Glossary of Global Health Agreement Terms

This glossary includes definitions of the key terms in the **GHIAA MAPGuide** and from other public health-related agreements, policies or publications, and serves as a reference for the common definitions used in global health alliance agreements. The source for each definition is listed in the footnote after such definition.

"**Access**" means

- Alternative One: an individual's ability to obtain appropriate health care services. Barriers to access can be financial, geographic, organizational and sociological. Efforts to improve access often focus on providing/improving health coverage.[1]
- Alternative Two: the degree to which services can be obtained within the cost and effort limits that are acceptable to the general population.[2]
- Alternative Three: having the product continuously available and affordable at public or private health facilities that are within one hour's walk from the homes of the population.[3]
- Alternative Four: the ability to secure the product, at a specified level of quality, subject to a specified maximum level of personal inconvenience and cost, while in possession of a specified amount of information.[4]
- Alternative Five: the potential for or actual entry of a population into the health system. Entry is dependent upon the wants, resources, and needs that individuals bring to the care-seeking process. The ability to obtain wanted or needed services may be influenced by many factors, including travel, distance, waiting time, available financial resources, and availability of a regular source of care. Access also refers to the extent to which a public health service is readily available to the community's individuals in need. Accessibility also refers to the capacity of the agency to provide service in such a way as to reflect and honor the social and cultural characteristics of the community and focuses on agency efforts to reduce barriers to service utilization.[5]

"**Access Right**" means

[1] https://aspe.hhs.gov/glossary-terms

[2] Global Health Learning Center - Glossary

[3] https://www.who.int/medicines/mdg/MDG08ChapterEMedsEn.pdf

[4] https://jech.bmj.com/content/58/8/655

[5] Turnock, BJ. *Public Health: What It Is and How It Works*. Jones and Bartlett. 2009, cited in Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

- Alternative One: the right to use results under the terms and conditions laid down in this Agreement.[6]

- Alternative Two: the rights to use.[7]

"Active Pharmaceutical Ingredient (API)" means the chemical substance responsible for a product's effect.[8]

"Affected Territory" means the geographic area of any country (i) where there is an Outbreak; (ii) for which there is an Increased Outbreak Preparation Need; or (iii) the Parties otherwise agree in writing and in each case, including healthcare workers providing healthcare in such a country regardless of their home country.[9]
Also see the definitions of "Outbreak" and "Increased Outbreak Preparation Need."

"Affiliate" means any Person which, directly or indirectly, is controlled by, controls or is under common control, with another such Person. For the purposes of this definition, the term control as used with respect to a Person shall mean the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.[10]

"Affordability" means the cost in relation to peoples' income. For the purpose of the specific WHO glossary quoted here, the daily wage of the lowest-paid unskilled national government worker is used for comparison with the cost of a defined course of treatment for a specific condition. [11]
Also see the definitions of "Affordable Pricing" and "Equitable Pricing."

"Affordable Pricing" means the lowest sustainable, competitive price for the Product(s) which covers the cost of raw materials, manufacturing, distribution and operational overheads, and includes a reasonable margin to help ensure the economic sustainability of the production and distribution of the Product(s).[12]
Also see the definitions of "Affordability" and "Equitable Pricing."

"Assessment" means collecting, analyzing, and using data to educate and mobilize communities, develop priorities, garner resources, and plan actions to improve public health.[13]

"Background" means

- Alternative One: information, including data and know-how which is held by participants prior to the accession to this agreement, as well as copyrights or other intellectual and

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[6] IMI 2 Model Grant Agreement §25.1
[7] IMI 1 Model Grant Agreement General Conditions
[8] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[9] Unattributed Funder Development Partnering Agreement
[10] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf
[11] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[12] MPP License Agreement with Pfizer re Sutezolid §3.3
[13] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

industrial property rights pertaining to such information, and which is necessary for carrying out the project and identified in the project agreement.[14]

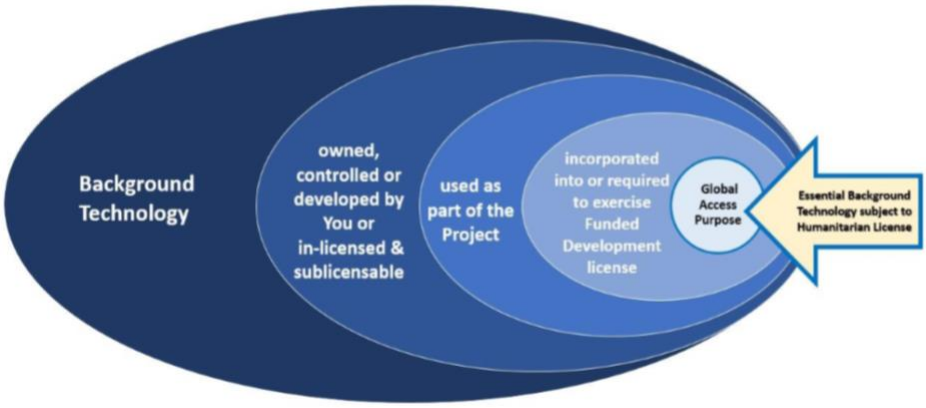
- Alternative Two: any data, know-how or information – whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights – that: (a) is held by the beneficiaries before they acceded to the Agreement, and (b) is needed to implement the action or exploit the results.[15]

- Alternative Three: any information, data, techniques, Know-how, inventions, software, discoveries and materials (regardless of the form or medium in which they are disclosed or stored) which are provided by one Party (whether belonging to that Party or to a third party) to another Party for use in the Project, and whether before or after the date of this Agreement, except any Result.[16]

  Also see the definitions of "Background Intellectual Property (IP)", "Background Technology" and "Essential Background Technology."

"Background Intellectual Property (IP)" means any Intellectual Property owned or controlled by a party at the Effective Date or which a party develops or acquires independently of the work under the Project, in each case, which is necessary or useful for undertaking any Work Phase, or the protection or exploitation of Foreground Intellectual Property.[17]
Also see the definitions of "Background", "Background Technology" and "Essential Background Technology."

"Background Technology" means any and all products, services, processes, technologies, materials, software, data, or other innovations, and intellectual property created by You (grantee) or a third party prior to or outside of the Project used as part of the Project (as illustrated by the diagram below).[18]



Source: Gates Foundation Global Access Commitment and Humanitarian License Clauses

[14] IMI 1 JU Model Grant Agreement §II.1
[15] IMI 2 Model Grant Agreement §24.1
[16] Lambert Toolkit Model Consortium Agreement D §1.1
[17] Unattributed Funder Development Partnering Agreement §1.1.6
[18] Gates Foundation Global Access Commitment and Humanitarian License Clauses

Also see the definitions of "Background", "Background Intellectual Property (IP)," and "Essential Background Technology."

