



ECDC Management Board

# Minutes of the Fifty-seventh Meeting

## Stockholm, 13-14 June 2023

*Adopted by the ECDC Management Board at its Fifty-ninth meeting, 14-15 November 2023*

## Contents

Opening and welcome from the Chair (and noting the Representatives) .....	3
Welcome from the Director, ECDC.....	3
Adoption of the draft programme (and noting the declarations of interest and proxy voting, if any) ( <i>Document MB58/01</i> ).....	3
Adoption of the draft minutes of the 57 <sup>th</sup> meeting of the Management Board (Stockholm, 21-22 March 2023) ( <i>Document MB58/02</i> ).....	3
Amended ECDC Strategy 2021-2027 ( <i>Document MB58/03</i> ).....	3
Results of the Stakeholder Survey 2022 and action plan ( <i>Document MB58/04</i> ) .....	5
Priorities for the Single Programming Document 2025 ( <i>Document MB58/05</i> ) .....	6
Timeline and process for selection of ECDC Director 2024-2029 .....	7
Update on the implementation of the Regulation on serious-cross border threats to health (SCBTH) .....	7
Summary of discussions held at the 52 <sup>nd</sup> meeting of the ECDC Audit Committee (Stockholm, 12 June 2023), including its recommendations.....	8
Update from the Director.....	12
ECDC Management Board meeting dates 2024 and 2025 ( <i>Document MB58/10</i> ).....	13
Update from the European Commission.....	14
Update from the European Parliament.....	14
Update from the Swedish Presidency of the European Council .....	14
Any other business.....	14
Annex: List of Participants .....	15

## Summary of Proceedings – ECDC Management Board Meeting

The Fifty-eighth meeting of the ECDC Management Board (MB) convened on 13-14 June 2023 in Stockholm, Sweden. During the meeting the MB:

- ❖ adopted the programme of the meeting;
- ❖ adopted the minutes of the Fifty-seventh meeting of the MB;
- ❖ approved the revised ECDC Strategy 2021-2027;
- ❖ approved the Final Annual Accounts 2022, including the proposed MB opinion. The final MB opinion will be signed by the Chair on 30 June 2023 and attached to the Final Accounts;<sup>1</sup>
- ❖ discussed the results of the ECDC Stakeholder Survey 2022 and action plan;
- ❖ discussed the Priorities for the Single Programming Document 2025;
- ❖ discussed the timeline and process for selection of the ECDC Director 2024-2029 in a closed session;
- ❖ took note of the update from the European Commission on the implementation of the EU Regulation on serious cross-border threats to health;
- ❖ took note of the summary of discussions held at the 52nd meeting of the ECDC Audit Committee;
- ❖ took note of the Progress report on implementation of the Work Programme 2023, including changes to the Financing Decision;
- ❖ took note of the Progress report – Overview of 2023 budget implementation;
- ❖ took note of the First Supplementary and Amending Budget 2023;
- ❖ discussed the proposed amendments to the MB Rules of Procedure and the Audit Committee Mandate and agreed that both documents be submitted for approval during MB59 in November 2023;
- ❖ took note of the update from the ECDC Director;
- ❖ took note of the update from the European Commission;
- ❖ took note of the update from the European Parliament;
- ❖ took note of the update from the Swedish Presidency of the European Council.

---

<sup>1</sup> Following the meeting, on the request of the European Court of Auditors (ECA), the paragraph in the annual accounts referring to the ECA annual audit had to be modified, and hence the opinion of the MB had to be re-signed with a new date (26 July 2023).

## Opening and welcome from the Chair (and noting the Representatives)

1. Anni Virolainen-Julkunen, Chair of the ECDC Management Board, welcomed all the participants to the Fifty-eighth meeting of the Management Board (MB), which took place in Stockholm, Sweden. A special welcome was extended to Gideon Ertner, newly appointed alternate from Denmark.
2. Apologies had been received from Liechtenstein, the Netherlands and Spain, as well as from DG HERA, European Commission. The following countries did not confirm their participation: Iceland and Poland.

## Welcome from the Director, ECDC

3. Andrea Ammon, Director, ECDC, warmly welcomed the MB members to the meeting noting that she was looking forward to fruitful discussions.

## Adoption of the draft programme (and noting the declarations of interest and proxy voting, if any) (*Document MB58/01*)

4. The draft programme was adopted without changes. The Chair asked each member whether s/he wished to add any oral declaration(s) of interest to her/his Annual Declaration of Interest (ADoI) submitted previously. None were declared. The Chair stressed the importance that potential candidates for the position of ECDC Director would not participate in the closed session in the afternoon.

The Management Board adopted the draft programme.

## Adoption of the draft minutes of the 57<sup>th</sup> meeting of the Management Board (Stockholm, 21-22 March 2023) (*Document MB58/02*)

5. The Chair noted that the draft minutes of the 57<sup>th</sup> meeting had been circulated to the MB ahead of the meeting. No requests for amendments had been received. There were no comments on the minutes.

The Management Board adopted the minutes of the Fifty-seventh meeting of the Management Board.

## Amended ECDC Strategy 2021-2027 (*Document MB58/03*)

6. Andrea Ammon, Director, ECDC, recalled that the amended ECDC Strategy 2021-2027 had been presented to the MB in March 2023 and the MB had agreed with the overall structure of the Strategy, i.e., the five Strategic Objectives (SOs) and the Action Areas. Since the previous discussion, some further explanations had been added to the text, including some of the key findings from the PESTEL and ecosystem analyses carried out by Ipsos.

