

MEETING REPORT

SUB-REGIONAL WORKSHOP ON VACCINE PROCUREMENT

Tbilisi, Georgia
April 10-12, 2019



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Introduction

This report summarizes key discussions and outcomes from the first Sub-Regional Vaccine Procurement Workshop co-hosted by the Learning Network for Countries in Transition (LNCT) and the UNICEF Vaccine Procurement Practitioners Network (VPPN), held April 10-12, 2019 in Tbilisi, Georgia. LNCT members Armenia, Georgia, Moldova and Uzbekistan joined fellow VPPN members North Macedonia and Serbia for three days of focused exchange to discuss vaccine procurement options and issues of registration, regulation, forecasting, budgeting, and performance assessment.

Vaccine procurement was identified as a priority challenge by several LNCT countries navigating the Gavi transition, as well as, countries attending the 2018 Global Vaccine Procurement Practitioners' Exchange Forum (VPPEF) in Copenhagen. Participants from the six European region countries included key representatives from ministries of health, ministries of finance, national regulatory agencies, and national public health institutions. Joining these country participants to discuss procurement-related issues were experts from UNICEF, WHO and LNCT. Please refer to [Annex 1](#) for the full participant list. The meeting was organized by LNCT's regional partner [Curatio International Foundation \(CIF\)](#) and opened by Dr. Akaki Zoidze, Head of the Health and Social Issues Committee for the Parliament of Georgia.

LNCT (pronounced, "linked") is a peer learning network for countries in various stages of transition from Gavi support. LNCT promotes dialogue, shared learning, and collaborative problem solving to support countries to effectively manage their transition, maintaining strong and sustainable immunization programs. LNCT uses a country-driven model of engagement in which members continuously work together to:

- Identify and address key challenges in transitioning from Gavi support;
- Assess their technical and organizational needs for addressing those challenges; and
- Share best practices and explore shared challenges.

Hosted by the UNICEF Supply Division in Copenhagen, Denmark, the VPPN is a network of senior-level practitioners and technical experts from middle-income countries, UNICEF and partner organizations who exchange knowledge and learn from each other's experiences online and at in-person events.

On the VPPN's discussion forum, participants meet to collaboratively solve challenges related to their vaccine procurement practices, for example:

- Establishing collaborative processes to help practitioners identify resources and organize around purposeful actions that deliver tangible results;
- Exchanging market intelligence;
- Developing procurement options and strategies; and
- Opting-in for vaccine tenders.

While this is the first sub-regional vaccine procurement workshop co-hosted by LNCT and the VPPN, the VPPN previously held another workshop in Bishkek in 2018.

Throughout the workshop, country participants discussed procurement-related challenges and experiences, shared successes, and revised their VPPEF country action plans to strengthen their regulatory and procurement systems based on learnings from the workshop.

Setting the Stage

To facilitate the sharing of experiences across countries, prior to the workshop, each country team



prepared a poster summarizing their vaccine procurement processes. Posters included the procurement mechanisms for routine vaccines; a vaccine procurement organogram; a summary of vaccine procurement in practice, including regulatory framework, sources of financing, sources of market information, recent vaccine introductions, and shortages and stockouts; as well as key procurement challenges and future plans. The posters were presented during set-aside “gallery walk” sessions across all three days

enabling all meeting participants to not only gain a detailed understanding of the experiences of other countries in the region but also to spark conversations among participants from different countries.

On the first day, participants were asked to articulate their main expectations for the workshop and describe their key issues and challenges related to vaccine procurement. The following were identified as the priority procurement-related issues among the participants: vaccine registration; high prices for vaccines; budgeting; procurement planning, timely delivery of vaccines; absence of multi-year contracting; and global vaccine shortages.



Day 1 – Vaccine Regulatory Challenges

The focus of the workshop’s first day was vaccine regularity and registration processes and challenges and was facilitated by WHO expert Alireza Khadem. WHO’s Global Benchmarking Tool (GBT) for evaluation of national regulatory systems was presented. Each country’s regulatory requirements were mapped, and the GBT Performance Maturity Levels were reviewed. Participants expressed interest in risk evaluation as a key step to balancing the risk and benefits prior to putting a vaccine product on the market.

