

Glossary

ACCREDITATION

Accreditation is an evaluative process in which a health care organization undergoes an examination of its policies, procedures and performance by an external organization (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 organizations created for the purpose of assuring the public of the quality of the accredited institution or program.

The State can recognize 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.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

ACTIVE INGREDIENT

An Active Pharmaceutical Ingredient (API) is the chemical substance contained in a pharmaceutical, which is responsible for its therapeutic effect. Some pharmaceuticals contain more than one active ingredient (combination product).

*[In: [OECD – Pharmaceutical Pricing Policies in a Global Market](#), at:
http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

ADVERSE REACTION (ADVERSE DRUG REACTION, ADR)

An adverse drug reaction is a response to a medicinal product 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. (WHO, 1972)

An adverse drug reaction, contrary to an adverse event, is characterized by the suspicion of a causal relationship between the medicine and the occurrence, i.e. judged as being at least possibly related to treatment by the reporting or a reviewing health professional.

[At: <http://www.who-umc.org/DynPage.aspx?id=13111&mn=1513>]

Serious adverse reaction: An adverse reaction which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, 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]

[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

ADR DATABASE

An ADR database is an ADR case management system which allows monitoring ADR occurrence and trends. The Uppsala Monitoring Center maintains a sophisticated WHO International ADR database called *Vigibase*.

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance corresponds to the emergence and spread of microbes that are resistant to cheap and effective first-choice, or "first-line" antimicrobial drugs. The bacterial infections which contribute most to human disease are also those in which emerging and microbial resistance is most evident: diarrheal diseases, respiratory tract infections, meningitis, sexually transmitted infections, and hospital-acquired infections. Some important examples include penicillin-resistant *Streptococcus pneumoniae*, vancomycin-resistant enterococci, methicillin-resistant *Staphylococcus aureus*, multi-resistant salmonellae, and multi-resistant *Mycobacterium tuberculosis*. The development of resistance to drugs commonly used to treat malaria is of particular concern, as is the emerging resistance to anti-HIV drugs.

[At: <http://www.who.int/mediacentre/factsheets/fs194/en/>]

AUDITING

Auditing is an independent and objective activity designed to add value and improve an organization's operations by helping an organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:

<http://infocollections.org/medregpack/interface/files/glossary.pdf>

AUTHORIZED PORT-OF-ENTRY

An authorized port-of-entry is a port where medicines may enter or leave a country under official supervision, i.e. where customs formalities may take place.

[From Managing Drug Supply, Second Edition, Management Sciences for Health. Available at

http://erc.msh.org/newpages/english/drugs/intro_pg.pdf

BOLAR EXCEPTION (PROVISION)

Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 30*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")

[In: WTO OMC Fact sheet: TRIPS and pharmaceutical patents, can be found on line at:

http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

BRAND NAME (INNOVATOR'S NAME, PROPRIETARY PRODUCT NAME, MEDICINE SPECIALITY PRODUCT NAME, MEDICINAL SPECIALITY PRODUCT 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.

[In: *PHIS Glossary 2009*, can be found on line at:
<http://phis.goeq.at/index.aspx?alias=phisglossary>]

CERTIFICATE OF PHARMACEUTICAL PRODUCT

A WHO-type certificate of the form described in Guidelines for implementation of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at:
<http://infocollections.org/medreqpack/interface/files/glossary.pdf>]

CIVIL SOCIETY

Civil society are individuals and groups, organised or unorganised, who interact in the social, political and economic domains and who are regulated by formal and informal rules and laws. Civil society offers a dynamic, multilayered wealth of perspectives and values, seeking expression in the public sphere.

[In: *Governance for sustainable human development, A UNDP policy document-Glossary of key terms*. Can be found online at: <http://mirror.undp.org/magnet/policy/glossary.htm>]

CIVIL SOCIETY ORGANIZATIONS

Civil society organisations are the multitude of associations around which society voluntarily organises itself and which can represent a wide range of interests and ties, from ethnicity and religion, through shared professional, developmental and leisure pursuits, to issues such as environmental protection or human rights.

[In: Governance for sustainable human development, A UNDP policy document-Glossary of key terms. Can be found online at: <http://mirror.undp.org/magnet/policy/glossary.htm>]

CLINICAL TRIAL (CLINICAL STUDY)

A clinical trial is any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, and/or identify any adverse reaction to, investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety.

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 performed 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 drug 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.

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:
<http://infocollections.org/medregpack/interface/files/glossary.pdf>]*

CODE OF CONDUCT (CODE OF BEHAVIOR)

A code of conduct is a set of conventional principles and expectations that are considered binding on any person who is a member of a particular group.

[At: <http://wordnet.princeton.edu/>]

COMPULSORY LICENSE

Compulsory license is a license granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder. The type of license is commonly referred to as a non-voluntary license connoting the lack of consent to the patent holder.

[The TRIPS rules on compulsory licensing are contained in article 31. from "Utilizing Trips Flexibilities for Public Health Protection through south-south Regional Frameworks", South Centre, <http://apps.who.int/medicinedocs/en/d/Js4968e/1.html#Js4968e.1>]

CONFLICT OF INTEREST

A conflict of interest is a situation in which a public official's decisions are influenced by the official's personal interests.

[At: <http://wordnet.princeton.edu/>]

The common meaning of conflict of interest is a conflict between an individuals' private or personal interest and his or her duty. However, conflict of interest may also refer to a situation where an individual has several duties which conflict without involvement of any private or

personal interest. Mitigating conflict of interest means eliminating a conclusive or a reasonable presumption of bias in decision-making processes.

[In PAHO Governance Manual]

CONTROLLED MEDICINES

Narcotic medicines and psychotropic substances regulated by provisions of national medicines laws.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:

<http://infocollections.org/medregpack/interface/files/glossary.pdf>

CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971

This international treaty establishes an international control system for psychotropic substances. It responded to the diversification and expansion of the spectrum of drugs of abuse and introduced controls over a number of synthetic drugs according to their abuse potential on the one hand and their therapeutic value on the other.

[At: http://www.incb.org/incb/convention_1971.html]

CONVENTION AGAINST THE ILLICIT TRAFFIC IN NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES, 1988

This international treaty provides comprehensive measures against drug trafficking, including provisions against money laundering and the diversion of precursor chemicals. It provides for international cooperation through, for example, extradition of drug traffickers, controlled deliveries and transfer of proceedings.

[At: http://www.incb.org/incb/convention_1988.html]

CONSUMPTION OF OPIOIDS

The amounts of opioid/analgesics distributed legally in a country for medical purposes to those institutions and programs that are licensed to dispense to patients, such as hospitals, nursing

homes, pharmacies, hospices and palliative care programs. In international drug control terminology, consumption does not refer to the amounts dispensed to or used by patients, but rather amounts distributed to the retail level.

[At: <http://www.painpolicy.wisc.edu/glossary.htm>]

CO-PAYMENT

Insured patient's contribution towards the cost of a medical service covered by the insurer. It can be expressed as a percentage of the total cost of the service (also known as co-insurance) or as a fixed amount.

