

RESOLUTION (EU) 2020/1854 OF THE EUROPEAN PARLIAMENT**of 14 May 2020****with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative 2 Joint Undertaking for the financial year 2018**

THE EUROPEAN PARLIAMENT,

- having regard to its decision on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative 2 Joint Undertaking for the financial year 2018,
 - having regard to Rule 100 of and Annex V to its Rules of Procedure,
 - having regard to the report of the Committee on Budgetary Control (A9-0046/2020),
- A. whereas the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines ('IMI Joint Undertaking') was set up in December 2007 for a period of 10 years to improve significantly the efficiency and effectiveness of the drug development process with the long-term aim of the pharmaceutical sector producing more effective and safer innovative medicines;
- B. whereas, following the adoption of Council Regulation (EU) No 557/2014 ⁽¹⁾ in May 2014, the Innovative Medicines Initiative 2 Joint Undertaking ('IMI2 Joint Undertaking') was established for the period up to 31 December 2024; whereas it replaces and follows the IMI Joint Undertaking in June 2014 with the aim of finalising research activities under the Seventh Framework Programme and launching a new project in the Horizon 2020 framework;
- C. whereas the Union, which is represented by the Commission, and the European Federation of Pharmaceutical Industries and Associations are the founding members of the IMI Joint Undertaking and IMI2 Joint Undertaking;
- D. whereas the maximum contribution from the Union to the IMI Joint Undertaking is EUR 1 000 000 000 for the period of 10 years, to be paid from the budget of the Seventh Framework Programme and the founding members are to contribute equally to the running costs, each with an amount not exceeding 4 % of the total Union contribution;
- E. whereas the maximum contribution, for the period of 10 years, from the Union to the IMI2 Joint Undertaking is EUR 1 638 000 000, to be paid from the budget of Horizon 2020 and the members, other than the Commission, have to contribute 50 % of the running costs and should contribute to operational costs through cash or in-kind contributions, or both, equal to the financial contribution of the Union;

Budgetary and financial management

1. Notes that the report of the Court of Auditors (the 'Court') on the IMI2 Joint Undertaking's annual accounts for the financial year 2018 (the 'Court's report') finds the annual accounts to be presented fairly, in all material respects, with regard to the IMI2 Joint Undertaking's financial position on 31 December 2018 and the results of its operations, its cash flows, and the changes in its net assets for the year then ended, in accordance with its financial regulation and with the accounting rules adopted by the Commission's accounting officer;
2. Notes the opinion of the Court on the legality and regularity of transactions underlying the annual accounts of the IMI2 Joint Undertaking for the year 2018, which concluded that those transactions are legal and regular in all material respects;
3. Notes that the final 2018 budget was EUR 275 600 000 in commitment appropriations (EUR 187 900 000 in 2017) and EUR 235 900 000 in payment appropriations (EUR 206 400 000 in 2017); including unused appropriations from previous years and assigned revenues, the total available commitment budget was EUR 485 596 000 (EUR 322 400 000 in 2017) and the available payment budget was EUR 235 963 021 (EUR 206 400 000 in 2017);

⁽¹⁾ Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (OJ L 169, 7.6.2014, p. 54).

