Guidance on the application of State aid rules in the context of the Critical Medicines Act

Disclaimer: this is a working document prepared by the services of the European Commission to contribute to a better understanding of how EU State aid rules apply to public support for critical medicines. This is intended purely as an information tool. It does not create any enforceable rights or obligations for third parties. This guidance is without prejudice to the position that the Commission might take in a specific State aid case or to the interpretation that the Court of Justice of the European Union may give. As this guidance reflects the state of the art at the time of its drafting[1], it should be regarded as a 'living tool' and the guidance may be updated to reflect potential new market and/or legal developments. The Commission invites stakeholders to share their practical experience with using this guidance.

In any case, the services of the Directorate-General for Competition (DG COMP) are available to provide further guidance on Member States' request.

I. Objective of the guidance paper

1. The European Union has been facing an increasing number of medicine shortages, posing a significant risk to public health and patient care across Member States. Shortages pose a particular concern for critical medicines[2], where limited or no alternatives exist, and where insufficient supply could result in serious harm or risk of harm to patients.

2. Recent global events such as the COVID-19 pandemic and Russia's military aggression against Ukraine have further exposed vulnerabilities in pharmaceutical supply chains. Shortages of critical medicines threaten public health, disrupt healthcare systems and can reduce trust in healthcare across EU Member States.

3. The root causes of shortages are multifactorial, with challenges identified along the entire pharmaceutical value chain. Shortages of medicines can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components.

4. A supply chain vulnerability may exist for example when there is a dependency on a supplier that is the only source of a particular raw material, intermediate or active

[1] The guidance is based on the text of Critical Medicines Act (CMA) proposal and the Proposal for a Regulation COM(2023) 193 final, as they stand at the moment when this guidance is published.

[2] According to the proposed Critical Medicines Act (CMA), and the Proposal for a Regulation COM(2023) 193 final, a critical medicinal product is a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients.

pharmaceutical ingredient (API) for the EU or when there is dependency on several suppliers located in only one geographical location.

5. In 2023, the European Commission, the European Medicines Agency (EMA) and Member States' Heads of Medicines Agencies published the first Union List of Critical Medicines[3]. This list was updated in December 2024[4] and includes over 270 active substances. It covers treatments for various illnesses such as infections, heart disease, mental health conditions and cancer.

6. Critical medicines are often medicinal products that have been on markets for a long time, many of them are generics: more than 65% of the sales volumes of critical medicines within the EU are generic products. Even though they are no longer covered by intellectual property rights or regulatory data protection, there may be certain cases where only one or two manufacturers supply the EU market or where the manufacturers rely on the same suppliers of active ingredients.

7. Suppliers often operate in a highly competitive environment, where price, environmental requirements and the possibility to achieve economies of scale are particularly relevant. In that context, companies have moved production or outsourced the supply of key ingredients outside the EU. As a result, the EU has become increasingly dependent on a limited number of suppliers or manufacturers for many critical medicines, with many being located outside the EU, especially in Asia. This heavy reliance on a handful of suppliers and production sites has made the supply chains for critical medicines particularly vulnerable to increases in demand, market withdrawals by suppliers, manufacturing and quality problems, or disruptions of supply from specific regions or countries.

8. According to Article 81 of Directive 2001/83/EC on the Community code relating to medicinal products for human use, the marketing authorisation holders and distributors have the obligation, within the limits of their responsibilities, to ensure "appropriate and continued supplies" of medicines to pharmacies and authorised persons to cover patients' needs in the concerned Member States.

9. The Commission proposed measures under the EU Pharmaceutical Reform to prevent and mitigate shortages and enhance security of supply of critical medicinal products. This includes measures to reinforce the above-mentioned supply obligation, requiring pharma companies to identify risk in their supply chains and put suitable measures in place to prevent shortages of the medicines they are supplying to patients in the EU.

10. The Commission proposal for a Critical Medicines Act[5] (CMA) adopted on 11 March 2025 provides a framework for strengthening the availability and security of supply of critical medicines, which complements the structural measures to improve the availability of

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3 First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU | European Medicines Agency (EMA)

4 Union list of critical medicines | European Medicines Agency (EMA)

5 Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795

medicines proposed in the EU Pharmaceutical Reform.[6] This CMA proposal is now subject to the legislative process in the EU Council and the European Parliament.

11. The CMA proposal includes measures to:

    a. Facilitate investments in manufacturing capacity for critical medicines, their active substances and other key inputs in the EU;

    b. Lower the risk of supply disruptions and strengthen availability by incentivizing supply chain diversification and resilience in the public procurement procedures of critical medicines and other medicines of common interest;

    c. Leverage the aggregated demand of participating Member States through collaborative procurement procedures, and

    d. Support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.

12. The CMA introduces the concept of Strategic Projects:

Strategic Projects

A project located in the EU and related to creating or increasing manufacturing capacity shall be considered as a strategic project if it meets at least one of the following criteria:

(a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances;

(b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency;

(c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances;

(d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.

13. The CMA proposal further includes in Article 15(1), "*Without prejudice to Articles 107 and 108 TFEU, Member States may prioritise financial support to strategic projects that address a vulnerability in the supply chains of critical medicinal products identified*

[6] On 26 April 2023, The Commission adopted a proposal for a new Directive and a new Regulation to revise and replace the existing general pharmaceutical legislation (Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC and Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006). The reform notably proposes measures to monitor and manage shortages and enhance security of supply (e.g. identification of critical medicines, analysis of supply chain vulnerability).

following a vulnerability evaluation and with due consideration to the strategic orientations of the Critical Medicines Group referred to in Article 26(2) point (a)."

14. Against this background, the purpose of this guidance is to provide explanations and illustrations on how Strategic Projects as defined in the CMA proposal, can receive financial support from Member States whilst complying with State aid rules. This guidance may also apply to other projects pursuing similar objectives of security of supply for instance before the CMA is adopted.

15. Section II of the guidance will first address the role of vulnerability evaluations in the identification of market failures which can justify public intervention in the form of State aid.

16. Section III will describe State funding measures that do not constitute State aid within the meaning of Article 107(1) TFEU and, therefore, do not need to be notified to the Commission. It also provides guidance on possible European services of general economic interest ('SGEI') for enhancing the security of supply for the critical medicines.

17. Section IV will describe the measures that constitute State aid but may be exempted from notification to the Commission if they fulfil certain requirements.

18. Section V will describe the measures that constitute State aid and need to be notified to the Commission.

19. Section VI provides practical indications as well different practical examples that illustrate the possible application of SGEI rules in critical medicines.

II. Market failures

20. The Union List of Critical Medicines has been compiled with the expertise of the Heads of Member State medicines agencies, the European Commission, and the EMA in consultation with key stakeholders, including patient organisations and industry associations. Published for the first time in December 2023 and updated one year later, the list contains 276 active substances used in medicines for human use that are deemed critical, based on two key criteria:

    a. The medicine's therapeutic indication targeting a serious condition;

    b. The limited availability of appropriate alternatives.

21. Among these critical medicines, some may present risks and weaknesses within their supply chain, that compromise the continuous supply of such medicinal products to patients in the Union, in particular in situations of crisis (e.g. COVID), potentially warranting public intervention and funding.

22. Determining whether a particular critical medicine requires public intervention via State aid specifically aimed at addressing supply chain vulnerabilities involves an objective and evidence-based analysis of such vulnerabilities. This assessment should consider the unique circumstances surrounding each critical medicine taking into account the EU, regional and national contexts.

23. Such an assessment should (1) identify the market failure behind the dependencies and vulnerabilities of the critical medicine with a forward-looking approach, (2) define clear and objective targets for the critical medicine that appropriately address the market failure, and (3) identify the public intervention or mix of public interventions that can efficiently address the identified market failure and deliver the targeted level of security of supply for the critical medicine. This assessment must recognise that full security of supply is generally unfeasible or inefficiently costly, and that trade-offs emerge between the benefits and costs of intervening to improve the security of supply.

