

ECDC Management Board

Minutes of the Fifty-seventh Meeting Stockholm, 21-22 March 2023

Adopted by the ECDC Management Board at its Fifty-eighth meeting, 13-14 June 2023

Contents

Opening and welcome from the Chair (and noting the Representatives)
Welcome from the Director, ECDC
Adoption of the draft programme (and noting the declarations of interest and proxy voting, if any) (Document MB57/01)
Adoption of the draft minutes of the 56 th meeting of the Management Board (Stockholm, 15-16 November 2022) (Document MB57/02)
Consolidated Annual Activity Report 2022 (Document MB57/03)
Amended ECDC Strategy 2021-2027 (Document MB57/04)
Timeline and process for selection of ECDC Director 2024-2029
Summary of discussions held at the 51st meeting of the ECDC Audit Committee (Stockholm, 20 March 2023), including its recommendations
Update from the Director9
Working Arrangements between ECDC and HERA (Document MB57/10)
Updated ECDC Long-term Surveillance Framework (Document MB57/11)
Memorandum of Understanding between ECDC and EASA (Document MB57/12)
Update from the European Commission
Update from the European Parliament
Update from the Swedish Presidency of the European Council
Any other business
Annex: List of Participants

Summary of Proceedings – ECDC Management Board Meeting

The Fifty-seventh meeting of the ECDC Management Board (MB) convened on 21-22 March 2023 in Stockholm, Sweden. During the meeting the MB:

- adopted the programme of the meeting;
- adopted the minutes of the Fifty-sixth meeting of the MB;
- approved the Consolidated Annual Activity Report (CAAR) 2022, including the MB analysis and assessment of the CAAR;
- approved the Provisional Annual Accounts 2022;
- approved the ECDC Long-term Surveillance Framework;
- approved the Memorandum of Understanding between ECDC and EASA;
- discussed the revised ECDC Strategy 2023-2027 and agreed to proceed with the MB Working Group tasked to review the amended ECDC Strategy and related documents and their alignment with the EU Health Union legal package;
- discussed the timeline and process for selection of the ECDC Director 2024-2029 in a closed session;
- discussed the proposed Audit Committee mandate amendment and its reflection in the Management Board Rules of Procedure;
- took note of the summary of discussions held at the 51st meeting of the ECDC Audit Committee;
- took note of the Third Supplementary and Amending Budget 2022;
- took note of the Progress report Overview of 2023 budget implementation;
- took note of the Progress report on implementation of the Work Programme 2023;
- took note of the update from the ECDC Director;
- took note of the working arrangements between HERA and ECDC;
- 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;
- took note of the address by Dr Antje Draheim, State Secretary at the German Federal Ministry of Health.

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-seventh meeting of the Management Board (MB), which took place in Stockholm, Sweden. A special welcome was extended to the newly appointed members: Patrick Smits, Alternate, Belgium; Line Raahauge Hvass, Alternate, Denmark; Caroline Semaille, Member, France, and Florien van der Windt, Member, The Netherlands.
- 2. The Chair informed the Board that Miriam Schmidt from Germany and Corine van Lingen from the Netherlands would be participating in the meeting as advisers.
- 3. Apologies had been received from Austria (proxy to Italy), Bulgaria (proxy to Slovakia), Denmark, Estonia (proxy to Finland), and Barbara Kerstiens, DG RTD, European Commission (proxy to John F Ryan, DG SANTE, European Commission).

Welcome from the Director, ECDC

4. 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 MB57/01)

5. The Chair suggested extending the closed session of the MB in the afternoon to allow sufficient time to discuss the timeline and process for selecting the ECDC Director 2024-2029 including the draft vacancy notice. The Draft Programme was adopted with the proposed change. 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.

The Management Board adopted the draft programme.

Adoption of the draft minutes of the 56th meeting of the Management Board (Stockholm, 15-16 November 2022) (Document MB57/02)

6. The Chair noted that the draft minutes of the 56th 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-sixth meeting of the Management Board.

Consolidated Annual Activity Report 2022 (Document MB57/03)

7. Andrea Ammon, Director, ECDC, presented the ECDC Consolidated Annual Activity Report (CAAR) 2022 noting that her presentation would cover the content part while the analysis and assessment of the CAAR and the internal control part would be discussed in the afternoon under the reporting back from the Audit Committee (AC). Concerning the implementation of the work programme 2022, she recalled that during spring and summer 2022, ECDC had supported simultaneously three Public Health Events (PHEs): COVID-19 (for the third consecutive year), outbreak of monkeypox and outbreak of hepatitis of unknown origin in children. In addition, ECDC had established the Ukraine Task Force (UTF), which actively coordinated and delivered technical and operational response activities based on identified needs. Under these circumstances, ECDC delivered 89% of the activities planned in its Single Programming Document (SPD) 2022. A vast number of media requests were addressed (471 compared to 91 in 2019). ECDC also

managed grants to 24 EU/EEA countries to strengthen their whole genome sequencing (WGS) and RT-PCR infrastructures (HERA Incubator grants). The total budget 2022 amounted to EUR 99.8 million.