The key qualifiers for a "functional" or "not functional" National Regulatory Agencies (NRA) were discussed based on the WHO Performance Maturity Levels. According to a WHO study, of the 194 member countries, only 50 (26%) have met the most advanced maturity levels (ML) 3 and 4; others (74%) have not met the requirements in terms of regulation, which results in many of the challenges countries noted in terms of regulation.

A key discussion topic was WHO's Prequalification (PQ) and Collaborative Registration Procedure, which allows countries to accelerate access to prequalified products by reducing duplication of efforts, optimizing use of resources, promoting collaboration and reliance concepts, and significantly reducing registration days.

Also discussed was the Good Regulatory Practice (GRP) system that includes four activities: scientific evaluation and oversight, vigilance and surveillance, inspection and audit, and quality control and testing. Based on NRA capacity, countries could choose different levels of effort across the NRA registration pathway. The steps along this pathway include: (1) Recognition (such as recognizing the evaluation of reference NRAs and WHO PQ); (2) Reliance (such as secondary or tertiary reviews of primary reports from other agencies e.g. SRA or WHO PQ); (3) Work-sharing (such as EU decentralized procedure, ZAZIBONA); (4) Joint activities (such as WHO-EAC joint assessments); and (4) Full assessment (decisions are based on information 100% generated by NRA).

Armenia presented its drug registration system. The country experiences challenges similar to many of the other countries in attendance, such as small market volume and an import-dependent market.



According to National Drug Registration rules, while the standard procedure needs only 140 days, registration through the Eurasian Economic Union (EAEU) requires 210 days. To simplify the registration process and make the country market more attractive, a revision of the Governmental degree allowed a simplified registration of WHO pre-qualified products within 40 days.

Day 2 – Vaccine Planning, Forecasting and Budgeting

The second day brought discussions on the importance of strong linkages between vaccine supply and management, procurement, budgeting and finance, and regulation, as well as presentations from UNICEF on vaccine planning and forecasting. Following a site visit to the National Center for Diseases Control and Public Health (NCDC), there were presentations and discussions around challenges, tools and approaches for optimization of vaccine budgeting and financing.

Loic Sanchez and Aurelia Gasca from UNICEF Supply Division presented the best practices and processes for successful procurement and emphasized the importance of effective communication between EPI managers, policy-makers and suppliers to avoid over-stocks and stockouts.

UNICEF presented its approach to providing technical support to governments to build strong, sustainable supply chains. They look at the supply chain enablers and operations to: 1) identify county needs; and 2) align these with UNICEF's comparative advantages.

The ViVa tool was presented to participants. ViVa is a free online tool that shows current stock levels and future stock projections, including confirmed and forecasted orders from UNICEF. ViVa helps countries to see if their stock levels are sufficient before the next order arrives, and whether additional funding is needed to confirm an order.



North Macedonia presented its procurement challenges, among which the most critical is low interest from manufacturers due to its small market size which creates a high risk of vaccine deficiency. To address the issue, the country introduced multi-year public procurement leading to high reliability of a sufficient quantity of vaccines.

The session on vaccine budgeting tools and best practices was hosted at the NCDC. Following an introductory presentation from Sviatlana Kavaliova (UNICEF RO) and Oleg Benes (WHO-EURO), countries shared their own best practices. Uzbekistan presented an excel-based tool which calculates the quantity and cost of vaccines to be purchased, while Georgia presented an e-module linked to civil registration and e-Health systems allowing for the generation of multi-dimensional immunization reports and real-time tracking of vaccines stocks down to the facility level.

Site Visit

Participants visited the NCDC where they had a chance to see the central vaccine warehouse and Lugar Center Laboratory and learn more about the NCDC's work. The Lugar Center consists of modern biosafety level (BSL)-2 and BSL-3 laboratories, which detect and identify human and animal pathogens in a timely manner. The BSL-3 facility is unique in the entire Caucasus and Central Asia Region. Strains of infectious disease causative agents, including Especially Dangerous Pathogens are stored at NCDC Bacterial and Viral National Repository. Currently the Lugar Center is in the process in obtaining status as a WHO Collaborating Center in antimicrobial resistance. The central warehouse has enough space to accommodate the nations vaccine supply and is equipped with modern freezer-refrigerators with temperature monitoring alarm systems.



