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EuroMeeting

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## EU Generic Medicines Industry and the New Pharmaceutical Package

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(EGA)



## Generic Medicines: Key to Sustainability and Patient Care

- EGA represents over 700 companies in 34 European countries
- Generic medicines companies employ over 130,000 people in the EU
- Generic medicines account for nearly 50% of packs dispensed in the EU and 18% of pharmaceutical expenditure



- Generic medicines bring savings of over €25 billion per annum in the EU-27
- Generic medicines companies cover a full spectrum of pharmaceutical needs
- Generic medicines companies also undertake incremental innovation



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## New Pharmaceutical Legislation

The EGA will be fully involved in developing new EU legislation:

1. Falsified Medicines
2. Pharmacovigilance
3. Industry Information To Patients (ITP)



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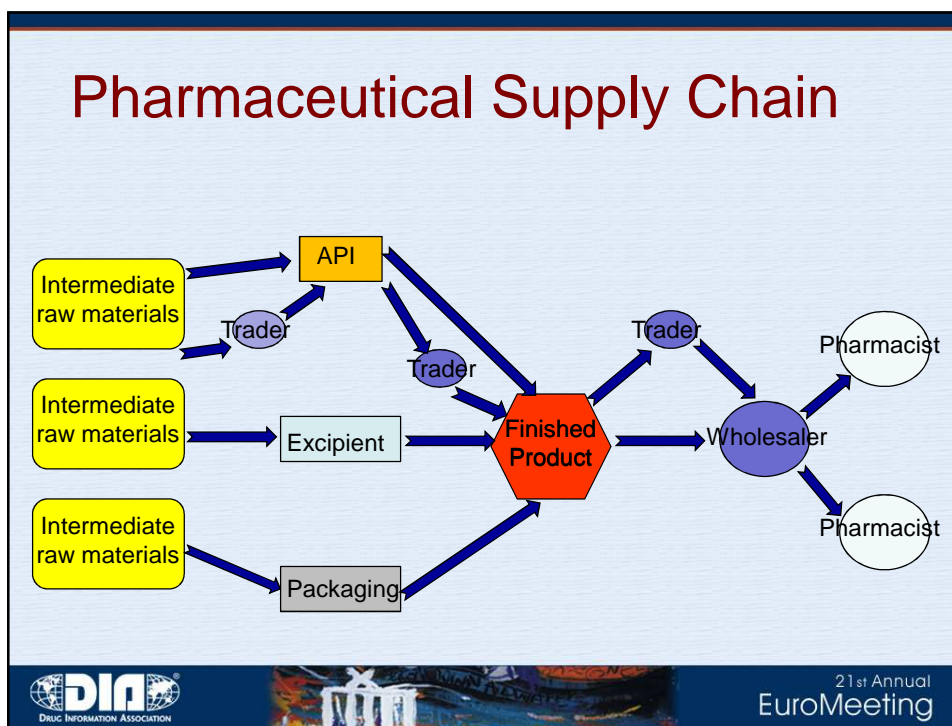
EC Proposal on

## **FALSIFIED MEDICINES**




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## Quality Aspects Active Substances (1/2)

- ✓ The EGA supports the medicines quality aspects of the EC proposal
- ✓ Pragmatic approach:
  - Enhanced efficiency of current EU quality framework
  - Optimised use of available resources through cooperation




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## Quality Aspects Active Substances (2/2)

- Addresses concerns in the European Parliament Written Declaration on pharmaceutical active principles (Sept 2006):
  - Creates a level playing field for medicines:  
Equivalence of Standards Concept
  - Enhances transparency of the distribution network, and traceability from source to patients



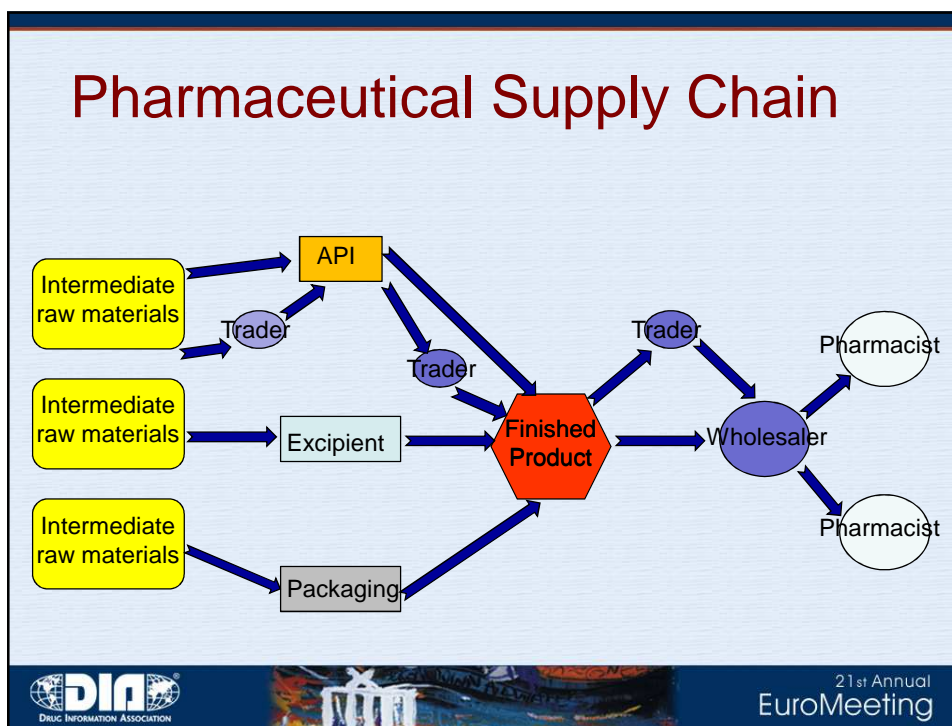
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## GMP as Only Remedy Against Falsified Medicines ?

