

**ECDC Management Board** 

### Minutes of the Twenty-sixth Meeting of the ECDC Management Board

### Stockholm, 14-15 November 2012

Adopted by the Management Board at its Twenty-seventh meeting, 20-21 March 2013

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#### **Summary of Proceedings – ECDC Management Board Meeting**

The Twenty-sixth ECDC Management Board (MB) meeting convened in Stockholm, Sweden, on 14-15 November 2012.

During the meeting, the Management Board:

- <u>adopted</u> the Draft Agenda, with a few changes;
- <u>unanimously adopted</u> the Draft Minutes of the Twenty-fifth Management Board meeting (19-20 June 2012);
- took note of the Director's briefing on ECDC's main activities since the last meeting of the Management Board (19-20 June 2012);
- took note of the Report on Implementation of the Work Programme 2012;
- <u>elected</u> the new Chair of the Board, Françoise Weber (30 votes were counted, of which 28 votes were 'for' with 2 abstentions), and the new Deputy Chair, Tiiu Aro, Member, Estonia (30 votes were counted, of which 28 votes were 'for', 1 abstention and 1 voting ballot left empty);
- <u>approved</u> the ECDC Work Programme 2013;
- <u>unanimously approved</u> the proposal to terminate the contract with PricewaterhouseCoopers and confirmed the new composition of the MB External Evaluation Steering Committee (MEES): Belgium, France, Germany, Latvia, Portugal, Slovenia, Spain, the United Kingdom, as well as representatives of the European Parliament and the European Commission;<sup>1</sup>
- <u>approved</u> the revised mandate of the ECDC Audit Committee with no further changes;
- <u>elected</u> the new ECDC Audit Committee: Johan Carlson, Chair (Member, Sweden), Colette Bonner (Member, Ireland), Audrius Ščeponavičius (Member, Lithuania) Robert Goerens (Member, Luxembourg), Pawel Gorynski (Member, Poland) Jacques Scheres, representative of the European Parliament, John F Ryan, representative of the European Commission and Michel Pletschette, representing the Internal Audit Capability of DG SANCO;
- <u>endorsed</u> the IAS Strategic Audit Plan 2011-2013;
- <u>approved</u> the Budget and Establishment Table for 2013;
- <u>approved</u> the Second Supplementary and Amending Budget 2012;
- participated in an extended *tour de table* session in order to provide ECDC with their vision of the ECDC Strategic Multi-annual Programme (2014-2020);
- <u>agreed</u> with the main principles of the Independence policy and implementing rules on Declarations of Interests;
- <u>took note</u> of the presentation on the Irish EU Presidency;
- took note of the presentation on the Cyprus EU Presidency;
- <u>endorsed</u> the IMI initiative in general terms.

<sup>&</sup>lt;sup>1</sup> With the exception of Estonia who had requested to resign from the Committee and with a caveat that the continued participation of Romania is not known since the member was not present for the MB26 meeting.

## **Opening and welcome by the Acting Chair (and noting the Representatives)**

1. Jacques Scheres, representative of the European Parliament and the Acting Chair, opened the meeting and welcomed all the participants to the Twenty-sixth ECDC Management Board (MB) meeting. He informed the Board that as Professor Hubert Hrabcik has recently retired and is no longer Member/Chair of the ECDC Management Board, he will be leading part of the morning's meeting as Acting Chair until the Chair and the Deputy Chair have been formally elected.

2. The following (new) members were welcomed: Pamela Rendi-Wagner from Austria, newly appointed member, Taneli Puumalainen from Finland, newly appointed alternate, Gesa Lücking, from Germany, newly appointed alternate, Antonis P Vasilogiannakopoulos from Greece, newly appointed member, Beatrix Oroszi from Hungary, newly appointed alternate, Iveta Cirule from Latvia, newly appointed alternate, Mario Camilleri from Malta, newly appointed member, Michał Ilnicki from Poland, newly appointed alternate, Karoline Fernández de la Hoz from Spain, newly appointed member, Johan Carlson from Sweden, newly appointed member, Jan Berg from Norway, newly appointed member and Isabel de la Mata Barranco from the European Commission, appointed alternate.

3. Apologies had been received from Bulgaria, Italy (proxy given to Estonia), Liechtenstein, Romania (proxy given to Germany) and Line Matthiessen-Guyader, European Commission (proxy given to John F Ryan, European Commission). It was noted that Minerva-Melpomeni Malliori, representative of the European Parliament, would arrive later in the afternoon (proxy given to Jacques Scheres), and that Finland and Sweden would arrive later during the morning.

4. Finally, the Board was informed that due to recent power cuts in the ECDC area, the technological equipment in the meeting room had been damaged and that technicians would do their best to ensure a smooth running of the meeting.<sup>2</sup>

#### Welcome from the Director, ECDC

5. Marc Sprenger, Director, ECDC, welcomed the meeting participants on his behalf. A special thank you was extended to Jacques Scheres for accepting the role of Acting Chair. The Board was also informed of two guest speakers (suggested by members of the MB) who would join the meeting directly after lunch, Dr David L Heymann (via video link) and Professor Dr Helmut Brand. In reference to this, the Board was asked for permission to live stream both presentations to all ECDC staff. The MB subsequently agreed to the Director's proposal.

# **Item 1 – Adoption of the draft agenda (and noting the declarations of interest and proxy voting, if any)** (Documents MB26/2 Rev.3, MB26/3 Rev.2)\*

6. In reference to written comments received by the Secretariat regarding the draft agenda, the Acting Chair noted that the update on reorganisational adjustments will be discussed in detail at the next MB meeting in March 2013. It was added that the internal evaluation process of same is currently on going. This was accepted, however, reference was made to the previous MB meeting where this issue was discussed and a comment was made that in the future, it should be made clear that only the MB should have the right to change a previously made agreement.

7. Regarding the Audit Committee agenda items, it was noted that it is vital to discuss them during Day 1 of the meeting and not Day 2, especially considering their status as decision items and the need to ensure sufficient time in which to revise documents, where applicable.

<sup>&</sup>lt;sup>2</sup> During the meeting, the Board members were filmed with a manual camera in order to ensure required visibility for the interpreters.

<sup>\*</sup> Item for decision

8. In reference to an agenda item on External Evaluation for 2012, it was requested to change this into a decision item.<sup>3</sup> It was also requested to change the paper, "ECDC vision on EU-level monitoring and evaluation of immunisation programmes and related vaccines", from 'For information' to 'For guidance'.

9. In general, it was pointed out that all decision items should be discussed prior to items for information and/or guidance. This was duly noted by the ECDC, however, it was also highlighted that due to logistical reasons, it was not feasible to follow this procedure for the current meeting.

10. No declarations of interests were declared verbally. The following written declarations were received: John F Ryan, Member, European Commission, noted that he is a member of the Audit Committee and thus attended the AC meeting on the previous day (agenda item: Update from the ECDC Audit Committee). He also stated that he is responsible for the EU Health Programme and Work Programme 2013 (agenda item: ECDC Annual Work Programme 2013) and a member of the MB External Evaluation Steering Committee (agenda item: External Evaluation for 2012). In reference to the item on implementation of the Position statement of the Commission and ECDC on human pathogen laboratories: a joint vision and strategy for the future, it was noted that he is the Director Public Health, European Commission. The same was declared in reference to items on Update from the European Commission and ECDC vision on EU-level monitoring and evaluation of immunisation programmes and related vaccines, respectively. Gesa Lücking, Alternate, Germany, and Anne-Catherine Viso, Alternate, France, referred to their status as members of the MB External Evaluation Steering Committee (agenda item: External Evaluation for 2012). France also stated that the InVS has two agreements with ECDC in the area of EPIET, for the coordination of EPIET and to host EPIET fellows (agenda item: Proposal for the future EPIET, based on the recent EPIET Consultation). Beatrix Oroszi, Alternate, Hungary, noted her affiliation as member of the I-Move consortium in reference to items on the ECDC Annual Work Programme 2013 and ECDC vision on EU-level monitoring and evaluation of immunisation programmes and related vaccines.

11. For proxy voting, please refer to apologies under 'Opening and welcome by the Acting Chair'.

The draft agenda was <u>adopted</u> with the above-noted changes.

# **Item 2** – Adoption of the draft minutes of the 25<sup>th</sup> meeting of the Management Board (Stockholm, 19-20 June 2012) (Document MB26/4)\*

12. The draft minutes from the Twenty-fifth Management Board meeting (19-20 June 2012) had been previously circulated to the Members of the Board.