- 8. In terms of COVID-19 response, ECDC offered need-based sequencing support to Member States that have not yet fully transitioned to WGS-based surveillance. In 2022, ECDC also launched support to the Member States for microbiology capacity-building for SARS-CoV-2 and Influenza. The Centre continued to address the social and behavioural aspects as well as effective risk communication for the prevention and control of specific diseases, with a particular focus on COVID-19 and promoting vaccination acceptance and uptake. ECDC also worked through different approaches to collate lessons identified from the COVID-19 pandemic.
- In the discussion that followed, several MB members congratulated ECDC for the impressive 9. amount of activities carried out considering the circumstances. The work on lessons learnt from the COVID-19 pandemic was welcomed. In this context, one MB member said that ECDC could be more transparent when it came to the assessment of the preparedness and crisis management during the pandemic and asked whether Member States' After-Action Reviews (AARs) would be published. She referred to figures from her country showing the negative effects of COVID measures, for instance among girls aged 15-17, and said that more should be done to analyse the impact of such measures on non-communicable diseases (NCDs). She suggested that this topic be discussed also in the Health Security Committee (HSC). Another MB member mentioned that the importance of ethical and human rights issues and learning how to deal with uncertainty were two important lessons from the pandemic. He thanked the ECDC Director for having initiated the ethical discussion in this context. It was noted that ECDC seemed to be a bit far from research while this was an important element for preparedness. In relation to future activities, several MB members requested clarifications on the timeline for Member States' reporting and development of national preparedness plans in accordance with the new Regulation on serious cross-border threats to health (SCBTH).
- 10. The Director thanked the MB members for their comments and said that a short version of the CAAR with pictures and graphs would be developed in the coming months. With regards to COVID-19 lessons learnt, ECDC was about to publish an updated guidance document on COVID-19 AARs. In response to the comment on transparency, she clarified that the overall conclusions from AARs would be published but not the single reports. She acknowledged that the impact of infectious diseases on NCDs was important to look at; however, this was currently not in the remit of ECDC. She agreed that ethics and community engagement should be part of the preparedness plans, which required strengthening of the behavioural science. It had been recognised that research was a weak point during the pandemic and there were now efforts to introduce clinical trials during emergencies; this was also reflected in the amended EMA mandate. The amended ECDC mandate includes references to operational research and ECDC has started discussions on this topic with the Advisory Forum.
- 11. Concerning the timeline for preparedness, the Director clarified that the first step is to develop the template for the reporting to be done by Member States in accordance with Article 7 of the SCBTH Regulation and this work is currently ongoing. Member States will have to respond to the questionnaire by 27 December 2023, and thereafter every three years. The EU prevention, preparedness and response plan (Article 5 of the SCBTH) is foreseen to be finalised in Q1 2024. As for the assessment visits to be performed by ECDC (Article 8), the finalisation of the process will require a delegated act tentatively scheduled for Q1 2024 and the actual assessment missions will only come later. The criteria for which Member States to visit and the sequence of visits will also have to be reflected and agreed upon. The EU Health Task Force (EUHTF) should be able to provide support in the assessment of preparedness gaps.
- 12. The MB Chair thanked the Director for the clarifications. She said that the formal decision on the CAAR would be made in connection to the reporting back from the AC.

The Management Board discussed the Consolidated Annual Activity Report.

Amended ECDC Strategy 2021-2027 (Document MB57/04)

13. Andrea Ammon, Director, ECDC, presented the draft amended ECDC Strategy 2021-2027. She clarified that the Strategic Objectives (SOs) had been slightly modified and some parts of the text further

elaborated on. She then presented the ECDC vision 2021-2027, which will remain unchanged. To fulfil the vision, ECDC needs to become better at translating complex scientific content into key messages to be used by policy and decision makers. ECDC should also become better at listening and understanding the needs of the Member States and other stakeholders and be internally fit to respond to these needs in a timely and effective manner. This requires a change in the approach with much more focus on real dialogue. Over the past couple of years, there were some good examples of this approach, e.g., the support provided to Member States having a lower COVID-19 vaccination coverage and the support provided to Member States neighbouring Ukraine. The Director then presented the amended SOs and the Action Areas under each of these.

