



TEXTS ADOPTED

P9_TA(2021)0210

2019 discharge: Innovative Medicines Initiative 2 Joint Undertaking

1. European Parliament decision of 28 April 2021 on discharge in respect of the implementation of the budget of the Innovative Medicines Initiative 2 Joint Undertaking for the financial year 2019 (2020/2186(DEC))

The European Parliament,

- having regard to the final annual accounts of the Innovative Medicines Initiative 2 Joint Undertaking for the financial year 2019,
- having regard to the Court of Auditors' annual report on the EU Joint Undertakings for the financial year 2019, together with the Joint Undertakings' replies¹,
- having regard to the statement of assurance² as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2019, pursuant to Article 287 of the Treaty on the Functioning of the European Union,
- having regard to the Council's recommendation of 1 March 2021 on discharge to be given to the Joint Undertaking in respect of the implementation of the budget for the financial year 2019 (05795/2021 - C9-0033/2021),
- having regard to Article 319 of the Treaty on the Functioning of the European Union,
- having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012³, and in particular Article 71 thereof,
- having regard to Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking⁴, and in particular Article 12 thereof,

¹ OJ C 380, 11.11.2020, p. 6.

² OJ C 380, 11.11.2020, p. 6.

³ OJ L 193, 30.7.2018, p. 1.

⁴ OJ L 169, 7.6.2014, p. 54.

- having regard to Commission Delegated Regulation (EU) No 110/2014 of 30 September 2013 on the model financial regulation for public-private partnership bodies referred to in Article 209 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council¹,
 - having regard to Commission Delegated Regulation (EU) 2019/887 of 13 March 2019 on the model financial regulation for public-private partnership bodies referred to in Article 71 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council²,
 - 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 (A9-0113/2021),
1. Grants the Executive Director of the Innovative Medicines Initiative 2 Joint Undertaking discharge in respect of the implementation of the Joint Undertaking's budget for the financial year 2019;
 2. Sets out its observations in the resolution below;
 3. Instructs its President to forward this decision and the resolution forming an integral part of it to the Executive Director of the Innovative Medicines Initiative 2 Joint Undertaking, the Council, the Commission and the Court of Auditors, and to arrange for their publication in the *Official Journal of the European Union* (L series).

¹ OJ L 38, 7.2.2014, p. 2.

² OJ L 142, 29.5.2019, p. 16.

2. European Parliament decision of 28 April 2021 on the closure of the accounts of the Innovative Medicines Initiative 2 Joint Undertaking for the financial year 2019 (2020/2186(DEC))

The European Parliament,

- having regard to the final annual accounts of the Innovative Medicines Initiative 2 Joint Undertaking for the financial year 2019,
- having regard to the Court of Auditors' annual report on the EU Joint Undertakings for the financial year 2019, together with the Joint Undertakings' replies¹,
- having regard to the statement of assurance² as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2019, pursuant to Article 287 of the Treaty on the Functioning of the European Union,
- having regard to the Council's recommendation of 1 March 2021 on discharge to be given to the Joint Undertaking in respect of the implementation of the budget for the financial year 2019 (05795/2021 - C9-0033/2021),
- having regard to Article 319 of the Treaty on the Functioning of the European Union,
- having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012³, and in particular Article 71 thereof,
- having regard to Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking⁴, and in particular Article 12 thereof,
- having regard to Commission Delegated Regulation (EU) No 110/2014 of 30 September 2013 on the model financial regulation for public-private partnership bodies referred to in Article 209 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council⁵,
- having regard to Commission Delegated Regulation (EU) 2019/887 of 13 March 2019 on the model financial regulation for public-private partnership bodies referred to in Article 71 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council⁶,
- having regard to Rule 100 of and Annex V to its Rules of Procedure,

¹ OJ C 380, 11.11.2020, p. 6.

² OJ C 380, 11.11.2020, p. 6.

³ OJ L 193, 30.7.2018, p. 1.

⁴ OJ L 169, 7.6.2014, p. 54.

⁵ OJ L 38, 7.2.2014, p. 2.

⁶ OJ L 142, 29.5.2019, p. 16.

- having regard to the report of the Committee on Budgetary Control (A9-0113/2021),
- 1. Approves the closure of the accounts of the Innovative Medicines Initiative 2 Joint Undertaking for the financial year 2019;
- 2. Instructs its President to forward this decision to the Executive Director of the Innovative Medicines Initiative 2 Joint Undertaking, the Council, the Commission and the Court of Auditors, and to arrange for its publication in the *Official Journal of the European Union* (L series).

