ECDC Advisory Forum

AF9/Minutes
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Minutes of the 9th meeting of the Advisory Forum
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Table of Contents

Page

Opening and welcome 1

Adoption of the draft agenda and noting the declarations of interest *(document AF9/1 Rev.1)* 1

Feedback form the Advisory Forum's Working Groups 2

- Preparedness and Response 2
- Surveillance 2

Adoption of the minutes of the 8th meeting of the Advisory Forum, Stockholm, 22-23 November 2006 *(Document AF9/3)* 3

Briefing on development at the European Commission 3

Presentation by Thomas Löngren, Executive Director EMEA 4

Surveillance issues 5

- Surveillance database *(document AF9/4)* 5
- Update on the evaluation of the surveillance networks *(document AF9/5)* 5

Presentation of the second Scientific Panel's opinion 6

International Health Regulations *((COM) 2006 552 final of 26.09.2006)* 6

Role of the Advisory Forum in the Work Programme of ECDC 7

Annual epidemiological report and Burden of Disease 8

ECDC's process for answering external scientific questions *(document AF9/6)* 9

Production of European STI guidelines *document AF9/11)* 12

Update on the Food and water-borne diseases Project *(document AF9/7)* 13

Update on other diseases of environmental and zoonotic origin Project *(document AF9/8)* 14

Update on the Clostridium difficile Project *(document AF9/9)* 14

Update on the influenza Project *(document AF9/10)* 15

Update on the ECDC Scientific conference on Applied Infectious Disease Epidemiology (ESCAIDE, 18-20 October 2007, and joint Scientific Symposium SMI/ECDC/ESCMID, 7 May 2007 17

Other matters and closure 17

Opening and welcome

1. The Chair, Director of ECDC, opened the meeting and welcomed the Advisory Forum (AF) members and alternates present to the ninth meeting. She welcome Dr Angel Kunchev appointed member from Bulgaria, Professor Mike Catchpole, the new member appointed by the United Kingdom and Mr Thomas Löngren, Executive Director of EMEA. Apologies were received from Greece.

Adoption of the draft agenda and noting the declarations of interest

(document AF9/1 Rev.1)

2. The draft agenda was adopted with no changes. However the Director proposed to give the floor later on to the EMEA's Executive Director and to the representative of the European Commission to brief the AF on new developments at the Commission.

3. The representative from France declared his role as supervisor of the heads of EuroHIV and EuroTB; the representative from Portugal declared that she focal point for HIV/AIDS surveillance in Portugal, linking with EruroHIV and also, she had been invited as an expert in virology and public health/epidemiology by a PHV vaccine manufacturer, for the purpose of consultancy if need arises. The representative from Sweden declared that he in his capacity as President of ESCMID he was involved in the evaluation of the surveillance networks; the representative from Denmark declared his role as leader of the disease-specific network EUVACNET; the representative of the United Kingdom declared that his Agency was the focal point for the ESSTI, EWGLI, EnterNet, DipNet and EU-IBIS networks.

Director's briefing on ECDC's work progress

4. The Director briefed the AF on the main events that had taken place since the previous meeting. The Management Board (MB) met in December 2006 and reviewed the programme of work for 2007 which was subsequently approved in January 2007. It also reviewed the draft 2006 annual report of the Director which will be resubmitted for approval at the MB meeting in March 2007. The MB approved the budget and establishment plan for 2007. The MB had established a Steering Committee to oversee the external evaluation process and draft the terms of reference and the specification for the call for tender which is expected to be launched by end of May 2007.

5. The Director also mentioned that she would like at the May meeting to review with the AF the work plans and the public health priorities. Country visits to Austria and Estonia had taken place and in this regard she introduced Alain Lefebvre newly recruited to coordinate ECDC country work. Finally, ECDC was preparing for the Bremen Conference on HIV/AIDS organized by the German Presidency on 12-13 March.

Feedback form the Advisory Forum's Working Groups

Preparedness and Response.

6. **Epidemic intelligence**. The Working Group (WG) discussed the threat tracking tool bulletin and the progress made in the building of the emergency operations centre.

7. **Response**. A 24 hours 7 days a week system was now in place. Exercises were scheduled in June and November. The transfer of EWRS should be completed in April 2007.

8. **Training**. A meeting for defining core competencies for intervention epidemiologists had taken place in January and 3 outbreak investigations courses were scheduled in March and April together with ASPHER

9. **Pandemic Influenza**. The next WHO/EC/ECDC workshop is scheduled 25-27 September. The country assessment visits should be completed by end of 2007.

10. The WG reviewed the lessons learnt from the cases of the legionnaires' diseases in Phuket; special attention need to be given to communication and information context for risk assessment. ECDC has a role to play in the coordination of investigation. There was also a need for a proportionate response. The Lassa fever case showed the importance of passenger lists and hotel lists, but also the need to clarify what patient identifiable information may be disclosed by MS within the context of the EU Directive on Data Protection.

11. Finally the WG discussed ECDC role in the implementation of the International Health Regulations. In this regard, several meetings took place with WHO.

Scientific Advice

12. The Working Group on scientific advice reviewed the active working groups and discussed possible procedures, remit, status of the planned or ongoing work. The WG suggested that SOPs for working groups and panels be developed and discussed at the next AF meeting to clarify membership, roles and responsibilities and ways of operation.