- Lieven De Raedt, MB Member, Belgium, briefed the MB about the work done so far by the MB 14. working group tasked to analyse the ECDC Strategy and related documents and their alignment with the legal texts of the EU Health Union. He said that the working group had held three virtual meetings since it was set up in November 2022. The working group had first discussed its own role and concluded that it should be restricted to providing guidance on relevant ECDC documents such as the amended ECDC Strategy in the first place and the Strategy implementation roadmap once available. There was consensus in the working group that the current draft amended Strategy was a big step forward compared to the first draft discussed in November. ECDC's vision and overarching mandate was now better formulated, and the working group also welcomed the emphasis on the role of the EU Health Union legal package and the necessity to implement it. The Strategy could however contain stronger language on ECDC's ambition to prevent future pandemics, while acknowledging that future crises are inevitable, and to present ECDC as a central player in the EU Health Security Framework. The document could also put more emphasis on the opportunities created by technological advances, as well as on the objectives for ECDC in the areas where its new legal mandate is most innovative, such as country support, the EU Health Task Force and communication. The Strategy could be more explicit on how ECDC proposes to bridge the gap between its current position and achieving the goals outlined in it. The working group also felt that the various objectives proposed would benefit from more granularity in terms of how they might be implemented in practice. Lieven De Raedt mentioned that there were other relevant documents under development, such as the Strategy implementation roadmap, and the working group was therefore asking for the mandate to continue its work.
- In the discussion that followed, one of the MB members representing the European Parliament 15. emphasised the need for differentiated country support as this was one of the lessons from the COVID-19 pandemic. She expressed disappointment that there was no reference to the European Parliament in the document, while the Parliament was one of the main pillars of the European Health Union. One MB member who was also part of the working group noted that one key element to consider when finalising the Strategy was the ongoing PESTEL analysis that would look at the political, economic, social, technological, environmental, and legal environment in which ECDC operates. One of the members representing the European Commission said that it had been very useful to have a more in-depth discussion in the working group on the shape of the document. In relation to the comment on technical advances, he added that there was legislation under way on both digital health and pharmaceutics and it would be beneficial to refer to the use of future elements of the digital health proposal in the Strategy. The Deputy Chair and MB member representing the European Parliament agreed that the MB working group discussions had been very valuable. She welcomed that the ambition of ECDC to get closer to the Member States was clearly expressed in the document and was happy to see the work on the Strategy moving forward even if the implementation roadmap was still to be developed. There were some external and internal challenges to take into consideration going forward, such as staff satisfaction and the fact that part of ECDC's higher management will be leaving the agency during 2024.
- 16. Other comments on the document concerned the need to consider the ethical aspects discussed earlier as well as health inequalities and it was suggested that the Strategic Goals 1-3 would benefit from giving this angle. It was inquired how the One Health principle was reflected in the action areas. ECDC's role on the global arena and the importance of EU speaking with one voice was also highlighted. Further clarification was requested on the articulation between the Strategy, the implementation roadmap and the Single Programming Documents.
- 17. The Director thanked the MB members for their feedback. She said that there was a balance to be found between the high-level and the granularity and her view was that the Strategy should give the overview while the roadmap should outline what ECDC will do in each area over the years. Concerning

country support she agreed that it had to be diversified and ECDC was working towards enhancing this approach. She clarified that the PESTEL and ecosystem analysis was carried out by IPSOS. The results of this analysis should be available on time for incorporating them into the next version of the Strategy. With reference to the comment from the member representing the European Parliament, the Director ensured that there was a close relationship with the Parliament in general, the ENVI Committee and individual MEPs but suggested looking into how this was formulated in the document. Concerning health inequalities, she commented that part of the new mandate is to pay more attention to health determinants in the analysis and ECDC will examine how this can best be done without too much burden on the Member States. She reminded that health determinants are already included in the data on TB and HIV. ECDC will also look at existing sources for collecting social determinants and other factors, but this will of course not allow for case-based data. Concerning the One Health approach, she said that ECDC was working on a One Health strategy foreseen to be finalised in the first half of 2024.

- 18. As a next step, ECDC would amend the Strategy document by incorporating the results of the PESTEL analysis (once available) and the MB comments. At this stage, she asked the MB members to indicate at least whether there was any objection to the overall structure of the Strategy. The expected timeline was to present the updated Strategy for approval in June while the implementation roadmap would probably have to be finalised after the summer.
- 19. Concerning the structure, one MB member suggested that it could be beneficial to look at strategies of other EU agencies as a comparison. She added that ECDC's independence and the EU added value should be stated at the very beginning of the document.
- 20. The Chair agreed that the scientific independence was indeed crucial and should be emphasised. She thanked the MB working group for its useful input and concluded that there was no objection for it to continue its work.

The Management Board <u>discussed</u> the draft amended ECDC Strategy 2021-2027. The Management Board <u>agreed</u> to continue the work of the MB Working Group tasked to review the amended ECDC Strategy and related documents and their alignment with the EU Health Union legal package.

