Meeting Report

Informal Meeting of Taskforce for Formulating Regional Alliance for National Regulatory Authorities (NRAS) in the Western Pacific Region

Canberra, Australia
31 May–1 June 2012

World Health Organization
Western Pacific Region

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REPORT

INFORMAL MEETING OF TASKFORCE FOR FORMULATING REGIONAL ALLIANCE FOR NATIONAL REGULATORY AUTHORITIES (NRAs) IN THE WESTERN PACIFIC REGION

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NOTE

The views expressed in this report are those of the participants in the Informal Meeting of Taskforce for Formulating Regional Alliance for National Regulatory Authorities (NRAs) in Western Pacific Region and do not necessarily reflect the policies of the World Health Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for the participants of the Informal Meeting of Taskforce for Formulating Regional Alliance for National Regulatory Authorities (NRAs) in Western Pacific Region, which was held in Canberra, Australia from 31 May to 1 June 2012.

SUMMARY

An informal meeting of the taskforce for formulating the Regional Alliance for National Regulatory Authorities (NRAs) in the Western Pacific Region was held at the offices of the Therapeutics Goods Association (TGA) in Canberra, Australia, from 31 May to 1 June 2012. A total of eight participants from the four member countries of the drafting group/task force, three observers from Japan International Cooperation Agency (JICA) and the TGA and three Secretariat staff from the WHO Regional Office for the Western Pacific and WHO Headquarters participated in the meeting.

The objectives of the workshop were:

(1) To finalize the draft concept paper for formulating the Regional Alliance for National Regulatory Authorities (NRAs), to be shared with Member States in the second regional NRA workshop.

(2) To discuss with the four countries with functional NRAs possible future support to other countries with non-functional NRAs.

Member States who participated in the first workshop for NRA for vaccines, organized by the WHO Western Pacific Regional Office and held in Seoul, Republic of Korea, in 2011, proposed the establishment of the Regional Alliance for NRA in the Region. They also suggested forming a drafting group/task force composed of the four countries with functional NRAs namely, Australia, China, Japan and the Republic of Korea to finalize the draft concept paper, road map and workplan for formulating the Regional Alliance in the Region and submit it to the second workshop for review and endorsement.

The workshop was conducted in three working sessions and was closely coordinated by staff from the WHO Regional Office for the Western Pacific and WHO Headquarters. The sessions on day 1 and day 2 were chaired by Dr Kentaro Hanada from Japan and Dr Peter Bird from Australia, respectively. The meeting on day 1 focused on the review of the draft concept paper prepared by the WHO Regional Office for the Western Pacific. Australia, China, Japan and South Korea also gave presentations on how best they can provide support to countries with non-functional NRAs. On day 2, the focus was on the development of the road map and workplan for the Regional Alliance.

At the end of meeting, conclusions were reached regarding actions required to finalize the draft concept paper, road map and workplan.

CONTENTS

Keywords:

Vaccines – standards, supply and distribution/ Regional health planning/ Technical cooperation

1. INTRODUCTION

An informal meeting of the taskforce for formulating the Regional Alliance for National Regulatory Authorities (NRAs) in the Western Pacific Region was held at the offices of the Therapeutics Goods Association (TGA) in Canberra, Australia, from 31 May to 1 June 2012. A total of eight participants from the four member countries of the drafting group/task force, three observers from Japan International Cooperation Agency (JICA) and the TGA and three Secretariat staff from the WHO Regional Office for the Western Pacific and WHO Headquarters participated in the meeting.

1.1 Objectives

(1) To finalize the draft concept paper for formulating the Regional Alliance for National Regulatory Authorities (NRAs), to be shared with Member States in the second regional NRA workshop.

(2) To discuss with the four countries with functional NRAs possible future support to other countries with non-functional NRAs.

1.2 Opening remarks

Dr Yoshikuni Sato, Medical Officer, Expanded Programme on Immunization, Western Pacific Regional Office, delivered the opening remarks on behalf of Dr Sergey Diorditsa, EPI Team Leader. Dr Sato welcomed everyone to the meeting. Highlighting that it was to be an informal meeting, he encouraged participants to contribute and exchange opinions in a frank and open manner. Dr Sato gave a brief overview of the history of the development of the Regional Alliance and the purpose and development to date of the draft concept paper.

