



ECDC Management Board

Minutes of the Fifty-fifth Meeting

Paris, 29-30 June 2022

Adopted by the ECDC Management Board at its Fifty-sixth meeting, 15-16 November 2022

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Summary of Proceedings – ECDC Management Board Meeting

The Fifty-fifth meeting of the ECDC Management Board convened on 29-30 June 2022 in Paris, France. During the meeting the Management Board:

- ❖ adopted the programme of the meeting;
- ❖ adopted the minutes of the Fifty-fourth meeting and the minutes of the Fifth Extraordinary meeting of the Management Board;
- ❖ approved the Final Annual Accounts 2021, including the Report on Budgetary and Financial Management;
- ❖ approved the meeting dates for 2023 and took note of the proposed meeting dates for 2024;
- ❖ discussed the lessons learnt from the pandemic and new ways of working - what to leave behind, what to continue, and what to improve;
- ❖ discussed the ECDC amended mandate and priorities 2024;
- ❖ discussed the topic Governing ECDC in the new era - room for enhanced interaction between the ECDC and the Management Board and other established structures
- ❖ took note of the update from the ECDC Director on activities related to COVID-19, hepatitis and monkeypox;
- ❖ took note of the intervention by Professor Jérôme Salomon;
- ❖ took note of the intervention by Professor Geneviève Chêne;
- ❖ took note of the summary of discussions held at the 49th meeting of the ECDC Audit Committee;
- ❖ took note of the Progress report – Overview of 2022 budget implementation;
- ❖ took note of the First Supplementary and Amending Budget 2022;
- ❖ took note of the Progress Report on the Implementation of the Work Programme 2022;
- ❖ took note of the update from the European Commission.

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-fifth meeting of the Management Board (MB), which took place in Paris, France. A special welcome was extended to Georgios Anastopoulos, newly appointed alternate, Greece, Darios Bidar, newly appointed alternate, Sweden, and Silvia Dehler, observer, Liechtenstein. The Chair informed the Board that Ms Miriam Schmidt from Germany would be participating in the meeting as an adviser.
2. Apologies had been received from Czech Republic (proxy to Bulgaria), Denmark (proxy to Finland), Lithuania (proxy to Latvia), Luxembourg (proxy to the Netherlands), Poland, Romania, Spain, Iceland, and Norway.
3. The Chair then warmly welcomed Professor Jérôme Salomon, Director General of Health at the French Ministry of Health and Prevention, who was shortly going to make an intervention. She thanked Santé Publique France, and in particular Geneviève Chêne, MB Member, France, and Anne-Catherine Viso, MB Alternate, France, for hosting the meeting in their premises.

Welcome from the Director, ECDC

4. Andrea Ammon, Director, ECDC, warmly welcomed the MB members to the meeting and thanked them for their flexibility given that the dates of the meeting had to be changed with short notice. She also thanked the colleagues in Santé Publique France and ECDC for their additional work with the practical set-up of the meeting. She was very pleased to meet the MB members in person and was looking forward to fruitful discussions.

Intervention by Professor Jérôme Salomon, Director General of Health, Ministry of Health and Prevention, France

5. Professor Jérôme Salomon, Director General of Health, Ministry of Health and Prevention, France, made a brief intervention focusing on the lessons learnt from the COVID-19 pandemic as well as the achievements of the French Presidency of the European Council. He welcomed the EU Health Union legal package and the strengthened mandate of ECDC and was pleased that the French Presidency had managed to support these decisions, including the political agreement on the new Regulation on serious cross-border threats to health that had been reached just a few days earlier. One of the main objectives of the Presidency was to build a stronger public health union and a more coherent EU. He noted that strengthening ECDC will be beneficial also from a pan-European and global perspective.

Intervention by Professor Geneviève Chêne, Director General, Santé Publique France

6. Professor Geneviève Chêne, Director General, Santé Publique France, gave a presentation focusing on the role and responsibilities of the national institute in the public health landscape in France. She also reflected on the lessons learnt from the COVID-19 pandemic noting that the EU collaboration had been intense during the last two years but that there was a need for even closer cooperation between Member States' public health institutes and EU agencies including ECDC. She felt that the resilience of the public health system had improved and remained optimistic as concerns the capacity to respond to future health crisis.
7. The Chair thanked Jérôme Salomon and Geneviève Chêne for their presentations, noting that it described well the challenges faced in the Member States during the pandemic and the need for resilience and flexibility, as well as the importance of collaboration and coordination at EU level.