[In: *OECD – Pharmaceutical Pricing Policies in a Global Market*, at: http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]

COST, INSURANCE, FREIGHT (CIF)

CIF is a shipping term meaning that the seller must pay the costs, insurance and freight charges necessary to bring the goods to the port of destination.

[In: *HAI/WHO Measuring medicine prices, availability, affordability and price components (2nd Edition)* and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

COUNTERFEIT MEDICAL PRODUCT

The term counterfeit medical product describes a product with a false representation of its identity and/or Source. This applies to the product, its container or other packaging or labeling information. Counterfeiting can apply to both branded and generic products.

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.

Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized 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.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

DATA EXCLUSIVITY

Data exclusivity is the protection of an originator pharmaceutical company's data preventing other parties from using these data for a commercial purpose. Concretely, this protection prevents generic product manufacturers from proceeding to clinical trials and health authorities from evaluating generic product market authorization applications during this period. In the European Union, this period was harmonized to eight years in 2004.

*[In: [OECD – Pharmaceutical Pricing Policies in a Global Market](#), at:
http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

DIRECT_TO_CONSUMER ADVERTISING

Direct-to-consumer advertising (DTC advertising) usually refers to the marketing of medicines aimed directly toward the public, rather than healthcare professionals. Forms of DTC advertising include TV, print, and radio.

*[Adapted from: [OECD – Pharmaceutical Pricing Policies in a Global Market](#), at:
http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]*

DISPENSER

A dispenser is a health care professional who is legally qualified to distribute medicines.

DISPENSING FEE

Normally a dispensing fee is a fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. The fee more accurately reflects the work involved in dispensing a prescription; a percentage mark-up makes profit dependent on the sale of expensive medicines.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

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.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:

<http://infocollections.org/medregpack/interface/files/glossary.pdf>]

DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.

They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016.

On one remaining question, they assigned further work to the TRIPS Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries. (This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in the separate Doha declaration on TRIPS and public health.)

[In: *WTO OMC Fact sheet: TRIPS and pharmaceutical patents*, can be found on line at:

http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]

DRUG

See [pharmaceutical](#)

DRUG AND THERAPEUTICS COMMITTEE

A drugs and therapeutics committee is a group of people established and officially approved by the health ministry and/or health facility management that promotes the safe and effective use of medicines in the area or facility under its jurisdiction.

[In: [Drug and therapeutics committees, a practical guide](http://apps.who.int/medicinedocs/en/d/Js4882e/3.html) Geneva 2003, can be found online at: <http://apps.who.int/medicinedocs/en/d/Js4882e/3.html>]

DUTY (IMPORT TARIFF)

Import tariff may apply to all imported medicines or there may be a system to exempt certain products and purchases. The import tax or duty may or may not apply to raw materials for local production. It may be different for different products.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](http://www.haiweb.org/medicineprices/manual/documents.html) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

ESSENTIAL MEDICINES

Essential medicines are defined by WHO as medicines 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."

[At: http://www.who.int/topics/essential_medicines/en/]

ETHICS COMMITTEE (EC, INSTITUTIONAL REVIEW BOARD, IRB)

Ethics Committees (EC) ensure that biomedical research follows international guidelines, including the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the WHO and ICH Guidelines for Good Clinical Practice. The purpose of an EC in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants. A cardinal principle of research involving human participants is 'respect for the dignity of persons'. The goals of research, while important, should never be permitted to override the health, well-being,

and care of research participants. ECs should also take into consideration the principle of justice. Justice requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture, and ethnic considerations. ECs should provide independent, competent, and timely review of the ethics of proposed studies. In their composition, procedures, and decision-making, ECs need to have independence from political, institutional, professional, and market influences. They need similarly to demonstrate competence and efficiency in their work. ECs are responsible for carrying out the review of proposed research before the commencement of the research. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision. ECs are responsible for acting in the full interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

[In: [Operational Guidelines for Ethics Committees That Review Biomedical Research](#) Geneva 2000, can be found online at: <http://apps.who.int/medicinedocs/en/d/Js6171e/2.3.html>
<http://apps.who.int/tdr/publications/training-guideline-publications/operational-guidelines-ethics-biomedical-research/pdf/ethics.pdf>]

EXCHANGE RATE

Several websites provide exchange rates and tools to express money values in \$US. For example, the following site automatically calculates average exchange rates for a given period of time (under currency tools) <http://www.oanda.com/currency/historical-rates>

FEE FOR SERVICE

Fee for service payments are payments to a services provider (for example a general practitioner, or a Medicines Regulatory Authority) for each act or service rendered.

[From: [PHIS Glossary 2009](#) , can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

FINISHED PRODUCT

A finished product is a product that has undergone all stages of production, including packaging in its final container and labeling.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:

<http://infocollections.org/medreqpack/interface/files/glossary.pdf>

FORMULARY

A formulary is a manual containing clinically oriented summaries of pharmacological information about selected drugs. The manual may also include administrative and regulatory information pertaining to the prescribing and dispensing of drugs).

A national formulary generally concentrates on available and affordable medicines that are relevant to the treatment of diseases in a particular country. Formularies are also frequently created for different levels of health care, different sectors and for individual hospitals.

[In: [How to develop a national formulary based on the WHO model formulary, a practical guide Geneva 2004](#), can be found online at: <http://apps.who.int/medicinedocs/en/d/Js6171e/2.3.html>]

GENERAL HOSPITAL

General hospitals are secondary care centers. Their main function is to provide a referral service for the primary health care centers and a direct service to the population under their jurisdiction. They usually offer acute medical, surgical, pediatric and obstetric services. They do not have a full range of specialty units such as oncology, cardiac or neurological surgery, although they may have 1-2 units providing sub-specialist tertiary care.

GENERIC

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

The 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 trade name) and unbranded generics (which use the international non-proprietary name and the name of the company). [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]

[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

GENERIC SUBSTITUTION

Generic substitution is the practice of substituting a pharmaceutical, whether marketed under a trade name or generic name (branded or unbranded generic), by a pharmaceutical, often a cheaper one, containing the same active ingredient(s).

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

GOOD CLINICAL PRACTICE

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]

[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

GOOD DISTRIBUTION PRACTICE (GDP)

Part of [quality assurance](#) which ensures that the quality of pharmaceuticals is maintained throughout the numerous activities occurring during the distribution process. A well-managed distribution system should achieve the following objectives: maintain a constant supply of drugs, keep pharmaceuticals in good condition through the distribution process, minimize pharmaceutical losses due to spoilage and expiry, maintain accurate inventory records, rationalize drug storage points, use available transportation resources as efficiently as possible, reduce theft and fraud, and provide information for forecasting pharmaceuticals needs.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

GOOD GOVERNANCE PROGRAM

The Good Governance for Medicines (GGM) program is a World Health Organization (WHO) program, started in late 2004, in line with the WHO Global Medicines Strategy 2004-2007. Its goal is to reduce corruption in the pharmaceutical sector by the application

of transparent, accountable administrative procedures and by promoting ethical practices. Through this initiative, WHO's objective is to support countries in maintaining efficient health-care systems.

