



Making Medicines Affordable

A Pragmatic Approach Towards Supply Chain and Patient Safety

Greg Perry

Director General EGA

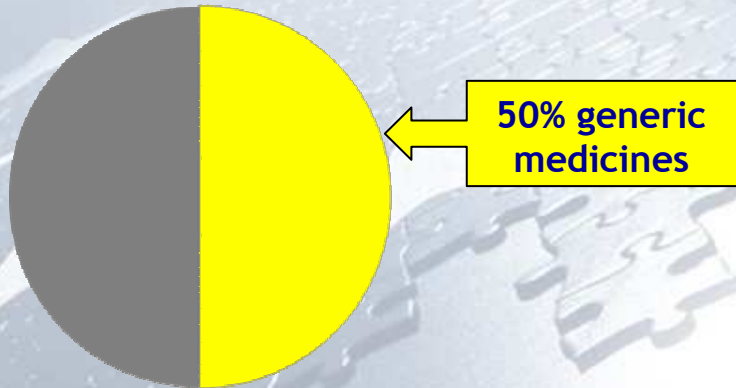
**How can the supply chain protect patients against
counterfeit medicines in the EU?**

European Parliament

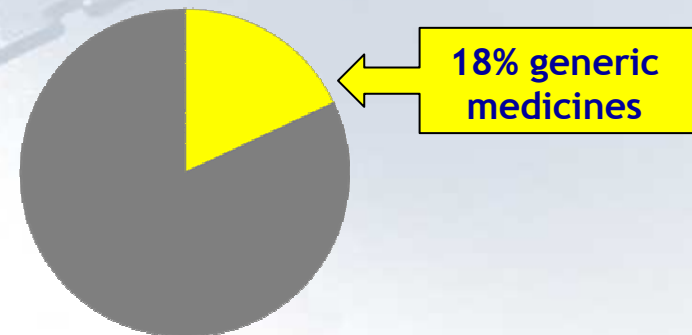
10 November 2009

Generic Medicines- Key to Healthcare Sustainability

Volume dispensed medicines in EU27



Pharmaceutical expenditure in EU27



Generic medicines in the EU27 represent more than €25 Billion of savings to governments every year



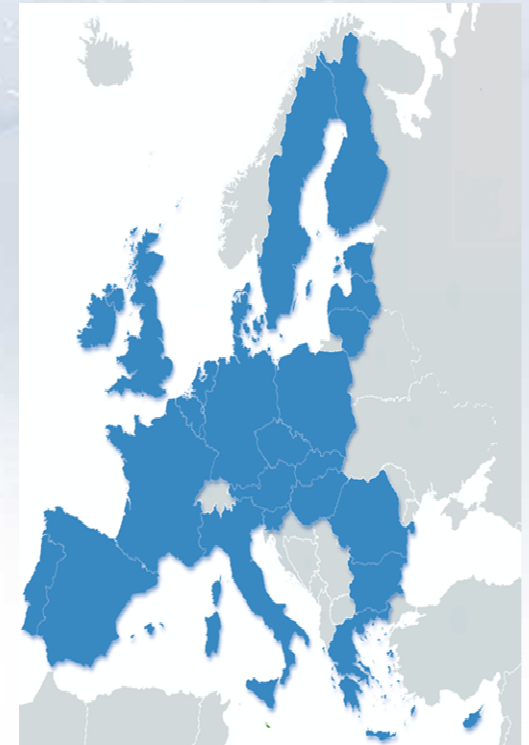
Affordable Generic Medicines Cover a Full Spectrum of Pharmaceutical Treatments

- Cancer
- Viral Infections
- Diabetes
- Bacterial Infections
- Depression
- Osteoporosis
- High Cholesterol
- Epilepsy
- High blood pressure
- Rheumatism
- Asthma
- Pain Relief
- Gastro-intestinal disorders
- Inflammation

Within the Generic Sector - Highly Competitive Industry



- Over 1000 companies in 34 European countries
- 130,000 EU jobs in R&D, production and sales
- 10-30 companies competing on one product
- Investments in incremental innovation