Timeline and process for selection of ECDC Director 2024-2029

21. This item was discussed in a closed session (Members of the Management Board only).

Summary of discussions held at the 51st meeting of the ECDC Audit Committee (Stockholm, 20 March 2023), including its recommendations

- 22. Daniel Shine, Chair of the Audit Committee, gave a summary of the discussions from the 51st Audit Committee (AC) meeting, which took place in the afternoon of 20 March 2023. He informed the MB that the Internal Audit Service (IAS) had presented the progress on the two ongoing IAS audits: 1) the 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", and 2) the audit on Information Security Management in ECDC. For both audits, the preliminary surveys were ongoing, including the work on the detailed audit scopes. The IAS had confirmed that they will discuss the scoping memoranda with the Director before starting the work. The AC had asked to be informed of the audit scopes and the Director had agreed to circulate these to the AC as part of the consultation process.
- 23. Concerning the regular update on audit activities, the AC Chair mentioned that no new observation had been received by ECDC and two had been closed by the Centre. Three observations were currently open; these were all delayed more than six months and new target dates had been set for Q1 2023 (one observation) and Q4 2023 (two observations). The AC had noted the delays, the explanations given and asked ECDC to keep the AC informed on the progress.

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

a) Fourth Supplementary and Amending Budget 2022 (Document MB57/07)

- 24. Anja Van Brabant, Accounting Officer and Head of Section, Finance and Accounting, Resource Management Services, ECDC, presented the Fourth Supplementary and Amending Budget (SAB) 2022, consisting of the budget transfers approved by the Director since the Third SAB that was presented to the MB for information in November 2022. She clarified that the main transfers were mentioned in the summary part of the document and the details of the distribution of the 2022 budget transfers were listed in the Annex. Between Titles, a transfer of EUR 119 223 was made from Title 2 to Title 3 to continue the provision of Whole Genome Sequencing (WGS) support services to the Member States.
- 25. The AC Chair reported that ECDC had explained that the missions and meetings expenditure was not expected to go back to the pre-covid levels. The AC had requested additional information on the expenditure for the budget line "Digital Transformation".

The Management Board took note of the Fourth Supplementary and Amending Budget 2022.

b) Provisional Annual Accounts 2022 (Document MB57/06)

- 26. Anja Van Brabant, Accounting Officer and Head of Section, Finance and Accounting, Resource Management Services, ECDC, presented the Provisional Annual Accounts 2022. She recalled that the Accounts consist of two parts: the financial statements of the Centre and the report on the implementation of the budget of the Centre. The provisional accounts would be audited by an external audit company (Mazars) during 20-24 March 2022 and their report would be issued to the European Court of Auditors (ECA) by 1 April 2023. ECA performed two audits related to the 2022 budget: the first one in November 2022 and the second one during 6-10 March 2023. ECA had decided to issue one report for the two audits together as the HERA grants implementation continued throughout the entire year 2022 and therefore across both audits. ECDC received their report on 10 March with a clean opinion on the annual accounts 2022.
- 27. Anja Van Brabant then presented the budget execution in 2022 as compared to 2021 noting that from the total 2022 budget of EUR 99.8 million, 98,6% had been committed (compared to 99,35% in 2021), while 73,61% had been paid (compared to 64,08% in 2021). From the EUR 59.3 million carried forward from 2021, EUR 45.5 million or 76,67% had been paid. In terms of the budgetary outturn, EUR 17.8 million are to be returned to the European Commission in 2023. The main source for the return of funds is the cancellation of carried-forward budget from 2021 related to the implementation of the HERA grants. In this context, as requested by the AC, a slide showing the multi-annual overview (2021-2023) of the HERA grant implementation was presented to the MB.
- 28. The AC Chair noted that DG SANTE had clarified that there would be no penalties for ECDC's 2024 budget due to the under-implementation of the HERA grants in 2022. The AC recommended the MB to approve the Provisional Annual Accounts 2022.

The Management Board <u>approved</u> the Provisional Annual Accounts 2022.

c) Progress Report – Overview of 2023 Budget Implementation

- 29. 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 15 March 2023.
- 30. She explained that from the total budget of EUR 90.2 million, EUR 54.9 million had been committed, and from the committed amount, EUR 11.1 million (12.4%) had been paid. A total of EUR 25.2 million had been carried forward from 2022; of this amount, EUR 5.4 million (21.4%) had been paid, while EUR 0.4 million was in the workflow to be paid.
- 31. In the AC meeting, ECDC had clarified that the 2022 budget had amounted to EUR 99.8 million (including EUR 10 million for WGS) and the 2021 budget (including HERA funding) to EUR 168 million. With

the amended mandate, ECDC expected the annual budget to be of approximately EUR 90 million as compared to the previous "normal" budgets of EUR 60 million within the old mandate.

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

d) Progress Report on the Implementation of the Work Programme 2022 (Document MB57/08)

- 32. 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 per Strategic Objective as of March 2023. Concerning ECDC response to emergency situations, she recalled that the PHE for COVID-19 had been downgraded to maintenance phase in June 2022. As a result of the PHE, there was some delay in individual activities and changes to the modes of delivery, e.g., virtual meetings instead of face-to-face. There were no changes to the Financing Decision at this stage.
- 33. The AC Chair reported that the AC had taken note of the fact that 92% of the activities had been started. The AC had requested that further details on some of the activities be given to the MB. ECDC had provided some further information and clarified that most of the ECDC activities are business as usual, but that some new tasks have been included for the amended mandate.