24. The Commission conducted, as a pilot project, a technical assessment of supply chain vulnerabilities for critical medicines at EU level.[7] The analysis focused on a selection of 11 critical medicines from the Union list. The pilot highlighted among others the significant dependencies on non-EU active substance suppliers for 4 of the 11 molecules analysed and identified risks stemming from market concentration. That pilot assessment provides valuable insights into conducting such vulnerability evaluations. It utilized a set of key vulnerability indicators—including EU industrial presence, market concentration, supply diversification, demand predictability, observed shortages, and economic viability—alongside data from marketing authorisation holders (MAHs), Member States, and the EMA. However, certain methodological shortcomings were noted by the Commission. An updated methodology is under development, by the EMA together with the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), to better identify vulnerabilities in supply chains of critical medicines at the EU level. The updated methodology should be available at the time of the adoption of the EU Pharmaceutical Reform. Vulnerabilities identified by EMA at the EU level can be related to market failures that can justify State aid measures.

25. The establishment of a robust vulnerability evaluation methodology will be particularly useful in substantiating the need for public intervention to increase security of supply of certain critical medicines, in particular through State aid support. Identifying vulnerabilities, which are not correctly addressed by market forces alone, is crucial for demonstrating the existence and extent of market failures, which in turn guides the design of targeted interventions to address them. Member States will also have to define the desirable security of supply targets and identify the most appropriate measures to reach these targets, ideally in a coordinated fashion.

26. While an assessment of supply chain vulnerabilities is necessary to demonstrate a security of supply related market failure, Member States may also consider other market failures, which do not require an assessment of supply chain vulnerabilities, to grant State aid that will finance Strategic Projects benefitting critical medicines. For example, aid granted to support the economic development of an assisted EU area may support critical medicine even absent specific supply chain vulnerabilities subject to applicable State aid rules (see sections IV and V below).

[7] Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines: Technical report - European Commission.

III. No aid measures

27. Certain funding measures that do not constitute State aid, as explained below, can be granted by Member States for the implementation of strategic projects, as defined by the CMA, without notification to the Commission.

28. Article 107(1) TFEU defines State aid as '*any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods* […]*, in so far as it affects trade between Member States*'. Article 107(1) TFEU requires that four cumulative conditions be met. First, the intervention must be made by the State or through State resources. Second, the intervention must be capable of affecting trade between Member States. Third, it must confer a selective advantage on the beneficiary. Fourth, it must distort or threaten to distort competition[8].

29. The following sub-sections present instances in which the application of State aid rules or the existence of State aid may be excluded in the funding of Strategic Projects as defined by the CMA proposal. Given the cumulative nature of the criteria of Article 107(1) TFEU, if one of the above criteria is not met, the presence of State aid can be excluded and therefore there is no need to notify the measure to the Commission for approval prior to its implementation. To the extent that any of the measures envisaged by the CMA proposal constitute State aid, such measures may still be found compatible notably on the basis of the State aid instruments described in Section IV and Section V.

A. No State resources

30. Resources stemming from the EU budget are considered as State resources only **if national authorities have discretion as to the use of these resources** (in particular as regards the selection of beneficiaries). By contrast, if the resources are attributed directly by the EU with no discretion on the part of the national authorities, they do not constitute State resources.

31. The proposal for the CMA Regulation notably refers in its Article 16 to possible funding under the EU4Health Programme[9], Horizon Europe[10], and the Digital Europe Programme[11] which are centrally managed and thus measures funded under these programmes fall

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8 This section is without prejudice to the interpretation by the Court of Justice of the European Union (CJEU) of the provisions on State aid in the Treaty on the Functioning of the European Union (TFEU), and it does not alter the Commission's understanding of how the notion of State aid under the TFEU should be interpreted, as laid out in the Commission's Notice on the notion of State aid (NoA).

9 Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of Health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, (OJ L 107, 26.3.2021)

10 Regulation (EU) 2021/695 of the European Parliament and of the council of 28 April 2021 establishing Horizon //Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, OJ L170, 12.5.2021, p. 1.

11 Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240, OJ L166, 11.5.2021, p. 1.

outside the scope of State aid control.

32. The proposal for the CMA also refers in its Article 28 to financial support based on the Strategic Technologies for Europe Platform (STEP). This typically involves funding from funds in shared management such as the European Regional Development Fund or the Cohesion Fund, or top-up funding from Member States. Financing of public interventions from such sources would normally involve State resources and may therefore involve State aid which may be found compatible using the instruments described in sections IV and V. See also the relevant guidance from the Commission on STEP.

B. No advantage: European SGEIs and Altmark

1. European SGEIs

33. Services of General Economic Interest (SGEIs) are commercial services of general economic interest subject to public service obligations (PSO) imposed on one or more providers, that would not be supplied by the market without public intervention or would be supplied under different conditions in terms of objective quality, safety, affordability, equal treatment, or universal access. Member States enjoy a wide margin of discretion in defining an SGEI, subject only to a 'manifest error' test by the Commission. An SGEI must be genuine, meaning aiming to remedy a real market failure.

34. The starting point of designing an SGEI for a critical medicine is to identify a market failure (i.e. a risk of shortages not addressed by market forces alone) affecting that critical medicine. This may the case for example if a certain API is only produced in one single production facility located outside the EU, resulting in a risk of shortages for all EU Member States. It can be noted that, while market failures may also exist at the level of one or several Member States, any vulnerability evaluation should consider the broader EU and global market context to determine the genuine risk of shortages in the relevant area. In fact, given the integration of the EU single market for medicines, market failures of security of supply are most likely to be identified at EU level, and EU-wide coordinated measure and EU-wide coordinated measures may often be the most appropriate.

35. When a security of supply related market failure is identified at EU level or at the level of one or several Member States for a specific critical medicine via a thorough vulnerability assessment, all Member States concerned may choose to entrust specific PSOs to operators to enhance the security of supply for the related critical medicines such as for example:

    1. **Reserving Manufacturing Capacity for the critical medicine for a certain period of time:** The designated operator could be required to invest in manufacturing capacity within the territories of these Member States or another reliable location to ensure readiness for ramping up production of the critical medicine in pre-defined circumstances.

    2. **Producing a Specified Quantity of the critical medicine for a certain period of time:** The designated operator could be obliged to produce a specified quantity of the critical medicine within the territories of these Member States or another reliable location ensuring availability to meet demand in pre-defined circumstances.

3. **Stockpiling a Certain Volume of the critical medicine for a certain period of time:** The designated operator could be required to maintain a stockpile of the critical medicine within the territories of these Member States or another reliable location, ready to fulfil demand in pre-defined circumstances.

36. Fulfilling the obligations above may require the launching of a Strategic Project, as defined by the CMA proposal (or other projects pursuing similar objectives of security of supply for instance before the CMA is adopted), e.g. to create or increase manufacturing capacity for a critical medicine presenting vulnerabilities in its supply chain, which may benefit from financial compensation from Member States under SGEI rules. It is important to note that while SGEI rules allow for the financing of such Strategic Projects, they also allow the compensation of operating deficit (if any) involved in the production of the relevant critical medicines after the Strategic Project is implemented.

37. Moreover, while it is possible to establish national SGEIs to address the national security of supply needs related to an EU market failure affecting all Member States for a given critical medicine (or for a market failure affecting at least that Member State), addressing security of supply needs beyond the national level through SGEIs calls for cooperation among Member States through joint or coordinated entrustments[12], since Member States can only unilaterally entrust SGEIs for delivery in their own territory.

38. For instance, two or more Member States might decide to collaborate to entrust an operator the task of reserving capacity commensurate to the needs for security of supply of a critical medicine in their territories. In such cases, the operator must be entrusted by the two (or more) Member States[13] and its obligations should be clearly defined. Such obligations cannot in any case include any restrictions to trade within the EU single market.

39. As an example, an operator, located in Member State MS1 could be tasked with reserving a given capacity for the production of a certain critical medicine for two Member States MS1, MS2. MS1 and MS2 could either jointly entrust the operator (e.g. through a public service contract signed by the operator and the two Member States) or have two different entrustments (one per Member State) for the same critical medicine. SGEI rules do not impose any particular constraint on these public service contracts as long as they describe sufficiently precisely the public service obligations and avoid overcompensation. In particular, in case of a joint contract, MS1 and MS2 might decide to share the amount of compensation to be paid in proportion to their respective needs, but they remain totally free to share the amount of compensation as they wish. All Member States could decide for example that one Member State will finance a SGEI for the whole EU.

