in the right qualities,
» the selection of reliable suppliers of high-quality products,
» procurement and distribution systems that ensure timely and undisturbed deliveries,
» processes that ensure the lowest possible total costs.

[Source: WHO. Operational principles for good pharmaceutical procurement]

Procurement Agency
Any organisation purchasing or otherwise acquiring any pharmaceutical product, vaccine or nutraceutical for human use.

[Source: WHO. A model quality assurance system for procurement agencies]

Procurement Methods (Purchasing Policies)
Purchasing, hiring or obtaining by any other contractual means goods, works or services or any mixture thereof.

See also: ➲ tendering

[Source: African Development Bank Group – Glossary of procurement terms]

The following procurement methods are being used in practice:

Open tender
An open tender is a formal procedure whereby quotations are invited from a potential manufacturer or supplier.

Restricted tender
A restricted tender, open only to prequalified suppliers, seems to work best in small countries. Although initial evaluation of suppliers is time consuming, when a core of prequalified suppliers has already been established, the recurring work for the procurement agency and the overall workload is significantly lower than that in an open tender. Product quality may be more easily assured through a restricted tender.

Competitive negotiations
A few selected companies are approached and requested price quotations. Usually, this method results in higher prices.

Direct procurement
This is the simplest but perhaps the most expensive procurement method of all as it involves direct purchase from a single supplier either at quoted prices or negotiated prices. This method is well suited for emergency situations, but is not the preferred choice for routine orders.

[Source: WHO. Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies]

Product-specific Reimbursement
Eligibility for reimbursement depends on the medicine in question (either a medicine is considered as ➲ reimbursable or as non-reimbursable).

[Source: PPRI Glossary]

Profit Control
A profit framework is negotiated periodically between the state and the pharmaceutical industry. This framework is fixed for each individual manufacturer. Within this framework manufacturers are free to set their medicine prices. The UK PPRS system is profit control.

[Source: adapted from PPRI Glossary]

Purchaser's Price
The amount paid by the purchaser in order to take delivery of a unit of a good or service at the time and place required by the purchaser.

It excludes any ➲ value-added tax/VAT (or similar deductible tax on products) which the purchaser can deduct from his own VAT liability in respect of VAT invoiced to his customers.

It includes supplier's retail and wholesale margins, separately invoiced transport and insurance charges and any VAT (or similar deductible tax on products) which the purchaser cannot deduct from his own VAT liability.

In the case of equipment goods it will also include installation costs if applicable.

Purchasers' prices are the prices most relevant for decision-making by buyers.

See also: ➲ list price

[Source: EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)]

Purchasing Committee
A committee of experts who meets on a regular basis to evaluate and approve the purchase of consumables and equipment not already present in the hospital.

[Source: PHIS Glossary]

Purchasing for Safety
Procuring presentations and formulations of medicines approved for use in local medicine formularies.

In this process, medicines are reviewed by purchasing and pharmacy groups, and products that are designed in such a way as to promote safer practice are selected. This process does not involve therapeutic substitution.

[Source: National Patient Safety Agency. Patient Safety Alert No. 20]

Purchasing Power Parities (PPPa)
Spatial deflators and currency converters, which eliminate the effects of the differences in price levels between countries, thus allowing volume comparisons of Gross Domestic Product (GDP) components and comparisons of price levels.

PPPs are calculated in three stages: first for individual products, then for groups of products or basic headings and, finally, for groups of basic headings or aggregates. The PPPs for basic headings are unweighted averages of the PPPs for individual products. The PPPs for aggregates are weighted averages of the PPPs for basic headings.

The weights used are the expenditure on the basic headings. PPPs at all stages are price relatives. They show how many units of currency A need to be spent in country A to obtain the same volume of a product or a basic heading or an aggregate that X units of currency B purchases in country B.

In the case of a single product, the 'same volume' means 'identical volume'. But in the case of the complex assortment of goods and services that make up an aggregate such as GDP, the 'same volume' does not mean an 'identical basket of goods and services'. The composition of the basket will vary between countries according to their economic, social and cultural differences, but each basket will provide equivalent satisfaction or utility. Also referred to as 'parity' or 'parities'.