Adoption of the draft programme (and noting the declarations of interest and proxy voting, if any)

8. The Chair mentioned that the agenda contained more discussion points than usually given that there were fewer mandatory decision items in the June MB compared to the March and November meetings. This provided the opportunity for more in-depth discussion and exchange, which was necessary considering the ongoing public health events as well as the foreseen changes related to the new ECDC mandate.

9. The Draft Programme was adopted without 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 Management Board adopted the draft programme.

Adoption of the draft minutes of the 54th meeting of the Management Board (Stockholm, 23 March 2022) and the draft minutes of the Fifth Extraordinary Management Board meeting (12 April 2022)

10. The Chair noted that the draft minutes of the 54th meeting had been circulated to the MB ahead of the meeting. The European Commission had requested a minor amendment to the minutes (correction in the participants list), which had been taken into account. There were no further comments on the minutes.

11. The draft minutes of the Fifth Extraordinary MB meeting that took place on 12 April 2022 had been circulated to the MB ahead of the meeting. There were no comments on the minutes.

The Management Board adopted the minutes of the Fifty-fourth meeting and the minutes of the Fifth Extraordinary Management Board meeting.

ECDC during the pandemic and new ways of working - what to leave behind, what to continue, and what to improve

12. The Chair briefly introduced the topic noting that she had asked the Director to present which new ways of working ECDC had introduced both internally and externally during the pandemic and what lessons could be drawn from this experience.

13. Andrea Ammon, Director, ECDC, said that this topic came in a critical time as ECDC was reflecting on how to implement its new mandate expected to be adopted in the autumn. An implementation plan for the new mandate will be presented to the MB during its next meeting in November. The Director then recalled that ECDC had started to work on the highest level of emergency, PHE Level 2 – acute phase, in January 2020 and had downgraded to PHE Level 1 – maintenance phase in June 2022. This was by far the longest public health emergency experienced by ECDC. An early review of ECDC's response to the pandemic was carried out in the autumn 2020. The outcome of the review and the implementation of the action plan was presented to the MB during 2020 and 2021.

14. The Director then summarised the lessons learnt with respect to the working methods introduced and what ECDC would like to continue doing. First of all, the pandemic brought much more visibility to ECDC, and the audience extended from technical to a more political one. With increased visibility comes increased responsibility and ECDC's messages underwent a much closer scrutiny. The lesson from this experience is that messages need to be adapted to different audiences. ECDC also introduced consultations with the Advisory Forum on outputs to be published. Internally, there was a much closer collaboration between colleagues in communication and technical teams. With the pandemic, ECDC also found new partners among the EU agencies, in particular in the area of transport (e.g. EASA, EMSA, ERA), within the

Commission services (Joint Research Centre, HERA) and the European Council (IPCR, EPSCO, Finance Ministers) and expanded the contacts with CDCs in different parts of the world. These new interactions showed the importance of understanding the interests of the partners and ECDC's approach to stakeholder management and partnership building will change based on this experience. During the pandemic, ECDC developed new types of outputs such as the COVID-19 Policy Briefs, Vaccine Tracker, infographics, leaflets, and audiovisuals. At the same time, existing ECDC output categories such as Rapid Risk Assessments (RRAs), threat assessments, epidemiological updates, guidance, and technical reports needed to remain relevant. As a lesson learnt, ECDC will further rethink its outputs and how they can be better targeted. Concerning interactions with and support to Member States, the experience from providing targeted support to eleven countries with lower COVID-19 vaccine coverage had shown the importance of listening carefully to the Member States' needs and then offering bilateral or multilateral discussions and support depending on the situation. The same principle had been followed for the support provided to Member States neighbouring Ukraine. The HERA Incubator grants provided to EU/EEA countries for enhancing their whole-genome sequencing infrastructure was a completely new way of supporting Member States and a similar model could possibly be used for the digitalisation of surveillance.

15. To conclude, the Director mentioned that ECDC had introduced virtual COVID-19 consultation meetings with the Advisory Forum during the pandemic, while no specific interactions took place with the MB nor with National Coordinators. She asked whether the MB members felt that virtual briefings would have been useful during the crisis and whether they would favour a digital platform of some kind for connecting and communicating among MB members.

16. The Chair then opened the floor for discussion. Several MB members congratulated the Director and her staff for their work during the pandemic and said that they had also experienced the increased visibility of ECDC in their respective countries. The MB members agreed that the increased political pressure had been a challenge during the pandemic; in this context it was crucial to deliver timely advice while maintaining scientific independence and to produce targeted messages according to audience. Concerning interactions with partners, one MB member mentioned that regular contact with scientific councils at national or European level would have been useful. Generally, the MB members were not in favour of additional meetings, but a somewhat more frequent exchange could have been helpful in particular at the beginning of the crisis. Some MB members also having the NC role said that they had been well informed during the pandemic. In general, the CCBs should however be more empowered. With regards to ECDC outputs, several MB members mentioned that the RRAs had been very helpful. The importance of common methods and comparable data was also stressed as well as the need for behavioural science. One of the MB members representing the European Commission welcomed ECDC's work on forecasting and modelling and added that the Commission would like to see this continued and further strengthened. The targeted country support was welcomed by several MB members.

