WHO-EM/EPI/324/E

Report on the

Intercountry workshop on the establishment of the pooled vaccine procurement system in the Eastern Mediterranean Region

Sharm El Sheikh, Egypt 25–27 June 2013



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1. INTRODUCTION

Given their challenges and immediate requirements, Member States of the WHO Eastern Mediterranean Region have expressed strong interest in establishing a regional pooled vaccine procurement (PVP) system and have requested the WHO Regional Office for the Eastern Mediterranean to initiate, lead and coordinate efforts. The main objective of this initiative is to support countries in introducing new vaccines, strengthening national Expanded Programme on Immunization (EPI) programmes and enhancing regional vaccine supply security.

In 2011 and 2012, during the Fifty-eighth and Fifty-ninth Session of the Regional Committee for the Eastern Mediterranean, two resolutions (EM/RC58/R5 and EM/RC59/R1) were adopted on the PVP initiative.

According to the 2012 resolution:

- Member States are urged to join the first stage of the PVP mechanism by utilizing UNICEF Supply Division (SD) vaccine procurement services, if they are middleincome countries that require procurement support for new vaccines: pneumococcal conjugate vaccine (PCV), rotavirus vaccine and human papillomavirus vaccine (HPV);
- the WHO Regional Director for the Eastern Mediterranean is requested to implement, as soon as possible, the second stage of the regional PVP mechanism.

During a side meeting on the PVP initiative at the Fifty-ninth Session of the Regional Committee in October 2012, some Member States requested procurement support on the pentavalent vaccine (Hib containing) for financial sustainability and supply security concerns.

This workshop represents a key milestone in fulfilling the requests of Member States and moving ahead in the process of establishing a regional PVP system.

The objectives of this workshop were to:

- brief Member States on the background details and progress of the PVP initiative.
- guide Member States interested in joining Stage 1 of the initiative through UNICEF's SD for PCV, rotavirus, HPV and pentavalent vaccines. This entailed a briefing on UNICEF's global middle-income country new vaccine introduction initiative, detailed discussions on UNICEF SD services and requirements from Member States in order to utilize UNICEF SD services. Member State's clear commitments on signing up for the current middle-income countries tender by UNICEF SD and indications of initial demands with a time line are important.

- develop the design of the PVP mechanism at the WHO Regional Office during the second stage of the initiative. This entailed discussions and development of consensus on all related areas to clearly define the rules of the system, such as product selections and specifications (harmonization of products), regulations and specifications of each participating country (harmonization of vaccine regulations), pricing structure and payment method, delivery schedules, roles, responsibilities and obligations of different entities, etc. An understanding of the details and requirements of the designated PVP system by Member States and reaching consensus on the critical aspects (i.e. product selection and harmonization procurement and funding mechanisms, regulation, pricing policy,) are important.
- agree on the next steps for implementation and develop detailed national actions plans to facilitate the required operations to initialize the PVP initiative as soon as possible.

Representatives of eight middle-income countries in the Region were invited to participate in the meeting: Egypt, Iraq, Jordan, Lebanon, Libya, Morocco, Syrian Arab Republic and Tunisia, in addition, Algeria from the WHO African Region. Syrian Arab Republic and Algeria apologised for not being able to participate but expressed their interest in the PVP initiative and the results of the meeting.

Participants included heads of ministry of health departments responsible for immunization; national EPI managers; heads of national regulatory authorities (NRAs) for vaccines; heads of financing departments at the ministry of health; heads of vaccine procurement departments; national focal persons delegated to coordinate PVP activities; if different from those mentioned above. In addition, representatives from UNICEF SD, UNICEF Middle-East and North Africa Regional Office (MENARO), US Centers for Disease Control and Prevention in Atlanta (CDC), the GAVI Alliance, the WHO Regional Office for the Americas (PAHO) and WHO headquarters participated in the workshop.