Thanking all participants for attending, he gave special mention to the Therapeutic Goods Administration (TGA) for their support in hosting the meeting and to the Government of Japan for their financial support.

Ms Jenny Hefford, Chief Regulatory Officer, TGA, formally welcomed all participants and commented on the expectation for high achievements as a result of the meeting. She discussed how the outbreak of severe acute respiratory syndrome (SARS) had changed the world and had emphasized the need for regulation and delivery of safe vaccines to deal with or prevent similar events in the future. She wished all participants every success for the meeting.

2. PROCEEDINGS

2.1 Introduction of the concept paper

Working Session 1

Working Session 1 was chaired by Dr Kentaro Hanada, Director, Department of Biochemistry and Cell Biology, National Institute of Infectious Diseases, Japan, and the moderator was Mr Lahouari Belgharbi, Technical Officer, Quality, Safety and Standards, WHO Headquarters.

Mr Belgharbi gave a presentation to introduce Working Session 1, stating that the objectives were to define a strategic approach and to finalize the draft concept paper provided by the WHO Western Pacific Regional Office. Mr Belgharbi's presentation outlined the global initiatives and coalitions to promote immunization from 1947 to 2020, their goals being to ensure the safety and assured quality of 100% of vaccines being provided in immunization programmes. The 2011 Forum in Bangkok, Thailand, highlighted the need for coordination of the Global Strategic Plan and the importance of consultation with industry. The first NRA regional workshop, held in Seoul, Republic of Korea, in 2011 established a Regional Alliance of NRAs that sought to align with the Global Strategic Plan. The initial draft concept paper for the Regional Alliance was prepared. The current meeting in Canberra was organized to develop the workplan and road map for the Regional Alliance and to finalize the draft concept paper. Mr Belgharbi noted that an effective mechanism for promoting support is a road map that lays out the work areas/timeframes to which stakeholders can contribute.

In the discussion on the draft concept paper, participants first agreed on the need for clarity of terminology and to the suggestion of Professor Chung Keel Lee, Special Advisor to the Commissioner, Korea Food and Drug Administration (KFDA), to incorporate a glossary in the paper. Mr Belgharbi stressed the importance of keeping the document as succinct as possible and this was agreed upon unanimously. Discussions then revolved around ways to best condense the document to avoid redundancy and repetition. Mr Belgharbi proposed that the document itself contained adequate information, but that it simply required re-organization and simplification. Professor Lee added that, in some cases, details of specific sentences thus needed to be reviewed in order to clarify possible misunderstandings. This was also agreed, but the document as a whole would not be reviewed sentence by sentence. Professor Lee also commented on the use of the terms "stakeholder" and "shareholder". He suggested that only one term should be used to avoid confusing the reader. It was mentioned that the final document would be reviewed by an official editor so discussions about minor editorial details should not be a concern.

With the aim of condensing and avoiding redundancy in the document, it was agreed that the Introduction and Background sections should be combined and simplified. The Chairperson commented that it was important to include in the introduction why each of the four countries (Australia, China, Japan and the Republic of Korea) consider it important to promote such an initiative to encourage the support of developing countries. The introduction should also mention the importance of vaccine quality.

Mr Naoyuki Yasuda, International Planning Director, Pharmaceutical Affairs of Ministry of Health, Japan, suggested that the Rationale section of the document would be a good place to include statements on why each country is promoting the initiative, and to highlight and clarify the reasoning behind the project. Discussions also raised the fact that the Rationale should acknowledge the important role of strong, functional NRAs in the global supply of assured vaccines, such as in pandemic situations. Strong NRAs are also important in promoting public confidence in vaccine products.

Participants agreed that the draft concept paper should be written with the audience in mind. The document would be read by the highest level of government and the paper must therefore be kept brief and non-technical. The Rationale section was highlighted as being of the utmost importance, as it provides the background. Significant discussion was undertaken on re-drafting the arrangement of the document into a short concept paper, with an appendix containing the details of the workplan. The title and content of the Management section was discussed and it was agreed that the content of the section is covered by the responsibilities of the Secretariat.

Mission/Strategic Objectives/Expected Outcomes were combined into one section, with the Expected Outcomes possibly being incorporated into an Expected Outputs section at a later date. The importance of a separate section to highlight the vision of the paper was agreed upon by all and was incorporated into the re-structured document outline.

