

ECDC Management Board 5th meeting Stockholm, 13-14 December 2005 MB5/4/4 13 December 2005

Minutes of the Fourth Meeting of the ECDC Management Board Budapest, 27-28 October 2005

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Opening and welcome

1. The Chair opened the meeting and welcomed Dr Jenö Rácz, Minister of Health of Hungary who addressed the Board and welcomed participants in Budapest. The Chair thanked the Minister on behalf of the Management Board for his kind and generous hospitality.

Adoption of the agenda (document MB4/2/1)

2. The agenda was adopted without changes. One item was raised under AOB (see below).

Declaration of interest

3. The issue of declaration of interest was raised. The Director informed the Board that the Audit Committee which met the day before agreed on a revised form which will be submitted to the Board the day after for approval. All members and alternates will be requested to complete the form which will be placed on the ECDC web site. Subsequently, the Chair asked the members if they wished to make any declaration of interest with regards to the agenda items being discussed. Netherlands declared their coordinating role in EARSS, Portugal in AMR project, France as the coordinator of the EuroHIV.

Adoption of the minutes of the previous meeting (document MB4/3/3)

4. The minutes had already been circulated and adopted through written procedure. No further comments were raised.

Briefing by the Director on progress made since last meeting and Implementation of the work programme 2005

(Documents MB4/4/19, MB4/12/16, MB4/12/17, MB4/12/18, MB4/12/19, MB4/12/20, MB4/12/21)

5. The Director briefed the Board on progress made since the last meeting in May. Since then, the Heads of Units and other scientific and technical experts have taken up their job at ECDC and therefore real progress has been made in the technical areas. The Director, in the spirit of accountability to the Board, gave information on the implementation of the work programme. The Director also informed the Board about the ECDC internal managerial process and mechanisms.

6. Under Governance, she highlighted that she would like to involve the Management Board more closely into the ECDC developments and she therefore envisages regular briefings to the Board between the meetings starting early 2006. She also highlighted the support of the Advisory Forum to ECDC through the three formal meetings as well as the working groups and the regular electronic contacts and teleconferences and thanked countries for this.

7. Under partnerships, she gave account of all external relations established inside and outside Europe to position ECDC as a credible player. This included first and foremost the EU Institutions (European Parliament, Commission, and Council), EU agencies and other players such as WHO, CDC Atlanta, links to CDCs in Asia. Beyond EU Countries, which are the "natural constituency" of ECDC, she envisaged to reach out to the neighbouring

countries and to other regions, such as USA and Asia to promote global health security, with public health being so much globalized.

8. The Director also reported on her recent visits to Member States. She highlighted the fact that with the new media and communication officer on board, a more proactive approach to the media would be followed, the website would be further developed and the overall communication and risk communication strategy finalized.

9. She then reported back on progress made in the four ECDC units and highlighted key developments and achievements. With regards to scientific and technical advice, a procedure for guidelines has been developed and the production of guidelines started; the role and terms of reference of scientific panels have been developed; horizontal projects have been drawn up to deal with influenza, AIDS, AMR. In Surveillance, among other things, the planning document leading to the future surveillance strategy has been produced as requested by the Board, following an extensive consultation with all stakeholders. As for preparedness and Response, a daily review of emerging health threats is made and a weekly briefing is prepared for the Commissioner, together with C3 unit. ECDC is playing its role in EWRS, developed the internal procedures for public health event operations, started preparations for the ECDC crisis centre, developed the training strategy for Europe. The overall administration and management is in place to support the implementation of the work programme.

10. Two recent developments have tested the ECDC capacity: bird flu and smallpox simulation exercise and it worked!

11. The Heads of Units briefed the Board on their work programme 2005 including issues previously approved by the Board and new ones suggested by ECDC to the Board. Project leaders also gave a short account of the progress made and highlighted key actions planned.

12. The Board welcomed the progress made at the Centre during the previous five months and congratulated the Director and her staff for this.

13. The content of the updated work programme has been approved by the Board. The budget lines will be amended in the light of the Board's decision on the Supplementary and Amending Budget (see paragraphs 21 and 22 below).

Rules of Procedure of the Advisory Forum (document MB4/5/4)

14. The Director presented the Rules of Procedure of the Advisory Forum (AF) to the Board for discussion for the second time, noting that the AF was happy with the text. The rules envisage close collaboration between the AF and the Centre on technical/scientific issues to advise the Director on the work programme, while the Board would play its role as the Governing Body of the Centre. AF would meet 4 times a year as envisaged in the Regulation; the working groups of the AF would have back to back meetings with those of the AF. There is flexibility in its operations, it may be convened to deal with emergency issues; ECDC may set-up teleconferences and written procedures may also be used for consultation. The teleconference facility has been tested on more than one occasion.