The workshop was inaugurated by Dr Samir Ben Yahmed, Director of Programme Management, WHO Regional Office for the Eastern Mediterranean, who delivered the message of Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean. He said that the workshop was of critical importance for understanding and agreeing on the requirements needed to make use of the services offered by UNICEF SD (the first stage of the initiative), for discussing the detailed design of the system to be established in the Region and for coming up with tangible action plans both at the regional and country levels to finalize the establishment of the regional system (the second stage of the initiative). He said that the decisions taken in the workshop would be important in reaching the goals and the final outcomes would be reported during the upcoming Regional Committee meeting in October 2013. Together with partners, the WHO Regional Office had put an extensive effort in this initiative and it was crucial to receive firm commitments from Member States at this stage. The request for the establishment of the pooled vaccine procurement system had come

strongly from Member States and without their firm commitments, it would not be possible to proceed further.

The programme and list of participants are included as Annex 1 and 2, respectively.

2. PRESENTATIONS

2.1 Session 1. Detailed briefing on the PVP initiative

During the first session, detailed background information was presented and a briefing provided on the rationale, progress, strategies, benefits and major aspects of the PVP initiative. Information was provided on:

- The introduction of new vaccines in the Region
- global vaccine market trends and features
- detailed information on the PVP initiative and future strategies
- WHO prequalification process and expedited review of vaccine procedures
- regulatory systems in Member States and PVP regulatory requirements
- overview of legal issues for the PVP system
- importance of sustainable financing for national immunization programmes
- importance of product harmonization for the PVP system.

The objective of this session was to equip country participants with background details on the initiative and to answer questions, concerns and requests through open discussion.

Major discussion points during this session are summarized as follows.

- Middle-income countries in the Region have been experiencing financial and
 operational difficulties with the introduction of some new and underutilized vaccines.
 It has been observed that the uptake of such vaccines has been slower in middleincome than high-income and GAVI-supported countries (lower income) in the
 Region despite the availability of information portraying the high burden of related
 diseases.
- Cost of new vaccines and country procurement mechanisms are among the major obstacles. Introduction of new vaccines might increase the overall cost of national immunization budgets multiple times (from four to sevenfold).
- Countries with small quantities or limited predictability of demand are not tempting for vaccine producers.

- The global vaccine market is evolving dynamically and it is important to understand its dynamics, constraints and business incentives. Given the current structure and future projections of the global vaccine market, establishing a regional PVP system emerges as an optimal solution. In the meantime, WHO and partners have been working on other options as well.
- Some participants requested reconsideration of country classifications and extension of GAVI support to remaining lower middle-income countries. The GAVI representative indicated that their Board of Directors mandated the GAVI secretariat to explore opportunities to help the remaining lower middle-income countries, however, changing the current threshold¹ (accordingly the classifications) is not part of their mandate. Currently, GAVI is working to explore opportunities to create some sort of financial security mechanism to back up the current UNICEF middle-income countries tender.
- To ensure that the designated PVP system functions well, the core requirements include:
 - harmonizing demand
 - ensuring demand predictability and reliability
 - aligning regulatory processes
 - establishing clear procurement procedures
 - ensuring sustainable financing.
- Moreover, a certain degree of trust, commitment and protection to the system are required by Member States.
- The quality of vaccines procured by the PVP system will be ensured by the WHO prequalification process and a well-functioning NRA. There are also existing WHO tools and procedures (i.e. expedited review of vaccines for registration,) that can be utilized by Member States. As part of the PVP system, Member States' regulatory requirements can be aligned in a way that creates added value.
- The PVP system is not only about supplying vaccines to Member States, it is about strengthening the capacities of national immunization programmes and immunization systems, in general, and ensuring vaccine quality and security for participating countries.

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¹ Currently, US\$ 1550 for gross national income per capita.

- During Stage 1 of the initiative, UNICEF SD will be working as a procurement agent to achieve an immediate goal: to help introduction of new vaccines in middle-income countries in the Region as soon as possible. In the long run (Stage 2), the PVP initiative envisions establishment of a regional system based on the principles of: country-ownership, solidarity, cooperation, transparency and sustainability. The envisioned PVP system will continue to collaborate with partners such as UNICEF SD and PAHO.
- The PAHO representative commented on the considerable demand potential from the Eastern Mediterranean Region if product harmonization can be achieved. PAHO is currently purchasing 8 to 10 million doses of rotavirus and pentavalent vaccines (of each) per year. Total demand of middle-income countries could reach more than 20 million doses for each of these vaccines if product harmonization and predictable demand are achieved.
- The PAHO representative commented that achieving competitive prices is not only about utilizing economies of scale and having greater negotiating power but is also about building trust with suppliers and ensuring consistency and reliability in the procurement system and financial sustainability.
- As a part of the Global Polio Endgame Plan, at least one dose of IPV is recommended to be introduced by all countries by 2015. Supply security and the prevailing high prices of the IPV are major obstacles in this transition period. However, the PVP initiative can represent an important opportunity in facilitating this transition smoothly, by creating a reliable pooled demand and utilizing economies of scale.
- Member States acknowledged the importance of collaboration with special focus on preserving the strong existing capacities in countries and creating added value for each Member State.

