The definitions given below apply to the terms as used in different fact sheets of the WHO global benchmarking tool (GBT) for evaluation of national regulatory system of medical products. These terms may have different meanings in other contexts.

**Accountability**

The result of the process which ensures that health actors take responsibility of what they are obliged to do and are made answerable for their actions.

**Advisory/Scientific committee**

See expert advisory body

**Benchmarking**

A formal process of evaluation of a process or system, preferably quantitative, but sometimes necessarily qualitative.

**Benchmark**

A measurement or point of reference at the beginning of an activity which is used for comparison with subsequent measurements of the same variable

**Commitment**

In accounting usage, commitments refer to a stage in the expenditure process at which contracts or other forms of agreement are entered into, generally for future delivery of goods or services. A liability will not be recognized until delivery of the item, but the government is contractually committed to meeting the obligation once delivery is made. The term is also used in a more general, non-contractual sense to mean firm promises of the government made in policy statements.

**Competency**

Combines knowledge, skills and attitude. Competencies describe how the work is to be carried out while objectives indicate what must be accomplished. They also provide a sound basis for consistent and objective performance standards by creating a shared language for what is needed and expected by the organization.

**Decentralization**

Political reform designed to promote local autonomy, decentralization entails changes in authority and financial responsibility for health services. Hence, decentralization can have a large impact on health service performance. There are several forms of decentralization affecting the health sector in different ways: (i) decentralization, which transfers authority and responsibility from the central level of the Ministry of Health to its field offices; (ii) delegation, which transfers authority and responsibility from the central level of the Ministry of Health to organizations not directly under its control; (iii) devolution, which transfers authority and responsibility from the central level of the Ministry of Health to lower level autonomous units of government; (iv) privatization, which involves the transfer of ownership and government functions from public to private bodies, which may consist of voluntary organizations and for-profit and not-for-profit private organizations, with varying degree of government regulation. ([http://www.who.int/health-laws/topics/governance-decentralisation/en/](http://www.who.int/health-laws/topics/governance-decentralisation/en/))
Effectiveness

The extent to which a specific intervention, procedure, regimen or service, when deployed in the field in routine circumstances, does what it is intended to do for a specified population.

Efficacy

The extent to which a specific intervention, procedure, regimen or service, produces the intended result under ideal conditions.

Efficiency

The capacity to produce the maximum output for a given input.

Emergency

Emergency is a term describing a state. It is a managerial term, demanding decision and follow-up in terms of extra-ordinary measures (Oxford Pocket Dictionary, 1992). A "state of emergency" demands to "be declared" or imposed by somebody in authority, who, at a certain moment, will also lift it. Thus, it is usually defined in time and space, it requires threshold values to be recognized, and it implies rules of engagement and an exit strategy. Conceptually, it relates best to Response.

Entities

In this document, refer to different composition units within the NRA such as divisions, departments, sections, etc…, or to different institutions, organizations, bodies which are involved in the national regulatory system.

Ethics committee (also called research ethics committee or independent ethics committee)

An independent body ( a review board or a committee, institutional, regional or national), constituted of medical professionals and non-medical members, whose responsibility is to verify that the safety, integrity and human rights of the subjects participating in a particular trial are protected and to consider the general ethics of the trial thereby providing public reassurance. Ethics committees should be constituted and operated so that their tasks can be executed free from bias and from any influence of those who are conducting the trial.

Event

A specific identifiable happening or occurrence, e.g. the taking of a medicine; the experience of an adverse effect.

Expert advisory body

An advisory board or committee of experts, including academic experts and practicing health care professionals.

Falsified medical products

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.
Findings

See inspection observation

Good governance

See governance

Good Clinical Practice

A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials or studies. It provides assurance that the data and results that are reported are credible and accurate.

Good review practices

Documented best practices for any aspect related to the process, format, content and management of a medical product review.

Governance

(i) the exercise of political, economic and administrative authority in the management of a country's affairs at all levels, comprising the complex mechanisms, processes, relationships and institutions through which citizens and groups articulate their interests, exercise their rights and obligations and mediate their differences. (ii) the traditions and institutions by which authority in a country is exercised for the common good, including the processes by which those in authority are selected, monitored and replaced; the capacity of the government to effectively manage its resources and implement sound policies; and the respect of citizens and the state for the institutions that govern economic and social interactions among them; (iii) the process of creating an organizational vision and mission—what it will be and what it will do—in addition to defining the goals and objectives that should be met to achieve the vision and mission; of articulating the organization, its owners and the policies that derive from these values—policies concerning the options that its members should have in order to achieve the desired outcomes; and adopting the management necessary for achieving those results and a performance evaluation of the managers and the organization as a whole. See stewardship.

