

Regulatory Systems Strengthening in the Philippines



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Brief demographic overview of the Philippines

- World Bank Income Group: low-middle income
- Population: 106.5 Million (WB, 2018) | Birth Cohort: 2.4 Million (WHO, 2017)

Philippines – Regulatory system overview/recent changes

- Administrative Order No.142 s. 2004 exempts the requirement of Certificate of Product Registration (CPR) for all commodities including vaccines procured through UN Agency including UNICEF
- Republic Act 9711 also known as FDA Act of 2009 mandates all government procurement including vaccines procured locally or internationally should bear a Certificate of Product Registration (CPR)
- The requirement of CPR was strictly implemented starting this year.

Philippines – Regulatory system good practices

- Most vaccines procured through UNICEF has CPR in the Philippines
- CPR is one of the requirements in local and international tender documents.
- FDA has designated a fast lane for the issuance of accelerated CPRs for commodities without CPR especially those routinely used in the public health programs
- Informed UNICEF to procure only vaccines with CPR in the Philippines

Philippines – Regulatory system challenges and lessons learned

- Vaccines procured without CPR (example – JEV), DOH had to apply for and LTO and CPR because we have not identified Marketing Authorization Holder
- Local Distributors for Vaccines with CPR will not join bidding because of the very low cost.
- Philippines need to have a National Regulatory Authority to ensure the safety and potency of the vaccine.

Conclusion/Way Forward

- The Philippines to identify an agency to be the Marketing Authorization Holder to apply for CPR in order to comply with the FDA Law.
- DOH to issue advisory for all distributors, manufacturers regarding the new requirements