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Draft global strategy and plan of action on public health, innovation and intellectual property

Glossary of terms

Report by the Secretariat

1. The following glossary has been produced in response to the request by some Member States in their submitted comments on the outcome document following the first session of the Intergovernmental Working Group.[1] It contains definitions for selected terms that appear in the draft global strategy and plan of action.[2]

2. Those definitions that are not taken from the Report of the Commission on Intellectual Property Rights, Innovation and Public Health[3] are marked with an asterisk (*).

***Access to drug leads.** Arrangements to use compounds that are efficacious in animal models, with a good pharmacokinetics profile and, based on animal data, no overt toxicity.[4]

***Accessibility of compound libraries.** Voluntary arrangements between the party that is seeking access and the party that has rights to a collection of structurally diverse chemical molecules, typically containing thousands or hundreds of thousand compounds used to identify new drug leads.[4]

***Affordability.** Extent to which the intended clients of a service can pay for it.[5]

Applied research. Research directed towards specific objectives, such as the development of a new drug, therapy or surgical procedure.

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[1] Document A/PHI/IGWG/1/5.

[2] Document A/PHI/IGWG/2/2.

[3] Document CIPIH/2006/1.

[4] Proposed Secretariat definition.

[5] Source: European Observatory on Health Systems and Policies: health systems glossary http://www.euro.who.int/observatory/Glossary/TopPage.

Basic research. Studies in the biomedical area that are typically designed to expand scientific knowledge of human biology, disease mechanisms and processes, as well as to understand how drugs work.

Bolar (early working) exception. An exception to patent rights allowing a third party to undertake, without the authorization of the patentee, acts in respect of a patented product necessary for the purpose of obtaining marketing approval for the sale of a product.

Clinical trials. Any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of an investigational product or to identify any adverse reactions to an investigational product or to study absorption, distribution, metabolism and excretion of an investigational product with the object of ascertaining its safety or efficacy. The clinical trial and clinical study are synonymous.

Compound library. A collection of different chemical molecules.

Compulsory licence. A licence to exploit a patented invention granted by the State upon request of a third party.

Counterfeit products. Products that are deliberately and fraudulently mislabelled with respect to identity and source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.

Data exclusivity. A legal protection that data collected (e.g. the results of clinical trials) for the purpose of obtaining marketing approval may not be used for a specified period by the regulatory authorities to grant approval to a generic equivalent.

Data protection. An obligation imposed on third parties to protect test data (e.g. the results of clinical trials) – usually collected in order to comply with government regulations on the safety, efficacy, and quality of a broad range of products (e.g. drugs, pesticide, medical devices). For example, the Agreement on Trade-Related Aspects of Intellectual Property Rights provides for the protection of such data against unfair commercial use.

Doha Declaration. The Ministerial Declaration on the TRIPS Agreement and Public Health adopted by the Fourth WTO Ministerial Conference (Doha, 9–13 November 2001).

Downstream research. Applied research usually directed at the development of a product or process with a potential commercial application.

***Drug lead.** A compound that is efficacious in animal models, with a good pharmacokinetics profile and, based on animal data, no overt toxicity.[1]

Intellectual property rights. Rights awarded by society to individuals or organizations over inventions, literary and artistic works, symbols, names, images, and designs used in commerce.

[1] Proposed Secretariat definition.

They give the titleholder the right to prevent others from making unauthorized use of their property for a limited period.

***Open source.** As applied to health research, a set of principles and practices that promote open and free access to, and exchange of, research information, data, technologies, and the like through various mechanisms such as journals and databases.[1]

Patent. An exclusive right awarded to an inventor to prevent others from making, selling, distributing, importing or using the invention, without licence or authorization, for a fixed period of time. In return, the patentee discloses the invention to the public. There are usually three requirements for patentability: novelty (new characteristics that are not "prior art"); inventive step or non-obviousness (knowledge not obvious to one skilled in the field); and industrial applicability or utility.

Patent pools. An agreement between two or more patent owners to licence one or more of their patents to one another or third parties.

***Prize fund model.** A mechanism to fund research and development whereby drug developers are rewarded for successful products through monetary "prizes" linked to the impact of the invention on improvements in health care outcomes. This model separates the incentives for innovation from the prices of health care products.[1]

Regulation. Typically refers to the process by which a governmental authority reviews medical interventions for marketing authorization. Although methods vary, this normally involves determination of product safety, quality and efficacy. Regulation also involves ongoing monitoring and evaluation of safety, efficacy, and quality of products that have already obtained marketing authorization.

***Research exemption.** Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (Article 30), governments can make limited exceptions to patent rights provided certain conditions are met. These exceptions must not conflict unreasonably with the normal exploitation of the patent and must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interest of third parties. A range of exceptions may be covered by this provision. For example, many countries provide for a "research" or "experimental use" exception to allow researchers to use a patented invention for research, in order to understand the invention more fully.[2]

Traditional knowledge. Although there is no generally acceptable definition, traditional knowledge includes, but is not limited to, tradition-based creations, innovations, literary, artistic or scientific works, performances and designs. Such knowledge is often transmitted from generation to generation and is often associated with a particular people or territory.

[1] Proposed Secretariat definition.

[2] Source: *WTO agreements and public health: a joint study by the WHO and the WTO secretariat.* Geneva, World Health Organization, 2002.

***TRIPS-plus.** The inclusion in trade agreements of additional commitments to the Agreement on Trade-Related Aspects of Intellectual Property Rights.[1]

Type I diseases. Diseases incident in both rich and poor countries, with large numbers of vulnerable population in each.

Type II diseases. Diseases incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries.

Type III diseases. Diseases are those that are overwhelmingly or exclusively incident in the developing countries.

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[1] See document A59/16 Add.1.