2.2 Session 2. Stage 1 of the PVP initiative through UNICEF's SD

During the first half of the second day, UNICEF representatives gave a briefing on their current global initiative to support the introduction of new vaccines in middle-income countries. The objective of this session was to clarify the details of support provided by UNICEF SD and country required procedures to utilize procurement services.

This global initiative for middle-income countries focuses on PCV, rotavirus and HPV vaccines and the bid solicitation process, which ended in February 2013. The bid solicitation process was based on non-binding initial demand indications from countries and currently UNICEF SD is engaged in analysis of the bids and price negotiations with the suppliers. At this point in time, Member States' clear commitment on signing up for the current tender with clear indications of demand and time lines is crucially important. In this

session, UNICEF SD representatives also clarified financial, administrative and operational requirements from Member States to utilize procurement services.

UNICEF SD indicated that procedures already existed to extend their middle-income countries initiative to pentavalent vaccine (Hib containing). Interested Member States can benefit from this procurement support starting from 2014 if they officially submit their demand indications by September 2013.

As communicated on many occasions (i.e. during the Fifty-ninth session of the Regional Committee) to partners and Member States by UNICEF SD, the procurement support for middle-income countries for the introduction of new vaccines was initially planned to be time limited. However, during the workshop, UNICEF SD representatives clearly indicated that they will be providing continuing support to middle-income countries as needed. This major change in UNICEF SD's previously envisioned plans was considered by country representatives present at the meeting as very positive. In addition to the fact that it gives more time to build capacities for the establishment of Stage 2 of the PVP initiative and extend future collaboration options with UNICEF SD. Moreover, UNICEF SD representatives indicated that interested middle-income countries can acquire procurement support for all other vaccines (including traditional vaccines) through UNICEF SD's procurement service mechanisms as well.

2.3 Session 3. Stage 2 of the PVP initiative through the WHO Regional Office

As a conceptual introduction to the design of the second stage of the PVP initiative, the PAHO representative briefed participants on PAHO's PVP system and the revolving fund. Member States of the Region iterated their appreciation of PAHO's system and their desire to adapt a similar system in the Region.

The afternoon session of the second day involved a group work activity. Participants were divided into three groups related to major aspects of the PVP initiative:

- programmatic
- procurement, operations, legal and financial
- regulation and quality.

The main objectives of the working groups were to discuss PVP guidelines, Standard Operating Procedures (SOPs) and other contracting documents drafted by the Regional Office PVP working group, in collaboration with partners (shared with participants in three languages prior the workshop), and develop consensus on all the above-mentioned aspects of the PVP initiative (both for Stage 1 and Stage 2), with particular focus on: product selections and specifications (harmonization of products), pricing structure and payment methods, delivery schedules, roles, responsibilities and obligations of different entities in operations and regulation. During the working group sessions, participants discussed the details of the pooled procurement system extensively and provided valuable inputs.

In reporting back to the plenary, the three groups clearly acknowledged the expected benefits of utilizing UNICEF SD services for the introduction of new vaccines during Stage 1 of the initiative, and requested time to brief their governments and return with their final decision about utilizing Stage 1. However, participants stated that they did not consider the PVP initiative as being just a procurement support mechanism but would like to see it as a sort of platform for collaboration and communication to strengthen their national immunization programmes in many aspects, inspired by the example of the PAHO system. In that regard, Stage 2 of the PVP initiative still carries special importance for them.

Participants expressed concerns about the need for more clarity on how UNICEF SD is considering the concept of pooling of demand. They clearly stated that they would like to be considered in the tendering process as one unified block of demand (rather than differentiating the demand and price for each country, pooling the whole demand for participating countries as one entity). They also requested the provision of continuous technical support and the close engagement of the Regional Office during every step of the process during Stage 1. In addition, UNICEF SD was requested to explore the possibility of the Regional Office's involvement in the tendering process and price negotiations (similar to the example of malaria drugs).

