ECDC Advisory Forum

Minutes of the 31st Meeting of the Advisory Forum

Stockholm, 26 September 2012

Contents

Item 1 – Opening and adoption of agenda *(Documents AF31/2 Rev.1; AF31/3 Rev.1)*

1. Johan Giesecke, Chief Scientist, in his capacity as the Chair, welcomed participants to the Thirty-first meeting of the Advisory Forum (AF).

2. A specific welcome was extended to Olga Dulovic, newly appointed Observer from Serbia, Jenny Kremastinou, appointed Member from Greece, Frank Van Loock from the European Commission, Karin Nygård, newly appointed Alternate from Norway and Guénaël Rodier from WHO, Regional Office for Europe.

3. Apologies were received from Cyprus, Ireland, Liechtenstein, Malta, Montenegro, The Former Yugoslav Republic of Macedonia, the United Kingdom and the Standing Committee of European Doctors.

4. No declarations of interest were made verbally. The following written declarations of interest were received by the secretariat: Petri Ruutu, Member, Finland, noted that he is working in an institution carrying out narcolepsy studies (in reference to item 6, Update on projects on narcolepsy and pandemic vaccines).

5. The agenda was adopted with one change: the presentation on *Aspergillus spp.* was postponed until further notice.

Item 2 – Adoption of the draft minutes of the 30th Advisory Forum meeting, Stockholm 3–4 May 2012 *(Document AF31/4)*

6. The draft minutes from the Thirtieth meeting of the AF had been circulated to members and were adopted, although some participants expressed a preference for a verbatim record of proceedings.

Item 3 – Update from ECDC on the main activities since the last Advisory Forum meeting (Marc Sprenger, ECDC Director) *(Document AF31/Info Note 1)*

7. The Director of ECDC gave an update on the main activities since the last meeting, followed by a discussion on a number of issues, including ECDC's objectives during its 2012 chairmanship of EU agencies and the role of ECDC in the area of immunisation and its visions for the future.[1]

Item 4 – Update on ECDC Annual Work Programme 2013 *(Document AF31/5)*

8. Following the Director's update[2] there was a discussion on the completion of questionnaires in Member States (quantity, scope, purpose, duplication).

9. Kåre Mølbak, Member, Denmark, felt that people had different understandings of the questions and contexts, thus it was more beneficial to meet and sit together to talk through priorities during working group discussions at the AF meeting.

10. Anders Tegnell, Alternate, Sweden, suggested that ECDC should clarify whether they wanted a Member State's opinion or that of a medical expert.

11. Irena Klavs, Member, Slovenia, pointed out that the disease networks were a good forum for discussions on strategy.

[1] Item 3 - Update on main ECDC activities

[2] Item 4 - ECDC WP2013 (M Sprenger)

12. Andreas Gilsdorf, Alternate, Germany, noted that it was not necessary to have an overview of the situation every year but preferable to have more specific goals.

13. Petri Ruutu, Member, Finland, expressed concerns about the overlap between work being done by the Commission's Health Security Committee and by ECDC.

14. The ECDC Director noted that Member States still needed to be convinced of the benefit of questionnaires and ECDC would investigate how to improve this situation, perhaps by studying some of the methods employed by WHO to deal with similar issues.

15. Maarit Kokki, Senior Advisor to the Director, ECDC, sought views from the AF to answer a question on the role of ECDC in the area of immunisation and its visions for the future, in the light of the Innovative Medicines Initiative (IMI) 7th call for proposals on various topics and ECDC's possible joint submission with EMA of an expression of interest in the development of a framework for rapid assessment of vaccination benefit/risk in Europe. She reminded the AF members that ECDC had sent its vision paper to them, following the Management Board meeting in June 2012, asking members to identify public health gaps in the area of vaccine programmes and comments had been gratefully received. These had almost entirely been either supportive of ECDC's preferred option, or on matters of detail, or both. She then explained how in mid-September, ECDC had had discussions with DG SANCO and EMA on their preference that ECDC respond to the IMI call for proposals which was perceived as a pragmatic way to move forward, though it was not optimal. The proposal was for ECDC to take the lead in a consortium together with EMA and then make a bid. The deadline for submission of expressions of interest was 9 October 2012. She also pointed out that it was a competitive call and the consortium would therefore have to get beyond the first phase before it could begin work on the full project proposal. It was estimated that the project would take around one year before funds could become available.

16. Silvia Declich, Member, Italy, questioned why the AF had not received the documents from ECDC until one month after the IMI call had been published in August. She also pointed out that the IMI call was for a five-year project and therefore wondered what would happen to ongoing effectiveness studies in the meantime (e.g. I-MOVE) and whether these would be stopped as a result of the new call.

