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Vaccine Procurement
Practitioners Network

Webinar Series
2018-19



Thematic discussion 4
Regulatory Systems Strengthening

27 March 2019

VPPN 2018-19 Webinar Series

1. Planning / Forecasting
2. Budgeting / Financing
3. Price
- 4. Regulatory Systems Strengthening (RSS)**
5. Supply Chain Strengthening
6. Strategic Procurement
7. Human Resources
8. Governance
9. Sourcing Products



Speaking now

Moderator: Leslie Paas
*VPPN Community of
Practice Manager*

Today's panelists/presenters

UNICEF SD Invited Expert:
Abraham Kofi Ntow



Contracts Specialist
Vaccine Centre

Copenhagen, Denmark

National Government:
Heba Almohtaseb



Procurement Officer
Joint Procurement Department

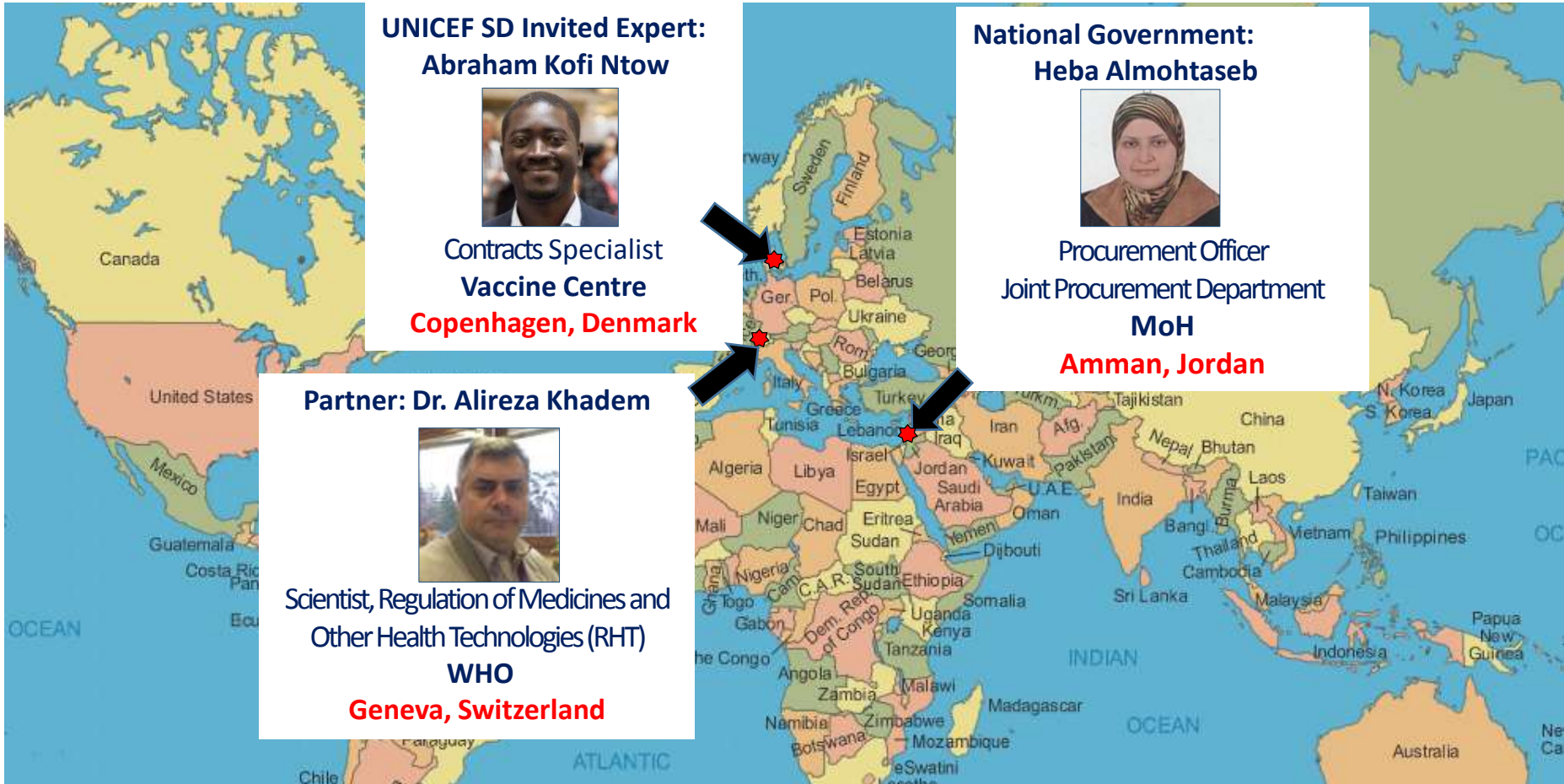
MoH
Amman, Jordan

Partner: Dr. Alireza Khadem



Scientist, Regulation of Medicines and
Other Health Technologies (RHT)