Acknowledging the requirements of UNICEF SD, country participants also stressed the specific characteristics of middle-income countries existing procurement, operational and regulative requirements, which are obviously more structured than many of the GAVI-supported countries that UNICEF SD used to deal with.

For this reason, participants clearly requested that their countries be treated in a way that respects their strengths and builds more their capacities related to above-mentioned specific characteristic and requirements. This request applies as well to the final stage of the PVP system.

Other major discussion points from this session are summarized by the following.

- UNICEF SD's requirements from Member States to officially subscribe are to:
 - submit a formal letter of intent indicating firm commitment
 - provide product, volume and timing preferences
 - sign a valid memorandum of understanding (MoU) with UNICEF for utilization of procurement services
 - produce clear documentation regarding the rules and regulations of the
 Member States for importation and clearance procedures of vaccines.
- The UNICEF SD representative indicated that the letter of intent could be submitted before the signature of the MoU (if it is not currently available).
- Member States stressed the importance of having more clarity on timelines. They requested from UNICEF SD to prepare a document describing the current tendering

process, expected timelines and price range indications (general information required for initial cost estimates, not necessarily the currently confidential information).

- Member States requested from UNICEF SD to consider incorporating some flexibility to the contracted amounts with the suppliers so that Member States can update the delivery quantities (i.e. the countries can change the initial forecasted amounts by +/-5% before each delivery). This request also applies to the PVP system during Stage 2 of the initiative.
- In addition to new vaccines, Member States requested that procurement support be extended to all vaccines. UNICEF representatives reminded participants of the existence of conventional procurement service mechanism that allows Member States to utilize UNICEF SD services for all vaccines depending on bilateral agreement. However, Member States requested that this service be provided in a coordinated and pooled manner, rather than bilateral agreement and on an ad-hoc basis.
- As a part of the practice to harmonize the demand for the pentavalent vaccine, most Member States expressed their initial interest in liquid and whole cell type pentavalent vaccine (DTwP-Hib-HepB) and presentation (number of doses per vial; single or multi-dose) to be subject to country experience with wastage and price difference. Only Jordan indicated an interest in a cellular pentavalent vaccine with combination type: DTaP-Hib-IPV.
- In terms of harmonizing demand for PCV, Member States agreed that single-dose PCV13 would be preferred if the local epidemiological data are not available and price difference is not significant (versus PCV 10). If local epidemiological data are available, the choice between PCV 13 and PCV 10 should be guided accordingly.

Table 1 indicates Member States' current utilization and interest in new vaccines.

Table 1. Current utilization status and interest of Member States in new vaccines

Country	Pentavalent (Hib)	PCV	Rota
Egypt	Introducing	Interested	Cost–effectiveness analysis required
Iraq	Introduced	Interested	Introduced
Jordan	Introduced	Interested	Interested
Lebanon	Introduced	Interested	Cost–effectiveness analysis required
Libya	Introduced	Introduced	Introduced
Morocco	Introduced	Introduced	Introduced
Tunisia	Introduced	Interested	Cost–effectiveness analysis required

In terms of vaccine regulation, discussion focused on the following:

- The WHO prequalification system is not being systematically used by all Member States.
- In many Member States, the registration process is complicated and lengthy.
- NRAs in countries supplied through UNICEF SD, generally perform two regulatory functions: registration and post-marketing surveillance. With the exception of Iraq and occupied Palestinian territory, middle-income countries in the Region are implementing two other regulatory functions: lot release and laboratory control. During the working group discussions, country participants requested from the PVP initiative (both in Stage 1 through UNICEF SD and Stage 2 through WHO Regional Office) to secure a mechanism to respond to Member States' requirements in all four functions.
- In order to meet this request, one possibility could be establishing a sort of intercountry working group (comprising three to four country NRAs on rotational basis) that would develop standardized procedures and meet regularly to provide recommendations and guidance to Member States to facilitate vaccine regulatory matters (registration, batch release, laboratory control and pharmacovigilance).

