



## Global Access to Medicines & the Role of Generic Competition

### ***Overview of generic drugs***

- A generic medicine is identical/bioequivalent to a brand name drug in intended use, performance characteristics, safety, quality, and dosage form.
- Generic medicines increase market competition which reduces prices over time.
- With first generic entry, price falls on average 40-80% and continues to fall with time.
- Reduced prices allow governments & international agency treatment programs to increase coverage.

### ***Recent measures that threaten to generic competition include:***

#### **Anti-Counterfeiting Trade Agreement (ACTA) Proposals:**

- Will increase seizures of generic medicines at customs borders.
- Grant broad authority to rights holders to trigger detentions.
- Increase the stringency of damages/injunctions to a harmful level.
- Establish liability for active pharmaceutical ingredients manufacturers.

#### **National Anti-Counterfeiting Laws in East Africa:**

- Gives customs officials and police authority to determine which medicines are counterfeit.
- Applies criminal penalties to civil infringers.

#### **EU Customs Regulations:**

- Create over-broad IP rights by not distinguishing trademark counterfeiting & civil trademark infringement.
- Give too much authority to customs officials who are not competent to take action.

#### **USTR's Annual Special 301 Reports:**

- Put countries that deny "adequate" IP protection on a watch list.
- Are guided by the priorities of big pharmaceutical companies

### ***Solutions***

- **Maintain & Promote TRIPS Flexibilities**
  - Promote knowledge of flexibilities, such as compulsory licensing, in developing countries.
  - Provide technical assistance to developing countries for utilizing these flexibilities.
  - Refrain from punishing/threatening trade partners who use flexibilities to advance health objectives.
  - Refrain from creating new IP measures, such as ACTA, that are more stringent than those in TRIPS.
- **Delineate definitions** of counterfeit, substandard and generic drugs.
- **Adopt more direct solutions**, such as pharmacovigilance, for protecting against falsified medicines

### ***Revolution in HIV/AIDS treatment has been fueled by generics competition.***

- Prices have been reduced from \$10,000 to \$100 per person, per year.
- Costs of antiretroviral medications have been reduced by 98+% over ten years.
- Competition has enabled more than four million people worldwide to access lifesaving antiretroviral therapy.
- Competition remains vital for extending access to expensive second and third-line HIV/AIDS treatments.

***The role of generics in competition is key to implementing access to medicines for all.***