WHO
Geneva, Switzerland



Today's moderators and participants



Loic Sanchez



Project Officer

**Vaccine Centre
Copenhagen, Denmark**



Leslie Paas



VPPN Community of
Practice Manager
(UNICEF SD)
Florianopolis, Brazil

Webinar format: country presentations followed by panel-style discussions

1 hour webinar

- Overview'/Introduction (*3 minutes*)
- Key Issues & Update on RSS by UNICEF SD (*5 min*)
 - Question/comments session (*10 min*)
- Jordan presentation (*10 minutes*)
 - Panelist & Participant reactions (*10 min*)
- Summary & Wrap-up (*2 min*)



Moderator: Leslie Paas
*VPPN Community of
Practice Manager*



Presentation 1: RSS Framing & Update



Speaking now:

Abraham Kofi Ntow
*Contracts Specialist,
Registration Focal Point,
Vaccine Centre, UNICEF SD
Copenhagen, Denmark*

RSS Main Challenges for Countries

- Increasing difficulty in vaccines supply due to **changing regulatory requirements**
 - Understanding the measures that can be taken to minimize the impact of these changes on vaccines delivery
- Current **lengthy process of vaccines importation**, including sample testing and issuance of green light before importation.
 - Potential risks to timely delivery of vaccines
 - Mitigation measures



Abraham K. Ntow
*Contracts Specialist,
Registration Focal Point,
Vaccine Centre*

Description and why it's important

1. The vaccines regulatory landscape is changing on both demand and supply sides

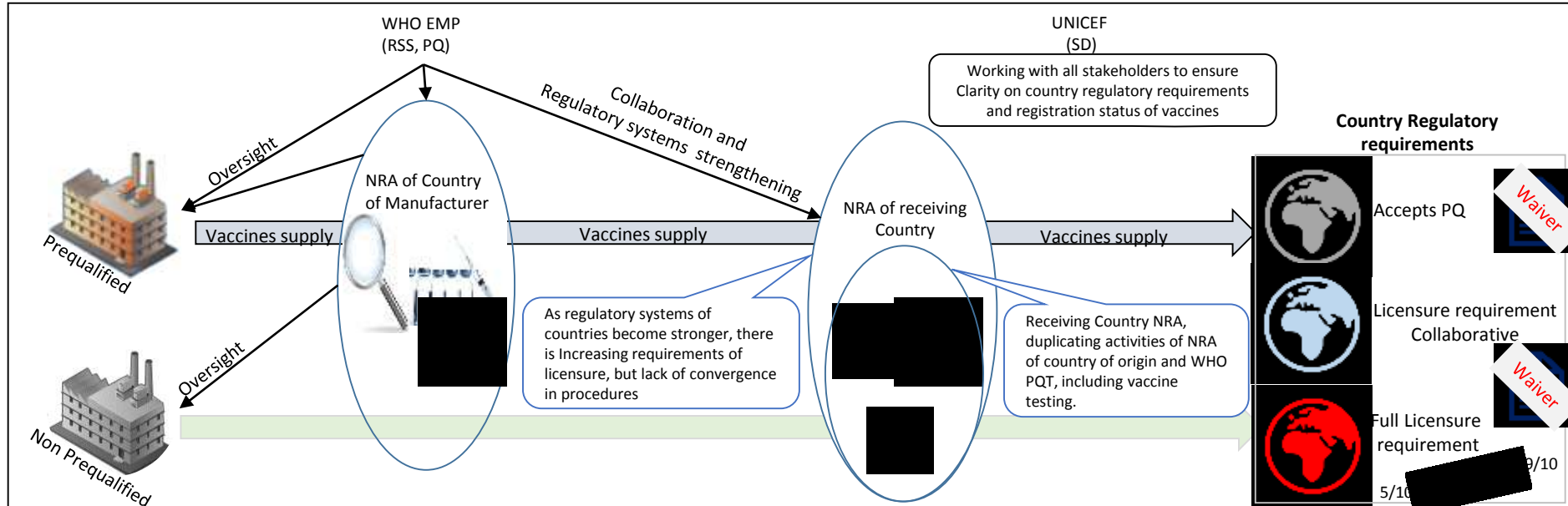
Demand

1. Some countries have local licensure requirements for vaccines, including WHO pre-qualified vaccines of assured quality.
2. The regulatory requirements of countries that accept WHO PQ vaccines may change without prior notice, clarity of registration pathway and sufficient time for manufacturers to register.

