Department for
Business, Energy
& Industrial Strategy

Medicines and Diagnostics Manufacturing Transformation Fund

Scheme guidance

April 2021

Any enquiries regarding this publication should be sent to us at:
mdmtf@beis.gov.uk

Contents

Scheme objectives

The Department for Business, Energy and Industrial Strategy (BEIS) is launching the Medicines and Diagnostics Manufacturing Transformation Fund (MDMTF) to support businesses in bringing their prospective manufacturing investments to the UK. The fund will provide capital grant funding for investments related to the manufacture of human medicines, medical diagnostics and MedTech products.

The aim of the fund is to increase the manufacture of medicines, medical diagnostics and MedTech products in the UK, creating high value jobs and economic growth. We are particularly interested in providing support to projects which create economic opportunities and will manufacture products which contribute to the building of the UK's health resilience as well as projects which use innovative technologies and approaches to drive up productivity and/or lessen the impact of production on the environment.

The fund will open for applications on the 7 April 2021 and the deadline for receipt of applications is 11:59pm on 30 June 2021.

This is a 1-year fund and to be eligible, applicants must be able to defray at least the equivalent of the total amount of grant funding requested under this fund before March 2022.

Eligibility

Manufacturers may apply for the fund if they meet the 7 mandatory criteria below:

1. Company type

During the application process, you will be required to confirm that that you are:

- a private sector business making investments in the UK – as opposed to fully or partly state-owned
- proposing a project that is a single company investment – as opposed to a project using a partnership model between companies or other types of organisations
- a product developer, a contract/development manufacturing organisation or a generics manufacturer

2. Project type

During the application process, you will be asked to confirm that grant funding applied for is only sought for eligible costs. This could include:

- capital equipment which can include the cost of purchase and installation but not the cost of maintenance or those related to staff costs
- costs related to the construction of a new facility or adaptations to an existing facility
- commercial scale manufacturing
- pilot plants

3. Sectorial scope

During the application process you will be asked to confirm that you are either a manufacturer of:

- human medicines – small molecules, biologics (including vaccines), advanced therapies, viral vectors products, active pharmaceutical ingredients, and the manufacture of blood derived products, but excludes veterinary medicines, herbal medicines, nutritional supplements or vitamins
- medical diagnostics – for both disease identification and monitoring in human health
- MedTech – all types of medical devices related to human health

4. Costs

During the application process you will be asked to confirm that your total eligible costs are no lower than £8m.

There is no upper limit on the size of projects that apply into the fund. Companies can submit more than one application, but these must be for clearly distinct investments.

5. Regulatory requirements

For medicines manufacturers

During the application process you will be asked to confirm that:

- You hold a Good Manufacturing Practice (GMP) Human Medicines Directive or Investigational Medicinal Products Directive (IMP) licence or are intending to apply for one of these licences.
- During the application process you may be required to explain where you are in the process of obtaining one of these licences. If this is unclear, we may not be able to proceed in assessing your application. If you have stated that you will be applying for a site licence from a regulatory body, we will seek evidence of this as part of the monitoring process.

For medical diagnostics and MedTech device manufacturers

During the application process you will be asked to:

- Demonstrate that your device meets the requirement in the Medical Devices Regulations 2002 (as amended), including safety and performance. Standards, both horizontal and product specific, can be used to demonstrated compliance. Such standards including ISO 13485 covering quality management systems for medical device manufacturers, ISO 14971 covering risk management for medical devices and other process-specific standards, such as those covering sterilisation, may be relevant in demonstrating that suitable manufacturing processes are in place. See the full list of designated standards.
- During the application process you may be required to confirm that you intend to do this and how. We may seek evidence of this as part of the monitoring process. If this is unclear, we may not be able to proceed in assessing your application.

6. Delivery

During the application process you will be asked to confirm that you can proceed with the project without delay, within four weeks, following the agreement to a grant offer letter.

7. Subsidy control

EU State aid rules no longer apply in the UK except in respect of aid in scope of the Withdrawal Agreement, for example, Article 10 of the Northern Ireland Protocol.

Subsidies must instead meet the terms of the EU-UK Trade and Co-operation Agreement (TCA) as well as the other Free Trade Agreements we have reached with the rest of the world and our World Trade Organisation commitments.

All awards will be made under Section 7 or 8 of the Industrial Development Act 1982. Chapter 7 of our guidance on international commitments also sets out how the Northern Ireland Protocol should be applied to aid.

