

### **Webinar: When Global Health Supply Chains Go Local: Partnering with Countries to Support Their Manufacturing Goals**

**Date: Thursday, February 24 from 8:00am-9:30am EST**

Wonderful. So it's my pleasure to introduce my commentator Dr. Christine Malati, a Senior Clinical Pharmacist. She serves as the contracting officer representative for the global supply health chain contract. Technical support on determining quality assured quality vendors. She's the primary reviewer of ABS312 requests for pharmaceuticals for the agency.

>> CHRISTINE MALATI: Thank you Alison and I would like to introduce you as well. Alison Collins is a health systems advisor with the U.S.A. ID Bureau for Global Health. Provides technical support in the areas of health system strengthening and pharmaceutical and COVID-19 prevention and response.

>> ALISON COLLINS: Thank you. We understand it can be confusing -- simply put the global health supply chain and the promoting the quality of medicines plus both contribute to the overarching goal of increasing the supply of quality assured medicines used in global health programs. Next slide, please.

>> CHRISTINE MALATI: Over the next 90s we have a robust task ahead of us to explore the current supply chain landscape including pain points, including all pain points. We hope to articulate the challenges as well as the opportunities associated with local and regional production and for those who have recently joined, we're inviting you to participate in our poll to help garner feedback from the audience on this topic. Because we at U.S.A. ID are in the process of defining our position on local production and we are hopefully using this forum as an opportunity to gain insight and feedback. We're going to be soliciting feedback and we hope to share US AID's procurement from vendors and how the evidence has yielded several qualified sources. We want to understand score the importance of a strong regulatory system. And finally identify procurement policy reform that would promote and enable an environment for local procurement. Next slide, please.

So as you all are aware the COVID-19 pandemic has highlighted numerous vulnerabilities within the global health supply chain such as the significant geographical concentration. In alignment with the agency's goal to localize across development programs US AID endeavors to support save and effective health products to diversify supply base and promote enhanced access to quality assured medicines and products closer to the end user whether it's a patient or recipient. In May 2012 the World Health Assembly passed a resolution. The US government signed onto the resolution and the inter-agency led by the National Security Council is seeking to strengthen support for local production. But this document, if you haven't had a chance to review it, it presents many potential benefits but also risks which we will explore further today to increase local production requires a wholistic approach that requires a focus on policy, capacity building, technical assistance, finances.

Next slide, please.

>> ALISON COLLINS: Over the past two decades USAID -- through technical assistants to manufacturers in low and middle income countries.

This work can expand supply and reduce prices.

Expand productions like we've observed with COVID-19.

The PQM+program -- and the GHSC - QA has provided technical assistance to a handful of many manufacturers.

USAID has worked to increase supply of antimedication and 30% API for antiTB medicines -- supports by PQM plus and its press says or PQM.

More recently PQM plus -- reducing the price of N95s there by more than 95% and greatly expanding access and in South Africa USAID project last mile supported small and medium enterprises to stimulate local production, generating over 1.9 million pieces of PPE creating 426 employment opportunities and leveraging more than 1.3 million in co-financing.

And to facilitate a viable marketplace from manufacturers of quality products while also removing sub standard and falsified products from the market.

USAID's investments focus on MTB, TB, malaria and maternal and child health conditions in the country where you were with.

As you can see by this table USAID has helped manufacturers with a total of 67 approval for quality assured medications or pharmaceutical active ingredients.

As demonstrated by this table US A provides TA manufacturing for both -- and the finished pharmaceutical product.

FPP helping to increase the supply of quality assured medicines used in global health programs.

>> CHRISTINE MALATI: Allow me to acquaint you with this slide.

We have the historical procurement data with all of our task orders which is the primary vehicle for which US AID funded procurements are occurring and so if you look at the why axis you'll see the total commodity costs that were procured the past five years and so what we have here is a breakdown of the procurements that explicitly came from African manufacturers.

You may hear us interchange African with local throughout this presentation.

I think that has been part of the challenge is understanding that definition but I think for this piece of data, we did want to highlight the work that's been happening in the African manufacturers and what you can see from this graph is although it's simply about 3% of the total procurements at \$26 million of the total procurements, you can see an increasing trend over the years and under the leadership of administrator power, we only anticipate that that would increase in the future.

The data has been grouped into these five commodity categories.

The four you see on the chart plus contraceptives but no contraceptives to date have been procured by African manufacturers and why they are not visible on the key.

Value of product based on the country of manufacturer and you can see Nigerians are playing the largest role in terms of providing manufactured goods.

With that, I would like to turn over the conversation to our panelists.

Next slide, please.

Iain Barton is an expert in innovating, incubating, and scaling best practices and global health.

Ten years of clinical practice, twenty years of health care supply chain management and two years of health care systems advisory.

Dr. Barton has a broad spectrum of experience and before launching his organization health for development he was the CEO for the Clinton Health Access Initiative.

Chryste Best has more than 30 years of experience in the pharmaceutical, food safety, medical device, and bio technology industries.