Supply

1. Documented waiver of registration is required, for countries where supplier's products are not registered.
2. Request for regulatory waiver, used to be limited to countries that require local licensure, this is now being extended to countries that accept WHO PQ vaccines

2. These changes are a risk to sustainable uninterrupted supply, shipments may be cancelled, quarantined, and/or programmes postponed where alternate supplier with a registered product is not available



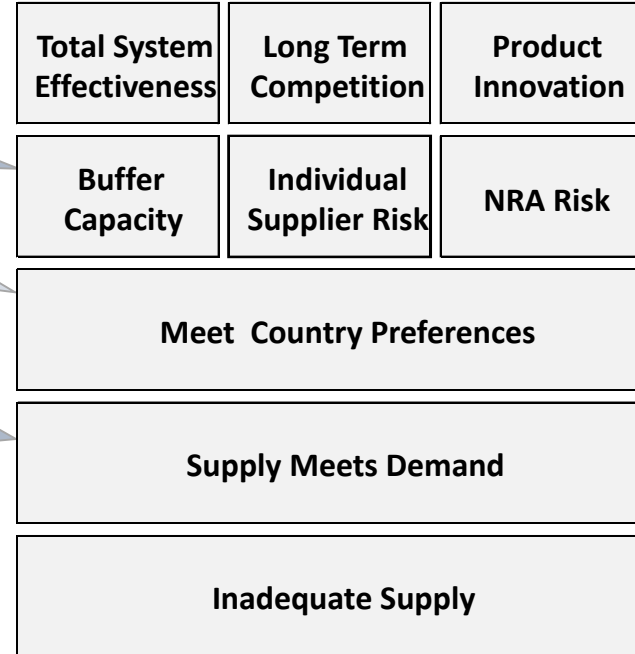
Why does this matter to vaccine markets

1. Market Shaping

Buffer capacity will be at risk, because additional capacity does not benefit markets where it's not registered, if local registration is required.

Countries that require full registration shall be limited to the products that are registered, therefore country presentation preferences may not be met where the alternate options are not registered.

Unmet demand until regulatory requirements in all target countries are fulfilled.
Registration could take 1 to 2 years to complete and several countries do not have fast track processes in place (e.g. WHO collaborative procedure).



2. Vaccine Markets

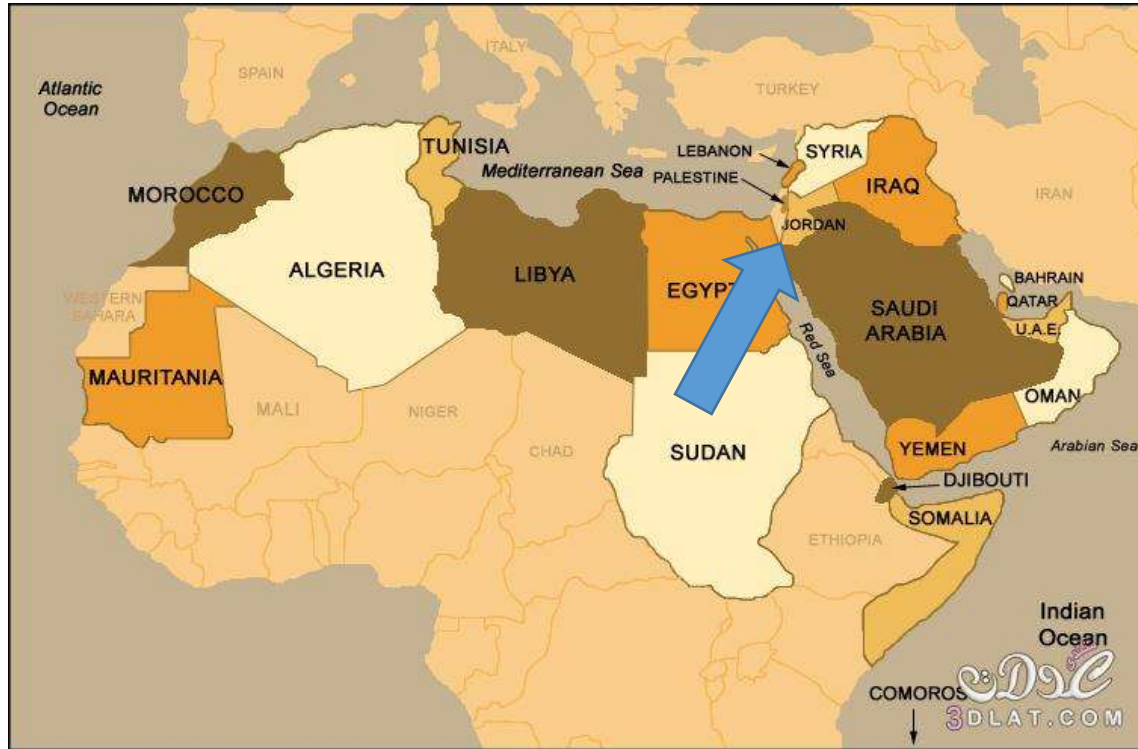
- Higher vaccine prices from additional costs due to regulatory challenges and additional investments to register vaccines across several countries.
- Operational challenges such as supply interruption arising from abrupt changes in registration requirements.

