EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2013)

Opinion

Title **DG RTD - Impact Assessment on a Council Regulation defining the objectives, legal status and operational rules of the Innovative Medicines Initiative Joint Undertaking for the period 2014-2024**

(draft version of 13 February 2013)*

(A) Context

Innovative Medicines Initiative (IMI) is a public-private partnership between the European Commission and the biopharmaceutical industry represented by its umbrella organisation the European Federation of Pharmaceutical Industries and Associations (EFPIA). It was established in 2008 (runs until 2017) and has a budget of €2 billion, equally shared between the partners. The objective of IMI is to improve the drug development process by supporting a more efficient discovery and development of better and safer medicines for patients.

The IMI2 is based on the Commission's proposal for the "Horizon 2020 Framework Programme for Research and Innovation in the European Union (2014-2020)" that provides a basis for future EU PPPs in Research and Innovation. The focus of IAB analysis has been adapted accordingly.

(B) Overall opinion

The report should be improved in a number of respects. It should explain the key challenges and barriers for biomedical research and development requiring public intervention at EU level, and explain at which stage of the innovation cycle they mostly occur. In this context it should clarify the concrete competitiveness issues that need to be addressed by IMI2. The report should clarify the policy choices still available for IMI2 within the Horizon 2020 context and how the recommendations from the interim evaluation and stakeholder input have been taken into account. It should then clarify which objectives and numerical targets can be reached with the different budgets proposed. In particular it should demonstrate how the significant budget increase proposed will lead to an effective and efficient achievement of the objectives. Finally, the report should improve the presentation of stakeholder views, in particular, explaining which stakeholder groups have (more) critical views and how those have been addressed.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Strengthen the policy context and problem definition. The report should better describe the scope, governance, financial and funding rules of the current IMI programme, as well as its link with the Horizon 2020 Framework Programme in order to clarify how the policy change options proposed differ. The report should also describe in greater detail the role of public intervention/ownership to overcome such problems, using examples from countries where a share of public companies is higher, such as the US. It should also better explain what concrete competitiveness issues need to be addressed by IMI2. It should develop a more complete baseline scenario by describing how the development of necessary biopharmaceutical interventions is likely to evolve with no further EU action taking place.

(2) Better present the objectives and corresponding monitoring indicators. The report should set a clear hierarchy of objectives by explaining the linkages among numerous specific and operational objectives. The objectives need to be aligned with the budget available (baseline € 1 billion). For the proposed budget increase, the report should clarify which additional objectives (and their numeric targets) can be achieved. While the problem definition is rather general covering broad issues such as the high failure risk of medical research and low productivity, the specific objectives are so detailed and precise that it is unclear how they relate to the broad problems and drivers identified. The report should therefore align the objectives and options more closely to the issues being addressed by this initiative taking into account the parameter already set in Horizon 2020. As many of the indicators suggested are simply participation statistics, the report needs to develop progress indicators that measure the effectiveness and efficiency of the policy. Furthermore, the overall intervention logic could be better explained by adding a clear problem tree.

(3) Better present, assess and compare the options. The report should describe what the available policy options are within the Horizon 2020 framework, focusing more on options of how to improve the IMI2 based on the recommendations from the interim evaluation and stakeholder input. It should provide a more systematic description of the components of the options under consideration, including their scope, financing rules and governance arrangements. It should also better explain and justify the discarded options. The report should then explain what the differences between options would actually imply for setting the strategic research agenda, selecting the projects, as well as financing levels and sources. It should also explain why an option where Member States are expected to contribute to the JU alongside the Commission and industry was not considered. The report should better justify the significant budget increase proposed by explaining what practical results (e.g. specific innovations, classification of diseases and overall health impacts) can be achieved with each additional €500 million and the extra conditionality each additional funding would entail. It should clarify if the higher budget will be also met by the industry. The report should at least indicate the magnitude of impacts of different options, where exact quantification is not possible. The assessment of impacts should be underpinned by more concrete evidence supporting or justifying the conclusions. The report should quantify any significant change in administrative burden, including any reduction resulting from the new JTI option for the potential programme beneficiaries. It should strengthen the assessment of the efficiency and effectiveness of different options in order to demonstrate that the preferred one is the most cost-effective solution to the problems identified. Finally, the report should assess and compare options in terms of the effectiveness, efficiency and coherence by which the objectives are reached.

(4) Better present stakeholder views. The report should clarify the views of all relevant stakeholder groups and explain how (more) critical views from those groups have been addressed. It should reflect stakeholders' views in a more balanced way throughout the report (including the most involved as academia and industry).

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report

(D) Procedure and presentation

The report should provide a glossary with the definitions of most frequent technical terms used. The report should be shorter, moving all non-essential information (e.g. large part of the industry description) to an annex. The executive summary should be revised in order to meet the standards required in the IA Guidelines.

(E) IAB scrutiny process	
Reference number	2013/RTD/008
External expertise used	No
Date of IAB meeting	13 March 2013 (Written Procedure)