Day 3 - Criteria to Assess Vaccine Procurement Performance

The sessions on the third and final day examined the principles of strategic purchasing and the various procurement modalities, including self-procurement, partial self-procurement, pooled procurement and UNICEF procurement. These sessions were led by Miloud Kaddar (LNCT) and Loic Sanchez (UNICEF SD).

Of particular interest to participants was understanding factors causing variations in the price of the same vaccine from the same manufacturer and supplier between the countries. The factors influencing the prices are: custom duties, taxes, insurance, transportation, packaging, and pricing. Also, the manufacturers set the price based on the country's economy level.

Following breakouts for group work in which countries discussed vaccine procurement challenges and issues, Moldova and Serbia presented. Moldova has graduated from Gavi support and faces a number of challenges related to rigid legislation that does not allow innovative procurement mechanisms and high registration prices. Serbia, like other countries in the region, faces challenges related to small market size and long waiting times for vaccines after procurement leading to the risk of stock-out. To address these challenges, Serbia engaged with industry manufactures and negotiated inclusion of vaccine delivery in the contracts. Serbia also established a separate budget line for vaccines to address resource challenges.

Country Team Work and Group Discussions

Over the course of the workshop, country teams regularly broke out to identify procurement-related challenges, discuss the applicability of learnings from technical experts and other countries during the workshop to those challenges, and finally develop action plans to address those challenges. Please find below summaries of the discussions during those breakout sessions.

One breakout session was dedicated to filling out country profiles on regulatory requirements. The results are presented below:

| Question | Armenia | Geo | Macedonia | MLDV | SRB | UZB |
|--|---------|-----|-----------|---------------|-----|-----|
| 1) Is there a policy, procedures and/or mechanisms for recognition and reliance on decisions of other NRAs, organizations or procurement agencies, etc.? | YES | YES | NO | NATIONAL ONLY | YES | YES |
| 2) Is there a specific regulatory pathway to register/authorize PQ vaccines? | YES | NO | YES | YES | NO | NO |
| 3) Do the legal provisions enforce registration/authorization of PQ vaccines in your country? (all PQ vaccines are registered already) | YES | YES | YES | YES | NO | YES |
| 4) Are there established guidelines that cover circumstances under which the routine Marketing Authorization/registration procedures may not be followed (e.g., for public- health interest) | Yes | YES | YES | YES | Yes | NO |
| 5) There is a vigilance system to report, analyse and provide feedback/decisions on Adverse Events Following Immunization (AEFI) cases? | Yes | Yes | YES | YES | YES | YES |
| 6) Is it necessary to conduct a GMP inspection for the purpose of registration of a PQ vaccine? | NO | NO | NO | No | NO | NO |
| 7) Is it necessary to test the vaccines either for the purpose of registration or lot release? | NO | NO | NO | NO | YES | NO |
| 8) Is it necessary to conduct a clinical trial for the purpose of registration of a PQ vaccine? | NO | NO | NO | NO | NO | NO |
| 9) Is it necessary to review the summary lot protocols (SLP) of the PQ vaccines before releasing them to the market? | YES | YES | YES | YES | YES | YES |

Another breakout session had countries consider the advantages, disadvantages, and feasibility of pursuing an alternative procurement modality. A summary of the country discussions is presented below.

- Uzbekistan.** UNICEF is the main procurement source for the country. The country faces several challenges in areas such as: weak capacity for data forecasting and planning; legal restrictions precluding the use of different procurement modalities; currency instability impacting cost; and a mismatch between ordered and received commodities (vial size) from UNICEF.
- North Macedonia.** Challenges include a very small market; legal restrictions will not allow direct procurements without tender procedures; delays from international suppliers leading to stock challenges; no legal recourse for holding suppliers accountable for delivery delays; and while the advantages of pursuing pooled procurement are obvious, they are not feasible under current regulations.