Questions/Comments?



Moderator: Leslie Paas
*VPPN Community of
Practice Manager*

Presentation #2: RSS in Jordan



Speaking now:
Heba Almohtaseb
Procurement Officer
Joint Procurement
Department
MOH
Amman, Jordan

- **World Bank Income Group: upper-middle-income**
- **Population: 9.9 Million (WB, 2018) | Birth Cohort: 247,000 (WHO, 2017)**

Jordan – Regulatory system overview / process of vaccines importation

- Self-procuring country of vaccines & medicines for public health sector.
- Jordan is an **Institutional** country, vaccines procurement is carried out through the collaboration of several institutions in the country (direct & indirect roles).
- JPD (joint procurement department), Jordanian FDA, MOH, NITAG, NPTC.
- NITAG & NPTC : responsible for adopting technical specifications & WHO recommendations especially for new vaccine introductions.
- JDFA: registration according to pharmacy law, import permissions, testing vaccines, pharmacovigilance, reporting.
- JPD :tender special conditions, signing contracts, execution management to ensure delivery on time.
- MOH : warehouses, vaccinations, determines quantities needed to tender.



Speaking now:
Heba Almohtaseb
MOH, Jordan

Jordan – Regulatory system good practices

- Specifications are adopted by technical professionals in the country, independent national committees(updated WHO recommendations).
- Priority is given to register new vaccines, sole resources, provide import permissions to unregistered vaccines or companies for awarded bidders in the tenders
- Tender Specific conditions give flexibilities to unregister companies &/or unregistered vaccines to have the award in the absence of registered ones.
- Contract management done by JPD helps to have vaccines on time.
- Priority in payment for vaccines contracts(increase competition).
- Multiyear purchasing helps in reducing the repetition in procedures yearly.
- E procurement for vaccines, JONEPS.



Speaking now:
Heba Almohtaseb
MOH, Jordan

Jordan – Regulatory system challenges and lessons learned

- Budget constrains: delay in applying recommendations & improvements.
- JPD sole resource for some vaccines (low competition, high prices, restricted conditions).



Speaking now:
Heba Almohtaseb
MOH, Jordan

Conclusion/way forward/thank you

- Electronic procurement will solve many delays that could happen in getting the vaccines, **JONEPS** is a system we depend on to solve many obstacles in the processes, we dream to be perfect & improved Inasha Allah.
- Design a vaccine contract that solves the problems we now face in the ordinary contracts, use framework agreements when it could fit.



Speaking now:
Heba Almohtaseb
MOH, Jordan

Thank you

Panel Discussion/Questions



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Dr. Alireza Khadem
Scientist, Regulation of
Medicines and Other Health
Technologies,WHO
Geneva, Switzerland



Moderator:
Leslie Paas
VPPN Manager

Next steps

- The **RSS webinar recording/Q&A transcript and Presentation Slides** will be available on the VPPN platform
- Please check ongoing VPPN discussions:
 - Price
 - Financing/Budgeting
 - LMIS
 - Market Intelligence



Moderator: Leslie Paas
*VPPN Community of
Practice Manager*

THANK YOU

*Take note: April's VPPN theme:
Supply Chain Strengthening.
The webinar will be on April 24th*