13. The WG on scientific advice was also briefed on the development of ECDC strategy for cooperation with laboratories and research institutes in the EU.

Surveillance

14. The working group discussed the AMR surveillance which was felt to be a priority for Europe. ECDC is currently recruiting experts. The WG felt that there was a need to address emerging issues such as Clostridium d*ifficile* and minimum standards so that each country has a guideline to follow. The question was raised on how to link this discussion to the work done by TESSY and to have a forum for discussion and a common minimal approach. IT systems to cope with this are crucial and patient advocacy is important in driving this forward. Investment of ECDC in outbreak surveillance needs to be considered.

Adoption of the minutes of the 8th meeting of the Advisory Forum, Stockholm, 22-23 November 2006 *(Document AF9/3)*

15. The representative of the European Public Health Association asked that her apologies for the 8th meeting be recorded in the minutes.

Briefing on development at the European Commission

16. The representative of the European Commission briefed the AF on a few developments at the European Commission. A new mandate for the Health Security Committee is to be adopted by EPSCO Council on 22 February and include a new item on generic preparedness. The new work programme for HSC will last until 2010.

17. The responsibility for ECDC is now all with C3 Health Threats Unit in Luxembourg, including IHR. G8 and European Neighbourhood Policy were moved to Health Measures Unit C6 in Brussels. The Public Health Executive Agency has started its work and an information day will be held in Luxembourg. The new Public Health Programme to cover the new financial perspective in not yet in place, there are still budget problems and discussions are ongoing between the Council and the European Parliament. It is not clear whether the new programme will be in place for 1st January 2008.

18. The AF was also briefed on SANCO work programme. Case definitions are still in the pipeline and the Commission is looking at novel solutions. A large document with over 100 pages is problematic for EC for several reasons. Health care infections work was delayed due to Avian Flu. The introduction of the new impact assessment Commission rules may delay developments even further. The transfer of EWRS to ECDC is a priority. Regarding the International Health Regulations, the Commission was keen to make progress on implementation and to facilitate and assist Member States.

19. Vaccines and in particular for HPV is an interesting subject and one that could contribute to improving human health. SANCO would like to co operate with EMEA.

20. The Pandemic Influenza report has been finalised and recent developments show that this issue has not gone away. ECDC/WHO/Commission will continue to work together on this issue. Once the final report is produced by ECDC, the Commission will look at new possible political commitments by Member States in EPSCO under the Portuguese Presidency. The Commission will look at preparedness in a more generic sense.

21. The Commission now has almost 3 years of experience with ECDC. ECDC has had enormous added value so far. The Commission wants to see that proper procedures are in place for swift communication and this is being discussed with ECDC.

22. As regards training and exercises, a new framework contract is being prepared, and this is an important part of the work.

23. The Director ECDC thanked the representative of the Commission for this update and added that ECDC has regular communication with C3 and in particular through weekly video conferences. In particular ECDC is keen to progress on the case definitions.

Presentation by Thomas Löngren, Executive Director EMEA

24. Mr Thomas Lönngren took the opportunity of a visit to Stockholm to join the Advisory Forum as he had been invited on previous occasions. He gave an overview of the EMEA which was established in 1995. A new centralised procedure for drug authorisation was introduced at this time also. All new innovative products on European market come through EMEA. EMEA has s 450 staff, with 4 scientific panels. It has 30 types of scientific experts in its panels. It works with 43 national competent authorities in 30 countries and 75% of its income comes from fees and the balance comes from the Commission.

25. Mr Lönngren underlined the challenges currently facing EMEA, in particular the rapid developments in the scientific field. As regards new products, the Commission was working on the Advanced Therapies Regulation which may enter into force in 2009. New medicines are emerging on the world market, particularly on cancer products. Other areas are neglected such as antibiotics and here there is unmet medical need. There is a global market and EMEA has a confidentiality agreement with the US FDA, and signed an agreement last week in Tokyo with Japan.

26. EMEA has developed a roadmap that spans to 2010 with 4 main priorities (improve safety of medicine, how to stimulate new vaccines, improve transparency around medicine and how to continue to operate the European regulatory network. For example, the database on safety on adverse reports (ADR) tracking. ADR is a long-term project and the hope is that it will help people. A European risk management strategy was needed and the methodology on risk evaluation and risk minimisation needed to be improved.

27. There is a developing European network on pharmacovigilance. The long term goal is to have a European data warehouse with data on 50 agencies, 18 countries and 10 networks.

28. Finally Mr Lönngren pointed to the very good collaboration with ECDC particularly on avian flu. There are two new products coming to market. The EMEA is working with Commission closely on these issues.

29. To the question on how EMEA could contribute to more prudent use of antibiotics, Mr Lönngren said that EMEA is working hard on guidelines on this issue, particularly on the veterinary side. There was a need for further research and development on the development of antibiotics. The development cost for new antibiotics is very high. It is difficult for companies to get the return on their investment. Some incentives are needed in this area to stimulate Research and Development.

30. Another question was about sharing the safety profiles which are confidentially shared with EMEA by manufacturers. EMEA said it has a special safety group for pandemics and to

put risk management plan in place, EMEA asked for contribution of Member States into this process.

