Glossary on Supply Chain Resilience and Reserves

With Legislative Cross-References: Critical Medicines Act · GPL Regulation

July 2026

Purpose

This glossary sets out agreed working definitions for terms relating to various types of reserves and supply-chain resilience, initially developed by the HCI Patient Access & Continuity of Supply (PACS) Working Group. Its purpose is to establish a harmonised common language across the healthcare value chain- spanning manufacturers, distributors, healthcare providers, regulators, and patient advocates — in the absence of a fully consolidated EU legislative framework for these concepts.

Each definition is accompanied by cross-references to the Critical Medicines Act (CMA, Council text ST-15503/25, March 2026), the GPL Regulation (ST-6366/26, March 2026), and the GPL Directive (ST-6367/26, March 2026) where relevant provisions exist. Where no formal legislative definition is available, this is explicitly noted. Such gaps represent areas where HCI's outputs may directly inform secondary legislation or Commission guidance under the CMA.

Sources

- Critical Medicines Act — provisional political agreement text (based on Council text ST-15503/25); provisional agreement reached 12 May 2026; pending formal adoption and publication in the Official Journal. Article references may change following legal-linguistic revision. Recital and paragraph numbering in this glossary follows the Council text and may be renumbered in the final Official Journal version. Referred to as CMA
- GPL Regulation — General Pharmaceutical Legislation Regulation, compromise text published 6 March 2026 (ST-6366/26), endorsed by Coreper 6 March 2026; pending formal adoption and publication in the Official Journal. Article references may change in the final text. Referred to as GPL
- GPL Directive — Council text (ST-6367/26, March 2026), referred to as GPLD
- HCI - Glossary on Supply Chain Resilience and Reserves (February 2026), this document

Terms are listed alphabetically. The HCI definition is the primary text. Legislative references appear in the annotation box beneath each entry.

Terms included in this glossary

Contingency stock

Contingency stock means the quantity of critical medicinal products that the marketing authorisation holder or other economic operators hold or are required to hold under national law, in the interests of improving continuity of supply in the event of unforeseeable supply disruptions or shortages, including those resulting from fluctuations in patient demand or supply.

Contingency stocks are primarily operational risk-management tools and remain under private ownership and responsibility, even where holding obligations exist.

Two distinct sub-categories of contingency stock can be distinguished in practice, reflecting different legal bases, scope, and purposes:

(a) **Operational buffer stocks** are stock-holding obligations typically imposed on wholesalers and distributors under public service obligation (PSO) frameworks established by Member States. They are generally universal in scope (applying across all authorised products), of shorter duration (commonly around two-four weeks), and form part of the regular operational obligations of the distribution chain. They have been in place in many Member States for many years and are embedded in normal commercial operations.

(b) **Resilience-oriented contingency stocks** are additional stock-holding obligations, typically imposed on marketing authorisation holders or other supply chain operators - separately from and in addition to PSO obligations - in response to supply chain resilience concerns. They are generally product-specific or list-based (for example, limited to critical medicines or products subject to rebate contracts), of longer duration (typically two to four months), and represent newer regulatory requirements. They are the primary form of obligation addressed by CMA Art. 3(18b) and Art. 20.

Both sub-categories fall within the scope of HCI's definition and CMA Art. 3(18b). The distinction is operational and contextual, not legislative: neither the CMA nor the GPL draws this sub-division explicitly. It is nonetheless important for supply chain actors and policymakers to recognise that 'contingency stock' encompasses these materially different instruments.

Core elements

- May be voluntary or legally required
- Privately owned and managed
- Improves, but does not guarantee, continuity of supply
- Not a public strategic reserve; distinct from public stockpiling
- Encompasses two distinct sub-categories: PSO (public service obligations) -based operational buffer stocks (typically short-duration, universal in scope, long-established in national law) and resilience-oriented requirements imposed separately on MAHs or other operators (typically longer-duration, product-specific, more recent)

Legislative cross-references

CMA Art. 3(18b): Defines 'contingency stocks requirement' as an obligation imposed by a Member State on MAHs and other supply chain operators to hold stocks of certain medicinal products. The definition also encompasses both PSO (public service obligations) -based operational buffer stocks (imposed on wholesalers as part of longstanding national distribution obligations) and the newer resilience-oriented contingency stock requirements addressed by CMA Art. 3(18b). Neither the CMA nor the GPL draws this distinction explicitly. HCI may wish to consider whether to advocate for recognition of this sub-division in Commission guidelines on contingency stock requirements under CMA Art. 20, which should address the relationship between PSO obligations and separately imposed resilience requirements to avoid double-counting and disproportionate burden on supply chain operators. to safeguard security of supply, imposed by law, regulation, or administrative provisions including stockholding obligations in public procurement procedures. *(See separate entry for Contingency stocks requirement.)*

CMA Recital 31: Distinguishes contingency stocks — privately held under operator obligation — from 'publicly owned national, regional or local stockpiling'. Notes that contingency stocks can negatively impact the internal market and must respect proportionality, transparency, and solidarity.