17. The Chair concluded the discussions noting that the scientific independence and integrity versus the need for speedy political decisions was something to seriously consider going ahead.

Update from the Director

18. Andrea Ammon, Director, ECDC, briefed the MB about ongoing activities and in particular the work related to COVID-19, monkeypox, and acute hepatitis in children. Before going to the presentation, she informed the MB that the *Eurosurveillance* journal had reached an all-time high impact factor of 21.

19. With regards to COVID-19, ECDC had been working with Member States on surveillance for the winter period, and a survey had been made to understand the future plans in Member States in terms of integrated surveillance sentinel systems for influenza, Sars-Cov-2, and RSV. Concerning the lessons learnt from the pandemic, several activities were ongoing with the aim of refining the understanding of the cost-effectiveness and social acceptance of non-pharmaceutical interventions (NPIs), developing and promoting methods to assess the public health response to COVID-19 (e.g., guidance and training on how to perform Intra-Action Reviews (IAR) and After-Action Reviews (AAR)), and supporting in-country assessments. Regarding COVID-19 vaccination, she noted that this was a complex area due to different number of doses received by the population and the fact that there might be new vaccines after the summer. The timing of the booster for those over 60 years of age would also depend on whether or not there was an increase in infections during the summer.

20. The Director then gave an update on the monkeypox outbreak focusing on the current epidemiological situation as well as ongoing and planned ECDC actions. Case-based data was being collected in TESSy and a joint weekly surveillance bulletin was being published together with WHO/Europe. The activities also included laboratory network support, risk communication and community engagement, and modelling work to support the development of targeted vaccination strategies. ECDC had also published a technical report on considerations for contact tracing and was working closely with the European Medicines Agency (EMA) on antivirals and vaccine products. Generally, she noted that contact tracing did not seem to be that helpful and risk communication and community engagement (e.g., with relevant NGOs and event organizers) was therefore crucial. Responding to a question on modelling, she clarified that ECDC's work in this area was mostly related to pre- and post-exposure prophylaxis.

21. She then provided an update on the outbreak of hepatitis of unknown aetiology in children which had started early April. Despite very detailed interviews of the cases, no common exposure had been identified. Due to a high proportion of cases with adenovirus infection, this was considered the main aetiological factor under suspicion. Approximately 500 cases had been reported in the WHO European region, most of which in the UK. She then briefly described the ECDC actions so far in surveillance (TESSy reporting protocol across WHO European Region; Joint ECDC-WHO Regional Office for Europe Surveillance bulletin) and microbiology (testing guidance, sharing of protocols for adenovirus testing and typing, metagenomics support) as well as ongoing work to help determine whether there is an exceedance of hepatitis cases compared to the baseline situation.

22. Following the presentation, the floor was opened for comments. Two MB members reported briefly about the situation in their respective Member State with regards to monkeypox. Both agreed that contact tracing and information sharing was a challenge, and it was suggested that Member States exchange on good practices in communication. Another difficulty was that a relatively long time might pass between the first signs of the disease and the diagnosis.

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

ECDC amended mandate and priorities 2024

23. Andrea Ammon, Director, ECDC, presented the priorities for 2024 and how the new ECDC mandate was taken into account in the planning. She highlighted a number of areas where the new mandate is expected to bring a changed or extended focus: digitalisation and integrated surveillance, preparedness and response support (including the EU Health Task Force (EUHTF)), scientific support (in particular foresight, modelling, prevention, SoHO). ECDC will also continue monitoring post-authorisation vaccine effectiveness and safety together with the European Medicines Agency (EMA) and strengthen its international collaboration.

24. The Director then presented briefly the main priorities noting that these were set at a high level at this stage and further details will come when the implementation plan for the new mandate is developed. The priorities are as follows: enhance support to the EU Member States and the European Commission in preparedness and response planning; reinforce epidemiological surveillance and monitoring using artificial intelligence and other advanced technological means; build profound knowledge of the EU Member States to better target ECDC interventions; intensify strategic partnerships at the EU and international level to create synergies and avoid duplication of actions, and address priority conditions and issues at European level by tackling antimicrobial resistance and providing support to the European Commission and the EU Member States in addressing the Sustainable Development Goals (SDGs) in the area of HIV, TB and hepatitis.