7. The Director explained that the objective of the PESTEL analysis was to identify drivers that would possibly shape the future of ECDC's working environment in three time-horizons: a) the present and the near future (0-3 years); b) less immediate future and thus less urgent (3-5 years); c) mid- to long-term future issues (6-10 years). The analysis produced seven drivers (two of which environmental in nature, two social, and three political/legal) covering key uncertainties for the coming decade. The ecosystem analysis focused on key players in public health in Europe and beyond. One conclusion from the ecosystem analysis was that COVID-19 has triggered a period of change across the ecosystem and most organisations are now implementing pandemic learnings leading to structural changes. Another conclusion was that One Health is rising worldwide, which provides the opportunity to reconsider the approach to public health and to build partnerships covering the full One Health spectrum. In this context, collaboration is key and ECDC should consider its future relationship with the Member States as well as what role it wishes to play on the global scene. Overall, ECDC will have a more prominent role but at the same time more will be expected

from the Centre. The findings from the two studies will not influence the content of the Strategy as such but rather the Strategy Implementation Roadmap to be developed in the coming months.

8. Lieven De Raedt, MB Member, Belgium, reported back from the MB working group tasked to analyse the ECDC Strategy and related documents and their alignment with the legal texts of the EU Health Union. The working group had held its fourth virtual meeting mid-May and received a presentation by the contractors on the PESTEL and ecosystem analyses. The working group had discussed the findings and the overall conclusion was that more time would be needed to analyse what these meant for ECDC in concrete terms and to reflect on what the MB and ECDC wanted to do with the results. A reference to foreseen geopolitical tensions had been included in the text but otherwise the findings did not require any fundamental changes in the Strategy document as such. The working group recommended allowing some time to reflect on the conclusions to be able to define more solid and operational next steps. In other words, this was the start and not the end of the process.

9. The floor was then opened for comments. One MB member noted that the ecosystem analysis did not mention the fact that many Member States were facing cuts in public health triggered by the Ukraine crisis and other factors. Concerning the Strategy, she stressed the importance of looking at health determinants for both communicable diseases (CDs) and non-communicable diseases (NCDs) in an integrated manner and added that the pandemic had shown that lower socio-economic groups have less favourable outcomes for both CDs and NCDs. Another MB member commented that there seemed to be a change of focus in public health following the pandemic and more attention was now put on NCDs including mental health. The importance of considering health in all policies was also mentioned. The Deputy Chair and MB member representing the European Parliament noted that the amended ECDC mandate implied a greater international focus compared to the previous mandate and asked how the Director saw the balance between EU Member States on one hand and the global arena on the other hand, including new international partners.

10. The Director, referring to the points made by Lieven De Raedt, said that the Strategy and the implementation roadmap will guide the work ahead but are not cast in stone; both documents will be regularly reviewed and adjusted where necessary. She agreed that there seemed to be a wave of change in many Member States following the pandemic and the shift of focus from CDs to NCDs was also something she had observed during her recent country visits. This was of course legitimate from the burden of disease point of view but if it impaired the possibility to respond to crisis there could be consequences. Concerning the point made on health determinants, she noted that the amended mandate clearly states that ECDC shall consider health determinants and how CDs influence NCDs. Concerning the balance between EU and global focus, she said that Member States' requests would continue to have priority over global ones. The development of the One Health approach was very positive knowing that most new viruses are zoonotic. The avian influenza was a good test case for developing integrated systems. She agreed that the health in all policies principle was important to keep in mind, and the pandemic had shown how health is interlinked with many other areas of society.

11. With reference to NCDs, one MB member commented that this topic had been debated for years and the last external evaluation of ECDC had tried to address the matter; however, this part was not reflected in the new ECDC mandate. She suggested that the 2025 evaluation should have a greater focus on NCDs. As this evaluation will be led by the European Commission, she made a plea to the Commission to ensure the NCD part is considered and that relevant stakeholders are involved for this.

12. One of the MB members representing the European Commission acknowledged the importance of NCDs but stressed the need to focus on the current mandate of ECDC, which had entered into force only six months ago. The Director agreed that it was necessary to stay within the current mandate while ensuring the link between CDs and NCDs. She noted that health determinants were mentioned several times in the Strategy document, and these will be covered also in the implementation roadmap.

13. In concluding the discussion, the Chair noted one challenge she saw in near future with regards to ECDC's influence in global negotiations, such as the ongoing discussions on the international pandemic treaty. Considering ECDC's strengthened international role, she felt that ECDC could have a more prominent role in these negotiations.

The Management Board approved the amended ECDC Strategy 2021-2027.

## **Results of the Stakeholder Survey 2022 and action plan (*Document MB58/04*)**

14. Andrea Ammon, Director, ECDC, recalled that the preliminary results of the 2022 Stakeholder Satisfaction Consultation had been presented to the MB in November 2022. The final report was now shared with the MB for information as well as the proposed action plan.

15. The Director summarised the main results of the stakeholder survey noting that it showed an overall satisfaction rate of 86%. The response rate (23%) was lower than expected but rather high compared to some other EU agencies and bodies. There was high satisfaction with key aspects such as use of ECDC scientific advice, support in the response to COVID-19, training, communication activities and Eurosurveillance. The areas for improvement include better involving Member States and other stakeholders in the development and consultation of ECDC's outputs, improving ECDC's understanding of Member States' issues and capabilities, ECDC's guidelines to contain realistic recommendations and improving the user friendliness of ECDC platforms and tools.

16. The Director then presented the proposed action plan focusing on the actions targeting the MB itself, the Advisory Forum and the CCBs. The actions targeting the MB include training of MB members, more information on ECDC plans and intended budgeting related to the strengthened mandate and more opportunities for information exchange.