GPL: No formal definition in Art. 3. Referenced operationally in Recital 139a as an example of uncoordinated national measures and in implementing act provisions (Art. 130 area) as a tool the Commission may require. *(Gap: no legislative definition in GPL.)*

Alignment note: The HCI definition extends beyond the CMA by explicitly covering voluntary holding, not only legally-required holding. This is intentional and should be preserved.

Contingency stocks requirement

Contingency stocks requirement means an obligation imposed by a Member State, in accordance with the principle of proportionality and the principle of subsidiarity, on marketing authorisation holders and other economic operators in the healthcare supply chain to hold defined stock levels.

Such obligations shall:

- Require the holding of stocks to safeguard the security of supply to healthcare providers and patients;
- Be imposed through law, regulation, or administrative provisions, including stockholding obligations linked to public procurement procedures;
- Be clearly defined, proportionate, risk-based, and not create unnecessary barriers to the free movement of goods within the Union.

Core elements

- Regulatory obligation, not ownership transfer
- Must be proportionate and product-specific
- Not a public strategic reserve; distinct from public stockpiling

Legislative cross-references

CMA Art. 3(18b): Formal definition: 'an obligation imposed by a Member State on marketing authorisation holders and other economic operators in the supply chain of medicinal products to healthcare providers and patients to hold stocks of certain medicinal products to safeguard the security of supply and which obligation is imposed by law, regulations or administrative provisions, including stockholding obligations in public procurement procedures.'

CMA Art. 20: Safeguards article — Member States imposing contingency stocks requirements must aim to avoid negative impact on other Member States' security of supply (para. 1); ensure requirements are proportionate and respect transparency and solidarity (para. 2); and inform the CMCG of their intention to impose or significantly change requirements (para. 3a — provisional paragraph numbering, subject to renumbering in the final OJ text).

CMA Recital 22: Guidelines context — Member States should give due consideration to forthcoming Commission guidelines on compliance with internal market and free movement obligations when designing contingency stock requirements.

GPL: No formal definition. Referenced in Recital 139a as a national measure that has led to restrictions in the internal market. Commission empowered to impose contingency stock requirements via implementing acts in response to critical shortages (Art. 130 area). *(Gap: no legislative definition in GPL.)*

Alignment note: Substantive alignment between the HCI definition and CMA Art. 3(18b). The HCI version adds 'risk-based' and 'not create unnecessary barriers' — both consistent with CMA Recital 31 and Art. 20 but not stated in Art. 3(18b) itself.

National stockpile

National stockpile means the reserves of a defined quantity of critical medicinal products established, financed, and held under national law by a Member State for public health purposes, including as part of its strategic reserves.

These reserves may include medicinal products in different forms across the supply chain, such as finished medicinal products, active pharmaceutical ingredients, or other essential raw materials required for the manufacture of medicinal products.

National stockpiles are publicly owned, publicly financed, and governed by public authorities, and are intended to support preparedness and response to serious supply disruptions or health emergencies.

Deployment of a national stockpile is a sovereign decision of the Member State. Where the trigger relates to a shortage affecting healthcare system capacity, the applicable threshold is defined in GPL Regulation Art. 3(13) (critical shortage in the Member State). Where Union-level coordination is engaged, Art. 3(14) (critical shortage of Union concern) is the relevant threshold. See also: Shortage; Emergency reserve; Redistribution of a National Stockpile.

