



U.S. Food and Drug Administration
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Building Effective National Strategies to Better Address Counterfeit Medicines

Expanding GMP, GDP, GPP, and Pharmacovigilance Systems

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Overview

- Importance of building national strategies to combat counterfeit medical products^{***}
- Applying GxP's to ensure quality and further safety/security from counterfeits
 - Good Manufacturing Practices (GMP)
 - Good Distribution Practices (GDP)^{***}
 - Good Pharmacist Practices (GPP)^{***}
- Importance of pharmacovigilance systems^{***}
- Pharmacist's Role^{***}

*****IMPACT efforts**

IMPACT
International Medical Products
Anti-Counterfeiting Taskforce 



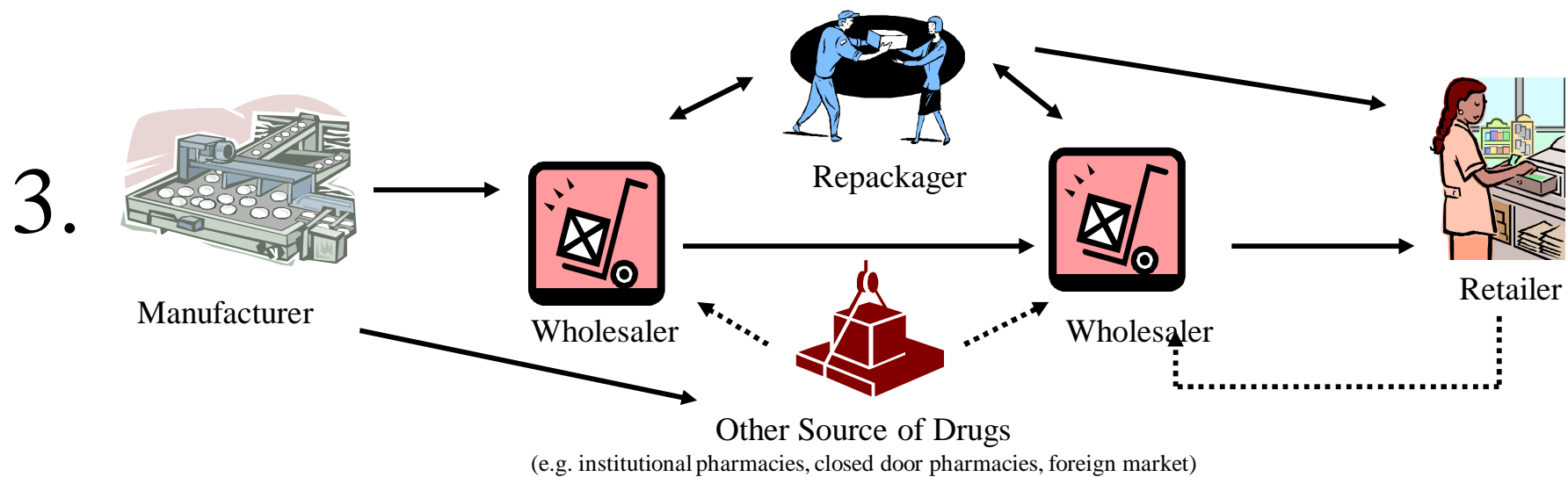
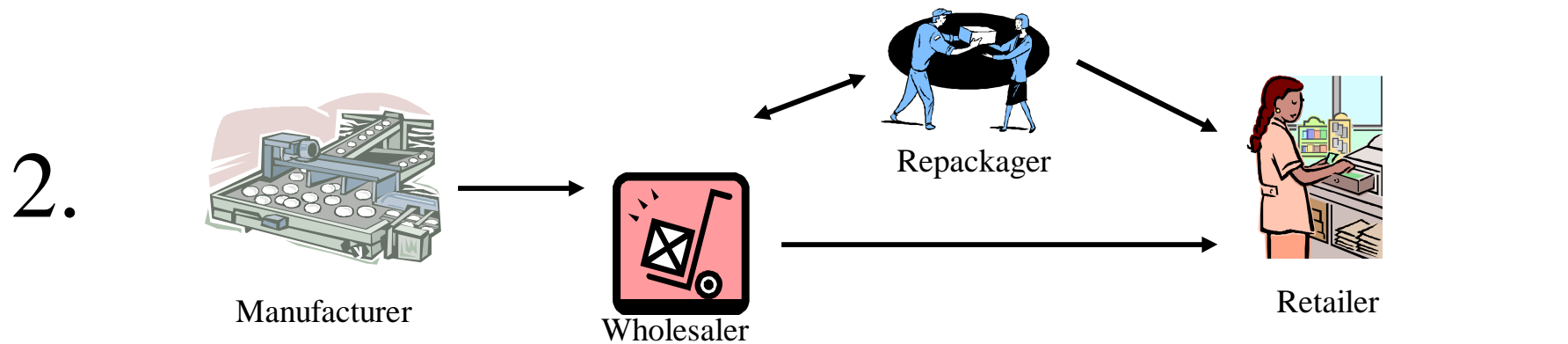
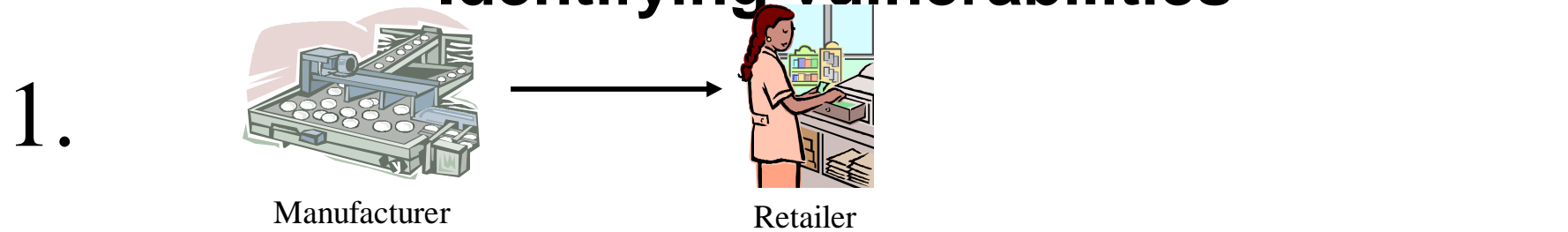
Multi-layer national strategies

