Subsidy Advice Unit Report on the proposed Life Sciences Innovative Manufacturing Fund

Referred by Office for Life Sciences

28 June 2024

Subsidy Advice Unit

Part of the Competition and Markets Authority

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1. Introduction

1.1 This report is an evaluation prepared by the Subsidy Advice Unit (SAU), part of the Competition and Markets Authority, under section 59 of the Subsidy Control Act 2022 (the Act).

1.2 The SAU has evaluated the Office for Life Sciences' (OLS) assessment of compliance of the proposed Life Sciences Innovative Manufacturing Fund 2025-30 subsidy scheme (LSIMF 25-30 or the Scheme), with the requirements of Chapters 1 and 2 of Part 2 of the Act (the Assessment).[1]

1.3 This report is based on the information provided to the SAU by OLS in its Assessment and evidence submitted relevant to that Assessment.

1.4 This report is provided as non-binding advice to OLS. The purpose of the SAU's report is not to make a recommendation on whether the Scheme should be implemented, or directly assess whether it complies with the subsidy control requirements. OLS is ultimately responsible for making the Scheme, based on its own assessment, having the benefit of the SAU's evaluation.

1.5 A summary of our observations is set out at section 2 of this report.

The referred scheme[2]

1.6 The Scheme will provide £520 million in capital grants for investments in the manufacture of human medicines, medical diagnostics, and medical technology products in the UK, to be allocated between financial years 2025/26 and 2029/30. It will build on previous smaller scale funds for the life sciences sector to incentivise the expansion of the UK life sciences manufacturing capabilities[3].

1.7 The Fund will be a grant competition and will contribute to a maximum of 25% of the applicants' expenditure costs; however, the typical intervention rate is expected to be 10-20%. Companies with projects with a total cost (including capital expenditure and associated R&D costs) of at least £8 million will be eligible to apply.

[1] Chapter 1 of Part 2 of the Act requires a public authority to consider the subsidy control principles and energy and environment principles before deciding to give a subsidy. The public authority must not award the subsidy unless it is of the view that it is consistent with those principles. Chapter 2 of Part 2 of the Act prohibits the giving of certain kinds of subsidies and, in relation to certain other categories of subsidy creates a number of requirements with which public authorities must comply.
[2] Referral of the proposed Life Sciences Innovative Manufacturing Fund by Office for Life Sciences - GOV.UK (www.gov.uk)
[3] Previous UK Government support includes the £20m Medicines and Diagnostics Manufacturing Transformation Fund (2021), £68m Life Sciences Manufacturing Fund (2022-2024) and £38m Biomanufacturing Fund (2023).

1.8 The funding available under LSIMF 25-30 will be open to companies registered in the UK. However, this referral and report relate only to grants made under LSIMF 25-30 which do not engage Article 10 of the Windsor Framework.[4]

1.9 This referral was made prior to the 22 May 2024 announcement of the General Election (to be held on 4 July 2024) and the subsequent dissolution of Parliament.

SAU referral process

1.10 On 10 May 2024, OLS requested a report from the SAU in relation to the Scheme.

1.11 OLS explained[5] that the Scheme is a Subsidy Scheme of Particular Interest because it expects to give individual grants exceeding £10 million in total value.

1.12 The SAU notified OLS on 17 May 2024 that it would prepare and publish a report within 30 working days (i.e. on or before 28 June 2024).[6] The SAU published details of the referral on 20 May 2024.[7]

[4] Article 10(1) of the Windsor Framework to the EU-UK Withdrawal Agreement provides that EU State aid rules will continue to apply to the UK in respect of measures which affect trade in goods or the electricity market between Northern Ireland and the European Union.
[5] In the information provided under section 52(2) of the Act.
[6] Sections 53(1) and 53(2) of the Act.
[7] Referral of the proposed Life Sciences Innovative Manufacturing Fund by Office for Life Sciences - GOV.UK (www.gov.uk)

2. Summary of the SAU's observations

2.1 The Assessment uses the four-step structure described in the Statutory Guidance for the United Kingdom Subsidy Control Regime (the Statutory Guidance) and as reflected in the SAU's Guidance on the operation of the subsidy control functions of the Subsidy Advice Unit (the SAU Guidance).