The Management Board <u>took note</u> of the Progress report on the implementation of the work programme 2023.

e) Final 2023 IAS Audit Plan for ECDC (Document MB57/05)

- 34. Stefan Sundbom, Internal Control Coordinator, Executive Office, Director's Office, ECDC, recalled that the 2022-2024 IAS Strategic Internal Audit Plan (SIAP) had been endorsed by the MB in November 2021. In line with the prospective topics proposed at the time, the IAS had now decided to perform the following three engagements in 2023: a) Audit on the adequacy of the design and effectiveness of the information security management in ECDC; b) Limited review on the adequacy of the cooperation and coordination mechanisms aimed to prevent, detect and respond to cross-border health emergencies in HERA, DG SANTE, EMA and ECDC, and c) Preparation, review and validation of external communication content. Engagements a) and b) are on-going audits carried over from the 2022 audit plan, while engagement c) is scheduled to start in 2023 with finalisation in 2024.
- 35. The AC had taken note of the ongoing and planned audits and considered the audit topics to be well selected as well as the order in which they were to be performed. The AC had reminded the IAS of the fact that the audit topics are intertwined, especially regarding IT. The AC recommended the MB to endorse the Final 2023 IAS Audit Plan for ECDC.

The Management Board endorsed the Final 2023 IAS Audit Plan for ECDC.

f) Audit Committee mandate amendment and its reflection in the Management Board Rules of Procedure (Document MB57/09)

36. Daniel Shine, AC Chair, MB Alternate, Ireland, reported that the AC had held an informal online meeting at the beginning of March 2023. The key focus had been on the AC charter/mandate and whether it was optimal with regards to how the AC currently operates. The AC has a rather technical role, and it was discussed that members would benefit from receiving some onboarding training on specific matters. The AC had also noted that its work focused on audit, internal control and risk management and discussed that it could be appropriate to include some elements of governance and strategy as well. With regards to the current phrasing of the AC mandate, there was no reference to alternates while several of its members were MB alternates. It was also noted that the MB Rules of Procedure (RoP) describe the mechanism for putting in place working groups but there is no explicit reference to the AC while this Committee provides a particular service to the MB. The AC Chair suggested working with ECDC to propose textual elements for both documents and thereafter presenting these to the MB for decision.

- 37. Gesa Lücking, MB Alternate, Germany, agreed that the AC mandate should refer also to MB alternates as possible members of the AC. Concerning the MB RoP, she pointed out that there was no legal requirement as such to put in place an Audit Committee. She recommended not going too much into details to allow for more flexibility. The AC Chair acknowledged the need for flexibility but felt that the AC should be at least referred to considering its specific role in advising the MB. In his view, the AC mandate would also benefit from being a bit more accurate.
- 38. The MB Chair invited the AC Chair and Gesa Lücking to discuss the matter further. Any proposed amendments to the texts will be brought to the MB for approval.

The Management Board <u>discussed</u> the proposed Audit Committee mandate amendment and its reflection in the Management Board Rules of Procedure.

g) Draft Assessment of the Consolidated Annual Activity Report (Document MB57/05)

- 39. The AC Chair mentioned that the policy achievements of the CAAR (Part 1) had not been discussed in the AC, but it had focused on the assessment of the Internal Control System and the implementation of Internal Control Framework (ICF). The AC endorsed the MB assessment and analysis of CAAR 2022, as well raised no objection regarding the Director's Declaration of Assurance, which was substantiated by the information provided.
- 40. Maarit Kokki, Head of the Executive Office, Director's Office, ECDC, then presented the proposed text for the MB analysis and assessment of the CAAR. The text focused on the following areas: implementation of the work programme 2022, human resources, budget, public health emergencies, stakeholder satisfaction survey, and preparations for the implementation of the amended ECDC mandate, including ASPIRE.
- 41. In the discussion that followed, one of the members representing the European Commission said that it would have been useful for the MB to receive the draft text in advance. In general, he stressed the importance of AC and MB documents being dispatched in a timely manner and called for a more participative discussion in the MB on these matters. As it was now, it was difficult for the MB to sign off on something it did not have full assurance of; he referred in particular to the sentence indicating that ECDC had made "an excellent budgetary result in 2022". One of the MB members representing the European Parliament agreed that a more sober language would be preferable throughout the text. It was agreed that ECDC would modify the text based on the input and bring it back for decision the following day.
- 42. During the second meeting day, Maarit Kokki displayed the modified text noting that the part on the stakeholder satisfaction survey had been removed as the survey was only briefly mentioned in the CAAR. The language had also been toned down in the text.
- 43. The members welcomed the proposed amendments. A few minor corrections to the text were suggested.
- 44. The Chair thanked the MB for the input and said that for future meetings, the MB and AC discussions on this item needed to be better synchronised for better clarity.

