ECDC Management Board

MB19/Minutes
11 November 2010

Minutes of the Nineteenth Meeting of the ECDC Management Board Menorca, 17-18 June 2010

Adopted by the Management Board at its Twentieth meeting, 9-10 November 2010

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Summary of Proceedings – ECDC Management Board Meeting

The Nineteenth ECDC Management Board (MB) meeting convened in Menorca, Spain, on 17-18 June 2010.

Opening and welcome by the Chair (and noting the Representatives)

Introduction from Dr Marc Sprenger, Director, ECDC, including Briefing on ECDC's Main Activities since the last meeting of the Management Board (Item 8)

With concrete examples of ECDC's outputs, the ECDC Director presented the added value of the Agency's work for Europe and how it contributes to saving lives. The focus is on customer orientation, scientific excellence and respect. Recent organisational changes were also explained. The importance of addressing any possible conflicts of interests in all areas of the Centre's work was highlighted during the discussion and clarifications were requested by Members of the Board on the procedures in place to ensure this is adequately addressed. Presentations of the Heads of Unit followed to highlight current activities.

The representative of Germany requested that the Director continue to provide updates on the results of the previous two quarters in future MB meetings, and also to forward to the Board information once the reorganisation of ECDC is in place.

The representative of the European Parliament requested a copy of the article recently published in the *British Medical Journal* on conflict of interests in relation with WHO's work and the pandemic to be circulated to the Members of the Board.

On the presentation by the Administration Unit on recruitment issues, staff exchanges and agency job market, it was agreed to send a presentation via the Extranet to further explain these issues.

It was promised to include in the agenda of the next MB meeting an update on the reference laboratory networks and the added value for Europe.

Keynote address from Dr Ildefonso Hernández Aguado, Director General of Public Health and Foreign Health Affairs of the Spanish Ministry of Health and Social Policy

Inaugural speech from Mr Vicenç Thomas Mulet, Regional Minister for Health and Consumer Affairs of the Autonomous Community of the Balearic Islands

Inaugural speech from Mr Marc Pons Pons, President of the Island Council of Menorca

Items for Decision

1. Adoption of the Draft Agenda (and noting the Declaration of Interest and proxy voting, if any) (Item 1 – MB19/2 Rev.1; MB19/3)

Proxies were given from Andrzej Rys and Pēteris Zilgalvis (European Commission) to John Ryan (European Commission) and one from the Slovak Republic to the Czech Republic.

The Board unanimously decided to adopt the Draft Agenda *(Documents MB19/2 Rev.1; MB19/3)*

2. Adoption of the Draft Minutes of the Eighteenth meeting of the Management Board (Stockholm, 17-19 March 2010) (Item 2 – MB19/4)

The Board decided to adopt the Draft Minutes of the Eighteenth meeting of the Management Board, with one comment from France regarding correction to the name of an agency mentioned in paragraph 140: Agency for Biomedicine. In addition, Belgium requested that in the summary of proceedings, when listing the discussions and decisions, the corresponding agenda points should be included. *(Document MB19/4)*

3. Proposal of the Seat Agreement negotiated by ECDC (Item 3 – MB19/5)

The Board unanimously decided to give the Director the mandate to sign the Seat Agreement. The progress of the Seat Agreement will be monitored by ECDC and Sweden and communicated at the next Management Board meeting. *(Document MB19/5)*

4. Solutions for ECDC Office Space: Building Project to Extend the Existing Premises and to install and Lease Temporary Containers for Office Space, including Notification of the Projected Building to the Budgetary authority (Item 4 – MB19/6)

The Board decided with only one vote against to approve the building project and decided in accordance with Article 22(10) of ECDC Founding Regulation and 74(a) of ECDC Financial Regulation to notify the European Parliament and the European Council of its intention to proceed with the project. Information on the development of the process will be disseminated to the Board and a status report will be given at the next Management Board meeting. *(Document MB19/6)*

5. Summary of discussions held at the 14th meeting of the ECDC Audit Committee (16 June 2010), including its recommendations:

a. Update from the Audit Committee (Item 5a)

Both the Court of Auditors and the Audit Committee pointed out the problem of the carry over. ECDC is encouraged to take any measures to reduce it.

b. Final Annual Accounts 2009, including the Report on Budget and Financial Management (Item 5b – MB19/7)

The Board unanimously decided to adopt the proposed opinion regarding the Final Annual Accounts 2009. *(Document MB19/7)*

c. Supplementary and Amending Budget 2010 (Item 5 – MB19/8)

The Board unanimously decided to approve the Supplementary and Amending Budget 2010. *(Document MB19/8)*

6. ECDC Language Regime (Item 6 – MB 19/9)

Members of the Board raised questions regarding how the current practice (four languages in MB meetings) evolved, as a vote on this matter never actually took place. Concerns were also raised on continuously postponing a decision to either change or to validate the current practice. A vote on this item is not possible at this stage, as the proposal circulated called rather for a decision to postpone the discussion until there are indications that an unanimous decision can be reached. Countries need to be prepared for a vote, as they need to hold strategic discussions at national level. Following requests for clarification on the proceedings, the ECDC Legal Advisor confirmed that unanimity is needed for any change in the language practice as it would be a decision on the language regime, whether a temporary arrangement or a permanent regime.

The item shall be included in the next MB meeting for decision. A vote will be carried out on whether to continue with the current practice and, if this is not approved unanimously, voting will be needed on the language regime for future meetings, a decision for which unanimity is also needed. In addition, the legal services of the European Commission shall present information on possible interim solutions if unanimity is not reached.

7. Confirmation of Dates and Places of 2011 Meetings of the ECDC Management Board and Future Meetings (Item 7 – MB19/10)

Due to time constraints, and based on a proposal of the Czech Republic, the Board decided to only confirm the dates and places of the 2011 meetings of the ECDC Management Board.

The Board unanimously confirmed and approved the dates and places of the 2011 meetings of the ECDC Management Board *(Document MB19/10)*. The decision regarding the hosting of future meetings abroad every two years is delayed to the November meeting of the Board.

Items for discussion and information and/or guidance

8. Director's briefing on ECDC's main activities since the last meeting of the Management Board.

See first page above.

9. ECDC 2011 Work Programme Priorities (Item 9 – MB19/10)

A decision on the ECDC 2011 Work Programme will be taken at the November meeting of the Management Board. MB members will be consulted electronically in July by the Director to provide feedback in order to refocus ECDC priorities.

10. ECDC Work with the EU Member States (Item 10 – MB19/12)

The Board Members welcomed the initiative to rationalise the architecture of the relationship between ECDC and the Member States. However, several Board Members expressed some concern to have one Competent Body per country only and pledged instead for a reduced number of two or three.

ECDC will take into consideration the comments of the Management Board and will present an amended paper to the Board in the November meeting.

11. Developing a European vigilance and traceability system for substances of human origin (SoHO) – Overview and potential role for ECDC (Item 11)

As a follow up to the discussions during the previous MB meeting, the EC presented the SoHO system, with an assessment on which of the two agencies (EMA or ECDC) should take on board the planned activities of interconnection of existing vigilance systems. This assessment concludes that such a system is best placed under ECDC activities, taking into account the Agency's mandate and the characteristics of its funding. MB Members stated that the information presented was not sufficient to assess adequately if such a task should be taken on board by ECDC. They understand the urgency of putting in place such vigilance and rapid alert system, but cautioned about implications in terms of human and financial resources, as well as the impact on other planned activities under the work plan priorities. They also highlighted the need to focus on the consolidation of ECDC activities rather than assuming additional tasks.

The ECDC Director committed himself to developing a document in time for the next Board meeting in close collaboration with the European Commission (EC) and the European Medicines Agency (EMA).

12. Progress to Date: Continuation of the long-standing Memorandum of Understanding between ECDC and WHO/Euro (Item 12)

The draft renewed Memorandum of Understanding will be circulated to the Board in due course.

The Board agreed with the Director's proposal to deal with this issue through a written procedure.

13. Cooperation between ECDC and the European Medicines Agency (EMA) in the area of Vaccine Safety Monitoring (Item 13 – MB19/13)

Although no decision was taken, the Board welcomed the start of a process.