- **Serbia** is considering a pooled procurement mechanism with neighboring countries and is aiming to reach WHO maturity level 3. The advantages of this mechanism are accessing additional suppliers and, possibly, better prices. The disadvantages include political issues and possible industry resistance to the idea. In terms of feasibility, there are no obstacles at the regulatory level. Serbia is supporting the harmonization process and considering a solution to ease registration for manufacturers.
- **Moldova.** The advantages of pooled procurement for Moldova would include: low prices, access to the global market, a memorandum with south Eastern part of EU, license collaboration and capacities. The main disadvantage would be current lack of human resource capacity needed. Challenges to pursuing this procurement modality include weak leadership and resource constraints. In terms of feasibility, key obstacles would be harmonization of the legislation, the registration process, financial instability, variations in schedule, political commitment, and weak capacity.
- **Armenia** considered pooled procurement. International tenders are beneficial as they often result in lower prices when compared to local tenders, and the current legislation does not preclude pooled procurement.
- **Georgia.** While the advantages of pooled procurement are clear and obvious, the feasibility is low for Georgia due to misalignment of legislation and procurement calendars across the countries, making use of this modality impossible.

Throughout the workshop some breakout sessions focused on country revision and further development of their VPPEF action plans. These were initially developed with countries in Copenhagen. The plans were updated based on learnings from the workshop, and then countries were grouped for peer review of the revised action plans, allowing countries to provide feedback on the plans of other countries at the workshop. The final action plans were provided to UNICEF SD and LNCT and will be followed up on during routine check-ins with countries.

Key Takeaways

The following section summarizes challenges and lessons learned shared during the workshop.

In the context of global supply constraints and small market sizes most of the countries face risk of sustainable supply of quality vaccines at best price. A rich discussion of best practices and country procurement experiences raised the following key points:

- Countries' vaccine regulation and registration systems as well as procurement practices present similar challenges across the countries such as regulations that limit market entry, procurement capacity deficiencies, misalignment of legislation for pooled procurement, etc.
- Smart vaccine regulation and registration systems and various vaccine procurement modalities is key to improve attractiveness to suppliers

- Recognition policies such as WHO PQ and collaborative registration procedures reduce regulatory burden and duplication to NRA and accelerates registration process;
- Pooled procurement may be difficult to achieve in the near future; however, some elements can already be introduced (e.g. exchange of market intelligence across countries).
- Strong vaccine planning, forecasting and budgeting practices coupled with vaccine procurement performance assessment is essential for effective strategic procurement
- Vaccine procurement involves wide range of actors and skills and requires strong coordination and alignment between entities in charge of immunization, budgeting, procurement and regulation.

Effective solutions shared by the countries:

- **Armenia** issued a governmental decree that allows drugs and vaccines that are registered in International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) countries or have WHO pre-qualification to undergo a simplified procedure to be registered in just 30 days instead of the standard 140;
- **Georgia** uses data on demographics, coverage, stock, vaccine loss, and warehouse and cold chain capacity from an electronic data management system to support immunization planning and budgeting. Watch [this video](#) to learn more about Georgia's electronic data management system. Over the years use of strong case justifications along with other factors led to introduction of three new vaccines, and contributed to a 500% increase in the EPI budget since 2012
- **Moldova** separated their procurement agency and national regulatory authority to avoid conflicts of interest that can arise when the same agency that procures vaccines is also in charge of evaluating vaccine quality and performance. Now, the independent national regulatory agency approves specifications proposed by the National Agency of Public Health, while tenders are carried out separately by the Center for Centralized Health Procurement
- **Uzbekistan** partnered with UNICEF to conduct a mapping of immunization financing sources and to develop a new multi-year budgeting tool that considers all components of an immunization budget, including the cost of cold chain equipment and maintenance. The Excel-based tool calculates the quantity and cost of vaccines and supplies to be purchased based on adjustable parameters including target population, coverage, vaccine stock, buffer, price, and exchange rates, and is fully compatible with the cMYP.
- **North Macedonia** increased the efficiency of its procurement process and reduced the frequency of stockouts by switching to multi-year procurement, centralizing procurement for vaccines and other drugs, and introducing an Electronic System for Public Procurement.
- **Serbia** has worked hard to strengthen its NRA as a vaccine producer to WHO maturity level 3 of a possible 4. Level 3 indicates a stable, well-functioning and integrated system for oversight of medical products. Serbia has also established a separate line item for vaccines and ensures that when the country does not spend the full allocated amount, the savings can be re-invested in the vaccine budget rather than being directed elsewhere.