2.2 Finalization of the concept paper

It was agreed that the paper should be short and to the point, and shoule follow a stream of logic, with large general points first, leading down to concrete sentences about more specific areas. Dr Md. Shafiqul Hossain, Technical Officer, Expanded Programme on Immunization, Western Pacific Regional Office, commented on the need to focus on the bulk of countries the Regional Alliance was formed to help. Many of these countries have less developed or no regulatory systems. Mr Belgharbi suggested that the draft concept paper needed to be consistent with the Millennium Development Goals (MDGs), as these are well understood by stakeholders and are useful in communicating the need for support. The need to specifically mention women and child health was discussed. Members agreed on the importance of national immunization programmes using quality-assured products and that the focus should be on products rather than individual vaccines. The linkage between health and the use of good quality vaccines was noted.

Dr Chris Rolls, Principal Scientist, Office of Laboratories and Scientific Services, Australia, suggested two points for possible inclusion in the paper:

(1) Manufacturing high quality vaccines is difficult, manufacturing cheap vaccines is easy.

(2) This decade (2010-20) has been declared to be the Decade of Vaccines.

Participants went on to discuss the problems associated with not using vaccines of assured quality.

Dr Peter Bird, Head, Office of Laboratories and Scientific Services, Australia, proposed that the discussion move on to the Rationale section to set the reasons for the paper in place in order to better understand what should be included in the Introduction. Mr Belgharbi reiterated the suggestion to move forward to the Rationale section and suggested that the participants should re-draft parts of the paper for discussion the second day of the workshop.

The Chairperson emphasized that the Introduction section should retain health as a priority, should focus on vaccines, and should be applicable to all countries. It should also mention NRAs. Delegates agreed that some wording regarding why the Regional Alliance was necessary should be included.

Dr Bird made the point that there may not be a need for an Executive Summary in addition to an Introduction. The Chairperson suggested that the first part of the document needed to capture and retain the attention of the reader. Mr Belgharbi added that if there was to be an Executive Summary it should only be four to five lines, followed by a brief (½ page) Introduction.

Members then focused on the Rationale section of the paper and edited paragraphs between the Introduction and Rationale. Mr Belgharbi suggested adding wording regarding WHO having a unique mandate to intervene and a role to develop collaborative programmes to strengthen NRAs.

Dr Bird noted that health issues, such as infectious diseases, affect both developing and developed countries. It was agreed that control of infectious diseases is a global concern and that a line such as "Health risks have no borders" should be used in the draft concept paper.

Members discussed capacity-building, its meaning and the importance of a country investing in its regulatory system. When a regulatory system is not rigorous enough, problems that may have been prevented can arise and cause harm. It was agreed that this concept should be included in the paper.

The use of various terms in the paper was discussed, in particular the word "harmonization." The use of a suitable alternative will be further discussed by the WHO Western Pacific Regional Office when drafting the next version of the concept paper.

Dr Zhang Shumin, Director, China State Food and Drug Administration (SFDA) and Mr Belgharbi discussed the definitions of some of the wording in the vision statement. The Chairperson expressed concern over the use of the term "100% assured." Professor Lee suggested using "all vaccines used are of assured quality." Participants agreed. Ms Saeda Makimoto, Director, Human Development Department, Japan International Cooperation Agency (JICA), initiated discussion on whether "all vaccines in the national immunization programme" should be used, or simply "all vaccines", stressing that these terms are different. Mr Belgharbi wanted to keep the national immunization programme wording because it is more difficult for the NRAs of some countries to have control outside the programme. Professor Lee proposed the addition of the word "including".

The Chairperson suggested that discussion should move to the Strategic Objectives section and opened the dialogue with why the draft concept paper needed the term "biological", considering the focus was on vaccines. Dr Hossain cited that many countries have a very tight link between vaccines and biologicals and that the wording cannot be removed. Mr Rolls proposed adding "provide the regulatory framework". It was decided that this point could also be an expected outcome. Many of the delegates agreed it should not be kept as a strategic objective.