“There is no single solution”

- Identify vulnerable parts of the legitimate supply chain
- Identify responsible stakeholders
- Identify realistic solutions across the supply chain
- Address legislative/regulatory needs
- Educate stakeholders
- Implement strategies
- Evaluate strategies

Example: U.S. Drug Distribution Models

Identifying vulnerabilities





Example – U.S. Action Plan

- Secure:
 - *product and packaging*
 - *movement of drugs* through the supply chain
 - *business transactions*
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- Enhance international ***collaboration***



Who is involved?

Supply Chain Stakeholders

Regulatory/Enforcement

- Manufacturers (legitimate)
- Wholesalers/Distributors
- Repackagers (if authorized)
- Dispenser
 - Pharmacy (retail/hospital)
 - Clinic
 - Doctor office
 - Long term care facility
 - Other outlets
- Others

- Drug regulatory authority (national/state)
- National/state/local police
- State/local health departments
- Other investigative authorities
- Customs
- Judges
- Ministry/Dept of Justice
- International components (if relevant)



Who is involved?

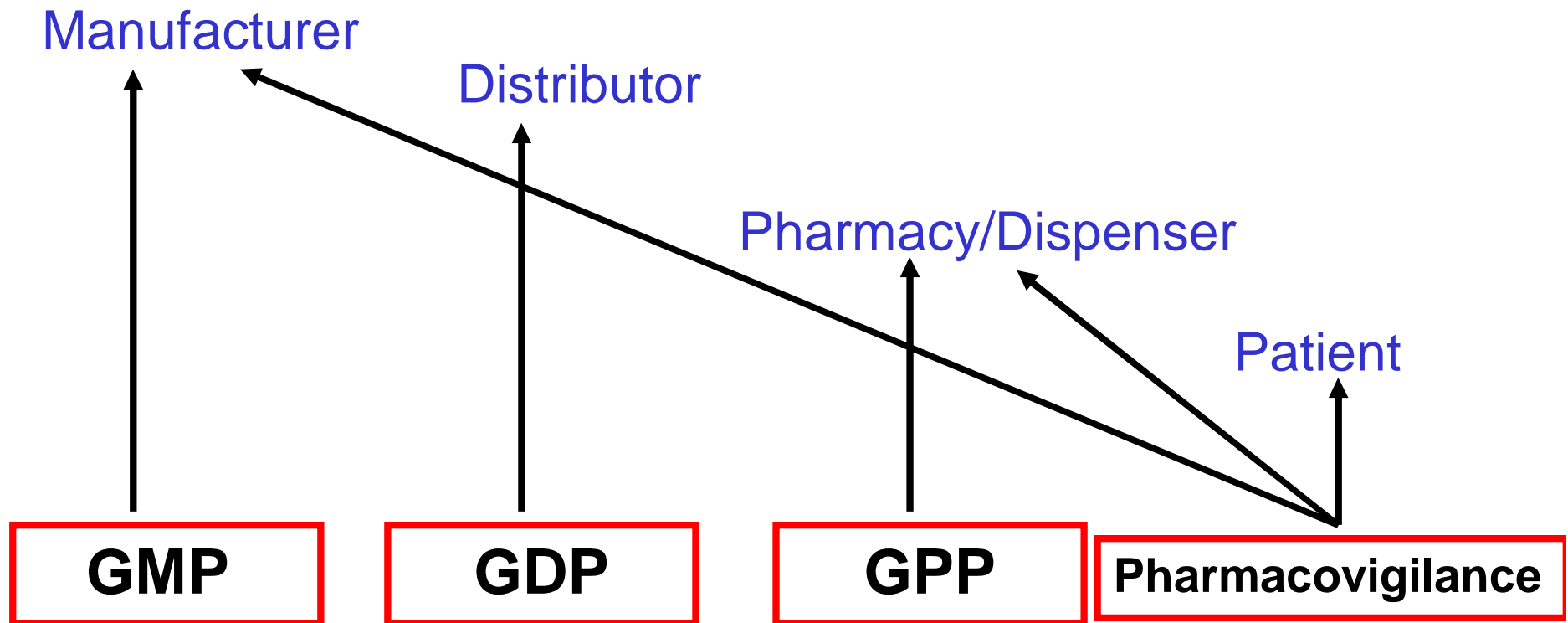
And of course.....

**THE COUNTERFEITERS AND
THEIR ACCOMPLICES!!!**



Building on GxP's & Pharmacovigilance

"Filling in the holes"





What are GMP's? (Good Manufacturing Practices)

- Ensure that pharmaceutical products are consistently produced and controlled to the quality standards
 - Minimizes risks involved in pharmaceutical production
 - Covers starting materials, premises, equipment, training, processes
 - Calls for systems to demonstrate that correct procedures are consistently followed at each manufacturing step.
 - Requires that manufacturing and testing equipment has been qualified as suitable for use
 - Process validation for operational methodologies and procedures (such as manufacturing, cleaning, and analytical testing) used in the manufacturing process to demonstrate that they can perform their purported function(s).
- Focus on quality systems
 - Quality by design -- Builds quality in during manufacturing