ECDC will develop a paper together with the European Medicines Agency (EMA) and the European Commission (EC) that will be presented to the Management Board at the November meeting.

14. Others matters:

a) Update regarding the Belgian EU Presidency

The Belgian Representative presented the Public Health Agenda of the Belgian EU Presidency to the Board.

b) Any other business

The Director reminded the Board of the election of the Chair and Deputy Chair which will take place at the November Board meeting. Potential candidates shall express their interest three weeks before the meeting. The Chair is willing to serve a second term; the Deputy Chair is considering the possibility.

Opening and welcome by the Chair

1. The Chair, Professor Dr Hubert Hrabcik, welcomed all representatives and warmly thanked Spain on behalf of the Board for generously hosting this 19th Meeting of the Management Board (MB) in Menorca. He took the opportunity to welcome Dr Marc Sprenger, the new ECDC Director since 1 May 2010. He also extended warm greetings to the newly appointed members Clara Swinson from the United Kingdom and Pēteris Zilgalvis from the European Commission. He also welcomed newly appointed alternates Kristiina Mukala from Finland and Anita Janelm from Sweden.

2. Apologies were duly received from Andrzej Ryś (European Commission), Liechtenstein and the Slovak Republic.

3. The Chair then informed that in the process of restructuring of the Ministry of Health in Austria, he has been appointed Minister Plenipotentiary for Health responsible for International Affairs, with particular emphasis on ECDC and WHO. He will commence his new post with the Austrian Ministry of Health effective 1 July 2010.

Item 8: Introduction from Dr Marc Sprenger, Director, ECDC, including Briefing on ECDC's Main Activities since the last meeting of the Management Board

4. Dr Marc Sprenger commenced his presentation by thanking Spain for hosting this MB meeting and expressed his honour to address the Board in his new capacity as ECDC Director. He then reflected on his first hearing before the European Parliament and took the opportunity to thank the MB Chair and Deputy Chair, as well as the ECDC staff, for their support on this occasion.

5. With concrete examples of ECDC outputs, he illustrated how the Centre's work addresses two specific questions that were raised during the EP hearing, namely, the added value of the Agency's work for Europe and how it contributes to saving lives.

6. The Director further highlighted the importance of managing conflicts of interest, as shown by a recent debate on the role of WHO during the A(H1N1) Pandemic and the publication of an article in the *British Medical Journal* (BMJ) on this. He explained the different procedures in place to ensure that this is properly addressed in all areas of the Centre's work.

7. He then explained that a specific working group has been established in order to develop the vision and core values of the Centre's activities. ECDC's vision is to strive towards scientific excellence, organisational performance and collaboration and partnership. The core values of the Centre will include a service minded and quality driven approach in which contributions from all staff members will be recognised and valued.

8. Recent organisational changes that lead to a more flexible and leaner ECDC structure were explained. The former Director's Cabinet is now identified as the Director's Office and specific operational activities have been transferred to other Units. The Country Cooperation function was integrated in the work of the Health Communication Unit, which has been renamed Communication and Country Cooperation Unit (CCU). In addition, the Director has appointed four advisors from within the Organisation on the following themes: Communications, European Commission, European Parliament and European Presidencies. In addition, three teams have been established to work on issues concerning Corporate Affairs, Corporate Governance and Planning and Quality. The format of the staff meetings has changed and the Director regularly updates all staff on strategic decisions via a blog and videos posted on the Intranet, encouraging feedback.

9. Following this introduction, one Member of the Board acknowledged the comprehensiveness of the information presented and the focus on the added value of ECDC. One delegate asked the Director to send to the MB the information once the reorganisation in ECDC is finalised, and also encouraged him to report back in the future meetings on the results of the past two quarters, including plans and achievements, in order to keep countries updated on ECDC activities.

10. During the discussions that ensued, the importance of addressing any possible conflicts of interest in all areas of the Centre's work was highlighted by Members of the Board. The challenges of avoiding the industries' strategies to seek influence in decisions or agendas were mentioned. Transparency was considered a key approach, while keeping in mind that the fears of any possible conflict of interest arising should not deter organisations from seeking expert advice.

11. Clarifications were requested on the outlined procedures ECDC has in place to address conflicts of interest. The ECDC Legal Advisor presented the policy developed based on the Founding Regulation. A guidance document is available and procedures are in place to ensure that staff and management, as well as Members of the MB, the Advisory Forum (AF) and experts in scientific panels and groups report any possible conflicts of interests. For example, Board Members sign Declaration of Interest forms annually and this information is made public. In addition, they fill in a form at the beginning of each MB meeting, and should there be any agenda item for which they have a conflict of interest, the Member would need to abstain from voting or withdraw from the discussion on this particular item. The Legal Advisor then informed on other related documents, such as a guidance document on invitations and gifts, continuous training for staff on ethics and integrity, and the development of a policy on relationships with industry.

12. The representative from the European Commission informed that the issue of conflict of interest is also being analysed by this body, and work is ongoing vis-à-vis a standardised approach for all agencies.

13. The representative from the European Parliament requested a copy of the article recently published in the *British Medical Journal* (BMJ) mentioned by the Director to be circulated to the Members of the Board. She also inquired if any response is forthcoming from ECDC. The Director explained that it was a matter for WHO to decide whether it would reply (or not) to the issues raised in the article.

14. A question was raised from the floor on why ECDC undertook a Threat Assessment on the Icelandic volcanic ashes, an area which is not within the Centre's remit. The representative from the Commission explained that this was done upon request from the Commission, as a rapid evaluation of possible threats was needed to present it to the Health Security Committee (HSC).

15. In reply to a question from the floor, Andrea Ammon, Head of the Surveillance Unit and Coordinator of the Working Group on ECDC values developed further the concept of "customer orientation" and explained how the core values will be aligned with all activities undertaken by the Centre.

Keynote address from Dr Ildefonso Hernández Aguado, Director General of Public Health and Foreign Health Affairs, Spanish Ministry of Health and Social Policy

16. Dr Ildefonso Hernández Aguado, Director General of Public Health and Foreign Health Affairs of the Spanish Ministry of Health and Social Policy, underlined that the Board meeting in Menorca was, in many ways, a momentous occasion for the Ministry of Health

due to the special relationship between Menorca and the Lazareto: for ECDC due to the EPIET programme and for himself since it is his birthplace.

17. Dr Hernández Aguado congratulated Marc Sprenger as new ECDC Director and expressed the satisfaction of the Ministry for both the choice and the timing as this took place under the Spanish Presidency. On behalf of the Spanish Authorities, he also commended ECDC for its good work during the pandemic.

18. Dr Hernández Aguado updated the Board on the Spanish Presidency. On 8 June 2010, the EPSCO Council adopted the conclusions regarding equity and justice: European citizens should have a minimum level of health. Some work was also conducted on organ transplantation. The adoption of the related regulation is very important just as the cross border directive was. Care and chronic disease were also considered. The form of presidency changed with close cooperation between Belgium and Hungary. As a result, the conclusions of a conference under the Spanish presidency will be presented under the Belgian presidency.

Inaugural speech from Mr Vicenç Thomas Mulet, Regional Minister for Health and Consumer Affairs of the Autonomous Community of the Balearic Islands

19. Mr Vicenç Thomas Mulet expressed his personal joy to host the ECDC Board meeting in the Balearic Islands. Menorca continues to be very closely tied with public health issues due to the presence of the Lazareto. Mr Thomas Mulet recalled the current major social changes with the world becoming increasingly global. There is an increase both in the ageing population and in immigration. It is a technological area wherein everyone is interconnected. With tourists visiting the Balearic Islands year round, the regional government has the responsibility to protect the health of both inhabitants and visitors and is continuously reformed for increased efficiency and effectiveness with respect to well identified health issues. These actions are not limited to health but touch upon health directly or indirectly. Given the geographical characteristics of the island, technology is crucial to remain informed and communicate. Some public health issues need to be addressed at community level, others, such as laboratory work, need to be addressed at national level, and also globally, in which collaboration and networking are essential. Dealing with all these levels is crucial to improve the health system. While encouraging the Board to have a successful meeting, Mr Thomas Mulet invited the Board members to return to the island for holidays with their families.

