Towards malaria elimination: ADB-supported work at Myanmar FDA

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Why we need to work with FDA

Medicines are not a normal commodity:

- **Information imbalance**: health professionals and patients have not enough information to assess quality, safety, efficacy, value for money.
- **External benefits**: immunizations and treatment of contagious diseases benefit all, if left to market alone many will not be immunized or treated and all society will be affected.
- **Market Asymmetry**: those who determine consumption do not pay, those who pay do not choose, those who take the drug do not decide much.
- **Equity**: those who cannot pay still need treatment or may die. There is a need to ensure availability of non-profitable drugs.
- **No** 'second hand', 'try and see', reliance on others' experience

Why we need to work with FDA

- health professionals and the public count on NRA for good quality, safe, & effective medicines
- any strategy to improve anything in the pharmaceutical sector involves NRA
- any problem encountered in the pharmaceutical sector has something to do with the NRA

1 – ASSESS SITUATION

Two simultaneous approaches:

1. CoRE survey

2. WHO benchmarking tool addressing the nine regulatory functions:

   01-NATIONAL REGULATORY SYSTEM (RS)
   02-MARKETING AUTHORIZATION (MA)
   03-PHARMACOVIGILANCE (PV)
   04-MARKET SURVEILLANCE AND CONTROL (MC)
   05-LICENSING PREMISES (LI)
   06-REGULATORY INSPECTIONS (RI)
   07-LABORATORY ACCESS AND TESTING (LA)
   08-CLINICAL TRIAL'S OVERSIGHT (CT)
   09-LOT RELEASE (LR)

2 – AREAS REQUIRING ACTION AND SUPPORT

Human resources and network of external expert advisers.

FDA financing and fee-for-services structure.

Quality Management System, setting of priorities, organization of work, transparency, accountability and communication.

Integrated Regulatory Information Management System to support FDA's pre-marketing and post-marketing work.

Monitoring safety and quality of marketed products

Inspection of manufacturers, importers, wholesalers, and retail outlets

Optimizing use of quality control laboratories' resources

3 –ACTION TAKEN

1. Drafted plan of action for implementation January-June 2018.

2. Drafted decision-trees and revised regulation for drug registration process.

3. Implementing key components of IRIMS: online drug registration, management of laboratory testing information, enabling inspectors to consult real-time validity of certificates, compare product images stored in online database, upload inspection reports and images of inspected premises and suspected SF products.

4. Drafted national coordination mechanism to combat SF products, endorsed at national workshop of concerned parties, November 2017

3 –ACTION TAKEN continued

5. Inspectors from all peripheral FDA offices trained by WHO on combating SF products.

6. Reviewing safety profile of all drugs approved for marketing to identify ‘safety watch’ items and setting up appropriate monitoring.