Core elements

- Public ownership and financing
- Public governance and activation
- Distinct from contingency stock

Legislative cross-references

CMA: No formal definition in Art. 3. Recital 31 uses the phrase 'publicly owned national, regional or local stockpiling' to distinguish public stockpiles from privately held contingency stocks, but does not constitute a legal definition. *(Gap: no legislative definition.)*

GPL: No definition or direct reference. *(Gap: not addressed.)*

Alignment note: Neither the CMA nor the GPL defines 'national stockpile' as a legal term. The HCI definition fills this gap. The public ownership and governance criteria are consistent with CMA Recital 31 and should be advanced in the context of CMA secondary legislation and Commission guidelines under Art. 20. The reference to stockpiles being 'financed' by Member States is intentionally broad: it covers both directly State-funded models and hybrid arrangements in which a private operator holds and manages the stockpile under contract, provided State control and ultimate financial responsibility are preserved.

Note: *Neither the CMA nor the GPL defines 'national stockpile' as a legal term. The HCI definition is the only operational definition currently available in a structured EU-level document.*

Strategic reserve

A strategic reserve is a subset of a national stockpile of essential products that forms part of a Member State's long-term preparedness and security strategy for major public health emergencies. The state assumes full ownership and full financial responsibility. Strategic reserves are typically centralised at country level, subject to defined rotation and quality-management rules, and activated under exceptional circumstances in alignment with national disaster or crisis preparedness plans. They are intended to guarantee availability under exceptional circumstances.

Activation of a strategic reserve is reserved for the most severe circumstances, typically a critical shortage of Union concern within the meaning of GPL Regulation Art. 3(14), or a major cross-border health emergency. At EU level, the rescEU medical stockpile (Decision No 1313/2013/EU, as amended) operates as the functional analogue. See also: Shortage; National stockpile; Emergency reserve.

Core elements

- Long-term preparedness tool
- Exceptional use only
- Fully public responsibility
- Distinct from contingency stock

Legislative cross-references

CMA: No formal definition. The term 'strategic reserves' is referenced in recitals only, without definition. *(Gap: no legislative definition.)*

GPL: No reference. *(Gap: not addressed.)*

Related framework — rescEU: The EU rescEU mechanism (under Decision No 1313/2013/EU, as amended by Regulation (EU) 2021/836 and Decision (EU) 2023/2671) maintains a European-level medical stockpile, which is the closest existing legal analogue to a 'strategic reserve' at EU level. This is not referenced in either the CMA or GPL.

Alignment note: Neither the CMA nor the GPL defines 'strategic reserve'. The HCI definition fills this gap and introduces a hierarchical relationship - strategic reserve as a subset of national stockpile — that has no current legislative basis. This is intentional HCI framing but should be flagged as proposed architecture pending CMA secondary legislation. The working group may wish to advocate for a formal definition in Commission guidance, and should proactively engage in the development of CMA implementation guidelines and the forthcoming EU Stockpiling and MCM Strategies, which — while non-legislative - present an early opportunity to establish agreed working definitions. The reference to 'full financial responsibility' of the Member State is intentionally broad and accommodates hybrid models where operational custody is contracted out.

Note: *Neither legislative text defines 'strategic reserve'. The HCI definition is the primary working definition available. Consider cross-referencing the rescEU stockpile framework as the nearest legislative analogue.*

Member State Redistribution of a National Stockpile

Redistribution means the transfer of critical medicinal products or medical devices from a national stockpile of one or several Member States to other Member States following a decision of the Commission in response to significant supply disruptions or shortages affecting one or more Member States.

Redistribution applies exclusively to publicly controlled stockpiles and does not extend to privately owned contingency stocks unless explicitly agreed.

Core elements

- Solidarity mechanism
- Public stock only
- Commission-coordinated

Legislative cross-references

CMA: No formal definition. The concept of redistribution is implicit in the solidarity framework but not defined. *(Gap: no legislative definition.)*

GPL Recital: References 'redistribution of available stocks in the event of shortage' in the context of the GPL's scope and objectives (recital area, line 83 of ST-6366/26), but no operative definition. *(Gap: no formal definition.)*

CMA Art. 20 / MSSG Solidarity Mechanism: Closest operative framework: the voluntary Solidarity Mechanism launched by the MSSG in 2023, referenced in CMA Art. 20 para. 3a (provisional paragraph numbering). CMA requires Member States not to prevent participation in this mechanism when imposing contingency stock requirements.

Alignment note: The HCI definition is more precise than anything in either legislative text, particularly the limitation to publicly held stockpiles. This precision is an asset — it avoids conflation with the separate (and voluntary) industry-based reallocation mechanisms. Recommend this definition be submitted as a proposed definition for the CMA secondary legislation process.