[In: [WHO Good Governance for Medicines Progress Report](http://apps.who.int/medicinedocs/documents/s16218e/s16218e.pdf) Geneva 2009 can be found online at: <http://apps.who.int/medicinedocs/documents/s16218e/s16218e.pdf>]

GOOD MANUFACTURING PRACTICE (GMP)

Part of [quality assurance](#) which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

[In: [WHO A model quality assurance system for procurement agencies](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

GOOD PHARMACY PRACTICE

Good Pharmacy Practice is the practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products by patients and members of the public. It requires that the welfare of the patient is the pharmacist/s prime concern at all times.

[In: [WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014](http://infocollections.org/medreqpack/interface/files/glossary.pdf) at: <http://infocollections.org/medreqpack/interface/files/glossary.pdf>]

GOVERNMENT HEALTH EXPENDITURE

Government health expenditure is health expenditure incurred by public funds (state, regional and local government bodies and social security schemes).

Private expenditure is the 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.

[In: *PHIS Glossary 2009*, can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

GROSS DOMESTIC PRODUCT (GDP)

Gross domestic product (GDP) corresponds to the value of all goods and services provided in a country by residents and non-residents without regard to their allocation among domestic and foreign claims.

[At: http://www.who.int/whosis/indicators/WHS09_IndicatorCompendium_20090701.pdf]

Gross domestic product is an aggregate measure of production equal to the sum of the gross values added of all resident institutional units engaged in production (plus any taxes, and minus any subsidies, on products not included in the value of their outputs). The sum of the final uses of goods and services (all uses except intermediate consumption) measured in purchasers' prices, less the value of imports of goods and services, or the sum of primary incomes distributed by resident producer units.

[At: <http://unstats.un.org/unsd/snaama/glossresults.asp?qID=5>]

GROSS NATIONAL INCOME (GNI)

Gross national income (GNI) is the sum of value added by all resident producers plus any product taxes (less subsidies) not included in the valuation of output plus net receipts of primary income (compensation of employees and property income) from abroad.

[At: http://www.who.int/whosis/indicators/WHS09_IndicatorCompendium_20090701.pdf]

Gross national income (GNI) is [GDP](#) less net taxes on production and imports, less compensation of employees and property income payable to the rest of the world plus the corresponding items receivable from the rest of the world (in other words, GDP less primary incomes payable to non-resident units plus primary incomes receivable from non-resident units). An alternative approach to measuring GNI at market prices is as the aggregate value of the balances of gross primary incomes for all sectors; (note that gross national income is identical to gross national product (GNP) as previously used in national accounts)

[At: <http://unstats.un.org/unsd/snaama/glossresults.asp?qID=8>]

GUIDELINES FOR MEDICINES DONATIONS

In 1999 WHO published guidelines for drug donations based on four core principles. The first and paramount principle is that a drug donation should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited drug donations are to be discouraged. The second principle is that a donation should be made with full respect for the wishes and authority of the recipient, and be supportive of existing government health policies and administrative arrangements. The third principle is that there should be no double standards in quality: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation. The fourth principle is that there should be effective communication between the donor and the recipient: donations should be based on an expressed need and should not be sent unannounced.

WHO advises that recipient countries formulate their own national guidelines for drug donations on the basis of international guidelines. These national guidelines should then be officially presented and explained to the donor community. Only after they have been presented and officially published can they be enforced.

*[In: [WHO Drug donations guidelines.pdf](http://apps.who.int/medicinedocs/pdf/whozip52e/whozip52e.pdf), can be found on line at:
<http://apps.who.int/medicinedocs/pdf/whozip52e/whozip52e.pdf>]*

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 programs, 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 (government) 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.

*[In: [PHIS Glossary 2009](http://phis.goeq.at/index.aspx?alias=phisglossary), can be found on line at:
<http://phis.goeq.at/index.aspx?alias=phisglossary>]*

HEALTH INSURANCE

The term health insurance refers to all types of health insurance programs, including private, public, for profit and not-for-profit programs and organizations, particularly those which include the poor. Health insurance programs pool financial risks across populations and pay part of or all health care expenses for their defined population of members (and possibly dependents) from premiums contributed by individuals, employers, nongovernmental organizations and/or government.

[In: Prescribing Cultures and Pharmaceutical Policy in the Asia-Pacific 2009 edited by Karen Eggleston, Walter H Shorestein Asia-Pacific Research Center Books.

Chapter 18: Insurance Systems in the Asia-Pacific Region: Improving Appropriate Use of and Access to Medicines by Anita Wagner and Dennis Ross-Degnan]

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 specialized accommodation services required by in-patients. Hospital provides in-patient health services, many of which can only be provided using the specialized 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.

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

Hospitals can be classified in general hospitals, mental health and substance abuse hospitals and specialty (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 **specialty 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.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeq.at/index.aspx?alias=phisglossary>]*

IMPORTER

An importer is an individual or company or similar legal entity importing or seeking to import a pharmaceutical product. A “licensed” or “registered” importer is one who has been granted a license or registration status for the purpose. In addition to a general license or permit as an importer, some countries require an additional license to be issued by the national drug regulatory authority if pharmaceutical products are to be imported.

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:
<http://infocollections.org/medregpack/interface/files/glossary.pdf>]*

INDICATOR

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 an accurate picture of a situation, and they facilitate the communication process for providing the reader with the results of measurement.

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).

[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

INFANT MORTALITY RATE

Infant mortality rate is the total number of infants dying before reaching the age of one year per 1,000 live births in a given year. It is an approximation of the number of deaths per 1,000 children born alive who die within one year of birth.

[At: <http://unstats.un.org/unsd/demographic/products/socind/health.htm#tech>]

INJECTABLE MEDICINES

Sterile medicines intended for administration by bolus injection, perfusion or infusion by any of the following routes: intravenous, intramuscular, intra-theccal, intra-arterial, subcutaneous, intra-dermal, intra-ventricular, epidural, intra-vesicular, intra-vitreall, intra-pleural 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.

*[In: [PHIS Glossary 2009](http://phis.goeq.at/index.aspx?alias=phisglossary), can be found on line at:
<http://phis.goeq.at/index.aspx?alias=phisglossary>]*

IN-PATIENT CARE

An in-patient is a patient who is formally admitted (or “hospitalized”) 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]

*[In: [PHIS Glossary 2009](http://phis.goeq.at/index.aspx?alias=phisglossary), can be found on line at:
<http://phis.goeq.at/index.aspx?alias=phisglossary>]*

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH)

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities

of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.

The objective of such harmonization is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.

[At: <http://www.ich.org/cache/compo/276-254-1.html>]

INTERNATIONAL NON-PROPRIETARY NAME (INN)

INN is a unique name that is globally recognized 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, INNs 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 recognize that the substance belongs to a group of substances having similar pharmacological activity.