Inaugural speech from Mr Marc Pons Pons, President of the Island Council of Menorca

20. Mr Pons Pons thanked both Mr Vicenç Thomas Mulet and Dr Hernández Aguado welcomed the Board Members to Menorca, an island that is well known for its hospitable spirit. He thanked the Spanish Authorities for having chosen Menorca as a venue for the meeting and expressed his satisfaction to host the Board meeting under the auspice of the Spanish Presidency. To Mr Pons Pons, the efforts of the Balearic Island Government to permit the Menorca Summer School on Public Health to convene again this year is a clear example of what can be achieved through consensus and cooperation. Mr Pons Pons wished the Board a productive meeting and hoped that everyone would have the opportunity to enjoy the beauties of the island.

21. The Chair thanked the Spanish representatives for their inaugural speeches.

Work of the Units

22. Johan Giesecke, Head of the Scientific Advice Unit (SAU), informed the Board on the current work of his Unit. The ECDC expert directory has been finalised. The Unit has also focused on Microbiology coordination. On 11 June 2010, the technical report on "Core functions of microbiology labs" was published on ECDC's website. The Burden of communicable diseases project is progressing well. He also reminded the Board that ESCAIDE shall be held in Lisbon in November 2010.

23. Andrea Ammon, Head of the Surveillance Unit (SUN), informed the Board that the new European Surveillance System (TESSy) was released. With regards to influenza, a survey demonstrated that users of the WISO report welcomed it. With respect to AMR, the EARSS network activities were transferred to ECDC. On HIV/STI, the enhanced surveillance for Hepatitis B and C is being prepared following a consultation with the Board. The IBD 2008-2009 data call is now complete and the report is in progress. The annual meeting on FWB will be held on 22 June 2010.

24. Denis Coulombier, Head of the Preparedness and Response Unit (PRU), updated the Board on the PRU consultation on the EU overseas territories. The strategic document was compiled and the Commission was provided with feedback on the exercises. The Q fever assessment was completed at the end of May. PRU experienced some successful calls for tenders: Romania was selected for the West Nile Assessment Tool and Norway for the toolkits on FWB. Denis Coulombier mentioned an interesting exercise on 25 May with Dr Åsa. Eighteen new threats were monitored since 18 March, mostly travel associated legionnaire diseases clusters (10). The Icelandic ash cloud disrupted some training, although PRU managed to conduct a series of modules in Brussels with 31 participants.

25. Karl Ekdahl, Head of the Communication and Country Cooperation Unit (CCU) explained that after the transfer of the Country Cooperation Team, his Unit changed its name. He explained that Marc Sprenger took over as Chair of the Country Cooperation Steering Committee, although the team now belongs to his Unit. Regarding health communication, the Knowledge and Resource Centre (KRC) is now well established and the website has been launched. KRC is proceeding with its mapping of the health communication activities in the Member States. Karl Ekdahl also informed about the new approach to scientific communication with spotlights eight times a year, for instance, TB, immunisation and tick borne diseases. *Eurosurveillance* focused on TB at the occasion of World TB Day and released a special edition that coincided with the immunisation week.

26. Anni Hellman, Head of the Administration, gave an update on the recruitment process (on 1 June 2010, ECDC employs 228 staff with 158 TA and 70 CA). All the vacancies were published, albeit a natural turnover persists. The Administration Unit enhanced collaboration with other agencies.

27. A member congratulated the Heads of Unit for the format of the presentations that allow the Board to clearly see how much added value is created. With regards to the work performed by ECDC with the laboratory network, he recalled a meeting in London on 17 June and requested to obtain a report from the European Commission and a commentary from ECDC to avoid duplication and clearly demonstrate the added value for Europe. The Chair invited the European Commission to give a report at the next meeting of the Board.

28. At the request of one Member, the Chair informed the Board members that they will be able to access all PowerPoint presentations and handouts via the Extranet (MB Collaborative Workspace) shortly following the meeting.

Item 1: Adoption of the Draft Agenda (and noting the Declarations of Interest and proxy voting, if any) *(documents MB19/2 Rev.1; MB19/3)*

29. The Chair recalled the importance of duly filling in the Declaration of Interest forms and asked delegates to declare any specific interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. He also announced that, due to scheduling constraints, he would need to depart from the MB meeting earlier during the second day.

30. Two proxies were given from Andrzej Rys and Pēteris Zilgaris (both from the European Commission) to John Ryan (European Commission) and one from the Slovak Republic to the Czech Republic.

31. Declaration of Interest forms were duly distributed to the Members of the Board for completion. Under agenda item 3 (Proposal of the Seat Agreement negotiated by ECDC), the representatives from Sweden declared their affiliation with the Ministry of Health and Social Affairs in Sweden. John F. Ryan expressed concern from the EC side for coordination of negotiations under agenda items 3 and 4. He also indicated that the Commission is responsible for issues that fall within the remit of the respective topics covered under item 8 (Director's briefing on ECDC's main activities). In terms of agenda items 9 (ECDC 2011 Work Programme Priorities), 10 (ECDC Work with the EU Member States), 11 (Developing a European vigilance and traceability system for substances of human origin (SoHO) – Overview and potential role for ECDC), 12 (Progress to Date: Continuation of the long-standing MoU between ECDC and WHO/Euro), 13 (Cooperation between ECDC and the EMA in the area of Vaccine Safety Monitoring and 14 (Update regarding the Belgian EU Presidency), he indicated that the Commission is responsible for work pertaining to issues contained therein. With respect to item 7 (Confirmation of Dates and Places of 2011 meetings of the ECDC MB and Future Meetings), Luke Mulligan, Alternate, Ireland, expressed that his country has offered to host the Board meeting in March 2011. Under item 14, Daniel Reynders, Member, Belgium, expressed that he is a member of the staff preparing the Belgian presidency.

The Board unanimously decided to adopt the Draft Agenda. *(Documents MB19/2 Rev.1; MB19/3)*

Item 2: Adoption of the Draft Minutes of the Eighteenth meeting of the Management Board (Stockholm, 17-19 March 2010) *(Document MB 19/4)*

32. One Member requested a specific format for future Minutes and Summaries of Proceedings, namely, that they follow the order of the agenda and that decisions shall be emphasised in boxes. The Chair confirmed that ECDC will disseminate the Summary of Proceedings and the Draft Minutes of the Board meetings in this manner.

33. The French Board member asked to replace the word "work" by "mandate" on the section "human origin and blood products" page 40. Françoise Weber also requested to correctly spell out the name of the "French Agency of Biomedicines".

The Board decided to adopt the Draft Minutes of the Eighteenth meeting of the Management Board (Item 2 – MB 19/4), with one comment from France regarding correction to the name of an agency mentioned in paragraph 140: Agency for Biomedicine. In addition, Belgium requested that in the Summary of Proceedings, when listing the discussions and decisions, the corresponding agenda points should be included. *(Document MB19/4)*

Item 13: Cooperation between ECDC and the European Medicines Agency (EMA) in the area of Vaccine Safety Monitoring *(Document MB19/13)*

34. The Chair noted that collaboration between ECDC and EMA has increased in 2009. Although EMA has a clear responsibility for vaccine matters, the rules and responsibilities on vaccine related issues between the two agencies need to be clearly defined in a document.

35. ECDC will be inevitably asked for risk assessments linked to vaccine concerns. In the U.S.A., the body that produces vaccine advice differs from the one that investigates adverse events. Shall such a division be the same in the EU? ECDC already finances the VAESCO project (a consortium in 10 EU/EFTA countries) that accelerated in 2009 due to the pandemic. Presenting a model on vaccine safety and risk assessment, Johan Giesecke pointed out that ECDC could play a role in the follow up. At a meeting in January 2010, ECDC and EMA came to a number of conclusions, namely, building and linking vaccination registries, creating an infrastructure for epidemiological studies, a sustainable model of funding, including terms of reference for various players.