Resilience of supply chains

Resilience of supply chains means the ability of the healthcare supply chain to maintain a patient-need-oriented supply of medicinal products, medical devices, active substances, active pharmaceutical ingredient starting materials, and key inputs within the Union, including during disruptions or unforeseen external shocks.

Supply-chain resilience is achieved through a combination of diversified sourcing (as far as possible), manufacturing capacity, transparency, risk-management practices, proportionate stockholding, and effective public-private coordination.

Resilience of supply chains is a specific application of the broader concept of health system resilience. Health system resilience encompasses the capacity of health systems to prepare for, absorb, adapt to, and recover from shocks - including workforce capacity, infrastructure, financing, and governance, as well as product availability. The HCI definition deliberately narrows this to the supply chain dimension: the ability to ensure continuous patient access to medicinal products and key inputs regardless of the origin or nature of the disruption. It does not address clinical, workforce, or health financing resilience, which fall outside the scope of this glossary.

Core elements

- Broader than stockpiling alone
- Structural, operational, and governance dimensions
- Central concept in CMA and ESG discussions
- Specific sub-concept of health system resilience - scoped to product availability in the supply chain; distinct from workforce, infrastructure, and health financing resilience

Legislative cross-references

CMA Art. 3(6): Defines 'vulnerability in the supply chains' as risks and weaknesses within supply chains of critical medicinal products, identified at aggregated level, that compromise continuous supply to patients. Related but narrower — specific to the MSSG vulnerability assessment methodology. *(Partial alignment — narrower scope.)*

CMA overall: Supply-chain resilience is the overarching objective of the regulation but is not formally defined. The CMA addresses it through vulnerability evaluation (Art. 3(6)–(7)), strategic projects, manufacturing investment, and procurement frameworks.

Regulation (EU) 2022/123 (EMA crisis regulation): This regulation — which expanded EMA's role in shortage monitoring, the Executive Steering Group on Shortages (ESGS), and crisis preparedness — is directly relevant as an existing operative framework for supply chain resilience. It predates the GPL and will be superseded or amended.

GPL: Resilience is referenced in Recital 5 as a systemic objective at the level of the Union pharmaceuticals framework — specifically the need to "strengthen its resilience" (referring to the resilience of the regulatory framework itself, not the supply chain specifically) in response to lessons from the COVID-19 pandemic — but is not formally defined. The recital links resilience to improved availability of medicinal products and ensuring the framework "serves the people under all circumstances." No legislative definition of supply chain resilience appears in the operative provisions. *(Gap: no legislative definition, resilience only used at the framework level in recitals.)*

Related framework -Health system resilience: The WHO and ECDC define health system resilience as the capacity of health actors, institutions, and populations to prepare for and effectively respond to crises, maintain core functions when under stress, and adapt and transform following shocks. This broader concept encompasses workforce, infrastructure, governance, financing, and supply dimensions. The HCI definition of resilience of supply chains is deliberately scoped to the supply chain and product availability dimension only and should be read as a specific application of - not a substitute for - the wider health system resilience framework. Neither the CMA nor the GPL references health system resilience as a defined concept.

Alignment note: The HCI definition is broader and more operational than the CMA's 'vulnerability in the supply chains' definition. The two are complementary. The HCI definition usefully elevates resilience above shortage-response to include structural and governance dimensions — consistent with the CMA's architecture but not explicitly stated. The GPL does not define or operationalise resilience of supply chains. The single reference in GPL Regulation Recital 5 is framing language only and is not developed in the operative provisions. The HCI definition therefore fills a legislative gap: it should be read as aligned with the CMA's overarching objective and as anticipating policy development expected to materialise in non-legislative instruments (MCM and Stockpiling Strategies, and DG ECHO civil protection files)

Security of supply

Security of supply is defined as the continuous and timely availability of medicines to patients, supported by flexible manufacturing, distribution, and regulatory systems.

It encompasses both the uninterrupted flow of products through the supply chain and their accessibility to patients at the point of need, under both normal conditions and during periods of stress or disruption.

