GLOSSARY OF TERMS RELATED TO BIOSIMILAR POLICIES

Working definitions of Biosimilar terms for the study on "Capacity building to support the uptake of biosimilars in a multistakeholder approach"

Version: 4 June 2025

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In July 2024, the AUGMENT Consortium was commissioned by the European Health and Digital Executive Agency (HaDEA) to conduct the project "Capacity building to support the uptake of biosimilars in a multistakeholder approach". The aim of the project is to **support national authorities in implementing policies and practices** that improve biosimilar competition, as a means to contribute to the **accessibility, affordability and availability of medicines** for patients in the EU. The AUGMENT Biosimilars project includes a research study in the first year and capacity building activities in the second and third years.

In order to **create and establish a common understanding** of terms related to biosimilars and policies for all stakeholdersinvolved in project activities, definitions of terms used in the project context is necessary.

Terms are listed **alphabetically** in the glossary.

Definitions were developed for the purpose of this study based on **previous terminology work**. The glossary also includes existing definitions of relevant terms from the online PPRI glossary of pharmaceutical terms of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.

Please note that **definitions may be subject to change during the project**. We appreciate any comments and suggestions for change, deletion or addition. Please contact: biosimilars@goeg.at

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GLOSSARY OF TERMS RELATED TO BIOSIMILAR POLICIES

Term	Definition
Active ingredient *Synonyms*: active substance, compound, active pharmaceutical ingredient (API)	Ingredient that alone or in combination with one or more other ingredients is considered to fulfil the intended activity of a medicine.
Anti-trust policy *Synonym*: antitrust	Rules that prohibit agreements between market operators that would restrict competition, and the abuse of dominance, and their enforcement.
Biological *Synonyms*: biological medicine, biopharmaceutical	A medicine that contains one or more active biological substances. A biological substance is produced by or extracted from a biological source and needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control. The following shall be considered as biological medicines • immunological medicines and medicines derived from human blood and human plasma • products developed by means of one of the following biotechnological processes: recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, hybridoma and monoclonal antibody methods • advanced therapy medicines.
Biosimilar *Synonym*: biosimilar medicine	A biological medicine that is developed to be similar to an existing biological medicine (the "reference medicine"). Biosimilar medicines can only be marketed following the patent expiry of the reference medicine. Biosimilars are not the same as generics, which have simpler chemical structures and are considered to be identical to their reference medicines. The active substance of a biosimilar and its reference medicine is essentially the same biological substance, though there may be minor differences due to their complex nature and production methods. Like the reference medicine, the biosimilar has a degree of natural variability.
Biosimilar literacy	The degree to which individuals (health professionals or patients) can obtain, comprehend, communicate, calculate and process patient-specific information about biosimilar medicines, to make informed medication and health decisions in order to safely and effectively prescribe, dispense or use biosimilars.
Biosimilar price link	Practice of setting the price of a biosimilar medicine, in relation to the price of the reference product (originator biological), usually at a defined percentage rate lower than the reference product price.
Biosimilar substitution *Synonym*: automatic substitution	Practice of dispensing a biosimilar medicine instead of the prescribed equivalent and interchangeable biosimilar or biological originator medicine at the pharmacy level without consulting the prescriber. In some countries also referred to as automatic (biosimilar substitution).

Co-payment *See also*: out-of pocket payments, prescription fee, percentage co-payment, deductible	Patient's contribution towards the expense of a medicine or health service covered by a third party payer (e.g., a public payer). Common types of co-payments include a percentage of the total expense of the medicine or service (percentage co-payment), a fixed amount (prescription fee) and a deductible.
Data exclusivity	A period from the initial authorisation of a medicine during which the marketing au-thorisation holder benefits from the exclusive rights to the results of preclinical tests and clinical trials on the medicine. After this period, the marketing authorisation hold-er is obliged to release this information to companies wishing to develop generic ver-sions of the medicine. In the European Union, there is data exclusivity of eight years (as of 2025).
Deductible *See also*: out-of pocket payments	One variant of a patient co-payment for a medicine included in public funding (reimbursement). An initial expense must be paid out-of-pocket up to a defined threshold or over a defined period of time by the patient; then all or a share of the remainder of the expense is covered by a third party payer (e.g., a public payer).
Delinkage	A pricing and reimbursement model which decouples the price (and thus profitability) of a medicine from its sales volume (e.g., applied for antibiotics).
Demand-side measure	Policies that are directed at stakeholders who prescribe (doctors), dispense (pharmacies) or ask for medicines (patients).
Educational and awareness-raising activities	Action by governments and their institutions, health care providers and further stakeholders to inform patients, health care professionals and others about biosimilar medicines, including clinical evidence on these medicines and regulatory and policy provisions and guidance as well as to build capacity regarding use of biosimilars.
External price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
Evergreening	Actions by pharmaceutical companies to artificially extent the period of patent protection and exclusivity.
Gain-sharing *Synonym*: benefit-sharing	Models which offer (portions of) savings (e.g., resulting from biosimilar use) to health care institutions (e.g., hospitals), health professionals (e.g., doctors) or patients, typically earmarked for further investments in health care.
Generic	A medicine which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicine, and whose bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies. Generics can be classified in branded generics (generics with a specific trade name) and unbranded generics (which use the international non-proprietary name and the name of the company).