"Barriers to Care" means barriers to receiving needed health care can include cost, language or knowledge barriers, and structural or logistical factors, such as long waiting times and not having transportation. Barriers to care contribute to socioeconomic, racial and ethnic, and geographic differences in health care utilization and health status.[19]

"Collaboration" means a mutually beneficial and well-defined relationship entered into by two or more organizations to achieve common goals.[20]

"Combination Products" means a product that includes one or more products or other components which are Licensed Products that is sold in combination with one or more separate products or other components which are not Licensed Products and that are sold by Company as stand-alone products.[21]

"Commercial Sale" means any sale of a Licensed Product or a Licensed Combination Product to a Third Party in any country in the Territory in the Field; provided, however, that a transfer of Licensed Products or Licensed Combination Products (i) for research and development purposes, or (ii) prior to receipt of Product Approval for use of such Licensed Product or Licensed Combination Product in humans, shall not be considered a Commercial Sale. ("Product Approval" means the grant of all necessary regulatory and governmental approvals required to manufacture, use, store, import, export, transport and/or sell Licensed Products or Licensed Combination Products in any country of the Territory.) [22]

"Commercialization" means

- Alternative One: any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Licensed Product, including activities related to marketing, promoting, distributing, and importing such Licensed Product, and interacting with regulatory authorities regarding any of the foregoing. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization, and "Commercialized" has a corresponding meaning.[23]

- Alternative Two: any and all activities directly and specifically relating to marketing, promoting, detailing, distributing, importing, offering for sale, having sold and/or selling a Licensed Product in the Field in the Territory, but excluding Development and Manufacturing. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization, and "Commercialized" has a corresponding meaning [24]

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[19] http://mchb.hrsa.gov/whusa11/hsu/downloads/pdf/303bcunc.pdf, cited in Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

[20] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

[21] https://www.sec.gov/Archives/edgar/data/1628738/000119312516623579/d892618dex1018.htm

[22] https://www.sec.gov/Archives/edgar/data/1356576/000104746912002789/a2207731zex-10_12.htm

[23] https://medicinespatentpool.org/uploads/2017/07/MPP-AbbVie-Agreement-Final1.pdf

[24] https://www.sec.gov/Archives/edgar/data/1587221/000119312515015033/d721131dex1041.htm

Also see the definition of "Commercialization Plan."

"Commercialization Plan" means a confidential plan, no later than [six (6) months] after the first approval of the Product, describing the key countries where it intends to market the Product.[25]
Also see the definition of "Commercialization."

"Commercially Reasonable Efforts" means the efforts and resources that a similarly situated company or institution, as applicable, would use for its own internally discovered [compounds/assets] of similar commercial potential and similar stage of development, taking into consideration the likely timing of the entry into the market, any patent and other proprietary position and issues of safety and efficacy.[26]

"Compliance" means a conformity in fulfilling official requirements.[27]

"Compulsory License" means

- Alternative One: an authorization granted by a government to someone other than the patent-holder to produce the product without the patent-holder's consent.[28]

- Alternative Two: the grant of permission for an enterprise seeking to use another's intellectual property without the consent of its proprietor.[29]

- Alternative Three: when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. It is one of the flexibilities in the field of patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.[30]

- Alternative Four: any valid, bona fide compulsory license pursuant to (a) the requirements promulgated under the Agreement or (b) valid laws within such country for any Product.[31]

"Confidential Information" means

- Alternative One: all trade secrets, processes, formulae, data, know-how, improvements, inventions, chemical or biological materials, techniques, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by a Party or any of its Affiliates, or has otherwise become known to a Party or any of its Affiliates, as well as any other information and materials that are deemed confidential or

[25] CARB-X Research Subaward Agreement, §6.04

[26] https://www.sec.gov/Archives/edgar/data/0001776985/000119312519241112/d635330dex1019.htm

[27] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

[28] Eric Bond and Kamal Saggi, *Compulsory Licensing, Price Controls, and Access to Patented Foreign Products*, April 2012.

[29] https://www.everycrsreport.com/reports/R43266.html

[30] WTO Compulsory Licensing of Pharmaceuticals and TRIPS FAQs

[31] Gilead HCV License Agreement with Indian Generic Manufacturers (September 2014), §2.1

proprietary to or by a Party or any of its Affiliates (including all information and materials of a Party's (or its Affiliates') customers and any other Third Party and their consultants), regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic or electronic form. Confidential Information will include the Licensed Manufacturing Know-How.[32]

- Alternative Two: any and all proprietary Know-How, information and data, including scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by or on behalf of one Party to the other Party and/or its Affiliate in connection with this Agreement.[33]

- Alternative Three: information, data or material in writing, that the Disclosing Party has prominently marked or otherwise prominently identified as confidential or proprietary in nature.[34]

- Alternative Four: subject to Section ____, (a) all information provided at any _____ related meeting with respect to any aspect of the Project, regardless of whether or not such information is identified or marked as confidential and regardless of whether or not a written record is subsequently provided if the information was provided orally, and (b) all recorded information, including data marked "Confidential" or bearing a similar legend.[35]

"Control" means possessing of the power to direct or cause the direction of the management and policies of a person whether by membership, ownership, contract or otherwise. "Controlled", "Controls" and other cognate words and expressions shall be construed accordingly.[36]

"Data" means

- Alternative One: any factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation, information in numerical form that can be digitally transmitted or processed.[37]

- Alternative Two: any recorded information used or generated in the performance of a [Project].[38]

[32] https://medicinespatentpool.org/uploads/2015/11/MPP-HCV-License-Agreement-BMS-FINAL-Web-00000002.pdf

[33] https://www.sec.gov/Archives/edgar/data/1426375/000095012315010748/filename10.htm

[34] Aridis and PVS Formulation Development Agreement §7.1

[35] Gates Foundation Data & Materials Sharing Agreement, Annex D

[36] https://www.knowledgetransferireland.com/Model-Agreements/Practical-Guides/KTI-Practical-Guide-to-Collaborative-Research-Agreements.pdf

[37] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

[38] Gates Foundation Data & Materials Sharing Agreement, Annex B

"Data Exclusivity" means that the data generated by the holder may not be referred to or used by another person or company for a specific period of time.[39]

"Developing Nations" means generally, nations with underperforming economies, undervalued currency, unstable democratic governments, lack of infrastructure and low standards of education and healthcare.[40]

"Development" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of applications to regulatory authorities, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a regulatory authority as a condition or in support of obtaining or maintaining a regulatory approval. When used as a verb, "Develop" means to engage in Development.[41]

"Direct Exploitation" means developing results for commercialization, including through clinical trials, or commercializing results themselves.[42]

"Disclosing Party" means the party disclosing Confidential Information to the other Party in connection with the Project.[43]
Also see the definitions of "Receiving Party."

"Dosage Form" means the administration form of the completed pharmaceutical product: e.g., tablet, capsule, suspension, injection. Also called dose form or dosing unit.[44]

"Epidemic" means the occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a particular period. Usually the cases are presumed to have a common cause or to be related to one another in some way.[45]

"Equitable Access" means

- Alternative One: that vaccines, medicines and other products developed, in whole or in part, often with public financial support must be first available to populations when and where they are needed to end an outbreak or manage a disease, regardless of ability to pay, while at a price that is sustainable to the manufacturer.[46]

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[39] https://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf?ua=1

[40] http://ghef.org/us/about-us/glossary/. The same term is also often referred to as "Developing Countries" in other agreements or sources.

[41] https://medicinespatentpool.org/uploads/2017/07/MPP-AbbVie-Agreement-Final1.pdf

[42] IMI 2 Model Grant Agreement §25.3

[43] The Amended and Restated License Agreement between the MPP and Gilead (July 2011), §11

[44] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[45] https://www.cdc.gov/csels/dsepd/ss1978/glossary.html

[46] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7130943/

- Alternative Two: equal access for equal need.[47]

- Alternative Three: that all individuals have access to affordable, high quality, culturally and linguistically appropriate care in a timely manner.[48]

  Also see the definitions of "Access", "Global Access" and "Global Access Objectives."