7. Organizing meeting with academic institutions to establish network of drug safety experts to support FDA.

8. Supporting FDA involvement in ASEAN Joint Assessment process.

9. Facilitating FDA membership in WHO International Drug Monitoring Programme.


Thank you

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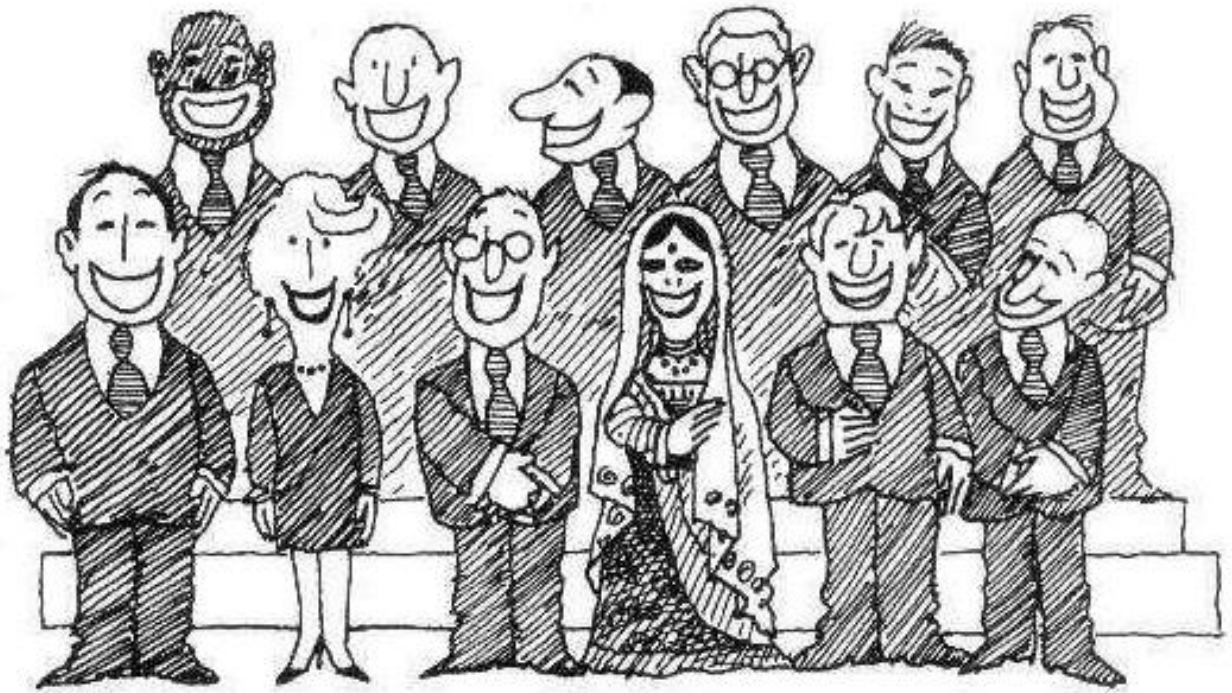
TO ADDRESS THE PROBLEM OF HUNGER
IN THE WORLD



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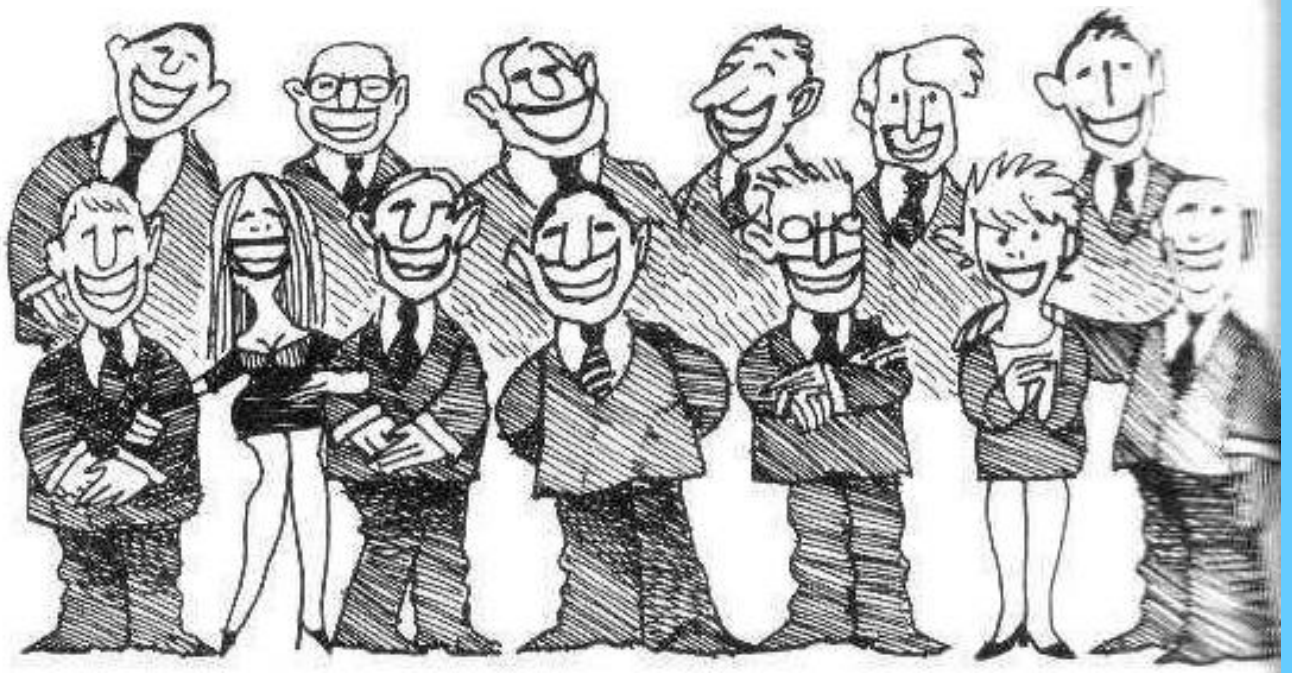

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