31. The excellent work of EMEA was acknowledged by the AF members and the Director thanked Mr Lönngren for the time he spent with the AF and for his interesting presentation.

Surveillance issues

Surveillance database *(document AF9/4)*

32. Edward van Straten, from the unit of Surveillance and Communication made a presentation on the current development of The European Surveillance System (Tessy). A more detailed paper can be made available if required.

33. The issue of access rights was raised and it was felt it was a crucial point. This issue will be discussed with the surveillance working group and it will be up to the Member States to decide on which access rights should be given. The EU spirit is to make public data widely available.

34. Andrea Ammon said that she would like to have disease specific task forces with disease specific experts in the task forces. This would bring the necessary expertise into the system. The remit of task forces has to be designed. In regards to early warning it will be necessary to have a special task force not to lose the achievements made to date. Tessy is not a database for ECDC, but a database for Europe.

35. A question was raised on how data from the sentinel system in one country will merge with data from the disease surveillance network in another.

36. Andrea Ammon said that ECDC appreciated the difficulties of combining sentinel and surveillance systems. Involvement of end users is difficult, but will be considered. Use by national systems is possible, but may not be suitable for Member States. ECDC will reflect on this. Wider availability of data to the public is something that is being actively pursued. There were technical issues but also interpretation issues and how systems could be aligned in the future. Export of system should be generically available to all Member States so copyright should not be a big issue. The Director ECDC added that the Centre was working towards multilingual easily available data.

Update on the evaluation of the surveillance networks *(document AF9/5)*

37. Johanna Takkinen from the unit of Surveillance and Communication briefed the Advisory Forum on the status of the evaluation of the surveillance networks. She said that the teams are still not complete. Feedback was received from the first evaluations and assessments. She described the main outcomes of the first evaluation. A short report on the evaluation will be put on the website.

38. One member asked about assessment which is about judgement and future needs of ECDC in this regards. As regards antibiotic consumption it is useful to have baseline data.

The evaluation team are facing challenging questions and lessons learnt from the first evaluations will be very useful for the next teams. The methodology for assessment has not yet been established. Ideally, the long-term strategy should have been developed before starting the evaluation but this was not possible due to the timing. Andrea Ammon thanked all the colleagues for their efforts in this exercise.

Presentation of the second Scientific Panel's opinion

39. Johan Giesecke, head of unit of Scientific Advice presented the conclusions and recommendations of the second ad hoc scientific panel on :

Pneumococcal vaccine for elderly.

- Age-based vaccination is more cost-effective than a high risk-based strategy and should result in higher vaccine uptake
- One dose of PPV23 recommended for persons who received their first dose at age 65 or older
- More data are needed on the clinical safety and effectiveness of revaccination in over 65s
- One time revaccination is recommended if a previous dose has been given more than 5 years previously at age <65 years

Influenza vaccine for children

- Any decision to introduce routine influenza immunisation for children requires knowledge of the national profile of age specific incidence rates and morbidity
- Little data exist on any potential long-term adverse effects of reiterated annual immunisations

Therefore:

- Annual revaccination poses a particular issue within a routine programme for children aiming at very high coverage, and require careful follow-up

International Health Regulations *((COM) 2006 552 final of 26.09.2006)*

40. The representative of the Commission briefed the AF on actions taken by the Commission with regards to implementation of IHR whose responsibility has now moved to the C3 unit.

41. The Commission communication was welcomed at the EPSCO Council in December 2006 and Member States committed to implement the IHR fully and in a timely manner. With regards to IHR contract points, it was generally felt that they should be the same as for EWRS although IHR has a wider coverage. So far 20 countries have nominated the same focal point. Also, Member States's obligations should be at least equivalent to those towards WHO. Currently this is not the case. Decision 2119/98 covers communicable disease. It does not

cover chemical, physical, radiological and nuclear threats. Implementation of IHR should be linked to the further implementation of 2119/98. The adoption of IHR should lead to reciprocity of information exchange with WHO. SANCO C3, A4 (Informatics Unit) and ECDC are working together to transfer the EWRS operations from Luxembourg to Stockholm.

42. A suggestion was made to establish a joint committee IHR/EWRS with national contact points for EWRS and IHR. Evidence-based planning is of pivotal importance for improving communications systems. There are 370 messages from 1999 in EWRS and the plan is to look at them from perspective of IHR. ECDC could be asked to analyse the database of EWRS on this basis. Exercises are a great way to test the functionality of a system. There will be two training courses in 2007 and in 2008 to be organised by the Commission on this basis. Next steps are that the IHR will be discussed in the various groups.

43. Then, Denis Coulombier, head of Preparedness and Response unit explained that there could be 3 areas where ECDC has to play a the IHR implementation: (a) guidance for annex 1, (b) minimum capacity for annex (2) and(c) exchange of best practices among Member States. These activities were included in the 2007 programme of work including country visits and developing check lists for member states to review their capacities based on requirements of Annex 1. There is a good cooperation with WHO and a number of coordination meetings are scheduled in the coming months. .

44. It was stressed that MS should be fully involved. Commission will put forward measures to make sure they are involved right from the start.