2.2 We consider that OLS has engaged with the Statutory Guidance and has considered the Scheme's compliance with the subsidy control principles. In particular, it clearly explains why OLS considered that a subsidy scheme is the most appropriate instrument (Principle E). It also sets out how the scheme is designed to ensure that additionality, proportionality, and potential distortions to competition are considered before individual grants are awarded, and that applicants must demonstrate, for each subsidy to be awarded under the Scheme, that the benefits would outweigh its negative effects.

2.3 However, we also identified the following areas for improvement:

(a) The Scheme covers a broad sector covering a range of different markets with different dynamics. The Assessment should focus on strategic areas where the Scheme is most likely to operate to allow OLS to better demonstrate the market failure and equity objective (Principle A) and to assess the overall impact of the Scheme (Principles F and G).

(b) While the Assessment demonstrates at a high level why the intervention is proportionate, it should explain more clearly why the level of the grant cap was set at 25% (Principle B).

(c) The Assessment should include a more systematic balancing exercise at Scheme level, ensuring that it includes all the benefits related to the policy objective, but also consider the extent to which the Scheme could have negative effects on international trade and investment, or how any geographical and distributional impacts have been taken into account (Principle G).

2.4 Our report is advisory only and does not directly assess whether the Scheme complies with the subsidy control requirements. The report does not constitute a recommendation on whether the Scheme should be implemented by OLS. We have not considered it necessary to provide any advice about how the Scheme may be modified to ensure compliance with the subsidy control requirements.[8]

[8] Section 59(3)(b) of the Act.

3. The SAU's Evaluation

3.1 This section sets out our evaluation of Assessment, following the four-step framework structure used by OLS.

Step 1: Identifying the policy objective, ensuring it addresses a market failure or equity concern, and determining whether a subsidy is the right tool to use

3.2 The first step involves an evaluation of the Assessment against:

(a) Principle A: Subsidies should pursue a specific policy objective in order to (a) remedy an identified market failure or (b) address an equity rationale (such as local or regional disadvantage, social difficulties or distributional concerns); and

(b) Principle E: Subsidies should be an appropriate policy instrument for achieving their specific policy objective and that objective cannot be achieved through other, less distortive, means.[9]

Policy objectives

3.3 The policy objective of LSIMF 25-30 is to expand the UK's life sciences manufacturing capacity and capabilities, to promote UK health resilience for a future pandemic and create economic opportunity.

3.4 The Assessment sets out that, despite the UK's significant investments in R&D, life sciences companies have tended to receive more favourable financial incentives (e.g. capital grants) from other countries, causing then to move their manufacturing capability offshore. This has led to a decrease in the UK's manufacturing capabilities over the last decade.

3.5 As a result, the Assessment states that the UK is losing out on opportunities to exploit innovation and achieve economic growth and that this decline will continue without further financial incentives.

3.6 The Assessment sets out these circumstances in the context of the Coronavirus (COVID-19) pandemic, which it says exposed the negative impacts of manufacturing decline, demonstrating that the UK population may be vulnerable to shortages of vital lifesaving medicines or technologies.

[9] Further information about the Principles A and E can be found in the Statutory Guidance (paragraphs 3.32 to 3.56) and the SAU Guidance (paragraphs 4.7 to 4.11).

3.7 The description of the policy objective in the Assessment focuses on UK health resilience for a future pandemic. In our view, the Assessment could frame the policy objective to better align with the rest of the Assessment and supporting evidence, which relates more to ensuring UK health resilience in general. Aside from this, we consider that the Assessment clearly describes the policy objective of the Scheme, which it supports with appropriate reasoning.

Market failure and equity objective

3.8 The Statutory Guidance sets out that:

(a) Market failure occurs where market forces alone do not produce an efficient outcome.[10]

(b) Equity objectives seek to reduce unequal or unfair outcomes between different groups in society or geographic areas.[11]

Market failure

3.9 The Assessment describes the market failure as an unreliable supply of medicines in the UK. It identifies the supply of medicines as a quasi-public good,[12] because it is non-excludable, meaning that consumers cannot choose their desired level of reliability without it being provided for everyone else.