"Equitable Pricing" means the adaptation of prices which are charged by the manufacturer or seller to countries with different purchasing power.[49]
Also see the definitions of "Affordability" and "Affordable Pricing."

"Essential Background Technology" means Background Technology that is (i) owned, controlled, or developed by the grantee, or in-licensed with the right to sublicense; and (ii) either incorporated into a Funded Development or reasonably required to exercise the license to Funded Developments. Grantee is required to retain sufficient rights in the Funded Developments and Essential Background Technology to grant this license. Grantee must ensure this license survives the assignment or transfer of Funded Developments or Essential Background Technology.[50]
Also see the definitions of "Background", "Background Intellectual Property (IP)", "Background Technology".

"Essential Medicines" means

- Alternative One: medicines intended to be available within the context of functioning health systems at all times, in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford.[51]

- Alternative Two: those medicines that satisfy the priority health care needs of the population.[52]

"Exploit" or **"Exploitation"** means to make, have made, import, use, sell, or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of.[53]

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[47] https://www.scielo.br/scielo.php?pid=S0102-311X2008000500025&script=sci_arttext

[48] http://www.lchc.org/health-equity-resources-data/social-economic-opportunity/equitable-health-care-access/

[49] https://apps.who.int/iris/bitstream/handle/10665/68571/WHO_EDM_2004.4.pdf;jsessionid=498508ED84BA76952588F133E024E50A?sequence=1. On a related note, PATH uses the term "Differential Pricing" instead of "Equitable Pricing" to mean the practice of selling the same product at prices that may be significantly different depending on the development status of the applicable country and/or the market within the country (private vs. public) where the product is sold.

[50] Gates Foundation Humanitarian License FAQs

[51] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[52] https://www.who.int/medicines/mdg/MDG08ChapterEMedsEn.pdf

[53] https://medicinespatentpool.org/uploads/2017/07/MPP-AbbVie-Agreement-Final1.pdf

"Field" means

- Alternative One: with respect to a particular Product, any use that is consistent with the label approved by the FDA or applicable foreign regulatory authority in the country of sale for the therapeutic use of such Product.[54]

- Alternative Two: the treatment or prevention of [HIV] which does not include the treatment or prevention of other viruses, including without limitation [HCV].[55]

- Alternative Three: the treatment of any and all therapeutic indications and uses.[56]

- Alternative Four: [pediatric] treatment or prevention of disease or other therapeutic area.[57]

"Foreground" means the results, including data, know-how and information, whether or not they can be protected, which are generated under the project and excluding Sideground (defined below).[58]
Also see the definitions of "Foreground Intellectual Property", "Program Know-How", "Project Invention", "Project IP", "Project Patents", "Project Results" and "Results."

"Foreground Intellectual Property" means

- Alternative One: any Intellectual Property (including the Project Patents and Project Inventions) arising out of the undertaking and performance of any Work Phase of the Project.[59]

- Alternative Two: Intellectual Property arising out of the performance of the Services under this Agreement (but for the avoidance of doubt excluding Background Intellectual Property).[60]

  Also see the definitions of "Foreground", "Program Know-How", "Project Invention", "Project IP", "Project Patents", "Project Results" and "Results."

"Funded Development" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the Project (including modifications, improvements, and further developments to Background Technology).[61]

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[54] https://medicinespatentpool.org/uploads/2013/12/MPP-Gilead-Sciences-Amended-Licence.pdf

[55] https://medicinespatentpool.org/uploads/2017/07/MPP-AbbVie-License-Agreement-for-Africa-execution-copy.pdf

[56] https://www.sec.gov/Archives/edgar/data/1356576/000104746912002789/a2207731zex-10_12.htm

[57] MPP' License Agreement with AbbVie

[58] IMI 1 Model Grant Agreement §II.26.1

[59] Unattributed Funder Development Partnering Agreement §1.1.35

[60] https://www.sec.gov/Archives/edgar/data/718130/000119312509100298/dex21d.htm

[61] Gates Foundation Global Access Commitment and Humanitarian License Clauses

"Gavi-Eligible Country" means a country whose three-year average Gross National Income (GNI) per capita is equal to or below the Eligibility Threshold. A Gavi-eligible country is either a Low-Income Country or a Phase 1 Country.[62]

"Generic Medicine" means any pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a license from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights.[63]

"GHO" means Global Health Organization.[64]

"Global Access" means

- Alternative One: grantees and partners to commit to making the products and information generated by the foundation funding widely available at an affordable price, in sufficient volume, at a level of quality, and in a time frame that benefits the people.[65]

- Alternative Two: (a) the knowledge and information gained from the Project will be promptly and broadly disseminated; and (b) the Funded Developments will be made available and accessible at an affordable price (i) to people most in need within developing countries, or (ii) in support of the U.S. educational system and public libraries, as applicable to the Project.[66]

  Also see the definitions of "Access", "Equitable Access" and "Global Access Objectives".

"Global Access Objectives" means

- Alternative One: to provide funding to support the development of drugs and vaccines to address diseases that have a disproportionate impact on people within developing countries, and to ensure that such products can be made available and accessible at reasonable cost and with all due speed to people within developing countries.[67]

[62] https://www.gavi.org/sites/default/files/document/gavi-eligibility-and-transition-policypdf.pdf. Gavi's GNI per capita threshold for eligibility was set at an amount of US $1,500 in 2011. The GNI threshold amount for Gavi is updated annually to account for inflation and published on the Gavi website following the annual release of updated GNI p.c. estimates by the World Bank. "***Phase 1 Country***" means a Gavi-eligible country whose GNI per capita is above the Low Income Country threshold and whose average GNI per capita of the previous three years is equal to or below the Eligibility Threshold.

[63] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[64] Alternative Provisions for Publicly Funded Medicines and Vaccines (Unattributed), Access Price

[65] http://globalaccess.gatesfoundation.org/

[66] Gates Foundation Global Access Commitment and Humanitarian License Clauses

[67] https://www.sec.gov/Archives/edgar/data/1426375/000095012315010748/filename9.htm

- Alternative Two: projects will be conducted and managed – along with the resulting products, services, processes, technologies, materials, software, data or other innovations – in a manner that ensures "Global Access." [68]

- Alternative Three: the objectives: (a) to improve the processes and technologies for the development, manufacture and delivery of Products for use in the Field, with the aim of making them more available and more accessible in terms of cost, quantity and quality to people most in need in the Developing Countries; and (b) to ensure that information and data resulting from activities under the Project are promptly and broadly disseminated - without jeopardizing intellectual property protection - to the relevant scientific and educational communities.[69]

Also see the definition of "Access", "Equitable Access" and "Global Access".

"Global Health" means the transnational impacts of globalization upon health determinants and health problems which are beyond the control of individual nations.[70]

"Goals" means general statements expressing a program's aspirations or intended effect on one or more health problems, often stated without time limits.[71]

"Humanitarian License" means a grant of license by a holder of certain intellectual property rights for humanitarian use, usually at a royalty-free basis or at very low costs. As an example, Gates Foundation requires its grantees to grant Gates Foundation a humanitarian license, which is a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform and display Funded Developments and Essential Background Technology.[72]
Also see the definition of "Public Health License".