45. One member said that the spirit of the IHR is to deal with public health emergencies of international concern and one should not forget this first principle. Commission fully agreed with this comment and added that it has 8 years experience of the operation of EWRS with both formal and informal sources and of working closely with the MS. WHO could learn from EU on the operation of the EWRS.

46. In conclusion, it was agreed to have regular updates on this issue in the future meetings of the AF.

Role of the Advisory Forum in the Work Programme of ECDC

47. The Director ECDC reviewed the role and responsibilities of the AF in relation to the implementation of the programme of work. She also gave an overview of the role and responsibilities of the Management Board and of the obligations of the Member States, as outlined in the Founding regulation. She stressed the AF's role in supporting the Director in ensuring a scientific excellence and independence of the Centre's opinions and in being a mechanism for exchange of information on health threats. She also added that the AF had an important role in ensuring close cooperation between ECDC and the competent bodies on a number of activities in the programme of work.

48. The participants thanked the Director for this helpful overview and asked for a copy to be circulated to the AF members. The AF was invited to give its input and suggestions for

agenda items to be discussed by it. Suggested items were for example, networking, scientific advice, emerging public health threats, public health priorities

Annual epidemiological report and Burden of Disease

49. The Director informed the AF that the current draft of the Report had not been tabled as work was in progress. A lot had been done taking into account the valuable comments from the AF. Andrea Ammon, Head of Surveillance and Communication Unit, described the progress made since the 8th meeting of the AF. She thanked the AF for their comments including those that had been sent in writing and those from the last meeting of the Management Board who had remarked positively on the last draft. These had been incorporated and the further work to be done was outlined. The rationale for the Burden of Disease (BoD) work, as one element and input (amongst others), for indicating priorities was explained. RIVM's considerable and intensive input to produce indicative results within a 3 month deadline was much appreciated. Given the AF interest in the BoD work, the special session to discuss this work would take place during the 10th AF meeting in May 2007.

50. In concluding, the key next steps were outlined including completion of the technical and scientific editing (with additional resources) and timeline for finalization of a glossy publication (early June 2007). The finalization process would include incorporating current comments into the next draft that would be presented to the MB (March 2007) for information. This draft would simultaneously be sent to Member States for written consultation with replies requested by Mid April 2007. The publication process (language editing, layout and printing) also requires time (6 to 10 weeks) and drafts of the Executive summary and the leaflet also need to be prepared.

51. The Director pointed out that the written consultation would be addressed to Chief Medical Officers. Involvement of AF members in the above process was likely and the 10th AF meeting would give an opportunity to collectively discuss the final draft (that would hopefully be in the publication process by then).

52. AF members asked for clarification on following points:

- The involvement of the DSN and BSN in data provision given the variability in the activeness and quality of data of the networks;

- The role and status of the MB comments on the draft given the technical nature of the Report and that the AF saw its role as advising strategically on structure of the present and future reports (including timescales for future reports);

- The BoD pilot done by RIVM and future plans.

53. Andrea Ammon clarified that the prime source for the 2005 data had been the BSN for all diseases except for HIV, TB and Influenza. For these three diseases the data had been taken from the respective DSNs, although for some of the other diseases the BSN data had been checked with the DSN coordinators. She also clarified that the next 2006

Epidemiological Report would hopefully be more timely with concentration on special topics on which the AF would advise during the 10th AF meeting in May 2007 (as had been discussed during the AF Working Group earlier that morning). The Director pointed out that the draft of the Report was being presented to the MB for their information (not their approval) and to ensure that they are aware of this flagship publication. The main input and advice would be from the AF, including on overall content, with the official consultation with Member States (being made at their request) ensuring accuracy of any country specific references and their general comments for example matching of data and conclusions.

54. One AF member further pointed out that this was a major Report and achievement. Therefore, it should be carefully promoted recognizing the probable keen interest by the press and media. The press release would need careful attention and although data issues were clearly an important aspect, the press would most likely focus on the inter-country aspects. The Director pointed out that the full Report was mainly directed towards a technical and Public Health audience whereas the Executive Summary would be for the Policy Makers and the leaflet for the press, media, general public and politicians. The official launch of the Report would be in June under the German Presidency with Commission and Parliament and at that stage the Press Release and publicity must be right.

55. Comments on the interim results of the BoD pilot (done by RIVM) were currently being collated both from internal ECDC staff and externally from WHO, the Commission and HPA. The report (plus a summary for sub-chapter 9.3 of the Annual Epidemiological Report) would be redrafted in time for the 10th AF meeting in May. This would enable the BoD methodology, which should be included in the Annual Epidemiological Report and the future steps and plans to be presented and discussed by the full AF (as the previous technical briefing during the 8th AF meeting could not be attended by all members). The key question was whether the results of this 3 month pilot were in the direction of what was needed and how best with the AF to continue and extend such work in the future, perhaps with a call for tender involving the relevant country institutions as part of a consortium.

56. Additional comments from the AF emphasized the importance of the data used, use of existing BoD competencies in countries and the setting up of a Working Group to take forward future work and approved methodology. It was also pointed out that during the 8th AF (and as recorded in the minutes) the AF would have an opportunity to discuss in more detail. The Director agreed to the points made and concluded with recording thanks to the RIVM who had funded and carried out the pilot, according to the Terms of Reference that were drawn up together with ECDC. The 10th meeting in May 2007 would give the AF an opportunity to have a full discussion, review the results of the pilot study and reach consensus.

