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Department of Enterprise,
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Call for Expression of Interest
Important Projects of Common European Interest (IPCEI) on Health

Criteria and Scope of Call

The Department of Enterprise, Trade and Employment invites project proposals under this call for expression of interest for the Important Project of Common European Interest (IPCEI) on Health. This call is intended to identify businesses active in the field of biopharmaceuticals, MedTech, and health that may wish to put forward projects that could fit within the scope of the upcoming Health IPCEI and, accordingly, be considered for possible funding.

Background

The COVID-19 pandemic has disrupted most health product supply chains (lack of production capacity, logistical challenges/difficulties etc.) and has created very high expectations among European citizens for improved co-ordination of Member States in the health field.

The crisis has further highlighted the market failures that characterise the health sector, leading to shortages of products that are essential to the health of Europeans, and hindering innovation and deployment of major medical advances in certain therapeutic areas. The need to accelerate medical research, to push for better co-ordination between actors to rapidly deploy care solutions, and to support the development of additional production capacity to cope with a sudden increase in demand has also been highlighted. Finally, the pandemic has underlined the EU's difficulties in developing products and medicines which currently have less market potential and which could be needed.

While Europe is very active in terms of the number of publications in health, analysis shows that it fails to transform the results of this research into patents, commercial and industrial applications. Action is needed now to enable the development of projects encompassing: R&D in key therapeutic areas; process innovation, especially in the area of biologics; innovative and essential manufacturing activities in the field of bioproduction capacities, building spare, flexible capacity for pandemic situations; securing/increasing production capacity (i.e. active pharmaceutical ingredients, medicines of key therapeutic interest); and strengthen digitalisation capabilities (e.g. data management) across the health value chain. These projects will enable industry within the EU to strengthen its competitiveness globally while contributing to some of Europe's key societal goals of strategic autonomy and health resilience.

As such, an IPCEI designed to respond to market failures in the health sector and to support the development of health innovations on a European scale has been proposed. It is expected that this IPCEI will contribute to three objectives of common European interest:

i. Fostering the deployment of major medical advances in therapeutic areas that will help to shape the health of tomorrow and improve patients' quality of care
ii. Reinforcing the European Union's capabilities and capacity, notably through the development of innovative production processes along the entire value chain; and
iii. Building an industrial tool for responding to unmet medical needs and preparing for health crises, with the aim of strengthening Europe's resilience.

Timelines

It is intended that pre-notification (part of the State aid process) will take place in Q1 2022 with notification in H1 2022. This will allow implementation to begin before the end of 2022.

Scope

The Health IPCEI is expected to cover four main themes / axes:

1) The modernisation of production processes
2) Innovative products in new therapeutical areas
3) Personalised medicine and MedTech
4) Health crisis preparedness

1. <u>The modernisation of production processes</u>

The modernisation of production processes axis aims to increase the European production of intermediates and precursors of active principles, in addition to developing green health production processes.

Examples of projects in this area could include:

- Seeking to promote the ecological transition of production processes in Med Tech. For example, some current manufacturing processes, typically in the field of optics, can generate a significant amount of waste
- Developing industrial microbiological control solutions, enabling quality control as close as possible to the bioproduction chain
- Manufacturing processes for medical devices using new manufacturing methods (e.g., 3D printers), allowing for greater efficiency in terms of costs and environmental externalities, as well as better customisation and adaptation of the offer to demand.

2. <u>Innovative products in new therapeutical areas</u>

The aim of this axis is to improve the effectiveness, safety, and production costs of new innovative and promising technologies for the development of new treatments, for example, as drug conjugates, cell and gene therapy, viral vectors, mRNA, etc.

The research, development, and production costs of cell and gene therapies (CGTs) are seen as very high and there is an opportunity to develop and bring them to market at more reasonable

prices for the patient and the taxpayer. Building a strong research and production apparatus in CGTs could give Irish and European citizens access to innovative and affordable treatments. Thus, this would give companies based in Ireland and in Europe a global leadership in health innovation.

In addition, there is a need to develop efficient and less costly industrial processes in the field of bioproduction. Analysis indicates that the EU does not have a sufficiently efficient industrial apparatus in this area, as evidenced for example, in the difficulties in developing and producing vaccines to deal with the health crisis. Mastering these production technologies is a key industrial and health issue for the coming decades.

Therefore, examples of projects in this area could include:

- Efforts to reduce the cost of research, development, and production costs of CGTs and Advanced therapy medicinal products (ATMPs) including by developing more innovative processes
- Developing efficient and less costly industrial processes in the field of bioproduction
- More sustainable and environmentally friendly processes.

3. Personalised medicine and MedTech

The scope of this axis is for personalised medicine and MedTech. It aims to offer personalised treatments in certain therapeutic areas, notably oncology, to develop certain technologies, such as digital twins and the improvement of medical imaging, and to promote the interoperability of data produced by medical devices.

Individual medical devices are increasingly connected, i.e., capable of producing, processing, and sending data. However, given the fragmentation of the market, there is currently no single communication system. It is seen as time-consuming and costly for companies to make their products interoperable and to harmonise their data processing systems.