Core elements:

- Outcome-oriented concept: security of supply describes the state of continuous patient access to medicinal products, as distinct from the structural capacities that enable it
- Encompasses availability, accessibility, and continuity: product must be present in the supply chain, reachable by patients, and reliably maintained over time
- Operationalised in EU law through shortage notification obligations, supply continuity requirements on MAHs and wholesale distributors and strategic stockholding provisions
- Longer legislative history than resilience: present in Directive 2001/83/EC and carried forward in the GPL texts; “resilience of supply chains” is primarily CMA framing
- Frequently used interchangeably with “resilience of supply chains” in EU policy documents and legislative recitals; this glossary treats them as conceptually distinct (see below)

Relationship to resilience of supply chains

Security of supply is the *outcome objective*; resilience of supply chains is the *systemic capacity* designed to deliver and protect it. Resilience addresses the structural, operational, and governance architecture - sourcing, manufacturing, risk management, and public-private coordination — that makes continuous availability achievable and sustainable over time.

The relationship is one of means and end, not equivalence. A supply chain may be temporarily secure without being resilient - for example, through large stockholding that masks a fragile single-source dependency. Conversely, a resilient system may still experience temporary insecurity during a severe or novel shock. Neither concept subsumes the other.

EU legislative texts and Commission communications frequently use the two terms interchangeably. This glossary treats them as conceptually distinct and users should apply that distinction when interpreting legislative provisions. See also: *Resilience of supply chains*.

Legislative cross-references

CMA: Used extensively as the governing purpose of the regulation but not defined in Art. 3. The phrase 'security of supply' appears throughout the operative articles and recitals without a formal definition. *(Gap: no legislative definition despite central use. Note: the CMA operationalises security of supply through vulnerability evaluation (Art. 3(6)–(7)), strategic projects, manufacturing investment, and procurement frameworks - giving effect to the concept without defining it.)*

GPL: Similarly used as an overarching objective in Art. 130 and throughout recitals, but not defined in Art. 3. *(Gap: no legislative definition Note: shortage notification obligations on MAHs and wholesalers, and supply continuity requirements in the GPL operative provisions, function as partial operationalisations of security of supply without the regulation defining the parent concept.)*

GPL Art. 3(14a)–(14b) — GPL Art. 3(14a)–(14b) — related terms: 'Demand' means the request for a medicinal product by HCPs or patients in response to clinical need, satisfactorily met when acquired in appropriate time and sufficient quantity for continuity of best care. 'Supply' means the total volume of stock placed on the market by a MAH or manufacturer. *(Gap: these are component definitions that together frame security of supply implicitly as the alignment of supply volume with clinical demand, but the GPL does not synthesise them into a composite definition of 'security of supply.)* Directive 2001/83/EC, repealed and replaced by the GPL: 'Security of supply' appeared in the context of wholesale distribution obligations and was the earliest EU pharmaceutical instrument to treat it as a standing obligation on distributors. The GPL carries forward the substance of those obligations but does not give 'security of supply' a formal definition. *(Gap: established practice existed under 2001/83/EC but was never codified, and the GPL does not remedy this.)*

Alignment note: The HCI definition fills a significant gap. Given the centrality of 'security of supply' in both instruments, the absence of a formal definition is a notable weakness in the legislative framework. Consider whether to recommend a formal definition for CMA secondary legislation or Commission guidance. The HCI definition — continuous and timely availability — is appropriately patient-centric and consistent with the GPL's demand definition.

Note: *'Security of supply' is undefined in both the CMA and GPL despite being each instrument's primary objective. The HCI definition is currently the most precise operational definition available in an EU-level stakeholder document.*

Shortage

Shortage means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State.

A shortage may be temporary or prolonged and may affect a single Member State or multiple Member States simultaneously. Shortages may arise from supply-side disruptions (manufacturing failure, raw material constraints, logistics breakdown), demand-side surges, or a combination of both. They may be notified by the marketing authorisation holder or detected by national competent authorities or the EMA through the European Shortages Monitoring Platform (ESMP).

The GPL framework establishes three legislative tiers of shortage, each carrying distinct legal consequences and engaging different response mechanisms:

Base shortage means any situation in which supply does not meet demand for an authorised, market-placed product in a given Member State, regardless of severity or cause. This is the foundational tier, defined in GPLD Art. 3, and underpins all contingency stock requirements, security of supply obligations, and reporting duties across the medicines value chain.

Critical shortage in the Member State means a shortage with significant impact on the healthcare system of a Member State that cannot be resolved by that Member State alone. This tier triggers national-level response measures, notification obligations to the CMCG and EMA, and is the primary activation threshold for national stockpiles and emergency reserves operating at Member State level.