12 years as a micro diagnosis and inspector for the United States Food and Drug Administration and works currently for FHI360 and serves as the deputy project Director of ASAIID's global health supply chain quality assurance program Khalid Mahmood --

>> ALISON COLLINS: Jude Nwokike has more than twenty years' experience in strengthening medical products regulation and quality assurance systems and is the recipient of the 2020I PS medal award. And finally Prashant Yadav is a globally recognized scholar, a Senior Fellow at the Center for Global Development.

And lecturer at Harvard Medical school, the author of many peer reviewed scientific publications and his work featured in prominent print and broadcast media.

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Without further ado with he would like to kick off the covers with a question for all of our panelists. How would you define local or regional manufacturing in the context of your work and how this has evolved.

>> IAIN BARTON: Thank you very much and thank you for allowing me to join.

I always enjoy joining these events and the range of personalities in the audience.

It's great to be here and to see so many names, many of whom I haven't seen for a number of years.

That's testimony to the fact that we've all been doing this for a long time which has a couple of implications but one of the most we do start to lose old friends as we are running for longer and I want to make a comment and reappearance for Paul Farmer, one of the people who taught us all so much and got us all involved so long ago and for him to have been lost earlier this week is a huge tragedy for not only the patients he served and in the market he operated but for all of us in general and his community.

A moment of thoughts and thanks around Paul.

So your question.

How would you define local or regional manufacturing.

I'm not sure I like the word local.

Is it domestic? I know it's hard to choose the right words.

Local has the feeling of almost a demeaning statement.

Our ambition is not to build up local firefighters.

Our ambition is to build businesses capable of supplying their over domestic markets and the world.

It's an ambitious word we need and that's one of the first things around the context.

One of the most important things that has evolved is if you talked three years ago about domestic manufacturer you got passed onto somebody at the local registration authority or someone in the ministry of health.

Today regional domestic manufacture is item one at the top of every meeting.

It's got the attention it deserves and the level of momentum that it needs.

The second thing is that people having that conversation have realized this isn't something where everyone will have to do their own little thing.

It's going to be regionalized and it's going to need all the players from different angles and aspects.

The third is that everybody gets that this is not a one year funding cycle solution.

This is going to take a 10 to 15 year journey and there was a beautiful symposium about this earlier on.

One of the folks from India said it took us 15 years but we have to start.

The last point I want to make in terms of the context is as I get it, pharma, is vital and vaccines are logical to be in the discussion.

If we're conspiracy about getting from ports to arms and serious about building robust systems we have to go all the way down the lists.

Vaccines, liquids and creams, diagnostics and as you recalls and all the way to PPE and all the way from finished goods right back to raw materials and in some cases that means drug substance and in some cases that means API.

This is a big conversation but it's important, apparent, and getting the focus it needs and it's really important and thank you, again, for facilitating this, because it needs lots of discussion and lots of buy in and for us to get on and do things differently.

Thanks.

>> ALISON COLLINS: Thank you so much, Iain.

I think your point about terminology is certainly well taken and something we have debated quite a bit internally.

I would like to turn the floor to you next Chryste to hear your thoughts on this question.

>> CHRYSTE BEST: Great thank you.

And I echo the sentiment of being able to sit on this panel to have these discussions and greetings to everyone, to all the participants.

I think in order to understand our perspective, at least coming from FHI, it's important to know what our role is and currently we have the quality assurance contract for the global health supply chain project where we're responsible foreign insuring that all the pharmaceuticals and health commodities regardless of where they're manufactured, if it's locally, international, wherever it's manufactured, that they are appropriate for intended use and meet specifics and quality standards.

That being said, when we're talking about the location of a manufacturing site, primarily we're taking into account the risk associated with that.

And looking into basically the maturity level of a regulatory authority that's overseeing that manufacture and then developing the vesicle risk mitigation strategies that would be appropriate in that case.

So then as far as the definition goes for local, quite honestly, this has been a challenge and we've struggled a bit to obtain a clear definition from our clients' perspective but understandably so.

It seems that the terms are a bit clearer when it's in reference to an implementing partner for local programs but not as clear when we're talking about commodities and so there could be a couple of ways to look at this, depending on what USAID's ultimate goal is.

One way to be to define local from a regulatory perspective.

For example.

From a regulatory perspective, local refers to a product manufactured in a country and registered in that same country of use.

An example, we have injectable contraceptives that was manufactured in Indonesia for the Indonesia market would be considered a local manufacturer and however now that that product is being exported to other countries that could be considered regional or even international.

When we regional it implies a product is manufactured in a country and exported into the general locale and based on certain associations or agreements or recognitions -- example the east African community which is comprised the several countries.

So using a definition that's more regulatory based is a way to normalize the definitions of local and regional without having to create artificial designations.

However, the con to this would be that it, again, would differ from the programmatic definitions that currently exist.

Another would be to define it based on target country or a country that has an active global health program.

The benefit of this is the definition is inconsistent across the board; however, this woman that, for example, an Indian manufacturer would be considered local.

As USAID has local programs in India and I'm not sure that fully aligned with USAID's vision in looking primarily for an.

We will align our risk mitigation strategies around however the ultimate definition is define first-degree a local or regional perspective.