3.10 The Assessment sets out that there is a risk of the UK having insufficient capacity to ensure a reliable supply of essential medications, thereby becoming a market failure if there is an undersupply of the public good in the absence of the proposed LSIMF scheme.[13]

3.11 OLS proposes that the LSIMF 25-30 will mitigate this market failure by (i) alleviating the uncertainty that businesses face in the current UK economic climate, which may lead to them withholding investment or disinvesting entirely; and (ii) addressing political economy considerations, such as the substantial international competition for investment, which may lead to businesses choosing alternatives to the UK if incentives are lacking.

3.12 In our view, although the reliability of medicine supply can reasonably be considered to exhibit public good characteristics, the Assessment should further engage with the evidence provided throughout to establish how this scheme is

[10] Statutory Guidance, paragraphs 3.35-3.48.
[11] Statutory Guidance, paragraphs 3.49-3.53.
[12] The Statutory Guidance defines a public good by two features: 'First, one person's consumption or enjoyment of the good or service will not diminish or deplete the amount of it available to others. Second, it is difficult to prevent people from accessing or enjoying the benefits of the good or service.', paragraph 3.41. In contrast, a quasi-public good has elements of a public good in being accessible to everyone, but still may be rivalrous in consumption and partially excludable.
[13] Statutory Guidance, paragraph 3.43.

specifically designed to remedy the market failure related to supply chain resilience. For example, although the Assessment gives examples of some medications that are facing shortages, the Assessment could be more granular in setting out the causes of supply chain resilience issues and how the Scheme would target these.

Equity objective

3.13 The Assessment sets out that improving the UK's access to medicines and minimising supply disruptions both in pandemic and non-pandemic times will also address an equity objective. The equity objective argument is articulated around two main considerations:

(a) relying on evidence from the coronavirus (COVID-19) pandemic, the Assessment explains that disadvantaged and minority groups are more likely to contract the disease, and to suffer its most severe consequences due to working in frontline jobs. The roll-out of a vaccination programme was key to end the pandemic; and

(b) outside of the pandemic, shortages of medicine can have a particularly negative impact on vulnerable groups, such as people with long-term health conditions who depend on specific medications to manage and alleviate these.

3.14 The Assessment explains that LSIMF 25-30 is an appropriate tool to address these inequities because increased onshore capacity to manufacture vaccines and other medicines will improve the reliability of the supply of medicines to the UK, in both pandemic and non-pandemic scenarios. It argues that this will reduce social or economic disadvantage, given the disproportionate impact that medicine shortages can have on vulnerable populations.

3.15 In our view, the Assessment describes and evidences credible equity objectives. However, it could more clearly describe how the Scheme will target the manufacturing of products that will directly address these inequities. It could also expressly clarify that the first consideration listed above would remain true in other pandemic situations than the COVID-19 pandemic.

Consideration of alternative policy options and why the Scheme is the most appropriate and least distortive instrument

3.16 In order to comply with Principle E, public authorities should consider why the decision to give a subsidy is the most appropriate instrument for addressing the

identified policy objective, and why other means are not appropriate for achieving the identified policy objective.[14]

3.17 The Assessment explains that OLS has considered a number of alternative options, from which it fully assessed three:

(a) Capital loans, which were dismissed as this would likely require 100% intervention rate compared to 10-20% for capital grants. OLS therefore believed that capital loans would support fewer projects and deliver lower economic benefits overall. The Assessment also argues that it would be more difficult to specifically target and deliver the policy objectives under a capital loans intervention.

(b) Tax incentives, which were dismissed because it would be difficult to link tax to specific key investments.

(c) Capital grants, which were selected as they would allow the public authority to specifically target strategic investments that will deliver the greatest benefit. Due to the greater capacity to set criteria for applications under capital grants, OLS argues that measures to limit distortions can also be directly implemented and monitored.