17. The MB members welcomed the proposed actions targeting the MB and agreed with the suggestion to review the roles of the CCB Directors and National Coordinators. It was discussed that the coordination and information sharing between MB, AF and CCB was also the responsibility of each Member State. One MB member said that the survey had triggered the question who ECDC's main stakeholders were. Concerning ECDC's scientific advice he said that there had been a few instances where the timeliness of ECDC's guidance had not been optimal or where no clear response had been delivered on a specific question. One MB member asked how ECDC was dealing with vaccine hesitancy and whether there was any training or other material available for Member States. The Deputy Chair and MB member representing the European Parliament commented on the low response rate and added that one reason was perhaps the survey length.

18. The Director thanked the MB members for their input. She agreed that there were many ways to intensify the interaction between MB, AF and CCB. This could be facilitated by ECDC but also required dialogue at national level. She said that she was taking seriously the comments on the timeliness of ECDC's guidance and asked all MB members to inform her of any similar experiences as this allowed ECDC to improve. With regards to stakeholders, she clarified that the survey had targeted ECDC's main stakeholder groups while there were of course also other stakeholders and new potential partners to be defined. ECDC will start a stakeholder mapping exercise during 2023 and this matter will be discussed also with the MB. Concerning vaccine hesitancy, she said that ECDC had plenty of material available but suggested that a discussion should take place with the Member State to better understand the specific needs given that the situation was very different from one country to another.

19. The Chair welcomed the proposal to further clarify different roles (e.g., CCB Director and National Coordinator) and suggested that this could be done as part of the stakeholder mapping. She was looking forward to receiving further updates on the implementation of the action plan.

The Management Board discussed the results of the Stakeholder Survey 2022 and action plan.

## Priorities for the Single Programming Document 2025 (*Document MB58/05*)

20. Andrea Ammon, Director, ECDC, presented the priorities for the Single Programming Document (SPD) 2025. She noted that 2025 will be the second year of implementing the adapted ECDC Strategy and the Strategy Implementation Roadmap. As concerns the general context of the SPD 2025, she mentioned that the new international pandemic treaty and the review of the International Health Regulations (IHR) should be finalised by May 2024 and thereby be in force in 2025. On the EU level, elections to the European Parliament will be held in June 2024 and a new European Commission will be in place in the autumn of 2024 and will set its new strategic agenda. In 2025, there will be an external evaluation of ECDC including assessment of the progress made in implementing the amended mandate.

21. The main priorities for 2025 are: 1) Support Member States with digitalised and integrated EU level surveillance; 2) Assist Member States and the European Commission in joint preparedness and response planning; 3) Enhance support through the assistance of a standing and ready-to-be deployed EU Health Task Force; 4) Support prevention and control activities, including enhanced post-authorisation monitoring of the effectiveness of vaccines, and assistance to countries to improve vaccine coverage in the EU; 5) Tackle antimicrobial resistance; 6) Support Member States and the European Commission in addressing the Sustainable Development Goals in the area of HIV, TB and hepatitis.

22. In accordance with the approved Multi-Annual Financial Framework 2021-2027 and considering changes in ECDC's mandate, it is envisaged that the requested total budget of the Centre for 2025 will be 93 184 711 EUR, of which 39 179 000 EUR are forecasted for operations. Additional resources are foreseen for the implementation of externally funded projects. The total number of staff foreseen for 2025 is 358 full time equivalent (FTE) posts, of which 225 temporary agent posts, 128 contract agents and five seconded national experts.

23. In the discussion that followed, some comments were made on the implementation of the EU Health Union legal package and the requirement of Member States to report on their prevention, preparedness and response planning by 27 December 2023. According to the indicated timeline, ECDC will provide guidance to Member States by 2025 while such guidance would be expected as soon as possible to ensure alignment between the countries. Similarly, it was said that the EU will develop criteria for the reporting, but these were still not known. Further clarification was also requested on the distribution of the budget as well as on the collaboration with DG HERA.

24. The Director replied that she would come back with more details on the budget distribution. In the meantime, she clarified that the distribution of the operational budget (EUR 39 million) can be decided once the detailed activities are known. She mentioned that there were regular interactions between ECDC and HERA and ECDC is part of the HERA Advisory Forum. Since recently, HERA was also represented at the ECDC MB. She recalled that ECDC had signed working arrangements with HERA earlier in 2023 and these would be reviewed within one year. She agreed that it would have been helpful to have the indicators for the Member States reporting already in place but ensured that the European Commission, ECDC and the preparedness working group of the Health Security Committee (HSC) were working intensively on the matter.

25. The Chair commented that the development of the indicators was indeed work in progress and suggested that it might be used as an opportunity for more collaborative work. The Director agreed that the work had to be collaborative both for the development of the reporting criteria and the assessment visits to be carried out by ECDC from 2024 onwards. It was worthwhile investing a bit more time on the preparations in order to have a common understanding among the concerned parties.

26. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC, clarified that the draft reporting template covered 17 areas, most of which included indicators. The details of the procedure will be included in an Implementing Act. She then briefly described the process for the assessment visits to be carried out by ECDC in 2024, 2025 and 2026 noting that 10 countries would be needed for the first year. More detailed procedures, standards and criteria will be adopted by means of delegating acts.

27. The MB member representing DG RTD said that more information would be provided in the afternoon by the MB member from DG SANTE. She added that all Member States were involved in the discussions through the HSC but given the complexity of the process she agreed that it was important to provide regular updates in the MB to keep MB members informed.

28. The Chair concluded the discussions noting that a more detailed draft SPD 2025-2027 will be presented to the MB in November 2023.

The Management Board discussed the priorities for the SPD 2025.

## Timeline and process for selection of ECDC Director 2024-2029

29. This item was discussed in a closed session (Members of the Management Board only). Before the discussion, the Chair repeated that potential candidates for the position of ECDC Director should not participate in the closed session.