- GMP alone will not be the answer to
  - counterfeiting, fraud,
  - intentional contamination
  - or any other criminal or illegal behaviour !
- Primary line of defence:
  - Better enforcement (cooperation, transparency) and adequate criminal sanctions
  - Business with certified partners only



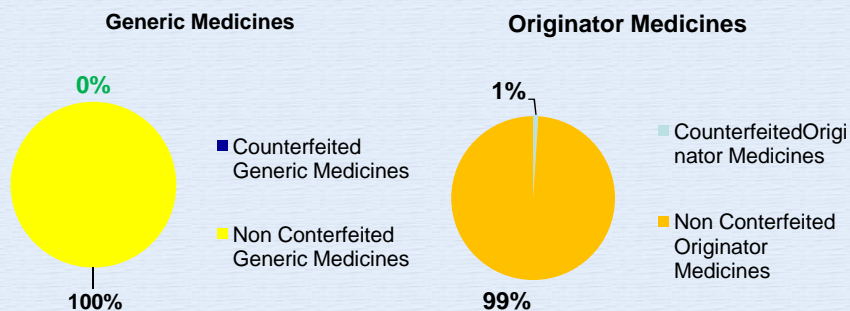
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## EGA Activities on the Fight Against Counterfeiting

- The EGA has been at the forefront of the fight against counterfeiting taking an active role at different initiatives:
  - WHO IMPACT (2006, Anti-Counterfeiting Task Force)
  - GS1 Healthcare (2005, Global Coding Entity)
  - Council of Europe (2004)
  - European Healthcare Initiative (EAN 2001)

## How Big is the Issue of Counterfeit Medicines?



Source: WHO Fact Sheet N275

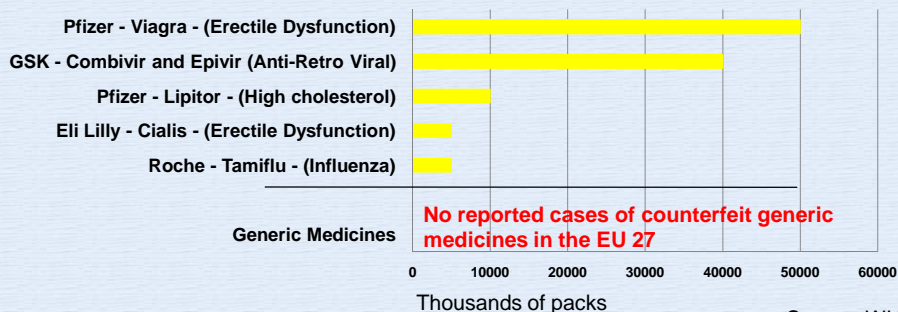


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## Counterfeiting of High-Price Popular Medicines

### Examples of Reported Cases of Counterfeited Medicines



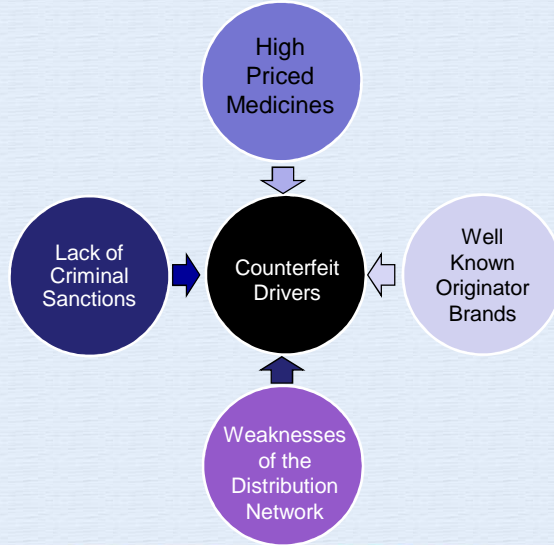
Source: WHO Fact Sheet N275, Council of Europe Report 2006



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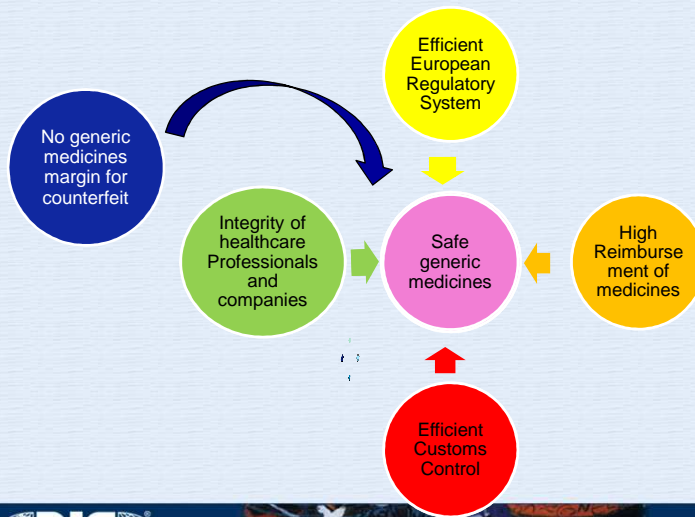
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## What are the Driving Forces...