The discussion moved to the section on Governance. Mr Belgharbi was asked to suggest some wording for this section. Mr Belgharbi, using a white board, demonstrated options for governance, but emphasized that the rest of the participants should have input into this section and that the entire group of (possibly) all Member States would need to agree to any proposals. Participants, led by Mr Belgharbi, added some points that could be written into this section, such as deciding on the membership, eligibility, types of members and the time intervals for any rotations. After brief discussions regarding the structure this might take, the Chairperson proposed that Dr Bird put together a draft Governance section to present on the second day of the meeting. It was noted again that the governance of the Regional Alliance is ultimately to be agreed upon by all Member States.

2.3 Bilateral aid

Working Session 2

An informative presentation was given by Professor Lee. Having spent the last five years with NRAs in Myanmar, the Philippines, Thailand and Viet Nam, he opened his talk with a history of the training he had overseen. He emphasized that a number of points will need to be taken into account in the workplan, such as the importance of the support of higher management in organizations for training, and the need for both theoretical and practical training to occur within a short time frame so that learning is reinforced.

2.4 Regional status of NRAs, vaccine procurement systems and associated challenges

Dr Md. Shafiqul Hossain presented an update on the regional status of NRAs, vaccine procurement systems and associated challenges including:

(1) the diversity of the Region (it includes countries with very large and very small populations);

(2) adverse events following immunization (AEFI) surveillance in Pacific island countries and areas;

(3) the functional status of the NRAs in Member States, particularly those who are vaccine-producing countries (Figure 1);

(4) countries requiring quality-assured vaccines regardless of the size of their populations;

(5) the fact that the UNICEF VII system is temporary and will come to an end in 2015. (Many countries in the Pacific have been using the system and will be in difficulty when it ceases.); and

(6) the limited resources of WHO.

Figure 1: Vaccine sources and NRA functional status

SN	Source of vaccine	No of countries/ areas	Functional NRA	Remarks
1	Vaccine-producing countries	5	4	Some countries also procure vaccines from outside
2	Vaccine procured through an independent mechanism	12	3	
3	Vaccine procured through a United Nations agency	19	Nil	Some countries have mixed vaccine procurement

Dr Hossain recommended that an institutional development plan (IDP) could be a major tool to address the training needs of NRAs not yet deemed to be fully functional. He emphasized the positive attitude of the developing countries. Dr Hossain discussed the challenges in strengthening NRAs in the Region, particularly in those countries with smaller populations. Many countries do not have the resources to develop functional NRAs and do not know who to approach for assistance. The challenges are compounded by the increasing numbers and complexity of vaccines available. He provided figures to give an idea of the scale of assistance needed (Figure 1).

2.5 Expected support from the NRAs of the four core countries to other countries

2.5.1 Australia

Dr Bird gave a presentation on behalf of the TGA and introduced his talk with some background information about the TGA, including the fact that the organization is 100% cost-recovered. He stated that the TGA has been involved in training NRAs within the Western Pacific Region for many years. He noted that in the future it would be useful to clarify the needs of NRAs within the Region, and careful planning would assist with effective provision and efficient utilization of resources for training and support. Dr Bird suggested that there

were multiple ways to provide support, including coordinated workshops for multiple NRAs in the Region, training of individual staff at their home NRA, or deployment and attachment of NRA staff to a host NRA. He also mentioned that the TGA had been participating in parallel reviews of new vaccine-marketing authorizations. Mr Belgharbi supported this strategy.

Mr Belgharbi observed that leveraging the time and skills from experts is a common problem in many functional NRAs. It was noted that finding a solution to this was difficult. One option could be to classify training activities on behalf of WHO as staff development. It was agreed that commitment to this work from senior levels within organizations was necessary.

2.5.2 People's Republic of China

Dr Zhang began by confirming that the meeting and the overall objectives of the project were very important. He commented on the fact that China is much "younger" in regulatory terms, having only recently made it through the NRA assessment to be instated as functional.

He said that China would nevertheless do what it could to help, and pointed to the number of vaccines that are regulated in China (against 27 diseases). He emphasized the recent willingness of the country to open up and provide information on such matters. He reported that China has recent experience with vaccines against Japanese encephalitis, H1N1, recombinant Hepatitis E, *Helicobacter pylori*, IPV and EV71.