3. European Parliament resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget for the Innovative Medicines Initiative 2 Joint Undertaking for the financial year 2019 (2020/2186(DEC))

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 2019,
 - 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 (A9-0113/2021),
- 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 Regulation (EU) No 557/2014 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 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 in 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 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, including the European Free Trade Association appropriations, 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 to 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, according to the report of the Court of Auditors (the 'Court's report'), the accounts of the IMI2 Joint Undertaking for the year ended on 31 December 2019 present fairly, in all material respects, the financial position of the IMI2 Joint Undertaking at 31 December 2019, 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 accounting rules adopted by the Commission's accounting officer; notes 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 2019 available budget, including re-entered unused appropriations of previous years, assigned revenues, and reallocations to the next year was EUR 261 371 750 in commitment appropriations (of which EUR 255 561 977 from the Union budget) and EUR 231 316 906 in payment appropriations (of which EUR 221 519 271 from the Union budget); notes that the execution of the commitment appropriations and the payment appropriations reached 99,17 % and 96,33 % respectively;
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 2019, the IMI Joint Undertaking had reported and validated in-kind and cash contributions of EUR 710 478 000 from private members, more precisely contributions of EUR 688 580 000 in-kind and EUR 21 898 000 in cash; notes that, in 2019, the amount of cost claims validated as well as the in-kind contributions was significantly lower compared to 2018, due to the fact that the number of IMI Joint Undertaking projects decreases as projects are finishing; notes that, by the end of the year, 11 projects were still ongoing out of the total of 59 projects under the Seventh Framework Programme;
4. Notes that the IMI Joint Undertaking utilisation rate for payment appropriations for the Seventh Framework Programme projects was 97 %;
5. Notes that, out of the EUR 1 425 000 000 of in-kind and cash contributions to be made by the Industry to the operational activities of the IMI2 Joint Undertaking, in-kind contributions of EUR 202 598 000 and cash contributions of EUR 15 554 000 were reported and validated, and that additionally, EUR 5 662 000 in cash and EUR 8 203 000 of in-kind contributions by associated partners were reported and validated;
6. Notes that, at the end of 2019, the total contributions of the Industry and associated partners to the Horizon 2020 activities of the IMI2 Joint Undertaking amounted to EUR 232 017 000, compared to the Union's total cash contribution of EUR 423 743 000; recalls that the Commission's interim evaluation of the IMI2 Joint Undertaking emphasised the lack of transparency as regards how the in-kind contributions of the Industry were calculated; reiterates, therefore, its previous demands for detailed information on the in-kind contributions of the Industry, especially on the type of the in-kind contributions and their respective value;
7. Notes that there are different procedures across the Joint Undertakings receiving financial contributions from Joint Undertakings' private members; calls for a harmonisation of the in-kind contribution calculation across the Joint Undertakings; considers that the common procedure should provide for transparent and effective methods of evaluation, having as a result the real value of the contribution; calls on the Court to scrutinise the audits performed by the independent external auditors; calls also for an appropriate legal framework that ensures that the required financial contribution will be achieved by the end of the Joint Undertakings notes also that the legal framework could include requirements for the private contribution to be paid before or at the same time as the corresponding Union contribution;
8. Notes that, regarding the 2019 budget available for Horizon 2020 projects, the implementation rates for commitment and payment appropriations were 100 % and 98 %

respectively; notes that, at the end of 2019, 79 out of the total 83 ongoing projects of the IMI2 Joint Undertaking were funded under the Horizon 2020 programme;

9. Notes that, according to the Court's report, following the implementation of several corrective measures, the IMI2 Joint Undertaking significantly improved in 2019 the planning and monitoring of its need for new payment appropriations; notes however, that it needed to return EUR 139 100 891 of 2019 commitment appropriations to the Union budget due to there being fewer topics for calls for proposals in the 2019 annual work plan; furthermore, notes that, according to the Court's report, due to the resulting decreased need for evaluation experts, the IMI2 Joint Undertaking only used EUR 2 821 000 (or 49 %) of the EUR 5 799 000 of the 2019 budget available for infrastructure expenditure (budget title 2); calls on the IMI2 Joint Undertaking to further improve the planning and monitoring of its payment and commitment appropriations;
10. Is concerned that the Industry exercises exclusive control on the priorities of the IMI2 Joint Undertaking, that the Industry alone draws up the strategic agendas and annual work plans and privatises the results and data of projects financed by public money;
11. Is outraged by the fact that the Industry, which takes decisions jointly with the Commission within the IMI2 Joint Undertaking, blocked the 2018 Commission proposal to integrate into the scope of the work of the IMI2 Joint Undertaking epidemiological preparation (i.e. anticipating and preparing for epidemics such as that caused by COVID-19); is concerned that the Industry refuses to disclose crucial documents, such as project proposals, grants or project agreements; recalls, in that regard, that those documents concern projects funded by public money; notes with regret that the above-mentioned problems are partly a logical consequence of the structure and mechanisms of this public-private partnership;