4. Notes that out of the EUR 1 000 000 000 of contributions to be made by industry members to the activities of the IMI Joint Undertaking, by the end of 2018 the IMI2 Joint Undertaking had validated in-kind and cash contributions of EUR 655 200 000, more precisely EUR 633 300 000 in-kind and EUR 21 900 000 in cash contributions; points out that a further EUR 80 600 000 of in-kind contributions without validation had been reported by the members to the IMI2 Joint Undertaking; highlights the fact that consequently, at the end of 2018, the in-kind and cash contributions of the industry members amounted to EUR 735 800 000, compared to the Union's cash contributions to the Seventh Framework Programme activities of the IMI2 Joint Undertaking, which amounted to EUR 916 000 000;
5. Notes with satisfaction that in 2018 IMI Joint Undertaking utilisation rates for payment appropriations for the Seventh Framework Programme projects were 88 %, an improvement from the previous period when the utilisation rates stayed below 75 % for four consecutive years; further notes that the implementation rate for payment appropriations under Horizon 2020 was 86 % and that in 2018 the implementation of commitment and payment appropriations for administrative and operational expenditure was greater than in 2017;
6. Notes that out of the EUR 1 425 000 000 of in-kind and cash contributions to be made by industry members and associated partners to the activities of the IMI2 Joint Undertaking, in-kind contributions of EUR 130 500 000 had been validated by the executive director, and a further amount of EUR 83 900 000 had been reported by the end of 2018; notes in addition that the executive director had validated cash contributions by the industry members of EUR 13 500 000; notes, moreover, that, at the end of 2018, the total contributions of industry members to the Horizon 2020 activities of the IMI2 Joint Undertaking consequently amounted to EUR 227 700 000, compared to the Union's cash contribution of EUR 241 900 000;
7. Notes that, in 2018, three budget amendments were adopted by the IMI2 Joint Undertaking's governing board:
 - (a) on 12 June 2018, to include the amounts carried over (EUR 209 698 405 in commitment appropriations and EUR 56 133 212 in payment appropriations) from the previous year;
 - (b) on 13 July 2018, to include additional carryovers (EUR 25 669 in commitment appropriations and EUR 25 669 in payment appropriations) from the previous year, specifically corresponding to the IMI Joint Undertaking amounts recovered from recipients in 2017 and carried over to the 2018 budget; and
 - (c) on 5 December 2018, to reduce operational payment appropriations by EUR 36 332 261 as a result of reducing the Union's contribution to operational costs (EUR 34 978 261) and postponing to 2019 the contribution of IMI2 Joint Undertaking partner (Bill and Melinda Gates Foundation) to the operational costs (EUR 1 354 000) carried over to the following year;
8. Notes that, at the end of 2018, the estimated unused payment appropriations for the operational and administrative expenditure approved by the board of directors of the IMI2 Joint Undertaking to be carried over to 2019 amounted to EUR 30 943 429; notes with concern the Court's observation that, while the situation has improved following the corrective measures taken by the IMI2 Joint Undertaking, there are still weaknesses regarding planning and monitoring of the need for new payment appropriations;

Performance

9. Notes that 2018 was the first year when the IMI2 Joint Undertaking reported on revised key performance indicators in its 2018 annual activity report ('AAR'); welcomes the fact that this step has proven to be an effective monitoring tool that has resulted in increasing the level of transparency regarding the IMI2 Joint Undertaking's achievements and thus attracted the interest of civil society members;
10. Notes that, according to the AAR, the analysis of the data collected up to 31 December 2018 shows that almost all the relevant priority areas in the IMI2 Joint Undertaking's strategic research agenda are addressed by the IMI2 Joint Undertaking's projects (11 out of 12);

11. Welcomes the fact that the IMI2 Joint Undertaking signed a total of 20 new grant agreements in 2018, bringing the total project portfolio to 119 (59 IMI Joint Undertaking + 60 IMI2 Joint Undertaking projects);
12. Observes that the management cost ratio (administrative/operational budget) remains below 5 %, thus pointing to the rather lean and efficient nature of the IMI2 Joint Undertaking's organisational structure;
13. Notes that in 2018 the IMI2 Joint Undertaking's leverage effect value was 0,99;
14. Notes that effective communication is an essential component of successful Union-financed projects; considers it to be important to increase the visibility of the achievements of the IMI2 Joint Undertaking, and to disseminate information on their added value; calls on the IMI2 Joint Undertaking to pursue a proactive communications policy by disseminating the results of its research to the public, such as by means of social media or other media outlets, thus raising public awareness of the impact of Union support, with particular regard to market uptake;
15. Welcomes the successful launch of EBOVAC3 in 2018 aimed at running clinical trials in children in Sierra Leone and Guinea; notes furthermore that the project is implementing a clinical study in health care providers in the Democratic Republic of Congo that is contributing to fight the disease; notes with satisfaction that the lessons learned through IMI2 Joint Undertaking's Ebola+ projects can be applied to other emerging infectious diseases;
16. Calls upon the IMI2 Joint Undertaking to consider revising the number of funded projects in the future; further notes that a smaller number of bigger and well-funded projects would greatly clarify the area of operation of the IMI2 Joint Undertaking, and make it easier for the general public to comprehend its benefits;

