Philippines: Effective Communication with Industries for Fast and Effective Access to Patients

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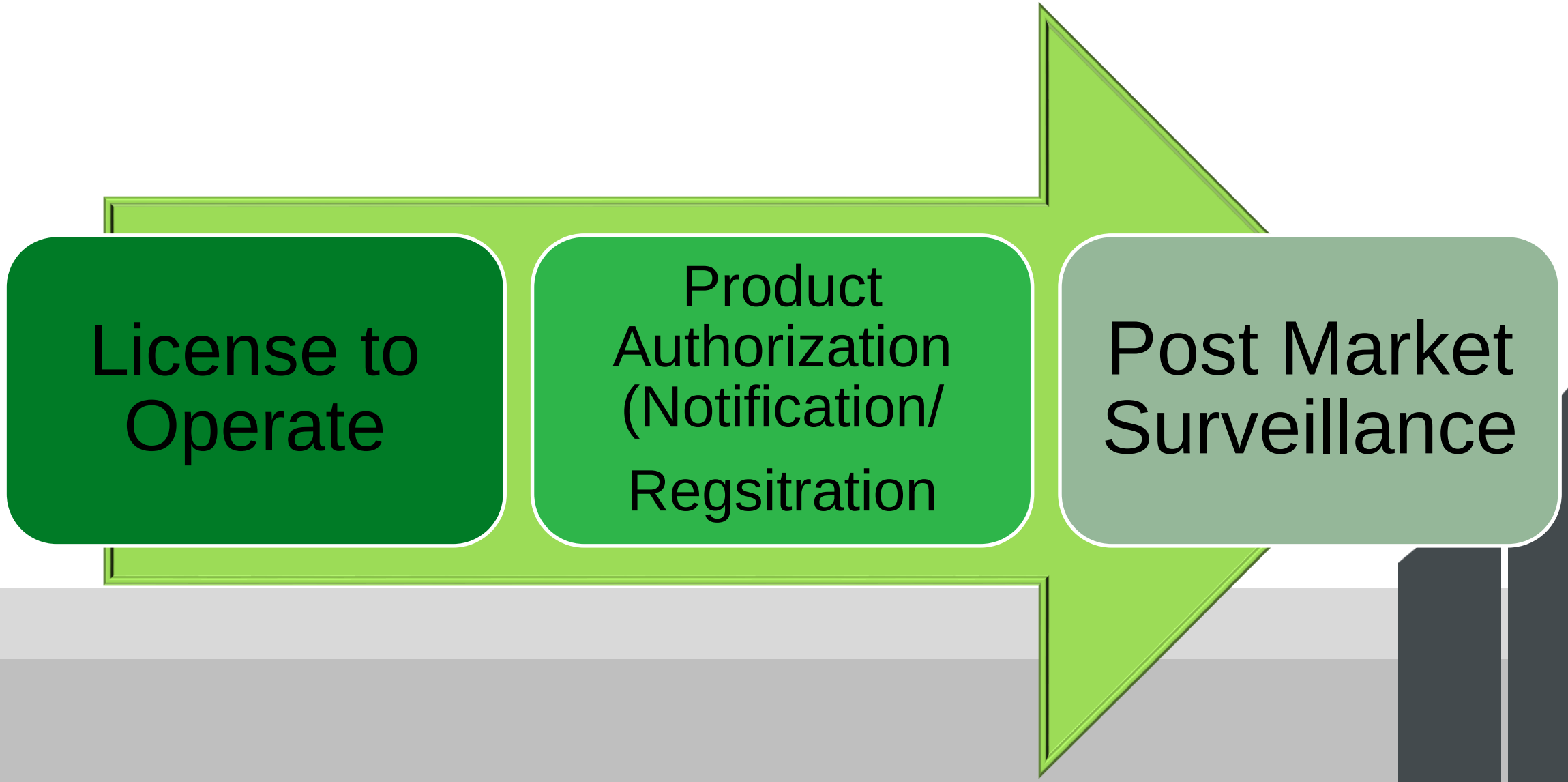
Protect the general public by ensuring the safety, efficacy, and quality of health products

MANDATE

While FDA protects the general public by ensuring the safety, efficacy, and quality of health products, it is imperative that there is always a balance with ACCESS to these health products

FDA Regulatory Controls



When do we Communicate with the Industry and with the general public

- During the Development of the Guidance Documents
- During the Implementation of the Guidance Documents
- During the Monitoring of Compliance to Regulation

Development of the Guidance Documents

Drafting of the Guidance Document

- Review
- Research
- Regulatory Impact Analysis

Internal

Consultative Meeting

Industry and other stakeholders are invited to take part in the series of consultative meetings until the final draft of a guidance document has been developed

Public Hearing

Posting in the FDA website for 60 days comment period

Public Hearing for all the stakeholders

WTO posting

Implementation of the Guidance Documents

Approval

- Posting in newspaper of general circulation
- Posting of the FDA Website
- Kapihan (informal forum with the industry)

Implementation

- Pilot Implementation
- DocTrack Status
- Officer-of-the-Day
- Seminars
- Lectures to different association
- Verification Portal

Monitoring of Compliance to Regulation

Post Market Surveillance Activity

- Annual PMS Plan which contain lists of medical devices that will be monitored by the Regional Offices
- Monitoring Ads in all Media platforms including the online selling of Products
-

Actions Taken for Violative Prodcuts

Issuance of Advisories for violative products

Corresponding enforcement activities

Seizure of violative products

Product Recall

Effective Communication to ensure the balance between access and regulation involves three things:

- **Ask**
- **Listen**
- **Communicate**

For both the regulatory agency and the regulated industry

MARAMING SALAMAT

THANK YOU!

For any questions, please email mccmatienzo@fda.gov.ph