Performance

12. Notes that the IMI2 Joint Undertaking has 10 key performance indicators (KPIs) that were tracked and reported on for the first time in its 2018 annual activity report, which also involved collecting data from the IMI Joint Undertaking, where relevant; notes that an analysis of the KPIs reveals that IMI2 Joint Undertaking projects are now, namely in the middle of the IMI2 Joint Undertaking's programme cycle, getting on track compared to the established targets and able to generate innovations and detectable impacts, given the complex and long-term nature of the projects; notes that, with regard to the longer-term outputs and impacts of its programmes, the IMI2 Joint Undertaking in 2019 carried out a significant assessment of the socio-economic impact of the 44 IMI Joint Undertaking projects that had been completed; calls on the IMI2 Joint Undertaking to also assess the environmental impact of its projects; furthermore, notes that the IMI2 Joint Undertaking collects data to report, based on the relevant standard KPI's of Horizon 2020;
13. Takes note of the Commission's final evaluation of the IMI Joint Undertaking which concluded that "no socio-economic benefits from IMI Joint Undertaking activities could be identified", nor did it find any examples of it "bringing new, safer and more effective therapies or products to patients" or shortening development time; furthermore, it also concluded that research topics "closer to the public interest than those identified by the industry" may be better identified under the wider research programme, and "at a lower cost for the public budget";

14. Is concerned that the interim evaluation of the IMI2 Joint Undertaking carried out by the Commission in 2017, concluded that, to date, “it cannot be said that IMI brings new, safer and more effective therapies or products to patients” and that in that regard, “the added value of IMI for patients and for society in general is difficult to demonstrate”;
15. Notes that the IMI2 Joint Undertaking should place a strong focus on areas where there is a major public health need and on the priorities of its strategic research agenda; notes that, in 2019, the IMI2 Joint Undertaking launched three calls for proposals with a total of 10 topics, and signed 29 grant agreements for new projects, expanding into new areas within the pharmaceutical industry, while also increasing its ties with other sectors involved in health research and innovation;
16. Is alarmed that the IMI2 Joint Undertaking has funded several projects that have enabled the pharmaceutical industry to lobby regulators in the Union to weaken safety assessment standards for new pharmaceuticals and to speed up the granting of marketing authorisations; calls on the IMI2 Joint Undertaking to inform the discharge authority about the details of the costs incurred for the projects in question;
17. Calls on the Commission to make sure that the future IMI2 Joint Undertaking activity programme will respect also the EU4Health Programme as established in Regulation (EU) 2021/522¹ and all other Union strategies in the domain;
18. Notes that, according to the Court’s report, at the end of 2019, the Horizon 2020 programme implementation rate stood at 75 % with regard to the call procedures for the activities assigned to the IMI2 Joint Undertaking;
19. Requests that the IMI2 Joint Undertaking reviews its communication strategy to ensure that relevant stakeholders are aware of its mission, activities and achievements;
20. Notes that, in 2019, the IMI2 Joint Undertaking’s leverage effect value was 1,03; points out with concern that this rate is below expectations; calls on the IMI2 Joint Undertaking to take steps to meet the target;
21. Welcomes the fact that, according to the 2019 annual activity report of the IMI2 Joint Undertaking, the KPIs regarding gender balance in 2019 show that 51% of the total staff working in IMI2 Joint Undertaking projects were women, 27 out of 89 project coordinators for IMI2 Joint Undertaking projects in 2019 were women and that women account for 45% to 60% of advisers and experts carrying out evaluations and analyses, and working on the scientific committee;
22. Calls on the Commission and the Court to provide an in-depth performance tracking method with a view to evaluating the added value of the IMI2 Joint Undertaking, and assessing its social and employment impact as well as its impact on the market; the results of the evaluation should be used for the future or for redistribution of Union financing;

¹ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).