[Source: EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)]

Quality Assurance
Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Quality Control
Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Quality System
An appropriate infrastructure, encompassing the organisational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Quality-adjusted Life Years (QALYS)
A measure of health outcome which looks at both length of life and quality of life.

QALYS are calculated by estimating the years of life remaining for a patient following a particular care pathway and weighting each year with a quality of life score (on a zero to one scale).

One QALY is equal to one year of life in perfect health, or two years at 50% health, and so on.

See also: ➲ disability-adjusted life years

[Source: NICE Glossary]

Radiation Therapy
Treatment with high-energy rays (such as x-rays) to kill or shrink cancer cells. The radiation may come from outside the body (external radiation) or from radioactive materials placed directly in the tumour (brachytherapy or internal radiation).

Radiation therapy may be used to shrink the cancer before surgery, to destroy any remaining cancer cells after surgery, or as the main treatment. It may also be used as palliative treatment for advanced cancer.

[Source: American Cancer Society. Glossary]

Rate
A measure of the frequency of occurrence of a phenomenon.

In epidemiology, demography, and vital statistics, a rate is an expression of the frequency with which an event occurs in a defined population in a specified period of time.

The use of rates rather than raw numbers is essential for comparison of experience between populations at different times, different places, or among different classes of persons.

[Source: Last. A dictionary of epidemiology edited for the International Epidemiological Association. 2001]

Rational Use of Medicines
Rational use of medicines requires that 'patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community'.

Such a definition covers the good-quality (i.e. proper and appropriate) use of pharmaceuticals by providers and consumers, including adherence to treatment.

[Source: WHO. The rational use of medicines: progress in implementing the WHO medicines strategy. Report by the Secretariat. 2006]

Rebate

Rebate is a payment made to the purchaser after the transaction has occurred. Purchasers (either hospitals or pharmacies) receive a bulk refund from a ➲ wholesaler, based on sales of a particular product or total purchases from that wholesaler or manufacturer over a particular period of time.

[Source: adapted from EUROSTAT-OECD. Methodological manual on purchasing power parities]

Recall

Process by which medications are removed from distribution channels and returned to the manufacturer due to safety concerns (such as inadvertent product contamination) or other product integrity concerns (including subpotency, inappropriate labelling, etc.).

[Source: Global Conference on the Future of Hospital Pharmacy]

Reference Group

A group of medicines of the same ➲ active ingredient (➲ ATC 5), in a given therapeutic class (➲ ATC 4) or clustered based on a broader definition but still considered interchangeable. These clusters of medicines form the basis for establishing a ➲ reference price system.

See also: ➲ reference price system

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Reference Price System (RPS)
A reimbursement policy in which identical medicines (➲ ATC 5 level) or similar medicines (➲ ATC 4 level) are clustered (➲ reference group). The ➲ third party payer funds a maximum amount (=➲ reference price), while the patient must pay the difference between the ➲ reference price and the actual ➲ pharmacy retail price of the medicine, in addition to any ➲ co-payments (e.g. ➲ prescription fees, or ➲ percentage co-payment rates).

See also: ➲ reference group, reference price

[Source: PPRI Glossary, refined by WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Reference Product (Reference Medicine)
A medicine which has been granted a marketing authorisation by a country or by the European Commission on the basis of submitted quality, pre-clinical and clinical data, to which the application for ➲ marketing authorisation for a ➲ generic or a ➲ biosimilar product refers.

In the context of ➲ external price referencing, the reference product is the one which is referred in the price comparison.

[Source (for the first paragraph): European Commission. Entreprise and Industry Directorate-General. Consensus Information Document: 'What you need to know about Biosimilar Medicinal Products'. Brussels: Process on Corporate Responsibility in the Field of Pharmaceuticals. Access to Medicines in Europe, 2013]

Referral
The direction of people to an appropriate facility, institution or specialist in a health system, such as a health centre or a hospital, when health workers at a given level cannot diagnose or treat certain individuals by themselves, or face health or social problems they cannot solve by themselves.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Reimbursable Medicines
Medicines which are eligible for ➲ reimbursement. Costs of reimbursable medicines may be fully covered by ➲ third party payers, or only partially (a specific percentage).

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Reimbursement
Coverage of the cost by a ➲ third party payer (e.g. Social Health Insurance/National Health Service).