17. Further questions were raised about the legal aspects of two EU agencies working together to bid in a call for proposals, the mandates of the two agencies and the need for clarification of their roles, given that vaccines was an area requiring a strong EU lead.

18. Kåre Mølbak, Member, Denmark, pointed out that the narcolepsy study (VAESCO), an in-depth investigation across a number of individual countries rather than a consortium, was an excellent example of cooperation in the area of vaccines, proving that consortia were not necessarily always the answer. He wondered whether countries would be involved in the tendering process from the start and whether countries would be empowered to conduct analyses on their own or whether they would just be asked to provide data.

19. Maarit Kokki, ECDC, hoped that communication with the AF would be smoother in the future, now that internal processes have been clarified and Member States would definitely be involved. The call was only for developing the framework for rapid assessment of vaccination risk/benefit and one idea was for ECDC to specify in its bid that studies were necessary, with a view to applying some of the ongoing studies in the framework packages. The roles and responsibilities of ECDC and EMA would be clarified along the way. A possible conflict of interest in working with private sector companies had been one of the main concerns during the internal discussion process. However, the IMI was an EU body established to encourage private/public partnerships and the call was open for independent EU bodies. ECDC would be conducting a virtual meeting of the potential consortium group shortly to agree to the next steps and would inform the AF of the outcome immediately thereafter.

Item 5 – Scientific advice: update on assessments, reviews and guidance

Item 5ai – Systematic reviews and guidance on peri-operative antibiotic prophylaxis (PAP)

20. Anna-Pelagia Magiorakos, Senior Expert, Antimicrobial Resistance and Healthcare-Associated Infections, Surveillance and Response Support Unit, ECDC, gave a presentation on systemic reviews and guidance on peri-operative antibiotic prophylaxis (PAP) and organisation of hospital infection control programmes (SIGHT).[3]

21. Andrzej Zielinski, Member, Poland, questioned the definition of "professionals" in the review and how data was analysed.

22. A number of members queried about plans for dissemination.

23. Anders Tegnell, Alternate, Sweden, questioned how it was possible to ascertain where in the review there was consensus and where not and what the scientific basis for the results was.

24. Frank Van Loock, European Commission, asked why information from specific external studies was missing and what the best method might be for in-country distribution.

25. Anna-Pelagia Magiorakos, ECDC, replied that for the purposes of the review, "professionals" were people adequately trained in infection control, which could apply to nurses, doctors, or anyone having received training in infection control. Data was not analysed because it was not always available. The review had looked at behaviour change and there had been no evaluation of the criteria since it was assumed in each case that the diagnosis was correct. The explanation for the absence of some studies from the review was that studies had to fulfil very stringent criteria to be included and some were not of sufficient quality. ECDC is aware that the conclusions were not new, nevertheless, this was the first systematic review ever undertaken and it reinforced the information available to help bring countries up to speed. The review combined evidence with expert opinions, and each component included a summary of evidence, grading in a table and a summary by an expert. ECDC took note of the recommendation that the conclusions should be clearer. A consensus had been achieved but only one study had been included due to the rigorous selection process. It was decided to leave out public disclosure and benchmarking as these were such sensitive issues which were inappropriate at the present time.

Item 5aii – Systematic reviews and guidance on organisation of hospital infection control programmes (SIGHT) (Document AF31/6 Rev.1)

26. See item 5ai (above).

Item 5b – ECDC Guidance on Risk Groups for Influenza and Seasonal Influenza Immunisation in Europe (Document AF31/7 Rev.1)

27. Angus Nicoll, Head of Disease Programme, Influenza, ECDC, gave a presentation of a scientific review just published by ECDC on the evidence for and against immunising pregnant women and children in Europe.[4] He explained that this was based on a systematic literature review followed by an expert panel the choice of members of which had been subject to review by the AF. He noted that the review was intended to give guidance for MS and that it had concluded that it was still the case that there was insufficient evidence to recommend routine influenza immunisation for either group in Europe. This was followed by a general discussion how ECDC and the Member States should proceed

[3] Item 5a - Hospital infection control programmes (SIGHT) (A-P Magiorakos)

[4] ECDC scientific advice on seasonal influenza vaccination of children and pregnant women October 2012 link here

and comparison with the new global recommendations from a WHO SAGE group[5] to include pregnant women as the highest priority for influenza immunisation and to add young children to the recommended groups.[6]

28. Anders Tegnell, Alternate, Sweden, said that Sweden had been very hesitant about the new advice from WHO and suggested making an unofficial inventory of what countries had done.