Staff and recruitment

17. Notes that, in December 2018, the total number of staff posts filled in the IMI2 Joint Undertaking was 48 (49 in 2017);
18. Notes that, at the end of 2018, the nationalities of 15 Member States were represented in the IMI2 Joint Undertaking, seven of them with one staff member; notes that 73 % of the 48 staff members were women and only 27 % men;
19. Notes with concern the Court's finding that, in 2018, the IMI2 Joint Undertaking's staff turnover rate was high at an average of 21 %, and particularly high at 60 % for contract agents, and the situation worsened due to eight people being on long-term sick leave of whom four were new cases in 2018, thus only half of the IMI2 Joint Undertaking's staff was fit for service in 2018, which increased the risk that the IMI2 Joint Undertaking's operational objectives would not be achieved as planned; notes that, to resolve the staffing difficulties, the IMI2 Joint Undertaking made use of interim staff, who represented 9,8% of its total staff in 2018 and has invested resources in retaining its talents through training and wellbeing activities on one side, and in reaching full staffing on the other; expresses concern about the number of members of staff on long-term sick leave and is concerned that some of those cases may relate to exhaustion and an unsatisfactory work-life balance; calls on the IMI2 Joint Undertaking to be proactive towards the staff concerned, to carefully evaluate the staff workload and to ensure a balanced distribution of tasks;

Internal audit

20. Notes that the Commission's internal audit service (IAS) final audit report on the 'Coordination with the Common Support Centre (CSC) and implementation of CSC tools and services in the IMI2 JU' issued in March 2018 concluded that IMI2 Joint Undertaking has implemented adequate governance, risk management and internal controls processes that effectively and efficiently support its coordination activities with the CSC and the implementation of the CSC tools and services;
21. Notes that the IAS audit did not result in any critical or very important issues being identified, and three 'important' recommendations were issued; notes that IMI2 Joint Undertaking prepared an action plan which translated the three recommendations into five actions, and four of those actions, which addressed two of the recommendations, were implemented by the end of 2018;

Internal control systems

22. Notes the Court's finding that the IMI2 Joint Undertaking has set up reliable *ex ante* control procedures, based on financial and operational desk reviews, in particular, for the Seventh Framework Programme interim and final payments; observes that the IMI2 Joint Undertaking performs *ex post* audits on beneficiaries' premises, whilst for Horizon 2020 project cost claims, the IAS is responsible for the *ex post* audits; notes that the residual error rates for the *ex post* audits reported by the IMI2 Joint Undertaking at the end of 2018 were 0,87 % for the Seventh Framework Programme and 0,67 % for Horizon 2020;
 23. Notes that, in December 2017, the IMI2 Joint Undertaking's governing board adopted the IMI2 Joint Undertaking's internal control framework, which is aligned with the Commission's control framework; notes that, in 2018, the IMI2 Joint Undertaking's internal control action plan focused on the implementation of the new principles of the internal control framework and revision, and on the development of the structure of the internal control environment; notes that new operational guidance for the implementation and measurement of the effectiveness of the control system was adopted;
 24. Notes that the Commission's Directorate-General for Budget (DG BUDG) carried out its annual evaluation of the local financial systems set up in the IMI2 Joint Undertaking, and reviewed the information on changes in the local systems and in the control environment, evaluated internal control deficiencies identified by audits and supervisory controls, and verified a sample of transactions for the operations; notes that DG BUDG concluded on 13 December 2018 that the IMI2 Joint Undertaking's internal control systems were working as intended; notes that the IMI2 Joint Undertaking completed the implementation of the action plan which was approved by the accounting officer on 5 February 2018, that the situation with regard to implementation of the action plan was assessed by DG BUDG, and that all five recommendations were closed by 28 January 2019;
 25. Invites the Court to assess the soundness and reliability of the methodology for calculating and valuing in-kind contributions, and the assessment should evaluate the design and the robustness of the guidance for the implementation of the in-kind contribution procedure in order to assist in the planning, reporting and certification process for the in-kind contributions.
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