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Reimbursement Category (Reimbursement Group)
Medicines eligible for reimbursement are often grouped according to selected characteristics, e.g. route of administration (oral, etc.), main indication (oncology, paediatric, etc.), ATC level, classification (hospital-only, etc.). In many countries different reimbursement rates are determined for different reimbursement categories.

[Source: PPRI Glossary]

Reimbursement List
A list that contains medicines with regard to their ➲ reimbursement status. They may either include medicines eligible for reimbursement (➲ positive list) or those explicitly excluded from reimbursement (➲ negative list). Reimbursement lists may target either the out-patient sector (usually ➲ positive lists or ➲ negative lists) or the in-patient sector (typically called ➲ hospital pharmaceutical formulary), or both.

See also: ➲ positive list, negative list

[Source: PPRI Glossary]

Reimbursement Market
The reimbursement market is the sub-market which includes medicines whose expenses covered bya ➲ third party payer.

[Source: PPRI Glossary]

Reimbursement Process
Decision-making process on the ➲ reimbursement status, ➲ reimbursement price, ➲ reimbursement rate of medicines that involves the roles and the composition of the

responsible bodies and committees, the application process, the decision-making itself, the information process around the decision and the arbitration process after the decision. The outcome of the process is the decision whether or not the medicine will be included in ➲ reimbursement lists, and at which cost.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Reimbursement Price

This price is the basis for reimbursement of medicines in a health care system, i.e. the maximum amount paid for by a ➲ third party payer. The reimbursed amount can either be the full reimbursement price (e.g. in Austria) or a percentage share of the reimbursement price (e.g. in Denmark).

[Source: adapted from PPRI Glossary]

Reimbursement Rate

The percentage share of the price of a medicine or medical service, which is reimbursed/subsidised by a ➲ third party payer. The difference to the full price of the medicine or medicinal service is paid by the patients.

See also: ➲ percentage co-payment

[Source: PPRI Glossary]

Reimbursement Review

Evaluation process of a reimbursement decision (i.e. decision about the ➲ reimbursement status and ➲ reimbursement rates of medicines), which may, or may not, include the price. Reimbursement reviews can be done systematically (e.g. once a year) for all reimbursed medicines or a group (e.g. specific indication), or out-of-schedule.

See also: ➲ price review

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Reimbursement Status
Defines whether a medicine is eligible for reimbursement (➲ reimbursable medicines) or not (➲ non-reimbursable medicines).

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Reimbursement Scheme
The reimbursement system which covers the majority of residents in a country, in some countries also referred to as 'general' reimbursement.

[Source: PPRI Glossary]

Remuneration (distribution remuneration)
The payment of a health care provider (individual or organisation) for the services provided.

The services may be paid directly by the patient or by a ➲ third party payer.

In the case of ➲ pharmaceutical distribution, ➲ wholesalers and ➲ pharmacies are remunerated by linear ➲ mark-ups, regressive ➲ margin schemes or, in the case of pharmacies, a ➲ fee-for-service remuneration.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Retailer (Dispensary)
An entity, a person or a company that sells goods to consumers.

In the pharmaceutical sector, this is the umbrella term for facilities that dispense/sell medicines (prescription-only medicines/ POM and Over-the-Counter medicines/ OTC) to e.g. ➲ community pharmacies, ➲ other POM dispensaries such as➲ dispensing doctors, ➲ hospital pharmacies, ➲ pharmacy outlets, medicine chests, drugstores, supermarkets, etc.

[Sources: WHO & HAI. Measuring medicine prices, availability, affordability and price components, PPRI Glossary]

Risk
The probability that an event will occur, e.g., that an individual will become ill or die within a stated period of time or by a certain age.

Also a nontechnical term encompassing a variety of measures of the probability of a (generally) unfavourable outcome.

[Source: Last. A dictionary of epidemiology edited for the International Epidemiological Association. 2001]

Risk-benefit Balance
An evaluation of the positive therapeutic effects of the medicine in relation to its risks (any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health and any risk of undesirable effects on the environment.)

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

Risk Sharing Schemes (RSS)
Agreements concluded by payers and pharmaceutical companies to diminish the impact on the payer's budget of new and existing medicines brought about by either the uncertainty of the value of the medicine and/or the need to work within finite budgets.