"Improvements" means

- Alternative One: any and all improvements, enhancements or modifications, patentable or otherwise, relating to the Compound or Licensed Products or Licensed Combination Products including, without limitation, any change or modification in the manufacture, formulation, analytical methodology, ingredients, preparation, presentation or means of delivery, administration or dosage of the Compound or Licensed Products or Licensed Combination Products.[73]

- Alternative Two: all improvements, methods, modifications and other know-how developed by or on behalf of a Licensee and relating to a Product.[74]

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[68] Global Health Vaccine Accelerator Platforms Data Sharing Guiding Principles
[69] Redacted Collaboration Agreement, §1.12
[70] WHO Health Promotion Glossary: New Terms
[71] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)
[72] Gates Foundation Humanitarian License FAQs
[73] https://www.sec.gov/Archives/edgar/data/1356576/000104746912002789/a2207731zex-10_12.htm
[74] The Amended and Restated License Agreement between the MPP and Gilead (July 2011), §2.3

"Incentives" means anything that encourages a party to do something or to work harder.[75]

"Increased Outbreak Preparation Need" means

- Alternative One: when, having considered all reasonably accessible and relevant information including epidemiological data, travel and migration patterns and the likely availability of other products or product candidates, there is a determination that there is a heightened need for a Product.[76]

- Alternative Two: when, having considered all reasonably accessible and relevant information including epidemiological data, travel and migration patterns and the likely availability of other products or product candidates in the Field, Funder determines, in its sole discretion, that there is a heightened need for the Product.[77]

  Also see the definitions of "Outbreak", "Outbreak Notice", "Outbreak Preparation Activities" and "Outbreak Response Activities."

"Information" means any communication or reception of knowledge or intelligence; knowledge obtained from investigation, study, or instruction: intelligence, news, facts, data.[78]

"Insolvent" means (a) having generally ceased to pay debts in the ordinary course of business other than as a result of bona fide dispute, (b) being unable to pay debts as they become due, or (c) being insolvent within the meaning of federal bankruptcy law.[79]

"Intellectual Property (IP)" means

- Alternative One: all intellectual property rights arising from or associated with the following, whether created, protected or arising under the laws of the United Kingdom or any other jurisdiction:

  - trade names, trademarks and service marks (whether registered or unregistered), domain names and other internet addresses or identifiers, trade dress and similar rights and applications to register any of the foregoing (collectively, "Marks");

  - patents and patent applications and rights in respect of utility models or industrial designs (collectively, "Patents");

  - copyrights (whether registered or unregistered) and registrations and applications therefor (collectively, "Copyrights");

  - know-how, inventions, discoveries, methods, processes, techniques, methodologies, formulae, algorithms, technical data, specifications, research and

[75] Global Health Learning Center - Glossary
[76] CEPI CfP3i Program Funding Agreement and Terms and Conditions, §16
[77] Unattributed Funder Development Partnering Agreement
[78] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)
[79] https://code.dccouncil.us/dc/council/code/sections/28:1-201.html

development information, technology, data bases and other proprietary or confidential information, including customer lists, in each case that derives economic value (actual or potential) from not being generally known to other persons who can obtain economic value from its disclosure, but excluding any Copyrights or Patents that cover or protect any of the foregoing (collectively, "Trade Secrets"); and

- any other proprietary, intellectual or industrial property rights of any kind or nature that do not comprise or are not protected by Marks, Patents, Copyrights or Trade Secrets.[80]

- Alternative Two: any or all of the following and all rights in, arising out of, or associated therewith:
  - all United States and foreign patents and utility models and applications therefor and all reissues, divisions, renewals, reexaminations, extensions, provisionals, continuations and continuations-in-part thereof, and equivalent or similar rights anywhere in the world in inventions, disclosures, and discoveries, whether or not patentable, and whether or not reduced to practice ("Patents");
  - all trade secrets, know-how, proprietary information, technical data, improvements, technology, computer programs (in source code and executable code form, and whether embodied in software, firmware or otherwise), documentation (including software documentation), drawings, designs, flow charts, specifications, logic diagrams, programmer notes, protocols, files, records, databases, formulae, compositions, processes, manufacturing and production processes and techniques, research and development information, improvements, proposals, and technical data ("Technical Information");
  - all copyrights, works of authorship, copyright registrations and applications therefor and all other rights corresponding thereto throughout the world ("Copyrights");
  - all industrial designs and any registrations and applications therefor throughout the world;
  - any similar, corresponding or equivalent rights to any of the foregoing anywhere in the world, including but not limited to computer program rights and registrations and applications therefor; and
  - all copies and tangible embodiments of the foregoing (in whatever form or media).[81]

- Alternative Three: all rights in Copyrights, Patents, Mask Works, Trademarks, Technology and any other proprietary rights relating to intangible property anywhere in

[80] https://www.sec.gov/Archives/edgar/data/718130/000119312509100298/dex21d.htm

[81] https://www.sec.gov/Archives/edgar/data/1096325/000119312504107692/dex1053.htm

the world, and all registrations and applications related to any of the foregoing and analogous rights thereto anywhere in the world.[82]

- Alternative Four: means any worldwide intellectual property or other proprietary rights (excluding trademark, service mark, and domain name rights), including but not limited to copyrights, trade dress rights (including audible characteristics), mask work rights registrations, moral rights, patent rights, patent applications and disclosures, know-how, inventions, rights of priority, and trade secret rights.[83]

"Interchangeable Pharmaceutical Products" means products within a therapeutic class, but with different active ingredients are interchangeable if they have equivalent therapeutic effect.[84]

"International Standard" means a biological standard accepted by WHO for use as an International Reference Preparation.[85]

"International Nonproprietary Name (INN)" means a common, generic name selected by designated experts for the unambiguous identification of a new pharmaceutical substance. The selection process is based on a procedure and guiding principles adopted by the World Health Assembly. INNs are recommended for worldwide use.[86]

"Investigational Product" means a Product that has not received a marketing approval.[87]

"Joint Program Know-How" means any Program Know-How (and Program Patent Rights that claim or cover such Program Know-How) that is conceived, discovered or reduced to practice by one or more employees, agents or consultants of [Party A], its Affiliates, or its subcontractors, together with one or more employees, agents or consultants of [Party B], its Affiliates, or its subcontractors.[88]
Also see the definitions of "Joint Program Patent Rights" and "Joint Project IP."

"Joint Program Patent Rights" means any Program Patent Rights that claim or cover such Joint Program Know-How that is conceived, discovered or reduced to practice by one or more employees, agents or consultants of [Party A], its Affiliates, or its subcontractors, together with one or more employees, agents or consultants of [Party B], its Affiliates, or its subcontractors.[89]
Also see the definitions of "Joint Program Know-How" and "Joint Project IP."

"Joint Project IP" means any Project IP which is conceived or reduced to practice, authored or contributed to, during activities carried out jointly by or on behalf of two (2) or more Parties under the Agreement.[90]

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[82] https://www.sec.gov/Archives/edgar/data/68505/000119312504137077/dex10d.htm
[83] https://www.sec.gov/Archives/edgar/data/1088825/000119312504154240/dex101.htm
[84] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[85] https://www.who.int/bloodproducts/ref_materials/en/
[86] Health Action International Glossary
[87] CEPI CfP3i Program Funding Agreement and Terms and Conditions, §14
[88] License and Collaboration Agreement between Merck and Bioprotection Systems Corp., §7.2
[89] License and Collaboration Agreement between Merck and Bioprotection Systems Corp., §7.2
[90] Redacted Collaboration Agreement §8.1(ii)

Also see the definitions of "Joint Program Know-How" and "Joint Program Patent Rights."

