VPPN 2018-2019 Webinar Series Regulatory Systems Strengthening Webinar (27 March, 2019)

Questions & Answers – Transcript Summary

Context: The Regulatory Systems Strengthening (RSS) webinar was held on Wednesday, March 27th, 2019, with 24 participants joining from around the world, including representatives from National Governments, UNICEF Country and Regional offices and UNICEF SD experts & Partners (WHO, Gavi, CHAI).

The panelists/presenters included:

- National Government: **Heba Almohtaseb**, Procurement Officer, Joint Procurement Department, Ministry of Health, Jordan
- UNICEF SD: **Abraham Kofi Ntow**, Contracts Specialist and Registration Focal Point, Vaccine Centre
- Partner: **Dr. Alireza Khadem**, Scientist, Regulation of Medicines and Other Health Technologies (RHT), WHO

Webinar agenda:

- Introduction/Objectives
- Update on Price by UNICEF SD
    - Questions/comments session
- Jordan presentation
    - Panel/participants discussion
- Wrap-up & Close

Below you find the edited transcript of the Question & Answers sessions.

Question/Comments Session after UNICEF SD presentation:

Question by Juliette Puret, Senior Programme Manager, Immunization Financing and Sustainability, Gavi:
How can countries get support to strengthen their national regulatory associations from UNICEF and/or WHO, or other partners?

> ➔ **Answer by Abraham K. Ntow, Contracts Specialist and Registration Focal Point, Vaccine Centre, UNICEF SD**
> From UNICEF side, we don't do the regulatory systems strengthening directly with countries. I'll suggest that is taken by Dr. Alireza because WHO has Regulatory System Strengthening Department.
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> ➔ **Answer by Alireza Khadem, Scientist, Regulation of Medicines and Other Health Technologies (RHT), WHO.**
> This is based upon the demand of the countries. They have to request WHO so we can engage

with these countries for Regulatory System Strengthening - in the case that these are the countries that are not producing vaccines, or they are not planning for exporting their vaccines. So, in this case, according to a resolution that we have in WHO known as Regulatory System Strengthening Resolution number 67.20; this is a non-mandatory - actually, "engagement" upon the request of the countries for this program.

For the countries that are planning to produce a vaccine and also to prequalify this vaccine, the engagement framework is mandatory. So for these countries, they have to be assessed by WHO. They have to enter into this regulatory system strengthening program, and then at the end they should be considered as a regulatory system which is functional - or what we call it - "maturity level 3". In this case they can have the prequalified vaccine.

Panel/Participants Discussion after Jordan's presentation:

Question by Abraham K. Ntow (UNICEF SD):
Before vaccines are shipped or delivered to Jordan, what I understand is that there is the requirement for "green lights" or pre-approval process, and this includes sample testing of the batches that have been shipped. Can you clarify this process and the impact on timeliness of delivery of your vaccines supplies?

➔ **Answer by Heba Al-Mohtaseb, Procurement Officer, Joint Procurement Department, Ministry of Health, Jordan**
The testing is supervised by the JFDA - a third party. So when I ask the supplier to deliver, first of all, he has to - with the shipment, or before the shipment, give these testing results to the JFDA first to be checked. And after all - when the vaccines enter the country, directly we take the samples - another plus for that result that is brought by the bidder. And all these will go to the JFDA to further testing. So we have the tests results from the manufacturer itself, the passing, from the country of origin, plus we have the recommended testing for the vaccines in the JFDA itself.

So, the testing - maybe it will need maybe 20 days... or let's say one month, and we put this in the contract. So I have the time for that period in order to be not disturbing anybody. So I tell the supplier "everything is okay this month, it will be within the delivery time, so there is no delays, don't bother yourself, (...) in the end it will have delivery on time". So, it is specified clearly in the contract, so I think it's perfect like that. We don't have any complaints for this.

Question by Juliette Puret (Gavi):
It's so nice to hear so many initiatives that have been implemented in Jordan. Thank you for the nice presentation Heba. So, one question: are there any regulatory aspects which limit your access to some specific vaccines?

➔ **Answer by Heba Al-Mohtaseb, Jordan:** Maybe the registration issue makes some problems maybe for the suppliers, because you know, even yes, we want to be registered in the JFDA, but I think maybe many documents are needed. I think they give priority to the fast-tracked registration, but I think even of that, I think they may have some problems. But in the end I have

- let's say - another “window” to open through my tender. So - of course, I can buy another registered vaccine - if it is recommended by the NITAG. So, yes, maybe for the regulatory, even by giving the priority, but also they will have some time in delaying. I can go over this problem by my standard conditions, to have in the end unregistered vaccine if it's needed.