29. Herman Van Oyen, Member, Belgium, noted that Belgium experienced strong opposition to vaccination which was a very sensitive issue, so unless there was evidence of its effectiveness, this WHO recommendation would not be implemented.

30. Petri Ruutu, Member, Finland, noted that in his country, childhood immunisation against influenza had been introduced four years before; however, coverage remained low against the background of the narcolepsy issue. He pointed out that though health economic assessments were positive, this was dependent on the healthcare system in a specific country and it was difficult to transfer results to other countries.

31. Haraldur Briem, Member, Iceland, mentioned that in Iceland, vaccination against influenza was recommended for pregnant women and this would not change unless Pandemrix displayed contradictions.

32. Ágnes Csohán, Member, Hungary, noted that, given the sensitivity surrounding the vaccination of pregnant women, Hungary would not change its recommendation and pregnant women would not be given the highest priority for influenza vaccination. She suggested that during the next influenza season, ECDC should obtain further information from countries with good surveillance systems for influenza.

33. Jean-Claude Desenclos, Member, France, felt that it was necessary to obtain a better appreciation of the burden of infection for influenza and undertake vaccine efficacy studies before embarking on such new immunisation programmes.

34. In response to an intention in the UK that school-age children would be immunised in order to reduce infection and disease in older people, Andreas Gilsdorf, Alternate, Germany, noted that including children in vaccine programmes for public health reasons would require work to change people's mindset, and adding a further vaccination to the long list of recommendations for children would complicate matters further. He also noted that it is unclear whether repeated vaccination of children induced sustained immunity, unless natural infections were also taking place.

35. In response to a comment concerning pregnant women, Angus Nicoll, ECDC, noted that the VENICE surveys undertaken by MS and ECDC found that in 2008-2009, only ten EU countries had recommended vaccination for pregnant women. However, that figure had risen to 16 in 2008-2009 and 22 countries in 2010-2011. But he also noted that hardly any countries had any information on implementation of this advice, but there were anecdotal reports of resistance to vaccinating this group from obstetricians, midwives and women themselves. He also pointed out that there was now a problem with the evidence based approach of *pandemic publication bias*, that is, the published literature was dominated by the 2009 experience with just one influenza virus when it had to be applied to all the human viruses in seasonal flu.

36. He agreed with AF members that it was crucial to obtain the information on burden year-in-year-out to have the proper evidence base for informed decisions. However, for the next five-to-ten years, the literature would probably be overburdened with information on the pandemic.

37. There was strong endorsement of ECDC continuing with its critical approach to evidence, to Member States developing routine hospital and mortality surveillance for laboratory confirmed severe influenza disease where that was possible and to looking at adapting WHO recommendations to fit the European experience.

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[5] WHO Meeting of the Strategic Advisory Group of Experts on immunization, April 2012 – conclusions and Recommendations (seasonal Influenza vaccine) WER 2012, 87, 201–216 http://www.who.int/wer/2012/wer8721.pdf and WHO SAGE Working Group Background paper on influenza vaccines and immunization http://www.who.int/immunization/sage/meetings/2012/april/1_Background_Paper_Mar26_v13_cleaned.pdf

[6] Item 5b - Guidance on Risk Groups for influenza (A Nicoll)

38. It was subsequently noted the Commission will present an interim report on the state of implementation of the Recommendation in the Member States and at EU level in spring 2013. Preparatory work, especially data collection on vaccination coverage in the different target groups, is currently being undertaken with the support of ECDC and its VENICE project. The question of maintaining the target groups for vaccination as included in the Recommendation and divergences with the WHO recommendations will also be addressed in the interim report.

Item 9 – Serious cross border threats to health

39. Frank Van Loock, European Commission, gave a presentation which was followed by a short discussion.[7]

40. In reply to a query, it was explained that there would be no impact on the role of ECDC and the way in which the Commission obtained information from ECDC. The proposal was essentially an expansion of the EWRS system and therefore the current thinking was that there would be no need to expand ECDC's Founding Regulation or amend its role.

41. In response to an inquiry by the Alternate from Germany as to how many Member States were involved in the process at country level and had regular contact with their representative in the Council Working Party/Group, a show of hands indicated around four or five people.

Item 7 – Epidemic intelligence: update on recent threats in the EU

Item 7a – Update on the novel coronavirus

42. Denis Coulombier, Head of Surveillance and Response Support Unit, gave an update which focused on the corona virus.[8]

43. Kåre Mølbak, Member, Denmark, gave an update on the possible cases of corona virus being investigated in Denmark. Little was known about the origins of the cases, apart from the link to Qatar. Symptoms were mild and tests for the virus were negative. The virology and PCR protocol were publicly available in Denmark and Member States could contact the Danish AF Member to obtain details. The main issue in Denmark was how to deal with the press and media activity.