"Know-how" means any unpatented, unpublished, technical information (including, without limitation, information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, materials, formulae, formulations, processes, research or experimental results, techniques and specifications, quality control data, analyses, reports and submissions) that is not in the public domain.[91]

"Laws" means the aggregate of statutes, ordinances, regulations, rules, judicial decisions, and accepted legal principles that the courts of a particular jurisdiction apply in deciding controversies brought before them.[92]

"Least Developed Countries" means

- Alternative One: a list of developing countries that, according to the United Nations, exhibit the lowest indicators of socioeconomic development, with the lowest Human Development Index ratings of all countries in the world.[93]

- Alternative Two: the countries listed on the United Nations List of Least Developed Countries. [94]

"Licensee" means one to whom or to which a license is granted.[95]

"Licensed Combination Products" means

- Alternative One: pharmaceutical compositions comprised of the Compound as a therapeutically active ingredient in combination with other active ingredients and which uses or is developed or manufactured using or in connection with the [licensed] Intellectual Property.[96]

- Alternative Two: pharmaceutical combinations and compositions that have been prepared and are in a tablet form containing [compound] ready for administration to Adult Patients solely for [indication] which contain the [compound] as an active ingredient in combination with (a) the [another specified compound] and/or (b) other active ingredients, and in each case where the resulting combination product has been recommended by the World Health Organisation for supply to and use by Adult Patients. [97]

"Licensed Compound" means the compound listed in [Schedule].[98]

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[91] https://dbei.gov.ie/en/Publications/Publication-files/Forf%C3%A1s/Template-Collaboration-Agreements.pdf

[92] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

[93] https://en.wikipedia.org/wiki/Least_developed_countries

[94] https://unctad.org/en/pages/aldc/Least%20Developed%20Countries/UN-list-of-Least-Developed-Countries.aspx

[95] https://www.yourdictionary.com/licensee#websters

[96] https://www.sec.gov/Archives/edgar/data/1356576/000104746912002789/a2207731zex-10_12.htm

[97] https://medicinespatentpool.org/uploads/2014/04/MPP_Huahai_DTG_Adults_23.06.2017.pdf

[98] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf

"Licensed Manufacturing Know-How" means all technical information and know-how known to or Controlled by [Licensor] or its Affiliates as of the Effective Date (including all manufacturing data, the percentages and specifications of ingredients, the manufacturing process, specifications, assays, quality control and testing procedures) that is identified by [Licensor] as primarily and directly relating to, and reasonably necessary for, the making of the Licensed Products in the same manner that such Licensed Products have been made by [Licensor] prior to the Effective Date.[99]

"Licensed Mono Products" means pharmaceutical compositions that are in a tablet form containing [compound] which have been prepared and are ready for administration to Adult Patients solely for [indication] which contain the [compound] as their sole active ingredient.[100]

"Licensed Patent Rights" means:

a) the patents and patent applications of ____ in the Territory related to the Licensed Compound;
b) any continuation, continuation-in-part (but only to the extent that such application includes new data in support of claims previously submitted in a prior originally filed application), divisional, and continued-prosecution applications of any patent applications included in paragraph (a);
c) any patents issuing from any patent applications included in the paragraphs (a) and (b), in each case, including any renewals, extensions, patents of addition, supplementary protection certificates, revivals, re-examinations, and reissues thereof.[101]

"Licensed Products" means

- Alternative One: any human pharmaceutical products produced under license from ____ and/or ____ in the Field and containing the Licensed Compound as one of its active ingredients (or as its sole active ingredient), in finished form or in such other forms, presentations, doses and formulations.[102]

- Alternative Two: pharmaceutical compositions comprised of the Compound as the therapeutically active ingredient and which uses or is developed or manufactured using or in connection with the [licensed] Intellectual Property.[103]

"Licensor" means one who grants a license.[104]

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[99] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf
[100] https://medicinespatentpool.org/uploads/2014/04/MPP_Huahai_DTG_Adults_23.06.2017.pdf
[101] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf
[102] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf
[103] https://www.sec.gov/Archives/edgar/data/1356576/000104746912002789/a2207731zex-10_12.htm
[104] https://www.yourdictionary.com/licensee#websters

"Low and Middle Income Countries" or **"LMICs"** are those countries defined by the Organisation for Economic Co-operation and Development as low and middle income countries based on gross national income (GNI) per capita as published by the World Bank.[105]

"Manufacture" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and holding of the Licensed Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control.[106]

"Manufacturing Consultation" means the process of making employees and consultants available to a party [as part of the technology transfer process] to provide consultation and technical assistance in order to ensure an orderly transition of the manufacturing technology and operations in the start-up of its manufacture of Compound and Product.[107]
Also see the definition of "Technology Transfer."

"Marketing Authorization" means an official document issued by a regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality.[108]
Also see the definitions of "Regulatory Approval" and "Registration."
"Marketing Exclusivity" means a fixed period of time following drug approval during which the sponsor can market their drug without direct competition from manufacturers of duplicate or reformulated products.[109]

"Mark-Up" means a certain percentage added to a purchasing price to cover the cost and profit of the distributor, wholesaler, retailer, medical store etc.[110]
Also see the definitions of "Modest Mark-Up", "Retail Mark-Up" and "Wholesale Mark-Up."

"Materials" means all types of tangible chemical, biological and/or physical materials.[111]

"Medicine" means any dosage form containing a substance approved for the prevention and treatment of disease.[112]

"Mitigation" means refers to measures taken to reduce the harmful effects of a disaster or emergency by attempting to limit the impact on human health and economic infrastructure.[113]

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[105] http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/daclist.htm
[106] https://medicinespatentpool.org/uploads/2017/07/MPP-AbbVie-Agreement-Final1.pdf
[107] https://www.sec.gov/Archives/edgar/data/1117480/000114420413004659/filename22.htm
[108] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[109] https://www.nuventra.com/resources/blog/types-of-marketing-exclusivity/#:~:text=Marketing%20exclusivity%20is%20a%20key,of%20duplicate%20or%20reformulated%20products.
[110] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[111] IMI 2 Joint Undertaking Model Consortium Agreement §9 Material Transfer Obligations
[112] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[113] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

"Modest Mark-Up" means a profit margin comparable to the profit margins commonly agreed to by GHO in its collaborative research and development agreements for the supply of any resulting products to Public Sector Agencies for distribution in the public sector of developing countries.[114]
Also see the definitions of "Mark-Up," "Retail Mark-Up" and "Wholesale Mark-Up."