Critical shortage of Union concern means a shortage that, due to its severity or cross-border scope, requires coordinated Union-level action. This tier engages the Commission's power to adopt implementing measures, activates EMA coordination, and is the relevant threshold for redistribution of national stockpiles and deployment of EU-level instruments including the rescEU medical stockpile.

The three tiers represent a sequential escalation. A shortage may begin at base level and escalate if it produces significant healthcare system impact, or further escalate to Union concern if it spreads across Member States or cannot be contained nationally. The applicable tier determines which authorities are competent to act and which instruments are available for deployment.

Core elements

- Supply does not meet demand in a given Member State for an authorised, market-placed product
- May be supply-side or demand-side in origin; may be temporary or prolonged
- Distinct from non-availability of a product not authorised or not placed on the market in that Member State
- Three legislative tiers apply — base shortage (GPLD Art. 3), critical shortage in the Member State (GPL Reg. Art. 3(13)), and critical shortage of Union concern (GPL Reg. Art. 3(14)) — with the applicable tier determining the level of response and the authorities competent to act
- Foundational concept underpinning contingency stock requirements, national stockpiles, security of supply obligations, and the tiered shortage response framework

Legislative cross-references

GPLD Art. 3 (GPL Directive, ST-6367/26): Formal legislative definition of the base shortage: 'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State. This definition sits in the Directive (which governs national-level obligations) and is the primary operative

definition under the new pharmaceutical legislative framework. All higher-tier shortage thresholds (GPL Reg. Art. 3(13) and Art. 3(14)) build on this base definition.

GPL Regulation Art. 3(13)–(14) — tiered shortage thresholds: These tiered thresholds build on the base shortage definition in the GPLD and establish the escalating regulatory responses under the GPL framework.

Art. 3(13) — Critical shortage in the Member State: a shortage with significant impact on the healthcare system of a Member State that cannot be resolved by that Member State alone. This threshold triggers national-level response measures and the obligation to notify the CMCG and EMA. It is the primary activation threshold for national stockpiles and emergency reserves operating at Member State level.

Art. 3(14) — Critical shortage of Union concern: a shortage that, due to its severity or cross-border scope, requires coordinated Union-level action. This threshold engages the Commission's power to adopt implementing measures (Art. 130 area of the GPL Reg.), activates EMA coordination, and is the relevant threshold for redistribution of national stockpiles and deployment of EU-level instruments including the rescEU medical stockpile.

These escalating tiers are the operative thresholds for the deployment cross-references in the National stockpile, Strategic reserve, and Emergency reserve entries of this glossary.

CMA: The term 'shortage' is used throughout the CMA (including in Art. 3(18b) on contingency stocks requirements) but not independently defined. The CMA presupposes the GPLD definition and addresses shortage at the level of supply chain vulnerabilities, security of supply obligations, and critical medicines.

Alignment note: The HCI definition mirrors the GPLD Art. 3 legislative text, which provides the formal legal anchor. The contextual elaboration added by HCXI (causes, notification mechanisms, ESMP reference) usefully extends the bare legislative text for working purposes. The tiered shortage definitions in GPL Regulation Art. 3(13)–(14) are defined and expanded above and cross-referenced in the National stockpile, Strategic reserve, and Emergency reserve entries, where they function as activation thresholds.

Dynamic stock allocation (integrated stock management)

Dynamic stock allocation refers to coordinated models in which national stockpiles, contingency stocks, and other reserves are managed in a connected and data-driven manner, operated on a first-expired-first-out (FEFO) basis, to improve responsiveness, reduce duplication and waste, and support equitable access across the Union. Dynamic stock allocation is a key operational mechanism through which both security of supply and resilience of supply chains are given practical effect: it translates structural reserve capacity into responsive, patient-oriented availability, bridging the gap between stockholding as a static safeguard and supply continuity as a dynamic outcome. See also: Rotational stockpiling.

Legislative cross-references

CMA: No definition or direct reference. The concept is implied by the CMA's transparency and solidarity framework, and by the role of the CMCG in coordinating Member State approaches. *(Gap: no legislative reference.)*

GPL: No definition or reference. *(Gap: not addressed.)*

Alignment note: This is a HCI-developed operational concept with no current legislative equivalent. It represents an approach that goes beyond existing CMA and GPL frameworks, which address stockholding obligations but do not address how reserves should be managed dynamically across Member States. The concept anticipates coordination mechanisms likely to be needed as CMA implementation progresses and as the CMCG develops its role in supporting Member State solidarity on supply continuity.

