

AU MODEL LAW

- ART 22: PROHIBITION OF SUBSTANDARD/SPURIOUS/FALSIFIED/FALSELY-LABELLED/COUNTERFEIT (SSFC) MEDICAL PRODUCTS
- **1) NO PERSON SHALL MANUFACTURE, IMPORT, EXPORT, SUPPLY, STORE, DISTRIBUTE OR SELL ANY SSFC MEDICAL PRODUCTS.**
- **2) THE AGENCY/AUTHORITY SHALL ISSUE GUIDELINES STIPULATING PROCEDURES FOR HANDLING SSFC MEDICAL PRODUCTS IN COLLABORATION WITH OTHER RELEVANT INSTITUTIONS.**

WHY SUBSTANDARD/FALSIFIED & NOT COUNTERFEIT

- DECEMBER 2008, CONSIGNMENT OF API FOR HYPERTENSION MEDICINE ON ITS WAY FROM GENERIC MANUFACTURER IN INDIA TO BRAZIL, VIA AMSTERDAM.
- ACTING ON THE COMPLAINT BY MERCK THE PATENT HOLDER ON THE API THAT ITS IP RIGHTS HAD BEEN VIOLATED, DUTCH AUTHORITIES SEIZED THIS CONSIGNMENT, ON THE BASIS THAT IT VIOLATED AN EC COUNCIL RESOLUTION THAT INFRINGING GOODS IN TRANSIT MAY BE SEIZED.
- AFTER HOLDING THE GOODS FOR OVER ONE MONTH, THEY RELEASED THEM WHEN SATISFIED THAT THE GOODS WERE NOT DESTINED FOR THE EUROPEAN MARKET.
- LATER, A SHIPMENT OF AMOXICILLIN SHIPPED BY AN INDIAN GENERIC MANUFACTURER AND DESTINED FOR VANUATU, WAS SEIZED BY CUSTOMS OFFICIALS IN FRANKFURT, ON A SIMILAR COMPLAINT.

WHAT IS WRONG WITH THIS PICTURE?

- WHAT DOES INTERNATIONAL LAW SAY ABOUT THIS?
 - GATT ARTICLE V: FREEDOM OF GOODS IN TRANSIT.
 - TRIPS ARTICLE 51: LIMITS SEIZURE COUNTERFEIT TRADE MARK OR PIRATED COPYRIGHT GOODS.
 - DOHA DECLARATION ON TRIPS & PUBLIC HEALTH: TRUMPS SUCH ENFORCEMENT PROCEDURES.
 - TRIPS DOES NOT INCLUDE PATENT INFRINGEMENTS IN ITS DEFINITION OF 'COUNTERFEIT'
- SHOULD THE EC COUNCIL RESOLUTION OVERRIDE INTERNATIONAL LAW?
- THE RESOLUTION WAS TARGETING GENERIC MEDICINES.
- ARE GENERICS THE SAME AS COUNTERFEIT?

WHAT OR WHO IS BEHIND THIS AGENDA?

- EU HAS SUPPORTED EAC COUNTRIES INSTITUTING ANTI-COUNTERFEITING LAWS.
 - KENYA – HIGH COURT DECLARED PARTS OF ANTI-COUNTERFEITING LAW UNCONSTITUTIONAL.
 - UGANDA –BILL WAS WITHDRAWN AFTER YEARS OF SITTING IN PARLIAMENT.
 - TANZANIA – DID PASS LAW BUT LIMITED SCOPE.
- EUROPEAN COUNTRIES HAVE SPONSORED ADOPTION OF THE MEDICRIME CONVENTION IN SOME WEST AFRICAN COUNTRIES.
 - INTENT IS THE SAME AS THE EC COUNCIL RESOLUTION RESPONSIBLE FOR GOODS SEIZURES.
 - AFRICAN COUNTRIES SHOULD GUARD AGAINST SUCH LAWS AGAINST THEIR BEST INTERESTS.

WHAT'S THE SOLUTION TO SF PROBLEM?

- PROPER REGULATION
 - LEGAL FRAMEWORK (MEDICINES REGULATION LEGISLATION) & REFORM IP LAWS
 - EFFECTIVE ENFORCEMENT
- EDUCATION
 - MAKE PEOPLE AWARE OF DANGERS
- MAKE MEDICINES AFFORDABLE
 - GOVERNMENTS TO INTERVENE IN VARIOUS WAYS