RESOLUTION (EU) 2022/1826 OF THE EUROPEAN PARLIAMENT

of 4 May 2022

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 (now the Innovative Health Initiative Joint Undertaking) for the financial year 2020

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 2020,

— 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 (A9-0072/2022),

A. whereas the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines ('IMI Joint Undertaking') was established 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 a period up to 31 December 2024; whereas it replaced and became the successor to the IMI Joint Undertaking in June 2014 with the aim of finalising research activities under the Seventh Framework Programme and launching a new project under the Horizon 2020 framework;

C. whereas the Union, which is represented by the Commission, and the European Federation of Pharmaceutical Industries and Associations (the 'industry') 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 a 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 IMI Joint Undertaking's 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, including European Free Trade Association appropriations, to the IMI2 Joint Undertaking is EUR 1 630 000 000, to be paid from the Horizon 2020 budget, and the members, other than the Commission, have to contribute 50 % of the running costs and to contribute to operational costs through cash or in-kind contributions, or both, of an amount 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 accounts of the IMI2 Joint Undertaking for the year ended on 31 December 2020 (the Court's report) finds the annual accounts to be presented fairly, in all material aspects, with regard to the IMI2 Joint Undertaking's financial position at 31 December 2020, 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; notes, moreover, that, according to the Court's report, the transactions underlying the accounts are legal and regular in all material respects;

2. Notes that the final IMI2 Joint Undertaking available budget for 2020, including re-entered unused appropriations of previous years, assigned revenues, and reallocations to the next year, was EUR 276 538 561 in commitment appropriations (of which EUR 269 829 327 from the Union budget) and EUR 241 559 114 in payment appropriations (of which EUR 232 349 880 from the Union budget); notes that the budget execution of the commitment appropriations and the payment appropriations reached 98,66 % and 97,08 %, respectively;

([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).

3. Notes that out of the EUR 1 000 000 000 of contributions to be made by private members to operational activities of the IMI Joint Undertaking, by the end of 2020 the IMI Joint Undertaking had reported and validated in-kind and cash contributions of EUR 759 471 000 from private members, of which EUR 737 573 000 in-kind and EUR 21 898 000 in cash contributions; notes that, during 2020, 11 projects were running under the IMI Joint Undertaking, of which 3 had ended by 31 December 2020;

4. Notes that the IMI Joint Undertaking utilisation rate for payment appropriations for the Seventh Framework Programme projects was 96 %;

5. Notes that out of the EUR 1 425 000 000 of in-kind and cash contributions to be made by industry members to the operational activities of the IMI2 Joint Undertaking, in-kind contributions of EUR 317 206 000 and cash contributions of EUR 20 717 000 were reported and validated, and that, additionally, EUR 7 064 000 in cash and EUR 34 972 000 of in-kind contributions by associated members were reported and validated; notes that, consequently, at the end of 2020, the total contributions of industry members and associated partners to the Horizon 2020 activities of the IMI2 Joint Undertaking amounted to EUR 379 959 000, compared to the Union's total cash contribution of EUR 643 180 000; acknowledges that pre-financing rules are set by the Financial Regulation and the model grant agreement and expects that industry contributions will match Union input at programme level by the end of the IMI2 Joint Undertaking; notes that, regarding the 2020 budget available for Horizon 2020 projects, the implementation rates for commitment and payment appropriations were 100 % and 99,7 %, respectively; notes that, during 2020, 92 projects were running under the IMI2 Joint Undertaking, of which 6 had ended by 31 December 2020; notes that the increase of commitments in 2020 of EUR 200 400 000 (Union funding) and EUR 182 300 000 (the industry and Associated Partner commitment), results from the conclusion of 19 new signed grant agreements by the IMI2 Joint Undertaking, including 8 projects for the emergency call for proposals on coronavirus treatments and diagnostics;

6. Notes that there are different procedures across the Joint Undertakings regarding the calculation for the in-kind contributions, and calls for a harmonisation of the in-kind contribution calculation across the Joint Undertakings;

7. Notes from the Court's report that the IMI2 Joint Undertaking is characterised by long project durations due to the nature of its research, and that this situation is an example of varying degrees of achievement of contribution targets set by the Joint Undertakings' regulations in relation to Horizon 2020 activities, and that this presents the risk that the level of administrative resources needed to manage the Joint Undertaking's funds in a timely manner may not be sufficient, due to an increasing number of projects from multiple Multiannual Financial Framework programmes being implemented simultaneously; invites the IMI2 Joint Undertaking to review its organisational structure and staffing needs in order to ensure business continuity in periods of significantly increased workflows; calls on the IMI2 Joint Undertaking to provide more transparency in the decision making process for its research priorities and to communicate the chosen method in its next annual report;