Remunerated stockpiling

Remunerated stockpiling is a hybrid model in which governments compensate suppliers, fully or partially, for holding specific stocks, usually limited to a defined list of strategic medicines. Ownership typically remains private, but the public benefit is acknowledged through compensation. So far, this model is rarely implemented in practice.

A procurement-based variant exists in which a private operator holds and manages stocks under a public contract, bearing capital costs as part of a service price, while governance and deployment authority remain with the State. See also: National stockpiling.

Legislative cross-references

CMA: No reference to remunerated stockpiling as a concept. *(Gap.)*

GPL: No reference. *(Gap.)*

Related — CMA Art. 20 / procurement: The CMA's collaborative procurement framework (Arts. 15–16) and Member State procurement tools could in principle be used to structure remunerated holding obligations, but no explicit provision exists for compensation of private holders.

Alignment note: This is a HCI-introduced descriptive term for an existing national practice model. It has no legislative basis. If the CMA secondary legislation or Commission guidelines address compensation frameworks for contingency stock obligations, this definition may require revision.

European Voluntary Solidarity Mechanism

A coordinated system for voluntary, needs-based reallocation of stocks across borders, supported by real-time data. It is positioned as an alternative to national stockpiling rather than a form of stockpiling itself.

Legislative cross-references

CMA Art. 20(3a) [provisional paragraph numbering]: Directly referenced: Member States shall not prevent participation in the voluntary Solidarity Mechanism launched by the MSSG in 2023 when imposing contingency stock requirements. This is the operative legal anchor for the mechanism. *(Referenced but not formally defined.)*

CMA Recital 31: Confirms that contingency stock requirements 'should not prevent Member States from assisting other Member States requesting support under the voluntary Solidarity Mechanism launched by the [MSSG] in 2023.'

GPL: No explicit definition or reference. *(Gap.)*

Alignment note: The CMA provides a legal anchor (Art. 20(3a) — provisional paragraph numbering) but no definition. The HCI definition is descriptively accurate and consistent with the CMA's intent. The EMVS reference is appropriate given the data infrastructure role.

Rotational stockpiling

Stockholding model in which designated preparedness inventories are systematically rotated into normal commercial supply channels before expiry, in line with the First-Expired-First-Out (FEFO) principle. Rotational stockpiling minimises waste, preserves product quality, and ensures preparedness stocks remain market-ready without creating static, non-usable reserves. See also: Dynamic stock allocation.

Legislative cross-references

CMA: No definition. CMA Art. 20 requires contingency stock requirements to be 'proportionate', which is consistent with rotational models but does not mandate or define them. *(Gap.)*

GPL: No reference. *(Gap.)*

Alignment note: Rotational stockpiling is a HCI-advocated operational approach with no current legislative equivalent. This definition supports the HCI position that dynamic, FEFO-based rotation

should be the legislative default for contingency stockholding obligations, replacing static stockpiling mandates.

Emergency reserve

Publicly or jointly governed stock held specifically for short-term crisis response, designed for rapid release under predefined trigger conditions and subject to mandatory replenishment after activation. Emergency reserves address 'grey-zone' events that exceed normal market flexibility but fall short of full-scale emergencies requiring activation of national strategic reserves. Despite the name, an emergency reserve is not limited to major public health emergencies - it covers any serious supply disruption that meets the predefined trigger conditions. Emergency reserves may exist within a national stockpile or strategic reserve, or as a jointly governed reserve with public-private elements.

This reserve is activated when a critical shortage threshold is met, as defined in GPL Regulation Art. 3(13)–(14). The applicable threshold determines the level of response and the authorities competent to act. See also: Shortage; Critical shortage (GPL Reg. Art. 3(13)–(14)).

Legislative cross-references

CMA: No formal definition. The CMA's crisis response framework is addressed through HERA tools and CMCG coordination, but 'emergency reserve' is not defined. *(Gap.)*

GPL Art. 3(13): 'Critical shortage in the Member State' (shortage with significant healthcare system impact that cannot be resolved) may be the trigger condition implied by this definition — though the GPL does not connect this threshold to an 'emergency reserve' as defined here. *(Related trigger concept.)*

GPL Art. 3(14): 'Critical shortage of Union concern' (requiring coordinated Union-level action) represents the upper threshold at which EU-level emergency reserves would be relevant.

rescEU: The rescEU medical stockpile (Decision No 1313/2013/EU, as amended by Regulation (EU) 2021/836 and Decision (EU) 2023/2671) is the closest existing EU-level legal analogue — maintained for health emergencies and managed by the Commission. Not referenced in either CMA or GPL.