This area will focus, in particular, on the production of medical devices, allowing better personalisation of treatments, the improvement of oncology treatments and medical imaging technologies. Projects in this area could include:

- Medical imaging with disruptive innovation projects in production processes as well as in diagnostic efficiency
- Systems enabling the interoperability of data produced by medical devices and the development of health software
- Developing platforms for information sharing and assisting project leaders, notably facilitating the clinical trial phase
- Optimising the use of data and AI in the area of health
- Promoting research into and development of innovative treatments for cancer:

- Developing innovative products in oncology
- Personalised use of nuclear medicine to improve the diagnosis and treatment of cancers
- Further developing flash radiotherapy
- Enhancing the detection of tumours by medical imaging assisted by AI.

4. Health crisis preparedness

The health crisis preparedness axis aims to allow organised European responses to health risks (in support of the aim and purpose of the EU Health Emergency Preparedness and Response Authority (HERA)), including providing Europe with flexible and modular production capacities for vaccines of all technologies or other medical countermeasures. It will also enable the anticipation of public health risks, such as antibiotic resistance or emerging infectious diseases.

Projects under this axis could include:

- building up available and flexible biomanufacturing capacities across the value chain in the EU
- encouraging the rational use of existing antibiotics (in particular through the "One Health" strategy)
- research into new antibiotics
- developing and producing new antibiotics
- innovative research into fighting emerging infectious diseases
- developing and producing treatments for emerging infectious diseases.

Criteria

It is hoped that these projects can be supported as an "Important Project of Common European Interest" according to Art. 107(3)(b) of the Treaty of the Functioning of the European Union. Specific criteria for the assessment of compatibility of State aid to promote the execution of IPCEI projects are further elaborated in European Commission's Communication no. 2014/C 188/2.[1]

Specific criteria set out in the State aid Communication on IPCEI

i. R&I projects must be of a major innovative nature or constitute an important added value in terms of R&I in light of the state-of-the-art in the sector concerned.

ii. Projects comprising of first industrial deployment must allow for the development of a new product or service with high research and innovation content and/or the deployment of a fundamentally innovative production process. Regular upgrades without an innovative dimension of existing facilities and the development of newer versions of existing products do not qualify as IPCEI.

[1] 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 (europa.eu)

- First industrial deployment 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, but neither mass production nor commercial activities. First industrial deployment activities can be financed with State aid as long as the first industrial deployment follows on from an R&D&I activity and itself contains a very important R&D&I component which constitutes an integral and necessary element for the successful implementation of the project. The first industrial deployment does not need to be carried out by the same entity that carried out the R&D&I activity, as long as the former acquires the rights to use the results from the previous R&D&I activity, and the R&D&I activity and the first industrial deployment are both covered by the project.

iii. Environmental, energy or transport projects must either be of great importance for the environmental, energy (including security of energy supply), or transport strategy of the Union or contribute significantly to the internal market, including, but not limited to, those specific sectors.
   - For this criterion, the project must be quantitatively or qualitatively important; either particularly large in size or scope and/or imply a very considerable level of technological or financial risk

Conditions

Participation of projects in this Health IPCEI, in addition to conditions stipulated in related Commission Regulations, shall be subject to the following conditions and **the proposal submitted should clearly address each of these**:

1. Applicants must form part of the health value chain (from research to raw materials, to processing right through to the recycling, and if unavoidable, disposal of products)
2. Proposed projects shall be implemented in Ireland
3. Proposed projects shall meet one or more of the specific criteria set out in the State aid Communication on IPCEI
4. Applicants will be required to be able to demonstrate prior work in the relevant area
5. Applicants will be required to provide evidence that the proposed project differs significantly from the existing “state of the art" and are of a highly innovative nature
6. State Aid may only be provided if the applicant can convincingly demonstrate that, under market conditions, the proposed project could not be financed or implemented without the funding
7. The proposed project should be of significant size/ambition to make a significant contribution to major European strategies
8. The proposed project must involve co-financing by the beneficiary

9. The benefits of the project must not be limited to the undertakings or to the sector concerned but must be of wider relevance and application to the European economy or society through positive spill-over effects, which are clearly defined in a concrete and identifiable manner
10. The project will have to be carried out either by:
    i. a company
    ii. a research organisation; or
    iii. a consortium of one or more companies and / or one or more research organisations

    Start-ups are eligible, in which case the proposal must be submitted by future shareholders.
11. Applicants must not be
    i. undertakings which are subject to an outstanding recovery order following a previous European Commission decision declaring an aid illegal and incompatible with the internal market; or
    ii. an undertaking in difficulty according to the definition of the European Commission Guidelines on State aid for rescuing and restructuring non-financial undertaking in difficulty ((2014/C 249/01) Article 2 point 2.2).

The above conditions will form the second stage of the evaluation. Proposals determined not to have addressed the above conditions sufficiently will not be considered for the next stage of the evaluation.