15. A few comments were made on the document, mainly concerning confidentiality issues, emphasizing that the ECDC Founding Regulation states that confidential information submitted by a Member State cannot be disclosed without the prior consent of

that Member State. The Board was supportive overall and it was agreed that the Director would incorporate the comments made and re-circulate the document for final approval.

Rules of Procedure of Scientific Panels (document MB4/6/5)

16. Professor Johan Giesecke, Head of the Scientific Advice Unit, presented the item. He explained that these panels would not be permanent and may change in time, but that they were important to engage academia, to operate with some speed when it can take months to engage consultants and the need for transparency identifying external scientific advice. He also pointed out that it was impossible to foresee the volume of scientific questions being put to the ECDC, and that a mechanism was needed to be prepared for a substantial number of such questions. The proposal is to have ad hoc panels for six disease groups roughly according to the groups of diseases in Decision 2119/98 with up to 11 members per panel; members of the Advisory Forum and ECDC staff could not be on these panels. Ad hoc meetings of these panels will be convened..

17. Some concern was expressed by the Commission that the proposal was not entirely in line with Article 6 of the Regulation which states that ECDC can only create ad hoc panels where there is not sufficient expertise in the Dedicated Surveillance Networks (DSNs) and in other European Agencies. It was further suggested that ECDC sets up large expert lists and simply appoint ad hoc panels from these when issues arise.

18. The Director pointed out that having such independent panels was crucial to ECDC's credibility and performance, especially at this stage as it is building up internal expertise and does not have its own research, laboratory and clinical scientific activities. She said that the envisaged panels were meant to be ad hoc and would be established for a 3-year period only. She pointed out the flow chart for dealing with the questions put to ECDC and how internal expertise and the capacity in the Surveillance Networks and other EU Agencies would be used. The Director stated that she wished to have transparency in recruiting experts and the envisaged process would allow for that and also to provide quick response to questions. She agreed that the rules of the scientific panels needed to reflect the Article 6 of the Founding Regulation and it was agreed to bring this document back to the next meeting of the Management Board.

Guidelines to promote a uniform response (document MB4/7/6)

19. Professor Johan Giesecke presented the issue of producing guidelines to promote a uniform response. He proposed some prioritisation criteria for topics and also some candidate topics that had been suggested by the Advisory Forum. He also outlined the procedure for monitoring diffusion and use. The terminology: *Guidance, Guidelines* needed to be looked at before producing the final document as it may raise translation/interpretation difficulties in some countries. Printed materials should be produced as well as web-based material and some members felt that the countries should take care of their own translation. The need for a formal review timetable was raised.

20. It was agreed that the document was approved subject to clarification on the terminology.

21. The Director explained that there had been pressure on specific budget lines notably recruitment, missions and travel. In future there will be sub-budget lines to increase transparency. This item will be on every Management Board meeting. She hoped the Parliament would approve the general 2006 budget as the next Board meeting will consider the budget for 2006. The detail was presented by Jef Maes Head of Administration. He reminded the Board of prior decisions in May and September to reinforce budgets for recruitment (May) and missions and rent (September). The proposal now was to reinforce staffing budget lines, bringing in more detail in budget structure and more in line with the original budget structure of 2005.

22. It was felt that the cases were very clear but the European Parliament should be informed of change informally. It was suggested that future papers with proposals could have provisional cost implications. The budget changes were approved.

Updated financial regulation (document MB4/9/8)

23. In line with the decision made at its third meeting, the Board agreed to apply *mutatis mutandis* the amendment to the implementing rules as set by a Commission Decision of 20 July 2005.

Draft Framework for a Strategy for infectious diseases surveillance in Europe (2006-2008) (*document MB4/10/9*)

24. Andrea Ammon, Head of the Surveillance and Communication Unit explained the basis of this in the founding Regulation and what would be the European added value: such as a coordinated approach to surveillance, timely detection of new trends and synergistic effects. She then explained the extensive consultation process that had been undertaken, led by a small group of external and internal experts that started working in May 2005 to determine the Surveillance Strategy being considered which had been approved by the Advisory Forum. The vision was set out including the assessment of surveillance objectives, the evaluation of existing surveillance networks, a prioritization exercise and establishing quality procedures. There will in future be routine surveillance (done by ECDC), enhanced surveillance (either by Member States or ECDC) and feasibility projects for new diseases or methods.

25. The strategy envisages the strengthening of the surveillance networks. It was noted that those Networks with alert functions would be integrated first into ECDC. There will be evaluations of each Network before proceeding. There will be a strategy for securing laboratory input in the surveillance process but an issue that requires solution is that of European Reference Laboratories (a separate process is underway on this). There will be involvement of learned societies and links with other networks on the borders of EU such as EpiNorth and there will be agreement and cooperation with WHO, other EU agencies (such as EFSA), international institutions and neighbouring countries.