Annex 1 – List of Participants

| ## | COUNTRY | PARTICIPANT | ORGANIZATION | POSITION | EMAIL |
|----|------------|----------------------|-------------------------------|---|---------------------------------|
| 1 | Armenia | Varduhi Grigoryan | MoH | Head of Department for Drug Policy and Medical Technologies | varduhig@mail.ru |
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|----|-----------|--------------------------|---|--|--|
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| | | | | | |
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| 47 | Guest | Akaki Zoidze | Parliament | Head of Parliamentary Committee for Health and Social Affairs | a.zoidze@parliament.com |
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Annex 2 – Workshop Agenda

| Wednesday April 10 th Setting the stage and vaccine regulatory challenges | Thursday April 11 th Vaccine planning, forecasting, and budgeting | Friday April 12 th Vaccine procurement options and performance assessment |
|---|---|---|
| 8:30-9:00 Check-in and registration | 8:30-9:00 Check-in | 8:30-9:00 Check-in |
| 9:00-10:00 Welcome <i>Opening ceremony, introductions and icebreaker</i> Facilitation: Miloud Kaddar (LNCT), Loic Sanchez (UNICEF-SD), Grace Chee (LNCT) Guest Speakers: Akaki Zoidze (Head of the Health and Social Issues Committee, Parliament of Georgia), Tamar Gabunia (Deputy Minister of the Ministry of Internally Displaced Persons from Occupied Territories, Ministry of Health, Labour and Social Affairs) | 9:00-9:30 Session 5 – Supply chain spectrum <i>Interlinkages between vaccine procurement and the supply chain spectrum</i> Facilitation: Loic Sanchez | 9:00-9:30 Site visit feedback <i>Discussion of key observations and lessons</i> Facilitation: Ivdity Chikovani (LNCT) |
| 10:00-11:00 Session 1 – Intro to vaccine procurement and regulatory issues <i>Expectations from the workshop, Presentation on WHO regulatory guidelines</i> Facilitation: Alireza Khadem (WHO) | 9:30-10:30 Session 6 – Intro to UNICEF vaccine planning and forecasting <i>Presentation and Q&A, Macedonia to present tools and practices</i> Facilitation: Aurelia Gasca (UNICEF-SD) | 9:30-10:30 Session 8 – Intro to vaccine procurement challenges and options <i>Review the vaccine procurement options and challenges</i> Facilitation: Miloud Kaddar, Loic Sanchez |
| 11:00-11:30 Coffee break & gallery walk | 10:30-11:00 Coffee break & gallery walk | 10:30-11:00 Coffee break & gallery walk |
| 11:30-12:30 Session 2 – Focused country exchange on vaccine regulatory issues & NRA functioning <i>Overview of country situations, Country groups develop action plans</i> Facilitation: Alireza Khadem, Miloud Kaddar | 11:00-12:45 Site visit – National Center for Disease Control and Public Health (NCDC) PASSPORTS REQUIRED. Please be in the hotel lobby at 11:00 AM for departure to the NCDC. <i>Groups will visit the vaccine warehouse and Lugar laboratory, and learn more about the NCDC</i> Facilitation: Khatuna Zakhshvili (NCDC) | 11:00-12:30 Session 9 – Focused country exchange on vaccine procurement challenges and options <i>Group exercise to identify procurement challenges which can be addressed by alternative procurement methods</i> Facilitation: Miloud Kaddar, Loic Sanchez, Oleg Benes Country Experiences: Alexei Ceban (Moldova), TBD (Serbia) |
| 12:30-12:35 Group photo Please stay in the room before going to lunch for a group photo. | | |
| 12:35-1:30 Lunch | 12:45-1:30 Lunch at NCDC | 12:30- 1:30 Lunch |
| 1:30-2:15 Session 2 cont’d– Country report outs | 1:30-3:00 Session 7 – Focused country exchange on vaccine budgeting tools and best practice (at NCDC) <i>Challenges, tools and approaches for optimization of vaccine budgeting and financing</i> Facilitation: Sviatlana Kavaliova (UNICEF RO), Aurelia Gasca, Oleg Benes (WHO-EURO) Country Experiences: Dilorom Tursunova (Uzbekistan), Natalia Kachlishvili (Georgia), Gia Kobalia (Georgia), TBD (Macedonia) | 1:30-3:00 Session 10 – Vaccine procurement performance assessment <i>Presentation on criteria to assess vaccine procurement performance, Shared country experiences on tools and practices, Q&A</i> Facilitation: Miloud Kaddar, Loic Sanchez, Oleg Benes |
| 2:15-3:30 Session 3 – Introduction to vaccine registration processes and issues <i>Panel discussion</i> Facilitation: Alireza Khadem Country Experiences: Vardui Grigorian (Armenia) | | |
| 3:30-4:00 Coffee break & gallery walk | 3:00-3:30 Travel from NCDC to the Hotel | 3:30-3:45 Coffee break & gallery walk |
| 4:00-5:30 Session 4 – Focused country exchange on vaccine registration processes and issues <i>Country group work, followed by peer review between 2-3 countries, quick report out</i> Facilitation: Alireza Khadem | 3:30-5:00 Side meetings as needed <i>Country teams work on transition and country action plans, facilitators available as needed</i> | 3:45-5:00 Session 11 – Country transition and action plans <i>Countries to review and update their action plans based on where they stand, what they have learned on procurement and regulation during the workshop, and priority needs</i> Facilitation: Loic Sanchez, Miloud Kaddar, Oleg Benes, Nata Gordeziani (LNCT), Ivdity Chikovani (LNCT), Joanna Wisniewska (Gavi), Galyna Romanyuk (LNCT), Sviatlana Kavaliova, Nilgun Aydogan (Gavi) |
| 5:30- Facilitator meet & greet – Transition and country action plans <i>Individual facilitators meet with each country: VPPEF Action Plan review, Discuss “Making the case for increasing investment”, Support needed</i> | 7:30- Tbilisi workshop welcome dinner Please be in the hotel lobby at 7:30 PM for departure to the restaurant <i>Welcome dinner for participants hosted at “Qalaqi” (45b, Kostava str.) Transport (Bus) to the hotel will be provided at 11:00 PM.</i> | 5:00-5:30 Closing <i>Feedback, evaluation and closing remarks</i> |