Manufacturing

- GMPs
 - GMP non-compliance vs. counterfeiting/adulteration/other criminal activity
 - Risk-based approaches
 - Starting materials (APIs and excipients)
- Other measures
 - Use authentication/anti-counterfeiting technologies
 - *Overt* - e.g., holograms, color shifting ink, watermarks
 - *Covert* – e.g., inks and dyes that fluoresce or absorb UV light, invisible bar codes, some watermarks
 - *Forensic* – e.g., chemical markers, taggants, other unique chemical features of a substance
 - Consider technology-based solutions



What are GDP's? (Good Distribution Practices)

- Guidelines for the distribution of pharmaceutical products as a tool to secure the drug distribution system from counterfeit and diverted drugs, unapproved, illegally imported, stolen counterfeit, substandard, adulterated, and/or misbranded human drugs and biological products.
 - WHO GDP currently under revision
 - Regulates the division and movement of products from the manufacturer to the end user and intermediate points between
 - Should be adapted to prevailing situations and conditions in individual countries
- Objective: Assist in securing the quality and identity of pharmaceutical products during all aspects of the distribution process



GDP – Good Distribution Practices

- Organization and management
- Personnel
- Quality management
- Premises, warehousing and storage
- Vehicles and equipment
- Shipment containers and container labelling
- Distribution
- Transportation and products in transit
- Documentation
- Repackaging and relabelling
- Complaints
- Recalls
- Returned products
- Counterfeit pharmaceutical products
- Importation
- Contract activities
- Self-inspection



GDP – Good Distribution Practices - Expanded

- New definitions
 - ex., pedigree, broker, logistics provider, short/full-line wholesaler
- Purchase only from the legitimate manufacturer or other authorized sources
- Sell only to legitimate supply chain entities
- Pedigree
- Track and trace
- Returns – only if items purchased
- Segregation and reporting of suspect counterfeits