Guidelines/guidance documents

Non-statutory advisory publications intended to assist those parties affected by legislation to interpret and apply requirements.

Impact

(i) the total, direct and indirect, effects of a programme, service or institution on a health status and overall health and socio-economic development. (ii) positive or negative, long-term or medium-term effects produced by a programme or intervention. (ii) the degree of achievement of an ultimate health objective.

Independent ethics committee (IEC)

See Ethics committee

Input
A quantified amount of a resource put in a process.

**Inspection observation**

A finding or statement of fact made during an inspection and substantiated by objective evidence. Such findings may be positive or negative. Positive observations should take the form of a description of the processes that the firm is carrying out particularly well and that may be considered as examples of particularly good practice. Negative observations are findings of noncompliance with requirements.

**Investigational product**

Any pharmaceutical product (new product or reference product) or placebo being tested or used as a reference in a clinical trial.

**Key performance indicators**

Factors that are under the control of the organization and are critical for its sustained success subject to performance measures.

**Legislation**

The first state of the legislative process, in which laws are passed by the legislative body of government with regard to a subject matter, e.g. control of pharmaceuticals. Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms. (see regulations).

**Medical products**

In this document, a term that includes medicines and vaccines.

**Non-conformity**

Refers to a failure to comply with requirements. A requirement is a need, expectation or obligation. It can be stated or implied by an organization, its customers or other interested parties. There are many types of requirements. These include quality requirements, customer requirements, management requirements, product requirements, process requirements and legal requirements. Whenever an organisation fails to meet one of these requirements, a nonconformity occurs.

**Observations**

See inspection observation

**Output**

The quantity and quality of activities carried out by a programme.

**Performance indicators**

Measurable values used to quantify quality objectives to reflect the performance of an organization, process or system, also known as “performance metrics” in some regions.

**Performance monitoring**
The continuous process of collecting and analysing data to compare how well a project, program, or policy is being implemented against expected results.

Post-Marketing

The stage when a drug is approved and generally available on the market.

Promotion

All informational and persuasive activities by manufacturers and distributors, the intended effect of which is to induce the prescription, supply, purchase and/or use of medicinal products. Ethical criteria for drug promotion, WHO, 1988. For the purposes of this manual, promotion includes advertising.

Public health emergency of international concern (PHEIC)

Defined in the International Health Regulation IHR (2005) as “an extraordinary event which is determined, as provided in these Regulations:

- to constitute a public health risk to other States through the international spread of disease; and
- to potentially require a coordinated international response”. This definition implies a situation that: is serious, unusual or unexpected; carries implications for public health beyond the affected State’s national border; and may require immediate international action."

Recognition

The routine acceptance by the NRA in one jurisdiction of the regulatory decision of another NRA or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. Recognition may be unilateral or multilateral, and may be the subject of mutual recognition agreement.

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.

Regulatory framework

The collection of laws, regulations, guidelines, and other regulatory instruments through which a government controls medical products manufacture, clinical evaluation, marketing, promotion and post-marketing safety benchmarking.

Reliance

The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to – i.e. totally or partially rely upon – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

Research ethics committee
See ethics committee

**Regulatory system (national regulatory authority NRA)**

The system composed of entities responsible for the registration, marketing authorization and other regulatory functions concerning medical products. The number of regulatory entities responsible for different regulatory functions may vary from one country to another (i.e. NRA may or may not be a single entity). The terms national medicines regulatory authority (NMRA) and/or drug regulatory authority (DRA) are also used, however less encouraged, for designating the national regulatory authority.

**Safety signal**

See signal

**Signal**

A hypothesis of a risk with a medicine, with various levels of evidence and arguments to support it. The complexity of the signal detection process cannot easily be captured in a single, precise definition. In addition to detecting previously unknown risks with medicines, signal detection should aim to find and communicate any important and relevant information that adds to previous safety knowledge about a medicine, including also risk factors/at risk groups, details of severity, time at risk, and duration of adverse effects.

**Stakeholders**

An individual, group or an organization that has an interest in the organization and delivery of health care.

**Stewardship**

The very essence of good government, the careful and responsible management of the well-being of the population. Includes: health policy formulation (defining the vision and direction of health system), regulation (setting fair rules of the game with a level playing field) and intelligence (assessing performance and sharing information). See governance.

**Substandard and falsified products (SF)**

See Substandard medical products and falsified medical products.

**Substandard medical products (also called “out of specification”)**

Authorized medical products that fail to meet either their quality standards or their specifications, or both.

**Summary of product characteristics (SPC)**

Product information as approved by the regulatory authority, may have different names globally e.g. also known as the ‘product label’. 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 (see also Product information).
Transparency

Defining policies and procedures in writing and publishing the written documentation and giving reasons to the public.

Unregistered/unlicensed medical products

Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Vigilance events

See event