Annex 3 – Workshop Evaluation Report

Participants were given a series of positive statements about the workshop and its content and were asked to indicate if they strongly disagreed (1) or strongly agreed (5).

Overview:

- Participants were highly satisfied with the workshop and responded to each statement positively, with an overall average of 4.7.
- When asked if they had “opportunities to build relationships with other workshop attendees”, participants strongly agreed (4.6).
- Participants strongly agreed that they were able to learn from other countries (4.7) and discussions were moderated effectively and occurred in an open and positive environment (4.7)
- When asked if they planned to share knowledge gained with their colleagues at home, and take action, participants strongly agreed (4.8, n=5) with two participants commenting they planned to share what they learned with the NRA and the Ministry of Health or some other centralized procurement institution. One participant said they planned to “implement a new tool on Forecast [sic] and IIS” as a result of this workshop while another said they aimed to bring “More attention on Global vaccin [sic] Marke [sic].
- When asked about to provide general comments for future engagements, one participant wrote “at some point exchanges between regions would be just as interesting & useful.”

| Session** | The content was informative and relevant to my work. (N*) | The presentation and structure were effective and engaging. (N) |
|---|---|---|
| Session 1- Intro to vaccine procurement and regulatory issues | 4.4 (20) | 4.7 (20) |
| Session 2- Focused country exchange on vaccine regulatory issues & NRA functioning | 4.6 (20) | 4.8 (20) |
| Session 3 - Introduction to vaccine registration processes and issues | 4.6 (20) | 4.8 (19) |
| Session 5- Supply chain spectrum | 4.7 (17) | 4.8 (17) |
| Session 6 - Intro to UNICEF vaccine planning and forecasting | 4.8 (17) | 4.8 (17) |
| Site visit - National Center for Disease Control and Public Health (NCDC) | 4.8 (17) | 4.9 (17) |
| Session 7 - Focused country exchange on vaccine budgeting tools and best practice (at NCDC) | 4.5 (17) | 4.6 (17) |
| Session 8 - Intro to vaccine procurement challenges and options | 4.5 (11) | 4.6 (10) |
| Session 9 - Focused country exchange on vaccine procurement challenges and options | 4.6 (11) | 4.7 (11) |
| Session 10 - Vaccine procurement performance assessment | 4.8 (11) | 4.7 (11) |
| Session 11 - Country transition and action plans | 4.6 (11) | 4.6 (11) |

* N=number of respondents

** Session 4 was measured through the overall rating as it was not formally moderated and new information was not presented.