ECDC's process for answering external scientific questions *(document AF9/6)*

57. Johan Giesecke, Head of the Scientific Advice Unit, introduced this topic by explaining that although the internal ECDC procedures for responding to questions had been endorsed by the MB, the process whereby questions arose and came to the ECDC from a Member State, Commission and the European Parliament had not been clarified and defined. The intention was not to be bureaucratic but to structure the process for questions being put to the ECDC.

58. Johan Giesecke, started by describing the current process to answer scientific questions making the distinction between the role of the Scientific Panels (for complex questions) and the role of Working Groups (when recommendations were required). A Gate-keeper function, placed in each Member State was proposed (with draft Terms of Reference) to improve coordination and give structure to the process; to act as one point of contact; and to be a mechanism for feedback and keeping the Member State (and the Commission) informed. The difference between a scientific opinion and answering scientific questions was also clarified. The Director also pointed out that Terms of Reference and SoP for the Working Groups were also needed as had been done for the Scientific Panels and approved by the MB.

59. The AF agreed that the procedures and process needed strengthening and the distinctions clarified. Consultation with appropriate DSNs would help even if this added to the length and complexity of the process. The possibility was also raised of whether conclusions and recommendations (recognizing technical and political boundaries and strength and status of the recommendations) were not the logical next steps, especially when this would be helpful to Member States. Many AF members pointed out that the example of Rotavirus illustrated some of the dangers especially those associated with "conflict of interest" which should be more clearly identified. There was universal support for development of SoPs for the Working Groups (as done for the SP) which should be presented to the AF. There was also support for the proposed transparency including publication on the internet of the questions, the results and also the SoPs so that the process was also known. The need for a Gate-keeper function was endorsed and a short Terms of Reference and profile of the person was needed bearing in mind compatibility with role of the AF and MB.

60. Stefan Schreck of the European Commission pointed out that "conflict of interest" was also an issue in other parts of the Commission. Scientific opinions and gaps once identified should go to Member States for Policy choice and therefore should be discussed with policy makers and this process should be described. He pointed out that Influenza vaccine issue went to the Council. AF members pointed out that SPs gives independent scientific advice which should not be "edited" but the results of the WGs are draft to the ECDC and it is for the ECDC (together with the AF) to decide further action.

61. Johan Giesecke thanked the AF for their valuable comments and agreed that SPs (having less broad Public Health background) gave independent scientific advice whereas the results of WGs were one of the instruments for ECDC and the AF to arrive at recommendations. Conflict of interest should be more clearly specified also for the WGs as done for the SPs. He also agreed that the Rotavirus recommendations were stated in strong terms and had significant policy and resource implications (natural for individual disease experts) and the AF could ask ECDC to amend as appropriate taking a balanced approach across all diseases. It was accepted that issues that had direct consequences and resource implications for Member States should be brought first for consultation with the AF. The acceptance of a Gate-keeper function and ToR was timely and SoPs for the WGs would be developed. Timeliness was an important consideration and answers to questions should not have to wait for 8 months.

62. The Director pointed out that the one coordinator/Gate-keeper proposal (being discussed with the AF and MB) would help to streamline the process. She also clarified that ECDC's role is scientific advice and Public Health measures were Member States' responsibility and

that this should be clarified. Even for SP sometimes ECDC had to revert to ensure that boundaries were respected. For WGs it was essential that the AF helped by recommending good experts, who ECDC could use when needed. The ToR of the WGs would be developed (with roles, outcomes, outputs and clarifying the differences between the WGs and SPs). This would be discussed by the AF at the next meeting before publication. She also agreed that the decisions re the precise output of the WGs was for ECDC and not the WGs and clarified that all members are required to sign "conflict of interest" forms. This is an issue that both Internal and External Auditors pay specific attention to and must also apply in this case. Therefore as pointed out by one AF member we can review the procedures but these should be in line with the Regulations which must be followed.

63. The AF agreed and further emphasized that transparent rules were needed even if currently in Regulations (i.e. perhaps SoPs to be the "translation" of Regulations into "transparent rules"). Also when "conflict of interest" arose one possibility was to exclude and the other was to mention those who had declared the conflict (as a minimum the latter was recommended). It was also mentioned that when ECDC issue recommendations for Policy Makers and scientific opinions, the SoPs should clarify that it was being sent to Member States (i.e. not for AF members). The SoPs also needed to specify the procedure if the AF regarded any SP opinion (which by many would be regarded as ECDC opinion) to be too biased. In cases such as vaccinations (e.g. Rotavirus) the WGs and ECDC role needs to be careful assessed especially given the considerable cost implications for Member States. To increase transparency and yet give protection it was suggested to create a password protected site for AF/MB which could contain list of names for SPs and WGs and information on their work. This would also minimize email communication problems. The procedure for recruitment for WGs should also be made clear as some members missed the one for Rotavirus.

