

Advancing Medicines Quality Assurance Systems in LMICs: Celebrating 10 Years of PQM Program Achievements

June 27, 2019

Crystal Gateway Marriott, Arlington, VA

Panel: Increasing global supply of priority public health medicines to save lives

Moderated by Dr. Emily Kaine, Senior Vice President, Global Public Health, USP

Panelists

1. Penny Smith, Technical Advisor for Neglected Tropical Diseases, USAID
2. Deus Mubangizi, Group Lead of Inspection Services, WHO Prequalification Team
3. Irvan Maulana, Manufacturing System Development Manager of Indonesia's Kalbe Farma
4. Lawrence Evans, Director of Core and Country Programs, PQM

Dr. Kaine:

- PQM is the flagship program of USP Global Public Health.
- A lot of work still needs to be done, particularly increasing the supply of quality-assured medicines needed to treat life-threatening diseases.
- There may be as few as one quality-assured manufacturer of an API around the world, and supply shortages continue to be a risk.
- PQM has worked with hundreds of manufacturers around the world to help them advance to having quality-assured laboratories.

Dr. Kaine: In your experience as a technical advisor for Neglected Tropical Diseases, what were the main challenges your portfolio faced with increasing the supply of NTDs, and how did the PQM program contribute to the progress made to date?

Penny Smith:

The NTD program exists because of the global donation program through the pharmaceutical industry. \$22 billion worth of drugs have been donated since 2006, but this program has restrictions and does not address all target audiences.

- Many of these drugs can only be administered to school-aged children (ages 5 to 14 years old).
- Merck, in Germany, is unable to source a high-quality API for praziquantel. USAID was buying the API from other manufacturers to fill that gap, but none of these additional manufacturers were prequalified. USAID had to trust that those APIs underwent quality standards.

So, USAID invested in PQM to buy better-quality products for NTDs. NTD drugs are low-profit drugs, so manufacturers do not have a big incentive to develop them. Entities that purchase NTD drugs operate in markets that do not require prequalification. At the time, the benefits of the WHO PQ program were unknown, and the program needed to be advocated for.

Dr. Kaine: What convinced Kalbe Farma to work with PQM?

Irvan Maulana: The PQM program was a good opportunity for us to improve our laboratories to comply with the international standard so we could supply not just our market in Indonesia, but other markets as well. We successfully changed our mindset from local to global with the support of PQM.

Dr. Kaine: Can you speak to the impact of the technical assistance you received from PQM?

Mr. Maulana: PQM's support had a big impact on our company. PQM provided hands-on training and helped us prepare for the good manufacturing practices (GMP) audit. PQM joined us in our regular meeting to discuss WHO requirements. Our desire to be GMP certified would not have been successful without the support from PQM. To help us get levofloxacin tablets WHO prequalified, PQM provided the following training:

- Mock audits
- Good laboratory practices
- Data integrity
- Method transfer
- Laboratory scale formulation and stability training
- Pilot scale
- Dossier submission and acceptance by WHO
- Preparation of WHO inspection

Dr. Kaine to Deus Mubangizi: Deus, you are currently Group Lead of Inspection Services for the WHO Prequalification Team. What are the main PQ program objectives and processes, and how has the PQM program contributed to meeting those objectives?

Mr. Mubangizi: WHO wants to see the impact from the ground. The PQ program began because one of the Millennium Developmental Goals was to improve health and expand treatment. With regulatory system strengthening, only 26 percent of the member states had a regulatory system that could assure the quality of medicine components. How do you achieve millennial goals if there is no system to ensure that member states have quality medicines?

With globalization we are moving from local hubs to global hubs, and medicines are moving without requisite control systems. Prequalification was designed to assure quality control of medicines in all member states. The objective is to improve access, not to deny compliance. WHO cannot wait for the dossier to come to us. We need to help manufacturers achieve international standards.

In 2004, there was only one supplier of the TB API in the whole world. We inspected with the European Directorate for the Quality of Medicines (EDQM), and the supplier was noncompliant. It is not just about getting products on the list, but also about how you monitor the quality of medicines that are being distributed. Countries must have access to products and quality control laboratories. I am here because we are going through a transformation and we are grateful.

Dr. Kaine to Lawrence Evans: What are some of the core lessons that the PQM program learned by supporting manufacturers to attain current good manufacturing practices and WHO PQ? What is next?

Dr. Evans: When we think of PQM, we think of technical assistance. But when you take a step back, we want to build sustainable systems. Initially, we focused on technical aspects, and we did not look at business aspects. We can do all the technical assistance, but if you do not have the business to sustain it, then it is not worth it. PQM is bigger than technical assistance.