So thank you.

Cal thank you so much Chryste.

I think your points around risk mitigation and the role of a strong regulatory system are taken and critical to this conversation.

Khalid we would like to continue to your thoughts on this question.

>> KHALID MAHMOOD: Thank you.

Thank you Alison.

Greetings from Pakistan.

I'm glad to join this group here and happy to talk about our experience from Pakistan, especially the local production and other questions that are coming.

I think from missions -- I will look at local production from a missions perspective.

Where the mission strategy guides us; where our rest of the work is expanding or spanning, keeping in view the health systems, all of those pillars where we are making lots of contribution to service delivery, to supply chain, to quality of medicine, and several other technical areas.

And we want to see how our country [indiscernible] in building of capacity of local production complements the rest of the world and achieves the targets within our mission strategy.

So looking beyond the local or regional manufacturing as usually we perceive it as production of genetic medical products that are manufactured in local or regional territory.

I think the idea is how we can ensure that essential supplies are available to people at the [indiscernible] at affordable prices and needed quality.

Those are some of the key aspects that if are within the country's capacity both in the public and private sector, I think we will think we have achieved our goal to improve the local capacity.

And I will connect here this local capacity concept within the work that we have done in Pakistan.

It's not only local capacity because when we see that our little work after the COVID pandemic struck, globally and including Pakistan, the work that we built in working with the private sector pharmaceutical considers and the best way to produce local PPE and local COVID treatments.

It was not local merely as production but it helps populations in the region as well as beyond the region, globally.

Again, semantics, the focus definitions, I agree with other colleagues but I think it's lots of level of effort involved and when we talk about local capacity and locate at production, I will just give an example of how we are creating a foot hold in this complex where we are building capacities around local production.

I will simply state that the local production or the capacity to produce locally is not only bringing quality or quantities to people but it's over all bringing resilience to country systems.

It contributes to an economic development and job creation.

In Pakistan, it's even a little bit more complex where the pharmaceutical sector is very complicated.

I'll give you an example.

It's unprecedented.

There is more than 800 pharmaceuticals in Pakistan and out of those 800, only top hundred carry to 97% of the market.

The rest of 700 compete for only 3% of market share in a \$3.2 billion Pharma industry. That's the environment we are working in in pry to create foot hold not only to bring the capacity at a level where it gets us to the pop you other relation needs but also it aligns with our visions objectives, our strategies, as well as contributing to serving life in the rest of the world. I'll stop here. Thank you.

>> ALISON COLLINS: Thank you so much Khalid for sharing those rich experiences from Pakistan. Jude, I would like to turn to you next for your response to this question, please.

>> JUDE NWOKIKE: Hello.

Thank you so much, Alison and this is really exciting and I want to thank you for inviting me with very wonderful co-panelists and they stimulate me so much just by virtue of the animals that everyone is taking within the definition.

For me to talk to that same question, I think angles that everyone talks about.

Could refer to the location of manufacturing and could refer to the ownership of the business but I would like to say that the term production as well can refer to, you know, the way that participants in the sector can progressively push different levels of sophistication in the operations in the pharmaceutical value chain.

Imports and research and development work.

What is often not sufficiently highlighted in the definition of local products is the word local refers to the focus of the -- disease.

Most people agree local is to produce the medicines close to the burden of the disease.

Epidemiology as well as that of the immediate neighbors.

You hear me see few things more about the burden of disease angle.

First is to say that we've been in the work we do, we've been working extensively on this for over 12 years, the program has supported hundreds of manufacturers, including dozens in China, in India, in south Korea.

That is traditional in both markets and so it took only until about another five, seven years, that we started looking at these burden of disease angle and focus on the burden of disease of their own country and region.

You know, so how, some of these manufacturers really supposed to participate in their markets? So I'll give few examples of that.

So Indonesia and Pakistan, these are two countries we know they have a high burden of tuberculosis.

Work closely with the manufacturer in the countries to get first line TB medicine.

We continue to work with Pakistan to ensure that they can produce first line combination TB medicine.

Nigeria is a country where upwards of 50 for postpartum and preeclampsia were -- -- Pakistan and Nigeria, we have burden of sepsis and we support to make trohexadine available.

Nigeria subsequently apply examined submitted to the west African health community and that was approved and what that translates no is that product is going to likely make it into the 16 member countries in Africa.

Nigeria and Ghana have high -- some of these manufacturers are taking advantage of the regional economic integration.

They're making advantage of that to really offer their products to the entire regional market and as we know, is when you put demand across countries and across regions.

When you get things like advanced purchase commitments, then you suddenly have markets and that is an incentive for manufacturer to get more into the markets.

Local production becomes even much more imperative.

That's what we are facing right now.

And it really happens that when you have built the foundational infra structure for adoption and compliance to international GMP quality standards you get the manufacturers in those countries primed ready to fulfill an opportunity that may arise during health emergencies and pandemic.

For example, in Pakistan, where, you know, when [indiscernible] signed the [indiscernible] agreement with -- sciences which is a subsidiary company, it provided an opportunity for that country to address its need for Remdesivir.

