

# Weak points of the legal distribution chain

Domenico Di Giorgio  
Director of Counterfeit Prevention Unit  
AIFA – Italian Medicines Agency



1

## Risk Evaluation

Some elements:

1. Dimensions of the market
2. Language on packaging
3. Number of wholesalers
4. Complexity of the distribution network
5. Track & trace system in place (ITALY)
6. Others?



2

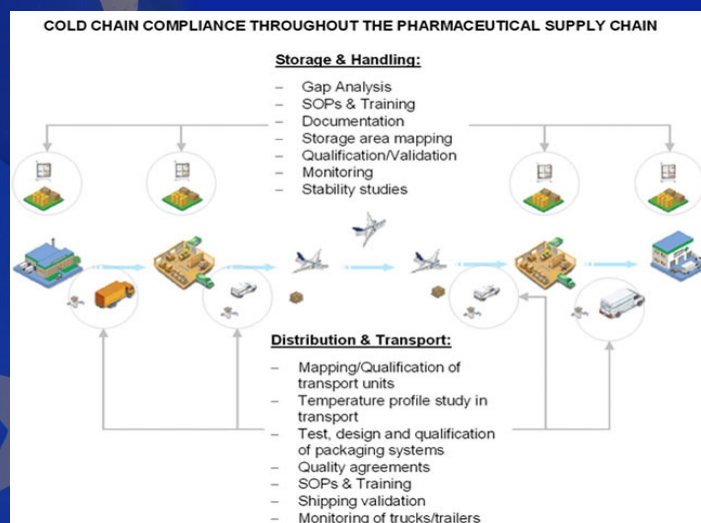
# Risk Evaluation

Some outcomes: possible entry points for counterfeits...

1. Parallel importation
2. Compassionate use (importation)
3. Unaware wholesalers
4. Infiltration at the manufacturer (API...) level
5. Infiltration at the distribution level
6. Others?



# Supply chain



## Real cases

Some examples of infiltration:

1. Parallel importation **LIPITOR (UK)**
2. Compassionate use **ANTICANCER (EU)**
3. Unaware wholesalers **ANTICANCER (USA)**
4. Infiltration at the manufacturer (API...) level **HEPARIN (USA), OTHER (EU)**
5. Infiltration at the distribution level **HOSPITALS (EU), ILLEGAL MEDICINES FROM THE NET IN PHARMACIES(EU)**



## What to do?

1. Parallel importation  
**ITALY: SAME CONTROLS AS FOR AUTH. MEDICINES**
2. Compassionate use (importation)  
**AUTHORIZED AT LOCAL LEVEL, CONTROLS AT MoH CUSTOMS OFFICES**
3. Unaware wholesalers  
**LOCAL INSTITUTION INSPECTIONS, MoH COORDINATION. NEW EU DIRECTIVE (2011/62) STRENGTHENS THE CONTROLS**



## What to do?

4. Infiltration at the manufacturer (API...) level

**AGENCY INSPECTIONS, COORDINATION BETWEEN GMP AND ANTI-COUNTERFEITING. NEW EU DIRECTIVE (2011/62) STRENGTHENS THE CONTROLS**

5. Infiltration at the distribution level

**LOCAL INSTITUTION INSPECTIONS, MoH COORDINATION. NEW EU DIRECTIVE (2011/62) STRENGTHENS THE CONTROLS**

6. Others?



7



## Using the SPOC system. EG Italy – IMPACT Italia



- Exchange of information through the formal network: Police, Customs (incl. MoH offices), Medicines agency (AIFA) and Justice
- Timely exchange of signals from external network, for intelligence activities
- Joint inspections (intelligence, investigation/activity on the field, lab analysis, follow up activities incl. court cases...)
- Restricted web space for sharing signals, informations, hint for investigations
- **Training: shared, intersectorial, central/local levels**



## What to do?

In a nutshell:

**COOPERATE**



9



## Weak points of the legal distribution chain

**THANK YOU**

Domenico Di Giorgio  
Director of Counterfeit Prevention Unit  
AIFA – Italian Medicines Agency  
[d.digiorgio@aifa.gov.it](mailto:d.digiorgio@aifa.gov.it)



10