25. The Single Programming Document (SPD) 2024-2026 is prepared based on the assumptions that ECDC's total budget will amount to EUR 91.4 Million and the number of full-time statutory staff to 353. Additional resources (staff and budget) will be based on contribution agreements for the implementation of projects (IPA6, EU Initiative on Health Security, ECDC4Africa CDC). The draft SPD 2024-2026 will be presented to the MB in November 2022, after which it will be sent to the MB and AF for written comments. In January 2023, the document including annexes will be sent to the MB for approval via written procedure following the usual process, with the final adoption taking place in November 2023.

26. The Chair thanked for the presentation and pointed out that it would be very important to have all the relevant legal and other documents at hand ahead of the November MB meeting.

27. In the discussion that followed, MB members expressed broad support for the proposed priorities while noting that vaccination seemed to be missing. Several MB members mentioned that the new mandate would need to be further referenced in the document. The MB also requested clarification on the EU Health Task Force and the distribution of work between ECDC and HERA. Concerning preparedness planning, the importance of aligning with the International Health Regulation (IHR) requirements was stressed. It was also mentioned that Member States' involvement should be further taken into account, as well as their capacity to implement the activities at national level. Some concerns were raised with regards to the collection of data, and it was stressed that data protection issues had to be carefully considered. The importance of agreeing on standards was also highlighted.

28. In response to the comments made, the Director ensured that the new mandate will be further referenced in the SPD document as soon as it is adopted, and that vaccination will be mentioned more explicitly in the text. She agreed that Member States' capacity to implement the activities was of course crucial and this would be looked at more closely when developing the implementation plan. With reference to a comment from the European Commission that countries had chosen their own way during the pandemic, she commented that risk management will remain under Member States' responsibility and the ECDC recommendations will be non-binding; it will therefore be a question of streamlining rather than harmonisation of approaches at EU level. ECDC can play a role in elaborating standards, and the EULabCap monitoring tool is a good example of where standards have been discussed and agreed jointly. Concerning the objective to better target the country support, she said that risk assessments can be further diversified but can of course not be done for each country separately. There are however areas such as preparedness planning or surveillance where individual support can be provided, or the support can be targeted to a group of countries. Regarding the European Health Data Space (EHDS), she commented that it can still be shaped to make it useful for ECDC and public health institutes. Regarding the distribution of work between ECDC and HERA, she mentioned that ECDC was working together with HERA on developing a Memorandum of Understanding to avoid overlaps.

The Management Board discussed the ECDC amended mandate and priorities 2024.

Governing ECDC in the new era - room for enhanced interaction between the ECDC and the Management Board and other established structures

29. The Chair briefly introduced the topic noting that after nearly two years of working in a remote mode, it was useful to discuss and agree on ways to enhance the communication and interaction between ECDC and the MB.

30. Maarit Kokki, Head of Executive Office, Director's Office, ECDC, briefly recalled the current situation in terms of frequency and conduct of meetings, the types of information regularly shared with the MB (e.g. bi-weekly policy briefs on COVID-19 and quarterly highlights on main ECDC activities and achievements) and the introduction to new MB members. She asked the MB members to share their views on the current way of working and what additional information or updates they would like to receive to support them in their role.

31. The MB members agreed that the current frequency of meetings (three face-to-face meetings per year) was appropriate. Several members mentioned that physical presence was preferable but remote participation should still be offered as a possibility to those unable to attend. Ad-hoc videoconference meetings could be arranged in case of crisis or in situations where a specific topic had to be addressed. It was noted that presentations should be shared in advance of the meetings to allow MB members to better prepare for the discussions, in particular for items where no document is provided. One MB member suggested that perhaps a couple of MB members could prepare or introduce the discussions in some specific areas as a way of increasing the participation and engagement. Some MB members noted that it would be useful to receive additional information on the scientific opinions expressed by the Advisory

Forum. The MB also welcomed the suggestion of developing an induction package for new MB members including on-line training sessions and information material on specific topics such as the SPD planning cycle or the budget preparation process. A more interactive communication platform than the current Extranet would facilitate the interaction among MB members.

32. The Chair thanked the MB members for their input and said that these points would be further discussed and hopefully promoted by the ECDC going ahead. Another issue that had been brought forward during the Audit Committee (AC) meeting the same morning was that the AC would need more time for its discussions and ECDC would look into how this could best be arranged.

The Management Board discussed possible ways for enhanced interaction between ECDC and the MB and other established structures.