A contract between two parties who agree to engage in a transaction in which there are uncertainties regardless concerning its final value. Nevertheless, one party, the company, has sufficient confidence in its claims of either effectiveness or efficiency that it is ready to accept a reward or a penalty depending on the observed performance of its product.

See also: ➲ managed entry agreement

[Sources: Adamski J. Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. BMC Health Services Research:2010, 10:153M de Pourville G.Risk-sharing arrangements for innovative drugs. A new solution to old problems. Eur J Health Econ 2006:7:155-7.]

Secondary Care
Services provided by medical specialists who generally do not have first contact with patients. These are typically specialists (e.g., cardiologists, urologists, dermatologists).

This can happen by a self-referral by patients for these services, or patients must first seek care from primary care providers and are then referred to secondary and/or tertiary providers, as needed.

In UK, 'secondary care' is understood as hospital care, whereas in the context of primary, secondary and tertiary care secondary care is considered as out-patient (ambulatory) care.

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, based on OECD]

Seamless Care
Continuity of care provided when transitioning from one health care setting to another, allowing pharmacy care to be carried out without any interruptions.

See also: ➲ continuity of care, ➲ integrated care (comprehensive care, ➲ transmural care), ➲ interface management

[Source: Canadian Society of Hospital Pharmacists and Canadian Pharmacists, Proceedings of the seamless care workshop. 1998; Ottawa]

Self-medication
Self-medication is the treatment of common health problems with medicines especially designed and labelled for use without medical supervision and approved as safe and effective for such use.

Medicines for self-medication are often called 'non-prescription' or 'Over-the-Counter' (OTC) and are available without a doctor's prescription through pharmacies. In some countries OTC products are also available in supermarkets and other outlets.

[Source: World Self-Medication Industry website: www.wsmi.org]

Sentinel Event
An unexpected occurrence at a health care facility involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.

The event is called 'sentinel' because it sends a signal or sounds a warning that requires immediate attention.

[Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

Short-line Wholesale (Short-Line Wholesaling, Short-Liner)
All activities consisting of the delivery and ➲ distribution of selected assortments of medicines on a defined market.

[Source: adapted from GIRP website]

Sickness Fund
A single social health insurance institution. In some countries there are several sickness funds operating (Austria) or even competing each other (Germany). Some sickness funds are operating on a regional basis whereas others are limited to specific professional groups like farmers or self-employed persons.

[Source: PPRI Glossary]

Single-channel System
Distribution system at wholesale level. A ➲ wholesaler has the exclusive right to distribute medicines – usually all products – of one manufacturer. In a single-channel system, there are usually only a few wholesale companies operating on the market.

[Source: PPRI Glossary]

Single-source Medicine
A medicine that can be purchased from one manufacturer since it is patent-protected (➲ on-patent medicine).

See also: ➲ generic

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Social Health Insurance (SHI)
Social health insurance is a type of health care provision, often funded through insurance contributions by employers and employees as well as state subsidies. In many countries there are obligatory schemes for (employed) persons whose income does not exceed a certain amount/limit (= insurance obligation) in place. Social health insurance is often organised in different ➲ sickness funds - in some countries allowing the patient to select a sickness fund (Germany) whereas in others the membership is determined mandatory, e.g. depending on the type of occupation (e.g. Poland, Austria). In some social health insurance countries persons with higher income as well as self-employed persons may opt for substitutive private health insurance. In addition to social health insurance in some countries voluntary health insurance, covering e.g. ➲ out-of pocket payments or allowing for free choice of doctors, is very popular.

[Source: PPRI Glossary]

Stakeholder
A person or organisation with a legitimate interest in a topic. Stakeholders related to health care may be:

» ➲ pharmaceutical manufacturers

» equipment suppliers
» patient organisations
» organisations representing health care professionals (e.g. doctors, pharmacists)
» other health care organisations
» civil society organisations.

[Source: adapted from NICE Glossary]

Standard of Care
A diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance.

[Source: PHIS Glossary]

Statutory Pricing
Pricing system, where medicine prices are set on a regulatory basis (e.g. law, enactment, decree).

[Source: PPRI Glossary]

Sterile Product
A pharmaceutical product (medicine) free of organisms and pyrogens.

[Source: Global Conference on the Future of Hospital Pharmacy]

Stock-taking
Management of medicine stocks in a hospital or any other step of a delivery chain.