Produce this and use it for local needs and support from -- and also that product is benefiting a host of other countries and has been distributed to dozens of countries and used to treat nearly 80,000 patients and similarly work has really provided a platform as well for all the things that may emerge in COVID-19 therapeutics.

Manufacturers that have received the patent license agreement for [indiscernible], those manufacturers are those that six of them are those that we had helped to build the foundation for GMP compliance so they are ready to go and they can now participate.

Some of the countries where manufacturers indicated interest to place a role in COVID-19 vaccine manufacture.

Quickly to say another aspect of this also is the global supply.

We have to address that.

That is what is the challenge now we saw with COVID-19 and so it helps and when these sources are producing this product to reduce vulnerability in the global supply chain.

Maybe diversification issue should be something also a factor in defining local production.

Lastly, to get into aspect of your question about evolving and how things have evolved, I think vaccine need and inequities that have surrounded that is brought to bear greater attention also.

Vaccines as a medical product.

Not just pharmaceuticals but I agree with Iain, it has to be entire medical products.

I will say the announcement last week WHO of the global and aid technology case in point that just like what happened previously with -- this may be happening in Africa and we look forward to really supporting our work with that.

Another area is technology transfer.

We know that new technologies require a lot of support to be able to succeed.

In terms of the technical information or the cloud or the skills that are needed, the materials that could be submit examined then my last point is across all of this is the huge need for work force.

Scientific technical work force that can enable those countries, whichever way we define sources of local and regional medical products, we have to build our work force ask that's an area we've been spending time and resources on.

We have to teach and build the capacity for quality CMC issues, for facility issues and for work we lease issues and for those areas and for bio pharmaceutical products.

And in closing I will again most important local production would be to produce and the held burden of the country and the region.

Thank you.

>> ALISON COLLINS: Great.

Thank you so much, Jude, and thank you for sharing the many much examples.

I would like to turn the floor over to Prashant.

>> PRASHANT YADAV: Thank you.

Great to be here with a very distinct topic of discussion and panelists.

Semantics do matter here because they become a part of the narrative and therefore, you know, lots of things start converging around the semantic use.

So I feel like saying local like Iain and others have said and I think most panelists have mentioned it's not just for your own country but for your neighbors.

We are talking about -- local signifies some idea that every medical supply chain has to be fully self-reliant and that is by no means what I think this is seeking.

We ought to not con found more distributed manufacturing and -- the former are important that need be recognized and everybody has to work on it but that doesn't necessarily translate into local production because local means we give up on the idea of global value chains in health technology production and manufacturing which has serious costs which I don't think our resource constrained environment can bear.

So one thing, that is a point to keep in mind.

Then I think when we talk about regional, how has this changed? So I think a lot of things have changed on the supply side.

New technology has become available which allows manufacturing at smaller scale and we hear about new flexible and manufacturing set up.

Allowing us to make things which were more difficult to make in a distributed sense and cost economics are become be more attractive.

Evolving rapidly.

Continuous will be the future and batch not for manufacturing but small molecules and even biologics in the future.

That changes the situation in interesting ways.

Sometimes it helps regional and sometimes it doesn't.

That equation needs to be very carefully talked through and otherwise it becomes everything can be done regional and everything can be done local.

That's the first part: The other thing that's evolved very rapidly is the idea that if you do regional manufacturing, it requires a route to market and a supply chain to distribute.

Rapid diagnostic test and rapid flow test manufacturing.

This is one technology where regional can work.

Lateral test flow manufacturing and the question is if you manufacture at one hub location in, let's say, west Africa or east Africa, do you then have the supply chain and distribution systems to get the product to all markets in the region? Earlier in the experience from such initiatives point us to the fact that it's not as easy.

I think we cannot decouple manufacturing from route to market supply chain distribution.

It is evolving slower because the political capital and political head wind has over indexed itself on manufacturing without necessarily also thinking about regional distribution.

So that's a second thing which I think has evolved or not truly evolved.

Third thing is that while the supply side is getting a lot of attention and as a supply chain academic, I love the fact that heads of state talk about supply chain, manufacturing networks, diversified manufacturing, the reality is for this to be sustainable it has to be accompanied by equal effort on demand side.

Purchasers.

Global and domestic purchasers to rethink how they procure.

If we say we want to continue procurements using the L1 lowest price percent of the contract then none of the regional manufacturers are going to be L1 in the short-term.

It's just reality.

Anybody who has looked at cost of goods scale of production has seen that.

Changing procurement and bringing divert it and split tender awards where L1 doesn't get entire 100%.

They get pores and other gets portion for other reasons.

That is not evolving.

If you ask me how things evolve.

Lots of things are getting attention.

Very good.

Very interesting.

Some things are not and I think we have to focus our attention on these parts.

When we think about regional manufacturing we have to keep in mind that the future market will remain uncertain.

Especially the discussions happening on manufacturing COVID vaccines or new vaccines more regionally whether in Africa or Asia.

I think we have to keep in mind the future of this market or any health technology market comes with significant uncertainty.