Any award of funding made to you will constitute a subsidy.

During the application process you will be asked to confirm:

- that you are not ailing or insolvent for the purposes of Subsidy Control compliance, and if Article 10 of the Northern Ireland Protocol may apply to your project or your company, then for the purposes of that Article you are not an 'undertaking in difficulty' within the meaning of EU State Aid rules
- if successful, that you understand that recovery of funds would be required in the event of any non-compliance with subsidy control requirements

Further information on eligibility

The fund is not open to supply chain companies such as:

- manufacturers of input materials used in the production of Medicines, Medical Diagnostics or MedTech products
- equipment suppliers to a Medicines, Medical Diagnostics or MedTech company

The fund also cannot support:

- salaries or consumables
- R&D related to product development
- training costs
- costs associated with the completion of the grant application

During the application process, you will also be asked to confirm that the project cannot viably proceed without public sector support.

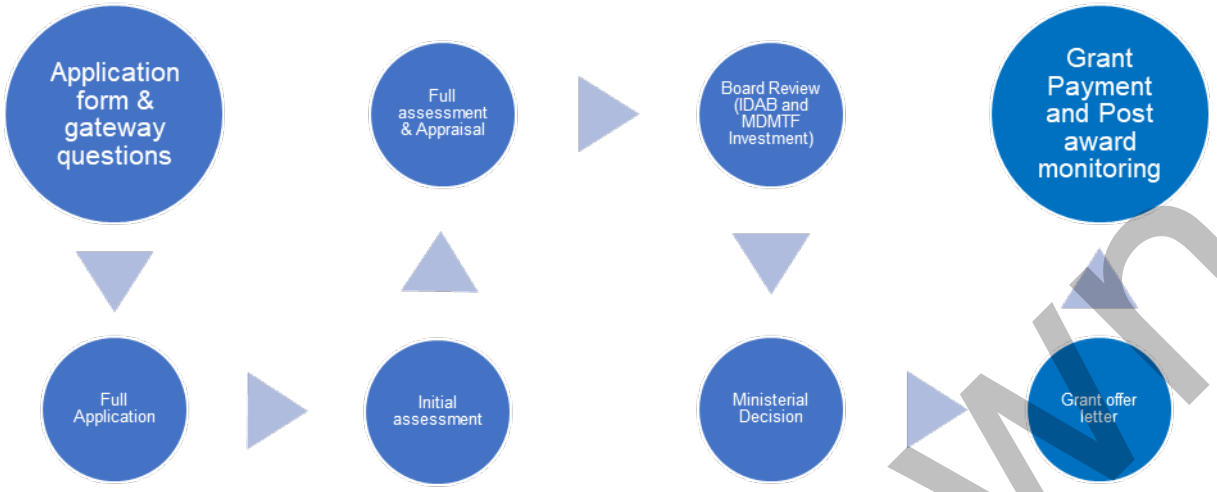
Support and advice

General questions about the application process and documentation should be sent to MDMTF@beis.gov.uk

If in preparing an application there are any clarifications required, Applicants should consult the guidance provided within this document. If the issue remains, Applicants should email MDMTF@beis.gov.uk with the subject heading: MDMTF Application Clarification [Project title], along with their query. It should be noted that if clarifications are deemed to be of relevance to other Applicants (or potential Applicants), the question and answer may be made available to others.

If an Applicant considers that their clarification is confidential, they should make such confidentiality expressly clear in the subject title of their email. Marking a clarification as confidential does not mean that BEIS will not make the clarification and response available to other Applicants or potential Applicants – it simply means that BEIS may redact or edit the clarification such that relevant information may be disclosed.

Assessment and decision-making process



Stage 1: Application and gateway questions

Five gateway questions must be answered to determine whether an application meets basic eligibility criteria. The Applicant can then proceed to completion of the full Application Form.

Stage 2: Full application

Throughout the Application Form, any gaps, omissions or responses to questions which are not compliant with the eligibility and/or rules of the fund will prevent the Applicant from completing that relevant section and submission of a completed form.

The full set of application questions must be completed to progress to the assessment stage. All fully completed application questions will move on to the initial sift stage.