Good ➲ distribution practices suggest the following principles for stock-taking:

» Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.

» All significant stock discrepancies should be investigated as a check against inadvertent mix-ups and/or incorrect issue.

» FEFO (First Expiry/First Out): A ➲ distribution procedure that ensures the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used; EEFO (Earliest Expiry/First Out) shall have a similar meaning.

» FIFO (First In/First Out): A ➲ distribution procedure to ensure that the oldest stock is distributed and/or utilised before a newer and identical stock item is distributed and/or utilised.

[Source: PHIS Glossary]

Storage
The storing of pharmaceutical products up to the point of use.

[Source: WHO. Good distribution practices (GDP) for pharmaceutical products]

Supplementary Protection Certificate (SPC)
SPC gives original products a complementary period of market exclusivity beyond patent expiry to compensate for delays of marketing in the pharmaceutical sector. SPC are available in EU countries but such complementary protection exists in other countries.

[Source: PPRI Glossary]

Supplier
Person or company providing medicines at request. Suppliers include ➲ manufacturers, ➲ distribution actors and (parallel) traders.

[Source: adapted from WHO. Good distribution practices (GDP) for pharmaceutical products]

Supply
Schedule of quantities of a product (good/service) that potential sellers are willing and able to sell at a given price during a certain period and at a certain location.

[Source:adapted from economics textbooks such as Samuelson & Nordhaus, Microeconomics]

Supply side Measures (Supply-side measures)
Policies that are primarily directed towards specific ➲ stakeholders in the health care system responsible for medicine regulation/registration/quality assurance, competition among ➲ manufacturers, intellectual property rights, ➲ pricing, and ➲reimbursement.

[Source: King DR, Kanavos P. Encouraging the Use of Generic Medicines: Implications for Transition Economies. Croatian Medical Journal 2002;43(4):462-469]

Surgery Day Care
All elective invasive therapies provided, under general or local anaesthesia, to day care patients whose post-surveillance and convalescence stay requires no overnight stay as an in-patient.

[Source: OECD. A System of Health Accounts]

Surgical Procedures
All types of medical interventions involving an incision with instruments mostly performed in an operating theatre which normally involves anaesthesia and/or respiratory assistance. Surgical procedures can be performed either as in-patient cases, day cases or out-patient cases. The procedure can be performed on a hospital stay, day case or out-patient basis.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

Surrogate Endpoint
A biomarker that is intended to substitute for a clinical endpoint. A surrogate endpoint is expected to predict clinical benefit (or harm or lack of benefit or harm) based on epidemiological, therapeutic, pathophysiologic, or other scientific evidence.

Surrogate endpoints are a subset of biomarkers. Although all surrogate endpoints can be considered biomarkers, it is likely that only a few biomarkers will achieve surrogate endpoint status. The term surrogate endpoint applies primarily to endpoints in

therapeutic intervention trials; however, it may sometimes apply in natural history or epidemiological studies.

It is important to point out that the same biomarkers used as surrogate endpoints in clinical trials are often extended to clinical practice in which disease responses are similarly measured. The use of biomarkers as surrogate endpoints in a clinical trial requires the specification of the clinical endpoints that are being substituted, class of therapeutic intervention being applied, and characteristics of population and disease state in which the substitution is being made.

The term surrogate literally means 'to substitute for'; therefore use of the term *surrogate marker* is discouraged because the term suggests that the substitution is for a marker rather than for a clinical endpoint.

See also: ➲ biological marker, ➲ clinical endpoint

[Source: Biomarkers Definitions Working Group]

Sustainability
The capacity to meet the needs of the present without compromising the ability to meet future needs.

[Source: WHO Regional Office for Europe. Terminology – A glossary of technical terms on the economics and finance of health services. 1998]

Switch
Reclassification of a ➲ prescription-only medicine (POM) to an ➲ Over-the-Counter (OTC) medicine.
Since in many countries the positive lists only include POM but no OTC medicines, a switch might also change the reimbursement status and might be considered as a 'hidden' ➲ de-listing measure.
In the context of ➲ biosimilars a switch is a decision by the treating physician to exchange one medicine for another medicine with the same therapeutic intent in patients who are undergoing treatment.