We will not be able to resolve that uncertainty any time soon because the platforms are uncertain.

What will be the right technology for the future is uncertain.

We need two things.

We need greater flexibility.

If we are setting up a new plan today we need to keep in mind flexibility so that it can switch from one product type so another and one manufacturing platform to another relatively quickly.

Current distribution networks are not as flexible.

The ones that exist in North America and Europe and India and Asia are not very flexible but we have a real opportunity here to build more flexible manufacturing in the regional sites that come up in the future.

What products will we make in them, how that's an important area to discuss and we can talk more about what USAID can do.

I'll store there.

Thank you.

>> CHRISTINE MALATI: Great.

Why don't we flip to our poll and see how the audience responded to the question.

So it looks like in terms of the primary benefits of producing locally, we saw that improving commodity security came in as the number one important benefit.

And secondarily, we see that improved access to saving quality ensured local sources and it's great to see in third place more of an economic priority here to ensure that not only is there availability of product but that the marketplace can become more responsive from a competitive perspective.

In the interest of time, let's go to the next question.

Great.

So Jude, how would you like to hand this question? What are some of the benefits if you want to build upon your opening remarks of producing locally.

>> JUDE NWOKIKE: Thank you Christine.

Yeah.

And I think there are so many benefits and some of them are come out in some of the remarks of my fellow panelists.

And I think ultimately and very much like the poll that you're showing on the screen right now, ultimately, it is that supply security concern -- why did this topic, all of a sudden become at the top of everybody's mind now? It is because of COVID-19.

We just physically saw the need for this.

The world saw also we find there is tremendous inequities.

I say that and -- we are seeing situations where people cannot agree on access and I think the first is improving access and health security.  
That is one of the most important benefits.

>> CHRISTINE MALATI: Iain, would you like to add a benefit as well?

>> IAIN BARTON: Resilience and reliability is important.  
What we saw with COVID is remote procurement doesn't work especially in times where we have to scale up.  
Let's not see what happened in COVID as being a COVID thing.  
It was the ultimate demonstration of a failed supply chain model and let's show that as a benefit evident event.  
I think -- we need strong regulators but we need standard regulators.  
If we're going to build manufacturers for economies of scale we need for global markets.  
As we build those strong authorities let's make sure we use this opportunity to drive standardization as well.

>> CHRISTINE MALATI: And this has not been a new coverings.  
Certainly, this conversation has always been involved in our conversations, I think.  
I've had the pleasure over the last ten years just engaging with the panelists in various capacities.  
Jude, to your point, it is great now that COVID has kind of heightened our awareness of these vulnerabilities, it's good that we have a collective movement to act on how we can look at more regional African manufacturing as an option.  
I think with that I'll hand it back to Alison for our next question.

>> ALISON COLLINS: Thank you so much Christine.  
If the producers wouldn't mind pulling up the results from our second poll.  
We would like to get responses from the audience about the main challenges that need to be addressed in the challenges around local production.  
So first, around the cost competitiveness of certain products.  
Economies of scale.  
Local and regulatory and legal challenges.  
Something we've discussed a little bit so far in the first part of our conversation and then the third major challenge identified was in terms of in extra structure and work force challenges and we can see there's a few others listed here and we would certainly invite our audience to add any additional responses in the chat as well and I would like to invite Chryste to come back on camera and comment on this question in particular and to add if you would like to comment on impacts of COVID-19 on this as well.

>> CHRYSTE BEST: Thank you.  
Of course, again, coming from primarily a quality perspective, one of the biggest challenges really is ensuring that the manufacturing sites employ good manufacturing practices and in order for this to happen key elements need to be in place.  
Significant capital to ensure the facilities, equipment, instruments, HVAC systems, water, laboratories that they all meet appropriate standards and often times, the capital is not readily available for this.  
Additionally, there are costs associated with API.  
There needs to be a skilled work force and the ability to maintain that work force.  
As we know, often times as employees learn skills and mature, they move on so ensuring there is a work force to backfill positions are pertinent.

Local universities are able to support such a work force.

Challenges with equipment maintenance and having in-house capability as well as in-house service contracts.

We've seen changes with doctors that lack the evidence to support -- and I know hats off to our PQM+ colleagues who work quite a bit in that arena.

But, again, I go back.

Perhaps one of the biggest is a mature regulatory authority that consistently oversees and ensures compliance to best practices.

As our role as the QA contractor we often times conduct audits and we know that audits are a point in time and with an exodus of skilled staff, the quality culture could quickly wain.

Having an authority conducting inspections routinely but there's also the element of ensuring that any manufacturing changes are reported and improved and left side that means there is a functioning feedback loop such that if there are adverse events that happen, there's a feedback loop for reporting. All of these provide a greater level of conversation that the products manufactured and distributed locally or regionally give that confidence.

What is somewhat of a unique challenge for us is ensuring there is incentive for the manufacturer that may already be approved by their national regulatory authority to legally manufacture product without implementing some of the things that we're suggesting here.

Why would they invest money in all of these efforts if their own regulatory authority is not requiring that.

So those things need to be congruent.

All of these things to say it's not impossible.