Regarding what is next, there are so many different aspects. In LMICs, there is a security issue with APIs. APIs are not produced in LMICs. Local manufacturers in LMICs need a good supply of quality-assured APIs, and in the long term, we need to build capacity in countries to meet that need. In the short term, we need to make sure there are pathways in place to get quality-assured APIs to LMICs.

Looking at the pharmaceutical ecosystem, we need to consider everything that goes into making sure we have good-quality products available. Aspects we have not taken a look at are supportive systems and auxiliary services. We need to address all the issues in these larger systems, otherwise the entire ecosystem will break. The ecosystem needs to be sustained.

Dr. Kaine: What's next?

Ms. Smith: Regarding future priorities, the global donation program will end. While we have diseases that are targeted for elimination, other diseases are considered controlled, and the treatment will need to go on indefinitely. We need to start preparing those countries for that inevitability. USAID now has an initiative for self-reliance. We want countries to sustain their gains. Countries only want to buy from their domestic manufacturing base and want solutions on a country-by-country level. We want countries to consider buying from neighboring countries.

Another aspect to consider is the applicability of NTD drugs for other health sectors. This applicability was a big surprise but also has long-term benefits. We had not anticipated the other avenues of these NTD drugs, and we want to support those efforts.

Mr. Mubangizi: We have expressed our support in our renewed memorandum of understanding (MOU) with USP. We have seen what PQM does, and we want it to continue. We are talking about antimicrobial resistance (AMR) now. We want to strengthen the regulatory systems, and we need partners involved in that. We need to make sure the systems actually work, and we cannot let our guard down.

Questions from the Audience

Ron Piervincenzi, USP CEO, to panelists: Do we see the initiative of working toward an international standard as an economic driver? It has an effect at the local level; do we see this effect being exported, or is that still a theory?

Mr. Maulana: A big investment is required to comply with the international standard. As participants in PQM, we invested in our facility and in our people. This positioned us well in our country and will ultimately increase our sales. Complying with the international standard is a good positive economic outcome.

Dr. Evans: USAID has seen the evidence and success of the program. USAID had the foresight and put out a call for PQM+. They are already thinking about next steps at a global scale.

Mr. Maulana: Kalbe Farma is implementing systems in all 46 of our manufacturing lines. We have adopted WHO standards into our corporate quality standard. The quality system has been implemented into our other sites. This experience has made us more confident to expand.

Ian Warthin, USP Senior Manager, Country Planning: When Jude presented, he talked about infectious diseases and the key drivers for PQM. Now we are talking about non-communicable diseases (NCDs). Do you have any sense about how to address access to quality-assured medicines outside of the key disease areas and outside of infectious diseases?

Mr. Mubangizi: Whatever we do, whatever support we give, it is catalytic. When you support a manufacturer, they will apply those standards to all products, not just the product you supported. Whatever support we provide will have a ripple effect. I applaud the movement from strengthening systems. We should look at all programs as catalytic.

Dr. Mojisola Adeyeye, Director General of Nigeria's National Agency for Good and Drug Administration Control: Speaking to the impact of PQM on trade, health and trade are linked. If quality is built into regulatory and manufacturing systems, it will translate into trade. This will reduce unemployment, violence, and ecoterrorism in the country. If people are jobless, they find something to do. Keep people healthy, and this effect will multiply country by country.

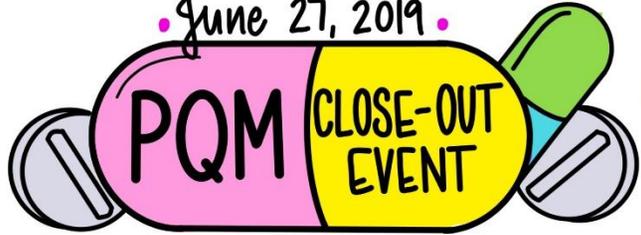
Dr. Evans: Policies around trade also need to be looked at. They can hinder local manufacturing if they remain unaddressed, resulting in an uneven playing field.

Dr. Kaine: What about localizing manufacturing production closer to the patient by increasing local pharmaceutical production?

Mr. Mubangizi: Nigeria has worked closely with PQM and has focused on local manufacturing. People who talk to each other and exchange information can move things forward. The ministry and government were willing to support local production, and there was enough local commitment from partners. Local manufacturing makes sense in Nigeria; it has a place, and it needs to be supported by all auxiliary systems. Government needs to support local manufacturing. It is one thing to say you support local production but investing in quality manufacturing should also be rewarded.

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moderator
Emily Kained