3.18 In our view, the Assessment adequately explains why a subsidy scheme is the most appropriate instrument.

Step 2: Ensuring that the subsidy is designed to create the right incentives for the beneficiary and bring about a change

3.19 The second step involves an evaluation of the assessment against:

(a) Principle C: First, subsidies should be designed to bring about a change of economic behaviour of the beneficiary. Second, that change, in relation to a subsidy, should be conducive to achieving its specific policy objective, and something that would not happen without the subsidy; and

(b) Principle D: Subsidies should not normally compensate for the costs the beneficiary would have funded in the absence of any subsidy.[15]

Counterfactual assessment

3.20 In assessing the counterfactual, the Statutory Guidance explains that public authorities should assess any change against a baseline of what would happen in

[14] Statutory Guidance, paragraphs 3.54-3.56.
[15] Further information about the Principles C and D can be found in the Statutory Guidance (paragraphs 3.57 to 3.71) and the SAU Guidance (paragraphs 4.12 to 4.14).

the absence of the subsidy (the 'do nothing' scenario').[16] This baseline would not necessarily be the current 'as is' situation (the 'status quo') but what would likely happen in the future – over both the long and short term – if no subsidy were awarded.

3.21 The Assessment identifies the counterfactual as the UK life sciences manufacturing capabilities not increasing to a level that will achieve sufficient health resilience. In a worst-case scenario, the UK would see a continued decline in manufacturing, with lost economic opportunities and a lack of capacity to increase health resilience. It sets out an analysis if trends in UK manufacturing activity (proxied by export volume and number of sites) compared to ten European, American and Asian countries.

3.22 In our view, the Assessment describes a credible counterfactual scenario where the policy objective would not be achieved, as life sciences manufacturing would continue declining. The Assessment could provide further evidence of the manufacturers' likely behaviour in such a scenario, to support the position that they would reduce their manufacturing capabilities. This could include evidence from potential beneficiaries and industry experts.

Changes in economic behaviour of the beneficiary

3.23 The Statutory Guidance sets out that subsidies must bring about something that would not have occurred without the subsidy.[17] In demonstrating this, public authorities should consider the likely change or additional net benefit.

3.24 The Assessment states that all subsidies under this Scheme must demonstrate that beneficiaries have been incentivised to change their economic behaviour as a result of the subsidy compared to the counterfactual of no subsidy (for example, that they would invest in the UK as opposed to overseas or not invest at all). The Assessment adds that Department for Science, Innovation and Technology accountants and economists will robustly challenge this analysis in due diligence reports, which is corroborated by an annex outlining the scope of the financial due diligence that will be undertaken.

3.25 The Assessment also explains the rationale and incentive effect of awarding subsidies to achieve the policy objective. By drawing on evidence comparing support to life sciences in the UK and EU countries, it states that a clear link exists between the lack of capital subsidies in the UK and the decline in manufacturing investment. The Assessment also points out that countries providing capital grants increase their share of investments.

[16] Statutory Guidance, paragraphs 3.60-3.62.
[17] Statutory Guidance, paragraph 3.64.

3.26 In our view, the Assessment sufficiently explains that the Scheme is designed only to include beneficiaries who demonstrate a change in behaviour. However, the Assessment could better explain how and the extent to which the change in the beneficiaries' behaviour will contribute to the policy objective - it could notably explain the type and scale of manufacturing projects needed to incentivise beneficiaries to expand their capacity and capabilities so that the Scheme achieves its policy objective.

Additionality assessment

3.27 According to the Statutory Guidance, 'additionality' means that subsidies should not be used to finance a project or activity that the beneficiary would have undertaken in a similar form, manner, and timeframe without the subsidy.[18] For schemes, public authorities should also, where possible and reasonable, ensure the Scheme's design can identify in advance and exclude those beneficiaries for which it can be reasonably determined would likely proceed with the project or activity without subsidy.[19]

3.28 The Assessment explains that the Scheme will ensure additionality because all individual grants will be assessed to ensure that they each meet the additionality principles. The appraisal will apply the Green Book's additionality principle.[20] For a project to be awarded a grant, OLS will need to be sure that the benefits associated with the project would not materialise without grant funding. The counterfactual could be that the project would either not go ahead at all, that it would go ahead overseas, that it would be smaller or significantly delayed.

3.29 The Assessment recognises the difficulty in predicting what would happen absent the subsidy. The additionality test therefore adjusts the project's estimated benefits for this risk. The Assessment supports this analysis in an annex, explaining the factors OLS would consider in changing the project's estimated benefits downwards.