EGA Activities in Patient Safety and Fight Against Counterfeiting

- **The EGA is at the forefront of the fight against counterfeiting, taking an active role with different initiatives:**
 - Participation in the EC Observatory of Piracy and Counterfeiting (2009)
 - EC Stakeholder Meeting on Internet - Internet Dialogue (2009)
 - WHO IMPACT (2006, Anti-Counterfeiting Task Force)
 - GS1 Healthcare (2005, Global Coding Entity)
 - Council of Europe (2004)
 - European Healthcare Initiative (EAN 2001)



Generic Medicines Industry Active in Patient Awareness of Medicines Sold Over the Internet

Bogin

62% VAN DE PILLEN BESTELD VIA INTERNET IS NIEP

BOND VAN DE GENERIEKE GENEESMIDDELENINDUSTRIE NEDERLAND

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Nieuws

Persberichten

NIEUW
9 juli 2009
[Europese commissie wil generieke concurrentie stimuleren](#)
[BOGIN positief over uitkomsten onderzoek Europese Commissie](#)

20 april 2009
[UNIVE, VGZ, IZA en TRIAS starten eenzijdig preferentie systeem](#)

14 mei 2008
[Zorgverzekeraars schenden vertrouwen](#)
[Bogin zegt Transitieakkoord op](#)
[Zorgverzekeraars voelen zich niet gehouden aan akkoord en laten Bogin geen keus](#)

2 april 2008
[Continuïteit levering generieke geneesmiddelen in gevaar](#)
[Verzekeraar kiest per product één aanbieder](#)

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[Zorgverzekeraars teruggefloten door de rechter](#)
[Uitspraak kortgeding Bogin - Zorgverzekeraars Nederland](#)

Overig Nieuws

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[Meer maagmiddelen voor minder](#)

6 september 2009
[Heemskerk: doorvoer generieke medicijnen mag niet onnodig gehinderd](#)

4 september 2009
[Generieke anti-epileptica goed onderzocht](#)

EGA persberichten, rapporten en bijeenkomsten

Nieuwsbrief

4 juni 2009
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Persbericht

[EPO Announces Four Candidates For Next President](#)

2 oktober 2009

**Key Message for the Patient:
62% of the pills ordered on internet are fake**

Dutch Generic Medicines Association Web Site in Association with the Dutch MOH



EGA Committed to Increase Risk Communications for Patient Safety



- EGA amongst other stakeholders working on how to improve and increase risk communication on counterfeit medicines



Making Medicines Affordable

The scale of the EU Problem



- “...counterfeit drugs are a relatively small problem in the US and Europe - found mainly as “lifestyle medicines” purchased over the internet...”

Source: Chirac demands action on fake medicines - The Financial Times Limited 2009

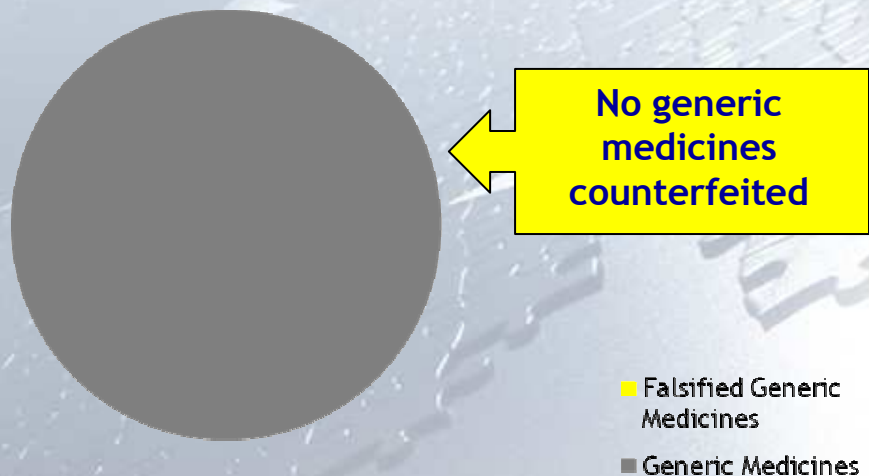


- “...less than 1% of medicines sold in developed markets such as the EU are counterfeited.”