64. Stefan Schreck agreed to provide the advice available on this issue in the Commission and pointed out that scientific advice/opinion should not be biased and so it was not enough to list the conflicts of interest. Especially if scientific advice was issued by ECDC then all efforts must be made to ensure that it was not biased. He also pointed out that there was no real forum at present for PH measures to be taken on the advice of ECDC. Can go to Council but this should be an exception for major issues. There were other possibilities including a new (informal) mandate for the Health Security Committee but this did not cover health threats in general; the (2119) Network Committee with limited role and the EWRS which had a coordinating role in an emergency situation. Finally he agreed with the points made re consideration of consequences for Member States of opinions and advice and suggested that ECDC could present policy options specifying advantages and disadvantages (pros and cons) rather than one "best for all" answer.

65. Johan Giesecke thanked the AF for their additional advice and idea of password protected site. He agreed that SP needed "steering"; that vaccine issues required careful consideration and handling; proposing options was best; procedures for selecting members of WGs should be more rigorously and carefully followed to ensure balance (especially in case of Industry even though sometimes they had all the data) and that AF advice must be sought as was done (and quite quickly) for "AI and cats". Also when there was a request from an individual Member States (e.g. the request for guidance re BCG vaccination for children) then along with meeting the response should it be circulated more widely, when for example it had implications for all Member States.

66. The Director pointed out that current procedure required the SP to give an opinion which goes to the AF and then to the ECDC Director. Therefore the AF comments were crucial as at a minimum ECDC had to publish. As previously discussed with the Commission and Director General SANCO, if the opinion is agreed then the next step could be to go the relevant competent bodies such as Council meetings (which had more difficult, complicated and complex procedures) or taken up with the Commission official EU fora which would give more strength and support to the scientific opinion coming from ECDC. The forthcoming external evaluation may be good time to look at all these issues and make changes if needed. There was a clear role for ECDC on vaccination policy issues (as clarified the day before by EMEA Director in his address to the AF). Also in the ECDC 2007 Work Plan there is activity to give advice on childhood vaccination schedules in the EU Member States as requested by the Commission. The Director concluded by fully agreeing with the need to be careful, especially when the opinions could result in resource consequences for Member States. How far to proceed down this path was the question and agreed that it would be best to present options with advantages and disadvantages and pros and cons identified.

67. Stefan Schreck agreed that vaccines were a focus of attention and ECDC opinion, advice and scientific perspective were needed. Cost benefit considerations needed to be discussed at different levels. Childhood vaccination schedules could be a Council Recommendation. This would require a proposal to be made and Ministers would decide in the end. This does not require consensus but a qualified majority. Scientific opinion (e.g. guidelines on protection) is advice to PH professionals but expect that Member States will use. Such advice does not need to go to the Council but AF consultation would add to ownership and take-up and use of the guidance.

Production of European STI guidelines *(document AF9/11)*

68. Francoise Hamers, of the Scientific Advice Unit, presented a protocol for the production and revision of the IUST/WHO European STD guidelines which had been developed by IUSTI, who's Director had sought ECDC involvement and contribution. The precise contribution requested of ECDC was outlined as Institutional (official endorsement), Technical (ECDC expert in editorial Board) and Financial (funding of annual Editorial Board and teleconferences). Guidance of the AF was sought on four specific questions related to the process; issues related to areas where ECDC plans to make its own guidelines; will AF members agree to be appointed as experts; and/or assist in identifying experts.

69. Guidance from the AF was divided. One group which was the majority expressed the opinion that collaboration should be encouraged as it would avoid duplication but that this should be loose. Formal endorsement of the guidelines should be avoided as there were a number of difficulties. A number of examples were given including that the underlying evidence must be mandatory for all guideline recommendations and not optional; the protocol could be too biased towards two countries (one from EU); it was a general policy issue and agreeing in this case could create a precedent; clinical guidelines were also needed for many other areas so justification was needed for ECDC to give "kite mark" in this case; signing up to recommendations of others needed a policy decision. So in principle the ECDC could sit on the Board, advise the IUSTI especially related to PH issues (e.g. screening, partner notification etc), identify and nominate experts (some AF members agreed to be considered

and/or nominate experts) but not to formally endorse the guidelines. Specific questions were raised regarding the financial support required and the process for including this activity in the current approved 2007 Work Plan as an additional item.

70. Another albeit smaller group pointed to the fact that Public Health measures and treatment were closely linked and good and fast treatment was very important for STI and good clinical guidelines would help. Also the practical utility, visibility and awareness of the ECDC would be greatly enhanced. It would also allow the ECDC to build on existing knowledge and practice with the learned society, professional bodies and although as pointed out by others there were potential hurdles, ECDC should not be afraid of entering the process. Consideration should be given to aspects for different levels of health care and the relevant DSN (ESSTI) should be involved.

71. Francoise Hamers thanked the members for their considered comments and agreed that endorsement of the full guidelines maybe problematic. The fact that certain important items were currently not covered (e.g. those already identified by the AF and notification and surveillance) was very helpful since it would allow ECDC to ensure that these were included. She also agreed about setting of a precedent which is why this had been put on the AF agenda for their guidance and also because it was so closely related to primary prevention which made it important for ECDC to be involved. The direct financial support was marginal (funding of annual Board meeting and teleconferences) and staff time involved participation as Board member.