26. There were many issues that had been agreed but there were also some issues where further discussion was needed. The next steps would include the publication of the final report including all questionnaires and a meeting with representatives of all the networks in November.

- 27. A number of comments and suggestions were made:
 - Annex 1 should be reviewed to make sure all the networks are included, EpiNorth and EpiSouth and include the financial implications.
 - The paper included many of the concepts adopted over the past 20 years but there was concern on the budget for surveillance.
 - The paper should include the concept of 'common property' of surveillance data and the difficulty of retaining the interest of the hubs if most of the activity moved to ECDC.
 - Need for standardization of IT and data and especially for laboratory results and the need for an inventory of laboratories.

28. The document was adopted and the Management Board thanked Dr Ammon for the work done.

Country and External Relations Strategy (document MB4/11/10)

29. Karl Ekdahl, Strategic Adviser to the Director, pointed out that though ECDC was an independent body it worked intimately with Member States, other Agencies, the Commission, WHO, etc. On the country cooperation, he noted that the Management Board will be asked to appoint and publish a list of national competent bodies which need to be identified. There is a plan to have an overview of public health systems and a detailed inventory of resources and expertise building on the original IRIDE project. A list for national directory of contact points was suggested. A few comments on terminology were made, and also a suggestion to request contact points for specific functions, rather than positions, since these could vary between the Member States. The Director emphasized how essential it was to have these contact points and for them to be accurate and updated. She made a plea for the work of identifying national counterparts to be supported. The Chair promised that the Board would assist.

30. The Board adopted the Country and External Relations Strategy but asked that its recommendations on external counterparts be taken into account.

Improved co-ordination and support to response in Europe in public health crises: ECDC Public Health Event Operation Plan (document MB5/13/11)

31. Denis Coulombier, Head of the Preparedness and Response Unit presented the policies and procedures ECDC plans to follow if a serious public health incident - a Public Health Event (PHE) - occurs. PHE's are events that present a threat to the health of citizens of a scale or of seriousness that requires an immediate and urgent response from the authorities. If the Director of ECDC decides such a situation exists, she will reallocate staff from dealing with non-urgent tasks and reassign them to dealing with the emergency. ECDC will also activate a process of regular internal meetings in ECDC and telephone conferences with Member State authorities to ensure the emergency is properly managed.

32.

decision to move to PHE mode would not necessarily have any significant implications for Member States, the Commission or the Parliament. However, the Advisory Forum would be involved and this is why this issue has been brought to the attention of the Board. The external part of the public health event operation plan is currently being developed and will be tested during the forthcoming exercise and presented to the Board at its next meeting.

33. It was important to recall the ECDC s obligation to give prior information to the Member States and the EU Institutions before making announcements to the media and the public.

Improved detection and monitoring of emerging health threats in Europe: ECDC' epidemic intelligence operations (document MB4/14/11)

34. Denis Coulombier, Head of the Preparedness and Response Unit presented the procedure in place at ECDC to detect and monitor emerging health threats in Europe. This covered the sources of information (such as the EU's Early Warning and Response System (EWRS) on public health incidents), the tools and procedures being developed by ECDC, and agreements reached with Member States, the European Commission and the WHO on cooperation and exchange of information.

35. A meeting on epidemic intelligence is planned on 18-19 January 2006.

Communication and risk communication strategy (document MB4/15/13)

Ben Duncan, ECDC Press Spokesman presented the paper on ECDC's risk 36. communication strategy. Before this, however, he outlined the actions undertaken by ECDC between 17 October and 27 October to communicate to the media, the public and risk groups such as people in close contact with infected poultry, about the threat to human health posed by A/H5N1 avian influenza (bird flu). On 13 October ECDC had been requested by Commissioner Kyprianou to produce advice to travellers and poultry workers in affected regions, following the finding of A/H5N1 in Turkey and Romania. ECDC had consulted intensively with Member State authorities during 17 and 18 October and had only presented its risk assessments and its advice to the media once consensus had been reached. Media interest in the risk assessment had been intense and ECDC had had numerous contacts with the media, including major press conferences in Stockholm (19 October) and Budapest (27 October). As a result the media aspect of ECDC's communication strategy has advanced more quickly than envisaged. Ben Duncan invited the Board members to nominate media contact points in their organisations. ECDC would circulate advance information about planned media activities to these contact points as well as to the Management Board.

A discussion then took place about the respective roles of EU level bodies and 37. national bodies in communicating to the media about infectious disease issues. The obligation of ECDC to give prior information to Member States and the EU Institutions before making announcements to the media was emphasised and the practicalities of what this should involve were discussed: the idea of ECDC liaising with a designated media contact point in each Member State was supported by some speakers while others thought contact points might need to vary depending on the issue under consideration. It was also observed that communication strategy is wider than just media relations and that other aspects of ECDC's external communications, such as the development of its website, publications, should continue to be priorities.