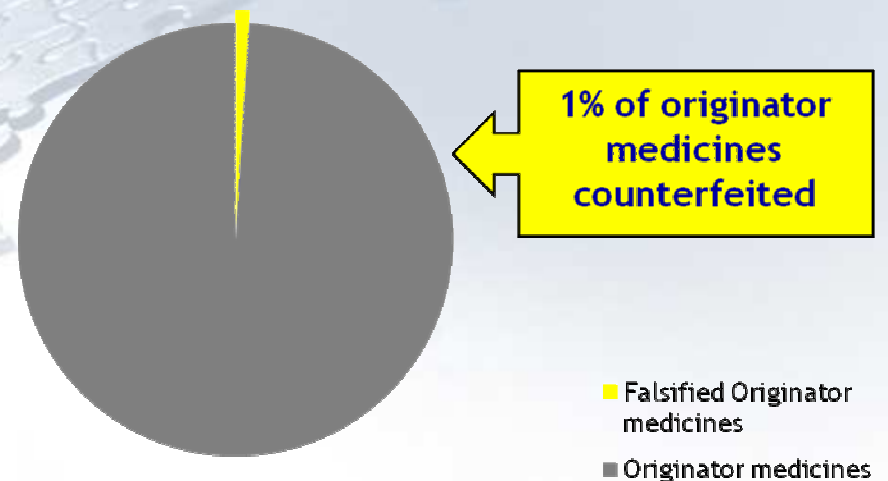
Source: WHO Fact Sheet 275

No Reported Cases of Generic Medicines Counterfeited Within the EU 27

Generic Medicines in the EU



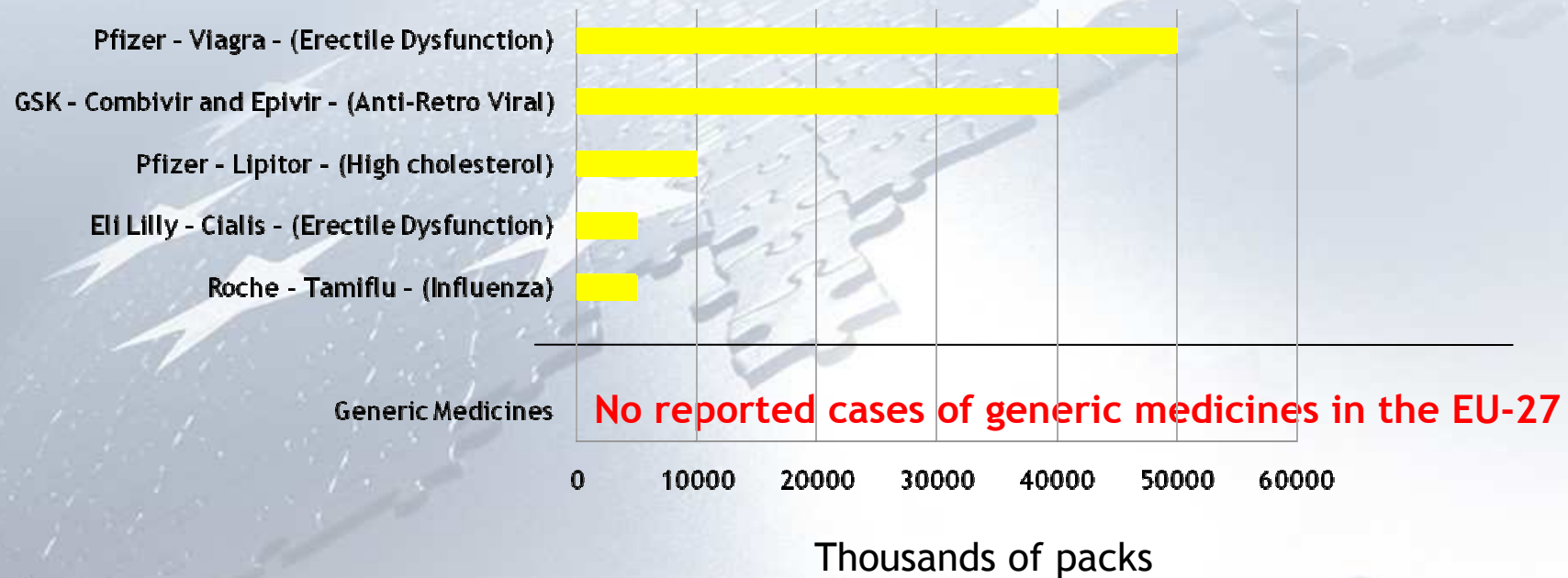