Non-proprietary names are intended for use in pharmacopoeias, labeling, 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 jeopardize the safety of patients, trade-marks cannot be derived from INN and, in particular, must not include their common stems.

[WHO Guidance on INN at:

<http://www.who.int/medicines/services/inn/innguidance/en/index.html>]

INTERNATIONAL ORGANIZATION OF STANDARDISATION (ISO)

ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. ISO is a network of the national standards institutes of 159 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organization that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations. Therefore, ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

Because "International Organization for Standardization" would have different acronyms in different languages ("IOS" in English, "OIN" in French for Organisation Internationale de normalisation), its founders decided to give it also a short, all-purpose name. They chose "ISO", derived from the Greek isos, meaning "equal". Whatever the country, whatever the language, the short form of the organization's name is always ISO.

[At: <http://www.iso.org/iso/about.htm>]

INTERNATIONAL REFERENCE PRICES

In the WHO/HAI survey measuring prices, availability, affordability and price components of medicines, medicine prices are expressed as ratios relative to a standard set of reference prices to facilitate national and international comparisons. Median prices listed in MSH's International Drug Price Indicator Guide have been selected as the most useful standard since they are updated frequently, are always available and are relatively stable. These prices are recent procurement prices offered by both not-for-profit and for-profit suppliers to developing countries for multi-source products.

How representative reference prices are generally depends on the number of suppliers quoting for each product. For example, if a medicine has a single, high supplier price, a low median price ratio (MPR) will be obtained, which can be misinterpreted as low national prices.

[From: [WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations: Guide for coordinators and data collectors](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf>]

LAW (LEGAL PROVISIONS)

Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms (see also [regulations](#) below).

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:

<http://infocollections.org/medregpack/interface/files/glossary.pdf>

LEGISLATION

Legislation corresponds to the first stage of the legislative process, in which laws are passed by the legislative body of government with regard to a subject matter such as the control of pharmaceuticals. Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms (see also [regulations](#) below).

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

LICENSE HOLDER

A license holder is an individual or a corporate entity possessing a marketing authorization for a pharmaceutical product.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:

<http://infocollections.org/medregpack/interface/files/glossary.pdf>

LICENSEE

A licensee is an individual or corporate entity responsible for the information and publicity on, and the pharmacovigilance and surveillance of batches of, a pharmaceutical product and, if applicable for their withdrawal, whether or not that individual or corporate entity is the holder of the marketing authorization.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:

<http://infocollections.org/medregpack/interface/files/glossary.pdf>

LICENSING SYSTEM

National legal provisions on who should manufacture, import or supply pharmaceutical products, what qualifications people in the supplying agency should have, and who should dispense and sell pharmaceutical products.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:

<http://infocollections.org/medregpack/interface/files/glossary.pdf>

LIFE EXPECTANCY AT BIRTH

Life expectancy at birth is an estimate of the number of years to be lived by a female or male newborn, based on current age-specific mortality rates. Life expectancy at birth by sex gives a statistical summary of current differences in male and female mortality across all ages. In areas with high infant and child mortality rates, the indicator is strongly influenced by trends and differentials in infant and child mortality.

[At: <http://unstats.un.org/unsd/demographic/products/socind/health.htm#tech>]

MANUFACTURE (MANUFACTURING)

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

[In: [PHIS Glossary 2009](#), can be found on line at:

<http://phis.goeg.at/index.aspx?alias=phisglossary>]

MANUFACTURER

A manufacturer is a natural or legal person with responsibility for manufacturing of a product.

[In: [PHIS Glossary 2009](#), can be found on line at:

<http://phis.goeg.at/index.aspx?alias=phisglossary>]

A local manufacturer is a business entity whose legal ownership is based in the country.

MANUFACTURER'S SELLING PRICE (MSP, EX-FACTORY PRICE)

Manufacturer's selling price is the price the manufacturer charges for a medicine.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](http://www.haiweb.org/medicineprices/manual/documents.html) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

Ex-factory price is the manufacturer's posted price, in some countries also referred to as list price. Discounts or other incentives offered by manufacturers result in an effective price that is lower than the ex-factory price.

[In: *OECD – Pharmaceutical Pricing Policies in a Global Market*, at: http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]

MARKETING AUTHORISATION (REGISTRATION)

A legal document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using [INNs](#) or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. "The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence"). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.

Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be "registered" or to "have registration". Market authorization may occasionally also be referred to as a "license" or "product license".

[In: [WHO A model quality assurance system for procurement agencies](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

MATERNAL MORTALITY RATIO

The maternal mortality ratio is the number of maternal deaths per 100,000 live births during a specified time period, usually 1 year.

Maternal death is the death of a woman while pregnant or within 42 days after termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

Complications during pregnancy and childbirth are a leading cause of death and disability among women of reproductive age in developing countries. The maternal mortality ratio represents the risk associated with each pregnancy, i.e. the obstetric risk. It is also a Millennium Development Goal Indicator for monitoring Goal 5, improving maternal health.

[Can be found online at: <http://www.who.int/whosis/indicators/compendium/2008/3mrf/en/>]

MARK-UP (DISTRIBUTION MARK-UP)

The mark-up is the percentage of the purchasing price added on to get the selling price.

A mark-up is added on to the total cost incurred by the producer of a good in order to create a profit.

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

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

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

MEDIAN PRICE RATIO (MPR)

In the WHO/HAI survey measuring medicine prices, availability, affordability and price components, medicine prices found are not expressed as currency units, but rather as ratios relative to a standard set of international reference prices:

$$\text{Medicine Price Ratio (MPR)} = \frac{\text{Median local unit price}}{\text{International reference unit price}}$$

The ratio is thus an expression of how much greater or less the local medicine price is than the international reference price, e.g. an MPR of 2 would mean that the local medicine price is twice that of the international reference price.

Median price ratios facilitate cross-country comparisons of medicine price data.

Since averages can be skewed by outlying values, median values are a better representation of the midpoint value. The magnitude of price variations is presented as the interquartile range. A quartile is a percentile rank that divides a distribution into four equal parts. The range of values containing the central half of the observations, that is, the range between the 25th and 75th percentiles, is the interquartile range.

[In: [*HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)*](#) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

MEDICATION ERROR

A medication error is 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 labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

[At: <http://www.nccmerp.org/aboutMedErrors.html>]

MEDICINE

See [*pharmaceutical*](#)

MEDICINES COVERAGE (MEDICINES BENEFIT)

Medicines coverage refers to the medicines benefits offered by a health insurance to its members. Medicines coverage may be complete if all medicines costs are paid or reimbursed by the health insurance. It may be partial if the insurance pays or reimburses part of the costs of medicines or if it excludes certain medicines from the benefits it offers to its members.