The Management Board <u>approved</u> the Consolidated Annual Activity Report 2022 including the MB analysis and assessment of the CAAR.

Update from the Director

45. The Director gave an update on ECDC activities focusing on her recent external engagements. In the past few months, she had visited Romania, Slovenia, Greece, Finland, and Montenegro. The general purpose of the country visits was to discuss expectations and questions regarding the amended ECDC mandate, to discuss country specific areas (e.g., vaccine confidence, AMR, preparedness) and future joint activities. If the country so wished, the visit could also include media work. There had also been many interactions at EU level and the Director had participated in the European Commission high-level meeting

on lessons learnt from COVID and the first high-level HSC in Luxembourg. She has also met the European Parliament COVID sub-committee, participated in a workshop on preparedness and attended EPSCO and other meetings and seminars organised under the Czech and Swedish EU Presidencies. At the end of 2022, she had attended the IANPHI international meeting in Stockholm and co-hosted a workshop with the Africa CDC during the Public Health Conference in Rwanda, Africa. At the beginning of 2023, she had also visited the Africa CDC to discuss long-term partnership and the WHO Hub on pandemic and epidemic intelligence.

- 46. The Director then gave a brief update on the ECDC transformation programme "ASPIRE", which had been launched in January 2023 with an event for all staff focusing on the ECDC vision. A first Townhall meeting was held in February with experts presenting specific topics related to the amended ECDC mandate and the SCBTH Regulation and the second part would take place at the end of March. The ASPIRE programme contains various ongoing and planned projects such as the development of future competencies and development of a stakeholder framework. Work on ECDC values will start at a later stage. Any substantial organisational changes will be left to the new ECDC Director.
- 47. The Chair thanked the Director for the update and asked if there was any systematic process in place for sharing the experiences from the international activities with the management team and other staff. The Director replied that she provided a weekly update via Teams to all staff where she informed about her missions and other relevant activities. There were also news items published on the ECDC intranet providing information on the Director's country visits and participation in conferences or seminars with links to presentations, recordings and other material. Responding to a question from the Deputy Chair and MB member representing the European Parliament on whether there was a similar understanding in the Member States regarding the national preparedness plans to be developed, she said that there had not been any detailed discussions on this topic yet.
- 48. With regards to the ASPIRE programme, one MB member asked whether there was any specific programme or approach in place to ensure that ECDC staff had sufficient energy to take on board new tasks considering the already high workload of many staff as described by the ECDC Staff Committee representative during the last MB meeting. Another MB member asked whether the Director saw any specific challenges or need for organisational changes arising from the new legislation.
- 49. The Director said that there was consensus among the Heads of Unit that it was necessary to look at which activities ECDC can take on board and which are not directly implementing the mandate and might be deprioritised. She added that prioritisation was always difficult both internally and in relation to stakeholders' expectations, but ECDC would have to become more forceful when it came to deprioritising activities. In terms of the evaluation of the ASPIRE programme, she clarified that there will be a staff survey at the beginning of 2024 (also including questions on ASPIRE) and possible pulse checks in between. At present, the Director did not see the need for organisational changes, but this could of course change once the actual implementation had started. Her approach was however that any modifications to the structure would be introduced only if there was clear evidence that this was necessary.

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

Working Arrangements between ECDC and HERA (Document MB57/10)

50. Andrea Ammon, Director, ECDC, briefed the MB about the recently signed Working Arrangements between ECDC and the European Commission Health Emergency Preparedness and Response Authority (HERA). The need for an arrangement arose from the fact that there were some ambiguities in areas such as epidemic intelligence, threat assessment and modelling. Discussions between ECDC and HERA had started one year earlier; the document had been developed step by step over the year and had then been sent for Commission interservice consultation. The areas listed for collaboration were exactly those where ambiguities had been identified. The Director explained that she had advocated for a more detailed text but, in the end, the wording remained rather general. A review clause was however added to the text (under point 6) that the working arrangements will be reviewed after one year; if there is a need for more clarity, further details can therefore be included at the time of the review. The Working Arrangements were signed by DG HERA and DG SANTE, and at the same time similar arrangements had been signed between DG HERA and DG SANTE with the European Medicines Agency (EMA), which gave a good basis for the

collaboration. As there were many questions on the collaboration and distribution of work between ECDC and HERA, the Director suggested publishing the Working Arrangements on the ECDC website.