2.4 Session 4. Developing country action plans

Participants worked by country to develop national action plans for participation in the PVP initiative. The objective of this session was to clarify major action points to be taken by each of the participating Member States following the workshop, that would lead to the signing of country agreements with the PVP mechanism, preferably by October 2013 at the time of the next session of the Regional Committee. The action points generally focused on seeking the endorsement of decision-makers to officially subscribe to the current UNICEF SD tender on middle-income countries for PCV, HPV and rotavirus vaccines as soon as possible, sending official demand indications for the pentavalent vaccine (2014 demand) by September 2013, and formulating national working groups to manage required changes and action, etc.

3. **RECOMMENDATIONS**

To Member States

- 1. Communicate the outcomes of this meeting with respective national decision-makers in order to seek endorsement on the decisions taken and to brief them on the expected actions to be taken in the following period.
- 2. Appoint a focal point and constitute a national working group to facilitate participation in the PVP system (fulfilling requirements and overcoming obstacles).

- 3. Discuss financial requirements (advance payment and paying in hard currency) of UNICEF SD with relevant authorities and obtain their approval on feasibility and implementation.
- 4. Countries planning to introduce new vaccines are encouraged to officially subscribe to UNICEF SD's current middle-income countries tender on PCV, HPV and rotavirus vaccines, as soon as possible. For that purpose, UNICEF SD's requires:
 - a formal letter of intent indicating firm commitment
 - information on product(s), volume and timing preferences
 - signing of a valid MoU with UNICEF for utilization of procurement services
 - ensuring clear documentation regarding the rules and regulations of the Member
 States for importation and clearance procedures of the vaccines.
- 5. Countries interested in using UNICEF SD services for pentavalent vaccine have to, in addition to the above requirements, provide initial commitment and demand indications for the pentavalent vaccine (for 2014 demand) by September 2013.
- 6. Provide feedback on the background, operating procedures and system policy documents that were drafted by the WHO Regional Office for the envisioned PVP system in the Region (for Stage 2), and share with country representatives to the meeting by the end of August.
- 7. Countries are encouraged to get ready to sign an official commitment (in the form of a MoU between the Member States and the WHO Regional Office) during the Sixtieth session of the Regional Committee in October 2013.
- 8. Decisions regarding the introduction of new vaccines are taken solely by the Member States. Member States should develop the necessary introduction plans, revise their country multiyear plans and secure the necessary funds.

To WHO Regional Office for the Eastern Mediterranean

- 9. Communicate the outcomes of this workshop to Member States, urging them to take necessary actions for the expected commitments from their side.
- 10. Continue collaboration with UNICEF SD to address country-specific requirements for joining Stage 1 through UNICED SD supply services.
- 11. Facilitate the pooled procurement of the pentavalent vaccine for interested Member States by UNICEF SD starting from 2014. The demand planning process will start by the end of August 2013.
- 12. Provide continuous technical support to Member States on programmatic, regulatory and demand planning aspects in order to help them to utilize UNICEF SD procurement services during Stage 1 of the initiative. As per the requests of the Member States, being closely and actively associated in all processes during Stage 1.

- 13. Design and implement Stage 2 of the initiative as requested by the Member States, as a platform for collaboration and communication to strengthen their national immunization programmes in many aspects.
- 14. Follow up with the GAVI secretariat and explore future opportunities for collaboration in the PVP initiative.
- 15. Provide detailed information on the progress of PVP during the upcoming session of the Regional Committee and encourage official commitments of the Member States through a customized MoU prepared for the PVP initiative.
- 16. Establish a coordination mechanism to respond to Member States' requirements to enhance their regulatory capacities. Coordinate the establishment of a regional committee to develop a standardized procedure and to meet regularly to provide recommendations and guidance to Member States in vaccine regulation issues (i.e. registration, batch release, laboratory control and pharmacovigilance).

To UNICEF SD

- 17. Send a letter to Member States to seek their official subscription to the tender on PCV, HPV and rotavirus vaccines with an attached explanatory document describing the process, expected timelines and price range indications (general information required for initial cost estimates, not necessarily the currently confidential information).
- 18. Finalize the bid analysis process on the current tender for PCV, HPV and rotavirus vaccines and inform WHO Regional Office and Member States about the results and financial and operational details.
- 19. Initiate the demand planning process for the pentavalent vaccine (2014 demand).
- 20. Respond to participants' requests to constitute a demand block for the middle-income countries of the Region (rather than differentiating the demand and price for each country, and pool the whole demand for the Region as one entity).
- 21. Explore the possibility of the WHO Regional Office's involvement in the tendering process and price negotiations (similar to the example of malaria drugs).
- 22. UNICEF country offices should assist, inform and guide Member States in fulfilling the requirements (letter of intent, MoU and forecasting procedures) to utilize UNICEF SD procurement services.