13. Several Board members highlighted that the summary of proceedings and the draft minutes should be made available to the Board shortly following the meeting as it is complicated to recall the precise discussions months after the previous meeting.

The draft minutes of the Twenty-fifth Management Board meeting (19-20 June 2012) were <u>adopted</u> without changes.

ECDC agreed to circulate the summary of proceedings and the draft minutes of each following meeting much earlier.

<sup>&</sup>lt;sup>3</sup> As a result thereof, the draft agenda, draft programme and relevant meeting documentation were revised accordingly to reflect the subsequent changes.

<sup>\*</sup> Item for decision.

### Item 3 – Election of the Chair and the Deputy Chair of the ECDC Management Board<sup>4</sup>

14. The Acting Chair requested the Board's permission to chair the session of the elections. This was accepted. He then recalled the procedure for the elections. The following nominations were noted: for the Chair of the MB: Dr Françoise Weber, Member, France, and for the Deputy Chair: Dr Tiiu Aro, Member, Estonia. Reference was made to rules and regulations of the voting procedure. Iceland and Norway volunteered to act as tellers. Proxy voting was recalled. In reference to this, the procedure was questioned, i.e. whether only the members present at the meeting are eligible to vote, excluding the proxy votes or should proxy votes also be included. Legal advice was requested. As ECDC requested time in order to respond to this query in an orderly manner, it was suggested to continue with the meeting agenda in the meantime.

#### Item 9 – Director's briefing on ECDC's main activities since the last meeting of the Management Board (19-20 June 2012) (Documents MB26/Info Note 1 Rev.1 and MB26/Info Note 3 Rev.1)

15. Marc Sprenger, Director of ECDC, updated the Board on the recent activities of the ECDC since the last meeting in June.<sup>5</sup> The Board members expressed their satisfaction with the Info Note briefing as it provides a succinct overview on all major activities of the Centre.

In reference to the aforementioned issue on the consequences of the recent reorganisation, it 16. was again noted that this item needs to be discussed in depth at the next meeting, as it was omitted from the MB26 programme. Additionally, it was requested to include the building project item as a separate discussion point in the agenda for the next meeting. Further on the same issue, the Director expressed his appreciation over the Board's enthusiasm over this complicated matter. The Board was informed of a meeting between the ECDC and the EU Minister of Sweden which, unfortunately, did not conclude with any solutions. It has been made clear that Sweden cannot interfere with contractual matters between the landlord and the Centre. Overall, the Swedish Government does not provide any kind of special treatment or support to any agency or organisation (neither domestic nor international) based within the country. Board members agreed that the situation should be resolved and Sweden should (at least) provide reasons as to why they cannot support ECDC in this respect. It was pointed out that it gives a highly negative impression to assume that the host country is not interested in keeping the Centre in Sweden. It was also mentioned that perhaps it would be worthwhile to investigate possible alternative solutions, such as relocation of the Agency. The Acting Chair proposed that the Building Project Working Group to meet again.

17. In reference to the evaluation of the reorganisation, the Board requested to receive the questionnaire, even if the survey results are not yet available.

The Board took note of the update on ECDC's activities.

It was requested to include the reorganisation adjustments as well as the ECDC building project issue as separate items for in-depth discussion at the next meeting in March 2013. A proposal was made for the Building Project Working Group to meet again, perhaps in combination with the agenda item on the same matter.

The Board requested to receive the questionnaire on the evaluation of the reorganisation survey.

<sup>&</sup>lt;sup>4</sup> According to Article 2 of the rules of procedure of the Management Board, a two-thirds majority of the Management Board voting members present and secret ballot is required for adoption of this item.

<sup>&</sup>lt;sup>5</sup> Item 8 - Update from ECDC.

### Item 3 – Election of the Chair and the Deputy Chair of the ECDC Management Board<sup>6</sup>

18. Rebecca Trott, Senior Legal Adviser and Head of the Legal and Procurement Section, Resource Management and Coordination Unit, ECDC, clarified the issue of proxies. A contradiction in the Rules of Procedure<sup>7</sup> of the ECDC Management Board was brought out, namely, Article 2a, Article 2a "The vote for the election of Chair shall be taken by a two-thirds majority of the Management Board voting members present and by secret ballot [*emphasis in italics*] versus Article 3(2) "Any Board member can also represent one other member, provided that a written authorisation from the absent member is provided to the Chair latest at the beginning of the meeting or during the course of the meeting for the remaining points on the agenda. The proxy shall be recorded in the minutes."

19. The Board was advised to include the proxy votes. A suggestion was made to revise the Rules of Procedure to ensure further clarity.

The Board agreed to vote with the proxy votes included.

A suggestion was made to further revise the Rules of Procedure in order to ensure further clarity.

#### **Item 5 – Report on Implementation of the Work Programme 2012 up until present** (*Document MB26/9*)\*

20. Philippe Harant, Head of Section, Quality Management, Resource Management and Coordination Unit, ECDC, updated the MB on the implementation of the Work Programme 2012 up until present. It was highlighted that ECDC is on track and that a further update with be presented at the next Board meeting in March as part of the Annual Report of the Director. It was noted that some activities are not monitored as such as they are processes (e.g. recruitment) where no specific deliverable is expected. In respect to possible budget carryovers, ECDC is now focusing on reaching the highest budget execution possible in order to avoid this.

The Board <u>took note</u> of the Report on Implementation of the Work Programme 2012. A further update will be made as part of the Annual Report of the Director at the Twenty-seventh MB meeting in March 2013.

### Item 3 – Election of the Chair and the Deputy Chair of the ECDC Management Board<sup>8</sup>

21. The voting for the new Chair of the ECDC Management Board was called into session.

Sveinn Magnússon, Member, Iceland, concluded the vote: 30 votes were counted, of which 28 votes were 'for' with 2 abstentions. The new Chair of the Board, Françoise Weber, Member, France, was elected.

22. The elections of the Deputy Chair were convened.

Jan Berg, Member, Norway, concluded the vote: 30 votes were counted, of which 28 votes were 'for', 1 abstention and 1 voting ballot left empty. The new Deputy Chair of the Board, Tiiu Aro, Member, Estonia, was elected.

<sup>&</sup>lt;sup>6</sup> According to Article 2 of the rules of procedure of the Management Board, a two-thirds majority of the Management Board voting members present and secret ballot is required for adoption of this item.

<sup>&</sup>lt;sup>7</sup> Please refer to the Rules of Procedure of the ECDC Management Board, adopted at its first meeting on 28 September 2004, including amendments adopted at its tenth meeting on 15 June 2007.

<sup>\*</sup> Item for decision.

<sup>&</sup>lt;sup>8</sup> According to Article 2 of the rules of procedure of the Management Board, a two-thirds majority of the Management Board voting members present and secret ballot is required for adoption of this item.

23. The Acting Chair congratulated the new Chair and Deputy Chair on behalf of the Board. The Board members extended a special thank you to Hubert Hrabcik for all this work as the former Chair of the MB as well as to Jacques Scheres as Deputy Chair.

24. The newly appointed Chair and Deputy Chair subsequently expressed their gratitude to all Board members for their trust and for having voted for them.

### **Item 6 – ECDC Annual Work Programme 2013**<sup>9</sup> (Document MB26/10 Rev.1)\*</sup>

25. Marc Sprenger, ECDC Director, updated the Board on the Annual Work Programme 2013.10 Philippe Harant, ECDC, added that the latest changes had been included into the revised document and the errors have been corrected.<sup>11</sup>

26. A general proposal was made to extend the deadline of submission of the MB documents to the Board to 15 working days<sup>12</sup> prior to the meeting. It was also recalled that the minutes of the meetings should be submitted to the Board much earlier to ensure that the memory is still fresh in order to make comments and/or amendments. Regarding the meeting documents, it was pointed out that in case a paper is not ready by the agreed upon deadline, the item should be taken off the agenda. After each meeting, a draft agenda for the next meeting, including any items which were postponed, should be circulated to the Board as soon as possible. From the ECDC's side, it was noted that even though the Board's proposal is generally understood, as a caveat, some documents, particularly financial documents, can only be sent to the Board within 10 working days. It was, however, agreed that the minutes will be forwarded to the MB much earlier, together with a draft agenda for the next meeting.