## Update on the implementation of the Regulation on serious-cross border threats to health (SCBTH)

30. Isabel de la Mata, MB Alternate, DG SANTE, European Commission, gave an update on the implementation of the EU Regulation on serious-cross border threats to health (SCBTH). She mentioned that, overall, the implementation was progressing according to the plan and the Health Security Committee (HSC) and its Technical Working Group on Preparedness had been very active. A first draft of the Union prevention, preparedness and response plan is under development and a second draft will be shared with the Technical Group on Preparedness in the coming months after which an informal consultation with all relevant DGs and EU agencies will take place in Q4 2023. The template for Member States to report on prevention, preparedness and response (*cf.* Article 7 of the SCBTH) has been discussed with the Technical Working Group over the last six months and the formal adoption is foreseen in July 2023. An online version will be ready for testing and training in September 2023 and Member States have to report by 27 December 2027 in accordance with Regulation (EU) 2022/2371. ECDC is producing a draft framework for the assessment of Member States' prevention, preparedness and response planning (*cf.* Article 8 of the SCBTH); a delegated act is foreseen to be adopted by the end of 2023 and volunteer countries are needed for the assessments to take place in 2024. DG SANTE is currently preparing the second draft of the "State of Preparedness Report" and the final report is expected to be delivered in Q4 2023. A training task force has been established under the Technical Working Group on Preparedness and an external contractor is working on several training elements targeting public health and healthcare staff.

31. The presentation also touched upon ongoing work to revise the Joint Procurement Agreement (JPA) with a view of enhancing the functioning of the JPA mechanism, the revision of the list of notifiable diseases, the ongoing Joint Action on surveillance, and the preparatory activities covered under the EU4Health Programme to support the implementation of the EU network of reference laboratories (EURLs). It was also mentioned that the EU Advisory Committee for Public Health Emergencies is to be established in July 2023 and a call for multi-disciplinary independent experts is planned for July-September. DG SANTE is also working on the shape and scope of the framework for enhanced cooperation with WHO regarding prevention, preparedness and response.

32. Following the presentation, a few questions were raised. One MB member asked whether the EURLs would only deal with communicable diseases or also with biological toxins and chemicals. Another MB member asked what was meant by "independent experts" in the context of the Advisory Committee for Public Health Emergencies. Further clarification was also requested on the Article 7 reporting template and whether Member States will have the possibility to comment on the content. There were also questions on the laboratory network of the DURABLE consortium that interacts with HERA, and possible overlaps with the EURLs.

33. Isabel de la Mata clarified that the reporting template had been discussed with all the Member State representatives in the HSC. In case of concerns, she encouraged the MB members to liaise with their

country counterpart in the HSC working group on preparedness. She added that the template can always be adjusted in case any issues are identified in September when it will be ready for testing. Concerning the Advisory Committee, she said that “independent experts” meant that they did not represent Member States but were selected based on their individual expertise. Regarding the EURLs she said that these will support national reference labs and the criteria will be discussed with the HSC.

34. The Director mentioned that there were currently 17 lab networks for different pathogens and ECDC was discussing with DG SANTE what the priority should be when transforming these into EURLs. She clarified that the EURLs will cover only communicable diseases and not biological toxins. Vicky Lefevre, Head of Unit, Public Health Functions, ECDC, added that the DURABLE network is more research oriented and focuses on medical counter measures with an all-hazards approach, while the EURLs will focus on quality assurance and training. Responding to a question on possible overlaps between the Member States reporting under the SCBTH and the IHR Joint External Evaluation (JEE), the Director clarified that the Article 7 reporting is designed to avoid duplication and any available results from the JEE and the IHR State-Party Self-Assessment Annual Reporting (SPAR) will be taken into account.

35. With reference to the preparatory action to support EURL implementation, one MB member asked for a clarification on the criteria used to evaluate the lack of conflict of interest. Isabel de la Mata replied that she would verify this point with HaDEA and get back with further details after the meeting.<sup>2</sup>

The Management Board took note of the update on the implementation of the EU Regulation on serious cross-border threats to health (SCBTH).

## Summary of discussions held at the 52<sup>nd</sup> meeting of the ECDC Audit Committee (Stockholm, 12 June 2023), including its recommendations

36. The Chair of the Audit Committee, Daniel Shine, MB Alternate, Ireland, gave a summary of the discussions from the 52<sup>nd</sup> Audit Committee (AC) meeting, which took place in the afternoon of 12 June 2023.

37. Concerning the regular update on audit activities, the AC Chair mentioned that no new observation had been received by ECDC since the last meeting and one had been closed by the Centre. Five observations had been formally closed by the Internal Audit Service (IAS). Two observations were currently open, with a target implementation date of Q4 2023. The AC had taken note of the good progress in implementing the audit recommendations.

38. The AC had also touched upon the scoping memorandum of the ongoing IAS limited review on “the adequacy of the cooperation and coordination mechanisms aimed to prevent, detect and respond to cross-border health emergencies in HERA, SANTE, EMA and ECDC”. The AC Chair mentioned that he had raised concern regarding the scope of this audit as it seemed to disregard some contextual issues and the fact that the new legislation was in place since only six months. The response from the IAS had not been fully sufficient and the AC might approach the IAS with some additional comments. Another audit on the Centre’s response to COVID-19 was being conducted by the European Court of Auditors (ECA) and six Member States (France, Germany, Greece, Italy, Poland, Sweden) had been contacted for this audit.

The Management Board took note of the summary of the AC discussions.