3.30 The Assessment further notes that subsidies awarded under the Scheme are for additional, specific, identifiable capital investment costs and will not be provided to fund the routine functioning of the business, for example, in the form of an operating aid.

3.31 In our view, the Assessment demonstrates that the Scheme is adequately designed to identify applicants in advance and exclude those who would likely go

[18] Statutory Guidance, paragraphs 3.63-3.67.
[19] Statutory Guidance, paragraph 3.66
[20] https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government/the-green-book-2020

ahead regardless of the subsidy and also ensure that the subsidy does not fund business-as-usual (i.e. operating) costs.

Step 3: Considering the distortive impacts that the subsidy may have and keeping them as low as possible

3.32 The third step involves an evaluation of the assessment against:

(a) Principle B: Subsidies should be proportionate to their specific policy objective and limited to what is necessary to achieve it; and

(b) Principle F: Subsidies should be designed to achieve their specific policy objective while minimising any negative effects on competition or investment within the United Kingdom.[21]

Proportionality

3.33 The Assessment sets out that the Scheme will offer strategic grant funding to private sector investments that would best stimulate further growth in the life sciences sector. It concludes that the grant funding is therefore 'proportional to reverse the deficit and support economic recovery.'

3.34 Elsewhere in the Assessment, it states that LSIMF 25 – 30 will have a budget of £520 million to be allocated between financial years 2025/26 – 2029/30. It further notes that grants will contribute to a maximum of 25% of an applicant's capital expenditure costs, with no absolute cap on grant size. Based on previous schemes, the typical intervention rate for a project is expected to be between 10-20%.

3.35 The Assessment details elements of the Scheme that, by design, limit the intervention. The Scheme will be an open competition rather than a direct grant award, and a due diligence process will be followed to ensure that companies are only awarded grants proportional to the strategic benefits that their application provides. As part of that process, grant applications will be challenged by accountants and economists to ensure that awards are the minimum necessary.

3.36 Grant will be monitored based on clear performance criteria and milestones, with failure to meet these resulting in non-payment of grants and potential clawback. Monitoring and evaluation will typically last for ten years per project and cover key metrics and outputs. Finally, independent research will be undertaken on the performance of the Scheme as a whole against its objectives.

[21] Further information about the Principles B and F can be found in the Statutory Guidance (paragraphs 3.72 to 3.108) and the SAU Guidance (paragraphs 4.15 to 4.19).

3.37 In our view, the Assessment explains at a high level why the intervention is proportionate, including consideration of relevant design features, such as payment in arrears, due diligence and clawback mechanisms.

3.38 However, it should better explain why the grant cap was set at 25%, and why OLS did not include an absolute cap, as well as a relative one. It could also more clearly explore the scale of the Scheme compared to the markets it covers and the expected distribution of the size of awards, either based on evaluation of previous capital grant competitions for the life sciences sector or other evidence.

3.39 Finally, the Assessment should consider any other subsidies given to the same recipients for similar purposes (including under the pre-existing scheme) as part of the assessment of the proportionality of subsidies to individual beneficiaries, and how these have been taken into account when setting Scheme limits, in line with Statutory Guidance.[22]

Design of subsidy to minimise negative effects on competition and investment

3.40 The Assessment sets out that the Scheme will be an open competition rather than a direct award, and therefore the Scheme will not disadvantage particular firms as all eligible projects will be assessed on their merits. We agree that the Scheme being an open competition, rather than a direct award, should help to minimise distortions. Other aspects that are relevant to Principle F are considered elsewhere in the Assessment, including the nature of the subsidies being provided and the nature of the costs covered.

3.41 In our view, the Assessment should more systematically consider the design features listed in the Statutory Guidance, in particular how the Scheme ensures a sufficient breadth of beneficiaries, and how they contribute to minimising distortions.

Assessment of effects on competition or investment

3.42 The Assessment explains that the exact impact of the Scheme on competition and investment in the UK cannot be measured at this stage and will be assessed for each grant awarded under it. It notes that individual awards may have some distortionary effect on competitors' outputs, but that these effects are considered in individual appraisals and awards may be reduced to reflect this. It includes as evidence a guidance on how an individual subsidy's competitive impacts should be assessed, as well as a case study demonstrating the application of that guidance.