40. It is crucial to emphasise that a Member State cannot entrust an operator to provide an SGEI in another Member State without coordination, since only the Member State concerned has the legal authority to entrust an operator to deliver a SGEI in its territory. However as explained above, several Member States can coordinate to address market failures which affect all of them. In a comprehensive approach, all 27 Member States may collaborate to designate one or more operators to secure the production of a critical

12 The Critical Medicines Coordination Group (CMG) introduced by the CMA may oversee such coordination.

13 As explained below this entrustment can take many legal forms.

medicines for the entire EU, if a market failure exists at EU level. Such SGEI could possibly be coordinated at EU level (e.g. through the CMG).

2. No advantage under Altmark

41. In case of SGEIs, the starting point to determine if the measure at stake grants an advantage is the Altmark judgment.[14] This judgment sets out four cumulative criteria which, if met, mean that the compensation does not constitute an advantage to the service provider, and, therefore, that the measure does not amount to State aid. The following sub-sections provide guidance[15] on how the four Altmark criteria can be fulfilled in the area of critical medicines. It is up to the Member State(s) concerned to self-assess whether the planned measure would comply with the Altmark criteria, and, thus, not constitute aid. In such cases, no formal notification to the Commission (under State aid rules) would be required.

1st Altmark criterion: the recipient undertaking must actually have public service obligations to discharge and those obligations must be clearly defined

42. Member States need to clearly define the obligations imposed on operators (e.g. the operator could be requested to reserve a **determined** level of capacity for a **determined** period of time to be activated under **pre-defined** conditions to deliver a **given** critical medicine). The first Altmark condition is only fulfilled if the service constitutes (a) a clearly defined public service obligation which has been (b) entrusted to the service provider.

43. The provision of an SGEI must, by definition, serve a general or public interest. In this respect, securing the supply of a critical medicine which involves a significant risk of shortages may certainly be considered to serve the public interest. Furthermore, the Member State must indicate the reasons why it considers that the service in question, because of its specific nature, deserves to be characterised as a SGEI and to be distinguished from other economic activities. In particular, an SGEI must be set up to remedy a market failure, which implies that the specific service in question, as stipulated in the entrustment act, is not and would not be performed absent the SGEI, taking into account any legal obligations, or would not be performed at the required level of quantity or quality (see section II).

44. The SGEI must be entrusted by means of an act which identifies the undertaking concerned and spells out the nature of the task as well as the scope and the general operational conditions of the SGEI. The specific form of the act (or acts) may be determined by each Member State. However, it must be an act having binding legal force under national law, and specifying at least: (a) the content and duration of the public service obligation(s); (b) the undertaking and, where applicable, the territory concerned; (c) the nature of any exclusive or special rights assigned to the undertaking by the

[14] Judgment of the Court of 24 July 2003, Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark GmbH ('Altmark' judgment), C-280/00, EU:C:2003:415, par. 88 to 93.

[15] For further reference, please see the Commission Communication on the application of the EU State aid rules to compensations granted for the provision of SGEIs (Communication from the Commission on the application of the European Union State aid rules to compensation granted for the provision of services of general economic interest, OJ C 8, 11.1.2012, p. 4.).

authority in question; (d) the parameters for calculating, controlling and reviewing the compensation; and (e) the arrangements for avoiding and recovering any overcompensation. The entrustment may for example take the form of a public service contract between public authorities and the entrusted operators.

2nd Altmark criterion: the parameters on the basis of which the compensation is calculated must be established in advance in an objective and transparent manner

45. Furthermore, the compensation for the provision of the SGEI must be determined on the basis of parameters established in advance, in an objective and transparent manner which should be laid down in the entrustment act stipulating the public service obligation(s) of the entrusted beneficiary.

46. The 2nd Altmark criterion however does not necessarily oblige the entrusting Member State(s) to quantify the amount of the compensation in advance, but rather to establish the parameters on the basis of which that compensation could be calculated in an objective manner (e.g. a certain amount per dose of the critical medicine produced or reserved).

3rd Altmark criterion: the compensation cannot exceed what is necessary to cover all or part of the costs incurred

47. In addition, according to the 3rd Altmark criterion, the compensation must not exceed what is necessary to cover all or part of the costs incurred in the discharge of the public service obligation(s), taking into account the relevant receipts and a reasonable profit. The beneficiary cannot be overcompensated. In concrete terms, this means that the profit of the entrusted operator in delivering the SGEI needs to be taken into consideration by the entrusting public authority and cannot be excessive.

48. The concept of reasonable profit is not defined in the Altmark judgment. It can be defined as the rate of return on capital that would be required by a typical undertaking considering whether or not to provide the SGEI for the whole period of entrustment, taking into account the level of risk.

4th Altmark criterion: least cost to the community

49. Finally, a compensation for the provision of an SGEI will not confer an advantage upon the entrusted provider (and therefore fall outside the scope of State aid rules) if it is either determined following a competitive tender, or, alternatively, on the basis of an analysis of the costs that a typical undertaking, well-run and adequately equipped so as to be able to meet the necessary public service requirements, would incur.

50. The conduct of an open, transparent and non-discriminatory public procurement procedure to select the provider of the SGEI will ensure that the service can be provided at the least cost to the community and is the simplest way to meet the 4th Altmark criterion. For the 4th Altmark criterion to be deemed fulfilled, the tenderer must either be selected on the basis of the lowest price, or on the basis of the most economically

advantageous tender (MEAT)[16]. The use of MEAT criteria favoring EU production, when used in compliance with the EU's international commitments, may in particular be consistent with the objective of an SGEI aiming at securing security of supply. As stipulated in point 66 of the Commission Communication on the application of the EU State aid rules to compensations granted for the provision of SGEIs[17], a restricted procedure[18] can also satisfy the 4th Altmark criterion, **unless interested operators are prevented from participating in the tender without valid reasons**. On the other hand, for example a competitive dialogue, a negotiated procedure with prior publication, or a negotiated procedure without publication confer a wide discretion upon the entrusting authority and are generally not deemed sufficient to satisfy compliance with the 4th Altmark criterion. As an example, a Member State or a pool of Member States could launch a tender to select an EU operator to reserve a determined level of capacity for a determined period of time to be activated under pre-defined conditions to deliver a given critical medicine which would present vulnerabilities in its supply chain. Several bidders could submit different candidate Strategic Projects to provide this capacity associated with different levels of compensation. The selection of the lowest bidder would ensure the absence of aid.

51. Alternatively, if the operator is selected without a tender, the compensation must be determined following either a comparison with an appropriate benchmark (i.e., market remuneration for a comparable service to a comparable supplier), or on the basis of an analysis of the costs that a typical undertaking, well run and adequately provided with material means so as to be able to meet the necessary public service requirements, would have incurred in discharging those obligations, taking into account the relevant receipts and a reasonable profit for discharging those obligations.

52. The reference to the costs of a 'typical' undertaking in the sector under consideration implies that there is a sufficient number of undertakings whose costs may be taken into account[19]. Those undertakings may be located in the same Member State or in other Member States. However, reference cannot be made to the costs of an undertaking that enjoys a monopoly position or receives public service compensation granted on conditions that do not comply with Union law, as in both cases its cost level may be higher than normal. Nevertheless, the costs can be estimated taking into account the historical costs of the service provided by the outgoing operator, if applicable.[20] As an example, if there is sufficient information on the average production costs of a certain type of critical medicine, this could serve as a basis for estimating a level of compensation of an obligation to produce that critical medicine which would not involve State aid.

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16 The inclusion of MEAT criteria to favour EU and/or Green production is envisaged in the CMA.

17 Communication from the Commission on the application of the European Union State aid rules to compensation granted for the provision of services of general economic interest, OJ C 8, 11.1.2012, p. 4.

