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# Sourcing quality assured vaccines

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## The Experience of Indonesia

Yangon, Myanmar  
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FIRST NAME LAST NAME Presenting

## Background

- Bio Farma is a State-owned Enterprise of Indonesian Government (BUMN); the only one vaccine manufacturer and National Vaccine Storage in Indonesia. Biofarma has a degree of autonomy in management. They make a regular report to Government of Indonesia.
- Bio farma supplies vaccines for National Immunization Programmes:
  - DTP-Hb-Hib, DT, TT, bOPV, Measles, HB Uniject, Td
- NVI recommendations from the Indonesia Technical Advisory Group on Immunization (ITAGI)
- NIPs vaccines – registered by NADFC/NRA (including vaccines import – HPV, PCV and JE vaccine)
- New Vaccine Introduction (NVI) 2015 – 2019 : IPV, PCV, HPV and JE vaccine → still imported

# Main challenges *with sourcing quality vaccines?*

1. IPV which is produced by Biofarma has not listed in the WHO PQ – limited vaccine **supply** options
2. Indonesia Law # 33/2014 has stipulated all public Goods (including Medicines and Vaccines) must be certificated by A Halal Product Guarantee Agency → currently by Indonesian Muslim Council (MUI). Currently, Government of Indonesia is encouraging all vaccine manufactures to provide Halal certificate for all vaccines that used in National EPI.
3. All eligible vaccines have been registered by NRA (National Regulatory Agency) / Food and Drug Control Agency (BPOM) National and listed in the e-catalogue for procurement process.
4. Ministry of Health is a coordinating unit for the procurement process. Vaccine Procurement process involve many stakeholders (Ministry of Planning, Ministry of Health, Ministry of Finance, Parliament, Food and Drugs Control Agency etc). Despite good collaboration process on vaccine procurement, procurement planning must be started earlier, appropriate schedule is planned thus longer time is needed.

## Best practices *implemented by Indonesia*

- **Demand forecasting process** – The Annual Drug/Vaccine Forecasting Supply Plan as a reference document with regard e-catalog and production planning for vaccine production. All NIPs vaccines listed in the National Formulary (Fornas)
- **Procurement process and Governance** – Self procurement mechanism and used e-purchasing method are in place since 2015. The advantage using e-purchasing method are increased accountability, transparent, good governance and timely procurement.
- **Quality and Safety** – all NIPs vaccines procured have been registered by NRA, WHO Pre Qualified Standard certificates and vaccine vial monitor (VVMs) written in vaccine vials package as a vaccine specification. Health facilities have standard and function cold chain equipment.
- **Capacity of AEFI Surveillance** – National and Sub National AEFI Committee was established to provide:
  - technical inputs to review the factors leading to the adverse events
  - inputs to improve the system and ensure safe and effective immunization.

## Looking ahead

*What are new vaccines under consideration? Are they locally produced? How would they be sourced?*

- Indonesia Government consider new vaccines to be introduced based on burden diseases and applicability nationwide.
- Rotavirus vaccine is the one priority vaccine as drafted in the cMYP milestone 2020 – 2024.
- Biofarma has been conducting Rotavirus vaccine clinical trial phase 2 at two districts in Java Island and to be finalized in 2021

THE END