Originator Medicines in the EU



Source: WHO Fact Sheet N275

Counterfeiters Target High Priced Popular Medicines

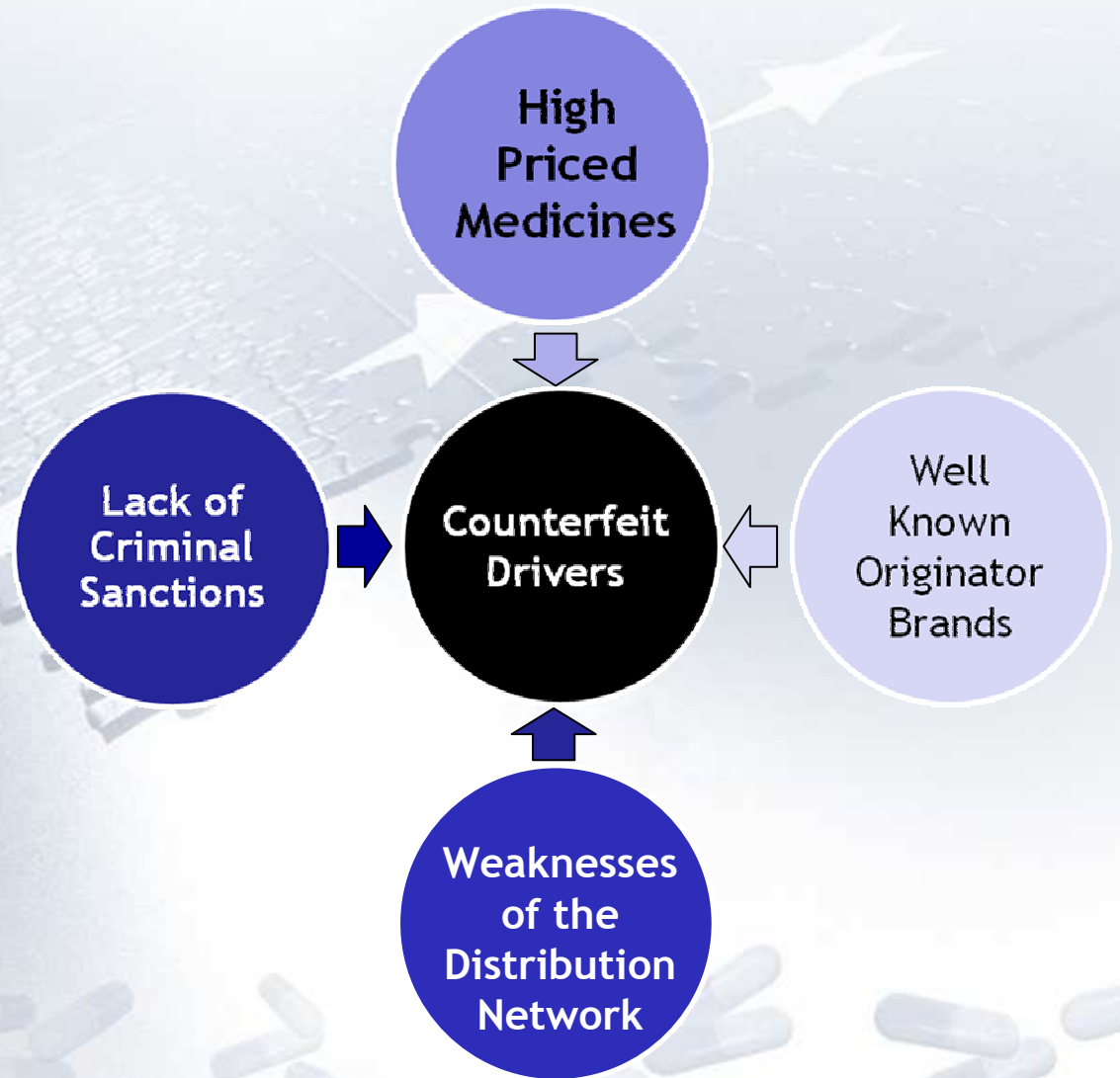
Examples of Reported Cases of Counterfeited Medicines