### **a) Final Annual Accounts 2022 (Document MB58/06)**

39. Anja Van Brabant, Accounting Officer and Head of Section, Finance and Accounting, Resource Management Services, ECDC, presented the Final Annual Accounts 2022. She recalled that the Provisional Accounts 2022 had been presented to the AC and approved by the MB in March 2023. The provisional

---

<sup>2</sup> A written response was shared with the MB on 21 June 2023.

accounts were audited by an external audit company (Mazars) during 20-24 March 2023 and no corrections were required. The underlying transactions of Q4 2022 to the accounts and budget implementation were audited by ECA during their second audit mission on 6-10 March 2023. In the final annual accounts, two corrections were made: 1) the accruals of 2022 had to be adjusted by EUR 535 600 due to several decommitments (release of funding) from 2022 done in the past months (mostly related to meetings held in Q4 2022 but with invoices received and paid in 2023 with carry forwarded amounts); 2) the pre-paid expenditures of EUR 239 400 related to the newly internally developed Planning and Monitoring Tool (PRIME) had to be re-booked, partially as an asset under construction and partially as a deferred cost to the 2023 accounts as the work is still ongoing in 2023. These changes had been highlighted in yellow in the document shared with the MB.

40. The clearing letter from ECA, containing preliminary findings, was received on 22 May 2023. On 26 May, ECDC received the "Draft annual report on ECDC for the financial year 2022" from ECA (included as Annex II). Although the ECA issued a clean opinion on the reliability of the accounts, they issued a draft qualified opinion on the legality and regularity of the HERA payments underlying the accounts and in particular the VAT included in those payments.

41. Christian Schultheiss, Head of Section, Legal Services, ECDC, then provided some background and further explanations on the matter. He recalled that the HERA grants were launched in 2021 to increase Member States' capacities to identify and characterise SARS-CoV-2 variants using WGS and RT-PCR. Grants worth 77 million EUR were awarded to national health authorities in 24 EU/EEA countries. The activities covered purchase of equipment, reagents and supplies, organisational alignment to make use of the purchased equipment, training activities, personnel, and consultancy services. The ECA had audited the grant and taken the preliminary view that VAT is not an eligible expense under the grants, because the beneficiaries could only be public health authorities for their actions within national health strategies.

42. Christian Schultheiss then explained ECDC's analysis of the matter based on the Financial Regulation, the VAT Directive and the applicable case law of the Court of Justice of the European Union. According to the VAT Directive, VAT is an eligible expense when it is not recoverable and is not paid by a non-taxable person. A body governed by public law is non-taxable if it engages in an activity as a public authority. According to the case law, a body engages in an activity as a public authority, if it acts in accordance with the special legal regime applicable to it, but not when it acts under the same legal conditions as those that apply to private traders. This is assessed by looking at the applicable national law; it is basically a test of whether national law has reserved an area for public authorities or whether there can be private enterprises, too. In the case of the HERA grants, the eligible activities are the purchase of equipment, reagents and supplies, organisational alignment to make use of the purchased equipment, training activities, personnel, and consultancy services for routine high-capacity WGS and RT-PCR.

43. There are several examples where WGS services were procured by ECDC from a private enterprise. A survey from 2015-2016 has also shown that Member States rely on external providers for WGS. It can thereby be concluded that there is no special legal regime for WGS and RT-PCR, but that private and public actors work under the same legal conditions. It is also important to note that the grant was limited to public health authorities to ensure an equal distribution of the grants, not because only public health authorities can carry out WGS or RT-PCR. The grants were linked to national public health strategies to ensure that they contribute to the improvement of national capacities in a structured way, not because only public health authorities can be part of the implementation of a national public health strategy. According to the law, it is the nature of the activity covered by the grant that should be assessed. It makes no difference for the qualification of the activity whether the grant was only open to public health authorities or linked to national public health strategies.

44. In summary, ECDC considers that the VAT costs were eligible under the grant, because the activities under the grant are not of a nature that they are carried out as a public authority. ECDC will submit its draft formal reply to ECA by 19 June.

45. The AC Chair then gave a brief summary of the discussions held in the AC. The AC had noted that all the relevant assurances on the accounts had been given apart from the matter raised by ECA. ECDC had explained the basis for its divergent opinion on the VAT issue. ECDC had drafted a suggested MB Opinion to be submitted together with the accounts by 1 July 2023. The AC had discussed the matter in detail and suggested a few changes to the proposed draft Opinion. In conclusion, the AC recommended the MB to approve the Final Annual Accounts 2022 and to express its expectations that the outstanding issue will be resolved.

46. Following the presentation, the floor was opened for comments. Several members noted that the annual accounts and the draft report from ECA had been shared too late to allow for necessary consultation at national level, e.g., with the Ministry of Health or Ministry of Finance, and the draft MB Opinion had not been shared in advance of the meeting, which made it difficult to sign off on the wording. One of the MB members representing the European Parliament asked whether it was possible to know which 24 countries had received the grants. Another MB member asked for some additional information on how the decision regarding the VAT had been taken and whether ECDC had exchanged with the European Commission about this matter and what ECDC's reply to ECA would consist of.

47. The Chair mentioned that the AC had discussed the matter at length the day before. While she was reassured that the accounts as such were valid and correct, there were still some points to be clarified and she saw several possible options: 1) leaving the discrepancy out of the opinion; 2) including a short paragraph indicating that the MB had taken note of the matter; 3) attaching a brief flash report describing the matter; 4) launching a written procedure on the matter to allow the MB members to consult with relevant colleagues at national level. One difficulty was that it was not possible to know when the issue would be solved. It was unlikely though that it would get solved in time to provide any additional information of value for the written procedure.

48. Anja Van Brabant clarified that the accounts for 2022 will remain unchanged independently of the final outcome of the discussion between ECA and ECDC; in case of a recovery, this will affect the accounts of 2023 or 2024. Concerning the beneficiaries, she said that ECA had audited four grant agreements and detected that VAT was included in three of these to a value of EUR 640 000. At present it was not known how much VAT had been paid altogether.