Intervention by Alireza Khadem (WHO):

Regarding the testing of vaccines I would like to clarify that WHO is not recommending at all that these vaccines, when it is a prequalified vaccines, should be tested and controlled by the receiving country. There are clear reasons for that: For example, these vaccines have been tested first by the manufacturers that have been controlled by the WHO through prequalification process. These vaccines are going to be either tested or released for sure by the national regulatory authority of the origin country that has been assessed by WHO, and therefore, we know that's how it has been tested and has been released. Many of the receiving countries, they do not have the proper settings for testing of the vaccines, and the way that they are testing vaccine it is not really testing the potency or the critical attributes of the vaccine. They are just sometimes testing the pH sometimes, the conductivity sometimes, and these are not what WHO is promoting there.

So basically, our position is that the prequalified vaccine doesn't need to be tested by the receiving country. Maybe they can just have a look at the result of the test - that is fine. Otherwise, retesting of this vaccine, as it has been controlled before several times, is not necessary. WHO has a guideline on lot release of the vaccines, and this position has been clearly mentioned in this lot release guideline.

➔ **Additional comments by Abraham K. Ntow (UNICEF, SD):** I wanted to add to what Dr. Alireza has said, which is perfectly in line with the UNICEF's position. From our perspective, vaccines that have *not* been prequalified by WHO - it's good to test those ones, or do further or more rigorous processes, or allocate their resources on those ones, as well as use the resources for pharmacovigilance and other responsibilities of the NRA, that will ensure vaccine safety. But duplicating the work that has been done by the WHO prequalification process is not the best use of resources.

➔ **Additional comments by Alireza Khadem (WHO)**: if I can also just to amend what Abraham mentioned - basically it is not only about testing. Any kind of regulatory oversight that has been properly done before, you don't need to repeat it. So it can be extended not only to testing it can be extended to any other kind of regulatory oversight (like full registration, inspection). This is what we advise the countries: you don't need to repeat what has been done by either WHO or any other reliable regulatory authorities.

What I would like to emphasize on, is that, basically any policy around medicines/vaccines is based on three major areas:

1. access;
2. the price or affordability of these products;
3. quality (the safety and efficacy - which we, in a nutshell, we call it quality).

Any imbalance that will be linked to these three areas, then it will create problem.

Exactly what the examples that Abraham mentioned too - when you stress too much on regulatory side that is trying to guarantee the quality safety and efficacy then you may make a

barrier into access - you may affect the price of the product. So all these three major areas they should be seen together and in a balanced manner. Otherwise you will have problem in any country. If you put too much stress and focus on access, then the price can be affected, then the quality of the product can be affected. So these are the most important concept that the countries should consider. It is not only the role of NRA or national regulatory authority, but we know that Ministry of Health or other entities/organizations in the country are dealing with access and price as well as quality. So this is the basic element.

We, in WHO, we are trying to promote "**good regulatory practices**" (**GRP**) and under these good regulatory practices there are several issues that we are trying to promote. There are major principles - important principles as part of the GRP. For example, what you are promoting is **reliance**. Reliance is when you are accepting a prequalified vaccine, this is reliance because you are relying on WHO or the prequalification program in WHO. When you are accepting the products coming from so-called "stringent" regulatory authorities, this is reliance also. You are relying on other countries. The level of this reliance can be different. Sometimes it is like a recognition – so, you fully recognize another organization (like PQ in WHO), or you fully recognize the NRA of one of these stringent regulatory authorities. And then you accept the product as such.

The other issue that we are trying also to promote (another area) is the **flexibility** in regulation. So the flexibility is exactly what we heard from Heba, in case the product is prequalified product coming to the country. They have this flexibility in their regulation that in this case you don't need to go for a full registration. Or, when you have a public health issue - an emergency, a shortage of the product - then you have to evaluate the risk, and also the benefit of this situation. This is what you have to consider as flexibility in your regulation, that what you have to allow to come to your country immediately to address this issue.

So what we see as a problem in these countries and the challenges that has been mentioned today, and all of you are aware of these challenges, is basically because the balance between these three areas has not been established in many of the countries, and the principles of good regulatory practice, like, as I said - reliance, flexibility in the regulations, and sometimes also, what we have also as part of GRP, is **consistency in the regulations**. You cannot change the regulations in one night and then expect that all the manufacturers/industry - they are able to adjust themselves with a new regulation.

So these are the things that we are trying to capture in this guideline. It is at the draft stage, and hopefully it will be published or will be finalized this year. And then we are also organizing implementation workshops for coming years in this area - which we hope that we can train policy makers at the level of the countries - to understand better the balance between access, affordability, and quality; and then to give them some tools to decide on these aspects.

Question by Aniqa Islam, International Coordinator, National Vaccine Institute, Thailand

timing in the recording: 00:56:39

Is information on which vaccines are going to be prequalified soon or in the coming years shared online, or would we be able to request this information anywhere?

➔ **Answer by Alireza Khadem:** I don't think it is online. My colleagues in the prequalification program should be able to answer this question. You can find a generic email on the WHO website for prequalification and contact them directly.

**note – here is the (generic) WHO vaccine prequalification priority list & info:*
> **Vaccines prequalification priority list 2018-2020.**
And this is the link to the page that explains how the prequalification priorities are set by WHO:
> **Priority setting for WHO vaccine prequalification.**