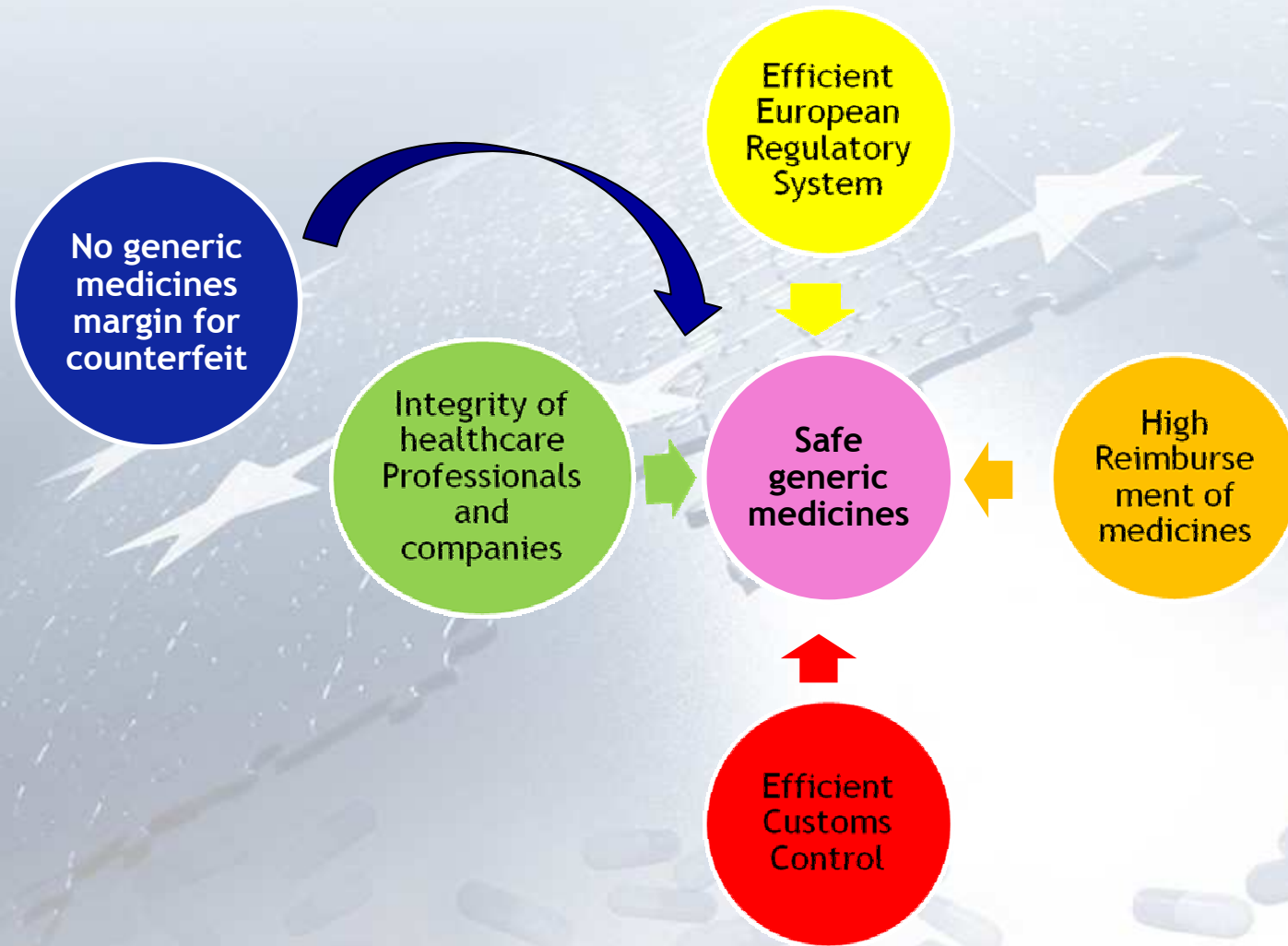
Source: WHO Fact Sheet N275,
Council of Europe Report 2006