3.43 In our view, the Assessment clearly sets out the process and criteria to assess any competitive distortions, including those factors in Annex 3 of the Statutory

[22] See Statutory Guidance, paragraphs 3.91-3.92.

Guidance,[23] for each grant application, to avoid granting excessively distortive subsidies. However, the supporting case study appears limited and does not appear to fully follow this defined process and criteria.

3.44 As LSIMF 25-30 builds on previous schemes made to support life sciences manufacturing, the Assessment could also look at evidence of competitive impacts from previous competitions to demonstrate how the process has worked in the past. Alternatively, (or in addition) it could include case studies on those markets most likely to suffer distortions, to the extent they can be identified, to demonstrate appropriate application of the Scheme's process and criteria.

3.45 This could then be extrapolated to help give a sense of the scale of the Scheme-wide distortionary impacts. Having this information would also improve the balancing assessment under consideration of Principle G.

Step 4: Carrying out the balancing exercise

3.46 The fourth step involves an evaluation of the assessment against subsidy control Principle G: subsidies' beneficial effects (in terms of achieving their specific policy objective) should outweigh any negative effects, including in particular negative effects on: (a) competition or investment within the United Kingdom; (b) international trade or investment.[24]

3.47 The Assessment considers benefits on volume of private investment and jobs and estimates to deliver a benefit to cost ratio of 2.3. This does not include any estimate of the benefits to UK health resilience (though these are expected to be substantial). However, those benefits are scored separately at an individual application level, which may mean applications with lower benefit to cost ratio (at least 1.0) receive funding.

3.48 The Assessment sets out that each grant awarded will be assessed[25] to ensure that its benefits are greater than any harmful impacts (grants are not awarded unless the adjusted[26] benefits exceed the costs), and that because of this, the benefits of the Scheme can be considered a net positive.

3.49 The Assessment sets out that the subsidies do not seek to move existing investments from another location but are instead intended to incentivise a company to locate a new capability in the UK rather than elsewhere.

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[23] See Statutory Guidance (paragraphs 17.52 to 17.63)
[24] See Statutory Guidance (paragraphs 3.109 to 3.117) and SAU Guidance (paragraphs 4.20 to 4.22).
[25] The Assessment sets out that when appraising applications, OLS considers the benefits of the proposed investment and the likely impact on other economic activity in the UK, including the potential for negative impacts on the output of another company located in the UK (the applicant is required to provide information about potential competitors operating in the UK, as well as information on market prices).
[26] The benefits are adjusted in proportion to any expected negative impact on the output of another company located in the UK.

3.50 The Assessment further sets out that the Scheme will not create overcapacity in the life sciences manufacturing market because in the UK capacity has been declining while global customer demand is growing, and the subsidies are intended to secure investments to exploit and commercialise new activities and capitalise on the growth arising from them.

3.51 OLS conclude that while the exact impacts of the Scheme on competition and investment in the UK cannot be measured at this stage, the assessment of potential distortionary effects at individual award level under the Scheme (where the level of award can be reduced) helps to ensure that any negative effects on competitors are outweighed by the benefits of the Scheme.

3.52 In our view, the Assessment should adopt a more systematic approach to the balancing exercise, reflecting more clearly the framework for analysis presented in the Statutory Guidance.[27] In particular, the Assessment should ensure that the listed benefits are all related to the policy objective, and that any benefits linked with UK health resilience are appropriately considered.

3.53 Whilst we acknowledge that it can be difficult to predict the likely impacts of a scheme in advance, the Assessment should have considered the extent to which the Scheme could have negative effects on international trade and investment, or any geographical and distributional impacts.

Other Requirements of the Act

3.54 This step in the evaluation relates to the requirements and prohibitions set out in Chapter 2 of Part 2 of the Act, where these are applicable. OLS stated that none of the prohibitions or other requirements in relation to the giving of subsidies apply.[28]

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[27] See Statutory Guidance paragraphs 3.109 to 3.114.
[28] Statutory Guidance, chapter 5.