36. Although agreeing with the cooperation modalities and welcoming the report, several members expressed some concerns for the future. If it is legitimate for ECDC to provide an epidemiological background - even not strictly on infectious diseases - and the methodology to the network, members warned that ECDC shall not become a service provider. ECDC shall not fill in gaps that are the responsibility of EMA and the pharmaceutical companies.

37. A member proposed to accept this request, with a caveat to remain extremely cautious with further demands in the future. The assessment of medicines remains the responsibility of pharmaceutical companies. Another member pointed out that the model proposes to integrate the knowledge of ECDC. He underlined that industry is responsible for vaccines that have been licensed. There is also room for cooperation as EMA required post marketing studies and they were not properly designed to respond to such threats. The industry shares some responsibility and studies should respond to all questions. Another member underlined that consumers also need to be considered as it has been done in the food safety field.

38. While agreeing on cooperation, especially on vaccine effectiveness, a member recalled that ECDC does not have a mandate on vaccine safety. Another member remarked that the same division exists in her country. A third member pointed out that the various regulations quoted in the paper are too broad and that the emergency work carried out during the pandemic should not be taken as a model.

39. Several members pointed out that Member States are absent from the diagramme presented by Johan Giesecke and that their role needs to be clarified. Member States and Competent Authorities need to be worked out in the Terms of Reference. A member underlined some conflict of interest both in the assessment and management phases, and pointed out a need for clarification and wished to hear the views of the Commission.

40. The Chair clarified that the Board is not requested to take any decision today but that delegates are invited to provide their input on collaboration arrangements. Special attention shall be given to legal rights.

41. A member pointed out that ECDC and EMA can contribute to solving the problem with other stakeholders.

42. The Representative of the European Commission conveyed that the presentation serves to clarify the roles of the different actors. In addition to working together, the regulation of pharmaceutical products shall also be considered. It is necessary to conduct a detailed legal analysis of the role of the different actors and of the entire regulatory system, and he proposed to present it at the next meeting of the Board in November.

43. The Chair welcomed the start of discussions with EMA and requested the Commission's legal services to investigate the existing draft of the working arrangements. Any legal difficulties shall be solved between the Commission and the Member States. The results of the consultation shall guide the decision of the Board on whether to accept it or not at the November meeting of the Board.

44. Johan Giesecke thanked the Board Members for their valuable comments. The paper ECDC is working on with EMA will be presented at the next Board meeting.

ECDC will develop a paper together with the European Medicines Agency (EMA) and the European Commission (EC) that will be presented to the Management Board at the November meeting.

Item 5: Summary of discussions held at the 14th meeting of the ECDC Audit Committee (16 June 2010), including its recommendations

Item 5a: Update from the Audit Committee

45. The Chair of the Audit Committee updated the Board Members on the outcome of the Audit Committee meeting held on 16 June 2010. She informed that the Audit Committee encouraged ECDC to take any measures to reduce the carryover. In recalling that the Court of Auditors pointed out a high turnover rate of staff, it was explained in the Audit Committee meeting that the turnover rate referred to internal turnover, rather than external turnover.

46. The Representative of the European Commission called for an internal action plan to resolve the carryover. He suggested listing the projects financed under Title III of the budget to permit a better overview on how the money is spent. The Commission is willing to work with the Agencies to develop performance indicators that clearly verify the spending.

47. Agreeing with the comments from the representative of the European Commission, the Director indicated that on 14 June 2010, the SMT discussed the carryover and that he planned to have an action plan in place that links the activities with the budget.

48. The Chair of the Board expressed his satisfaction that the work on reducing the large carryovers has actually commenced and that advice from the Audit Committee will be taken on board. He invited the Board to approve both the Final Annual Accounts 2009 and the Supplementary and Amending Budget 2010.

Item 5b: Final Annual Accounts 2009, including the Report on Budget and Financial Management *(Document MB19/7)*

49. The Chair of the Audit Committee kindly requested the Management Board to formulate an opinion on the Final Annual Accounts 2009.

The Board unanimously decided to adopt the proposed opinion regarding the Final Annual Accounts 2009. *(Document MB19/7)*

Item 5c: Supplementary and Amending Budget 2010 *(Document MB19/8)*

50. The Chair of the Audit Committee informed the Board of a reduction of the European Commission and EEA contributions (no decision for the Board). The Board was requested to approve the proposed transfer of € 674 000 from Title 1 to Title III as it is over 10% of the total source budget line. Additionally, the Board was informed of a list of budget transfers

approved by the Director, within his mandate. The Chair of the Audit Committee also informed the Board that the new Accounting Officer will start work on 1 August 2010.

51. At the request of a member, Stefan Sundbom clarified that the ECDC budget is decided based on contribution estimates. The final amounts were received after the last Board meeting. At the request of another member, he explained that the transfer of € 674 000 is a technicality. It relates to the transfer of the funding for the EPIET programme from Title I (contract agent) to Title III (operational expenditure).

The Board unanimously decided to approve the Supplementary and Amending Budget 2010. *(Document MB19/8)*

Item 6: ECDC Language Regime *(Document MB19/9)*

52. The Chair introduced the item by presenting background information on what is stipulated in the ECDC's Founding Regulation regarding the language regime. Article 13(5)(f) gives the Board a mandate to "determine by unanimity of its members" the language regime of the Centre. The language regime for meetings of the MB has been discussed several times, without reaching the required unanimity. As no decision has been reached, the Board meetings have continued the practice to offer interpretation in four active languages (English, French, German and Spanish).

53. The Chair also informed that he received feedback from meetings of the Heads of EU agencies and the European Commission and observed that there is no standard solution in place. Different agencies have different approaches. However, in all cases, unanimity is needed to reach a decision on the language regime for ECDC MB meetings. He also recalled some security issues that had been discussed during MB18 regarding a translator's booth blocking a fire escape door in the ECDC premises, but understood this issue has now been solved provided the limit in the number of persons in the room is complied with.

54. As it is unlikely to reach a unanimous decision in the near future, he advised to continue with the existing practice and to postpone any further discussion on this matter. The floor was then opened for discussion.

55. The representative of the European Parliament expressed her dissatisfaction with the proposal as presented to the Board. A decision on the language regime keeps being postponed and the question of when and by whom the decision to have the current practice was taken remains unanswered. She recalled that a vote never took place and that several MB Members are against this practice. She acknowledged the difficulties in reaching unanimity but considered that the Board needs to validate the practice by a unanimous vote; otherwise the Founding Regulation's requirements would be contravened. She asked for further information on how other agencies are proceeding and for advice from the Commission on how the current practice came into place.

56. The Chair clarified that the Legal Advisor of the Commission was consulted on how the current practice was decided. As this is an agreed practice, there is no contravention of the Regulation. He added that there was no intention to postpone a decision again.

57. The representative from the Czech Republic agreed with the issues raised by the EP representative, and considered that the proposal presented to the Board addresses side issues without answering the core questions, such as the criteria on which the current selection of languages is based. The present practice is therefore discriminatory and a vote is needed.

58. Some Members of the Board cautioned against reengaging in lengthy and circular discussions with no concrete outcomes.

59. It was highlighted during the discussion that careful consideration is needed on the practical aspects regarding difficulty to reach a unanimous decision and the costs of having a rotation system in place so that each language stands a chance to be used every so often, which some members consider ineffective while others regard as positive as it addresses equality. Some members expressed that one language would suffice and be more cost-effective. One representative stated that if one country had a particular issue with the corresponding language not being used, then such issue should be discussed with the Commission. It was also mentioned that with the current regime, some countries are favoured. Other members stated that English should not be used as the sole language.

60. The Chair recalled the exploration undertaken on how other EU agencies are dealing with the issue and referred to the annex of document MB19/9. Currently, other agencies use between three to five languages in their respective Board meetings.

61. Some members then called for a vote in order to either validate the current practice or to change it to continue with either one language or several.

62. The representative of the European Parliament raised the question if a change in the current practice, which was never voted for unanimously, would require a unanimous decision.

63. The representative from the European Commission stated that it is the Commission's policy to promote multilingualism, therefore opting for a one language regime in MB meetings was considered a step back. This was supported by another Member of the Board, who added that ECDC needs to look into how, through language, the widest audience possible can be reached.