I'm not being a pessimist but these things need to be in place and the necessary controls, processes, and procedures.

And we would have to ask, what is USAID's risk tolerance for failure.

And the reason I say that is certainly if things happen with manufacturers if they are sophisticated matured regulatory authorities, things happen.

Ensuring we have a certain risk tolerance for that and it's because of this we say when developing procurement strategies, maybe start with low risk products or manufacturing processes that are not so complex.

And when I say low risk products, there, the caveat depending on the failure type but a product where there would be minimal impact if there was a failure.

Again, for starters.

Things like nonsterile creams or lower risk orals.

Coming into COVID and challenges and all of the challenges I just mentioned become multiplied when you have a pandemic and we don't currently deal with a lot of local manufacturers but certainly there are notable issues with international ones such as reducing staffing levels at facility.

QAQC units are delayed in releasing lots.

Supply chain issues.

Container availability.

Impact to access to key starting materials.

So these are just a few challenges that I want to highlight and I'm sure my colleagues will add to that discussion.

So thank you.

>> ALISON COLLINS: Thank you so much and I would like to turn it over to you Khalid if there is anything you would like to add from the Pakistan context, briefly.

Moo sorry.

I was not getting unmuted.

I think you can hear me now.

Thank you.

I think this is great discussion and I see the challenges.

Everybody is talking from their context and it's very, very -- here it's only the severity or focus in certain settings.

If I look at Pakistan, Pakistan is, as I earlier mentioned, there is only 100 top level pharmaceutical that are getting to the 97% of the market.

That's kind of setting, it's so hard for the rest of the market pharmaceutical companies to get an opportunity to contributor chances or opportunities to build their capacity.

That's something that is not even listed but it is a big challenge for Pakistan and that's where I think COVID pandemic came with opportunity to look into this market and identify those potential manufacturers who had the capacity and who wanted to expand, improve upon their infrastructure and human resources and their even technology transfers.

They mention they were able to procure or needed help from donors or partners: So there are existing challenges of scaled availability that is required.

Technology regulates and quality environment is another factor.

But I see where lots of development partners are focusing on service delivery.

But quality of medicine and then building the capacity of local pharmaceutical companies to ensure that these capacities improve Bonn.

It's very pertinent.

I think among those challenges, formal industry, it's very important to first demonopolize the overall environment and then move on to addressing those additional challenges.

Certainly as earlier mentioned, these challenged affects countries even before COVID and even with COVID, many countries had more problems even than the several countries -- equipment and API so these problems were exacerbated but I see this as a challenge also and see how other countries globally have addressed those issues or challenges.

And then learning, taking that learning and then implementing in other country where those best practices can be applied.

And local production could be improved.

Those challenges could be minimized so that people have access to quality medical products.

So I think I will stop here to see any additional input from other colleagues.

Thank you.

>> ALISON COLLINS: Thank you Khalid and I think we'll invite Prashant if you would like to add anything before we move onto the next question.

>> PRASHANT YADAV: Thanks Alison.

I'll be very short and I feel some of the reasons that have come out here, I would agree with them but I think if you go one level deeper and ask questions as to why aren't we achieving economies of scale or regulatory challenges, I think there are slightly group cost picture emerges.

So first thing is related to capital.

I hear two versions of the story.

So tricky on one side we have a lot of unspent capital sitting at development finance institutions we have earmarked money to invest in manufacturing and regional and diversified.

They could not final deals which not did have a demand side risk.

They are willing to take supply side risk.

They don't have staff and we'll get them staffed over time but is there a clear buyer in the market who will continue to buy from these.

Currently listed as six, insufficient demand from local market in my opinion is a much bigger challenge. Out of market pharmaceuticals is largely indexed on foreign and imported product and that goes back to Chryste's comment on regulation.

Higher quality comes from production as a perception.

When you look at public procurement, similar story.

It's either a cost or quality of regulatory apparatus and gets us on other larger producers.

Unless the demand side can be fixed, we can't resolve the supply side problems. We have capital available.

I think it's about solving the demand side issues.

And then on regulatory, I think one interesting thing that has continued to come up in discussions every time we've talked about it in different countries, health sector leadership in different countries, the global purchasing for generic medicines from India started long before India drug regulatory achieved the status it has now achieved.

We were using the programs created by the buyers of such products to ensure quality.

We were not waiting for the regulator to reach a maturity level of four and five.

Many health in the other country ask why now suddenly our national regulator be security level four before we can embark on a local production environment whereas you were buying long before any of the producing countries reached mature level.

I'm a strong proponent of focusing on capacity strengthening but we have to give focus on the point rightfully brought up by many health ministers embarking on this.

I will stop there.

>> CHRISTINE MALATI: Next slide, please.

I think we're going in the -- one more, please.

So we do want to make sure we can see how we can practically at USAID and create an enabling environment that would allow for more local manufacturing.

We've heard from our panelists about procurement reform, how we have to think about instructing the tenders.

We've heard about from some of the questions that have come through, we've heard about how importation levies can be different depending on importation of API.