18 As defined in Article 1(11)(b) of Directive 2004/18/EC and Article 1(9)(b) of Directive 2004/17/EC.

19 In the case of the production of generics, it can be expected that the typical production costs can probably be established.

20 See Case C-186/22, *Sad Trasporto Locale SpA v Provincia autonoma di Bolzano*, ECLI:EU:C:2023:795.

C. *No effect on trade: de minimis aid*

53. In cases of very low amounts of aid, distortion of competition can be excluded. This is known as de minimis aid. For cases falling under de minimis, there is no need for prior approval from the European Commission. Member States do not have to inform the Commission of such aid.

54. Support granted under the de minimis Regulation[21] is not regarded as State aid if no more than EUR 300 000 is granted to a single undertaking over a period of three fiscal years and the other conditions laid down in the respective de minimis Regulation are also respected.

55. In the same vein, public funding granted for the provision of an SGEI not exceeding EUR 750 000 over three years is not regarded as State aid, provided the other conditions of the SGEI de minimis Regulation[22] are also fulfilled.

IV. State aid exempted from notification

56. Certain funding measures constitute State aid but can be granted by Member States for the implementation of strategic projects, as defined by the CMA, without notification to the Commission provided that certain conditions are fulfilled.

A. *SGEI compensation exempted from notification*

57. Public service compensation that qualifies as State aid (typically in the case when the 4th Altmark criterion is not met) can be directly implemented by Member States and exempted from notification to the Commission, if it complies with the conditions set out in the SGEI Decision[23]. Similar to the Altmark assessment, the SGEI in question must be a genuine one and aim to remedy a market failure. The SGEI Decision may allow to finance a Strategic Project related to the SGEI (e.g. to increase manufacturing capacity for a critical medicine presenting vulnerabilities in its supply chain) but may also allow to finance the operating deficit (if any) of producing that critical medicine.

58. Under Article 2(1)(a) of the SGEI Decision, the average annual compensation cannot exceed EUR 15 million per year, while, as stipulated in Article 2(2) of the SGEI Decision, the entrustment period must be limited to 10 years, unless the service provider is required to make a significant investment that needs to be amortized over a longer period, in accordance with generally accepted accounting principles. However, the EUR 15 million per year threshold is per SGEI. Therefore, an undertaking can be entrusted with multiple SGEIs (for example linked to ensuring the security of supply of different critical medicines

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21 Commission Regulation (EU) 2023/2831 of 13 December 2023 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid, OJ L, 2023/2831

22 Commission Regulation (EU) 2023/2832 of 13 December 2023 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid granted to undertakings providing services of general economic interest, OJ L, 2023/2831

23 Commission Decision of 20 December 2011 on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest, OJ L 7, 11.1.2012, p. 3–10.

presenting vulnerabilities in their supply chains, or the same critical medicines for several Member States in case of coordinated national entrustments) and receive up to EUR 15 million for each SGEI under the SGEI Decision[24].

59. According to the Strategic Report of the Critical Medicines Alliance[25], in the context of investment support for the manufacturing of Active Pharmaceutical Ingredients, a typical project would involve investment costs between EUR 5 to 20 million in total, depending on the complexity of the product. In many cases, support for such projects may therefore fall under the SGEI Decision. This means that it should in principle be possible for Member States to finance the Strategic Projects aiming at increasing manufacturing capacities of Active Pharmaceutical Ingredients without notification to the Commission under the SGEI Decision.

60. Furthermore, Article 4 of the SGEI Decision requires an entrustment act specifying (a) the content and duration of the public service obligation(s); (b) the undertaking and, where applicable, the territory concerned[26]; (c) the nature of any exclusive or special rights assigned to the undertaking by the granting authority; (d) a description of the compensation mechanism and the parameters for calculating, controlling and reviewing the compensation; (e) the arrangements for avoiding and recovering any overcompensation; and (f) a reference to the SGEI Decision.

61. Pursuant to Article 5 of the SGEI Decision, the amount of the compensation for the provision of the SGEI cannot exceed what is necessary to cover the net cost incurred in discharging the public service obligation(s), including a reasonable profit. The net cost can be calculated as the difference between the costs incurred in operating the SGEI (including if applicable common costs determined on the basis of generally accepted cost accounting principles) and the revenues generated from the SGEI (cost allocation methodology). Alternatively, the net costs may be calculated as the difference between the net cost[27] of the entrusted undertaking when operating with the public service obligation (factual scenario) and the net cost or profit of the same undertaking operating without the public service obligation (counterfactual scenario). The latter is also referred to as the Net Avoided Costs methodology (NAC). Pursuant to Article 5(5) of the SGEI Decision, a reasonable profit (which can be used in the cost allocation methodology) is defined as the rate of return on capital that would be required by a typical undertaking considering whether or not to provide the SGEI for the whole period of entrustment, taking into account the level of risk. The 'rate of return on capital' means the internal rate of return that the undertaking makes on its invested capital over the duration of the period of entrustment. The level of risk depends on the sector concerned, the type of service and

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[24] For example, if two Member States entrust the same operator with two SGEIs for the production of a given critical medicine presenting vulnerabilities in its supply chains for their respective territory, the operator could obtain up to EUR 30 million under the SGEI Decision. By contrast, if they entrust jointly this operator through one SGEI to produce the critical medicine for both Member States, it can only receive up to EUR 15 million.

[25] The strategic report is available at : https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance_en

[26] As explained above, it is notably essential to determine whether the SGEI covers the territory of multiple Member States entrusting the given operator.

[27] Including capital costs.

the characteristics of the compensation. Where, by reason of specific circumstances, it is not appropriate to use the rate of return on capital, Member States may also rely on other profit level indicators to determine what the reasonable profit should be, such as the average return on equity, return on capital employed, return on assets or return on sales.

62. Pursuant to Article 5(9) of the SGEI Decision, if the entrusted undertaking carries out activities falling both inside and outside the scope of the SGEI[28] in question, its internal accounts must show separately the costs and receipts associated with the SGEI and those of the other services, as well as the parameters for allocating costs and revenues. The costs linked to any activities outside the scope of the SGEI must cover all the direct costs linked to those activities, as well as an appropriate contribution to the common costs linked to both the SGEI and the other activities, and an adequate return on capital.

63. Article 6 of the SGEI Decision obliges Member States to ensure that the compensation granted for the operation of the SGEI does not exceed the net costs needed for the provision of the public service obligation and a reasonable profit. To that end, Member States must carry out regular checks (at least every 3 years). If the entrusted undertaking has received more than the calculated net costs and a reasonable profit, the beneficiary must either repay the overcompensation, or, if the overcompensation does not exceed 10 % of the amount of the average annual compensation, the entrusting Member State may decide to deduct it from next year's compensation.

64. Finally, pursuant to Article 7 of the SGEI Decision, if an undertaking which also has activities falling outside the scope of the SGEI, receives a total compensation exceeding EUR 15 million, the entrusting Member State(s) must publish online or by other appropriate means (e.g., Member State Official Journal) at least the entrustment act or a summary thereof which includes the elements listed in Article 4 (see above) and the amounts of aid granted to the entrusted undertaking on a yearly basis.

B. Aid exempted under the General Block Exemption Regulation

65. The General Block Exemption Regulation (GBER)[29] enables Member States to directly implement State aid measures without prior Commission authorisation, for certain categories of aid and up to certain maximum thresholds. Eligible categories are set out in a Council Regulation[30] (the 'Enabling Regulation'). The Commission may therefore only block-exempt the categories listed in the Enabling Regulation. While this does not explicitly mention critical medicines, certain categories listed therein may nonetheless apply to Strategic Projects for critical medicines as defined in the CMA proposal.

66. According to the Strategic Report of the Critical Medicines Alliance, production capacity investment support has been identified as the top priority, particularly investing in modernization and greener production technologies, and enhancing process efficiency,

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28 E.g. if the entrusted pharmaceutical operator also produces medicines which are not critical medicine which can be expected to be likely.