8. Notes that, in 2020, the IMI2 Joint Undertaking still made final Seventh Framework Programme grant payments; notes, moreover that, according to the Court, the IMI2 Joint Undertaking reported residual error rates below the materiality threshold of 2 %, based on the *ex post* audit results at the end of 2020;

9. Notes from the Court's report that the IMI2 Joint Undertaking's practice of reactivating unused payment appropriations from previous years to the extent of open administrative commitments, results in an accumulation of unused payment appropriations and that, aggravated by the impact of the COVID-19 pandemic, it resulted in a low budget implementation rate for the IMI2 Joint Undertaking's Title 2 administrative budget of 51 %; acknowledges that the unspent amount of Title 2 payment appropriations was EUR 3,2 million, against the amount of EUR 241 559 114 of the total budgeted payment appropriations; notes the IMI2 Joint Undertaking's reply that rigid budget planning and the amendment mechanism did not allow appropriate adjustments to be made to the fast changing and uncertain global pandemic-driven crisis situation, and that, for 2021, it is planning to carry over a lower amount of administrative payment appropriations than the amount of commitments carried forward to 2021 under Title 2 Infrastructure expenditure, and that it plans to pay the difference out of the current year budget; calls on the IMI2 Joint Undertaking to develop a plan to limit the reactivation of the unused payment appropriations as a way of preventing a low budget implementation rate;

Performance

10. Notes that the IMI2 Joint Undertaking launched a fast-track call for proposals on coronavirus treatments and diagnostics, resulting in 8 projects; notes, moreover, the launch of three additional calls for proposals relating to topics such as rare diseases, infectious diseases, cancer, neurodegenerative diseases and autoimmune diseases; notes, furthermore, the signing of 19 new grant agreements for projects with a total combined budget of over EUR 380 000 000, bringing the total IMI2 Joint Undertaking's portfolio to 167 projects; notes that the new projects focus on cancer, diabetes, obesity, digital health, artificial intelligence, advanced therapies, drug discovery and environmental issues;

11. Notes that the annual activity report 2020 highlighted that for the evaluation experts, IMI2 Joint Undertaking used 235 experts from 29 countries. Of the members of that group of experts, 105 were female and 130 male; welcomes the fact that the IMI2 Joint Undertaking continues to improve gender balance in this respect;

12. Notes that the IMI2 Joint Undertaking, besides collecting data to report against the relevant standard Horizon 2020 key performance indicators (KPIs) for the assessment of the results and impacts of the specific objectives of the programme, uses KPIs to track activities in 10 strategic areas; notes, furthermore, that the IMI2 Joint Undertaking gathers data on those points via a dedicated web platform through which project coordinators can submit their project's results, allowing also the IMI2 Joint Undertaking to aggregate and analyse data, and build a picture of project achievements as they evolve; notes that, although those KPIs are designed for the IMI2 Joint Undertaking, where relevant the IMI2 Joint Undertaking also gathers the data for IMI Joint Undertaking projects, allowing the impacts of the Joint Undertaking since its inception to be examined; notes, moreover, that the analysis of the data collected up to 31 December 2020 shows that almost all the relevant priority areas in the IMI2 Joint Undertaking Strategic Research Agenda are addressed by IMI2 Joint Undertaking projects (11 out of 12);

13. Notes that several new tools and processes generated by IMI2 Joint Undertaking projects have been implemented by the industry participants (examples of such implementation are animal models, standards, biomarkers, standard operating procedures, use of screening platforms, clinical trial networks, etc.). Data also shows that there were 176 implementation results for the IMI2 Joint Undertaking (versus a target of 50) and 482 implementation results for the IMI Joint Undertaking and IMI2 Joint Undertaking considered together; notes, in addition, that 60 % of the projects involve patient organisations and healthcare professionals' associations as consortium partners, members of advisory boards, members of stakeholder groups, etc., and that this trend has remained stable during the course of the IMI2 Joint Undertaking; is concerned however that IMI2 Joint Undertaking projects still fail to guarantee affordability, accessibility and availability of publicly funded research results; calls in this regard for the IMI2 Joint Undertaking successor, the Innovative Health Initiative Joint Undertaking, to introduce new requirements immediately, in accordance with which all beneficiaries of the Union public funding for research and innovation for treatment, prevention or diagnosis would be obliged to commit to access, effectiveness, affordability and availability principles;

14. Notes that this reveals a dynamic in which the IMI2 Joint Undertaking's projects are getting on track and in some cases surpassing the established targets now that a number of the IMI2 Joint Undertaking's projects have finished and are reaching the end of the IMI2 Joint Undertaking's programme cycle;

15. Notes from the Court's report that the IMI2 Joint Undertaking made an important contribution to the common European response to the COVID-19 pandemic and that the IMI2 Joint Undertaking reallocated EUR 45 000 000 of its 2020 budget to a fast-track call for proposals launched in March 2020; notes that, in addition, Horizon 2020 funds from the Commission increased the call amount to EUR 72 000 000;