- 51. The MB Chair thanked the Director for the update noting that the MB had hoped to see the document before it was signed but it had not been possible this time. She invited the MB members to ask for any clarifications if needed.
- 52. Several MB members agreed that a more detailed document would have been beneficial to ensure a clear distribution of work and to avoid duplication including the risk of double reporting for Member States. The need for more specific communication to Member States was emphasised as currently there were uncertainties for instance around how the health emergency preparedness laboratory network (DURABLE) will work and what data Member States will have to provide.
- 53. The Director said that ECDC had discussed the lab networks with HERA and had been reassured that there will be no overlaps. It should be noted though that many of the labs in the DURABLE network are also part of the ECDC network and the funding provided by HERA is substantially higher than the funding coming from ECDC. She said that she would liaise with the Director Generals of SANTE and HERA respectively to see how further clarification could be provided to the Member States. The Director ensured that ECDC was attentive not to add to the burden of Member States and to find a good synergy with HERA.
- 54. Vicky Lefevre, Head of Unit, Public Health Functions Unit, ECDC, explained that HERA was currently doing a mapping exercise to see what data they can get from ECDC and what they can provide themselves. ECDC has been very collaborative and provided HERA with access to EpiPulse, Rapid Risk Assessments, daily Round Table Reports, etc. ECDC will also be on the Board of the DURABLE network. She added that the HERA network will focus more on the research agenda while the EU Reference Laboratories (EURLs) will concentrate more on training and country support.
- 55. The Chair thanked for the explanations which showed that ECDC was actively involved and collaborating with HERA. This was however a complex area, and she was looking forward to the results of the ongoing audit on the adequacy of the cooperation between DG HERA, DG SANTE, ECDC and EMA.

The Management Board took note of the working arrangements between ECDC and HERA.

Updated ECDC Long-term Surveillance Framework (*Document MB57/11*)

- 56. Vicky Lefevre, Head of Unit, Public Health Functions Unit, ECDC, recalled that the ECDC Long-term Surveillance Framework 2021-2027 had been presented to the MB in June 2021. The framework was now resubmitted for endorsement following revision to reflect the amended ECDC mandate and the SCBTH Regulation. The relevant changes had been highlighted in yellow in the document. Following discussions during the last AF meeting in February, a clarification had been added regarding the implications of the General Data Protection Regulation (GDPR) and the One Health perspective strengthened in the text. The framework focuses on four main objectives: 1) improving the public health relevance, standardisation and efficiency of EU/EEA surveillance; 2) unlocking existing and new data sources needed for effective disease prevention and control; 3) improving its public health and scientific impact; and 4) contributing to surveillance capacity building within Europe and beyond.
- 57. Following the presentation, a few points were raised. One MB member asked whether the urban wastewater directive was going to be taken into consideration when developing wastewater surveillance. She said that these issues were dealt with by the ministry of environment in her country and the question was whether it was an environmental or a health question. Another MB member welcomed the holistic approach in the framework and the use of automated epidemic intelligence. With regards to the review of the list of diseases under EU/EEA surveillance, he asked for a confirmation that this did not exclude that Member States could collect data on other diseases. It was also inquired whether there were any GDPR considerations to take into account in the sharing of data between ECDC and HERA. One MB member made a comment on the challenges in getting data from regional hospitals. It was also stressed that the

recruitment of many staff to ECDC to support Member States in surveillance was not very helpful as at the same time national public health institutes were losing many of their colleagues to ECDC.

- 58. Concerning the review of the list of diseases under EU surveillance, Vicky Lefevre clarified that this list included the diseases reportable at EU level, while countries might of course collect surveillance data on additional diseases depending on specific needs at national level. To draw up the list, ECDC had worked both internally and with a group of Member States to look at the objectives of the EU surveillance, the timeliness of data, etc., and the AF had been asked for input on the draft. The legislative process would now start under the comitology procedure whereby all Member States would be consulted. With regards to wastewater surveillance, she said that ECDC had mainly been working with HERA and the Joint Research Centre (JRC) to support Member States for COVID wastewater surveillance, but the plan was to further explore this area. In relation to GDPR, she said that the legislation was sometimes interpreted in a restrictive manner in Member States which led to surveillance data not being reported. In the document ECDC had tried to emphasise that the GDPR explicitly permits the processing of personal data when it is in the interest of public health. She added that the ECDC legal team was in contact with the European Data Protection Supervisor (EDPS) on these matters including how to support Member States.
- 59. The Director said that the EDPS was going to visit ECDC the following week and this was an opportunity to bring the GDPR related matters forward. Concerning the recruitment to ECDC, she understood the dilemma but did not have any solution at hand. Some colleagues chose to return to their home countries after some time, but this did of course not provide any immediate solution.
- 60. One of the MB members representing the European Commission suggested adding a footnote in the document to indicate that discussions on the GDPR were ongoing. Concerning wastewater surveillance, he said that this point would be further examined with the Commission services.

The Management Board approved the updated ECDC Long-Term Surveillance Framework 2021-2027.