64. The Member from Spain highlighted that not a single strategic document from ECDC is available in another language other than English, while Europe is the first donor to Global Health.

65. The ECDC Legal Advisor explained that the proposal presented called rather for a decision to postpone the discussion until there are indications that a unanimous decision can be reached. She further confirmed that unanimity is needed for any change in the language regime, even if this implies a change in a practice established by consensus. No further information was available at this stage on how the current practice had been established.

66. Several representatives confirmed that it would be premature to vote at this stage, as they first would need to hold strategic discussions at national level. In addition, the importance of avoiding lengthy discussions in the MB was reiterated.

67. Following discussions, it was decided that the item shall be included in the next MB meeting for decision, based on a clear proposal and written legal advice, including the legal standard for the existing decision, to be submitted by ECDC. Voting will be on the following:

- Whether to continue with the current practice (unanimity needed);
- If this is not approved, voting will be needed on the language regime for future meetings, as to which language(s) (unanimity needed);
- In addition, the legal services of the European Commission shall present information on possible interim solutions if unanimity is not reached, based on an interpretation of the Founding Regulation.

The item shall be included in the next MB meeting for decision. A vote will be carried out on whether to continue with the current practice and, if this is not approved unanimously, voting will be needed on the language regime for future meetings, a decision for which unanimity is also needed. In addition, the legal services of the European Commission shall present information on possible interim solutions if unanimity is not reached.

Item 3: Proposal of the Seat Agreement negotiated by ECDC *(Document MB19/5)*

68. The Director underlined that the very same day he took up his functions at ECDC he met with the Swedish authorities in order to resolve the Seat Agreement. He remarked that the Staff Committee had also been closely involved in the negotiations. He also took the opportunity to pay tribute to Anni Hellman, including Elisabeth Robino and Riccardo Malacalza for their solid work.

69. At the invitation of the Director, the Swedish representative informed the Board that much work has been carried out and satisfactory results have been achieved to date since the previous Board meeting. The Swedish authorities met all the requirements as requested by the Management Board in March 2010, and delivered a Seat Agreement proposal for ECDC addressing all the pending points that were set as an ultimatum by the Board, thus responding to the needs of the Centre. She expressed with certainty that the proposed Seat Agreement shall serve to ensure that the living standards of the ECDC staff are in line with EU requirements. The Ministry of Finance has worked extremely hard to enable a change in legislation that will integrate ECDC staff and their families into the population register. Likewise, due to the efforts of the Ministry of Foreign Affairs, spouses are able to work on similar terms as any EU migrant worker. As well, once ECDC staff and their families are included in the population register, they will be granted voting rights. The letter from the Ministry of Finance demonstrates its commitment. The Swedish Government cannot foresee any further challenges to prevent the progress of the legislation change; however, the change in law will not occur prior to the autumn 2010 elections in Sweden and therefore ECDC staff and families will be unable to use their right to vote in the Municipal election in Sweden this year.

70. The European Commission representative thanked the Swedish authorities for the substantial results achieved to date, especially regarding the population register and voting rights.

71. The representative of the Staff Committee thanked the previous speakers and expressed the satisfaction of the Staff Committee for representing the ECDC staff during the negotiation of the Seat Agreement. The inclusion of the staff in the population register should solve the first five points as shown on the slide. However, ECDC staff continues to be classified as having no income in the Swedish tax register, which affects their credit rating.

72. In May, the Staff Committee invited all staff to a consultation in an effort to obtain feedback on the latest version of the Seat Agreement. There was a satisfactory representation of staff from all units. The staff believed that the majority of their problems will be solved if the proposal for an amendment of the *Population Registration Act* is approved by the Swedish Parliament. Asked by a member, she clarified that it is not the role of the Staff Committee to agree or disagree with respect to the signing of the Seat Agreement, but welcomes any solutions.

73. The Swedish representative informed that the Government has considered the question of “no income” but it is not within the remit of the Government to solve this issue. This information emanates from the tax register and the income of ECDC staff will not be

registered as it is not taxable in Sweden despite their inclusion in the population register. She expressed her hope that ECDC will solve this issue directly with the credit companies.

74. In closing, the representative of the Staff Committee conveyed that pressure should be maintained on the Swedish authorities until the promised solutions have been delivered.

75. Several delegates thanked and congratulated the Swedish authorities and also ECDC for the work achieved to date. Although ECDC staff has not been granted full advantages, it is an acceptable compromise. To members, the Swedish Government has done as much as it can and a pragmatic approach is now needed. Despite the uncertainty about laws being passed by the Swedish Parliament, members opined that the Seat Agreement should be approved with an approach based on confidence and trust. The majority of the Board conceded that the text would enter into force and lead to a genuine improvement of the living conditions of the staff in Sweden. The Board requested to be regularly informed on the implementation process and welcomed the legal verification by the Commission.

76. Several members expressed their regret over the lengthy process. One member expressed some concern that voting rights would not be in place before January 2011. The Board will need to act very quickly and strongly if the Seat Agreement is not implemented soon.

77. In referring to Annex I of Document MB19/5, the Member from Germany pointed out that in Article 1 (Definitions), a reference to paragraph 5b might have been omitted and should be reviewed in order to prevent concerns regarding discrimination.[1] It was confirmed that this had been spotted and the aforementioned clause was corrected in the Seat Agreement as signed between the ECDC and the Government of Sweden.

78. At the request of a member, the Swedish representative clarified that her government is ready to sign the Seat Agreement next week. Still, the text cannot enter into force without the vote of the Swedish Parliament that will take place only at the next session. She welcomed the legal verification by the Commission.

79. In order to clarify the timetable, the Chair explained that if the Board approves the Seat Agreement, he will sign it in the coming week.

80. Given the proxies, the representative of the European Commission informed the Board that he would vote three times in favour of the Seat Agreement on the condition that the legal verification be carried out by the Legal Services of the Commission.

81. The Chair proposed to monitor the progress of Seat Agreement at future Board meetings with reports from both the Swedish representative and ECDC.

The Board unanimously decided to give the Director the mandate to sign the Seat Agreement. The progress of the Seat Agreement will be monitored by ECDC and Sweden and communicated at the next Management Board meeting *(Document MB19/5)*

[1] The original note was submitted in German and translated as follows: Regarding article 1, paragraph 5: Why do paragraphs 5d and 5e only refer to paragraphs 5a and 5c, and not to 5b? Thereby a person of the same sex with a registered partnership would be discriminated against a spouse or a person of the same or opposite sex who does not have a registered partnership but is living in the same household. The current formulation could be in conflict with European anti-discrimination provisions from primary and secondary law. In this way, children of a registered life partner would not be recognised as "family members", respectively the "couple of mothers" would be forced to subsume itself under c), while they have entered a registered partnership under b). In order to avoid potential discrimination claims, the following should be stated in d) and e): "of the person in question and of his/her spouse or of a person as defined in b) and c).

Item 4: Solutions for ECDC Office Space *(Document MB19/6)*

82. The Chair recalled that the Board discussed the extension of the main ECDC building in November 2009 and March 2010, when the question was linked to the Seat Agreement.

83. Per Wessman, Project Manager, Akademiska Hus, outlined that ECDC currently rents three buildings (8 200 m^2 in total). Preliminary studies suggested linking the two main buildings by an environmentally-friendly glass roof. The innovative solution will serve to reduce maintenance expenditures in the long run. Notwithstanding the three main themes of flexibility, efficiency and sustainability, the expansion of the building is tailored to ECDC's needs, for instance, efficient communication between Units, appropriate working conditions in times of crisis, etc.

84. Anni Hellman underlined that the overall budget of the building extension had been further reduced by 10% compared to the initial plan. One of the building's floors was removed in order to increase the use of multifunctional spaces. Given the temporary solution of the containers, extending the Centre's office space remains a priority: 181 staff members are currently working in a space acceptable for 102, and the total staff is planned to exceed 360 experts in addition to visiting experts. Consequently, a more effective working space will decrease the overall rent per square metre (11 700.00 SEK per year). ECDC is expected to move to the new premises in January 2014.