16. Notes that the issue of intellectual property rights needs to be addressed in all contracts which may produce an intended outcome of the performance, or result, such as studies, analysis, or evaluations; notes that it aims at safeguarding the rights of individual creators but also at providing details as to how the rights will be used in the future; notes that since the purchases are made with public money, the results should be transparent and accessible to the public; calls on the IMI2 Joint Undertaking to provide a clarification of the intellectual property rights and more transparency when it comes to the results of the research;

17. Notes that in 2020 the IMI2 Joint Undertaking's leverage effect was 1,01;

Recruitment and staff coping with COVID

18. Notes that on 31 December 2020, 53 of the 56 positions in the staff establishment plan of the IMI2 Joint Undertaking were occupied, five positions were filled during 2020, three for temporary agents and two for contract agents;

19. Notes that during the lockdown period, the IMI2 Joint Undertaking's staff switched to full-time teleworking, with staff able to access all the files, tools and resources they needed from day one; notes that the switch to working from home was also facilitated by the fact that the IMI2 Joint Undertaking had adopted a number of the Commission's standard tools, such as ARES, Sysper and the full set of Horizon 2020 programme management IT tools; notes, moreover, that the IMI2 Joint Undertaking and the other joint undertakings who work in the same building agreed on a single set of rules for staff who exceptionally have to work at the office, to ensure staff safety and well-being, and also outlined a phased return to the office; notes with concern the challenges associated with the COVID-19 pandemic for staff, especially taking into account different living circumstances, lack of access to office space and possible effects of isolation; asks the IMI2 Joint Undertaking to focus on staff well-being, stress management and work-life balance; asks management to ensure there are appropriate support structures in place to ensure the psychological well-being of staff;

Internal audit

20. Notes that in 2020, the internal audit service (IAS) performed an audit on Horizon 2020 grant implementation in the IMI2 Joint Undertaking, as originally provided for in the 2019–2021 strategic internal audit plan; notes, moreover, that the objective of that audit was to assess the adequacy of the design and the efficiency and effectiveness of the internal control system in place for the implementation of grant agreements under Horizon 2020;

21. Notes that, in November 2020, the IMI2 Joint Undertaking's executive director informed the internal auditors of the latest IMI2 Joint Undertaking organisational and operational developments and the results of the latest risk assessment, and provided feedback on the potential audit topics in preparation for the IAS strategic plan;

Internal control systems

22. Notes that the Court concluded that the IMI2 Joint Undertaking set up reliable *ex ante* control procedures for financial and operational desk reviews and that, in 2018, the IMI2 Joint Undertaking implemented the Commission's internal control framework, which is based on 17 internal control principles;

23. Notes from the Court's report that, for Seventh Framework Programme interim and final payments, the IMI2 Joint Undertaking performs *ex post* audits at the beneficiaries' premises, whilst for Horizon 2020 project cost claims, the Commission's Common Audit Service (CAS) is responsible for the *ex post* audits, and that, based on the *ex post* audits results available at the end of 2020, the IMI2 Joint Undertaking reported a representative error rate of 2,16 % and a residual error rate of 1,14 % for its Seventh Framework Programme projects, and a representative error rate of 1,13 % and a residual error of 0,74 % for Horizon 2020 projects (clearings and final payments); notes, moreover, that according to the Commission's proposal for the Horizon 2020 regulation, the ultimate aim for the residual level of error at the closure of the programmes, after the financial impact of all audits, correction and recovery measures have been taken into account, is to achieve a level as close as possible to 2 %;

24. Notes that, according to the Court's report, as part of the operational controls, the Court audit randomly sampled Horizon 2020 payments made in 2020 at the level of the final beneficiaries, to corroborate the *ex post* audit error rates, and that those detailed audits revealed, in one case, a systemic error above 1 % of the audit costs related to the declared direct costs, due to the fact that the beneficiary had wrongly declared as 'other direct costs', several indirect cost items not directly attributable to the project; notes, however, that such indirect costs are covered by a flat rate of 25 % of the direct cost amount;

25. Emphasises that the Court's report found persistent systemic errors in the personnel costs declared by beneficiaries, in particular on the part of SMEs and new beneficiaries; notes that such errors were also regularly reported in the *ex post* audits of the CAS and its contracted auditors; highlights the fact that, on page 39 of its report, the Court states that the streamlining of Horizon 2020 rules for the declaration of personnel costs and the wider use of simplified cost options is a precondition for future research framework programmes, in order to stabilise error rates to below the materiality level; encourages the Joint Undertaking to strengthen its internal control systems, given that SMEs and new beneficiaries are more error-prone.