Memorandum of Understanding between ECDC and EASA (Document MB57/12)

- 61. Antonis Lanaras, Head of Section, European and International Affairs, Director's Unit, ECDC, recalled that the draft Memorandum of Understanding (MoU) between ECDC and the European Union Aviation Safety Agency (EASA) had been presented to the MB in November 2022. During the discussion, the European Commission and some Member States' representatives had requested additional time to review the document and to consult with relevant parties. In the meantime, the document had been updated with references to the amended ECDC Founding Regulation and the SCBTH Regulation, and the updated MoU was now presented to the MB for final approval. Antonis Lanaras also informed the MB that in January 2023, ECDC and EASA had jointly published an Addendum to the already existing Aviation Health Safety Protocol after the agreement of EU Member States on a coordinated precautionary approach in the light of the COVID-19 situation in China in December 2022/January 2023.
- 62. Following the short presentation, one MB member noted that the MoU was also welcomed by the Ministry of Transport in her country as these matters were very important for the transport sector. Another MB member congratulated ECDC for the important document and added that the electronic Passenger Locator Form developed during the pandemic was an important tool that should not be lost going forward.

The Management Board approved the Memorandum of Understanding between ECDC and EASA.

Update from the European Commission

63. Isabel de la Mata, MB Member, DG SANTE, European Commission, briefed the MB about ongoing activities in the area of health. The presentation focused on the work to implement the SCBTH Regulation, the ongoing work to develop an international pandemic agreement and the negotiations on amendments to the International Health Regulations (IHR). She also informed the MB of ongoing activities under the

Research Programme. It was agreed that a written summary of the update would be shared with the MB following the meeting.

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

Update from the European Parliament

64. Zofija Mazej Kukovič, Deputy Chair and MB Member, European Parliament, noted that the European Parliament had been driving the development of the EU Health Union for many years and was one of the main pillars of the future Health Union. She stressed that the Parliament's ENVI Committee looks at how to tackle all factors impacting on people's health, such as climate change, food production and water quality. AMR has been on the Parliament's agenda for a long time and the One Health approach is central with focus also on zoonotic diseases and animal welfare. The access to healthy food and promotion of healthy lifestyles are also high on the agenda.

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

Update from the Swedish Presidency of the European Council

65. Karin Tegmark Wisell, MB Member, Sweden, briefed the MB on the Swedish EU Presidency that is ongoing since 1 January 2023. The Presidency had hosted high-level meetings on cancer and AMR respectively. A formal EPSCO meeting had taken place in Brussels on 14 March and included a policy debate on the Regulation on fees and charges payable to the EMA and an exchange of views on the European Global Health Strategy. Negotiations were ongoing on several major legislative files such as the Regulation on the European Health Data Space and the Regulation on Substances of Human Origin (SoHO). Upcoming legal proposals include the revision of the EU Pharmaceutical Legislation and a Council Recommendation on AMR.

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

Any other business

- 66. Dr Antje Draheim, Stare Secretary at the German Federal Ministry of Health, gave a brief address to the MB. She highlighted the important role of ECDC during the pandemic and welcomed the strengthened ECDC mandate, which will make the whole Europe stronger and better prepared. She said that the access and use of quality data was a key issue, and the development of the European Health Data Space was very useful in this context. She also stressed the need for coordination and synergy and wished the ECDC and the MB success going forward.
- 67. The Chair thanked all the MB members for their active participation during the meeting. The next regular Management Board is scheduled to take place in Stockholm on 13-14 June 2023.

Annex: List of Participants

Country/Organisation	Representative	Status
Belgium	Lieven De Raedt	Member
	Patrick Smits	Alternate
Croatia	Bernard Kaić	Member
Cyprus	Maroussa Konnari Jeronymides	Alternate
Czech Republic	Pavla Svrčinová	Member
Finland	Anni Virolainen-Julkunen (Chair)	Member
	Taneli Puumalainen	Alternate
France	Caroline Semaille	Member
	Anne-Catherine Viso	Alternate
Germany	Gesa Lücking	Alternate
	Miriam Schmidt	Advisor
Greece	Theoklis Zaoutis	Member
Hungary	Ágnes Dánielisz	Member
Ireland	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
The Netherlands	Florien van der Windt	Member
	Corine van Lingen	Advisor
Poland	Dariusz Poznański	Member
Portugal	Rui Portugal	Member
Romania	Amalia Serban	Member
Slovakia	Ján Mikas	Member

ECDC Management Board

Country/Organisation	Representative	Status		
Spain	Manuel Cuenca Estrella	Alternate		
Sweden	Karin Tegmark Wisell	Member		
European Parliament				
	Zofija Mazej Kukovič	Member		
	Maria Eleni Koppa	Member		
European Commission				
DG SANTE	John F. Ryan	Member		
DG SANTE	Isabel de la Mata Barranco	Member		
EEA Countries				
Liechtenstein	Silvia Dehler	Member		
Norway	Øystein Riise	Member		