44. Angus Nicoll, ECDC, noted that one strategy for surveillance, developed with WHO, had been to take a sensitive approach to possible cases in the epidemiological sense, especially given the significant media coverage and the approaching Hajj. The evidence so far was more consistent, i.e. this was probably a zoonotic virus that did not transmit easily among humans. He also noted that this event had demonstrated a new phenomenon of 'stealth' patients, entering Europe and going directly to private clinics rather than official channels. This was an important factor which should be described and quantified and that in future this could become more important with it being difficult to know where such patients would turn up or where they would be likely to come from.

45. Anna-Pelagia Magiorakos, ECDC, pointed out that, although there was no known evidence of human-to-human transmission as yet, the situation could change. Consequently, it was advisable to take the best possible precautions in terms of infection control and use FFP3 (high filter) rather than FFP2 masks.

46. Guénaël Rodier, WHO Regional Office for Europe, noted that the corona virus had been isolated in the UK and the information shared through EWRS. WHO was working closely with colleagues in the WHO/Europe region to monitor the situation, but to date, there had been no further cases. Bat-type zoonotic diseases of this type were frequent occurrences in Indonesia and Malaysia and the Ministries of Health in Malaysia, China and Indonesia were fully informed. At present, there was no indication that it would be necessary to change travel recommendations ahead of the Hajj.

[7] Item 9 - Serious cross-border threats to health (F Van Loock)

[8] Item 7a - Update on the novel coronavirus (D Coulombier)

47. Andreas Gilsdorf, Alternate, Germany, commented that the EWRS risk assessment and information provided by ECDC over the weekend had been highly appreciated.

Item 6 – Update on projects on narcolepsy and pandemic vaccines

Item 6a – VAESCO – major findings and way forward

48. Kari Johansen, Expert, Vaccine-Preventable Diseases, Surveillance and Response Support Unit, gave a short presentation on the preliminary results of the VAESCO studies.[9]

Item 6b – Main findings from the French study

49. Jean-Claude Desenclos, Member, France, gave a short presentation entitled 'Pandemrix and narcolepsy – French case-control study results'.[10]

Item 6c – Discussion

50. Petri Ruutu, Member, Finland, pointed out that there had been a strong association between the cases of narcolepsy and a specific genotype in Finland. He also asked how the scientific disclaimer was being handled in the VAESCO report.

51. Anders Tegnell, Alternate, Sweden, queried whether the incidence was increasing in adults and what the next steps were for VAESCO.

52. Kari Johansen, ECDC, replied that the disclaimer had been published in the annex to the report as requested. Most countries were now planning to study the incidence in adults as a follow-up; however, young adults were the main focus and they were difficult to study since they did not have stable lifestyles. The next steps for VAESCO, particularly in the light of the fact that over 100 new cases had been reported to EMA during 2012, would be to continue with further studies. New studies were being formalised in Finland, Norway and Sweden; however, funding was a difficult issue. GlaxoSmithKline had consulted with EMA and sent some cases to a specialist at Stanford University, USA. ECDC's attempts so far had been industry-independent and it was hoped that this would continue to be the case.

53. Kåre Mølbak, Member, Denmark, pointed out that narcolepsy had been discussed recently at a session of the Nordic Vaccine Meetings and described as an auto-immune disease in individuals with a specific genotype. It was likely that Pandemrix had triggered the onset of the disease in individuals with this genotype, in which case there was no expectation that the number of cases would continue to increase.

Item 7 – Epidemic intelligence: update on recent threats in the EU *[Continued]*

Item 7b – Multi-country outbreak of Salmonella Stanley infections

54. Josep Jansa, Head of Section, Response, Surveillance and Response Support Unit, ECDC, gave a presentation on this issue.[11] The subsequent discussions focused mainly on whether action should be taken and if yes, then when, given that ECDC was on the opinion that counter measures should be applied, particularly after collaborating with EFSA on this issue to obtain conclusive proof.