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## Why is the 0.1% of Counterfeit Medicines in the EU?



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## Product Traceability and Risk Based Assessment

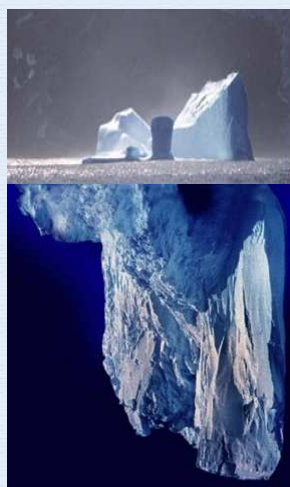
- The EC Proposes safety features for medicines depending on the risk based assessment of being counterfeited based on price and past incidents within the EU
- ✓ EGA welcomes risk based approach as generic are not targeted and since the implementation costs of safety features are to cost 6.8Bn to 11Bn Euro to the pharmaceutical industry !
- But there is over reliance on technological solutions and sub-optimal problem assessment



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## Impact of the EC Proposal on the Fight Against Counterfeiting



Legal Supply Chain

Subject all actors of the distribution chain to pharmaceutical legislation  
GMP Supervision & Enforcement  
What about wholesalers licences and pharmacist responsibility ?



Illegal Supply Chain & Internet

No measures on the EC Proposal to fight counterfeiting in illegal supply chain & on the Internet

“50% of medicines purchased over the internet from sites that conceal their physical address are counterfeit”(source: WHO)



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## Falsified Medicines: Additional EGA perspectives

- Primary lines of defence should deserve appropriate attention
  - Better enforcement
  - Adequate sanctions
  - Reliable business with certified partners
- Creation of a European Inspectorate
- Harmonisation of wholesale/import licensing
- Internet medicines sales regulation



EC Proposal on

## PHARMACOVIGILANCE

## Strengthening and Rationalising EU Pharmacovigilance

- EGA support in general the EC proposal on Pharmacovigilance – win – win – win ✓
- However, the new PIL/SmPC section '*summary of essential information*' raises major concerns
- In line with EMEA/EC, PhV requirements should remain the same for all biopharmaceuticals, including biosimilar medicines

EC Proposal on

## INFORMATION TO PATIENTS

## 3 EGA Principles on Patient Information

1. Citizens need easy access to high quality information
2. Information should be unbiased and independent
3. Personalised information via physician and pharmacist is crucial

→ In line with the EC proposal (art. 100d)  
Quality Principles



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## Already Existing in Europe ...

- Transparency rules (2004) oblige Medicines Agencies to publish patient leaflets
- In some member states, company websites publish approved patient leaflets (eg, UK, Germany)
- FASS in Sweden: standardised system with leaflets sponsored by industry



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## If No Clear Distinction Between Information & Advertising = MARKETING =

*"Pharmaceuticals companies in future will really have to draw clear divisions between their marketing and public information departments. They cannot be one and the same. The risk for abuse is too great."*

*Hans-Joachim Rothe,  
Vital Business Manager,  
Bayer*

*"Two New Zealand public health academics are warning Europe not to allow pharmaceutical companies to supply direct-to-consumer information to patients as it will open a 'Pandora's Box'"*

*"Studies suggest that DTC advertising has contributed to increases in drug spending and utilization by prompting consumers to request the advertised drugs from their physicians"*

**GAO**  
(US Government  
Accounting Office)

*BMJ 2007 - Oct. 6*



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## EC Pharmaceutical Package **CONCLUSIONS**



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## EC Falsified Medicines Proposal

- Generic medicines sector is committed to ensuring patient safety and high quality
- 1<sup>ary</sup> line of defence is key: better enforcement (incl. sanctions) & enhanced supply chain integrity (eg, certified partners)
- Safety features as 2<sup>ary</sup> line of defence against falsified/counterfeit medicines
  - Risk based assessment on price, past incidence and evolution of incidence

## Information to Patients Proposal

- Opportunity to improve and harmonise the current system throughout the EU
- Opportunity to provide BETTER information (high quality, independent, unbiased), if appropriate safeguards



## Pharmacovigilance Proposal

- Opportunity to better protect Public Health by strengthening and rationalising the existing EU Pharmacovigilance system
- Drastic changes to Product Information should have been proven to
  - Maximise benefits for patients
  - Minimise risks of medicines



**THANK YOU FOR YOUR  
ATTENTION !**

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