Health technology assessment (HTA)	A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.
Herfindahl Hirschman Index (HHI)	A commonly used measure of market concentration to inform about the level of competition in a market.
Horizon scanning	The systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to affect health, health services and/or society. For the purpose of this study, horizon scanning systems are considered which inform in advance about the loss of exclusivity of originator biologicals and thus support public payers and procurers to be well prepared to harness the benefits of biosimilars from day zero.
Hospital pharmaceutical formulary *Synonym*: hospital formulary	One variant of a reimbursement list which is applied in the inpatient sector and includes medicines that may be prescribed and administrated by physicians in a hospital.
INN prescribing *Synonym*: international non-proprietary name prescribing	Requirements for prescribers (e.g. physicians) to prescribe a medicine by its INN, i.e. the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory/obligatory INN prescribing).
Inpatient sector Synonym: hospital sector	Health care setting where patients are formally admitted ("hospitalised") to an institution for treatment and/or care and stays for a minimum of one night in the hospital or other institution providing inpatient care.
Loss of exclusivity See also: patent, Supplementary Protection Certificate (SPC), data exclusivity, market exclusivity.	The point in time when a medicine loses its exclusive marketing rights, potentially due to expiry of its patents and further intellectual properties as well as exclusivity periods for marketing after marketing authorisation.
Managed-entry agreement (MEA)	An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financial-based and performance-based MEA. The latter links price (reward for manufacturers) to health outcomes.
Market exclusivity	The 10-year period after the marketing authorisation of an orphan medicine when similar medicines for the same indication cannot be placed on the market.
Outpatient sector Synonyms: ambulatory sector, community sector, community pharmacy sector, in the community	Health care setting where patients are not admitted to hospitals.
Out-of-pocket payment	The expenses of a person for medical care or medicines that are not covered by reimbursement of a third party payer – often for a defined period (e.g., a year). It includes: • Expenses for non-reimbursable medicines • Any form of co-payment, e.g. prescription fee, percentage co-payment, deductible

Positive list *Synonym*: formulary	One variant of a reimbursement list which includes medicines may be prescribed at the expense of a third party payer (public payer).
Percentage co-payment	One variant of a co-payment requiring the patient to cost-share in the form of a set proportion of the price of medicine.
Prescription fee *Synonym*: prescription charge	One variant of a patient co-payment for a medicine in the form of a fixed amount for each prescription item dispensed on the expense of a third party payer (e.g., a public payer).
Prescription guidelines	Instructions to physicians and further prescribers to ensure responsible prescribing of medicines (i.e., to ensure that the right medicine in the right dose is given to the right patient at the right time). For the purpose of this study, they relate to recommendations and instructions with regard to the prescription of biological medicines, including biosimilar medicines.
Prescribing quota *Synonym*: prescription quota	Requirement to physicians and further prescribers to achieve defined thresholds in prescribing, typically determined shares of generic and biosimilar prescribing for defined active substances or other ATC groups.
Pricing *Synonym*: pricing policy, price control, price regulation	Action by a government authority to set the price of a medicine and/or indirectly influence it (e.g., through pricing policies) for different price types (e.g., ex-factory price, pharmacy retail price) and to monitor and review and eventually adapt it.
Procurement	Procurement is the process to purchase goods and services (e.g., medicines) that involves several steps and several stakeholders based on national, or supranational, regulation, policies, structures and procedures. Different procurement procedures and different techniques can be applied.
Reference price system	A reimbursement policy in which identical medicines (ATC 5 level) or similar medicines (ATC 4 level or other groups) are clustered (reference group). The public payer funds a maximum amount (the reference price), while the patient must pay the difference between the reference price and the pharmacy retail price of the medicine, in addition to any co-payments (such as prescription fees or percentage co-payment rates).
Reference product *Synonym*: reference medicine	A medicine which has been granted a marketing authorisation by a country or by the European Commission on the basis of submitted quality, pre-clinical and clinical data, to which the application for marketing authorisation for a generic or a biosimilar product refers.
Reimbursement *Synonym*: funding	Coverage of the cost of reimbursable medicines by a public payer (such as social health insurance / National Health Service).
Reimbursement list	A list that contains medicines with regard to their reimbursement status. They may either include medicines eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list). Reimbursement lists may target either the out-patient sector (usually positive lists or negative lists) or

	the in-patient sector (typically called hospital pharmaceutical formulary), or both.
Reimbursement rate	The percentage share of the price of a medicine or medical service that is reimbursed/subsidized by a public payer. The difference between the reimbursed amount and the full price of the medicine or medicinal service is paid by the patient.
Reimbursement policy	Action by a government authority to decide whether the cost of a medicine is funded by a public payer (such as social health insurance or National Health Service), and if yes, to which extent and under which conditions.
Supplementary Patent Certificate (SPC)	An intellectual property right that serves as an extension to a patent right.
Subscription model *Synonyms*: subscription fee-based model, subscription-based procurement model	Implementing delinkage of price from volume, through granting a predefined fixed award to suppliers in return for the supply of medicines.
Switching	Action by a prescriber to change medication (e.g., from an originator biological to a biosimilar medicine or from one biosimilar to another biosimilar medicine).
Tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.
Tendering-like policies	Pricing and procurement policies which include competitive components (e.g., tenders for medicines of the same active ingredient and selection of one or a few for inclusion in reimbursement).