85. The European Commission representative informed the Board that the Commission recently wrote to ECDC regarding this matter (see Annex IV of document MB19/6) and intends to closely monitor the construction of the building. Independently from the Board's decision, the Commission shall verify the notification with other services - DG Budget in particular – prior to receiving the budgetary authorities' decision. Asked to clarify the figures of staff members presented this morning, Anni Hellman explained that she presented the figures up to the cut-off date of 1 June 2010.

86. The Chair stated that the project can be tailored to the number of staff members at any given time. The Board today is only requested to authorise the sending of the notification to the budgetary authorities. The next step relies on the latter's answer.

87. Several members refused to assume that additional funding will cover the costs linked to both the building extension and the containers and questioned the financial implications for ECDC; namely, which projects would need to be amended or even cancelled.

88. Anni Hellman clarified that the additional € 1.2 million needed would only take effect in 2014, and would be well justified in terms of the 2014-2020 financial perspective. In the event of any unforeseen scenarios, the funds could be transferred within ECDC's budget. She clarified that the notification to the budgetary authorities is not binding and that ECDC will continue with the design phase until late 2011, a date that allows for monitoring the progression of the Seat Agreement.

89. Several members pledged to make a decision only when the Seat Agreement enters into force, or to take a conditional decision until then.

90. The Director appealed to the Board to authorise the notification to the budgetary authorities despite the additional costs. He also announced that he will be downsizing to a much smaller office space.

91. The European Parliament representative underlined the financial difficulties currently faced by Greece. While sympathising with the staff's working conditions, she opposed taking any decision without fully understanding the financial consequences.

92. Prior to adjourning the meeting that day, the Chair clarified that approving the transmission of the notification was not synonymous with deciding on the finalisation of the project.

93. During the opening of the Board meeting on 18 June, the Chair warmly thanked the Spanish authorities for the magnificent evening organised for the Board. He also reminded the delegates that Jacques Scheres would act as Deputy Chair following his departure at 10.20 a.m.

94. On the question of the ECDC space office, the Chair made three statements based on Document 19/6: 1) the Board is only requested to give their green light to send the documents to the budgetary authorities; 2) no payment is required until the end of the preparatory study; 3) if a decision is taken to proceed today, but if there is a negative result, the financial risk will be estimated at € 500,000. The Chair clarified that the planning phase would start only following a positive decision from the budgetary authorities, and reiterated that any modifications remain possible as the building period will not start before 2011.

95. Several members evaluated the financial risk of € 500,000 as acceptable and therefore authorised ECDC to send the documents to the budgetary authorities. Still, two members insisted on receiving more details on the overall financial impact on public health projects in the event of additional expenses incurred as a result of the aforementioned risk.

96. The Director thanked the Board for their strong support on this matter and promised to report on progress to date at the next meeting of the Board.

The Board decided with only one vote against to approve the building project and decided in accordance with Article 22(10) of ECDC Founding Regulation and 74(a) of the ECDC Financial Regulation to notify the European Parliament and the European Council of its intention to proceed with the project. Information on the development of the process will be disseminated to the Board and a status report will be given at the next Management Board meeting. *(Document MB19/6)*

Item 11: Developing a European vigilance and traceability system for substances of human origin (SoHO) – Overview and potential role for ECDC

***Note 1**: During this item, the Chair departed earlier, as already announced the previous day, and the chairing of the meeting was then continued by the MB Deputy Chair, Jacques Scheres.*

***Note 2**: During this item, the French position on SoHO was circulated to all MB members (in hard copy format) and was subsequently explained to the MB (please see Annex I).*

97. As a follow up to discussions held during the previous MB meeting, the European Commission presented the European Vigilance and Traceability System for Substances of Human Origin (SoHO). Before the presentation started, the representative from Germany inquired why no document was distributed on this item, as this would have aided immensely in assessing any changes since the previous discussions. The Commission's representatives clarified that the presentation would focus on main developments since the last MB meeting and on consultations held with the European Medicines Agency (EMA). As these consultations took place very recently, it had not been possible to prepare a document in advance of the meeting. They also highlighted the importance of continuing discussions with the MB on such a relevant topic, even if no formal decision would be taken at this stage.

98. During his presentation, Thomas Brégeon, DG Sanco, explained the aims, scope and characteristics of SoHO. He described the different levels of responsibility for vigilance in the EU – from the national to the EU level –, and emphasised that SoHO will focus on interconnecting existing vigilance systems, and would address issues such as coding for traceability purposes. In terms of staffing, the tasks will require between five to seven full-time equivalents.

99. The assessment made by the Commission as to which of the two agencies (EMA or ECDC) should take on board the planned SoHO activities concluded that such a system would be best placed under ECDC. The Centre's systems can be adapted for the detection, epidemiological screening and alert functions; the mandate is open for this field, and the characteristics of ECDC's funding – as opposed to EMA's funding – are more adequate to incorporate SoHO.

100. In the discussion that ensued, Members of the Board stated that the information presented was insufficient to assess adequately if the SoHO tasks should be taken on board by ECDC. While acknowledging the urgency of having in place such vigilance and rapid alert system, several members cautioned about the implications in terms of human and financial resources, as well as the impact on other planned activities stated as priorities in the work programme. They also highlighted that ECDC needs to focus on the vigilance of communicable diseases and on consolidation, rather than assuming additional tasks. It was felt that the Commission was transferring a burden for which it did not have a solution to ECDC, and that the arguments as to why SoHO was best accommodated within ECDC's mandate were not convincing. Some delegates argued that SoHO appeared better suited to EMA's mandate.

101. The Member from France also drew the attention of the MB to the conclusion of the external evaluation of ECDC: ECDC should focus on communicable diseases in line with the Strategic Multi-annual Work Programme (2007-2013) and budget, meaning no extension of the mandate of ECDC.

102. The difficulty of finding a solution was acknowledged by one delegate who highlighted that SoHO tasks appeared to be unsuitable to either ECDC's or EMA's mandate or funding characteristics. Moreover, it was not the MB's responsibility to solve this problem. The Commission needs to present a clear proposal on options. Other delegates supported this suggestion and recommended that the Commission presents an impact study to demonstrate the SoHO tasks required and the existing skills in both agencies.

103. Some Members of the Board expressed concerns over other issues where more clarifications are needed, including:

- How the planned unification of codifications will occur, as a single system could imply that countries will be pressured to adopt this with a specific provider, which in turn would lead to a monopoly situation;
- The budgetary implications;
- An analysis on whether there is enough staff available to perform the tasks and also on where new staff required would be located, as it became obvious from the discussions of previous agenda items that existing staff need to work on other priorities and that working space is insufficient;
- Whether the system also applies to "organs" or only in relation to "transplants";
- Assess what is available in terms of quality of infectious disease contamination.

104. John Ryan, European Commission, clarified a number of issues raised during the discussion. He stressed the urgency of finding a solution, as an emergency in the field could happen at any moment and sustainable systems need to be ready to act. He also clarified that the Commission does not intend to transfer all kinds of tasks to ECDC. The majority of SoHO activities are already being carried out in the countries, and the Centre's experience in taking over networks, integrating and evaluating them is in line with SoHO's functions. All options were analysed by the Commission, but the creation of a new agency for SoHO is not plausible since the current policy is rather to rationalise. Due to the way in which EMA's budget is financed, SoHO could not justifiably be taken over by this agency. As for the staffing requirements, the figure of five to seven staff is based on an independent study on impact assessment – a study that can be shared with the Board if this is so wished. He concluded that at this stage a feasibility approach is envisioned in order to assess which agency will take over SoHO.

105. The representative from Germany informed that he had a recent discussion with his counterpart in the EMA Management Board, and was informed that the agency could consider taking on the responsibility with partial involvement of ECDC.

106. The ECDC Director posited that if the Centre would take over the SoHO tasks, a balanced assessment would be needed in order to evaluate the following: If the mandate accommodates the activities, what is the impact and which resources are needed (staff and expertise) and available to outsource tasks? As the information currently available is insufficient for such an assessment, he suggested that a document be prepared well in advance for the next meeting. He added that the views of the Member States are highly valuable in this process as it concerns ECDC's future.