72. The Director agreed that normally ECDC would not be involved in treatment issues but in this case the association with prevention was so close this is why the AF's guidance and advice had been sought. If they had just been clinical guidelines then ECDC would not have considered involvement leave alone endorsement. Regarding inclusion into the 2007 Work Plan, the procedure differed depending upon the resource implications (funds and staff time). If these were high then ECDC would revert back to the MB via the AF, if not then it could be a decision made by ECDC management provided of course there were no consequences on delivery of existing approved Work Plan deliverables. Potential endorsement of the guidelines would be examined on a case-by-case basis and would be put before AF.

Update on the Food and water-borne diseases Project *(document AF9/7)*

73. As the project leader, Johanna Takkinen from the Surveillance and Communication Unit introduced this horizontal project pointing out that of the 17 disease covered Norovirus and HEP E were not on the EU list. The 3 main strategic objectives were described and the key activities for 2007 were described under 5 main groupings (enhanced surveillance, outbreak detection and response mechanisms, risk assessment for norovirus and HEP E, surveillance of FWD outbreaks and criteria for FWD prioritization). Close collaboration with EFSA and WHO was emphasized.

74. One AF member mentioned that there was a need to change the culture so that there was a positive reaction when one country mentioned problems related to the product of another country. Johanna Takkinen agreed with this point.

Update on other diseases of environmental and zoonotic origin Project

(document AF9/8)

75. Arnold Bosman of the Preparedness and Response Unit presented the key events that had led to the setting up of the "Diseases of environmental and zoonotic origin" project and listed the diseases to be covered under this horizontal project. The diseases were grouped into vector-borne diseases, travel related diseases, intentional release agents, (re) emerging diseases and other diseases (legionnaires and Q-fever). The long term aim and strategic (3 to 7 year) focus of the project were described and finally the main planned activities, deliverables and key actions for 2007 outlined.

76. In the subsequent discussion, the advisory forum advised to introduce a prioritisation among the diseases in this project group. The current list was considered as quite extensive and each disease grouping could be considered a project in its own right. Prioritization was thought could help to make the project more manageable. In addition, the AF suggested focusing on the link between public health and the veterinary sector, as this has proven to be weak in many Member States, and strengthening this link could contribute substantially to a successful coordination of prevention and control of zoonoses.

77. Arnold Bosman agreed with the need to prioritize but how to do this was not clear. Each group had its own urgency, for example whereas the intentional release and the vector groups were respectively small and localized but both were important albeit for different reasons. Linking to other sectors (especially the veterinary sector) was an important suggestion for the project. Both the Director and Denis Coulombier agreed with the principle of prioritization and although all the diseases were listed in the current Work Plan, these would be reviewed and brought back to the AF for a joint decision.

Update on the Clostridium difficile Project *(document AF9/9)*

78. Johan Giesecke, Head of the Scientific Advice Unit, presented on behalf of the *Clostridium difficile* Working Group the background, history and work done by this ECDC working group on limiting the spread of *Clostridium difficile*. The AF was invited to review the guidelines developed and to send any comments they may have to the ECDC before the end of February 2007. A proposal for a project to develop a lab-based network in Member States was also presented. The objectives of the network were to provide information on CDAD, recognition of outbreaks and changing trends at an early stage. The method and plan for the network were presented for information of the AF and it was pointed out that there was no staff member recruited as yet to undertake implementation.

79. The AF whilst agreeing that this was an important topic and needed to be tackled were concerned that there was no single "language" in use. Even within one country there were at times 5 different names used (and 027 was not one of them) by different laboratories. There was also support for adding an additional specific objective related to continuous surveillance. As *Clostridium difficile* fitted well with Nosocomial infections it could be added to the list of diseases under surveillance. The guidelines document was well done and could also be important for national guideline development once adapted.

80. Johan Giesecke agreed that a common name should be part of the project nomenclature and that *Clostridium difficile* (full group and/or specific pathogens) should be added to the list of diseases requiring notification. Andrea Ammon, Head of the Surveillance and Communication Unit, informed that it was foreseen for 2007 that with expert help indicator pathogens for AMR would be identified and agreed that *Clostridium difficile* could be one along with others. Stefan Schreck of the European Commission pointed out that the list of diseases requiring notification need to be changed anyway and *Clostridium difficile* could be added during this process.

Update on the influenza Project *(document AF9/10)*

81. As the Project Leader, Angus Nicoll of the Scientific Advice Unit explained that the focus in the ECDC's 2007 Work Plan for this disease is to reduce the burden of seasonal influenza and to improve pandemic preparedness, whilst completing the work on AI. A number of action items arising from the paper were highlighted.

82. The **Status Report on pandemic preparedness:** Influenza preparedness was at least a 5 year project requiring all MS to work to: Integrate planning across governmental sectors; make plans locally operational; interoperability at national and regional levels; increase prevention against seasonal influenza; and extend research. The report to be launched on February 22nd would benefit from all member states drawing to the attention of the media the conclusions (adequate level of Pandemic Preparedness in the EU), the commendable work done and the many innovations developed.