23. Notes that the issue of intellectual property rights (IPRs) needs to be addressed in all contracts which may produce an intended outcome or result of the performance; recalls that IPRs aim to safeguard the rights of individual creators, but also provide details on how the rights will be used in the future; notes that since the activity is financed in part with public money, the results should be transparent and accessible to the public; calls on the Commission to propose a legal framework regarding IPRs and their implementation on the market, including special requirements and profit distribution;

Staff and Recruitment

24. Notes that, in December 2019, the total number of staff posts filled in the IMI2 Joint Undertaking was 53 (48 in 2018) out of 56 in the establishment plan;
25. Notes that, according to the Court's report, in 2019 the Joint Undertaking significantly stabilised its staff situation, in particular, the staff turnover rate decreased from 21 % to 5,6 %, the number of members of staff on long-term sick leave decreased from four to one, and the use of interim staff decreased from 5,1 to 3,8 full time equivalents;
26. Notes that, at the end of 2019, the nationalities of 13 Member States were represented in the IMI2 Joint Undertaking, four of them with one member of staff; notes that 72% of the 53 members of staff were women and only 28% men;
27. Calls on IMI2 Joint Undertaking to introduce a compulsory training scheme for newcomers and already operational members of staff;

Internal audit

28. Notes that, in June 2019 the Internal Audit Service (IAS) issued the 2019-2021 strategic internal audit plan for the IMI2 Joint Undertaking, based on the results of the IAS risk assessment conducted in December 2018; furthermore, notes that the IMI2 Joint Undertaking continued implementing the action plan stemming from the 2018 audit report on the 'Coordination with the Common Support Centre and implementation of CSC tools and services in the IMI2 JU', and that, in January 2020, the recommendation on the common Horizon 2020 IT system was closed;

Internal control

29. 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, and that at the end of 2019, it had implemented the new internal control framework and developed indicators for assessing the effectiveness of the control activities for all internal control principles and related characteristics; furthermore, notes that 2019 was the second year of the IMI2 Joint Undertaking's self-assessment of its internal control activities under the new framework; calls on the IMI2 Joint Undertaking to present to the discharge authority reports on the self-assessment exercise;
30. Notes that, according to the Court's report, for the Seventh Framework Programme interim and final payments, the IMI2 Joint Undertaking performs ex-post audits at the beneficiaries' premises, whereas, for Horizon 2020 project cost claims, the Commission's Common Audit Service is responsible for the ex-post audits, and that, based on the ex-post audit results available at the end of 2019, it reported a representative error rate of 2,05 % and a residual error rate of 0,66 % for its Seventh Framework Programme projects,

and a representative error rate of 0,85 % and a residual error rate of 0,52 % for Horizon 2020 projects (clearings and final payments); notes, moreover, that, according to the Commission's proposal for Regulation (EU) No 1291/2013¹, the ultimate aim for the residual level of error at the closure of the programmes, after the financial impact of all audits and correction and recovery measures will have been taken into account, is to achieve a level as close as possible to 2 %;

31. Notes with satisfaction that, according to the Court's report, as part of the operational payment controls, the Court audited randomly sampled Horizon 2020 payments made in 2019 at the level of the final beneficiaries to corroborate the ex-post audit error rates, and that those detailed audits showed no significant errors or control weaknesses at the sampled IMI2 Joint Undertaking's beneficiaries;
32. Notes that, in 2018 and 2019, the Court reviewed, on a sample basis, the ex-post audits carried out by the Commission's Common Audit Service and its contracted external auditors; mentions that the residual error rate reported by the seven Horizon 2020 Joint Undertakings (Single European Sky Air Traffic Management Research, Clean Sky, IMI2, Fuel Cells and Hydrogen, Electronic Components and Systems for European Leadership, Bio-based Industries and Shift2Rail) in their respective annual activity report is not directly comparable with the error rate published in the 2019 annual report of the Court for the Commission's research expenditure;
33. Notes with satisfaction that, as regards suspected fraud cases, in 2019 the IMI2 Joint Undertaking did not identify any new cases of irregularities or suspected fraud while managing its project portfolio and did not receive any European Anti-Fraud Office enquiries or requests for information;

Prevention and management of conflicts of interest, and transparency

34. Notes that the IMI2 Joint Undertaking adopted rules on conflicts of interest and has published CVs and declarations of interest of its members of the governing board;
 35. Notes that in 2019 the IMI2 Joint Undertaking put in place a robust ethics framework following the governing board's adoption of the "Innovative Medicines Initiative 2 Joint Undertaking policy on protecting the dignity of the person and preventing psychological harassment and sexual harassment"; notes also the work done to prepare for the governing board's adoption of the IMI2 Joint Undertaking guidelines on whistleblowing early in 2020;
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36. Notes that negotiations and preparatory work are underway for establishment of an Innovate Health Initiative (IHI) as a possible successor of the IMI2 Joint Undertaking; notes that the key objectives for the IHI should be to adopt fully balanced and transparent

¹ Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104).

decision making processes, continuously monitor environmental and socio-economic impacts, and put a new system in place to help prevent private partners from being unable to fulfil their financial obligations; regrets that such improvement efforts were not undertaken already in 2019 to improve the IMI2 Joint Undertaking's performance and transparency.