MEDICINES REGULATORY AUTHORITY

A national body that *has the legal mandate to set objectives and* administer the full spectrum of medicines regulatory activities, including at least all of the following functions in conformity with national drug legislation:

- Marketing authorization of new products and variation of existing products;
- Quality control laboratory testing;
- Adverse drug reaction monitoring;
- Provision of medicine information and promotion of rational medicines use;
- Good Manufacturing Practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels;
- Enforcement operations;
- Monitoring of medicines utilization.

*[Adapted from: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:
<http://infocollections.org/medregpack/interface/files/glossary.pdf>]*

MORTALITY RATE

Mortality rate is 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.

[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

NARCOTIC DRUG

is a legal term encompassing substances covered by the Single Convention on Narcotic Drugs, 1961, and the 1972 Protocol Amending that Convention, including opiates, opioids, as well as cocaine and marihuana.

[At: http://www.incb.org/incb/en/convention_1961.html]

NATIONAL ESSENTIAL MEDICINES LIST

The list of [essential medicines](#) that has been defined, adopted, and published at country level. This list is normally used by all health facilities, including main hospitals.

To generate its own list of essential pharmaceuticals, each country may adapt the [WHO Model List of Essential Medicines](#) (EML) updated by the WHO's Expert Committee on the Selection and Use of Essential Medicines at two-year intervals.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

NATIONAL HEALTH SERVICES SYSTEMS (NATIONAL HEALTH INSURANCE)

National health services systems are characterized by three main features: their funding comes primarily from *government* general revenues, they provide medical coverage to the whole population, and they usually deliver health care through a network of public providers.

[In: World Bank [A practitioner's guide: Health Financing Revisited](#) (2006) and at:
<http://siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf>]

NATIONAL HEALTH POLICY (NHP)

A national health policy document is a written expression of the government's medium- to long-term goals and priorities for the health sector and the main strategies for attaining them.

[From WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at:

http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/]

NATIONAL MEDICINES POLICY (NMP)

A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field. A national drug policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general overview of what is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood.

The policy document should be developed through a systematic process of consultation with all interested parties. In this process the objectives must be defined, priorities must be set, strategies must be developed and commitment built.

[In [How to develop and implement a national drug policy](#) and at:

<http://apps.who.int/medicinedocs/en/d/Js2283e/#Js2283e>]

NATIONAL MEDICINES POLICY IMPLEMENTATION PLAN

A national medicines policy implementation plan is a written expression of the government plans to put into action the national medicines policy, setting activities, responsibilities, budget and timelines.

[From WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at:

http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/]

NATIONAL PHARMACOVIGILANCE CENTER

Organizations recognized by the governments to represent their country in the WHO program (usually the medicines regulatory agency). A single governmentally recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyze and give advice on all information related to drug safety.

[At: <http://www.who-umc.org/DynPage.aspx?id=13111&mn=1513>]

NEW CHEMICAL ENTITY (NCE)

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 drug 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.

[In: *PHIS Glossary 2009*, can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

NON-GOVERNMENTAL ORGANIZATION (NGO, CIVIL SOCIETY ORGANIZATION)

A non-governmental organization (NGO) is a not-for-profit, voluntary citizens' group, which is organized on a local, national or international level to address issues in support of the public good. Task-oriented and made up of people with common interests, NGOs perform a variety of services and humanitarian functions, bring citizens' concerns to governments, monitor policy and program implementation, and encourage participation of civil society stakeholders at the community level. They provide analysis and expertise, serve as early warning mechanisms, and help monitor and implement international agreements. Some are organized around specific issues, such as human rights, the environment or health. Their relationship with offices and agencies of the United Nations (UN) system differs depending on their location and their mandate.

[United Nations definition at: <http://www.un.org/dpi/ngosection/criteria.asp>]

NURSE

A nurse is a person who has completed a program of basic nursing education and is qualified and authorized in his/her country to practice 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)]

[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeq.at/index.aspx?alias=phisglossary>]

NURSING AND MIDWIFERY PROFESSIONALS

Nursing and midwifery professionals are those who plan, provide and evaluate treatment, support and care services for people who are in need of such care due to effects of ageing, injury, illness or other physical or mental impairment, or potential risks to health including before, during and after childbirth. Occupations included in this category typically require knowledge and skills obtained as the result of study in nursing or midwifery at a higher educational institution. Examples of national occupations classified here are: nurse practitioner, clinical nurse, public health nurse, nurse anesthetist, professional nurse, and professional midwife.

WHO reference?

OMBUDSPERSON

An ombudsman is a government appointee who investigates complaints by private persons against the government

[At: <http://wordnet.princeton.edu/>]

ORIGINATOR PHARMACEUTICAL PRODUCT/ORIGINATOR BRAND

An originator brand is generally the product that was first authorized world wide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization: e.g. Valium. The originator product always has a brand name; this name may, however, vary across countries.

Some substances (e.g. prednisolone, izoniazid) are so old that no originator can be identified and the patent was probably never claimed.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](http://www.haiweb.org/medicineprices/manual/documents.html) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

OUT-OF-POCKET PAYMENTS (OPP)

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:

Deductibles: Amounts required to be paid by the insured under a health insurance contract, before any payment of benefits can take place. Deductibles are usually expressed in terms of an "annual" amount.

Once the deductible is reached, the insurers then pays up to 100% of approved amounts for covered services provided during the remainder of that benefit year.

Co-payment: cost-sharing in the form of a fixed amount to be paid for a service.

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

[In: *OECD. A System of Health Accounts at*
http://www.oecd.org/document/8/0,3343,en_2649_34631_2742536_1_1_1_1,00.html]

OUT-PATIENT CARE

Out-patient care comprises medical and paramedical services delivered to out-patients. 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.

It should be noted that the term "out-patient" used in the OECD-System of Health Accounts 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]

[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

OVER-THE-COUNTER MEDICINE (NON-PRESCRIPTION MEDICINE)

Over-the-counter medicines are medicines that can be sold from licensed dealers without professional supervision and without prescription. These medicines are suitable for self-medication for minor disease and symptoms.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at:
<http://infocollections.org/medregpack/interface/files/glossary.pdf>]

PARALLEL IMPORT

Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner (or trademark- or copyright-owner, etc) or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.

[In [National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey](#) and At: <http://apps.who.int/medicinedocs/en/d/Js7916e/3.html>]

PATENT

Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.

A patent is not a permit to put a product on the market. A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market.

[In: [WTO OMC Fact sheet: TRIPS and pharmaceutical patents](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf), can be found on line at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]

PHARMACEUTICAL (MEDICINE, DRUG)

A pharmaceutical is any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the terms drug, medicine, and pharmaceutical are used interchangeably.

[In: [WHO A model quality assurance system for procurement agencies](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

PHARMACEUTICAL FORM

The pharmaceutical form is the pharmaceutical-technological form in which an active substance is made available. Pharmaceutical may be administered in solid form (e.g. tablets, powers), in semi-liquid form (e.g. ointments, pastes), in liquid form (e.g, drops, injectables, infusions) or in gaseous form (inhalation).

