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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT
Accompanying the document

Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe

European Partnership on Innovative Health

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 37 final}

Impact assessment of a European Partnership on Innovative Health
A. Need for action
What is the problem and why is it a problem at EU level?
The EU suffers from the fact that its excellent health research does not translate sufficiently into innovative products and services to improve people's health. In parallel, the EU is at risk of losing its global leadership in health and care. These problems result from: - incomplete understanding of diseases; - insufficient collaboration between academia and the health industry; - limited collaboration across industry sectors; and - market barriers that affect the uptake of innovation in health and care. If not tackled, these problems will result in a decline of health research and innovation (R&I) activities in the EU and in limited improvement in the quality of healthcare, negatively impacting public health and wellbeing. The proposed initiative addresses these challenges and responds to the main recommendation from the interim evaluation of the predecessor initiative, the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU), i.e. to enable the active engagement of industry sectors other than the pharmaceutical industry.
What should be achieved?
- a contribution to the creation of an EU-wide health R&I ecosystem that facilitates the translation of scientific knowledge into innovations that respond to the needs of end-users, patients and healthcare professionals; - a facilitated development of people-centred innovations that address unmet public health needs; and - a more competitive EU health industry thanks to enhanced cross-sectoral collaboration.
What is the value added of action at the EU level (subsidiarity)?
Health challenges are global in nature and so is the R&I needed to address them. Most health-related legal frameworks regulating the development and market introduction of novel health technologies (e.g. on clinical trials, medicinal products, medical devices, in-vitro diagnostics and advanced therapies) are based on EU regulatory frameworks. Most companies active in the field of health have an EU-wide presence. The initiative's scope and scale go beyond the capacity of individual Member States and require the mobilisation of resources and stakeholders at EU level.
B. Solutions
What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?
The options are as follows: - regular Horizon Europe calls; - a co-programmed partnership; and - an institutionalised partnership under Article 187 TFEU. An institutionalised partnership is the preferred option. It offers the best ratio of cost versus impact, also

taking account of the associated risks, and promises to deliver efficiently on the objectives and achieve the expected impacts.

What are different stakeholders' views? Who supports which option?

The institutionalised partnership option enjoyed the most support in all consultation activities, in all stakeholder categories (Member States, industry associations, researchers, public authorities, NGOs and the general public). Thanks to long-term commitment and funding, it was considered to be the most effective in terms of scientific, economic and societal impacts. The legally binding arrangement was appreciated as offering confidence, in particular on intellectual property management, hence facilitating the sharing of data required to realise impacts. All stakeholder groups, but in particular the public sector, saw the opportunity to play a key role in research agenda setting as crucial for achieving societal impact.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise of main ones)?

An institutionalised partnership would best ensure that the private and public sectors remain fully engaged in the implementation of a jointly agreed, long-term strategy for health R&I. It is consistent with leveraging industrial financial and in-kind resources to maximise the impact of EU funding. It would support the development of a strategy for health innovation that is fully aligned with the Commission's political priorities. The preferred option would also enable the setting-up of a Programme Office for dedicated administrative support, coordination and communication activities.

What are the costs of the preferred option (if any, otherwise of main ones)?

The EU and member industry associations will jointly fund the partnership, with the latter providing at least 50% of the total budget. The partners will also need to mobilise the resources required to cover the operational costs of funded actions and the administrative costs of the Programme Office. The associations will also undertake additional activities, as stipulated in the legislative act.

What are the impacts on SMEs and competitiveness?

Thanks to the close interaction of the health industry (including SMEs) with academia, all partners would strengthen their scientific base to deliver innovative health solutions. Thereby, and with the early involvement of other public health actors, the industry would be able to respond better to the needs of end-users, i.e. patients, healthcare professionals and health care providers. It would also improve their competitive position in global markets and strengthen the EU's economy and technological sovereignty. The integration of several industry sectors would create a more agile and SME-friendly collaborative R&I ecosystem.

Will there be significant impacts on national budgets and administrations?

No significant impact on national budgets and administrations.

Will there be other significant impacts?

Positive contribution on fundamental rights (right to health and right to access to health care, including preventive and treatment-related care);

Newly developed data-based health products and digital tools could have implications for the handling of personal health data and hence privacy rights;

The digital tools could positively impact the 'smart health' value chain and standardisation, supporting EU industrial leadership; No impact on simplification, regulatory aspects or administrative burdens.
Proportionality?
The preferred option is proportional to what is necessary to tackle the problems in question.
D. Follow up
When will the policy be reviewed?
The initiative would be reviewed in line with the Horizon Europe provisions and decisions to be laid down in the relevant Council Regulation.