29 Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, OJ L 187, 26.06.2014

30 Regulation (EC) No 994/98 on the application of Articles 92 and 93 of the Treaty establishing the European Community to certain categories of horizontal State aid, OJ L 204, 31.7.2013, p. 11–14

notably – but not only - in the manufacturing of Active Pharmaceutical Ingredients (as mentioned above, a typical project would involve investment costs between EUR 5 to 20 million, depending on the complexity of the product). In some cases, support for such projects may fall under the General Block Exemption Regulation.

67. **Article 14 GBER** (regional investment aid) allows the granting of State aid for investments that take place in assisted areas[31](less developed 'a'-areas and more developed 'c'-areas). If the relevant conditions are fulfilled, in 'a' areas, regional aid under Article 14 GBER can cover any form of initial investment[32] to produce medicines, including critical medicines, regardless of the size of the beneficiary.

68. In 'c' areas, regional aid may be granted to SMEs for any form of initial investment, while aid to large enterprises can only be granted for an initial investment in favour of a new economic activity in the area concerned. This means, for instance, that in 'c' areas SMEs only can receive regional aid for projects that are related to the setting up of a new establishment; the diversification of the activity of an establishment, provided that the new activity is not the same or a similar activity to the activity previously performed in the establishment; or an acquisition of assets belonging to an establishment that has closed or would have closed had it not been purchased, provided that the new activity to be carried out using the acquired assets is not the same or a similar activity than the one carried out in the establishment before the acquisition.

69. The maximum aid intensities applicable in the assisted areas are established for each Member State in the regional aid maps and can vary across the assisted areas. The eligible costs[33] are investment costs in tangible and intangible assets, estimated wage costs arising from the job creation as a result of the eligible investment, calculated over 2 years, or a combination thereof. The investment shall be maintained in the assisted area for at least 5 years (3 years if the beneficiary is an SME). Additional bonuses apply for investments by small enterprises (20%) and medium-sized enterprises (10%). Aid for intra-EEA relocation purposes is not allowed under Article 14 GBER.

70. Large investment projects (with eligible costs exceeding EUR 50 million) can also be supported under Article 14 GBER, provided that the aid does not exceed the adjusted aid amount (based on the so-called "scale down mechanism"[34]).

71. **Article 17 GBER** allows granting investment aid to SMEs (in both assisted and non-assisted areas), not exceeding the threshold of EUR 8.25 million per undertaking per investment

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31 'Assisted areas' means areas designated in an approved regional aid map, valid at the time of award of the aid in application of Articles 107(3)(a) and (c) TFEU.

32 Including investments related to the set-up of a new establishment or to the expansion of already existing production capacity.

33 Please note that the references to 'eligible costs' in this guiding template are to be understood exclusively for the purposes of State aid.

34 'Adjusted aid amount' means the maximum permissible aid amount for a large investment project, calculated according to the following formula: maximum aid amount = R × (A + 0,50 × B + 0 × C). Where: R is the maximum aid intensity applicable in the area concerned established in an approved regional map and which is in force on the date of granting the aid, excluding the increased aid intensity for SMEs; A is the initial EUR 50 million of eligible costs, B is the part of eligible costs between EUR 50 million and EUR 100 million and C is the part of eligible costs above EUR 100 million (Article 2(20) GBER)..

project. Eligible investments include among other investments in tangible and/or intangible assets relating to the setting up of a new establishment (e.g. a new production facility for a critical medicine), the extension of an existing establishment, diversification of the output of an existing establishment into new additional products or a fundamental change in the overall production process of an existing establishment. The maximum aid intensity is 20 % of eligible costs for small enterprises and 10 % for medium-sized enterprises.

72. **Article 25 GBER** allows granting State aid for R&D projects with high notification thresholds (EUR 55, 35 or 25 million, per undertaking per project depending on the research category[35]) and aid intensities between 100% to 25% depending on the closeness of the R&D activities to the market. When an R&D project is predominantly experimental development, aid of up to EUR 25 million, with an aid intensity of 25 % of eligible costs, can be granted without notification to the Commission. These include personnel costs, costs of instruments, equipment, buildings and land to the extent and for the period used for the project, as well as costs of contractual research.

73. The aid intensity of 25 % applies to undertakings of all sizes and can be increased when the aided project is carried out by an SME; when the aided project involves effective collaboration, or its results are widely disseminated, or the beneficiary commits to make available licences for IP-protected results; or the aided project is carried out in an assisted region. A bonus is also foreseen for R&D projects delivering cross-border benefits in terms of effective collaboration and knowledge dissemination, where such projects have been selected following an open call to form part of a project jointly designed by at least three Member States or contracting parties to the EEA Agreement, presuming that all relevant conditions are fulfilled.

74. The vast majority of aid for R&D is granted under the GBER. Article 25 GBER may, if the conditions are fulfilled, be available for R&D projects e.g. on innovative production processes for critical medicines or even alternative medicines which may replace some critical medicines in the medium to long term.

75. **Section 7 of the GBER** covers aid for environmental protection. Investments in the decarbonisation and energy efficiency of the production processes of critical medicines may, under certain conditions, fall under **Article 36 of the GBER and Article 38 of the GBER**. Aid intensities under this provision may reach 100% of the eligible costs when competitive bidding is used.

76. **Article 47 GBER** covers resource efficiency investments. This provision targets investments achieving a net reduction in the resources consumed in the production of a given quantity of output compared to a pre-existing production process. Resource efficiency could be a valid strategy for addressing security of supply issues not only for critical medicines but also for API. Aid intensities under this provision may reach up to 60% for small, 50% for medium and 40 % for large enterprises.

[35] Fundamental or industrial research, experimental development or feasibility studies.

V. Notifiable aid

A. Notifiable SGEI compensation

77. If the compensation exceeds the threshold applicable in the SGEI Decision, it can be found compatible under the SGEI Framework, subject to several requirements being met ([36]). The SGEI Framework requires prior notification and authorisation from the Commission, before any aid is granted. Similar to assessment under Altmark and the SGEI Decision, the SGEI in question must be a genuine one and aim to remedy a market failure. Like the SGEI Decision, the SGEI Framework may be used to finance a Strategic Project aiming to provide the SGEI (e.g. to increase manufacturing capacity for a critical medicine presenting vulnerabilities in its supply chain) or a project pursuing similar objectives but may also allow to finance the operating costs of producing that critical medicine.

78. Pursuant to point 14 of the SGEI Framework, Member States must give proper consideration to the needs of the public service. They are required to carry out a public consultation or use another appropriate instrument to identify the interests of users and providers of the relevant service, so that the public authority can define the public service obligation in an appropriate and proportionate manner.

79. Pursuant to point 16 of the SGEI Framework, Member States must draw up an SGEI entrustment act clearly specifying the content and duration of the relevant public service obligation(s), the undertaking and the territory concerned, the nature of any exclusive or special rights assigned to the undertaking by the granting authority, the description of the compensation mechanism, the parameters for calculating, monitoring and reviewing the compensation, and the arrangements for avoiding and recovering any overcompensation.

80. Pursuant to point 17 of the SGEI Framework, the duration of the entrustment must be justified by reference to objective criteria. In the context of an SGEI for the manufacturing of vulnerable critical medicines, the nature and expected duration of the market failure that is being addressed can be relevant in this regard.

81. Pursuant to point 19 of the SGEI Framework, whenever EU public procurement rules apply, a measure cannot be approved under the SGEI Framework if it does not comply with those rules. Therefore, if the applicable public procurement rules require the organisation of a competitive tender procedure for the selection of the beneficiary or beneficiaries, such a tender must be organised. This also includes any requirements of transparency, equal treatment and non-discrimination resulting directly from the Treaty and, where applicable, secondary Union law. SGEI compensation that does not comply with the above rules and requirements is considered to affect the development of trade to an extent contrary to the interests of the Union within the meaning of Article 106(2) TFEU and could therefore not be approved.

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[36] Communication from the Commission, European Union framework for State aid in the form of public service compensation (2011) Official Journal C8, 11.01.2012, p. 15-22.

82. Pursuant to point 20 of the SGEI Framework, where the authority assigns the provision of the same SGEI to several undertakings, the compensation should be calculated by the same method for each entrusted undertaking.