Alignment note: Neither the CMA nor the GPL defines 'emergency reserve' as a distinct category. The HCI definition fills this gap by capturing the 'grey-zone' between normal market disruption and full-scale emergency activation. The GPL shortage thresholds in Art. 3(13)–(14) provide the closest legislative anchor for the trigger conditions described.

Operational buffer stock

Inventory held at wholesaler, distributor, hospital, or care-provider level to ensure continuity of day-to-day operations and patient care. Operational buffer stocks support routine service reliability and short-term demand variability but are not designed to address systemic shortages or public emergencies.

At wholesaler and distributor level, buffer stock obligations have long been embedded in national Public Service Obligation (PSO) frameworks - typically across all authorised products - and are distinct in character from the more recently introduced resilience-oriented contingency stock requirements imposed on MAHs for critical medicines. See also: Contingency stock

Legislative cross-references

CMA: Not defined. The CMA's scope for stockholding obligations (Art. 20) covers the supply chain to healthcare providers and patients, which includes this level, but operational buffer stocks as a category are not distinguished. *(Gap.)*

GPL: Not defined as such. The operative legislative basis for buffer stock obligations at wholesaler and distributor level is the public service obligation framework carried forward into the GPL Directive (PD, ST-6367/26) from Art. 81 of Directive 2001/83/EC. Under the compromise text, the general supply obligation is

split: MAHs must ensure appropriate and continuous supply to distributors and other authorised actors; distributors are responsible for onward supply (PD Arts. 56 and 167; provisional numbering, subject to confirmation in the final OJ text). Note: the GDP Guidelines (Commission Guideline 2013/C 343/01) govern *good distribution practice* — safe storage, temperature control, handling. *(Gap: no standalone definition of operational buffer stock; PSO/supply continuity framework in PD Arts. 56 and 167 is the operative basis.)*

Alignment note: HCI introduced this operational distinction — important for the tiered stockpiling framework — with no current legislative equivalent as a defined category. PD Arts. 56/167 is the closest legislative anchor. The definition correctly excludes this category from the public emergency reserve framework, which is a necessary clarification for the overall architecture. Any future CMA secondary legislation or Commission guidelines should preserve this distinction to ensure that existing PSO-based wholesaler obligations and new resilience-oriented contingency stock requirements remain separately defined, separately counted, and separately enforced. Recommend HCI advocates for a formal definition in that context.

Tiered stockpiling (EU / national / regional / local)

A structured preparedness framework distinguishing stockholding responsibilities and objectives across governance levels:

- EU-level strategic reserves: centrally coordinated stocks intended for major cross-border crises and solidarity-based deployment.
- National emergency or contingency stocks: country-level reserves addressing national risk profiles and medium-scale disruptions.
- Regional, institutional, or local buffers: operational stocks held by healthcare providers and supply chain actors to ensure continuity of care.

Legislative cross-references

CMA: No formal tiered framework. CMA Recital 31 implicitly acknowledges national, regional, and local tiers in the phrase 'publicly owned national, regional or local stockpiling', but does not construct an operational architecture. *(Partial — architectural precedent only.)*

GPL: No reference to a tiered framework. *(Gap.)*

rescEU (EU tier): The rescEU medical stockpile represents an existing EU-level tier, managed by the Commission under Decision No 1313/2013/EU, as amended by Regulation (EU) 2021/836 and Decision (EU) 2023/2671. This is the practical analogue for the EU-level tier described here.

Alignment note: This is the most conceptually ambitious definition in the glossary — it proposes an architectural framework rather than defining a single term. It has no current legislative basis as a unified model. It is consistent with the direction signalled in CMA Recital 31 and with the EU Stockpiling Strategy direction, but HCI should be explicit that this represents a proposed framework rather than a description of existing law. This definition is the centrepiece of the Module 1 and Module 2 deliverables.

Note: *The tiered stockpiling framework is an analytical and policy model proposed by HCI's PACS working group. It does not currently reflect EU legislation. Its adoption, in whole or in part, as the architecture for CMA secondary legislation is a primary objective of the HCI PACS 2026–2028 work programme.*