What are GPP's? (Good Pharmacy Practices)

- Framework for standards to suit national situation and needs for pharmacy practice
- Goal to provide consistent, quality, pharmacy services
- Other Tools:
 - Pharmacist and Other Healthcare Provider Good Practice Guidelines For the Detection and Prevention of Counterfeit Drugs
 - Partnership for Safe Medicines
 - “Simple Steps for S.A.F.E. Sourcing”
 - <http://safemedicines.org/resources/documents/safesourcing.pdf>



Pharmacovigilance Systems

- Relates to the detection, assessment, understanding and prevention of adverse effects of medical products
 - Reports from manufacturers, healthcare providers, and patients on the adverse effects
 - Purpose:
 - identifying new information about hazards associated with medicines
 - preventing harm to patients



Pharmacovigilance Systems Expanded

- Adapt to receive reports of suspect counterfeits
- Educate health professionals re: reporting
- Identify signals that might suggest suspect counterfeit
 - Eg., regionally focused therapeutic failures or adverse events; product quality issues
- Communication tool if counterfeit confirmed



Pharmacist's role

- Minimize the risk of and exposure to counterfeit medical products
- Be vigilant
- Counseling patients about counterfeit medical products
- Report Suspect Counterfeit medical products



Pharmacist's Role

- **Minimize the risk of and exposure to counterfeit medical products**
 - Know who you are doing business with
 - Stay informed
 - Be suspicious of wholesalers/vendors if no previous business relationship exists if:
 - Not licensed; want cash payment; refuse to give documentation or certification that product not diverted/counterfeit/stolen; refuse to divulge where they got it; refuse to disclose expiry date or lot number; offer a price that is too good to be true; don't have a physical address; only have internet presence; offer generic form when non are approved; offer products for sale that are in short supply
 - Educate staff on ordering, receiving, dispensing, product integrity
 - Safeguard drug product returns
 - Destroy empty packages/containers



Pharmacist's Role

- **Be vigilant (1)**

- Pharmacies, clinics, hospitals should have internal policies and procedures for detecting and reporting suspect counterfeit medical products
- Know high risk products
 - High market value
 - In high demand
 - In short supply
 - Previous history of counterfeiting
- Consider counterfeits if:
 - New/unusual side effects
 - Lack of therapeutic effect
 - Products tastes/smells abnormal
 - Patient experiences pain, burning, redness at injection site



Pharmacist's Role

- **Be vigilant (2)**

- Inspect product and packaging. Consider counterfeit if:
 - Tablets are cracked or chipped
 - Wrong color
 - Incorrect markings
 - Packaging looks different and no warning from manufacturer
 - Different dosage forms than are approved
 - Package insert or components are missing
 - Multi-unit package has multiple lot numbers
 - Boxes look worn, tattered, not up to quality
 - Package labels or label colors near the expiry day are discolored
 - Package missing overt markings, such as color-shifting ink, hologram, raised printing
 - Seals are missing, broken, or abnormal
 - Labeling or packaging has misspellings
 - Labeling is in a foreign language
 - Extra glue or tacky residue remains on outside edge of label
 - Labeling indicating “not for resale”



Pharmacist's Role

- **Counseling patients about counterfeit medical products**
 - Encourage your patients to:
 - Shop only at licensed pharmacies
 - Tell their pharmacist if they obtain medical products from other sources, such as the internet, foreign pharmacies, or open markets. If they are, educate them about the risk
 - Ask about assistance programs that might help pay for medical products or offer discounts to prevent them buying from illegitimate or untrustworthy sources
 - Tell your patient if you dispense a drug that may look different from their previously dispensed drug
 - Instruct patients to contact their pharmacist or other healthcare provider if:
 - They experience new or unusual side effects
 - Drug looks, tastes, smells unusual
 - They experience pain, redness, burning that is out of ordinary at injection site
 - Signs and symptoms persist or recur



Pharmacist's Role

- **Immediately report suspect counterfeits**
 - Know how to contact appropriate regulatory or law enforcement authority
 - Immediate report to appropriate authority
 - Immediate inform others in the distribution channel in the community
 - Keep all suspect counterfeit medical products and paperwork, invoices, packaging, labeling, website addresses, and accompanying info for investigative follow up by law enforcement
 - Advise patients to immediately seek medical attention if adverse reaction from counterfeit



COMMENTS OR QUESTIONS???

THANK YOU!!!!

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