Summary of discussions held at the 49th meeting of the ECDC Audit Committee (Paris, 29 June 2022), including its recommendations

33. Daniel Shine, Chair of the Audit Committee, gave a summary of the discussions from the 49th Audit Committee (AC) meeting, which took place in the morning of 29 June 2022. Concerning the regular update on audit activities, he mentioned that two observations had been closed by the ECDC, while some delays had been experienced in the implementation of the remaining audit recommendations. Five observations were currently open, one of which had the target date set in Q2, one in Q3, and three in Q4 2022. ECDC had provided additional information on the delays in the recruitment of the Head of Legal Services/Ethics officer as well as on the training activities being performed in the area of ethics and reported that a specific page for ethics issues is being developed on the new intranet. The AC had requested to be further updated on the matter in the next meeting. The AC had also proposed that the document on audit activities and observations should be presented for opinion in the future as it goes to the very heart of the work of the AC. The document, or a summary thereof, should also be submitted to the MB for information.

34. One of the MB Members representing the European Commission supported the suggestion to keep the MB informed about the main audit observations and their implementation without going into too much detail.

35. The Director welcomed the suggestion of sharing the document on audit observations with the MB. Concerning the audit on ethics performed early 2020 she noted that it had taken more than a year to receive the final report. Some actions had been implemented in the meantime, but the recruitment of the ethics officer was still to be completed.

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

a) Progress Report – Overview of 2022 budget implementation

36. Anja Van Brabant, Accounting Officer and Head of Section, Finance and Accounting, Resource Management Services, ECDC, gave an overview of the 2022 budget implementation up until 26 June 2022. This item had not been discussed in the AC due to time constraints.

37. She explained that from the total budget of EUR 95.9 Million, EUR 75 Million had been committed (78.3%), and from the committed amount, EUR 31 Million (32.3%) had been paid, while EUR 0.5 Million was in the workflow to be paid. A total of EUR 59.3 Million had been carried forward from 2021; of this amount, EUR 16 Million (27%) had been paid. Roughly EUR 40 Million of this budget was related to the HERA Incubator grants to support Member States in strengthening their capacities for whole-genome sequencing (WGS).

38. Responding to a question on the current status of the HERA Incubator activities, Anja van Brabant mentioned that there were three applicants for further financing and a few more were expected to come during the summer. She hoped that it would be possible to fully implement the budget, otherwise the money would be returned to the European Commission.

The Management Board took note of the Progress Report – Overview of 2022 budget implementation.

Final Annual Accounts 2021, including the Report on Budgetary and Financial Management (Document MB55/05)

39. Anja Van Brabant, Accounting Officer and Head of Section, Finance and Accounting, Resource Management Services, ECDC, presented the Final Annual Accounts 2021. She recalled that the Provisional Accounts had been presented to the MB in March 2022. The accounts had been audited by an external audit firm (Baker Tilly) during 7-10 March 2022 with no preliminary findings. In May, the audit firm examined the subsequent events of 2022 potentially affecting the accounts and re-examined the accruals versus the invoices received and paid in 2022 related to carry forwarded amounts from 2021. Due to a material de-commitment (release of funding) from 2021 done in May 2022, related to COVID-19 sequencing, for an amount of EUR 567 460, the accruals of 2021 had to be adjusted by EUR 512 197. The changes to the accounts 2021 were highlighted in yellow. The report from the European Court of Auditors (ECA) on the annual accounts 2021 had been received on 25 May 2022 with no preliminary observations. She then read out the proposed draft opinion of the Management Board on the Final Annual Accounts 2021 to be signed by the Chair of the MB.

40. Daniel Shine reported that the AC had been given confirmation on the clean opinions received from the auditors, including on the reliability of the accounts. The AC recommended the MB to approve the Final Annual Accounts 2021.

The Management Board approved the Final Annual Accounts 2021.

b) First Supplementary and Amending Budget 2022 (Document MB55/06 Rev. 1)

41. Anja Van Brabant, Accounting Officer and Head of Section, Finance and Accounting, Resource Management Services, ECDC, presented the First Supplementary and Amending Budget (SAB) 2022, consisting of the budget transfers approved by the Director since the beginning of the year. A transfer of EUR 1.3 million between the titles has been executed to cater for increased staff costs and an increased correction coefficient applied to remunerations compared to 2021.

42. Daniel Shine said that the AC had taken note of the budget transfers made by the Director and the further explanation provided on the additional needs for funding for the remunerations of staff (salary adjustments made January-June 2022) and the fact that the additional funding was provided from the meetings budget which remained unspent due to hybrid formats of those meetings. The AC had also suggested that future SAB-documents were to include a summary of the main budget transfers for better clarity.

43. One MB member welcomed this suggestion as the possibility to have such a summary had been brought up in the MB previously.