83. Pursuant to point 21 of the SGEI Framework, the compensation may not exceed what is necessary to cover the net cost of discharging the public service obligations. Member States should use the NAC methodology for calculating the net cost of a public service obligation(as explained in section IV.D above), except when duly justified, case in which other alternative methodologies may be used, such as the cost allocation method.

84. Furthermore, pursuant to point 39 of the SGEI Framework, in devising the method of compensation, Member States must introduce incentives for the efficient provision of the SGEI at a high standard, unless they can duly justify that it is not feasible or appropriate to do so. Member States have a wide margin of discretion in devising the method for compensation and determining the efficiency targets. However, the compensation mechanism should be based on objective and measurable criteria set out in the entrustment act and subject to transparent ex post assessment carried out by an entity independent of the SGEI provider(s). A simple example is a decreasing yearly compensation over the duration of the entrustment to account for expected efficiency gains (i.e. cost reductions).

85. Pursuant to point 44 of the SGEI Framework, undertakings carrying out activities falling both inside and outside the scope of the SGEI must maintain an internal separation of accounts of costs and revenues associated with the SGEI and those of other services provided. Also, SGEI compensation will be considered compatible only where the undertaking complies, where applicable, with the Transparency Directive (Directive 2006/111/EC[37]).

86. Pursuant to point 48 of the SGEI Framework, Member States must ensure that overcompensation does not occur and perform regular checks at least every 3 years (2 years for compensations granted following a public procurement procedure with publication – point 49).

87. Finally, pursuant to point 60 of the SGEI Framework, Member States must publish for each SGEI compensation (i) the results of the public consultation; (ii) the content and duration of the public service obligation(s); (iii) the undertaking(s) and the territory concerned; and (iv) the amounts of aid granted to the undertaking(s) on a yearly basis.

B. Regional investment aid

88. Regional investment aid can be granted to establish manufacturing capacity of critical medicines[38] to large companies as well as to SMEs in assisted areas (less developed 'a'-

[37] Commission Directive 2006/111/EC of 16 November 2006 on the transparency of financial relations between Member States and public undertakings as well as on financial transparency within certain undertakings, OJ L 318, 17.11.2006, p. 17.

[38] The Commission considers that in assisted areas, the market does not deliver outcomes resulting in a sufficient level of economic development and territorial cohesion without State intervention. Therefore, aid in those areas is considered necessary.

areas and more developed 'c'-areas), subject to the conditions of the Regional Aid Guidelines[39] (RAG). Each Member State has a regional aid map in which the assisted areas are defined. Almost half of the EU qualifies as an assisted area.

89. Since regional aid to large enterprises for their investments is unlikely to have an incentive effect, as a rule[40] it cannot be considered as compatible with the internal market under Article 107(3)(c) TFEU, unless it is granted for initial investments that create new economic activities in these 'c' areas[41]

90. Regional investment aid is expressed as a percentage of the total (eligible) cost of an initial investment ('regional aid intensity') and can be granted up to the maximum aid intensity applicable in the respective assisted area. In principle, the less developed the region is, the higher the aid intensity. The aid amount cannot exceed the net extra costs of implementing the investment in the area concerned as compared to the counterfactual in the absence of aid, with maximum aid intensities as a cap.

91. If Member States consider granting regional investment aid for the investments described:

    a. the aided project must contribute to economic development of the area (e.g. taking account of direct and indirect jobs created, sustainability (duration) of the investment in the region, transfer of technology and knowledge spill-over in the region) (section 5.1. RAG)[42];

    b. the aid must have an incentive effect (i.e. the aid must change the behaviour of the undertaking concerned in such a way that it engages in additional activity which it would not carry out without the aid, or it would carry out in a different location) (section 5.2 RAG);

    c. the aid must be necessary to achieve the objective of regional development and territorial cohesion (section 5.3 RAG) and constitute an appropriate policy instrument to this end (section 5.4 RAG)[43];

    d. the aid must be limited to the minimum necessary and in any event below the maximum aid intensity for the region (section 5.5. RAG);

    e. potential negative effects on competition and trade between Member States should remain limited (e.g. aid for manufacturing pharmaceutical products for growing markets would be less harmful than in declining markets, aid for an

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39 Communication 2021/C 153/01 Guidelines on regional State aid, OJ C 153, 29.4.2021, p. 1.

40 The RAG provides for exceptions, i.e. aid can be also granted to large enterprises in 'c' areas for the diversification of the output of an establishment into products not previously produced or for a fundamental change in the overall production process of the product(s) concerned, in certain Just Transition Fund areas, under specific conditions.

41 Paragraph 19(14) RAG.

42 To demonstrate how the aided project contributes to regional development, the notifying Member State may use a variety of indicators such as the ones mentioned in paragraph 50 RAG.

43 The RAG underline that a measure will not be considered compatible if other, less distortive, policy instruments, or other, less distortive, types of aid instruments make it possible to achieve the same positive contribution to regional development and territorial cohesion.

undertaking with lower market power is less harmful than for undertakings with significant market share) (section 5.6. RAG); and

f. information concerning the aid must be published in the European Commission's transparency award module or on a comprehensive State aid website, in compliance with the RAG transparency provisions (section 5.7 RAG).

92. It is the responsibility of the notifying Member State to prove that the above conditions are met. For instance, in 2024, the Commission approved an individual regional aid for the diversification of output of an existing establishment into biological Drug Substances for biosimilars, in an assisted 'a'-area in Slovenia.[44]

C. CEEAG

93. If applicable, Member States may award State aid for projects regarding critical medicines based on the Guidance on State aid for climate, environmental protection and energy (CEEAG)[45]. The CEEAG allows support inter alia for the reduction and removal of greenhouse gas (GHG) emissions or for improving energy efficiency in industrial plants (Section 4.1), resource efficiency and transition towards circular economy (Section 4.4) and prevention or the reduction of pollution other than from greenhouse gases (Section 4.5).

94. Section 4.1 of the CEEAG is technologically neutral, thus covering all technologies that reduce GHG emissions and/or improve energy efficiency. It is required that projects deliver overall GHG emission reductions or reduced energy consumption through investments in energy efficiency. Projects must not merely result in the displacement of GHG emissions from the industrial sector concerned to the energy sector. Section 4.4 of the CEEAG covers aid for investments improving resource efficiency and for the prevention and recycling of waste or other products, materials or substances. Section 4.5 of the CEEAG covers aid for the prevention or reduction of pollution and emissions other than GHG (e.g. nitrogen oxides, sulphur dioxide, noise, phosphate, etc.).

D. R&D&I Framework

95. Under the R&D&I Framework[46], notifiable R&D&I aid will be assessed in detail to establish whether all the relevant compatibility criteria are met, notably necessity, appropriateness and proportionality of the aid, and that the negative effects of the R&D&I aid on competition and trade are minimised or avoided. If that is the case, higher aid intensities[47]

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44 In case SA.112940 – Slovenia LIP – Biopharmaceuticals Lendava the Commission approved a EUR 52 million aid to Lek Pharmaceuticals for the construction of a new high-tech plant to produce biological drug substances for biosimilars. The project concerned the diversification of output of an already existing establishment and was performed by a large enterprise in an assisted 'a' region. The Commission considered the investment necessary to achieve the objective of regional development and territorial cohesion with no need for the Member State to conduct any specific analysis of the market failures for the pharmaceutical products at stake (paragraph 77 RAG).

45 Communication from the Commission — Guidelines on State aid for climate, environmental protection and energy 2022, OJ C 80, 18.2.2022, p.1.

46 Communication from the Commission Framework for State aid for research and development and innovation (R&D&I Framework) available via this link.

47 See Annex II and Section 3.2.3.2. of the R&D&I Framework.

than under the GBER can potentially be allowed based on the so-called detailed assessment to make sure that the aid amount is necessary, has an incentive effect on the beneficiary and is limited to the minimum needed for carrying out the aided activity by the beneficiary.