27. On more specific items, it was questioned what the plan is for molecular vigilance and how ECDC will incorporate this into its activities. Further elaboration was also requested on EPIET and MedIPIET (Mediterranean Programme for Intervention Epidemiology Training). On the latter, it was clarified that the activities and budget of the EPIET were already discussed in the June meeting and that no further changes are needed. In reference to MedIPIET, the Board was informed that ECDC is currently in discussions with the Commission. It has been decided that ECDC would carry out this programme and will receive funds for this. The first planned step is a two-year project setting up the infrastructure with a grant of 400 000  $\in$  (not from ECDC's budget), based on the example of EPIET MS-track. The project plan will hopefully be finalised shortly. Contribution from ECDC will be through staff time. Further updates can be provided to the Board at the March meeting. It was further questioned whether it is envisioned to work together only with non-EU countries. Clarification was provided that the planned consortium would include four EU countries (France, Greece, Italy and Spain) and non-EU countries, Albania, Egypt, Morocco and Syria. In the future, it is expected that more countries will join the project.

28. Following further queries from the Board, it was informed that unfortunately no budget is foreseen for the I-Move project, as was comprehensively discussed in the June MB. In reference to the legionella twinning project,<sup>13</sup> it was confirmed that no epidemiologists will be involved. It was also noted that the AMR is shifting the focus from MRSA to carbapenemase-producing Enterobacteriaceae (CPE).

29. Following a comment on the activities related to the new legislation on serious cross-border health threats proposed by the European Commission, it was noted that funding for such projects should only be allocated once the legislation is adopted by the European Parliament and the Council. The representative of the Commission agreed that there should be a link between the proposal of the legislation and the activity ECDC is carrying out and indeed, the legislation in question has not yet

<sup>&</sup>lt;sup>9</sup> According to Article 8 of the rules of procedure of the Management Board and Article 15 of the Founding Regulation, a twothirds majority of all members is required for adoption of this item.

<sup>\*</sup> Item for decision

<sup>&</sup>lt;sup>10</sup> Item 6 - ECDC Annual Work Programme (M Sprenger)

<sup>&</sup>lt;sup>11</sup> Please also refer to the tabled document MB26-10 Rev.1 ECDC Annual Work Programme 2013 (corrigendum), available on the MB extranet, MB26, handouts.

<sup>&</sup>lt;sup>12</sup> Not including holidays.

<sup>&</sup>lt;sup>13</sup> To get better quality of surveillance data it is important that laboratories are using validated methods. This is a pilot project where laboratory staff from one Legionella laboratory will be encouraged to visit another Legionella laboratory in order to exchange methods and experiences. ECDC will support this by paying the costs for travelling and accommodation.

been adopted. However, the activity is a planning tool for next year and it is hoped that the legislation will be finalised during 2013. Although one member suggested changing the wording in the Programme, it was finally agreed that the activities will only be implemented as part of the work programme once the legislation is in place.

30. In reference to the Work Programme 2013 document, reference was made to the discussions at the last meeting in June and it was questioned whether the ECDC Advisory Forum has given their opinion. The Board was informed that the AF viewed an earlier version of the Work Programme 2013, but that it has not been discussed in detail. Additionally, it was suggested that the national programmes could be shared at the Advisory Forum meetings as this would provide a good opportunity for the Member States to better collaborate with ECDC as well as to save money. If an activity is foreseen in the plan, the same activity is not necessarily automatically dropped at the national level; yet the effectiveness in both cases could be increased. It was recalled that, during the Joint Strategy Meeting earlier in September, it was reiterated that the AF provides technical and scientific advice to the Director on non-clear cut issues, and the role to see how to align wherever possible the national priorities with ECDC and vice versa is the responsibility of the Coordinating Competent Bodies. The Board requested that the Advisory Forum should be able to comment on the Work Programme at their next meeting in December.

31. The Board expressed regret that the key messages from the Joint Strategy Meeting were not communicated to the Board in any greater detail, other than that which was noted in the Info Note.

32. Further clarity was requested in respect to the I-Move issue, and it was queried how the gap between 2013 and 2014 would be solved, considering that the project will be discontinued in 2013.

33. The Director of ECDC recalled that the Board is always consulted on which activities should be discontinued. For the Advisory Forum, a scoring system is used in order to ascertain the priorities. However, this system touches more on the scientific work of ECDC. The role of the Advisory Forum is primarily to advise and to support technical and scientific evidence on ECDC priorities and activities and that the role of the Coordinating Competent Bodies should be to communicate the information from the national level to ECDC and *vice-versa*.

34. In general, while the Board should discuss which activities ECDC should/should not carry out, the details of same should be discussed via some other platform. A comment was made that the discussion could also be directed more towards improving how the work is carried out and not only which activities to drop, particularly since activities are planned at the Member State level.

35. In reference to collaboration between the Member States and ECDC in the field of data collection, it was noted that much of this is dictated by the European legislation, i.e. what, who and how to report. However, perhaps this list should be critically reviewed to find solutions to save money from the point of view of both the Member States and ECDC/Commission.<sup>14</sup> In relation to communicating the link between the national and MB level, it was suggested as part of the future Strategic Multi-annual Programme (SMAP) to create a list of topics at the EU and national level that is easily comparable to track either possible duplications or possible synergies. This list would also help to better understand where the Member States and ECDC could work jointly, which should be developed in articulation with the Coordinating Competent Bodies.

36. The Chair noted that, based on the varying size of each of the Member States, and due to possible limitations of resources, a more effective level of dialogue could be achieved if the MB received documents much earlier. An example from the Council of Ministers was given in terms of effective time management of the meeting agenda and it was proposed to decrease the number of items for discussion and to focus solely on priority items by allowing more time for in-depth discussions, including the possibility for all members of the Board to express their views. The Chair noted that this approach could be used already for the next meeting in March 2013.

37. The unresolved issue regarding I-Move was raised again and ECDC reconfirmed that there is no budget available. Due to the importance of this project, and considering that it has not been included in the Work Programme 2013, the Member from Ireland informed that she is against the

<sup>&</sup>lt;sup>14</sup> Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (<u>http://eur-lex.europa.eu/LexUriServ.do?uri=CELEX:31998D2119:EN:NOT</u>).

Programme and noted that ECDC should find the funds to support this initiative. The Director indicated that this topic will be covered later in the agenda of this meeting.<sup>15</sup>

38. The Chair concluded the session and sympathised that due to the crisis, all countries and institutions are faced with the same difficult issue of having to drop activities. The Board has the right to express its concerns, however, the MB should also be able to discuss which activities can be stopped and which cannot and thus help ECDC make the difficult decisions.

The Board recommended revising the Rules of Procedure of the Management Board meetings by increasing the deadline for submission of documents from 10 to 15 working days. It was also proposed to forward a draft agenda, including the postponed items, to the Board well in advance before the next meeting. It was also suggested to consider the approach of the Council of Ministers to facilitate important discussions.

The ECDC Work Programme 2013 was approved.

#### Item 8 – External Evaluation for 2012\*

39. Daniel Reynders, Member, Belgium, and Chair of the MB External Evaluation Steering Committee, updated the MB on the recent developments regarding the second independent evaluation of ECDC. To provide further background, it was recalled that the first kick-off meeting between the ECDC and PricewaterhouseCoopers (PwC) took place on 13 August 2012 where PwC were briefed in general by the ECDC technical team. The Acting Chair of the MB External Evaluation Steering Committee (MEES), Jacques Scheres, also met with them and clarified the expectations of the Committee. PwC then met with the ECDC Senior Management Team (SMT) in order to hear their expectations on a broader level. Following this kick-off meeting, bi-weekly/weekly audio conferences were held with the technical support team. The Acting Chair was also included during the discussions on the selection of case studies. PwC was provided with 159 essential documents through a secure FTP server. PwC was also present during the Joint Strategy Meeting in September in order to familiarise themselves with ECDC terminology and partners and to carry out background exploratory interviews.

40. The first Inception Report was received on 1 October 2012 and distributed for approval by the MEES. The MEES met with PwC during a face-to-face meeting in Brussels on 15 October 2012 to share their major concerns about the report, especially that PwC needed to better understand the role of ECDC and the environment in which it operates. In relation to stakeholder mapping, PwC was told that they need to realise that there are different kinds of stakeholders at the Member State level and the presented Inception Report did not reflect this. A letter was sent to PwC on 22 October 2012 with a list of deficiencies, after having discussed the main ones in person during the meeting on 15 October. A further main issue was the lack of senior expertise, in particular, specific public health expertise, to lead the process on the PwC side. PwC promised to take these points on board and a revised version of the Inception Report was submitted one week later.