Are we going to set a company at a higher price as opposed to companies able to import final formulations getting a tax levy from the government and how can we engage with trade counterparts In addition to engaging with the national medicine regulatory.

How else can USAID and other development partners support local regional manufacturing and this enabling environment? We would like to hear from all of the panelists on this question.

Why don't we start with Iain, please.

>> IAIN BARTON: I'm going to duck your question on what else, Christine because I'm going to circle back again.

I promise this is not a bumper sticker for the administrator.

Administrative power.

But your bumper sticker is play the game.

17 years ago Indian manufacturers did have not the quality standards.

USAID initiated a policy and practice that said if you build it, we will buy.

And the space of very short period of years we saw not only single and then multiple manufacturers move to the quality standards necessary to be able to supply into these markets, we saw a highly competitive landscape develop within Indian pharmaceutical manufacturing. You have it in your power. Set the standards,, coach them to your standards, and then buy your stuff from them.

Make that commitment and then the investors will line up in order to be able to capitalize those enterprises in order for them to be able to respond to that promise.

The power you possess as major donors, not only setting and coaching the standards but rewarding people's efforts to meet those standards is the most important power you have.

You have political support and power around taxation and incentives and often is not just the government of the countries we're talking tom make changes but it's for them to understand that in order to level the playing field they have to counter the incentives given on the other side.

For exportation out of India, if you want to compete we have to allow for people to counter for the incentives.

We are not going to get the Indian government to change their incentives.

The last thing of what I was saying in terms of what you can be dock directly.

You have a great big blended finance unit within the organization.

Let's put it to work.

Let's get it out there looking for investments with capital and financing models will enable the crowding in of private sector capital into those enterprises so that we can create the businesses and structures and deliver the products.

>> CHRISTINE MALATI: Thank you.

Over to Chryste.

>> CHRYSTE BEST: Thanks Christine.

Yeah.

Just to add and I really appreciate the comment from Prashant and Iain regarding the regulatory authorities.

Just to say that from our perspective, we would not -- we're not suggesting to not procure where the quality standards may not be where we would like for them to be but rather that we look at it from a risk based approach and as we're building the capacity, maybe having some starting points with lower risk products that we're really willing to support as we continue to build that capacity.

And then in terms of other support, as I mentioned in the challenges earlier, investments in supporting programs at local universities that would help with development of technical work force that we would be looking for to help maintain certain standards.

When we're looking at maybe products to support local procurement, local manufacturing, there should be some sophistication around the strategy behind the products that are selected.

For example, we probably would not want to develop or implement quite a bit of time and money and effort in supporting products where treatment regimens are constantly changing.

What happens if we invest all of this time and money and only a year or two later the regimen changes.

Would the manufacturing site be able to diversify? Some strategic thinking around the products that USAID would want to support.

And finely, coming back to and I think Prashant touched on this earlier.

We've had several discussions with our procurement colleagues and we understand that local manufacturing and local manufacturer products are not always the lowest cost and so would USAID be willing to pay a premium for local product to help this along? We understand with that there could be some challenges because the manufacturer may not always be able to compete from a volume per expect and I have timelines and what have you, again, costs.

But, perhaps, there could be an additional or higher rating for a product manufactured locally to be part of the procurement rules.

And so USAID would maybe need to consider what is the tolerance for potentially paying more for a local product to be able to usher in this effort. So yeah. Thank you.

>> CHRISTINE MALATI: That's an interesting point about the higher price premium and I know, Chryste, you and I have discussed this over the last few years.

I think if we could find a way to quantify some of the non-direct costs and non-direct benefits of a regional manufacturing, I think it would be easier to reform the policy regarding procurement.

So if we could quantify economic development or quantify human capital retention somehow, that helps to counteract the higher commodity, higher price premium.

Prashant, would you like to offer your thoughts as well? Vaccine okay.

Thank you Christine.

I want to build on what you just said about the premium.

So I think this is an important area.

Without a procurement change, many of the other efforts will not yield the outcomes we are seeking.

I commend the work that PQM does, that we do building the local manufacturers' capacity but at the end of this there has to be purchasing and there I think the cost equation is where some of the biggest barriers lie.

I mean, yes, we can go down the journey of thinking about why pay a premium because it leads to economic development, human capital development.

But I think the risk, diversification, and the resilience premium -- I have been using this and I have been working on this which I'm happy to send along your way -- if you think about geographical diversification and the need for resilience and supply security as a global public good, we all benefit collectively from it. Not just the country in which the local producer is located.

That's where we can say we want to spend taxpayer dollars on a resilience premium because we will all collectively get the benefits of supply security.

We have to outline it in a particular manner.

That's one.

I think USAID has a lot of potential of using demand side work.

Whether it is signing demand side guarantee instruments, which other DFI and DFC and others could join in but, you know, USAID could take the lead on how to design them.

Which product categories and regions matter more and how.

Also what Chryste said around reform or procurement modalities.

I think this, once again, gets into what would be the market shaping strategy and how much would it attach wage to purchasing such resilience enhancing manufacturers' products.

That, once again, goes directly into the kind of work you lead and can all influence in significant ways.

That's one thing.