96. To this end, Member States must explain the supported R&D&I activity, the technical and commercial risks involved for the beneficiary, as well as how the minimum aid amount has been established. The Member State must also provide market information on the impact of aid on competition and trade within the relevant market. In cases where there are multiple potential candidates for carrying out the aided activity, the proportionality requirement is more likely to be met if the aid is awarded on the basis of transparent, objective and non-discriminatory criteria as defined in the call for the selection of candidates and used by the granting authorities to evaluate and select the candidates.

97. R&D&I could contribute to long-term solutions to solve some of the critical medicines shortage issues where it leads to new technologies/medicines treating medical conditions/sickness.

E. IPCEIs

98. Finally, four or more Member States may cooperate to design an Important Project of Common European Interest (IPCEI). To this end Member States can benefit from expertise and guidance provided in the scope of the Joint European Forum for IPCEI ("JEF"), as well as request involvement of the Commission in the design phase to ensure smooth, effective and efficient IPCEI design and further IPCEI assessment.[48] - As announced in the Clean Industrial Deal[49], the Commission will work closely with the Member States to speed-up the design of new IPCEIs, to strengthen the efficiency of the tool to support industrial decarbonisation and the clean technology manufacturing in the EU. In particular, it will offer a new IPCEI design support hub to accelerate getting IPCEI projects off the ground.

99. The Commission assesses the IPCEI projects based on a common prenotification and notification against the criteria set out in the IPCEI Communication[50]. The Commission treats IPCEI cases as a matter of priority.

100. The purpose of IPCEIs is to bring together knowledge, expertise, financial resources and economic actors throughout the Union, so as to overcome important market or systemic failures and societal challenges which could not otherwise be addressed. IPCEIs are set up in view of their positive spillover effects throughout the EU, beyond the companies, Member States and sectors involved. To be compatible under these rules, an eligible project must address a market failure or other important systemic failures and fulfil all IPCEI Communication cumulative conditions, including among others:

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48 For more information about the Joint European Forum for IPCEI please see: https://competition-policy.ec.europa.eu/state-aid/ipcei/joint-european-forum-ipcei_en

49 See: Clean Industrial Deal - European Commission

50 Communication from the Commission – Criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest, OJ C 528, 30.12.2021, p. 10.

a. significantly contribute to strategic EU objectives in a concrete, clear and identifiable manner;

b. involve normally at least four Member States;

c. involve important private co-financing by the beneficiaries;

d. generate positive spillover effects across the EU that spread the benefits of the project beyond the participating undertakings and Member states and the sector concerned, and limit potential distortions to competition;

e. R&D&I projects must be of a major innovative nature or constitute an important added value in terms of research and innovation in the light of the state-of-the-art in the sector concerned;

f. projects comprising of first industrial deployment (FID[51]) must allow for the development of a new product or service with high research and innovation content or the deployment of a fundamentally innovative production process[52].

101. Openness and transparency need to guide the coordination of the IPCEI process. All Member States must be given an opportunity to participate; the selection of individual projects through calls for the expression of interest constitutes a means to ensure openness and transparency.

102. It is to be noted that IPCEIs are not the appropriate tool to support mass production of existing products such as, e.g.: generic medicines, if no innovation is involved and the project concerns a mere reshoring of production or commercial activities. Therefore, the investment costs of projects aiming at setting up factories for the mass production of such medicines cannot be supported by an IPCEI.

103. IPCEIs could however offer a long-term solution to reduce risks of shortages for critical medicines, since conducting R&D&I of a major innovative nature and FID of a new product or service with high research and innovation content could bring new technologies/medicines to treat medical conditions/sickness that were treated before by using existing treatments or critical medicines, as is the case for example in the first health IPCEI (Med4Cure) regarding healthcare products and innovative production processes of pharmaceuticals adopted in May 2024[53]. Such new solutions/technologies could constitute alternative treatments to certain antibiotics/critical medicines. Therefore, IPCEIs could support research of new medicines and fundamental innovation of production process of critical medicines.

104. Practical information about the IPCEIs including the process and templates can be found via a dedicated website available via this link.

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[51] First industrial deployment under the IPCEI Communication (FID) means the upscaling of pilot facilities, demonstration plants or of the first-in-kind equipment and facilities covering the steps subsequent to the pilot line including the testing phase and bringing batch production to scale, but not mass production or commercial activities.

[52] Regular upgrades without an innovative dimension of existing facilities and the development of newer versions of existing products do not qualify as first industrial deployment.

[53] More information about the Med4Cure IPCEI is available via this link.

F. Direct approval under Article 107.3(c) TFEU

105. Under Article 107(3)(c) TFEU, the Commission may in exceptional cases consider compatible with the internal market State aid to facilitate the development of certain economic activities within the European Union, where such aid does not adversely affect trading conditions to an extent contrary to the common interest.

106. Where the Commission has examined whether any of its guidelines or other texts setting out compatibility conditions for different categories of State aid measures (such as the texts mentioned in sections IV and V(A), V(B), V(C),V(D) and V(E) of this note) could be applicable to a measure under assessment but found that it does not fall within the scope of any such guidelines, the Commission may assess the measure directly under Article 107(3)(c) TFEU.

107. It is recognised, however, in the case-law[54] that the Commission may depart from State aid guidelines, or other texts setting out its decisional practice, where the Member State raises specific exceptional circumstances justifying departure from those guidelines. In such cases, if duly justified, the Commission may apply the Treaty provisions directly.

108. In order to assess whether State aid can be considered compatible with the internal market on the basis of Article 107(3)(c) TFEU, the Commission must verify (i) whether the aid contributes to the development of an economic activity or an economic area (positive condition); and (ii) whether the positive effects of the aid outweigh the negative effects triggered by the distortion of competition it creates so that there would be no undue affectation of trading conditions between Member States (negative condition).

109. Therefore, in its compatibility assessment, the Commission will check whether the conditions of Article 107(3)(c) TFEU are met, in particular using the following criteria:

a. The aid measure needs to facilitate the development of economic activities and have an incentive effect without resulting in an infringement of relevant EU law affecting the compatibility test;

b. The aid measure must not unduly affect trading conditions to an extent contrary to the common interest. For those purposes the Commission will check whether the State intervention is necessary, appropriate and proportionate to achieve the objectives pursued by the measure. The Commission will also verify that transparency of the aid is ensured. Together, these conditions ensure that the distortive effects of the aid are as limited as possible;

c. The Commission will assess the negative effects of the aid measure in terms of distortions of competition and impact on trade between Member States against the common interest of the Union. Assessment of this criterion depends on the relevant product and geographic market;

[54] For example, judgment of the Court of Justice of 8 March 2016, *Hellenic Republic v Commission*, C-431/14 P, EU:C:2016:145, paragraphs 70-72.

d. The Commission will finally balance the positive effects with the negative effects of the aid on competition and trade.

110. Concerning the necessity, appropriateness, and proportionality of aid, Member States are required to provide detailed information on (i) a credible and realistic counterfactual scenario, and (ii) a funding gap[55] analysis. In general, the proportionality of a measure can be ensured by carrying out a tender.

111. Negative effects on competition and trade are affected by factors such as the market position of the potential beneficiary and whether the measure would have a positive effect on the beneficiary's production capacity. Where the beneficiary has or would gain a significant market share, or where the measures have the objective of increasing capacity, this could increase the risk of significant negative effects on competition and trade. Moreover, investment aid to large undertakings, and in particular to international corporations, involves a higher likelihood of negatively affecting competition and trade, which may be contrary to the common interest and hence requires a particularly cautious balancing of its positive and negative effects.

112. In 2023, the Commission approved State aid to Sandoz Austria (SA.62915)[56] directly on the basis of Article 107(3)c) TFEU.

VI. Practical indications and examples of possible application of SGEI rules for critical medicines

113. When considering financing possibilities for strategic projects as defined by the CMA, Member States may consider the following orientation points:

i. Whether the Strategic Project addresses a security of supply market failure which is evidenced by a proper assessment of supply chain vulnerabilities: in such case SGEI solutions may be considered (see examples of application below).

ii. Whether the Strategic Project may be financed by measures addressing other market failures which do not require an assessment of supply chain vulnerabilities:

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55 "Funding gap" means the net present value of the difference between the positive and negative cash flows, including investment costs, over the lifetime of the investment.