"Net Sales" means

- Alternative One: with respect to a given calendar quarter, the total amount invoiced by a Sublicensee for sales of the Licensed Products in the countries within the Territory where Licensed Patents Rights are in force, less freight, insurance, packing, shipping and custom duty, VAT, excise tax, sales tax, and packing for shipment, to the extent consistent with generally accepted accounting principles as consistently applied across all products of the Sublicensee and in line with the deductions reasonably expected in the relevant market.[115]

- Alternative Two: the gross consideration invoiced or received by Licensee or any of its Affiliates or Sublicensees for Sales of Licensed Product (including any cash amounts plus the fair market value of any other forms of consideration), less the following deductions (to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged) to the extent reasonable and customary and solely related to the sale of the Licensed Product:
    - trade discounts, including trade, cash and quantity discounts or rebates, credits or refunds;
    - allowances or credits granted upon claims, returns or rejections of products, including recalls, regardless of the party requesting such recall;
    - charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the sale, transportation, delivery or return of such Licensed Product;
    - customs duties, sales, excise and use taxes and any other governmental charges (including value added tax) actually paid in connection with the transportation, distribution, use or sale of such Licensed Product (but excluding what is commonly known as income taxes);
    - rebates and chargebacks or retroactive price reductions made to federal, state or local governments (or their agencies), or any Third Party payor, administrator or contractor, including managed health organizations; and
    - payments required by law to be made under Medicaid, Medicare or other government special medical assistance programs (including, but not limited to, payments made under the new "Medicare Part D Coverage Gap Discount Program" and the "Annual Fee on Branded Pharmaceutical Manufacturers", specific to the Licensed Product for which the deduction is taken).

  Even if there is overlap between any of deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation. Each of the above deductions to Net Sales shall be calculated in accordance with the Accounting

[114] Alternative Provisions for Publicly Funded Medicines and Vaccines (Unattributed), Access Price
[115] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf

Standards (with the applicable Accounting Standard used clearly indicated on any reports).

In the event that the Licensed Product is sold as a Combination Product, Net Sales will be determined by multiplying Net Sales of such Combination Product by the fraction A/(A+B), where A is the invoice price of the Licensed Product, when sold separately, and B is the invoice price of any other therapeutically active ingredient(s) in the combination, when sold separately, in each case in the same country and similar class, purity and dosage as in the Combination Product. If, on a country-by-country basis, the Licensed Product or the other therapeutically active ingredient that is not a Product in the Combination Product is/are not sold separately in such country, Net Sales shall be determined by multiplying actual Net Sales of such Combination Product by the fraction C/(C+D), where C is the fair market value of the Licensed Product portion of such combination and D is the fair market value of the other therapeutically active ingredient that is not a Product (such fair market value is to be determined by mutual agreement of the Parties or, in the absence of such mutual agreement, by a neutral Third Party).[116]

"Objectives" means targets for achievement through interventions.[117]

"Open Access" means the practice of providing online access to scientific information that is free of charge to the end-user and reusable.[118]

"Operations" means the performance of a practical work or of something involving the practical application of principles or processes.[119]

"Originator Brand Premium" means the difference in price between the originator brand and a generic equivalent.[120]

"Originator Product/Originator Brand" means a product that was first authorized worldwide 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.[121]

"Other Territories" means countries that are not the key countries where the Product is intended to be marketed.[122]
Also see the definition of "Targeted Territory."

"Outbreak" or **"Disease Outbreak"** means

- Alternative One: a Public Health Emergency of International Concern declared by WHO or a public health emergency on a national or regional scale declared by one or more

[116] https://www.sec.gov/Archives/edgar/data/0001776985/000119312519241112/d635330dex1019.htm
[117] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)
[118] EDCTP2 Policy on Clinical Trials Registration, Publication and Data Sharing
[119] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)
[120] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[121] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[122] CARB-X Research Subaward Agreement, §6.04

national governments and in each case for a material increase in the number of cases of people infected in the Field including any regional outbreak, an epidemic or a pandemic.[123]

- Alternative Two: the occurrence of disease cases in excess of normal expectancy. The number of cases varies according to the disease-causing agent, and the size and type of previous and existing exposure to the agent.[124]

- Alternative Three: the Occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a specific period. Usually, the cases are presumed to have a common cause or to be related to one another in some way. Sometimes distinguished from an epidemic as more localized, or the term less likely to evoke public panic.[125]

  Also see the definition of "Pandemic", "Outbreak Notice", "Outbreak Preparation Activities" and "Outbreak Response Activities."

"Outbreak Notice" means a notice, in writing in the event of an Outbreak.[126]
Also see the definition of "Increased Outbreak Preparation Need", "Outbreak", "Outbreak Preparation Activities" and "Outbreak Response Activities."

"Outbreak Preparation Activities" include: (i) develop the Product in accordance with the Development Plan and as more particularly detailed in the Work Phase Statements; (ii) provide free of charge or at a discounted rate the services and facilities outlined in Schedule 3 in accordance with the timeframe (if any) set out at Schedule 3, the Application, and in more detail in specific Work Phase Statements; and (iii) use its Reasonable Efforts either to establish directly or to enter into an agreement with Funder, a Public Sector Agency or another third party, for supply of Product into an Investigational Stockpile before the first subject receives the first dose in a Phase II Clinical Trial and perform the related obligations.[127]
Also see the definition of "Increased Outbreak Preparation Need", "Outbreak" and "Outbreak Response Activities."

"Outbreak Response Activities" include: (i) the collection and sharing of trial subject information in accordance with Funder Policies, including information about pathogens such as sequence data; (ii) engagement with affected communities to establish mutual trust; (iii) integration of Partner research efforts into Public Sector Agencies' epidemic response; (iv) manufacture of additional investigational doses of Product (if necessary) or manufacture to replenish Investigational Stockpile; (v) negotiation of clinical trial contracts; (vi) performance of independent ethics reviews; and (vii) implementation of prepared clinical trial designs.[128]
Also see the definition of "Increased Outbreak Preparation Need", "Outbreak" and "Outbreak Preparation Activities."

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[123] Unattributed Funder Development Partnering Agreement
[124] https://www.who.int/environmental_health_emergencies/disease_outbreaks/en/
[125] https://www.cdc.gov/csels/dsepd/ss1978/glossary.html
[126] CEPI CfP3i Program Funding Agreement and Terms and Conditions, §16
[127] Unattributed Funder Development Partnering Agreement, §3.2
[128] Unattributed Funder Development Partnering Agreement

"Pandemic" means an epidemic occurring over a widespread area (multiple countries or continents) and usually affecting a substantial proportion of the population.[129]

Also see the definition of "Outbreak."