2.5.3 Republic of Korea

Dr Chiyoung Ahn, Director, Biologics Research Division, speaking for the KFDA, introduced his talk by noting that international health initiatives are recognized in overall Korean Government planning, including continued collaboration with WHO and recent application to PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme).

The KFDA held the first NRA workshop in Seoul and there was a willingness to do more, but funding was limited. He also mentioned he would try to request KOICA (Korea International Cooperation Agency) involvement in establishing the Regional Alliance and providing some assistance.

2.5.4 Japan (Ministry of Health and Labour Welfare, National Institute of Infectious Disease, Japan International Cooperation Agency)

Mr Yasuda commenced by emphasizing the effect of the recent earthquake disaster and financial crisis in Japan. He also demonstrated Japan's generous contributions to United Nations and WHO funds in the past.

Mr Yasuda agreed with other participants that experience could be shared, and developing NRAs could be provided with training opportunities.

Ms Makimoto then outlined the involvement of JICA. She observed that the agency had recently become integrated with the Japan Bank for International Cooperation on the functions of overseas economic cooperation. There are currently two schemes running:

(1) project-type cooperation; and

(2) a training operation (which takes place in Japan).

Ms Makimoto gave examples of a number of past recipients of JICA grants and the successes and challenges associated with them.

JICA is currently running three programmes:

(1) Good governance and general drug administration — a three-week programme with a focus on Asian countries.

(2) Quality manufacture of essential medicines — a four-week programme focusing on GMP, including inspection of facilities.

(3) Vaccine QC technology — in conjunction with the WHO Western Pacific Regional Office and University staff.

All three programmes will finish shortly and JICA is in the process of deciding how to reorganize projects for the future. The new structure needs to be finalized by September 2012, but there is a possibility that there may be more focus on developing NRAs.

The Chairperson thanked the representatives from all core countries for their presentations and moved into final discussions for the day. He asked participants to compose different sections of the draft concept paper for discussion on Day 2 of the workshop.

Mr Belgharbi commented that one way smaller countries could utilize the knowledge and expertise of the core countries was to establish written agreements with functional NRAs. The Chairperson agreed that this type of system may be effective. Dr Hossain mentioned that a similar system had already been used during the H1N1 influenza pandemic, including for AEFI surveillance. Dr Sato added that, in his experience, all the smaller countries would like a subregional system to be established, particularly an AEFI monitoring system. Dr Sato suggested that participants should consider including this in the concept paper. Dr Bird noted that there would be a range of solutions depending on the diverse needs of Member States.

Dr Mitsuhiro Ushio, Executive Technical Advisor to the Director General, Human Development Department, JICA, observed that, 10 to 15 years ago, it was expected that many of the smaller countries in the Region would have functional NRAs by this time; however, it is recognized now that this may not be the solution. Mr Belgharbi remarked that access to regulatory intelligence from a functional NRA may be useful for smaller nations. Participants acknowledge that Pacific island countries have particular requirements that need to be addressed within the context of them having ultimate sovereignty over their regulatory systems.

The workshop reconvened on Day 2 with Dr Bird as Chairperson and Mr. Belgharbi as moderator. Participants who had been assigned to edit sections of the draft concept paper on Day 1 were asked to present their sections. Some of the points raised were that links to Women and Child Health was important, as is a link to the increasing number and complexity of vaccines.

Further discussions were held over the use and meaning of the word “harmonization” and it was agreed that the WHO editors would decide on an appropriate substitute word, which may be “convergence”. Participants agreed that all vaccines should be included in the intent of the vision section.

The discussion moved to the Strategic Objectives section of the paper and there was agreement that the draft presented was acceptable.

Participants noted that detail was required in the Governance section so that Member States could endorse the paper at the next meeting. Some discussion was held regarding the inclusion of observers in the membership of the Regional Alliance. It was agreed that observers are necessary and that the Governance section could go to an appendix in the concept paper. There was agreement about the importance of the consideration of conflict of interest in the section.

2.6 Regional Alliance workplan

The Chairperson suggested dividing into the participants into groups to draft the workplan, based on the strategic objectives presented in the previous part of the workshop. Mr Belgharbi provided a template with appropriate headings to draft the details of the plan. Three groups were formed, each working on separate strategic objectives.