56 Commission Decision C(2023) 4922 final of 27 July 2023 in case SA.62915 (2022/N) – Austria – Aid for maintaining Sandoz penicillin production in Kundl (Tyrol) (OJ C, 2024/6477, 28.10.2024) . In that case, the Commission concluded that the particular circumstances characterising the product and the particular characteristics of the investment concerned (namely the rarefication of production in the EU, the decision taken by the EU's last 6-APA producer to cease production, the presence of a significant funding gap for modernising the production in the EU, the strict limitation of the aid to the identified funding gap, and the contribution of the investment to reducing supply chain risks) warranted a positive assessment. The Commission also took into account that the measure's impact on competition and trade between Member States was in practice very limited, given that Sandoz Austria is the only vertically integrated Amoxicillin producer in the EU (with a much lower market share than its main competitor) and the aid would not result in any capacity increase in the internal market.

a. GBER allows granting aid without notification under certain conditions in relation to regional economic development (Article 14), support for SMEs (Article 17), decarbonisation and energy efficiency (Articles 36 and 38), process optimization (Article 47);

b. Regional aid targets regional economic development and CEEAG targets decarbonisation and energy efficiency beyond the limits of the GBER but requires a notification.

iii. Whether the Strategic Project aims at innovation:

a. Beyond state-of-the-art innovation: support in line with the IPCEI Communication may be considered

b. Other R&D&I aid: if within the thresholds of GBER (Article 25), aid may be considered without a notification, if above thresholds, aid under the R&D&I Framework may be considered.

114. The mock examples below illustrate the variety of situations of application of SGEI rules for critical medicines.

For illustrative purposes only: compliance with State aid rules should always be assessed on case-by-case basis.

Example 1: Altmark approach

1. A proper vulnerability evaluation shows that a critical medicine relies on an API produced in one single factory outside of the EU and that this situation leads to a significant risk of shortages of that critical medicine.
2. A Member State envisages a SGEI to ensure that a certain volume of this API is made available to market operators on its territory. Four other Member States show interest for securing access to the API and the five Member States agree to set up collectively a joint SGEI that they will finance jointly in proportion of their use.
3. The five Member States define obligations to be imposed on the entrusted operator. These obligations may include, for example:
   a) Putting in place the necessary manufacturing capacity to be able to provide the desired volume of the API in the five Member States concerned under pre-agreed terms (e.g. volume, price, duration…) in case of disruption in the supply chain of that critical medicine;
   b) Maintaining that manufacturing capacity in place for a certain duration (e.g. 15 years);
   c) Producing and delivering the volume of API for the five Member States concerned if a disruption materializes.
4. The five Member States organise an open, transparent and non-discriminatory public procurement procedure to select an operator. The tender requires bidders to ensure that they will not be overcompensated and includes criteria to favour EU and/or green production.

5. Several bidders submit a bid describing notably how they intend to deliver on the public service obligations and the amount of aid they need to do so, while not being overcompensated. This amount may cover both investment and operating costs.
6. The five Member States select the operator on the basis of the most economically advantageous tender.
7. A public service contract is signed between the five Member States and the selected operator, describing precisely the obligations and the compensation modalities of the future operator, which ensures there is no overcompensation. Penalties will apply in case of breach of contract by the operator.

Example 2: SGEI Decision

1. A proper vulnerability evaluation shows that a critical medicine is no longer produced in the EU and this situation leads to a significant risk of shortages of that critical medicine.
2. A Member State envisages a SGEI to produce and deliver a certain volume of this critical medicine to address that vulnerability in its territory. No other Member State joins the initiative.
3. The Member State defines obligations to be imposed on the provider such as for example:
   a) Produce and deliver the desired volume of the critical medicine in the Member State concerned under pre-agreed terms (e.g. volume, price …)
   b) Maintain that delivery under the agreed conditions for a certain duration (e.g. 7 years)
4. The Member State selects an operator through a negotiated procedure with prior publication[57].
5. The operator will receive less than EUR 15 million/year over 7 years which allows Member States to rely on the SGEI Decision without notification to the Commission. This amount covers both investment and operating costs over that period.
6. A public service contract is signed between the Member State concerned and the selected operator stipulating the obligations of the provider, the compensation modalities, ensuring the absence of overcompensation and the compliance with the other conditions of the SGEI Decision. Penalties/recovery of the whole amount of compensation apply in case of breach of contract.

Example 3: SGEI Framework

1. A critical medicine (or API) is produced at too small quantities in the EU to face crisis situations.
2. A proper vulnerability evaluation shows that this situation leads to a significant risk of shortages of that critical medicine (or API) in the EU.
3. A Member State envisages a SGEI to stockpile a certain volume of this critical medicine (or API) to address that vulnerability in its territory. All other EU Member States decide

[57] Assuming this is in line with public procurement rules

to join the initiative. All EU Member States define jointly the obligations to be imposed on the provider such as for example:

a) Stockpiling the desired volume of the critical medicine (or API) in question under pre-agreed terms (e.g. volume, delay, price, duration…) to meet the needs of all Member States in case of crisis.
b) Maintaining the stock for a certain duration (e.g. 5 years) and/or reserving the API/product produced for a certain period for supply in the EU.

4. The Member States organize an open, transparent and non-discriminatory public procurement procedure to select an operator. The tender requires bidders to ensure that they will not be overcompensated.
5. Only one operator submits a bid[58] to stockpile/reserve the relevant critical medicine/API for an amount exceeding EUR 15 million/year.
6. After notification of the measure to the Commission and its validation by the Commission, the EU Member States decide to sign a public service contract with the only bidder, stipulating its obligations and the compensation modalities, ensuring the absence of overcompensation and the compliance with all the other conditions of the SGEI Framework, in particular, penalties or recovery of the whole amount of compensation in case of breach of contract.
7. Member States decide that the SGEI will be coordinated at EU level and agree that the Member State in which the selected operator is located will pay proportionally more of the compensation amount.

Comparative grid

	Altmark (example 1)	**SGEI Decision (example 2)**	**SGEI Framework (example 3)**
Notification of the measures to the Commission	No	No	Yes
Vulnerability in the supply chain	Yes	Yes	Yes
Entrustment describing the obligations of the SGEI provider (capacity reserve, production, stockpiling….)	Yes	Yes	Yes
Joint entrustment by several Member States	Possible	Possible	Possible
IProduction capacity investment costs financing	Yes	Yes	Yes
Operating costs financing	Yes	Yes	Yes
No overcompensation	Yes	Yes	Yes
Maximum amount	None	EUR 15 million/year	None
Selection through competitive tender ensuring lowest price	Yes	Not necessarily (but recommended)	Not necessarily (but recommended)

[58] This would in general not meet the 4th Altmark criterion

VII. References

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- Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC and Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.
- Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of Health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, (OJ L 107, 26.3.2021)
- Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon //Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, OJ L170, 12.5.2021, p. 1.
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- Commission Regulation (EU) 2023/2832 of 13 December 2023 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to de minimis aid granted to undertakings providing services of general economic interest, OJ L, 2023/2831
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- Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, OJ L 187, 26.06.2014
- Regulation (EC) No 994/98 on the application of Articles 92 and 93 of the Treaty establishing the European Community to certain categories of horizontal State aid, OJ L 204, 31.7.2013, p. 11–14
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- Commission Directive 2006/111/EC of 16 November 2006 on the transparency of financial relations between Member States and public undertakings as well as on financial transparency within certain undertakings, OJ L 318, 17.11.2006, p. 17.
- Communication 2021/C 153/01 Guidelines on regional State aid, OJ C 153, 29.4.2021, p. 1.
- Communication from the Commission — Guidelines on State aid for climate, environmental protection and energy 2022, OJ C 80, 18.2.2022, p.1.
- Judgment of the Court of Justice of 8 March 2016, Hellenic Republic v Commission, C-431/14 P, EU:C:2016:145, paragraphs 70-72.
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