49. The MB continued the discussion on the following day. The possibility of adding an explanatory text as an annex to the MB Opinion was debated, with some MB members being in favour of this solution while others supported the inclusion of a short paragraph in the Opinion itself or leaving the matter out of the opinion altogether given that the MB was requested to give an opinion on the accounts only and not to take a position on the controversy between ECA and ECDC, which was a separate discussion relating to the interpretation of tax law. Several members, however, stressed the importance of at least acknowledging the matter in the MB Opinion for reasons of transparency and for safeguarding the reputation of the MB.

50. The AC Chair noted that it was prudent to mention the matter in the Opinion as it was now too late to refer to it in the Consolidated Annual Activity Report 2022 since the CAAR had already been approved by the MB in March 2023. The MB members representing the European Parliament conveyed that they would abstain from the vote in case the proposal was to omit any reference to the unsolved matter in the MB Opinion. It was a question of taxpayers' money in the end and transparency was crucial. They therefore favoured adding an annex to the Opinion to explain the issue, also because it was unlikely that anyone would read the MB minutes at the time when the Parliament would vote for the discharge.

51. The MB Chair asked ECDC if there were any examples of similar situations in other agencies and how the matter had been handled in this case. She also inquired whether adding an annex to the Opinion was common praxis. Pontus Molin, Head of Unit, Resource Management Services, ECDC, reported that he was aware of one situation where the Management Board of another agency had issued an opinion on the accounts with a short mentioning of the fact that the Board had taken note of the preliminary observations of the ECA. These observations had later been withdrawn. With regards to adding an annex to the Opinion, Christian Schultheiss, Head of Section, Legal Services, ECDC, noted that from ECDC's experience this would not be common praxis. An Annex would have the same legal value as a mention in the Opinion itself.

52. Based on the information provided, the Chair concluded that the best option seemed to be the inclusion of a clear and neutral sentence to indicate that the MB had taken note of the issue. A more detailed explanation would be included in the minutes.

53. Following consultation by one MB member with the Ministry of Finance in her country and input received from the European Commission, a final proposed text for the MB Opinion was put forward for approval by the MB: "The Management Board is assured and confident that the final annual accounts for the year 2022, as presented by the Director, form a correct basis for requesting the discharge of the Director to the European Parliament in respect of the implementation of the budget for year 2022. Further, the Management Board has taken note of the draft annual report of the Court of Auditors, including their observation related to the eligibility of VAT in the HERA grant."

54. The Chair suggested proceeding with a conditional decision whereby the MB was asked to approve the Opinion with the above-mentioned wording. In the event that the issue is solved by 30 June 2023 (i.e.

in case ECA's preliminary observations were withdrawn), then the last sentence will be removed from the Opinion before submitting it with the final accounts. The MB will be informed of how the matter is progressing.

55. Before proceeding with the vote, the Chair noted the following proxies: 1) Zofija Mazej Kukovič, European Parliament: proxy given to Marilena Koppa, European Parliament; 2) Romania: proxy given to Bulgaria. The Chair asked the MB members whether there were any objections to the proposed MB Opinion and the proposed way forward. No objections were raised. One member abstained from the vote due to the lack of time to consult relevant actors at national level.

The Management Board approved the Final Annual Accounts 2022, including the proposed MB opinion. The final MB opinion will be signed by the Chair on 30 June 2023 and attached to the Final Accounts.

### ***b) Progress Report on the Implementation of the Work Programme 2023 (Document MB58/07)***

56. Maarit Kokki, Head of the Executive Office, Director's Office, ECDC, briefed the MB on the current level of implementation of the work programme 2023. She presented the implementation status as of June 2023 noting that 92% of the activities had been started, 3% were planned to start later in the year and 5% were delayed. Most of the delays occurred due to the impediments in the procurement process. In April 2023, the Director had further downgraded the COVID-19 PHE to Recovery phase – Level 0. The remaining COVID-19 PHE structure and functions will be dismantled, and all COVID-19 related work will now be integrated within ECDC's regular organisational structure. The COVID-19 Task Force will remain active during this phase. She then highlighted some of the main achievements under each of the five Strategic Objectives (SOs). Minor changes had been made to the Financing Decision; these did not influence the planned activities or foreseen outputs and the document was therefore presented to the MB for information only.

57. The AC Chair reported that the AC had taken note of the progress in the work programme implementation. ECDC had provided some further information on the ECDC ASPIRE programme and the Director had agreed to update the MB on the TB situation in Europe and on recent work in relation to Ukraine.

The Management Board took note of the Progress Report of the implementation of the Work Programme 2023.

### ***c) Progress Report – Overview of 2023 Budget Implementation***

58. Anja Van Brabant, Accounting Officer and Head of Section, Finance and Accounting, Resource Management Services, ECDC, gave an overview of the 2023 budget implementation up until 7 June 2023.

59. She explained that from the total budget of EUR 90.2 million, EUR 64.7 million (71.8%) had been committed, and from the committed amount, EUR 20.7 million (23%) had been paid, while EUR 4.5 million were in the workflow to be paid. A total of EUR 25.2 million had been carried forward from 2022; from this amount, EUR 11.3 million (44.9%) had been paid, while EUR 1 million was in the workflow to be paid.

60. In the AC meeting, ECDC had clarified that the increase in in Title I expenditure was due to a combination of additional staff hired and salary increases due to inflation. The AC had taken note of the budget implementation as of 7 June and the explanations given.

The Management Board took note of the Progress Report – Overview of 2023 Budget Implementation.