107. A Member of the Board clarified that producing such document is the responsibility of the EC, not ECDC. The representative from the European Commission conceded, adding that the matter is rather urgent and thus should be put for decision in the next MB meeting.

108. The Board concluded that the Commission will prepare a comprehensive document with input from EMA and ECDC, with a detailed analysis of tasks, resources, tools, existing systems and their interactions, as well as the expertise available in both agencies and the impact on other planned activities. This document shall be available in time so Members of the Board can review it carefully and the item will be presented at the next MB meeting for decision.

The ECDC Director committed himself to developing a document in time for the next Board meeting for decision in close collaboration with the European Commission (EC) and the European Medicines Agency (EMA).

Item 9: ECDC Work Programme Priorities for 2011 *(Document MB19/10)*

109. The ECDC Director presented to the Board the document produced by Philippe Harant, Planning and Monitoring Manager, ECDC, who explained the highly thorough nature of the planning process at the Centre. The document includes inputs received from the Advisory Forum on Scientific priorities through a scoring exercise. At a Senior Management Team (SMT) meeting, the Director discussed ECDC's priorities and sought to structure them by integrating input from various key stakeholders, for instance, the European Commission, European Parliament. He then posed the following three queries re priorities to the Board:

- What activities should be prioritised in the 2011 Work Programme?
- What are the activities we should stop doing / phase out?

- What are the activities we should do because of their European added value or value for Member States?

110. Even if ECDC may not be able to implement all the inputs from the Board in 2011, the SMT will definitely take them into account in the long run, in consultation with the World Health Organization.

111. The Chair thanked the Director for his concise presentation and asked to obtain the scores given by the Advisory Forum. The Director agreed to circulate this scoring document to the Board members.

112. Several delegates expressed their satisfaction on the quality of the paper in terms of its structure and clarity of priorities. Some members noted that the programme is an ambitious one and look forward to an in-depth discussion at the next Board meeting.

113. A member pointed out that linking activity with resources would be beneficial to prioritisation. She also requested to place more emphasis on the working relations with WHO/Europe in the field of infectious diseases to avoid duplication, but also due to threats emanating from eastern countries outside the EU. She called for an increased focus on geographical areas that might be the source of the main threats, for instance, TB. She also underlined the major challenge with AMR vis-à-vis humans and animals.

114. The representative of the European Commission informed the Board that he will transmit a number of detailed comments in due course. He asked to consider the Work Programme in the light of the discussions on SoHO scheduled at the November meeting of the Board. He expressed his gratitude for the work on HIV/AIDS and will have some suggestions on the surveillance side. Cooperation with third countries needs to be more focused. While Mediterranean countries are enthusiastic to work with ECDC, they draw resources from the EU-27 Member States and thereby create expectations (if there is an agreement with one country, another may seek one as well). He supported the proposal to collaborate increasingly with WHO/Europe.

115. A member requested to specify in the Work Programme where ECDC is leading the work and where it is coordinating with other agencies. Another member called for a broader approach that would integrate all the dimensions (social, geographic in the EU and European region in general, strategic, historical, etc.).

116. A member underlined that the burden on Member States is increasing with ECDC being operational. Infectious diseases are not fought by the establishment of ECDC but via cooperation between ECDC and Member States. It is incorrect to rationalise that simply due to the establishment of ECDC, less people are needed at national level. Without qualified staff at national level, ECDC and the Member States will face difficulties. Another member pointed out that there is a need to explain that the better ECDC becomes, the more resources are needed at national level.

117. A member noted that blood transfusion has already been integrated in the ECDC Work Programme Priorities for 2011 document, although no decision has been taken yet on this matter. Pointing out the risks linked to the use of social media, a member sought clarification with regards to paragraph 68 of the Work Programme.

118. A member stressed the importance of overlap and efficiency and that there is room to do more. He then posed the following queries: What is the ECDC added value? How does ECDC integrate the work performed by the Member States? How are decisions made to choose one activity over another one, for instance, expertise, added value, threats, etc.? Another member

stated that after five years ECDC conducts a number of routine tasks and the Board needs to have a clear vision of where ECDC's priorities lay.

119. A member remarked that the link between social and economic determinants of health is excluded from the document. ECDC should monitor the determinants (they should be included in the document), although usually these do not fall under the remit of public health.

120. The European Parliament representative suggested the document should underline behavioural expertise. It is connected to the pandemic but it should be considered more broadly, for AMR but also the general public. He also questioned the added value of country missions.

121. In response to comments from the delegates, the Director explained that the Work Programme is based on the Founding Regulation and the ECDC Strategic Multi-annual Programme, as well as the views from the staff and the AF. Linking activity and resources is difficult, but it is a key focus for the SMT. He informed the Board that at the next meeting, he will address how performance indicators will be developed, including collaboration with neighbouring countries and WHO/Europe. He agreed with the remark regarding AMR ('One world, one health') and also behaviour changes (it is important to pay attention to patients but also to doctors). He also assured the Board that he will strive to convince governments of the importance of investing in public health.

122. In response to a request on budget implementation, the Director agreed that ECDC needs to ensure full implementation of the budget in 2011 and informed the Board that a special programme will be developed to tackle this issue.

123. A member pointed out the need for transparency and increased dialogue in this context.

124. A member insisted on the need to validate the relevance of activities by adding two or three justification lines in the Work Programme. In the long term, it will be important for ECDC to understand the rationale for which decisions have been taken.

125. The Director informed Board that they would have the opportunity to provide their comments and/or suggestions to add or remove items via an electronic written procedure in July. He then informed the Board that the email will contain some more concrete information on how to answer the three questions and welcomed the discussion in November. He asked for some time and promised to come back to the Board.

The decision on the ECDC 2011 Work Programme will be taken at the November meeting of the Management Board. MB members will be consulted electronically in July by the Director to provide feedback in order to refocus ECDC priorities.

Item 10: ECDC Work with the EU Member States *(Document MB19/12)*

126. Johan Giesecke, Chief Scientist, ECDC, explained that the Centre needs to simplify the way in which it works with Member States and that the current architecture is too complex. The Founding Regulation is the basis for the discussions that started at the Uppsala meeting last October. Currently, there exists 79 Competent Bodies (CB), the minimum per country is one and the maximum eight. The CBs are linked to ECDC's internal structure, which is impractical and makes it difficult to modify. The nomination process is unclear for both ECDC and the Member States. The Chief Scientist proposed to have one CB per Member State. Each CB would work with ECDC and would play an important role in the nomination of experts in a cascading fashion. Each CB would represent the main channel for communication. With regards to the Advisory Forum (AF), its members shall not represent

their country and it should have an overview although some issues could be discussed in the disease networks.

127. ECDC's Chief Scientist also presented four kinds of groups to assist and advise the Centre:

Table 1: Four types of Groups to assist and advise ECDC

	Nominated by Member States (and usually has representation from all Member States)	**Invited by ECDC (and usually not on any country representation basis)**
Long term	Examples: – Our sets of Competent Bodies in various areas – The disease-specific networks – The AMR Focal Points – The NMFPs – Etc.	The so-called 'Consultation groups' – SAGE for vaccines – Others?
Short term	The AF Working Group on pandemic mortality (a subset of AF members, but also some other external experts) More?	The *ad hoc* Scientific Panels – One on varicella vaccines is running right now – One on pneumococcal vaccines coming up Other short-term groups, such as the one for the meeting on Q fever in Paris in April

128. At the invitation of the Chair, the European Commission representative pointed out that this issue is closely linked to the evaluation and welcomed the efforts to rationalise given the burden on the Member States.

129. Several members supported the rationalisation as something profitable to both ECDC and the Member States and thanked ECDC for the quality of the paper and preparatory work.

130. While agreeing that a lower number of CB would be more suitable, several members opposed the idea to have a single CB per country and pledged for some flexibility with two or three. They opined that ECDC will not attain everything with only one CB per country. A member pointed out that the choice of CB reflects the division between risk management and risk assessment. Some other members disproved of ECDC guiding Member States in their choices and reiterated that each country is free to choose its own CB.