Selection Criteria

The following selection criteria will also be taken into consideration when evaluating proposals and **should be addressed in the proposals**:

A. *Relevance to National and EU objectives and strategies*

   The primary focus of this IPCEI is on meeting three objectives of common European interest:

   i. Foster the deployment of major medical advances in therapeutic areas that will help to shape the health of tomorrow and improve patients' quality of care
   ii. Reinforce the European Union's capabilities and capacity, notably through the development of innovative production processes along the entire value chain; and
   iii. Contribute to building an industrial tool for responding to unmet medical needs and preparing for health crises, with the aim of strengthening Europe's resilience.

   The proposed project should fall under one of the four themes / axes identified:

1) The modernisation of production processes
2) Innovative products in new therapeutical areas
3) Personalised medicine and MedTech
4) Health crisis preparedness

The proposed project must contribute, in a concrete, clear and identifiable manner, to one or more Union objectives and must have a significant impact on competitiveness of the Union, sustainable growth, addressing societal challenges or value creation across the Union. These include, in particular objectives set out in the European Green Deal, the Digital Strategy and European Strategy for Data, the New Industrial Strategy for Europe, Next Generation EU, the new European Research Area for Research and Innovation, the new Circular Economy Action Plan, EU4Health, the Pharmaceutical Strategy for Europe, Europe's Beating Cancer Plan, the future work of HERA, and / or the EU's objective to become climate neutral by 2050.

The proposal should set out how the proposed projects meets both the scope and objectives of the IPCEI, how it will contribute to the objectives of the European Union, as well as how it aligns with national priorities and strategies.

B. *Innovative and value-added products or services developed*
The proposal should set out how the proposed project is beyond global state of the art for the sector. The proposal must meet the specific criteria as set out in the State aid communication for IPCEI outlined above.

C. *Quality and relevance of proposed partnerships*
The proposal should set out how benefits of the proposed project must not be limited to the undertakings or to the sector concerned but must be of wider relevance and application to the EU economy or society including through positive spillover effects (such as having systemic effects on multiple levels of the value chain, or up- or downstream markets, or having alternative uses in other sectors or modal shift) which are clearly defined in a concrete and identifiable manner.

D. *Quality of business model, business plan and financing presented*
The proposal should give a clear, high-level outline of the proposed project, with timelines and costings included. The proposal should clearly show that under market conditions the proposed project could not be financed or implemented without the State aid funding.

E. *Socio-economic impact and expected benefits*
The proposal should set out how the proposed project will benefit the Irish and EU economy and wider national and European society. Positive indicators here will include

how the proposed project will support national and EU competitiveness, sustainable growth, addressing societal challenges and / or value creation across the Union. In particular, a clear indication of how the proposed project will support the development of the wider health value chain will be positively received.

F. *Environmental impacts and, if necessary, expected positive effects from an ecological point of view*

Within the proposal, any expected impacts to the environment should be set out and any positive environmental effects identified along with an indication of how these can be measured provided.

Positive indicators here include indications of how the proposed project helps to achieve national and European green objects, supports climate targets, addresses the phasing out of harmful substances and / or includes information on mitigating actions that will be taken to ensure any negative impacts on the environment are limited.

Submitting a Proposal

Companies, in particular SMEs (as defined by the European Commission[2]), and / or consortia from the field of biopharmaceuticals, MedTech and health and other companies in the relevant value chains with research and production in Ireland that are willing to participate in an integrated European project can submit their project proposals, expressing their interest in possible funding, by **noon on 8 October 2021**. These should be sent, using the proposal template, to industrialpolicy@enterprise.gov.ie with *Health IPCEI Proposal* as the subject line.

The submission of a project concept within the framework of the expression of interest neither establishes a claim to, nor is it a prerequisite for, public funding in the intended IPCEI or any other form of public funding.

Evaluation

All proposals will be evaluated by a team of experts as part of a multi-stage process.

- The first stage of this process will be to ensure all sections of the proposal template have been completed and the proposal is no more than 10 pages, excluding the cover page. Incomplete proposals or those more than 10 pages in length (excluding the cover page) will not progress to the next stage of the evaluation.
- The second stage will evaluate the proposals against the conditions set out above. Proposals determined not to have addressed these conditions sufficiently will not be considered for the next stage of the evaluation.

[2] 'The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.' Extract of Article 2 of the annex to Recommendation 2003/361/EC

- The third stage will be a more detailed evaluation using the selection criteria outlined above.
- Depending on the number and quality of proposals received, an initial selection or shortlisting of proposals may be required at this point.
- These shortlisted applicants may then be asked to provide greater detail on the proposal submitted and / or participate in an interview / presentation stage.

It should be noted that selection at a national level does not guarantee inclusion in the IPCEI. All proposals must fit into the overall IPCEI and be approved by DG COMP during the State aid notification process.

The decision of the evaluation team is final and no further negotiations or conversations will be entered into once a decision has been made.

Contacts

For any queries, please first see the FAQs.
For anything further, please contact industrialpolicy@enterprise.gov.ie.

Confidentiality

All parties involved in this call for expression of interest for participation in the Health IPCEI make a commitment to ensure the confidentiality of all documents, and information sent as a result of an application related to this call, regardless of result of pre-selection process.