[In: [OECD – Pharmaceutical Pricing Policies in a Global Market](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html), at: http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]

PHARMACEUTICAL PRODUCT

A pharmaceutical product is a unique product defined by its active pharmaceutical ingredient, the strength of the active pharmaceutical ingredient, its pharmaceutical form and route of administration.

[In: [ICH Consensus Guideline Released for Consultation on 10 May 2005](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073307.pdf), at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073307.pdf>]

PHARMACEUTICAL TECHNICIANS AND ASSISTANTS

Pharmaceutical technicians and assistants perform a variety of tasks associated with dispensing medicinal products under the guidance of a pharmacist or other health professional. Occupations included in this category typically require knowledge and skills obtained as the result of study in pharmacy services at a higher educational institution. Examples of national occupation titles classified here are: pharmaceutical technician, pharmaceutical assistant, dispensing technician.

WHO reference?

PHARMACIST

Pharmacists are persons who have completed studies in pharmacy at university level (granted by adequate diploma) and who are licensed to practice 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)]

[In: [PHIS Glossary 2009](http://phis.goeq.at/index.aspx?alias=phisglossary), can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]

Pharmacists are those who store, preserve, compound, test, dispense and monitor medicinal products and therapies for optimizing human health. Occupations included in this category normally require completion of university-level training in theoretical and practical pharmacy,

pharmaceutical chemistry or a related field. Examples of national occupation titles classified here are: hospital pharmacist, industrial pharmacist, retail pharmacist, dispensing chemist.

WHO reference?

PHARMACY

Pharmacies are premises which in accordance to the local legal provisions and definitions may operate as a facility in the provision of pharmacy services in the community or health facility setting.

[In WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at: http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/]

PHARMACOVIGILANCE

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.

*[In: [WHO The importance of pharmacovigilance](http://apps.who.int/medicinedocs/en/d/Js4893e/#Js4893e), can be found on line at:
<http://apps.who.int/medicinedocs/en/d/Js4893e/#Js4893e>]*

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
- Auditing the outcomes of action taken and 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 /Pharmaceutical / Pharmacovigilance available at:
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/pharmacovigilance_en.htm]

*[In: [PHIS Glossary 2009](http://phis.goeg.at/index.aspx?alias=phisglossary), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

PHYSICIAN (MEDICAL DOCTOR)

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

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

They 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 specialized 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)]

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

Physicians (Medical Doctors) are those who study, diagnose, treat and prevent illness, disease, injury, and other physical and mental impairments in humans through application of the principles and procedures of modern medicine. Occupations included in this category require completion of a university-level degree in basic medical education plus postgraduate clinical training or equivalent.

POST-MARKETING SURVEILLANCE

Post-marketing surveillance is testing medicine samples to assess the quality of medicines that have already been licensed for public use.

[In WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at: http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/]

POST-MARKETING SURVEILLANCE STUDY

A post-marketing surveillance study is usually synonym of Phase IV study. (See [clinical trial](#)) 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.

[Adapted from: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medreqpack/interface/files/glossary.pdf>]

PREQUALIFICATION

The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises **to supply the product or service**, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of [good manufacturing practice](#) (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the decision. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture/registration, but the amount and type of information requested from the supplier for assessment by the procurement agency may differ.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

PRESCRIBER

A prescriber is a health care professional who is legally qualified to write a [prescription](#).

PRESCRIPTION

Is 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 receipt is in many countries regulated.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.qoeq.at/index.aspx?alias=phisglossary>]*

PRESCRIPTION-ONLY MEDICINES

Prescription-only medicines are medicines supplied only in licensed pharmacies on the presentation of signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only), and/or licensed and/or registered veterinarian (for animal treatment only), and the supply and dispensing of these medicines must be carried out by a pharmacist or under the supervision of a pharmacist. Prescription-only medicines are further subdivided into controlled medicines (narcotic medicines and psychotropic substances) and non-controlled medicines.

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:
<http://infocollections.org/medreqpack/interface/files/glossary.pdf>]*

PRIMARY HEALTH CARE UNIT

Primary health care units are units where primary health care is provided.

Primary health care is 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, behavioral, or social.

Such care is generally provided by physicians (general practitioners, family practitioners, internists, obstetricians and pediatricians) but in some countries is increasingly provided by other personnel such as nurse practitioners or physician assistants.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.qoeq.at/index.aspx?alias=phisglossary>]*

PRIVATE HEALTH EXPENDITURE

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.

By opposition, government (public) health expenditure is health expenditure incurred by public funds (state, regional and local government bodies and social security schemes).

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

PRIVATE SECTOR

The private sector in a mixed economy is the part of the economy not under government control and that functions within the market; private enterprise.

[In: Governance for sustainable human development, A UNDP policy document-Glossary of key terms. Can be found online at: <http://mirror.undp.org/magnet/policy/glossary.htm>]

PROCUREMENT

Procurement is the process of acquiring supplies, including those obtained by purchase, donation, and manufacture.

[In: Managing Drug Supply Second Edition, Chapter 13, page 182 Management Sciences for Health, 1997]

The process of purchasing or otherwise acquiring any pharmaceutical product, vaccine, or nutraceuticals for human use.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

“There are many steps in the procurement process. No matter what model is used to manage the procurement and distribution system, efficient procedures should be in place to:

- Select the most cost-effective essential drugs to treat commonly encountered diseases;

- Quantify the needs;
- Pre-select potential suppliers;
- Manage procurement and delivery;
- Ensure good product quality;
- Monitor the performance of suppliers and the procurement system.

Failure in any of these areas leads to lack of access to appropriate drugs and to waste.”

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

PROCUREMENT AGENCY

A procurement agency is any organization purchasing or otherwise acquiring any pharmaceutical product, vaccine, or nutraceutical for human use.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

PROMOTION

Promotion refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

[In: [C:\Documents and Settings\CVialle\Desktop\Country profile - Instructions and glossary 14 Sept 2010\WHO. A model quality assurance system for procurement agencies.pdf](#) [Criteria for Medicinal Drug Promotion](#) can be found online at: <http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf>]

PUBLIC SECTOR (CIVIL SERVICE)

Public sector is the part of the economy that is not privately owned, either because it is owned by the state or because it is subject to common ownership. This includes the national government, local authorities, national industries and public corporations.

[In: *Governance for sustainable human development, A UNDP policy document-Glossary of key terms.* Can be found online at: <http://mirror.undp.org/magnet/policy/glossary.htm>]

PURCHASING POWER PARITY (PPP)

Purchasing power parities are 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 expenditures 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. PPPs are also referred to as “parity” or “parities”.

*[In: [PHIS Glossary 2009](http://phis.goeq.at/index.aspx?alias=phisglossary), can be found on line at:
<http://phis.goeq.at/index.aspx?alias=phisglossary>]*

QUALITY ASSURANCE

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a pharmaceuticals. It is the totality of the arrangements made with the object of ensuring that pharmaceuticals are of the quality required for their intended use.