The other part is on the supply side, I think we see -- Jude brought this up -- you see that the work that has happened voluntary licenses happening and other COVID therapeutics, that is also an opportunity to think about manufacturers who are receiving such licenses.

The market side seems to be a little bit more working there.

What can USAID do to make sure those things happen at the right quality.

They happen fast enough.

They happen in ways that those manufacturers find it sustainable to be in that business.

I think those would be areas which I think there is an immediate fine limited opportunity for USAID to do something which fits in the area of local manufacturing, but also fits into the area of improving access to improving therapeutics globally.

I will mention that USAID has a lot of connects with both on the country procurement side how this happens, the country distribution side.

But when there are efforts happening around local and regional manufacturing, trying to connect them with regional distribution, regional supply chain, supply chain enhancement so those two pieces do not work as decoupled pieces and they have to be coupled together.

That's important for the agency to think about. Thank you.

>> CHRISTINE MALATI: Great.

And maybe, Jude, if you want to give, and then followed by Khalid.

>> JUDE NWOKIKE: Thanks Christine and I think time is running out.

I will say this is a topic that has been discussed a lot and we have two publications on investment priorities, both for local production and as well as strengthening regulatory against this.

If you are interested I will send a link for that.

What typically comes about is we have to have a complete mindset shift to even get to converge and what we recommend to USAID and [indiscernible] to support.

We have to have a mindset that really, first agree that advocacy for local production does not in any way mean advocacy for -- there is only one GNP standard so it is to, the host important is we can now say we need more.

We need other people that can make this product and we need to be able to invest, build the capacity to make the product.

Have met CEO too many to mention saying this is what we need to invest in and land the technology required. Thank you.

>> CHRISTINE MALATI: Khalid?

>> KHALID MAHMOOD: Thank you.

Very quickly, I think most has been set and I agree with most of what has already been said.

But I think for USAID, I see that in Pakistan it was first time that USAID started looking at quality of medicine.

No other development partner looked at the quality of medical products or equipment of pharmaceuticals.

It was -- when went out and looked at and met different stakeholders and what they are doing.

People looked amazed that this is something new that is coming.

But I think in an unregulated or leg regulated setting like Pakistan, the first priority was to regulate it as much as possible.

Build human resource capacities to go out in the market and look at the medical products available in the local market and then devise systems to fill the gaps, quantity gaps.

And I think that's where -- started working in Pakistan and did a lot of progress.

The second thing I would adhere is the lack of data.

Based on our work in other areas, service delivery, supply chain, health systems, I think we have learned that where there is data available, it's easy for the government, the development partners, the private sector to make quick decisions and allocate resources.

Unfortunately, in the private sector there is very little data available, including pharmaceutical sector.

Public health and labs in the private sector and so many other areas in the private sector which minimizes visibility into what is the actual problem in a certain setting and especially if I'm talking about Pakistan.

It was first time when we started talking to the manufacturers, we realized there's 80 to 90% manufacturers who had the capacity who wanted to improve their -- but there was nobody who would let them come in the mainstream and contribute, or expand.

So for USAID, I will just summarize it that for USAID to be very, very strategic and get development partners, advocate to work hand in hand in different technical areas so not only the public sector because so far our work has been mostly to support the public sector.

Not the private sector.

Even if you look at the current work we are supporting the public sector.

The ministry of health, indirectly we are impacting the private sector.

It's only because of COVID that we made direct contacts with the private sector but I think we need to expand a little bit more to include in our programming and in our designs the private sector so that we work with them, understand their challenges, and create win-win situations because working with private sector requires another set of, you know, skill sets and diplomacy, unlike the work with the public sector.

So I think we just need to consider some of these aspects when we are thinking to work with the private sector in pharmaceutical industry.

Over.

>> CHRISTINE MALATI: Thank you so much to all of our rich discussions from the panelists.

I think what I have taken away from this is really to consider how we can look at procurement reform; how we can engage better with the private sector; and look at some of the development financing organizations that are available; how can we ensure that the data that we have available for demand is robust to create an environment where companies are going to see that they need to participate in this marketplace and that they would want to participate in this marketplace because they can see clear, returns on investment for raises that level of quality? And I think all of this really cannot be done in the absence of a strong regulatory system; however, we shouldn't wait until, in light of the new WHO listed authorities designations, he we shouldn't wait for necessarily all authorities to get to a four or five before we can deem the products availability in the countries and available for procurement.

I do want to extend my sincere gratitude to all of the panelists and at this point I would like to pass it back to Alison for her closing remarks as well.

Thank you.

>> ALISON COLLINS: Thank you so much Christine, and, again, huge thank you to our panelists and it was a very robust discussion.

We want to thank the audience for submitting questions and we've taken note of those and will do our best to post responses on the Marketlinks website.

I want to take a moment to remind everybody that all of the materials will be posted on the Marketlinks website along with a couple of blogs that we've written on the topic as within and we certainly encourage you to check when you have a moment.

Thank you to Marketlinks for making this possible.

I'll turn it over to Julia.

Thank you Alison and Christine and to all our panelists as well.