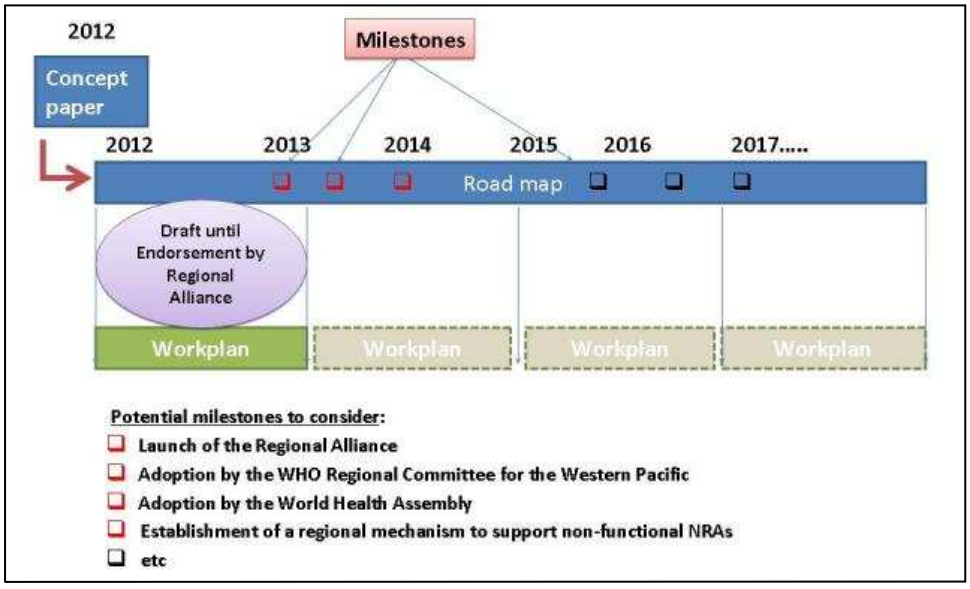
Once the groups had finished drafting their respective sections, a member from each group presented their ideas for the workplan. Mr Rolls presented for Group 1, Mr Belgharbi for Group 2 and Dr Lisa Kerr, Operations Adviser, Office of Laboratories and Scientific Services, for Group 3.

2.7 Road map for implementation of the Regional Alliance workplan

Working session 3

Mr Belgharbi gave an informative and detailed presentation on options for the relationship between the road map and workplan. It was noted that the road map is a long-term plan, covering perhaps five years, while the workplan is intended for a shorter period of time (Figure 2). Therefore several workplans may be developed over the lifetime of one road map. The road map should contain clearly defined milestones. Participants noted the importance of a situation analysis to inform the planning process and it was observed that the WHO Regional Office for the Western Pacific has a considerable amount of data that may assist. Members noted again that the workplan, road map and concept paper remain drafts until endorsed by all Member States.

Figure 2: Western Pacific NRA Regional Alliance road map: Outline



3. CONCLUSIONS

A discussion was held on the next steps to be taken in developing the Regional Alliance and finalizing the outcomes of the meeting. Dr Bird suggested holding a teleconference if further discussions were required to finalize the drafts produced at the meeting. It was concluded that in order to finalize the draft concept paper and workplan, the following steps need to be taken:

(1) WHO and the TGA will coordinate the draft concept paper and draft the workplan to match information.

(2) WHO Headquarters will merge some redundant objectives by 1 June 2012.

(3) The TGA will compile the workplan and send it to the WHO Regional Office for the Western Pacific by 15 June 2012.

(4) The WHO Regional Office for the Western Pacific and WHO Headquarters will develop a template for preparation of a situation analysis by 11 June 2012.

(5) Task force members will provide a situation analysis to the WHO Regional Office for the Western Pacific by 31 July 2012.

(6) The WHO Regional Office for the Western Pacific will circulate the draft concept paper and workplan to task force members for comments by 20 June 2012.

(7) Task force members will provide comments by 16 July 2012.

(8) The WHO Regional Office for the Western Pacific will share both documents with all Member States in the Region by 31 August 2012.

(9) Member States will provide feedback by 31 Oct 2012.

(10) A teleconference or videoconference between all task force members will be organized by 30 November 2012.

(11) A launch meeting will be organized in the first quarter of 2013.

Participants noted their agreement with the proposed next steps, and discussed plans for a second workshop or task force meeting.