Driving Forces...

What are the
driving forces
behind the
counterfeiting
of medicines?



Current Barriers to Counterfeit of Generic Medicines in Europe





EU Member States are also Fighting Against Counterfeiting

- Efficient EU recall systems
- Member States sharing information and cooperating
- Partnership with Authorities (e.g. Police, Customs and Medicines Agencies)

Impact of the EC Proposal on the Fight Against Counterfeiting



Legal Supply Chain

Traceability - safety features cost 6.8bn to 12bn

Not proven successful in guaranteeing patient safety

Not proportionate to the risk

Not clear about data base independence

Illegal Supply Chain & Internet

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

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



Impact Assessment: A Missed Opportunity

- **Assessment of the counterfeiting problem within the EU**
 - Lack of figures referring to the legal and illegal market
 - Non harmonised member state information on the most affected type of therapeutic areas, medicines and countries

Technological Systems do not Guarantee Patient Safety

- ***"Our experience is that counterfeiters can replicate anti-counterfeiting technology within six to 12 months of those technologies coming onto the market," said Mr Muller.***

Source: "Counterfeits, a growing scourge"
SCRIP - World Pharmaceutical News
[Mike Muller, director of global anti-counterfeiting operations at Eli Lilly]





EGA Recommendations Focus on Real Solutions and Patient Safety

1. Criminalisation of pharmaceutical crimes
2. Internet law enforcement and patient awareness on sales of medical products
3. Business with “certified partners only”
 - Improve business ethics in the distributor network and supply chain
4. Increasing requirements for wholesaling licences





Key Players Support Real Solutions



- Criminalisation of Pharmaceutical Crimes - Drafting of an international convention, initiated in the Council of Europe



- Increasing requirements for wholesaling licences - MHRA currently preparing a proposal on this issue



- Business with “certified partners only & patient awareness -

“...a United Nations convention to fight fake medicines by imposing tough penalties, strengthening manufacturing and distribution controls and improving awareness.”

Source: Chirac demands action on fake medicines - The Financial Times Limited 2009

EGA Recommendations Focus on Real Solutions and Patient Safety

5. The so called safety features should be considered only as a second line of defence and be:

- Risk assessed with the criteria based on:
 - **past incidents and price only**
- Cost effective
- Proportional Costs (by price and not by volume)
- Independent (database ownership)

These principles should be in Article 54 a)



Growing Concerns Over Technical Solutions



- Risk assessment of medicines art 54a) (4) of the EC proposal -

MHRA - focused on ensuring the exercise of due diligence and the reporting of suspicious transactions by those engaged to improve the integrity of the supply chain and adopting a risk based approach to the protection of products

- Technological systems only if cost-effective, cost proportional and with an independent database

Beuc recommendations on safety features:

- the new safety measures should be efficient and proportionate;
- the new track and trace technologies should be safe and cost-effective;





EP Must Seek Real and Effective Solutions

■ Possible amendments to:

- Call upon MS to introduce tough criminal measures
 - Create guidelines and actions for the Internet and rules for internet pharmacists
 - Increase the GDP requirements wholesalers, traders and brokers
 - Require database of established certified supply chain operators
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