[In: [WHO A model quality assurance system for procurement agencies](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

QUALITY CONTROL

Quality control is the part of [Good Manufacturing Practices \(GMP\)](#) concerned with sampling, specifications, and testing and with the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials

are not released for use, or products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at:

<http://infocollections.org/medregpack/interface/files/glossary.pdf>]

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.

[In: *Promoting rational use of medicines: Core components* Geneva 2002, can be found online at:

<http://apps.who.int/medicinedocs/pdf/h3011e/h3011e.pdf>]

REFERRAL HOSPITAL

Referral hospitals are tertiary care centers. Their main function is to provide a referral service for secondary care centers (general hospitals) in all main subspecialties. In some cases, they may also provide secondary or even primary care. There are two categories of referral hospitals:

- Major hospitals offering a full range of services including specialty units
- Specialty hospitals dedicated to specific types of patients, e.g. children, or specific range of conditions, e.g. oncology.

REGULATIONS

The second stage of the legislative process (the first stage being legislation, see above). Regulations are specifically designed to provide the legal machinery to achieve the administrative and technical goals of legislation.

[In: *WHO A model quality assurance system for procurement agencies* Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

REGULATORY INSPECTION

A regulatory inspection is an officially conducted examination (i.e. review of quality assurance processes, personnel involved, any delegation of authority and audit) by relevant authorities at sites where pharmaceutical activities take place (i.e. manufacturing, wholesale, testing, distribution, clinical trials) to verify adherence to Good Practices

*[Adapted from: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:
<http://infocollections.org/medreqpack/interface/files/glossary.pdf>]*

REIMBURSEMENT LIST

Reimbursement is the percentage of the reimbursement price (for a service or a medicine) which a third party payer pays. So 100% reimbursement means that the third party payer covers 100% of the reimbursement price / amount of a medicine or service except a possible prescription fee.

A reimbursement list is the list of medicines which a third party payer pays in part or completely.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

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, pediatric, etc.), ATC level, classification (hospital-only, etc.). In many countries different reimbursement rates are determined for different reimbursement categories.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

RETAIL DISTRIBUTOR

A retail distributor is a company that sells goods to consumers, e.g. a pharmacy or other medicines outlet. Many low- and middle- income countries have at least two different types of shops in which medicines can be purchased: pharmacies with a registered pharmacist and medicines stores, chemists or medicines outlets with paramedical or lay staff.

RETAIL MARK-UP

The retail mark-up is the percentage that retailers (pharmacies) add to cover their costs, including their profit. These costs include those overhead costs that retailers incur in their practice, such as rent, staff salaries, repackaging and loss, as well as profit. Retail mark-ups are not limited to the private sector: the public and other sectors can also use mark-ups to cover their costs.

Mark-ups can vary between products: imported and locally produced medicines often have different mark-ups. Pharmacies may also charge different mark-ups on originator brands and generically equivalent products. In some countries, for example, the mark-ups are higher on generic equivalents because, even with the markup, they are considered to be affordable.

Maximum retail mark-up: In some cases, the government applies a ceiling or maximum percentage limiting the mark-up that a retailer can add. However, it is also common to find that this mark-up is not enforced and much higher percentages can be found in practice.

Regressive retail mark-up: In some countries, there may be different maximum mark-ups for different price bands: this is called a 'regressive mark-up' and means that the mark-up decreases as the price of the medicine increases.

In countries where prices are not regulated or where regulations are not enforced, there might be great variation in retail mark-ups. If medicines are sold in the informal sector (medicine outlets), price variations can be even greater.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](#) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

RISK MANAGEMENT PLAN

A Risk Management Plan is meant to document not only what is known about the safety of a medicine at that particular point in time, but also potential risks that require further elucidation, and how the pharmaceutical sponsor intends to investigate those risks. The sponsor is required to establish a plan for monitoring the new medicine when it is approved (a so-called Pharmacovigilance Plan) and consider whether there is a need for additional risk minimization activities (such as additional prescribing and educational material, restrictions on promotion of and access to the medicine) and outline these in a Risk Minimization Plan.

[Adapted from: *The Australian Prescriber* by the Australian Government at <http://www.australianprescriber.com/magazine/33/1/10/11/>]

SAMPLE

A sample is a portion of a material collected according to a defined sampling procedure. The size of any sample should be sufficient to allow all anticipated test procedures to be carried out including all repetitions and retention samples. If the quantity of material available is not sufficient for the intended analyses and for the retention samples, the inspector should record that the sampled material is the available sample and the evaluation of the results should take account of the limitations that arise from the insufficient sample size.

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:
<http://infocollections.org/medreqpack/interface/files/glossary.pdf>]*

SAMPLING

Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments, batch release. (See [sample](#) above)

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:
<http://infocollections.org/medreqpack/interface/files/glossary.pdf>]*

SICKNESS FUND

A sickness fund is a single social health insurance institution. In some countries there are several sickness funds operating or even competing each other. Some sickness funds are operating on a regional basis whereas others are limited to specific professional groups like farmers or self employed persons.

*[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]*

SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

The adoption of this international treaty is regarded as a milestone in the history of international drug control. The Single Convention codified all existing multilateral treaties on drug control and extended the existing control systems to include the cultivation of plants that

were grown as the raw material of narcotic drugs. The principal objectives of the Convention are to limit the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes and to address drug trafficking through international cooperation to deter and discourage drug traffickers. The Convention also established the International Narcotics Control Board, merging the Permanent Central Board and the Drug Supervisory Board.

[At: http://www.incb.org/incb/en/convention_1961.html]

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 organized 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.

[In: *PHIS Glossary 2009*, can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

SOCIAL SECURITY

Social security funds as defined by the National Health Accounts constitute special kinds of institutional units which may be found at any level of government - central, state or local. Social security schemes are social insurance schemes covering the community as whole or large sections of the community that are imposed and controlled by government units. They generally involve compulsory contributions by employees or employers or both, and the terms on which benefits are paid to recipients are determined by government units. The schemes cover a wide variety of programmes, providing benefits in cash or in kind for old age, invalidity or death, survivors, sickness and maternity, work injury, unemployment, family allowance, health care, etc. There is usually no direct link between the amount of the contribution paid by an individual and the risk to which that individual is exposed. Social security schemes have to be distinguished from pension schemes or other social insurance schemes which are determined by mutual agreement between individual employers and their employees, the benefits being linked to contributions.

[In: *Guide to Producing National Health Accounts*, can be found on line at:
http://www.who.int/nha/docs/English_PG.pdf]

STANDARD TREATMENT GUIDELINES (STG)

STGs summarize recommended treatments for commonly occurring conditions. They should represent a consensus on what is regarded as the most appropriate treatment for each condition. The aim of providing such information is that treatments become standardized throughout a health system and that prescribing for the conditions covered is rationalized.

Widespread adoption and application of standardized treatments also make it possible to use these, together with morbidity and patient attendance data, as a basis for quantification of drug requirements.