"Partnership" means a relationship among individuals and groups that is characterized by mutual cooperation and responsibilities.[130]

"Patent Rights" or **"Patents"** means

- Alternative One: any and all patents and patent applications in the Territory (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, and the like of any such patents and patent applications, and foreign equivalents of the foregoing.[131]

- Alternative Two: a title granted by public authorities that confers a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly.[132]

"Person" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association or other entity or other form of business organization. [133]

"Pharmaceutical Equivalence" means products with identical amounts of the same active ingredient in the same dosage form and route of administration, that meet the standards of strength, quality, purity and identity.[134]

"Pharmaceutical Product" means any product intended for human use, presented in its finished dosage form that is subject to control by pharmaceutical legislation (registered).[135]

"Policy" means the general principles by which a government entity is guided in its management of public affairs.[136]

"Priority Review Voucher" means a voucher issued by FDA to the sponsor of a rare pediatric disease product application at the time of the marketing application approval pursuant to section

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[129] https://www.cdc.gov/csels/dsepd/ss1978/glossary.html

[130] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

[131] https://www.lawinsider.com/dictionary/patent-rights

[132] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[133] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf

[134] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[135] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[136] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

529 of the Federal Drug and Cosmetic Act, which entitles the holder to designate a single human drug application submitted under section 505(b)(1) of the FDCA or section 351 of the Public Health Service Act as qualifying for a priority review.[137]

"Procurement Price" means the price paid by the government, wholesalers, retailers and other purchasers to procure medicines. Different prices may be paid for the same product by a public sector purchaser, such as the Ministry of Health, the medicine outlet that supplies the medicine to the patient, and the individual who purchases the medicine.[138]

"Product Profile" means the recommendations for and limitations upon use of a pharmaceutical product that must be included in product labeling and packaging pursuant to any Regulatory Approval for such product.[139]

"Program Know-How" means any Know-How (including any Compounds) that is first conceived, discovered, made and/or reduced to practice (as would be necessary to establish inventorship under United States patent law (regardless of where the applicable activities occurred)) by or on behalf of either Party or its Affiliate (or their respective employees, agents or consultants) or jointly by both Parties or their respective Affiliates (or their respective employees, agents or consultants) in performing the Transition Program or other activities under this Agreement.[140]
Also see the definitions of "Foreground," "Foreground Intellectual Property", "Project Invention", "Project IP", "Project Patents", "Project Results" and "Results."

"Project Data" means to all data and information, including all clinical study data, produced or arising as a result of the Project.[141]

"Project Invention" means any discovery, development, Know-How, invention or improvement created, devised or arising out of the undertaking and performance of any Work Phase.[142]
Also see the definitions of "Foreground," "Foreground Intellectual Property", "Project IP", "Project Patents", "Project Results" and "Results."

"Project IP" means any discoveries, inventions, know-how, patents, trademarks and other forms of intellectual property that arise under the Project.[143]
Also see the definitions of "Foreground," "Foreground Intellectual Property", "Project Invention", "Program Know-How," "Project Patents", "Project Results" and "Results."

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[137] https://www.lawinsider.com/dictionary/priority-review-voucher. See more about Priority Review Voucher at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rare-pediatric-disease-priority-review-vouchers. Note that priority review voucher may also apply to products intended to treat tropical diseases or to medical countermeasures to terrorism.

[138] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[139] https://www.lawinsider.com/dictionary/product-profile

[140] License and Collaboration Agreement between Merck and Bioprotection Systems Corp, §7.2

[141] CEPI CfPi3 Program Funding Agreement and Terms and Conditions, §11

[142] Unattributed Funder Development Partnering Agreement §1.1.67

[143] CEPI CfP3i Program Funding Agreement Term and Conditions §13.2

"Project Materials" means any biological samples, vaccines (including Product), animal models and other tangible materials produced under the Project.[144]

"Project Patents" means any patent applications made which claim any Project Inventions, any patents resulting from any such applications, utility certificates, improvement patents and models and certificates of addition and all foreign counterparts of them in all countries, including any divisional applications and divisional patents, refiling, renewals, continuations, continuations-in-part, patents of addition, extensions (including patent term extensions), reissues, substitutions, confirmations, registrations, revalidations, pipeline and administrative protections and additions, and any equivalents of the foregoing in any and all countries of or to any of them, as well as any supplementary protection certificates and equivalent protection rights in respect of any of them.[145]
Also see the definitions of "Foreground," "Foreground Intellectual Property", "Project Invention", "Project IP," "Program Know-How", "Project Results" and "Results."

"Project Results" means the outcomes and results of the Project, may comprise biological samples, data, intellectual property, materials, any Product and Investigational Product, publications, reference standards, technology and other results and shall include all Project IP, Project Data and Project Materials.[146]
Also see the definitions of "Foreground," "Foreground Intellectual Property", "Project Invention", "Project IP," "Program Know-How", "Project Patents" and "Results."

"Publication" means any written, oral or other public disclosure of Results, including the public use or sale of an invention based on the Results.[147]

"Public Health License" means a non-exclusive, fully paid-up, sublicensable and worldwide license under the Project Results and Enabling Rights to develop, manufacture, market and/or supply the Product worldwide; in each case for use in preparation for or response to an Outbreak or Increased Outbreak Preparation Need. For the purposes of this definition, the term

"Product" shall mean the [Vaccine] in any form or dosage of pharmaceutical composition or preparation for use in humans.[148]
Also see the definitions of "Humanitarian License", "Increased Outbreak Preparation Need" and "Outbreak."

"Public Sector" includes general government and public corporations. Quasi-corporations owned by government units are grouped with corporations in the nonfinancial or financial corporate sectors, thus part of public corporations (2008 System of National Accounts).[149]

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[144] CEPI CfPi3 Program Funding Agreement and Terms and Conditions, §12

[145] Unattributed Funder Development Partnering Agreement §1.1.68

[146] CEPI CfP3i Program Funding Agreement and Terms and Conditions

[147] https://dbei.gov.ie/en/Publications/Publication-files/Forf%C3%A1s/Template-Collaboration-Agreements.pdf

[148] CEPI CfP3i Program Funding Agreement and Terms and Conditions

[149] https://www.oecd-ilibrary.org/docserver/7574da9d-en.pdf?expires=1606688910&id=id&accname=guest&checksum=C5B51C861999C52DF9DAED3E7190B567 References to "Public Market" or "Public Purchasers" should be construed accordingly.

"Qualitative Data" means

- Alternative One: any data concerning information that is difficult to measure, count, or express in numerical terms.[150]

- Alternative Two: any data concerning information that can be expressed in numerical terms, counted, or compared on a scale.[151]

"Rebate" means a bulk refund that pharmacies may receive from a wholesaler, based on sales of a particular product or total purchases from that wholesaler over a particular period of time. It does not affect the price the patient pays, but the retailer's profits will be higher.[152]

"Receiving Party" means the party receiving Confidential Information from the other Party in connection with the Project.[153]
Also see the definition of "Disclosing Party."

"Registration" means the process of obtaining the necessary regulatory approval to distribute the Product.[154]
Also see the definitions of "Marketing Authorization" and "Regulatory Authority."

"Regulatory Approval" means any technical, medical, scientific or other license, registration, authorization or approval of any Regulatory Authority necessary for the development, manufacture or commercialization of a pharmaceutical product in any regulatory jurisdiction.[155]
Also see the definitions of "Marketing Authorization" and "Registration."

"Regulatory Authority" means any national or supranational governmental authority that has responsibility in the Territory over the Development and/or Commercialization of the Licensed Compound and Licensed Products.[156]

"Regulatory Documentation" means all applications, registrations, licenses, authorizations and approvals (including all Marketing Authorizations), all correspondence submitted to or received from Regulatory Authorities (including [*]) and all supporting documents in connection therewith, and all reports and documentation in connection with clinical studies and tests (including [*]), and [*] in any of the foregoing, including all INDs, BLAs, [*], in each case related to a Compound and/or Product.[157]
Also see the definitions of "Regulatory Approval" and "Regulatory Authority."