See also: ➲ prescription-only medicine, ➲ Over-the-Counter medicine

[Source: adapted from PPRI Glossary]

System of Health Accounts (SHA)
The System of Health Accounts provides for health accounting an economic framework and accounting rules which are methodologically compatible with the System of National Accounts, 1993 Revision (SNA 93).

[Source: OECD, World Health Organization, Eurostat. A System of Health Accounts. 2011]

Taxation
A compulsory transfer of money from private individuals, institutions or groups to the government.

It may be levied upon wealth or income (direct taxation) or in the form of surcharges on prices (indirect taxation). It may be paid to the central government (**central taxation**) or to the local government (**local taxation**). Taxation is one of the principal means by which a government finances its expenditure, including health care systems.

[Source: Penguin Reference. Dictionary of Economics]

Taxonomy
A taxonomy in general is a classification method of elements in groups or categories. Such groups have to be determined and defined according to the characteristics of the elements of the taxonomy and the objectives of the taxonomy.

[Source: PHIS Glossary]

Tendering
Any formal and competitive ➲ procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.

In the in-patient pharmaceutical sector, tendering is a major purchasing strategy.
In the out-patient pharmaceutical sector, tendering is applied by a few European countries (e.g. the 'preferential pricing policy' in the Netherlands). For specific medicines for which equivalents (e.g. ➲ generics) exist, public payers ask (generic) manufacturers for bids, and the best tender will be awarded a contract for a specific time.

See also: ➲ procurement methods

[Source: African Development Bank Group – Glossary of procurement terms; adapted and extended]

Therapeutic Benefit (Therapeutic Value)
The effect conveyed on a patient following administration of a pharmaceutical which restores, corrects or modifies a physiological function(s) for that patient.

[Source: PPRI Glossary]

Therapeutic Equivalence
Two pharmaceutical products are considered to be therapeutically equivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and after administration in the same molar dose, their effects, with respect to both efficacy and safety, are essentially the same when administered to patients by the same route under the conditions specified in the labelling. This can be demonstrated by appropriate bioequivalence studies, such as pharmacokinetic, pharmacodynamic, clinical or in vitro studies.

[Source: WHO. MultiSource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability]

Therapeutic Group
Group of medicines according to their indications of use.

[Source: UNI ENV 12610 Medical informatics. Medicinal product identification]

Therapeutic Referencing
The practice of using the price(s) of similar medicines (➲ ATC 4 level) or with therapeutically equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or ➲ reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.

See also: ➲ ATC, ➲ reference price system

[Source: adapted from PPRI Glossary]

Tertiary Care
Services provided by highly specialised providers (e.g. neurosurgeons, thoracic surgeons, intensive care units), usually in ➲ in-patient facilities. Such services frequently require highly sophisticated equipment and support facilities. The development of these services has largely been a function of diagnostic and therapeutic advances attained through basic and clinical biomedical research.

[Source: PPRI Glossary]

Third Party Payer (Payer, Insurer, Purchaser)
Public or private organisation that pays or insures health or medical expenses on behalf of beneficiaries or recipients.

Recipients pay a premium for this coverage in all private and some public programs of social insurance, while the system is supported by general taxation in the National Health Services.

The payer then pays bills on behalf of covered individuals, which are called third party payments.

They are distinguished by the separation among the individual receiving the service (the first party), the individual or institution providing it (the second party), and the organisation paying for it (third party).

[Source: PPRI Glossary]

Tissue Establishment
A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or ➲ distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells.

Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications.

They submit to the competent authority or authorities an annual report on these activities. This report shall be publicly accessible.

[Source: Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004)

Traceability of Pharmaceuticals
Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of pharmaceutical products.

External traceability takes place when instances of a traceable item are physically handed over from one traceability partner (traceable item source) to another traceability partner (traceable item recipient).

Internal traceability takes place when a traceability partner receives one or several instances of traceable items as inputs that are subjected to internal processes, before one or several instances of traceable items are output.

[Source: GS1 Standard Documents]

Transaction
The buying and selling of a product on terms mutually agreed by the buyer and seller.

[Source: EUROSTAT-OECD. Methodological manual on purchasing power parities]

Transparency Directive
Directive 89/105/EEC (of 21 December 1988) relates to the transparency of measures regulating the pricing of medicines for human use and their inclusion in the scope of national ➲ third party payers.