41. On 24 October 2012, the MEES held an audio conference to discuss this second version of the Report. This resulted in a formal letter of concern sent by ECDC Director to PwC on 25 October 2012, explaining that the revised report again did not meet the expected standard, especially the lack of specific public health expertise which remained evident. PwC thereafter presented a new project leader on 6 November 2012. The MEES reviewed his credentials, but decided to defer any decision on the future of the Inception Report until they had the opportunity to meet the new project leader at a face-to-face meeting. This meeting was held during the morning of 13 November. During that meeting, the MEES concluded that they were not confident that the contract could be completed and result in a report with the expected quality. It was proposed that the MB discuss the option of the contract with PwC be cancelled and the Call for Tender be re-issued, with the inclusion of some possible amendments to prevent a repeat of this problem.

42. The Board was advised that if, based on the MEES report, a decision was made to terminate the contract, the contractors could challenge this decision, which could result ultimately in legal proceedings and the associated expenses and damages, thereby incurring a cost for ECDC.

<sup>&</sup>lt;sup>15</sup> Agenda item 12, "ECDC vision on EU-level monitoring and evaluation of immunisation programmes and related vaccines". \* Item for decision.

Consequently, issuing a new tender will necessarily delay the evaluation, notwithstanding possible challenges in finding a suitable contractor to take up this task.

43. Should the MB agree to recommend terminating the contract, the MEES should be dissolved and a new steering committee should be established. The new steering committee should discuss and consider any possible amendments to the terms of reference to mitigate the risk of shortcomings identified in the current performance.

44. A special note of appreciation was extended to all members of the current MEES by the Chair, Daniel Reynders, for all their efforts and time invested into this process. The Chair of the MEES in turn extended his appreciation to the hard work of the technical support team, both from the side of the ECDC staff as well as from DG SANCO who worked hard to try to make this contract succeed and were not to share any blame in the failure of the contractor.

45. The Chair of the MB on her behalf also thanked the MEES for their hard work. The item was put up for a decision. It was also noted that the current MEES should discuss the composition of the next Steering Committee amongst the Board members and inform the MB of the results during Day 2 of the meeting.

The MB External Evaluation Steering Committee (MEES), Chaired by Daniel Reynders, Member, Belgium, proposed that the Board recommend terminating the contract with PricewaterhouseCoopers. The Board <u>unanimously approved</u> this proposal.

A new tender process should be initiated as soon as possible. A confirmation of the composition of the new MEES was agreed to be announced before the end of the meeting.

### Item 11 – ECDC Strategic Multi-annual Programme (2014-2020)

46. The Director of ECDC welcomed the two guest speakers and expressed his gratitude for their willingness to participate in the meeting in order to provide some fruitful dialogue on this subject.

### Item 11b – Presentation from guest speaker (Professor Dr Helmut Brand)<sup>16</sup>

47. Professor Dr Helmut Brand thanked the Director of ECDC and the Management Board for the opportunity to participate in the meeting and give his presentation.<sup>17</sup>

#### Item 11a - Presentation from guest speaker (Dr David L Heymann)<sup>18</sup>

48. Dr David L Heymann joined the meeting via video link from the United Kingdom and gave his presentation.<sup>19</sup>

#### Item 11c – Questions and discussion

49. The Board expressed their appreciation for the excellent, stimulating presentations. Some questions were raised, including the importance and relation of the climate change in health threats. Dr Heymann noted that climate change is a vital component of the health issues. Professor Brand added that some parts of the veterinary concept should also be adopted.

50. A comment was made by one of the members that ECDC should not only look at diseases, but also surveillance methods, at least when dealing with infectious diseases, which can be very local, for instance, balancing the EU perspective while maintaining flexibility in collecting surveillance data at the local level.

<sup>&</sup>lt;sup>16</sup> Live-streamed to all ECDC staff.

<sup>&</sup>lt;sup>17</sup> Item 11b - Presentation by Helmut Brand.

<sup>&</sup>lt;sup>18</sup> Live-streamed to all ECDC staff.

<sup>&</sup>lt;sup>19</sup> Item 11a - Presentation by David Heymann.

51. Another comment was made concerning the wide possibilities for the future of ECDC in respect to non-communicable diseases and closer collaboration with EFSA on the veterinary side; however, all this should only be considered via a change in the legislation and mandate. The European Commission as well as the European Union should be in agreement. It is important for the ECDC not to go beyond its remit.

52. It was also noted that, worldwide, the focus on non-communicable diseases is nearing the same level as that of communicable diseases. This trend should not be taken lightly and non-communicable diseases should not be connected to one specific institution or agenda, as they are precisely non communicable, which changes the scene. It would not be helpful to forcibly connect the two areas. In conclusion, a lot of fieldwork should be done before considering connecting the non-communicable diseases to ECDC.

53. While noting the reference to austerity, another member of the Board remarked that the current crisis situation should be considered in order to ascertain what the limits are. The impact of the economic indicators should be investigated. Even when working in the light of crisis and economic limitations, one can still do many things. Some examples noted were: i) the utility and importance of networks of laboratories; ii) how alert systems work and how information is shared; iii) examining health from a more cross-cutting perspective. It is vital to support the Member States by developing more tools, namely, training. With regards to the interface between human and animal health, as well as some other more elaborate ideas, it was noted that some of this might already fit into the current mandate while as for other activities the legislation should be changed.

54. The representative of the European Commission noted that indeed, some of the areas of work discussed previously are already underway, such as the "One Health" concept. In reflecting on the proposals highlighted in the presentations, it was noted that the issue surrounding health information and how to speed up this process is already being explored by Eurostat and the Commission. This process is costly, and if it is not possible to secure funding at the European level, it must emanate from the national level. However, due to the present economic situation, it would be important to discuss how to work more efficiently as opposed to chasing after the desired end result. As to the extension of the mandate, there are indeed links between the communicable and non-communicable diseases, but this should be considered with caution due to budgetary considerations. On the issue of collaboration and duplication of work with WHO/Europe, significant savings could be achieved by settling the areas of responsibilities between the two organisations.

55. Some of the members supported the idea of linking the non-communicable diseases to ECDC's future work; however, it was noted that in that case, in-depth discussions should take place, as this is indeed a sensitive issue.

The Director of ECDC thanked the guest speakers for their presentations as well as the Board 56. for their comments. It was noted that the Senior Management Team has also already discussed some of these thoughts and ideas for the future. The first phase of ECDC (2005-2013) was to establish the infrastructure and put all the platforms in place. The second phase should focus on decreasing the burden of communicable diseases for Member States. It is also believed that more information and data should be given out via modern platforms (Internet; applications, etc.) and not only on paper. TESSy is a rich database which should be tapped increasingly. As to networks of laboratories, in the light of austerity, ECDC should establish these networks in order to save money and ensure consistency. In reference to disease networks, ECDC should have a clearer vision of what is expected from them, as it cannot be only about meetings since the organisation of meetings costs money. In respect to other organisations, ECDC should improve its collaboration with WHO/Europe and EFSA. Considering the limited resources in-house, it should be considered what can be outsourced. With regards to burdening Member States with many questionnaires, etc., it has been planned to establish a "Gatekeeper" function within the Director's Office in order to better monitor this. ECDC has a lot of expertise on disease surveillance and other health information systems that could benefit from this knowledge. This is something to discuss in the future, even considering the additional resources needed.

57. The Director of ECDC stated that the ECDC Strategic Multi-annual Programme will be developed within the current mandate.

The Board members viewed the presentations given by the two external guest speakers and the subsequent discussion elaborated on the future and possibilities for the ECDC. This item was discussed in more depth during Day 2 of the meeting.

#### **Item 7 – Independence policy and implementing rules on Declarations of Interests** (Documents MB26/11 and MB26/Info Note 2)\*

58. The Director of ECDC reinforced the importance of having a solid policy in place on declarations of interests, especially considering recent events related to other EU institutions. The Board was cautioned not to postpone the approval of the policy and it was noted that any subsequent changes and clarifications could be made at a later stage.

59. Rebecca Trott, Senior Legal Adviser and Head of the Legal and Procurement Section, Resource Management and Coordination Unit, ECDC, acknowledged the importance of the matter and provided some background on the recent developments around the presented independence policy and implementing rules on declarations of interest. Reference was made to the ECDC Founding Regulation, which states that such policy should be in place in the Centre.<sup>20</sup> Reference was also made to the OECD standards which, however, are not internationally adopted, and it was noted that no clear guidelines have been provided to develop a policy that would satisfy all the requirements.