131. In reference to above-noted groups mentioned by Johan Giesecke, a member explained that in terms of scientific opinion, ECDC can select experts without consulting the countries as long as the procedure is transparent. The second group is the day-to-day practice with ECDC (no commitment in the name of the countries) and one CB will be useful. The third group makes commitments and decides on appointments; for this reason an additional CB may be useful.

132. While acknowledging the challenges experienced by larger countries, some members of smaller ones agreed with ECDC's proposal to have a single CB. A member called for the same definition of CB in the paper (page 2, paragraph 10[3]) and in the Founding Regulation.

133. Several members questioned the role of the AF as presented by Johan Giesecke. A member stated that the Regulation contradicts the proposal that members do not represent their country. Another member supported the proposal as it would improve the quality of the scientific work. An additional member called for changing the Founding Regulation to have a proper AF with an overview in place.

134. Several members insisted in getting more information on the procedure used by ECDC to appoint experts. A member asked for more information on the scientific panels as well as the definition of an expert according to ECDC. Another member asked the Director to clearly state which tasks will be implemented if the Board is requested to approve the paper at the next meeting.

135. In response to the comments from the members, Johan Giesecke pointed out that a system with a few national CBs, of which one would be the coordinating CB – as proposed by a member – could be a viable solution. Some of the experts are appointed by the Member States and others via ECDC, for instance, the Advisory Forum. ECDC is working towards more clarity with regards to the selection process of experts.

136. The Director expressed his satisfaction that the Board generally supports the spirit of the document. He acknowledged their concerns for a single CB, but welcomed the idea of having a coordinating CB. He added that it is vital for both ECDC and the Member States to work together in an efficient way.

ECDC will take into consideration the comments of the Management Board and will present an amended paper to the Board in the November meeting.

Item 12: Progress to Date: Continuation of the long-standing Memorandum of Understanding between ECDC and WHO/Euro

137. The Director informed the Board that the Memorandum of Understanding between ECDC and WHO shall be renewed. The new text will be developed together with the European Commission. The Director sought agreement from the Board to have a written procedure to deal with this issue. The draft renewed MoU will be circulated to the Board in due course.

138. A member of the Board clarified that the Board agrees to receive the draft renewed MoU from ECDC with the understanding that the Board will not necessarily approve it immediately.

The Board agreed with the Director's proposal to deal with this issue though a written procedure.

Item 7: Confirmation of Dates and Places of 2011 Meetings of the ECDC Management Board and Future Meetings

139. The Director sought agreement from the Management Board to endorse the convening of meetings held outside Sweden every two years, and to confirm and approve the proposed meeting dates and venues for 2011.

140. A Member pointed out that he could not approve the item pertaining to biennial meetings hosted abroad without sufficient time for discussion and proposed to postpone it until the next meeting of the Board.

141. The Irish delegate confirmed that the 21st meeting of the Management Board shall convene in Dublin during 15-16 March 2011.

The Board unanimously confirmed and approved the dates and places of the 2011 meetings of the ECDC Management Board *(Document MB19/10)*. The decision regarding the hosting of future meetings abroad every two years is delayed to the November meeting of the Board.

Item 14: Other matters

Item 14a) Update regarding the Belgian EU Presidency

142. The Belgian Board Member presented the Public Health Agenda of the Belgian EU Presidency to the Board. The Belgian Presidency is working in close cooperation with the Spanish and the Hungarian Presidencies. The main themes of the Belgian Presidency are Solidarity and Innovation. Different clusters are envisaged, including the following:

1. Health security (1-2 July 2010): The conclusions of the conference will be used as a basis for discussion at the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) during 5-6 July 2010 in Brussels.
2. Health systems: a high-level ministerial conference with experts will be held on 9-10 September 2010, including an expert conference on dementia on 25–26 November.
3. Pharmaceutical products: a high-level conference will convene on 23–24 September 2010.
4. Chronic disease: a conference will be held on 19-20 October 2010.

143. The Deputy Chair thanked the Belgian Board Member and complimented him on his informative presentation of the Belgian EU Presidency programme.

Item 14b) Any other business

The Director reminded the Board of the election of the Chair and Deputy Chair which will take place at the November Board meeting. Potential candidates shall express their interest three weeks before the meeting. The Chair is willing to serve a second term; the Deputy Chair is considering the possibility.

144. The Deputy Chair thanked the Director for the reminder as well as the Spanish Government for having generously hosted the meeting. He also took the opportunity to thank the Management Board for their meaningful contributions, the interpreters for their flexibility and professionalism, and ECDC staff for their excellent contributions and support.

Annex I: French authorities position on the European Commission initiative regarding vigilance/traceability/coding for substances of human origin (courtesy translation)

COURTESY TRANSLATION

French authorities position on the European Commission initiative regarding vigilance/traceability / coding for substances of human origin

General remarks

Considering the public health issues, the French authorities are in favour of :

- setting up a "quick alert system" at European level
- pursuing the activities of the register "Eurocet" for tissues / cells

The risk of infection is not the major one. In addition, there is already an early warning and response system (EWRS) for the prevention and control of communicable diseases at the EU level (e.g.:Creutzfeld Jacob disease) with which it will be essential to find a good co-ordination.

The Commission is willing to delegate the implementation of these projects to one (or more) EU agency(ies). However, except for infectious concerns, the French authorities consider that neither the regulation establishing the ECDC, nor the regulation establishing the EMA allow the implementation of these projects without triggering a legislative revision. Therefore, given the lack of emergency and the need to ensure legal security of the system, the French authorities ask the Commission to prepare a substantial work based on an impact assessment, prior to launch any binding initiative.

Specific remarks

1. Needs for tissues/cells

Vigilance
First, the French authorities support the improvement of information exchange systems when alert affects more than one Member State. They are also in favour of the implementation of a vigilance system in all the EU Member States to work on a common approach. But, the objective of improvement of the vigilance systems within the EU should not be confused with the establishment of an EU coordinated vigilance system.
The French authorities feel that, given the lack of strong emergency in the matter, it is first necessary to consider carefully how to implement a co-ordination of vigilance system. They wonder about the role that could have the EMA or the ECDC in these issues given the mandates provided to these two agencies via the current legislation.

Codification
Pursuant to Article 25 of Directive 2004/23/EC, *"the Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells".* This coding system could include at least the information specified in Annex VII of the Directive 2006/86/EC.
The French authorities wonder about the monopolistic situation created by the potential use of the unique system (like ISBT128), its cost and the time needed for the implementation. They are willing to pursue discussions within the specific working group set up by the Commission.

Register
Pursuant to Article 10.3 of Directive 2004/23/EC, *"Member States and the Commission shall establish a network linking the national tissue establishment registers"*.

The French authorities are willing to pursue the work achieved under the project EUROCET which is a register listing the banks of authorised tissues and cells, the performed activities, the volume of activities, the types of tissues and cells prepared and also identifying competent authorities in each Member State. The objective is to provide operators and competent authorities with a visibility on activities of each tissue establishment, which is important to facilitate exchanges in the EU.

2. Needs for human blood and blood components

Vigilance
The current legislation (Directive 2002/98/EC, Directive 2005/61/EC) does not envisage setting up a surveillance system co-ordinated at EU level.
Nevertheless, we believe that it could be useful to develop a system for the co-ordination of alerts when several Member States are concerned (terminology to be defined) like a "quick alert" system. This system should envisage the collect by the Commission of information provided by each Member State on quality and safety of products and the dissemination of this information at all the competent authorities in Member States. This system is already in testing phase since February 2010 for tissues and cells and could be extended to human blood and blood components bearing in mind that it may only be a warning dissemination system. Indeed, the Committee can not interfere in the risk management which is performed by each Member State taking into account its own risk assessment.

Codification
The current legislation (Directives 2002/98/EC, 2004/33/EC, 2005/61/EC, 2005/62/EC and 2009/135/CE) does not envisage implementing of a coding system at European level. For information, in France and for the year 2009, the volume of export activities to other Member States was low (13 requests for 63 blood products). The French authorities consider that there is no specific need in this field.

Register
The current legislation (Directives 2002/98/EC, 2004/33/EC, 2005/61/EC, 2005/62/EC and 2009/135/CE) does not envisage implementing a register at European level. The French authorities consider that there is no specific need in this field.