Stage 3: Initial assessment

The initial sift of applications involves an assessment against the criteria of the fund, project deliverability and an initial financial viability check. This will enable us to identify applications that have a strong fit with our objectives of economic growth, health resilience and deployment of innovative technologies. Following the sift:

- Applications that fail to meet the strategic criteria of the fund and/or are not seen to be deliverable or fail the initial financial assessment will be informed that they have been unsuccessful.
- Applications that strongly align with both the strategic criteria of the fund, deliverability, and satisfy the initial financial assessment will progress straight to the full assessment. At this stage, BEIS will appoint a Case Officer who will act as the Applicant's initial point

of contact throughout the remainder of the process. Moving to the full assessment stage does not guarantee that grant funding will ultimately be awarded.

- Applications that are considered deliverable, satisfy the initial financial assessment but demonstrate only moderate alignment with the strategic criteria of the fund, will be placed on hold until the close of the fund. At this point we will either take projects through to a full assessment or Applicants will be informed that have been unsuccessful.
- If no application meets the strategic criteria of the fund, deliverability and initial financial assessment then no grant funding will be awarded.
- Notwithstanding the conclusion of this initial sift, if, at any time during this assessment process, it is determined upon closer investigation that an application does not pass the requirements of the broad strategic criteria of the fund, deliverability and/or financial assessment, BEIS reserves the right to discontinue that assessment and notify the Applicant that their application will be refused and not be progressed.

Stage 4: Full assessment and appraisal

At this stage, BEIS will undertake a full assessment of applications. During the full assessment stage, the appointed Case Officer may request further details in relation to applications and it is essential that these requests are responded to within the time specified (as set out by the Case Officer). Failure to do so may result in an application being rejected / refused.

Further requests may cover a range of topics and may include a request to supply executive decision-making documents supporting the proposed project (for example, demonstrating the approval of authorised individuals to apply to the fund).

Full assessment will consist of an economic and further financial assessment. This assessment will (amongst other things) consider the evidence to support the funding and need for grant, the expected outcomes and the deliverability of the project.

As part of the economic and financial assessment, BEIS will assess (amongst other things) factors including Value for Money and additionality (including an assessment of the counterfactual case), in line with Green Book guidance. This guidance is aimed at public servants and sets out an approach to appraising policies, programmes, and projects, including models and methods to support the provision of advice to clarify the social – or public – welfare costs, benefits, and trade-offs of alternative implementation options for the delivery of policy objectives.

There is no requirement on Applicants to ensure compliance with these approaches - however, as this Guidance Document and principles will be used in assessing applications it can be a useful point of reference for Applicants developing the business case for projects.

Stage 5: Board review

Once full assessments have been undertaken by BEIS, the Industrial Development Advisory Board (IDAB) or – for grant applications under £5m - an internal MDMTF investment board will be asked to advise on the applications. The Board will be asked to advise on whether the full amount of grant requested is appropriate and if not what level of grant funding would be appropriate.

Stage 6: Ministerial decision

Following the completion of the assessment process, ministers will be presented with the full results of the assessment and IDAB advice relating to any application.

The agreement to make an offer to an Applicant will be taken by ministers, taking account of all relevant matters in respect of an application and fit with strategic priorities.

Ministers retain full discretion in whether, and what, offers of public funds they make to Applicants - considering all the factors outlined in the application process.

Stage 7: Grant offer letter

If applications have been successful, BEIS will set out to the Applicant the level of grant the department is prepared to offer in the form of a grant offer letter. This will set out the specific conditions of the grant award. The level of grant will be non-negotiable.

Once an Applicant has received the grant offer letter, they must confirm within ten working days (or such other time as BEIS reasonably requires) whether they will accept the terms and conditions of the grant offer and proceed with the project. Failure to do so can result in the offer being retracted by BEIS.

Stage 8: Grant payment and post-award monitoring

A Monitoring Officer will be appointed to the successful Applicant for the duration of the project to ensure value for money and deliverability. The Monitoring Officer will explain monitoring requirements, which will be in line with Managing Public Money guidance. Grant recipients will typically need to complete and provide various monitoring reports on a quarterly basis (or more regularly where the Grant Funding Agreement sets this out). All relevant information will be provided in the grant offer letter.

Applicants may be contacted at various stages for evaluation purposes to help inform the design and development of future schemes.

This publication is available from: www.gov.uk/government/publications/medicines-and-diagnostics-manufacturing-transformation-fund

If you need a version of this document in a more accessible format, please email enquiries@beis.gov.uk. Please tell us what format you need. It will help us if you say what assistive technology you use.