### ***d) First Supplementary and Amending Budget 2023 (Document MB58/08)***

61. Anja Van Brabant, Accounting Officer and Head of Section, Finance and Accounting, Resource Management Services, ECDC, presented the First Supplementary and Amending Budget (SAB) 2023, consisting of the budget transfers approved by the Director since the beginning of 2023. She clarified that the main transfers were mentioned in the summary part of the document and the details of the distribution of the 2023 budget transfers were listed in the Annex. No transfers were executed between Titles at this stage.

62. The AC Chair reported that ECDC had explained that the increased expense of EUR 40.000 in budget line 1180 "Recruitment" referred to its publication of the vacancy notice of the Director in relevant media. The increased expense of EUR 36.000 in budget line 3009 "EU and External Cooperation" referred to ECDC's participation in the Health Forum Gastein.

63. Concerning the cost related to the vacancy notice, Pontus Molin, Head of Unit, Resource Management Services, ECDC, clarified that this budget also included possible travel linked to the recruitment process.

The Management Board took note of the First Supplementary and Amending Budget 2023.

### ***e) Amendments to the Management Board Rules of Procedure and Audit Committee Mandate (Document MB58/09)***

64. Daniel Shine, AC Chair, MB Alternate, Ireland, presented proposed amendments to the AC mandate to clarify the role and responsibilities of the AC. With this, the mandate of the AC would be expanded to also cover governance and risk management matters. In addition, some clarifications are made concerning the possibility for MB alternates to be appointed as members of the AC and the requirement for the AC to have access to necessary information. An advisory provision is also included to indicate that the AC can be consulted on specific issues where necessary. In tandem to these amendments, a new article 9A is proposed to be added to the MB Rules of Procedure (RoP) to address the specific role of the AC and its relationship to the MB. The AC Chair thanked the ECDC as well as the MB Chair and the MB Alternate from Germany for useful input on the documents and added that both texts were now put forward to the MB for consideration and possible approval.

65. In the discussion that followed, the Deputy Chair of the MB suggested adding a sentence in Article 2 (5) of the MB RoP to clarify that all relevant information and documents should be shared with the Deputy Chair in real time. This was important to make sure that the Deputy Chair has all the necessary information to smoothly replace the Chair whenever the need arises.

66. The Chair noted that she had no objections to adding such a clarification to the text but said that MB members should be able to see the concrete formulation in written form. It would also be necessary to clarify the communication ways with the IAS and ECA as documents sent by these institutions were often password protected. She suggested bringing both documents back for approval during MB59 in November 2023.

The Management Board discussed the proposed amendments to the Management Board Rules of Procedure and the Audit Committee Mandate.

## **Update from the Director**

67. The Director gave an update on ongoing ECDC activities. As requested, she briefed the MB on the tuberculosis situation in EU/EEA noting that the incidence in 2021 was 7.4 cases per 100 000 population, which makes it clear that the Sustainable Development Goal (SDG) target for 2030 (2.4 cases/100 000) will not be met if no measures are taken to accelerate the decrease. One reason for the slow decline is the negative effect of the pandemic on TB, HIV and hepatitis programmes in many countries, in particular as concerns treatment. Concerning the ECDC ASPIRE programme, she said that the monthly town hall meetings had continued with different themes to explain the amended ECDC mandate. The following day, the Strategy campaign would start focusing on Strategic Objective 1. Videos with involved staff and other content were displayed on screens and there was a dedicated ASPIRE page on the ECDC intranet. Pulse checks were carried out to collect staff feedback on past events. The Director then briefed the MB about

her recent country missions to Portugal and Slovenia and planned missions to France and Ireland (September-October). The main topics for discussion during these missions were questions and concerns of countries regarding the amended ECDC mandate as well as concrete actions for support. There had also been several high-level visits to ECDC due to the ongoing Swedish EU Presidency (health ministers from Germany and Cyprus, health attachés, COREPER II). In May, for the first time ever, the European Commission had agreed to include ECDC as part of the EU delegation at the WHO World Health Assembly.

68. The Director then informed the MB of a recent incident whereby pseudonymised personal data from TESSy was shared with another EU agency by an ECDC staff member without following the appropriate procedures. Even if there is no evidence that the data was compromised, it is considered a data breach as personal data was uploaded on a cloud server without password protection. ECDC immediately notified the European Data Protection Supervisor (EDPS) of the incident and has thereafter been in contact with the EDPS to confirm ECDC's risk assessment and discuss the next steps. ECDC's assessment is that even in the hypothetical case of unauthorised access, recipients (except for the Member States themselves that provided the data) would not have the means to reidentify data subjects due to pseudonymisation. ECDC is awaiting the decision of the EDPS on the case. If the EDPS concludes that there is a "high risk" for the data subjects, there is a legal obligation to inform them about the data breach. In such case, as the data subjects are not known to ECDC (due to pseudonymisation), it will be necessary to make a public announcement.

69. To avoid similar incidents in the future, a review of ECDC's internal procedure on dealing with TESSy access requests has been initiated. A dedicated Data Protection Officer is also in place since 1 May. Another area where ECDC wants to improve is general awareness of staff. Therefore, ECDC has made an online training by the EDPS mandatory for all staff.

70. Following the presentation, a few clarifications were given by ECDC in response to questions from MB members regarding the timeline for the final decision by the EDPS and the diseases concerned. Christian Schultheiss, Head of Section, Legal Services, clarified that there was no defined timeline as such. ECDC had presented its risk assessment to the EDPS and a written response would be sent later in the day. From ECDC's perspective, a public announcement of the data breach would not provide any added value for the patients given that ECDC cannot identify the data subjects in any case and hence cannot even confirm to a data subject whether their data were included. The Director said that the TESSy datasets included case-based data from all Member States for 10-11 food and water-borne diseases, vector-borne diseases and Legionnaire's disease. Vicky Lefevre, Head of Unit, Public Health Functions, added that ECDC's IT security team had made tests and concluded that neither the links nor the folders were searchable online.