[Source: PPRI Glossary]

Value Added Tax (VAT)
A sales-tax on products collected in stages by enterprises.

It is a wide-ranging tax usually designed to cover most or all goods and services, including medicines. The VAT rate of medicines in European Union Member States is often lower than the standard VAT rate.

Deductible VAT is the value added tax payable on purchases of goods and services intended for intermediate consumption, gross fixed capital formation or for resale which producers are permitted to deduct from their own VAT liability to the government in respect of VAT invoiced to their customers.

Non-deductible VAT is the value added tax payable by purchasers that is not deductible from their own VAT liability, if any.

[Source: adapted from EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)]

Value Based Pricing

The concept of value-based pricing has gained momentum, though there is no widely accepted definition of value. In general, it is meant that countries set prices for new medicines and/or decide on reimbursement based on the therapeutic value which medicine offers, usually assessed through ➲ health technology assessment (HTA) or economic evaluation.

[Source: adapted from Paris V, Belloni A. Value in Pharmaceutical Pricing, OECD Health Working Papers, No. 63, OECD Publishing. 2013]

Value For Money

A definition of quality that assesses the quality of provision, processes or outcomes against the monetary cost of making the provision, undertaking the process or achieving the outcomes.

[Source: adapted from Harvey L. Analytic Quality Glossary 2004, Quality Research International, http://www.qualityresearchinternational.com/glossary/]

Volume Control

Measures applied by authorities (e.g. state, ➲ third party payers) or actors (e.g. hospitals) in order to affect and limit the amount of medicines prescribed and/or dispensed (e.g. ➲ pharmaceutical budgets).

[Source: PPRI Glossary]

Voluntary Health Insurance (VHI)
Health insurance that is taken up and paid for at the discretion of individuals or employers on behalf of individuals. VHI can be offered by public or quasi-public bodies and by for-profit (commercial) and non-profit private organisations.

In the European context, VHI can be classified in three different ways:

Substitutive Private Health Insurance provides cover that would otherwise be available provided by state. In a social health insurance system people who have no insurance obligation (in some countries e.g. self-employed) may opt for substitutive private health Insurance.

Complementary VHI provides cover for services excluded or not fully covered by the state (e.g. dental care), including cover for co-payments imposed by the statutory health care system.

Supplementary VHI provides cover for faster access and increased consumer choice.

[Source: PPRI Glossary]

Vulnerable Groups
Groups within a society facing higher risks of poverty and social exclusion compared to the general population. These vulnerable and marginalised groups include but are not limited to: people with disabilities, isolated elderly people and children, migrants, homeless people, ex-prisoners and drug addicts.

[Source: adapted from European Commission – Employment, Social Affairs and Equal Opportunities]

Wholesale
All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicines to the public in the Member State concerned.

Wholesalers may have a 'public service obligation': the obligation to guarantee permanently an adequate range of medicines to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

Wholesale Outlet
Logistics facility of ➲ wholesale companies

[Source: PPRI Glossary]

Wholesaler (Wholesale Company)
Entities performing ➲ wholesale activities

[Source: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies]

Wise List
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[Source: Gustafsson, LL et al. The 'wise list'- a comprehensive concept to select, communicate and achieve adherence to recommendations of essential drugs in ambulatory care in Stockholm. Basic Clin Pharmacol Toxicol. 2011;108(4):224-33]

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Acknowlegdements

We deeply thank all those persons who contributed to the development of this updated glossary by their contributions to previous versions of the glossaries. Particular thanks go to Pietro Folino Gallo and Luisa Muscolo from the Italian Medicines Agency (AIFA) and Simone Gritsch, Christine Leopold and Bettina Heindl from Gesundheit Österreich GmbH (Austrian Health Institute) for working on a previous version, the so-called PHIS Glossary, and to Barbara Fröschl of the Gesundheit Österreich GmbH (Austrian Health Institute) for her work on the original PPRI Glossary, together with authors of later versions.

Furthermore, our deep thanks go to the members of the PPRI (Pharmaceutical Pricing and Reimbursement Information) network, the World Health Organisation, particularly the Department of Essential Medicines and Health Products and the Regional Office for Europe for their input, suggestions, comments and review of this and previous versions of the glossary.