STGs are useful to prescribers as ready reference texts for consultation during the course of daily clinical work and also as resource materials for basic and in-service prescriber training.

[In: [Producing national drug and therapeutic information: The Malawi approach to developing standard treatment guidelines Geneva 1999](http://apps.who.int/medicinedocs/pdf/whozip24e/whozip24e.pdf) can be found online at: <http://apps.who.int/medicinedocs/pdf/whozip24e/whozip24e.pdf>]

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Product information as approved by the Regulatory Authority. The SPC serves as the basis for production of information for health personnel as well as for consumer information on labels and leaflets of medicinal products and for control of advertising.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medreqpack/interface/files/glossary.pdf>]

TENDER

Tender is the procedure for procuring pharmaceuticals by seeking quotations from suppliers in response to a public request for quotations.

Competitive tender is a procedure which puts a number of suppliers into competition to obtain lower price. Asking potential suppliers to present their quotes in a standardized and comparable format ensures fair competition.

[In: [WHO A model quality assurance system for procurement agencies](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

THIRD-PARTY PAYER

A third-party payer is any entity, public or private, that pays or insures health or medical expenses on behalf of beneficiaries or recipients of the coverage.

[In: OECD – Pharmaceutical Pricing Policies in a Global Market, at:

http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html]

TOTAL POPULATION

Total population is based on the de facto definition of population, which counts all residents regardless of legal status or citizenship--except for refugees not permanently settled in the country of asylum, who are generally considered part of the population of their country of origin.

[Source: World Bank – Data and Statistics]

TRADE-RELATED ASPECTS of INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement.

The balance works in three ways:

- Invention and creativity in themselves should provide social and technological benefits.

Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.

- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes available for others to use. All of this avoids "re-inventing the wheel".
- The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled. For pharmaceutical

patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. The enhancement was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory license. In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement, which will take effect when two thirds of members accept it.

[In: [WTO OMC Fact sheet: TRIPS and pharmaceutical patents](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf), can be found on line at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]

TRADITIONAL MEDICINE (TM)

Traditional medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses.

Herbal medicine: plant derived material or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. In some traditions, material of inorganic or animal origin may also be present.

Complementary/alternative medicine (CAM): often refers to a broad set of health care practices that are not part of a country's own tradition and are not integrated into the dominant health care system. Other terms sometimes used to describe these health care practices include "natural medicine", "nonconventional medicine" and "holistic medicine".

[In [National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey](http://apps.who.int/medicinedocs/en/d/Js7916e/3.html) and At: <http://apps.who.int/medicinedocs/en/d/Js7916e/3.html>]

UNDER 5 MORTALITY RATE

Under-five mortality rate is defined as the probability of dying before reaching age 5 and is expressed as the number of deaths under age 5 per 1,000 live births.

[At: <http://unstats.un.org/unsd/demographic/products/socind/health.htm#tech>]

URL

URL is the acronym of Universal Resource Locator which means the address of a web page on the World Wide Web.

VALUE ADDED TAX (VAT)

VAT and GST can be levied on sales. These taxes vary from country to country, and also from state to state within a country. In many countries, medicines or certain sectors are exempted from VAT or GST; in other countries, VAT is collected at each stage of the supply chain. Each participant in the supply chain pays cost plus VAT, and then adds VAT to its selling price. The VAT is thus refunded to the participant so that the final purchaser is the only one who pays VAT.

In some countries, Goods and Services Tax (GST) and/or other national/regional taxes are charged on medicines.

[Adapted from: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](#) and at:

<http://www.haiweb.org/medicineprices/manual/documents.html>]

WHOLESALE

All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public.

Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned.

Wholesalers have a public service obligation: the obligation to guarantee permanently an adequate range of medicinal products 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]

[In: [PHIS Glossary 2009](#), can be found on line at:
<http://phis.goeg.at/index.aspx?alias=phisglossary>]

WHOLESALE MARK-UP

The wholesale mark-up is the percentage added by the wholesaler or Central Medical Stores to cover overhead costs. These costs encompass overhead expenses such as rent, security, electricity, staff salaries and loss. In some situations, it includes costs to transport medicines to retailers. In the private sector, the markup also includes a profit margin; in the public and mission sector, the margin can provide capital for future investment or cover unforeseen increases in costs (e.g. inflation or devaluation).

If the medicines move through more than one wholesaler on their way to the patient, multiple wholesale mark-ups might be levied. This tends to happen as medicines move from central, urban areas to more rural ones.

Maximum wholesale mark-up: In some countries, the government applies a ceiling or maximum percentage limiting the mark-up that a wholesaler can add. In some cases, this mark-up is not enforced and much higher percentages can be observed.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](#) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

WHO LEVEL II FACILITY SURVEY

Level II health facility indicators provide systematic data to measure outcomes on access (affordability and availability of key medicines and geographical accessibility of dispensing facilities) and rational use of quality medicines, including some indication of the quality of medicines at health facilities and pharmacies. Data on these indicators are collected through systematic surveys of public health facilities, public and private pharmacies and public warehouses. The results of country surveys can be used to indicate the extent to which the objectives set by the pharmaceutical sector - specifically the government and the national medicines policy - have been achieved. The results show the areas and gaps that should be addressed and which strategy can be prioritized for facilities, districts and countries.

[In: [WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations: Guide for coordinators and data collectors](http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf>]

WHO CERTIFICATION SCHEME

The WHO Certification Scheme offers to importing countries information about:

- a) the status of the pharmaceutical product;
- b) the status of the manufacturer of the pharmaceutical product;
- c) the quality of individual batches of the exported pharmaceutical product;
- d) product information as approved in the country of export.

As at December 1994, the WHO Certification Scheme has been accepted by health authorities in 138 countries, both exporting and importing pharmaceuticals, which indicates their willingness to share the responsibility for the quality of drugs moving in international commerce.

[In: [Use of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce](http://apps.who.int/medicinedocs/en/d/Jwhozip43e/4.2.html), can be found online at: <http://apps.who.int/medicinedocs/en/d/Jwhozip43e/4.2.html>]

WHO PREQUALIFICATION PROGRAMME

Launched in 2001, partnered with UNAIDS, UNICEF and the UN Population Fund, and receiving support from the World Bank, the WHO [prequalification](#) program is tackling the quality problems commonly associated with medicines in the area of HIV/AIDS, Tuberculosis, Malaria and Reproductive Health Research. It provides a stringent assessment of pharmaceutical product dossiers, inspection of pharmaceutical manufacturing sites and of contract research organizations (CROs), prequalification of pharmaceutical quality control laboratories (QCLs), and advocacy for medicines of assured quality.

[In: WHO [Prequalification of Medicines Programme - Update for 2006](#), can be found on line at: <http://apps.who.int/medicinedocs/documents/s14150e/s14150e.pdf>]

WHISTLE BLOWER

A whistle blower is an informant who exposes wrongdoing within an organization in the hope of stopping it.

[At: <http://wordnet.princeton.edu/>]