60. In order for ECDC to develop the policy, a stakeholder analysis was carried out earlier in the year and the draft policy was reviewed and revised according to comments received. The Board was informed that during the Audit Committee meeting on 13 November, further comments were received. However, due to time constraints, it was not possible to produce a revised version including these comments for the MB meeting.

61. It was informed that it will be mandatory for all staff to fill in declarations of interests. At the same time, ECDC is responsible for the protection and the privacy of its staff members. Reference was made to the timetable in Annex II of the document. It was also pointed out that some of ECDC's activities are unique, and respectively, special declarations have been therefore developed, such as rapid risk assessments. The Board was also informed that a Compliance Officer, Ben Duncan, Senior Advisor to Director, was recently appointed to develop further an action plan on the implementation, which will be presented to the Senior Management Team (SMT) of ECDC on 20 November 2012. It was proposed to invite the Compliance Officer to the next MB meeting in March to further elaborate on the implementation of the policy. The Compliance Officer will be reporting annually to the Director. The Chair of the MB emphasised the need for the Board to approve the presented policy.

62. Some further clarification was requested on the procedure of the selection of experts. It was stated that previously, the experts in ECDC were appointed on *ad hoc* basis. However, an electronic database is now in place, whereby all external experts who wish to express their interest to work with ECDC can upload their CVs and ECDC can, when the need arises, "shop" and select an expert, who will be requested to fill in a declaration of interest which will be published. For the internal experts, ECDC has a different system for internal experts and their declarations of interests made will also be published.

The representative of the Commission noted that, prior to its adoption, several steps need to 63. be completed. Firstly, the impact on the staff regulations and staff needs to be clarified, given the inherent supplementary obligations. Secondly, the Commission requested confirmation that the opinion of the European Data Protection Supervisor (EDPS) had been sought and given due consideration in the policy. Again, the policy also needs to be in line with the staff regulations. Additionally, as ECDC is indeed unique compared to some other agencies, it was suggested to add a statement explaining such in the summary of the document. A distinction should be made between the principles and the overall policy and the more specific implementing rules. With regards to the treatment of experts, it was acknowledged that the making of oral declarations alone was insufficient and thus the policy identified the need for written ADoI (Annual Declaration of Interests) and SDoI (Specific Declaration of Interests) to be the norm. Whilst the need for speed of response was acknowledged, it was emphasised that there remained a necessity to ensure that all experts carrying out rapid risk assessments should provide full disclosure of all interests which could potentially be viewed as compromising the independence of the advice provided. To ensure that any conflicts of interests were identified in an appropriate manner it was held that oral declarations only would not suffice and thus it is preferred that another approach is used. In reference to outsourced activities, comparable standards to those referenced in the body of the text should be applied to ensure that

<sup>\*</sup> Item for decision.

<sup>&</sup>lt;sup>20</sup> Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (Chapter 4, Article 19).

the conflicts of interests procedure is applied equally to all providers of services and supplies, ensuring uniform standards. It was proposed that the Commission will discuss the specific issues with ECDC during the coming weeks and then a written procedure shall be carried out in anticipation of adopting the policy. It was added that track changes should be applied to the text to facilitate the procedure.

64. The Chair agreed to the suggestions made by the Commission. There was also support from the Board members to follow the proposed procedure and it was suggested to insert a preamble, rectify any outstanding issues, and finally send a written procedure in anticipation of approving the final version of the policy.

65. The Acting Chair of the ECDC Audit Committee noted that the independence policy was also discussed at the Audit Committee meeting and that the Committee expresses their support to the policy, also in the light of the proposed line of actions.

66. A comment was made on the address of the content of the policy, i.e. different forms and deadlines and it was recommended to take into consideration the additional workload. It was also added that it should be reviewed with critical eyes to ensure that it is feasible to implement the policy as described in practice.

67. The Director of ECDC took note of the discussions and reinforced the need to approve the policy as soon as possible. It was proposed that the ECDC, in collaboration with Commission, will take on the last issues pending and that a revised policy will be submitted to the Board before the end of the year. It was highlighted that it is preferred that the implementation process would start from 1 January 2013. This proposal was acceptable to the Board and it was recalled that track changes should be used in order to facilitate the approval process.

The Management Board <u>agreed</u> with the main principles of the ECDC Independence policy and implementing rules on Declarations of Interests. Based on the discussions, ECDC, in collaboration with the Commission, will revise the document accordingly, and the final version with track changes will be sent to the Board before the Christmas holidays 2012 for approval via written procedure.

The implementation of the policy is expected to commence from 1 January 2013.

#### Item 4 – Update from the ECDC Audit Committee<sup>21</sup>

### *Item 4a – Revised Mandate of the ECDC Audit Committee (Document MB26/5 Rev.1)*

68. Stefan Sundbom, Internal Control Coordinator, Resource Management and Coordination Unit, ECDC, presented the revised mandate of the ECDC Audit Committee.<sup>22</sup>

69. A comment was made in respect to the wording "Deputy to the Director" as being invalid. It was later confirmed that the term is in fact correct.

70. Further clarification was requested on the final decision regarding the authority of the Chair of the Audit Committee, and it was clarified that this applies to requests for participation via video/audio conference. It was also questioned whether the deadline for submission of the Audit Committee meeting documents should not also be extended from 10 working days to 15 working days. Additionally, it was suggested that the minutes of Audit Committee meetings be circulated shortly after the meeting. The potential need for extending the deadline for document submission was taken into account; however, it was pointed out that with some documents, especially with financial content, it is not possible to provide papers well in advance of the meetings. The opinion of the Audit Committee on this matter was sought and it was noted that the Audit Committee does not object if the documents are sent later, especially considering receipt of the latest figures, which is appreciated. The experience of the Audit Committee members was taken into account and it was agreed not to change the deadline for submission of the documents to the Committee.

<sup>&</sup>lt;sup>21</sup> Item 4 - Summary of 21<sup>st</sup> AC meeting (J Scheres).

<sup>&</sup>lt;sup>22</sup> Item 4a - Revised mandate of AC (S Sundbom).

Based on the experience of the Audit Committee members, it was agreed not to increase the formal deadline for the submission of meeting documents from 10 working days to 15 working days.

The revised mandate of the ECDC Audit Committee was <u>approved</u> with no further changes.

#### Item 4b – ECDC Audit Committee elections: Chair and Members

71. The Chair called for volunteers for the new ECDC Audit Committee. The Chairmanship of Sweden was favoured by all members of the Board. The Acting Chair of the Committee, Jacques Scheres, noted that Poland has confirmed interest for membership.

The new ECDC Audit Committee was elected: Johan Carlson as Chair (Member, Sweden), Colette Bonner (Member, Ireland), Audrius Ščeponavičius (Member, Lithuania) Robert Goerens (Member, Luxembourg) Pawel Gorynski (Member, Poland) Jacques Scheres, representative of the European Parliament, John F Ryan, representative of the European Commission and Michel Pletschette, representing the Internal Audit Capability of DG SANCO.

#### *Item 4c – Update of the IAS Strategic Audit Plan 2011-2013* (Document MB26/6)\*

72. Stefan Sundbom, Internal Control Coordinator, Resource Management and Coordination Unit, ECDC, provided an update of the IAS Strategic Audit Plan 2011-2013. The Acting Chair of the Audit Committee added the comments and opinion of the Audit Committee.

The Management Board <u>endorsed</u> the IAS Strategic Audit Plan 2011-2013.

#### Item 4d – Budget and Establishment Table 2013 (Document MB26/7)\*

73. Anja Van Brabant, Accounting Officer, Head of Finance and Accounts, Resource Management and Coordination Unit, ECDC, presented the Budget and Establishment Table 2013.<sup>23</sup> The Acting Chair of the Audit Committee added the comments and opinion of the Audit Committee.

74. Reference was made to the amount of 300 000  $\in$ , which was originally budgeted for the external evaluation and for which it had now been postponed. It was questioned whether this change should be reflected within the budget for 2013. It was noted by ECDC that since the funds for the external evaluation had already been put aside, it has to be decided what to do with it. A suggestion was made to keep the money in reserve for possible court expenses arising from the termination of contract with PricewaterhouseCoopers, as well as for the possible initiation of the new tender process.

The Management Board <u>approved</u> the presented Budget and Establishment Table for 2013.

Due to the change in the process of the external evaluation, if applicable, ECDC proposed to present an amended budget at the next meeting in March 2013.