71. The MB requested to receive some further information on the incident in written to be able to share it with concerned counterparts. The Director confirmed that additional information including ECDC's risk assessment would be shared with the MB following the meeting.

The Management Board took note of the update from the Director.

## **ECDC Management Board meeting dates 2024 and 2025 (Document MB58/10)**

72. Maarit Kokki, Head of Executive Office, Director's Office, ECDC, presented the proposed MB meeting dated for 2024 and 2025. She noted that the suggested date for the March meeting 2024 meant that the Provisional Annual Accounts might not reach the MB within the set deadline for dispatch of financial documents (ten days prior to the meeting). This date was chosen to avoid overlap with the negotiations on the international pandemic treaty scheduled to take place in the weeks before and after. No objections were raised, and the MB agreed with the proposed schedule of meetings in 2024 as below:

- MB60: 13-14 March 2024
- MB61: 12-13 June 2024
- MB62: 26-27 November 2024

In addition, the Management Board took note of the following meeting dates proposed for 2025:

- MB63: 27-28 March 2025
- MB64: 17-18 June 2025
- MB65: 25-26 November 2025

The Management Board approved the proposed meeting dates for 2024 and provisionally for 2025.

## Update from the European Commission

73. Isabel de la Mata, MB Alternate, DG SANTE, European Commission, briefed the MB about ongoing activities in the area of health. The update focused on recent and upcoming meetings of the HSC, ongoing activities under the EU4Health Programme and the work on AMR. She also informed the MB of the timeline of the negotiations on the pandemic agreement and International Health Regulations (IHR) amendments. Lastly, she mentioned that the European Commission and the European Observatory on health systems and policies were arranging a Summer School in Venice on 23-29 July on the topic of health security. She confirmed that a written summary of her update would be shared with the MB following the meeting.<sup>3</sup>

The Management Board took note of the update from the European Commission.

## Update from the European Parliament

74. Marilena Koppa, MB Member, European Parliament, gave a brief update noting that climate change was one of the main topics on the agenda of the ENVI Committee. She also reported on the work of the Parliament's Special Committee on lessons learnt from the COVID-19 pandemic (COVI). Among the topics currently under debate in the plenary, she highlighted the Artificial Intelligence (AI) Act and the strengthened mandate of EMCDDA.

The Management Board took note of the update from the European Parliament.

## Update from the Swedish Presidency of the European Council

75. Karin Tegmark Wisell, MB Member, Sweden, briefed the MB on the achievements of the Swedish EU Presidency that was ending on 30 June 2023. The Presidency had hosted high-level meetings on cancer and AMR respectively. An informal EPSCO meeting had taken place on 5-6 May focusing on safe access to medicinal products as well as shortages and crisis preparedness. During the formal EPSCO meeting in Luxembourg on 12-13 June, Council Recommendations on AMR were adopted. Negotiations were ongoing on several major legislative files such as the Regulation on the European Health Data Space, the Regulation on Substances of Human Origin (SoHO) and the Regulation on fees and charges payable to the European Medicines Agency as well as on Council Conclusions on EU's Global Health Strategy. Negotiations on the revision of the EU Pharmaceutical Legislation had also been initiated during the Swedish Presidency.

The Management Board took note of the update from the Swedish Presidency of the European Council.

## Any other business

76. The Chair thanked all the MB members for their active and supportive attitude during the meeting noting that the legal and financial issues were at the core of the MB's business. She also thanked the interpreters and the MB Secretariat for their support.

77. One MB member recalled that before the pandemic, the MB had the opportunity to meet ECDC colleagues during one of the coffee breaks and suggested restoring this practice. The Chair supported this proposal considering also that there were many new colleagues in ECDC. She suggested introducing this possibility starting from the next MB meeting scheduled to take place in Stockholm on 14-15 November 2023.

<sup>3</sup> The written summary was shared with the MB on 14 June 2023.

## Annex: List of Participants

Country/Organisation	Representative	Status
Austria	Sigrid Kiermayr	Member
Belgium	Lieven De Raedt	Member
	Patrick Smits	Alternate
Bulgaria	Angel Kunchev	Member
Croatia	Bernard Kaić	Member
Cyprus	Irene Cotter	Member
Czech Republic	Pavla Svrčinová	Member
Denmark	Gideon Ertner	Alternate
Estonia	Heli Laarmann	Member
Finland	Anni Virolainen-Julkunen ( <i>Chair</i> )	Member
	Taneli Puumalainen	Alternate
France	Anne-Catherine Viso	Alternate
Germany	Gesa Lücking	Alternate
Greece	Theoklis Zaoutis	Member
Hungary	Ágnes Dánielisz	Member
Ireland	Colette Bonner	Member
	Daniel Shine	Alternate
Italy	Francesco Maraglino	Member
Latvia	Jana Feldmane	Member
Lithuania	Audrius Ščeponavičius	Member
Luxembourg	Jean-Claude Schmit	Member

Malta	Patricia Vella Bonanno	Member
Portugal	Cristina Abreu Santos	Alternate
Romania	Amalia Serban	Member
Slovakia	Ján Mikas	Member
Slovenia	Mario Fafangel	Alternate
Sweden	Karin Tegmark Wisell	Member
<b>European Parliament</b>		
	Zofija Mazej Kukovič	Member
	Maria Eleni Koppa	Member
<b>European Commission</b>		
DG SANTE	Isabel de la Mata Barranco	Alternate
DG RTD	Barbara Kerstiens	Member
<b>EEA Countries</b>		
Norway	Øystein Riise	Member