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

c) Progress Report on the Implementation of the Work Programme 2022 (Document MB55/07)

44. Maarit Kokki, Head of Executive Office, ECDC, briefed the MB on the current level of implementation of the work programme 2022. She recalled that periodic updates on the status of implementation of the work programme are provided during MB meetings, while selected main achievements are showcased quarterly in the "ECDC Highlights". She then presented the implementation status per Strategic Objective as of June 2022 compared to March 2022. Some delays were observed in the work on the "repository for guidance developed by national authorities in Member States", in the development of EpiPulse dashboards, and in the implementation of the "ECDC 4 Africa CDC" project. In response to a question from the European Commission, and after verifying with concerned colleagues, Maarit Kokki clarified that the delay in the EpiPulse development concerned the indicator-based module only while the event-based module was already in place. As there was the TESSy system operating for the indicator-based surveillance, the delay had no impact on the work as such.

45. As requested during the MB meeting in March, she also briefly summarised the impact of the ongoing emergency situations (Ukraine, hepatitis, monkeypox, COVID-19) on the work programme

implementation noting that there was a delay in the implementation of individual activities and changes to the modes of delivery, e.g., virtual meetings instead of face-to-face. Lastly, she mentioned that the MB was requested to approve the proposed changes in the Financing Decision (Annex 11 of SPD 2022-2024). These changes were mainly due to the overestimation of the budget of planned contracts, savings due to organisation of hybrid meetings instead of face-to-face, delays due to unsuccessful outcomes of the procurement (lack of suitable contractors), and cancellation of planned contracts because of work being performed in-house. Responding to a question from one MB member as to what mitigation measures were foreseen to avoid these situations in the future, she mentioned that more pertinent guidance would be given to units to avoid overestimation of the budget for procurements, but it was of course difficult to reach fully correct planning. Concerning failed procurements, market analysis can be done as far as possible to see what providers are on the market. Advice on costing of meetings can also be provided where necessary.

46. Daniel Shine reported that ECDC had clarified to the AC that the ESCAIDE conference will be more expensive than in the past due to an increased number of participants and the fact that it will be a hybrid event. ECDC had also clarified that the Agency's working conditions were back to normal, however, with the staff now spending a minimum of two days a week in the office. ECDC had also explained that the COVID-19 PHE had been downgraded due to the Commission communication "COVID-19 - Sustaining EU Preparedness and Response: Looking ahead", but also due to the staffing needs for the two new PHEs declared. It had also been mentioned that ECDC was happy to work with the European Commission regarding the need for additional funds for the whole genome sequencing in 2022.

47. In conclusion, the AC had taken note of the progress and the explanations given and recommended the MB to approve the amended Financing Decision 2022.

The Management Board took note of the Progress Report on the Implementation of the Work Programme 2022 and approved the proposed changes in the Financing Decision 2022.

Update on the ECDC Targeted Country Support

48. Andrea Ammon, Director, ECDC, gave an update on the ECDC Targeted Country Support as requested during the previous MB meeting in March. The update focused on the support provided to countries neighbouring Ukraine on one hand, and on the core country support project on the other hand.

49. Concerning Ukraine, ECDC held regular discussions with the four EU Member States neighbouring Ukraine (Hungary, Poland, Romania, Slovakia) as well as Czechia and Moldova. Following the request from the MB to include also other Member States, ECDC was now arranging monthly meetings with all EU/EEA countries. One additional meeting took place where Greece explained their experience from the 2015 refugee influx. ECDC has published a significant number of guidance and other documents on its website and training courses on various topics (such as vaccine acceptance and strategies for increased vaccine uptake, addressing online vaccine misinformation, communication strategies, etc.) will be freely accessible on the virtual learning platform EVA. Between mid-March and end of May, seven ECDC staff members have been consecutively deployed to Poland through DG ECHO. Currently, one staff member is deployed to the Regional Health Extension hub in Krakow and one staff member to the WHO country office in Romania, both coordinated by GOARN. At this point, the influx and outflux of displaced persons has stabilised and the documents published so far seem to cover the existing needs. Based on input from the Member States, possible further ECDC support actions will focus on vaccination uptake, surveillance, continuity of care, and microbiology capacity and be carried out at three levels depending on the topic: targeting a single EU Member State specifically, covering the Member States neighbouring Ukraine, or targeting all EU/EEA countries.

50. The Director then gave an update on the core targeted country support work (TCS) including the ongoing work to develop country overviews, which will facilitate the process of identifying Member States' strengths and vulnerabilities. The country overviews will be based on data from existing sources and will focus on seven areas to be launched progressively. An external IT tool has been procured for this work and the aim is to have a first release internally by the end of 2022 and to then have a discussion with the Member States to validate and improve the indicators and other key content.