[9] Item 6a - VAESCO study (K Johansen)

[10] As per the request of France, the presentation shall not be made available on the AF Extranet

[11] Item 7b - Multi-country outbreak Salmonella Stanley (J Jansa)

Item 8 – Role of the Advisory Forum and its interactions with the Coordinating Competent Bodies (CCBs), the National Microbiology Focal Points (NMFPs) and the National Surveillance Focal Points (NSFPs)

55. The item was introduced by Andreas Gilsdorf, Alternate, Germany, who felt that since the inception of the Advisory Forum, it had not been clear whether its members should be giving ECDC the views of their Member States or their opinions as experts. The CCBs' representatives did not necessarily have the same scientific background as the AF members who had to work with them but were not part of the CCBs network. The issue had been raised due to the reform of the NFP/NMFP system and the new terms of reference discussed at the AF earlier in 2012. Moreover, AF members often did not know what their national expert counterparts in surveillance or microbiology were discussing or who was being consulted in the country. A more structured approach was required as well as a definition of roles and functions.

56. Johan Giesecke, Chief Scientist and Chair, ECDC, pointed out it was important for AF members to offer a European perspective when giving their opinions. Around half of the CCBs' representatives were national directors and the other half were national coordinators with a more administrative profile. It was evident to ECDC that the meetings of the two groups should remain separate and the content different.

57. Kåre Mølbak, Member, Denmark, noted that the AF members gave advice to ECDC as experts on the basis of their experience. The CCBs was a heterogeneous group of coordinators who dealt with the whole network and all focal points.

58. Petri Ruutu, Member, Finland, wondered whether the CCBs should have a back-up and pointed out by way of example that he was attending the meeting as National Coordinator, NFP and AF Member. He suspected that this was the case for a number of countries.

59. Johan Giesecke, ECDC, said that for some of the networks it was unclear to ECDC how nominations were made and more information was required on the procedures.

60. Requests were made for more flexibility in the roles of a National Coordinator and AF Member; a written case definition to give some terms of reference; a directory of appointees and clarification of the existing structures and a redefinition of the AF Members' role.

61. A number of members were uncertain as to whether it was expedient for ECDC to organise large meetings of the various groups since regular meetings of the networks could be arranged in-country.

62. Petri Ruutu, Member, Finland, felt that a vaccination policy expert from the national immunisation programme could be a useful addition since this was such an important public health function.

Item 10 – The EURLOP initiative: concrete options for future actions *(Document AF31/8 Rev.1)*

63. John Parry, Health Protection Agency, Microbiology Services, United Kingdom, gave a presentation which was followed by a general discussion.[12]

64. Frank Van Loock, European Commission, pointed out that the European Parliament was currently looking at a legal proposal and there was also activity going on in this area with WHO and under international agreements. The Commission has planned to have stakeholder involvement to finalise any aspects that could be included in a legal proposal.

65. Jean-Claude Desenclos, Member, France, asked about the next steps for the initiative.

[12] Item 10 - EURLOP initiative (J Parry)

66. Jenny Kremastinou, Member, Greece, mentioned that Greece struggled with the concept of reference laboratory and questioned if there were recommendations on how to deal with this.

67. Andreas Gilsdorf, Alternate, Germany, wondered whether there might be conflicts of interest or problems with duplication in relation to the European designation of laboratories. He also wondered whether it would facilitate data sharing.

68. Guénaël Rodier, WHO Regional Office for Europe, expressed full support for the initiative, however, he emphasised that it would be important to coordinate the work as WHO has already established a number of reference laboratories under its disease elimination and influenza programmes.

69. Responding to AF members' questions, John Parry noted that they had not attempted to find a solution to be applied in-country as this was a matter for each individual Member State. Having one reference laboratory per country would simplify matters, but if there were several, they would still be able to link into the European-level network and collaborate on certain clusters of disease. With regard to sharing of data, he pointed out that the data was being held by DG SANCO. He recognised the parallel between WHO/Europe, ECDC and perhaps even third-party national reference laboratories and his team had attempted to take account of this.

Item 11 – Confirmation of 2013 and 2014 Advisory Forum Meeting Dates *(Document AF31/9 Rev.1)*

70. The meeting dates for 2013 and 2014 (provisional dates) were presented to the AF.[13] Following discussions, it was agreed that the dates in May would be amended due to scheduling constraints.

71. In response to a question as to whether it was necessary to meet four times per year, it was confirmed that this was stipulated in ECDC's Founding Regulation; however, it might be possible to review this situation at a later date. Shorter Advisory Forum meetings arranged back-to-back with ESCAIDE or other ECDC meetings as well as web conferences instead of physical meetings could be considered in the future in order to reduce costs and travel time.

Item 12 – Any other business

72. Johan Giesecke, Chief Scientist and Chair of the Advisory Forum, thanked all the members for their fruitful discussions and lively debates.

[13] Item 11 - AF meeting dates 2013 and 2014 (C E Skarstedt)