#### *Item 4e – Second Supplementary and Amending Budget 2012* (Document MB26/8)\*

75. Anja Van Brabant, Accounting Officer, Head of Finance and Accounts, Resource Management and Coordination Unit, ECDC, presented the Second Supplementary and Amending Budget 2012.<sup>24</sup> The Acting Chair of the Audit Committee added the comments and opinion of the Audit Committee.

<sup>\*</sup> Item for decision.

<sup>&</sup>lt;sup>\*</sup> Item for decision.

<sup>&</sup>lt;sup>23</sup> Item 4d - Budget and Establishment Table 2013 (A Van Brabant).

<sup>\*</sup> Item for decision.

The Management Board <u>approved</u> the Second Supplementary and Amending Budget 2012.

#### Item 8 – External Evaluation for 2012<sup>\*</sup> (continued)

76. The previous discussion on the composition for the 'new' MB External Evaluation Steering Committee (MEES) was recalled. Overwhelming support was expressed toward the 'old' members of the Committee and it was highlighted that it would be very useful to include as many 'old' members as possible, not only for corporate memory sake, but also to be able to re-launch the Call for Tender as soon as possible.

77. On one hand, it was found that the Committee fulfilled its purpose in this case and thus a new Committee should be selected. However, it was also understood that, based on the knowledge and lessons learned from this recent experience, it would be of significant value to use this knowledge while revising the Terms of Reference for the Call for Tender, in order to reach better results. It was also pointed out that this was not an easy job and that membership in this Committee should be taken with complete seriousness. Meetings must be attended fully in order to progress in the process.

78. In reference to this, a general comment was made that a possible handover meeting should be arranged between the 'old' and 'new' Steering Committee.

79. Jacques Scheres, representative of the European Parliament and former member of the MEES, indicated his willingness to continue working with the 'new' Steering Committee. Tiiu Aro, Deputy Chair, requested to be taken off from the membership of the Steering Committee.

The Management Board discussed the work and possible composition of the MB External Evaluation Steering Committee and it was agreed to confirm the final composition of the Committee during Day 2 of the meeting.

#### **Opening and welcome by the Chair (Day Two)**

80. Françoise Weber, Chair of the ECDC Management Board (MB), opened the meeting and thanked the ECDC for the dinner the previous evening. A special note was made on the guests of honour at the dinner, Professor Hubert Hrabcik and Iréne Nilsson-Carlsson.

81. The Director of ECDC informed the Board of the former delegates of the MB who shall be receiving the ECDC medal: Athanasios Skoutelis, former alternate from Greece, Márta Melles, former alternate from Hungary, Dace Viluma, former member from Latvia, Mario Fava, former member from Malta, Jon-Olav Aspås, former member from Norway and Ronald Haigh, former alternate representing the European Parliament. It was also noted that a procedure for the ECDC awards policy has been developed and approved. Warm thanks of appreciation were extended to all the former members and alternates of the ECDC MB.

82. In reference to previous discussions on the composition of the MB External Evaluation Steering Committee (MEES), the Board was informed that all previous members of the Committee, i.e. Belgium, France, Germany, Slovenia, United Kingdom, as well as representatives of the European Parliament and European Commission, have indicated their willingness to continue<sup>25</sup> and in addition, Latvia, Portugal and Spain have indicated their willingness to participate. It was hoped that the new Committee will have better success with the evaluation process.

The final composition of the new MEES Committee was confirmed.

<sup>&</sup>lt;sup>24</sup> Item 4e - 2nd Supplementary and Amending Budget 2012 (A Van Brabant).

<sup>\*</sup> Item for decision.

<sup>&</sup>lt;sup>25</sup> With the exception of Estonia who had requested to resign from the Committee and with a caveat that the continued participation of Romania is not known since the member was not present for the MB26 meeting.

## Item 11 – ECDC Strategic Multi-annual Programme (2014-2020) (Continued)

83. The Chair recalled the presentations on the topic form Day 1 of the meeting, aimed to facilitate 'out of the box' discussions on the possible directions for ECDC, namely, what is feasible and what is not. To build a vision for ECDC, the Board's input is vital. It was noted that this item will be discussed again in March 2013 and perhaps a final decision can thereafter be made in June 2013.

84. Jan Mos, Senior Advisor to the Director, ECDC, presented a few topics selected from the presentations made during Day 1.26

85. The Chair proposed a tour de table, even in the light of a tightly scheduled agenda, in order to provide a possibility for every member to express his/her vision:

86. <u>European Commission</u>: Since the external evaluation has been postponed, it should be kept in mind when discussing the possible change of the mandate. It was noted that the relations with WHO are important and on top of the priority list for the Commission, including the "One Health" agenda, the joint approach with EFSA and the veterinary authorities. On the issue of separating risk management from risk assessment, it was commented that one agency cannot change this without strong justification. 'Stress testing' is something that is already underway, at least to a certain extent. The SMAP should also be linked closely to the external evaluation process.

87. <u>United Kingdom</u>: The "One Health" agenda, collaboration with WHO. Additionally, information linkages between complementary systems could be strengthened.

88. <u>Sweden</u>: The issue of resources within Member States was highlighted. The more issues are put up on the EU level, the more resources are needed at the Member State level. Better acceptance should be received from the Member States.

89. <u>Spain</u>: Supporting Member States and offering tools to control communicable diseases should be an essential task for ECDC. The current situation in the Member States should be taken into consideration. A more sustainable model for both ECDC and Member States should be used to move forward in order to decrease the burden in countries. When considering indicators to determine what needs to be developed, we should look first at what already exists and identify what is really useful. Training should be further developed according to the needs of the Member States. A "One health" approach should be taken into account in the new Strategic Multi-Annual Programme.

90. <u>Slovenia</u>: Support was expressed towards a holistic approach and broadening the activities into non-communicable diseases, at least to start thinking along these lines. There was also support to stop paper reporting and investing more in IT to create more user-friendly options. It was also questioned whether the focus should be on data for the sake of data or should there be an analysis of different data. ECDC/Member States would need more than just basic disease data.

91. <u>Slovak Republic</u>: The selected topics are interesting; however, it was requested to consult with the colleagues in the country in order to get back with more detailed comments.

92. <u>Portugal</u>: The experiences and methods on communicable diseases could also be used and applied to non-communicable diseases. Additionally, considering the emerging diseases, the use of classic surveillance could be reconsidered, whether it is needed for all diseases, i.e. 'same size fits all'. Notification systems and duplication of work between the ECDC and WHO are also important. It was recalled that rapid risk assessments remain one of the most important products of ECDC. A bare bones analysis of data should be re-considered (same note made by Slovenia and Slovak Republic). Scientific advice on specific topics should be continued. Also, the strategy for training needs to be clear (while many people in the EU receive training, it should be considered how these people can be placed operationally in the countries).

93. <u>Norway</u>: Support was expressed for the "One Health" approach, as this would match with the national agenda. It was also agreed that digital services are preferable to paper-only reports.

94. <u>Netherlands</u>: Opportunities for European or bilateral collaboration could be found if we have a clearer view of the most important risks in each country and the strengths and weaknesses of its infectious disease control infrastructure. A "One Health" approach was supported. It would be welcome to see more concrete plans on how ECDC will collaborate with EFSA and the veterinarian

<sup>&</sup>lt;sup>26</sup> Item 11 - ECDC Strategic Multi-annual Programme (2014-2020) (J Mos).

sector. The relationship with WHO was deemed important as well. Non-communicable diseases are not preferred as a task for ECDC, this brings no added value in addition to existing collaboration on the EU/WHO level. More specific strategies might be developed on the different ways ECDC collaborates with Member States.

95. <u>Malta</u>: Request was made to communicate with colleagues back in the country prior to elaborating any further.

96. <u>Luxembourg</u>: Collaboration with WHO is rated as very important. In reference to country visits to various Member States, it is always questioned who does what and since this is an issue, it should be further clarified. Expectations versus perception of ECDC. Larger countries versus smaller countries and the balance between the two.

97. <u>Lithuania</u>: Risk management and risk assessment could be combined and continuity of these activities should be guaranteed. The economic austerity is understood. In reference to the burden of Member States, it is a complex question and thus difficult to express any clear views at this point. The relationship between the WHO and ECDC is important, however, WHO deals with many more countries compared to ECDC.

98. <u>Latvia</u>: Training activities should definitely be continued and the resources invested into this should not be decreased. For further comments, time to harmonise the views with the colleagues in the country was requested.