51. Concerning the process of providing targeted country support, there are useful experiences from the TB and AMR disease programmes to build on. The ad-hoc support provided during the pandemic to eleven Member States with lower COVID-19 vaccination coverage and more recently to the countries neighbouring Ukraine have also provided useful insights for the further development of the comprehensive TCS model including how to structure the dialogue and collaboration with Member States. ECDC is proposing to pilot the comprehensive TCS approach in one Member State starting 2023. The criteria are that the country is volunteering to do the pilot, that there is political will and sufficient human resources, and that a real need is identified.

52. Following the presentation a few points were raised. The Chair inquired about ECDC's current capacity to provide support in microbiology given that the Centre does not have own laboratories. Referring to possible country evaluations to be carried out in the framework of the TCS, she asked how these visits related to the Joint External Evaluations (JEE) of WHO as to avoid duplication. Concerning the indicators for the country overviews, one MB member recalled that these had also been discussed in one of the JSM working groups and asked whether these would cover also other aspects than public health. The JSM working group had also supported a stepwise approach in building up the country overviews. One of the MB members representing the European Commission commented that the new cross-border health threats regulation (CBTR) called on ECDC to carry out country visits to monitor Member States' preparedness plans and cautioned against setting up parallel mechanisms. One MB member commented that the sharing of best practices and exchange between Member States seemed to be somewhat missing in the approach. Another MB member noted that his country was restructuring its preparedness set-up and collaboration with ECDC was very welcome in this regard. He also stressed the need for coordination with WHO and IHR. One of the MB members representing the European Parliament agreed that political support was crucial in implementing the TCS and suggested that the Director would include information on this matter in her public hearing in the Parliament.

53. Responding to the questions from the Chair, the Director said that in the country overviews the indicators for microbiology will be taken from the EULabCap system. As for the laboratory support, she mentioned that EU reference laboratories will be set up as part of the new ECDC mandate; until these become operational, there are lab contracts in place for 16-17 disease groups which can provide support. ECDC has also recently recruited several microbiology experts. Concerning evaluations, she noted that these would only be carried out if considered useful by the Member State. Where available, information from a JEE could complement but this information was usually not very detailed. Concerning the indicators, she clarified that the country overviews would indeed be built up with a stepwise approach and using only publicly available data. Concerning the visits referred to in the CBTR, she agreed that it was important not to duplicate the work but noted that those visits would not cover all the aspects of the prevention and control system. Lastly, she agreed that sharing best practices was important and should be included explicitly in the TCS model.

The Management Board took note of the update on the ECDC targeted Country Support.

Annex to the MoU between ECDC and EMA on Vaccine Monitoring Platform

54. Andrea Ammon, Director, ECDC, presented the current status of the discussions between ECDC and the European Medicines Agency (EMA) with respect to the establishment of a Vaccine Monitoring Platform (VMP) for the monitoring of post-authorisation effectiveness and safety of vaccines. According to the new mandates of EMA and ECDC respectively, this platform is to be established and operated jointly by the two agencies. ECDC and EMA are currently negotiating a technical Annex to the existing Working Arrangement on the VMP to set out the principles for the collaboration and the division of work.

55. According to the Annex, the VMP will be supported by an Advisory Board and operationally led by a Steering Group and a joint secretariat with staff from both agencies. The Advisory Board will have a consultative non-binding role and from ECDC side it is suggested that the concerned NFPs from all Member States be represented in the Board. The text of the Annex is now largely agreed but one difficulty is that it can only be signed once the new ECDC mandate has been formally approved while the new EMA mandate has already been adopted. Another remaining discussion point is the approach to conflict of interest (CoI)

as there are some divergences in how the agencies collect and determine the CoI. Due to these differences, the experts contributing to the work of the VMP will need to submit a separate declaration of interest to both agencies, which is a burden for the individual but inevitable given the close scrutiny that such studies are subject to. It also needs to be very clear that experts in the Advisory Board cannot participate in future procurements. In conclusion, the Director mentioned that the final Annex will be brought to the Management Board in November or submitted via written procedure depending on the timing of the final adoption of the legal package.

56. The Chair thanked the Director for the update noting that this was a great achievement as it would finally pave the way for independent post-marketing studies, which had been subject for discussion also in the MB since several years.

57. In the discussion that followed, several MB members congratulated the ECDC noting that this was indeed a huge step forward. A few questions were raised concerning the prioritisation mechanism for the studies and the involvement of the public health institutes, the relationship with routine pharmacovigilance, the expected workload for Member States in terms of data collection, and the funding available for this work. One of the MB members representing the European Commission commented that as EMA is a fee-based organisation it could be explored whether EMA might bare a bigger cost. The AC Chair suggested that the final Annex could perhaps be reviewed by the AC in an on-line meeting prior to submitting it to the MB given the nature of the document and particularly the CoI matter.