38. It was agreed that the communication policy paper should be reviewed and submitted to the Board at its next session.

Apportionment of tasks between Commission and ECDC *(document MB4/16/15)*

39. Mr Fernand Sauer, Director of Public Health, DG SANCO, presented the two letters he had sent to the ECDC Director "handing over" certain responsibilities from SANCO to the ECDC. The first letter concerned the financial and administrative responsibilities handed over to ECDC in July when Zsuzsanna Jakab became the authorising officer for all matters relating to the Centre's budget. The second letter concerned policy matters. Mr Sauer made clear that this letter is not a legal document and that it in no way limits the right of the Management Board to interpret the Centre's Founding Regulation. Rather, the letter and the accompanying documentation give details of all the activities SANCO is currently engaged in that may have implications for, or be of interest to, ECDC. Annex III of the letter sets out SANCO's view on how the division of tasks between it and ECDC should be handled in the immediate future. Annex III was developed in close consultation with ECDC's senior officials, however it does not bind the Management Board.

40. The Management Board received Mr. Sauer's letters on the handover of files from the Commission to ECDC. The Board noted that the letter on the division of policy tasks does not bind ECDC legally and that the Management Board's discretion to interpret the Centre's Founding Regulation remains unchanged by the letter.

Weekly epidemiology report (document MB4/17/14)

41. Karl Ekdahl, Strategic Advisor to the Director, briefed the Management Board on the strategic partnership ECDC has concluded with *Eurosurveillance* in order to help ECDC deliver the Weekly Epidemiological Report foreseen in ECDC's 2005 Work Programme. The partnership gives ECDC access to *Eurosurveillance*'s long editorial experience in reporting Europe-wide epidemiological news and its network of contacts with editors of national epidemiological bulletins in Member State public health institutes. ECDC will build on and develop the current *Eurosurveillance* weekly release using its privileged contacts with the Disease Specific Networks, though of course care would be taken only to use public domain information in ECDC's public reports. *Eurosurveillance* remains a European Commission funded project until 2007. ECDC's partnership with *Eurosurveillance* therefore has to respect the obligations of *Eurosurveillance* under its contract with the Commission. To ensure an effective and strong partnership, Karl Ekdahl has joined the editorial board of *Eurosurveillance* while Candice Pettifer of the team in United Kingdom has been seconded to work at the ECDC in Stockholm.

42. Karl Ekdahl's report was received by the Management Board without comment and the approach set out in it endorsed.

Feedback from the Audit Committee

43. The Director of ECDC gave on oral report on the first meeting of ECDC's Audit Committee, which took place in Budapest on 26 October 2005. A written report of this meeting will be circulated to the Management Board. In the meantime, however, the ECDC Director asked the Management Board to approve the revised Declaration of Interest approved by the Audit Committee. Three changes have been made to the form: the period for conflict of interest covered by the form is now three years (instead of five), the declaration is now titled "Annual declaration" (making clear it only has to be filled in once a year) and ECDC Director and Management Staff were included on the form.

44. The Board approved the revised form. The ECDC Director requested that all members and alternates complete the form and return it to ECDC by the end of the following week. As agreed by at the third meeting of the Management Board, the completed forms will be published on the ECDC's website.

45. ECDC Director informed the Management Board that the next Audit Committee meeting would be held in Stockholm on 13 December, immediately before the next Management Board meeting. The 2006 meetings of the committee would also be scheduled to take place to coincide with Management Board meetings, though if needed further Audit Committee meeting could be scheduled for other dates.

Any other business

46. The issue of membership of the Board was raised, in particular regarding the members' commitment to attend all meetings, as provided in the Rules of Procedure

47. There was a discussion concerning media reports about the development of a vaccine against A/H5N1 avian influenza in Hungary. The representative of Hungary briefed the Management Board on the current state of development of the vaccine. The work is being carried out by a public sector vaccine institute that had received a sample of the A/H5N1 from WHO. The Hungarian institute has produced an experimental vaccine that is currently being tested for safety and efficacy. However, it is too early to say how – or even whether - such a vaccine could be deployed. The representative of the Commission reminded board members that any vaccine intended for human use would have to be approved by the European Medicines Agency (EMEA) before it could be deployed. The Commission also observed that a number of private sector vaccine manufacturers are also developing experimental human vaccines based on A/H5N1. No file has been submitted to any of the EU institutions on the Hungarian vaccine and therefore none of them were involved in any discussions on this issue with the Hungarian side. The role of ECDC in assessing the safety and efficacy of vaccines would be further discussed and developed. The Chairman of the Management Board concluded that the Board would continue to follow this issue closely and keep the situation under review.

48. In the absence of any further issue, the Chair declared the meeting closed.

On behalf of the Management Board

Marc Sprenger Chair