99. <u>Ireland</u>: It would be welcomed to see ECDC's role extending to non-communicable diseases. It would be thus important for ECDC to follow the developments in the non-communicable diseases, to start with. The impact of economic crisis was also emphasised.

100. <u>Iceland</u>: As risk assessment and risk management should be in the same hands, no objections would be made if the two activities would be brought even closer together. Collaboration between WHO and ECDC is a significant burden for the countries as information has to be fed to different stakeholders which is a lot of work. Electronic versions of reports were supported as well as the "One Health" approach.

101. <u>Hungary</u>: It is vital to look at activities at the country level in comparison with ECDC targets and try and harmonise the two. "One Health" is supported as well as establishing laboratory networks to ensure capacity. ECDC's work on decreasing the burden on Member States is much appreciated. Training activities are important. The expertise of experts should be valued and perhaps it would make sense to look into non-communicable diseases in some way.

102. <u>Greece</u>: New technology must be emphasised. "One Health" approach is supported. With regards to austerity, 'stress-tests' are good in order to ensure that health indicators are inserted into the political agenda. In relationship with the WHO, ECDC's role should be central and perhaps the WHO/CDC model could be used.

103. <u>Germany</u>: The Board was cautioned that as the long-term plan must be developed for ECDC between now and next year, the focus should remain on activities within the mandate of ECDC, even though it is good to exercise some thoughts and visions extending outside the legal remit of the Centre. A distinction should be made between the mandate and the vision. The needs of different sized Member States should be taken into account. Upon receipt of a draft Strategic Multi-annual Programme 2014-2020 (SMAP), further and more detailed comments could be shared. It was requested to receive the draft of the SMAP at least four weeks prior to the next MB meeting. It was questioned how the different stakeholders of ECDC, such as the Advisory Forum, Coordinating Competent Bodies, etc., know what the other group has discussed on the same matter. This question was supported by the MB Chair who noted the importance of providing the opinion of the other bodies.

104. <u>France</u>: ECDC should be careful about the route chosen to extend the mandate. Considering the skills and competences of ECDC, in particular with rapid risk assessment and the needs for other areas of work, the model used for the infectious diseases should not simply be 'copy-pasted' to other priorities. With regards to the SMAP within the existing mandate, in the light of austerity, the focus should be on what ECDC can do with its existing budget. Further, the financing of new activities within the existing mandate or within an extended mandate should also be clarified. The second external evaluation will look at these issues as well. The architecture of the interactions between ECDC and the Member States should be further improved (for example, there is no need to send the same questionnaire to different levels in the Member States since the Coordinating Competent Bodies already exist with identified contacts for the different functions.

105. <u>Finland</u>: Less interest towards extending the mandate towards non-communicable diseases. 'Stress-tests' can be good; however, they require additional resources. IT development should play an important role and added value to ECDC in the future. Duplication of work between WHO and ECDC is of concern. The reference laboratory capacity is a priority.

106. <u>Denmark</u>: A "One Health" approach is a must, even though it is not easy. Clarity on collaboration between WHO and ECDC, as well as collaboration in general at the EU level, who does what, is important. With regards to the Member States and their needs, it is not only based on the size of the country, but also its culture, etc., thus more complex. Incorporating non-communicable diseases should be considered cautiously, as this is no easy task. However, at the national level, countries should definitely explore this further. Lowering the burden for the Member States is vital and ECDC should strategise about this more proactively. Also, the external evaluation should be closely linked to the programme, as previously mentioned.

107. <u>Czech Republic</u>: Uncertainty about incorporating the non-communicable diseases. Decreasing the burden on Member States is welcome and added value should be provided to both parties.

108. <u>Cyprus</u>: ECDC and its work are much appreciated. Perhaps the Centre should be more of a think-tank in the future and be more proactive. ECDC should empower the Member States. A "One Health" approach is supported. It was also noted that the economic climate surely affects health issues.

109. <u>Belgium</u>: The Strategic Multi-annual Programme should be discussed in depth with all partners of ECDC. Possible thought should be given to whether the data for all diseases should be monitored in the same way. With regards to risk assessment, in the future, ECDC could think more on the theoretical aspect, as it is currently done as an operational activity. Additionally, not sure if all events should be considered in the same manner. On the notion of urgency, ECDC is the most geographically distant institution from which the quickest response is expected. So this should be analysed. Training and capacity building are important. In reference to collaboration between WHO and ECDC, perhaps the best result might be to try to find synergies and improve on the existing (developed) collaboration. The IT is good to develop; however, ECDC should be a bit careful on this matter. When it comes to communicable diseases, the expectation is that the level zero will be reached. However, ECDC should reflect more on how to cope with issues such as anti-vaccination lobbying per se.

110. <u>Austria</u>: Work with communicable diseases is supported; extending the mandate towards non-communicable diseases needs to be discussed in detail, but is viewed rather cautiously. As a rather small Member State, Austria highly appreciates the bilateral collaboration with ECDC, particularly the high level of expertise available to Member States. Collaboration between ECDC and WHO is supported; however, there should be no overlap regarding the tasks of WHO and ECDC and communication and information exchange needs to be improved. Risk management and risk assessment should not be supported in the presented form; these activities should not be separated. ECDC could also think about innovative tools. Extending the mandate should be approached with caution and any related activities should be carefully planned.

111. <u>European Parliament</u>: ECDC's mandate should be kept in mind. A "One health" approach is supported; however, the use of the words "health" and "holistic" does not only involve communicable diseases but also non-communicable diseases. Therefore, the word "holistic" should be dropped or non-communicable diseases could be added to ECDC's mandate at a later stage, when the work with communicable diseases would allow for this. Risk assessment and risk management – risk communication: not within the duties of ECDC. Additionally, it is clear that there is an overlap of work between WHO and ECDC, but there are also gaps which could be filled at the same time when decreasing overlaps.

112. <u>Ireland</u>: "Doing and dreaming" should be differentiated. ECDC should think about the practical aspects initially and only after that dreams could be considered in order to see if it is possible to realise those dreams. A "One Health" approach is supported. The gaps between institutions, WHO, Member States, other bodies, should be investigated to eliminate them. The assessment tool and stress-tests represent good tools that would serve to highlight both the gaps and strengths of countries. Training is very important as well as capacity building.

113. <u>Estonia (Deputy Chair)</u>: The "One Health" approach could be considered in the sense of beginning to think in that direction. Changing from paper to more digital services would be appreciated. Support to laboratory networks development and more collaboration between the WHO and ECDC.

114. The Chair affirmed the session has provided the Board as well as ECDC with invaluable information in order to proceed with the development of the Strategic Multi-annual Programme. The Director of ECDC on his behalf thanked the Board members for the inspiring session and most valuable input.

The Management Board participated in an extended *tour de table* session in order to provide ECDC with their vision of the ECDC Strategic Multi-annual Programme (2014-2020).

ECDC agreed to develop a draft Strategic Multi-annual Programme document and submit this to the Management Board at least four weeks prior to the next meeting in March 2013. This draft document will take into account the current mandate.

#### **Item 10 – Update regarding the EU Presidencies**

#### Item 10b - Update from Ireland (2013)

115. Colette Bonner, Member, Ireland, gave a presentation on the Irish EU Presidency.<sup>27</sup>

The Management Board took note of the presentation on the Irish EU Presidency.

#### Item 10a - Update from Cyprus (2012)

116. Irene Cotter, Alternate, Cyprus, updated the Board on the Cypriot EU Presidency.<sup>28</sup>

The Management Board <u>took note</u> of the presentation on the Cyprus EU Presidency.

#### **Item 12 – ECDC vision on EU-level monitoring and evaluation of immunisation programmes and related vaccines** (Document MB26/16 Rev.1)

Maarit Kokki, Senior Advisor to the Director, ECDC, updated the Board on the recent 117. activities in this matter since the last meeting in June. Reference was also made to the document submitted to the MB prior to the meeting. The last time this issue was discussed in June, it was agreed to set up a working group in order to discuss the options as set out in the original document. The 7<sup>th</sup> call of the Innovative Medicine Initiative (IMI) was published shortly after the June MB meeting. ECDC sent a letter to Martin Seychell, Deputy Director General, DG SANCO, stating that the IMI call would overlap with the activities set out in the paper and interfere with the activities agreed by the ECDC Management board, and therefore requested the call to be put on hold or postponed. Meeting(s) convened between the Commission/DG SANCO, EMA and ECDC provided an opportunity to proceed and apply. The Advisory Forum was consulted on this matter during their meeting in September; many opinions were received, positive ones with regards to the public health needs and options presented in the ECDC document. The main message was that both ECDC and EMA should be involved, in order to achieve the third option. A meeting was held with the Commission and EMA on 14 September 2012 discussing the public health gaps. An agreement was reached that public health and regulatory agencies at all levels should work closer together to address the issues related to monitoring and evaluation of immunisation programmes and related vaccines; however, this cannot be achieved without the inclusion of the industry. ECDC and EMA were asked to develop a common approach. Further on, possible risks were discussed, such as the question of independence. An internal decision was made to submit the call and thus the proposal was submitted together with around 30 partners on 9 October 2012. An independent expert evaluation of the proposal took place during the week before the 26<sup>th</sup> meeting of the MB, and as a result, ECDC was requested to further clarify a few points via audio conference. The role of the industry is under discussion as the call

<sup>&</sup>lt;sup>27</sup> Item 10b - Irish EU Presidency (C Bonner). Please note that due to request, this presentation is not available on the MB extranet.