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[150] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

[151] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)

[152] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[153] The Amended and Restated License Agreement between the MPP and Gilead (July 2011), §11

[154] Redacted Collaboration Agreement, §2.9.2

[155] https://medicinespatentpool.org/uploads/2019/10/Final-MPP-Pfizer-licence-sutezolid.pdf

[156] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf

[157] Redacted Collaboration Agreement, §2.9.2

"Report" means any written or spoken description of a situation, event, etc.; an official document that gives information about a particular subject.[158]

"Research" means

- Alternative One: any quantitative data, methodology and analysis.[159]
- Alternative Two: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.[160]

"Research Data" means any to information, in particular facts or numbers, collected to be examined and considered as a basis for reasoning, discussion, or calculation.[161]

"Research Use" means the use of results or background needed to use results, for all purposes other than for completing the action or for direct exploitation, and which includes but is not limited to the application of results as a tool for research, including clinical research and trials, and which directly or indirectly contributes to the objectives set out in the Societal Challenge health, demographic change and well-being.[162]

"Results" means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.[163]
Also see the definitions of "Foreground," "Foreground Intellectual Property", "Project Invention", "Project IP," "Program Know-How", "Project Patents" and "Project Results."

"Retail Mark-up" means a percentage added to the purchasing price to cover the retailer's costs and profit.[164]
Also see the definitions of "Mark-Up", "Modest Mark-Up" and "Wholesale Mark-Up."

"Retailer" means company that sells goods to consumers.[165]

"Sideground" means tangible or intangible output generated by a beneficiary under the action, such as data, knowledge and information whatever their form or nature, whether or not they can be protected, but which are outside of the action objectives as defined in this Agreement and which therefore are not needed for implementing the action or for research use of results.[166]

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[158] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)
[159] http://ghef.org/us/about-us/glossary/
[160] Public Health Accreditation Board Acronyms & Glossary of Terms (Version 1.5)
[161] EDCTP2 Policy on Clinical Trials Registration, Publication and Data Sharing
[162] IMI 2 Joint Undertaking Model Consortium Agreement §8.1
[163] IMI 2 Model Grant Agreement §26.1
[164] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[165] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[166] IMI 2 Model Grant Agreement §26.1

"Step-in Rights" means the right of the funder to assume the development and commercialization of the funded products in the event of the actual or anticipated failure by the grantee/developer to develop or commercialize the funded products to ensure access and affordability thereof in the applicable field and territory. Also referred to as "March-in Rights."[167]

"Stewardship" means

- Alternative One: the wide range of functions carried out by governments as they seek to achieve national health policy objectives.[168]

- Alternative Two: the careful and responsible management of the well-being of the population.[169]

"Stewardship and Access Plan" means when the Product enters Phase III trials, the Subrecipient shall create a plan reasonably describing how it intends to meet the stewardship and access obligations for the Product. The Stewardship and Access Plan shall not include confidential business information and shall include:

- Strategy to support access and stewardship (e.g. proposed reliable production with sufficient capacity, supply systems, the broad approach to product labelling, and the broad approach to ensure economic barriers to access are as low as reasonably possible);

- Identifying obstacles and constraints to access and stewardship;

- Exploitation strategy for Project IP Rights, including whether it is planned for the Project IP Rights to be transferred to a third party;

- Strategy to ensure marketing approvals are received for key territories in a timely manner; and

- Strategy for monitoring effectiveness of access and stewardship, including proposed metrics to measure success.[170]

"Supplementary protection certificates (SPCs)" means an intellectual property right that serve as an extension to a patent right. They apply to specific pharmaceutical and plant protection products that have been authorised by regulatory authorities.[171]

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[167] Definition by GHIAA.

[168] https://www.who.int/healthsystems/stewardship/en/#:~:text=Stewardship%2C%20sometimes%20more%20narrowly%20defined,achieve%20national%20health%20policy%20objectives.&text=Stewardship%20is%20a%20political%20process%20that%20involves%20balancing%20competing%20influences%20and%20demands

[169] https://www.who.int/whr/2000/en/whr00_en.pdf?ua=1

[170] CARB-X Research Subaward Agreement, §5.01

[171] https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en

"Target Product Profile (TPP)" outlines the desired "profile" or characteristics of a target product that is aimed at a particular disease or diseases. TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics.[172]

"Targeted Territories" means the key countries where the Product is intended to be marketed.[173]
Also see the definition of "Other Territories."

"Technology Transfer" means promptly and diligently providing all necessary guidance, information, materials and assistance reasonably required by the [Licensee] to accomplish the activities that may be requested by the Agreement.[174]
Also see the definition of "Manufacturing Consultation."

"Territory" means

- Alternative One: the countries set forth in [Schedule].[175]

- Alternative Two: the countries listed in [Schedule] and such other or different countries as the Parties may agree in writing.[176]

"Tiered Pricing" means providing products/services at different price points by limiting or expanding the features/functionalities corresponding to each tier price.[177]

"Third Party" means any person or entity who or which are neither a Party nor an Affiliate of a Party.[178]

"Trade-Related Aspects of Intellectual Property Rights (TRIPS)" means an agreement annexed to the World Trade organization convention aimed at strengthening and harmonizing aspects of the protection of intellectual property at the global level. It includes trademarks and patents as well as other forms of intellectual property.[179]

"Trial Steering Committee" or **"TSC"** means a group of independent experts who are not involved in the clinical study that will approve the clinical study protocol and monitor the progress of the clinical trial, including any changes to the protocol.[180]

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[172] https://www.who.int/research-observatory/analyses/tpp/en/#:~:text=A%20target%20product%20profile%20(TPP,a%20particular%20disease%20or%20diseases

[173] CARB-X Research Subaward Agreement

[174] Gilead HCV License Agreement with Indian Generic Manufacturers (September 2014), §5.5

[175] The Amended and Restated License Agreement between the MPP and Gilead (July 2011), § 2

[176] https://medicinespatentpool.org/uploads/2017/07/MPP-License-and-technology-transfer-agreement-Signed22.pdf

[177] https://www.chargebee.com/resources/glossaries/tiered-pricing-model-strategy/

[178] https://www.sec.gov/Archives/edgar/data/1356576/000104746912002789/a2207731zex-10_12.htm

[179] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1

[180] CEPI CfP3i Program Funding Agreement and Terms and Conditions

"Trusted Collaborator/Partner" means a third party, that is capable of performing the work and would be prepared to undertake activities in the event that Awardee declines [Funder's] request to do so, or if Awardee and [Funder] do not reach agreement on a new Work Package.[181]

"U.S. Government Bayh-Dole Rights" means the U.S. Government march-in rights [codified in USC 35 §§ 200 et seq. and implemented by][182] 37 CFR Sect. 401.6 and 401.14 (j).[183]

"WHO" means the World Health Organization.

"WHO Prequalification" means a systematic process to determine the capacity of a manufacturer to produce a product of consistent quality in accordance with international standards and WHO/UNFPA specifications. The purpose of prequalification is to protect the buyer and the end user by ensuring good quality products are procured and distributed.[184]

"Wholesale Mark-Up" means a percentage added to the purchasing price to cover the wholesaler's costs and profit.[185]
Also see the definitions of "Mark-Up," "Modest Mark-Up," and "Retail Mark-Up."

"Wholesaler" means a company that buys goods from a manufacturer or importer and sells it to retailers.[186]

[181] CEPI CfP3i Program Funding Agreement and Terms and Conditions
[182] Editor's note.
[183] CARB-X Research Subaward Agreement, §6.04
[184] https://www.who.int/rhem/en/.
[185] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1
[186] https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf?ua=1