83. The **Pandemic Preparedness Assessment Visits** (led by and with significant input of country experts) continue with last 12 countries due for completion in 2007. An Indicators Group is working with WHO to look at the next generation of preparedness indicators which will be piloted during the above visits. The Commission led 4th Joint EC-ECDC-WHO Europe Pandemic Preparedness Workshop will be held in Luxemburg (25th-27th September 2007) with associated regional meetings. Attention was drawn to some informal groups and pieces of work that were underway including practical guidance for "Preparing hospitals and communications to health care workers"; an options menu for "Public health measures (e.g. closing schools etc)"; specialist focused workshops on "Distribution of anti-virals"; and a group working on "Surveillance in a Pandemic". There would be a report back on the above to the next AF meeting.

84. The AF's attention was also drawn to three future important topics that would arise concerning pandemic preparedness which ECDC wanted MS to be aware of and/or to ask their advice. Concerning *Masks to be used in health care settings*, there was a conflict between theoretical risks and practicalities and need for further operational research. ECDC proposed to hold a meeting on this to identify the issues and research needs. Attempts to produce plans *to increase the capacity of hospitals to ventilate patients in a pandemic* were proving very difficult in the USA. AF members were asked if they were aware that some *large employers were working with drug companies to stockpiling antivirals* in addition to national stockpiles or even to supply antivirals to all employees as personal family stockpiles.

85. The **trends in seasonal influenza** (from EISS) suggest a worse season than those in recent years with EU countries to the North and East being prepared for a possible increase in

influenza. The current seasonal vaccine should work well as the match between the available vaccine and circulating strains was good. A small group was developing a methodology for monitoring vaccination coverage and in addition to Spain, UK & Germany, WHO and the Venice Project would be represented.

86. **Bird flu (Avian Influenza)** issues being worked on included the peer-review of the "Tool Kit" for investigating suspected H5N1 cases (non-imported) and this would be sent to MS shortly. A detailed "risk assessment on H5N1 exposure for people handling uncooked food and poultry products" was being prepared following the recent outbreaks of H5N1 in commercial poultry in Hungary and the UK. ECDC thought the risk was extremely small but no related work seemed to have been done on this issue to date. The results of this work would be coming to the AF and other specialists shortly for their rapid review. Denmark, Netherlands and the UK had met and raised an issue with ECDC about the recommendations for "personal protective measures that related to bird infections confirmed to be Low Pathogenicity Bird Flu". They had found that the national guidance was out of balance compared to the very low risk resulting in problems in implementation. The AF was informed that there were two groups working on "Human H5N1 Vaccines" (on the science and application of that science) which would report by the end of March 2007.

87. An AF member agreed that intensified surveillance had identified quite a few instances of H5N1 amongst poultry in the EU, at times of low pathogenicity. Guidance was needed as there were diverging opinions regarding the appropriate measures required during the resulting culls. If the same measures were used also in cases of low pathogen, complacency may develop negatively impacting on a "real" emergency. It was accepted that this was important as it could happen in any MS and the Director agreed to raise this formally with the relevant parts of the Commission.

88. At the request of an AF member it was agreed that monitoring the uptake of seasonal influenza vaccination should also include representation from smaller countries. The same member also questioned the readiness of the H5N1 "tool-kit" for dissemination. Feedback on the current situation was provided by Denis Coulombier, Head of the Preparedness and Response Unit, including that comments received from WHO and others had been reviewed and it would be sent out within 2 weeks to everyone. The proposal concerning the use of Masks in health care settings was supported and at least two members gave feedback that companies were creating their own antiviral stockpiles (in one case advocated by a clinician). The Director indicated that this issue would also be taken up with the Commission.

89. Following concern expressed by an AF member that the EU surveillance definition for human H5N1 infection was different from that of WHO's, Andrea Ammon, Head of the Surveillance and Communication Unit, explained the process, highlighting the different objectives. It was also explained that the proposals were now more aligned to that of WHO and that the revised case definition would come out again to MS before being finalized.

Update on the ECDC Scientific conference on Applied Infectious Disease Epidemiology (ESCAIDE, 18-20 October 2007, and joint Scientific Symposium SMI/ECDC/ESCMID, 7 May 2007

90. Johan Giesecke, Head of the Scientific Advice Unit, informed about the planned SMI/ECDC/ESCMID joint Scientific Symposium which was linked to the next AF meeting in May. It would start on the afternoon of the 7th May 2007 and the programme was amongst the documents distributed to the AF.

91. The AF were also informed about a 3 full day ECDC Scientific Conference (Stockholm, 18-20 October, 2007) to which the MB and AF members would be invited. The conference was as an extension of the Epiet seminars, aimed at a wide audience with more people from the surveillance institutes and about 500 people were expected to attend. Questions were raised regarding call for presentation and deadlines for the October meeting and replied to by Johan Giesecke.

92. The Director reminded the AF that the next AF meeting would be for 2 full days with the AF working groups taking place on 7 May in the morning (so it was important to arrive the night before), the 7th May afternoon would be the scientific symposium and the 8th would be devoted for the whole day to the AF formal agenda

Other matters and closure

93. The Director requested the AF members to give their thoughts and ideas on how the AF could be made more interesting by use of working groups and including topics outside the ECDC Work Programme (e.g. the scientific symposium and past technical briefings). At the next meeting time will be set aside to discuss this and in the meantime all input and ideas were welcome.

94. Johan Giesecke informed the AF that ECDC was hosting a small “climate change” meeting later in the year and in preparation for it a small questionnaire had been designed and would be handed out to members. He would be grateful if it could be filled in and returned