<sup>&</sup>lt;sup>28</sup> Item 10a - Cyprus EU Presidency (I Cotter).

proposal emanates from the industry, at the same time, the industry is not involved in the scoring process. However, the winning proposal will negotiate with EFPIA the industry proposal for a full project proposal, which will still go through an independent expert evaluation. It was noted that there are two kinds of agreements between partners, and the grant agreement is the one signed between the full consortium and IMI Executive Office. The second part, the project agreement, has to be signed before the grant agreement by a full consortium. In summary, the first stage of the call process has now been finalised and it is not yet confirmed whether the ECDC consortium has been successful or not.

118. Concerns were expressed on collaboration with the private sector and on the independence. Positive remarks were noted on the initiative in general and it was pointed out that even though it is a very delicate matter, considering the involvement of the industry, it should be carried out.

119. One member of the Board expressed strong concerns about the participation of ECDC in IMI projects given the risk to jeopardise ECDC independence as the private sector is part of the consortium in any IMI project. Comments were also made on the lack of satisfactory information on the IMI itself. It was noted that more information should have been provided to the Board to ensure better clarity about the role of the private sector at the different phases prior to signing the consortium agreement and the project contract, and during the project so to allow the Board to appraise the full implications of the participation of ECDC in IMI projects. It would be useful for the Board to have further information on IMI and which projects were selected so far that involve EU Agencies, and in which stages the industry comes into play. It was noted that the WG agreed upon at the 25<sup>th</sup> MB meeting was not set up as planned on all three options. This member called for a more comprehensive analysis of what EC instruments would allow such important projects to remain within public hands (regular calls of FP7, Public Health Programme).

120. Further on the question of independence, it was noted that transparency is very important and in case a total lack of conflicts of interests is not achievable, the initiative will be rejected.

121. A comment was made that it should be further clarified how to finance this kind of studies. It is preferred to keep this in the framework of public health institutions. It was requested that the Board would be regularly informed on the developments in order to follow the process closely. It was also questioned what happened to the working group which was supposed to be established after the last MB meeting. The Chair of the MB echoed the last question and requested clarifications as to why the opinion of the Board was not followed. In reference to the question of independence, it was suggested that it might be a good opportunity to test the previously discussed independence policy.

122. It was stated that ECDC has also been critical about the project and there might come a time when the project must be rejected by the Centre. Many of the questions raised by the MB are explained in the project proposal, which unfortunately cannot be shared at this stage. It was reconfirmed that the private sector will not be a part of choosing the winning project as they will only conduct their shadow review. It was also explained that the IMI Joint Undertaking, being an EU body, works under the same rules and financial/auditing regulations as ECDC.

123. The representative of the Commission referred to the website of the IMI<sup>29</sup> and noted that all necessary information can be found there. In general, the IMI call is only one of the funding sources looked at. However, it is specifically designed for public and private partnerships. IMI calls have been published several times before and always under strict rules and ensuring no conflicts of interest. From the Commission's perspective, the IMI call is a valid initiative and it follows all the rules. Indeed, some information and data are not available and thus, the involvement of the pharmaceutical industry is vital. Additionally, based on the rules and procedures, it is preferred that the pharmaceutical industry is officially involved, in order to ensure transparency. All relevant documents would be made available to the Board, for example via the Extranet, in due course and in a structured manner, upon the continuation of the tender process. It was also pointed out that there is no real obligation for ECDC before signing a document. In reference to the MB working group which was proposed during the last MB meeting, the Commission opined that as there are more parties involved in the process of the call, it would not suffice to only include the members of the ECDC MB.

124. The Director of ECDC added that studies related to vaccines are vital and thus an initiative such as IMI is important as this may provide a possibility to gain funds for the studies. The issue of

<sup>&</sup>lt;sup>29</sup> <u>http://www.imi.europa.eu/#&panel1-3</u>.

independence is fully understood and the Board was reinsured that in the case of evident conflicts of interest, ECDC would pull out from the initiative.

125. Further on the issue of the working group, a comment was made that this working group would not be put in place to supervise the project, but to investigate the possibilities for securing additional funding. Additionally, it was agreed during the last meeting that the group should be composed of the ECDC, EMA and Member States.

126. Written legal advice was requested on the issue of transparency and independence in order to confirm the lack of conflict of interest. Accepting money from the private sector is a complicated issue.

127. In response to concerns of the MB, the Commission's representative noted that it is in no way the aim of the Commission to counteract the decisions of the ECDC MB, which is why transparency is so important. The Commission will commit to make all relevant documents available. The Board was informed that one of the bodies of the IMI is an advisory group, composed of representatives of Member States, who steer the IMI initiative. It was proposed to invite a member from the IMI to the next MB meeting to obtain additional answers to possible questions.

128. The Chair summarised the discussions and noted that in general, the Board agrees that the effective management of issues related to immunisation programmes should be accommodated by ECDC. However, IMI is new for ECDC and it is a strategic turning point in which way the projects are developed. It is therefore important that this turning point has been based on clear and precise grounds. A request from the Board would be a clear and concise document, a written analysis on the possible risks and conflicts of interest. It was proposed to have this item on the agenda for the next MB meeting in March 2013. The Chair also requested that the MB decisions be followed up more closely and shared with the MB to increase clarity.

129. Following the previous comments on the working group, it was commented that the purpose of this group was to find alternative financing in order to support ECDC. As this has nothing to do with IMI in general, it should make sense to go ahead and put the group together, in order to continue the search for alternative ways of financing such projects.

130. The Chair noted that as there seems to be no general objections toward the initiative, the next steps would be for ECDC to provide the Board with a further document including the legal advice as well as further background on why this initiative is important for the ECDC, in order for the MB to be fully aware of all information and thus be able to further support the Centre in this matter.

The Board <u>endorsed</u> the IMI initiative in general terms. Further information was requested, including legal advice on the conflict of interest and independence. The item should be discussed further at the next MB meeting in March 2013.

It was <u>agreed</u> that the working group, discussed at the June meeting, would be set up in order to investigate alternatives to find funding.

In reference to the discussion, it was requested that the MB decisions be followed up more closely and shared with the MB to increase clarity.

131. The following agenda items were postponed until the next meeting(s): 1) Sustainable development and implementation of EPIET: Multi-annual strategic vision: report on the follow-up of fellowship training (suggested action: written communication); 2) Update on implementation of the Position statement of the Commission and ECDC on human pathogen laboratories: a joint vision and strategy for the future; 3) Long-term Surveillance Strategy; 4) Interactions with Member States for support to response activities; 5) Update from the European Commission: a) 12 point action plan: proposed approaches for AMR, animal health, food safety and research, b) Substances of human origin, c) Proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health; 6) Overview of all Agreements signed between ECDC and other organisations.

#### Item 13 – Any other business

132. The Director of ECDC thanked all the Members for their participation and fruitful discussions. He also extended his appreciation to the Senior Management Team (SMT) and also a special thank you to Silja Marma who was responsible for the *ad hoc* MEES only one day before the MB and

Corinne Skarstedt, Head of Section, Corporate Governance, Office of the Director, and her team for having smoothly prepared and organised this meeting.

133. Françoise Weber took the opportunity to thank the Management Board for their excellent work and expressed that she is looking forward to serving the Board in her new capacity as Chair. She also thanked ECDC Director for his excellent work. The new Chair also extended her thanks to the interpreters for their work and also to Corinne Skarstedt and her team.

134. There was no any other business. The meeting was adjourned. The next meeting of the ECDC Management Board will convene on 20-21 March 2013.