58. The Director welcomed the suggestion to share the document with the AC for review. Concerning the prioritisation of studies, she clarified that the responsibility of the Advisory Board will be to identify the studies to be done; based on this input ECDC and EMA will decide what to procure. She said that the role of the routine pharmacovigilance is to give signals on adverse effects, but more in-depth epidemiological studies are needed to generate information on which to base recommendations on vaccine use. As for the data reporting, the aim is to get as much as possible from routine data, but this will depend on the kind of studies to be conducted. With regards to funding, she clarified that in the Multi-annual Financial Framework (MFF), EUR 5 Million is estimated for EMA and EUR 7 Million for ECDC but she would raise the question of the distribution with EMA.

The Management Board took note of the update on the Annex to the MoU between ECDC and EMA on the Vaccine Monitoring Platform.

ECDC Management Board Meeting Dates 2023 and 2024

59. Maarit Kokki, Head of Executive Office, Director's Office, ECDC, presented the suggested Management Board meeting dates for 2023 and 2024. The MB agreed with the proposed schedule of meetings in 2023 as below:

- MB57: 21-22 March 2023
- MB58: 13-14 June 2023
- MB59: 14-15 November 2023

In addition, the Management Board took note of the following meeting dates proposed for 2024:

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

The Management Board approved the proposed meeting dates for 2023 and provisionally for 2024.

Update from the European Commission

60. John F Ryan, MB member, DG SANTE, European Commission, briefed the MB about ongoing activities in the area of health. He said that the new regulation on cross-border threats to health was expected to be adopted in the autumn together with the ECDC mandate and the HERA regulation, and

recommended to read the texts side by side to have the full overview and see the linkages between the regulations, in particular concerning the paragraphs on preparedness planning and the link to the IHR. The update also touched upon the situation in Ukraine and the support provided for the transfer of patients through the civil protection mechanism. Concerning monkeypox, he mentioned that HERA had secured vaccines and therapeutics for the Member States most in need. Lastly, he noted that there was a substantial increase in the funding of the Joint Action on AMR and added that France had agreed to lead the second stage of the JA.

61. Barbara Kerstiens, MB member, DG RTD, European Commission, gave a brief update on ongoing research initiatives on COVID-19, for instance funding of trials on COVID-19 vaccines and therapeutics and large-scale cohort studies on COVID-19 including long COVID. The Work Programme 2023 includes research on pandemic preparedness with the aim of creating partnerships and addressing public health questions. She suggested providing further updates on these research activities in future MB meetings.

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

Any other business

62. The Chair reiterated her thanks to the colleagues in Santé Publique France for hosting the meeting. She also thanked all the MB Members for their active participation and valuable contributions, and the ECDC staff for their support. The next regular Management Board is planned to take place in Stockholm on 15-16 November 2022. The Chair recalled that elections of MB Chair and Deputy Chair will take place during the meeting; in accordance with the MB Rules of Procedure, nominations shall be sent to the MB secretariat four weeks ahead of the meeting, i.e., by mid-October 2022.

Annex: List of Participants

Country/Organisation	Representative	Status
Austria	Sigrid Kiermayr	Member
Belgium	Lieven De Raedt	Member
Bulgaria	Angel Kunchev	Member
Croatia	Bernard Kaić	Member
Cyprus	Maroussa Konnari Jeronymides	Alternate
Estonia	Heli Laarmann	Member
Finland	Anni Virolainen-Julkunen (<i>Chair</i>)	Member
	Taneli Puumalainen	Alternate
France	Geneviève Chêne	Member
	Anne-Catherine Viso	Alternate
Germany	Gesa Lücking	Alternate
	Miriam Schmidt	Advisor
Greece	Georgios Anastopoulos	Alternate
Hungary	Ágnes Dánielisz	Member
Italy	Francesco Maraglino	Alternate
Ireland	Colette Bonner	Member
	Daniel Shine	Alternate
Latvia	Jana Feldmane	Member
Malta	Patricia Vella Bonanno	Member
Netherlands	Ciska Scheidel	Member
Portugal	Rui Portugal	Member
Slovenia	Mario Fafangel	Alternate
Slovakia	Lucia Paulíková	Alternate
Sweden	Dariosh Bidar	Alternate

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
DG RTD	Barbara Kerstiens	Member
EEA Countries		
Liechtenstein	Silvia Dehler	Member