Annex 1

PROGRAMME

Tuesday, 25 June 2013

08:00–08:30 08:30–09:00	 Registration Opening session Message from Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean Objectives of the workshop and adoptation of the agenda Expected outcome and decisions Introduction of participants Session 1. Detailed briefing on the PVP initiation	Dr S. Ben Yahmed WHO/EMRO ve
09:00-09:20	New vaccines introduction in the Eastern Mediterranean Region	Dr N. Teleb EMRO/VPI
09:20-09:40	Global vaccine market	Dr M. Kaddar HQ/IVB
09:40–10:00	Comments from partners on shaping the vaccine market	Partners
10:00 -11:00	Discussions	
11:00–11:20	PVP Initiative: rationale, background, benefits, challenges, principles, stages, progress and upcoming actions	Dr E. Mohsni EMRO/VPI
11:20-11:40	Discussions	
11:40–12:05	WHO prequalification process	Dr N. Dellapiane HQ/QSS
12:05- 12:20	Discussions	
12:20 –12:45	WHO procedures for expedited review of imported prequalified vaccines for use in national immunization programmes	Dr N. Dellapiane HQ/QSS
12:45–13:45	Discussions	
13:45–14:05	Current status of vaccine regulatory systems in participating countries to the PVP system and PVP regulatory requirements	Dr H. Langar EMRO/VRP
14:05–14:30	Discussions	

14:30–14:50	Overview of legal issues and requirements for the PVP system	Mr I. Matta HQ/Legal
14:50-15:30	Discussions	
15:30–15:50	Importance of sustainable financing for national immunization programmes	Mr J. Fitzsimmons CDC/Atlanta
15:50–16:10	Product harmonization	Dr I. Chaudhri EMRO/VPI
16:10-16:40	Discussions	
16:40–17:00	Wrap up for Day 1	

Wednesday, 26 June 2013

Session 2. Stage 1 of the PVP initiative through UNICEF SD

08:30-8:40	Introductory remarks	Dr J. Mahjour		
		EMRO/DCD		
08:40-09:10	UNICEF SD initiative on middle-income countries	UNICEF SD		
	for the introduction of new vaccines			
09:10-09:30	Discussions			
09:30-10:00	UNICEF procurement procedures and requirements:	UNICEF SD		
	roles and responsibilities for Stage 1			
10:00-10:30	Overview of UNICEF procurement operations	UNICEF SD		
10:30-11:30	Discussions			
S	Session 3. Stage 2 of the PVP initiative through WHO Reg	gional Office		
11:30-1:50	PAHO revolving fund experience: benefits and	Ms M. Pereira		
	challenges, roles and responsibilities, procurement	PAHO		
	cycle and governance structure			
11:50-12:15	Discussions			
	Group work on major aspects of the PVP system			
12:15-12:30	PVP Initiative: introduction to group work sessions,	Mr M.H. Ozturk		
	objectives, background documents and expected	EMRO/VPI		
	outcomes			
12:30–14:15	Group work			
	Group 1: Programmatic aspects			
	Group 2: Procurement, operational, financial and			
	legal aspects			
	Group 3: Regulatory aspects			

17:00–17:30 Wrap up for Day 2 (within each group)

Thursday, 27 June 2013

Session 4. Developing country action plans

11:15–11:20	Introduction to the session	Dr E. Mohsni EMRO/VPI
11:20–14:30	Group work: countries working on their requirements and action plans supported by participants from WHO, UNICEF, CDC Atlanta and PAHO	
14:30–17:30	Presentation from each country on action plans 10 minutes presentation followed by 10 minutes discussion for: Egypt, Iraq and Jordan, Lebanon, Libya, Morocco and Tunisia	
17:30–18:00	Steps and closing remarks	

Annex 2

LIST OF PARTICIPANTS

EGYPT

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