- The launching of awareness-raising campaigns to warn consumers/patients about the risks of buying medicines on websites;
- The introduction of measures to foster international cooperation as counterfeiting is an international crime that does not recognise any borders;
- The creation of an International Criminal Convention to fight the counterfeiting of medicinal products on a global scale;
- The enforcement of drug control legislation with mandatory inspections throughout the whole supply chain;
- The strengthening of the relevant provisions on sanctions – counterfeiting medicines is an organised criminal activity that puts human lives at risk and must be heavily sanctioned;
- The same stringent rules that are in place for medicines that enter the European market must apply to third countries.

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Counterfeit Medicines:
A Threat to Patients' Lives

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The extent of the problem

Counterfeiting drugs is an organised criminal activity which undermines public trust in medical treatments and healthcare systems. All countries are implicated in this scourge whether in transiting, as a source, or as a market place for products or ingredients. According to available data, falsified medicines account for 1-3 % of the market in developed countries, 10-30 % in Asia and Latin America, and up to 70 % in certain African countries. 34 million counterfeit tablets were seized in the EU in 2008, a rise of over 380 % compared to 2005. It is a rapidly growing criminal activity worth 45 billion Euros a year.

"Counterfeit medicines are silent killers because they are either placebos devoid of effect or they contain toxic substances which can harm or kill patients. Counterfeiting medicines is a crime which respects no borders and should be severely punished. Patients' safety and confidence are our top priorities when it comes to fighting fake medicines"
GUE/NGL rapporteur Marisa Matias.

Preparing the ground for binding European legislation

In order to address the risk of counterfeit medicinal products entering the legal supply chain, the European Commission proposal on falsified medicines is based on 3 pillars:

1. **Full traceability** to secure the legal supply chain against the infiltration of counterfeit medicines by means of safety features;
2. **Stricter rules** on active ingredients, which are responsible for the health effects of the medicinal product;
3. **Enhance transparency and supervision** of actors in the legal supply chain.

The Commission proposal is a step in the right direction but not enough to fully ensure patient safety as the following crucial questions remain unanswered:

Internet sales: the "Trojan horse" for fake medicines.
Medicines purchased over the internet are estimated to be counterfeit in more than 50 % of cases. They contain the wrong dosage, the wrong ingredients or no active ingredients at all. The EC proposal does not address internet sales although e-commerce is in operation on the legal market.

Exports to third countries: stringent provisions are in place for medicines that enter the European market but the Commission proposal does not contain any provisions for medicines which are exported to third countries in Africa, Asia and South America. The manufacturing and distribution of medicines from the EU to third countries must adhere to the same criteria as those applied for imports.

Mandatory inspections: the Commission inspection system is based on audits and good manufacturing practices. All actors in and around the supply chain should be subject to mandatory inspections to guarantee the safety of medicines throughout the supply chain.

Penalisation of counterfeit medicines: enforcement is a key issue and strong sanctions help prevent fake medicines from infiltrating the EU market.

A strong stance is needed

The GUE/NGL position places the patient at the heart of legislation and seeks the immediate introduction of the following measures to guarantee patient safety:

- Strategies developed to combat counterfeit medicines must be in line with the principles of patient-centered healthcare, in terms of access to safe, quality and appropriate treatment and information;
- A compulsory safety feature for authentication, identification and traceability of medicines from the factory to the patient to prevent content-tampering;
- All actors in and around the supply of medicines (manufacturers, wholesalers, traders and brokers, pharmacists) must bear full liability for any counterfeit medicine that enters the legal supply chain as a result of their activities;
- Measures to ensure that patients/consumers do not bear the costs of the new safety features and that any costs are spread along the supply chain;
- Safeguarding jobs in the parallel trade on condition that traders replicate equivalent safety features;
- Zero tolerance on counterfeits should not be confused with intellectual property rights or patent infringements;
- Generics should be exempted from the scope of the new legislation;
- The extension of the scope of the planned new legislation to all pharmaceutical sales on the internet. Websites selling medicinal products and e-pharmacies must be certified with a specific EU logo to distinguish legal from illegal sales, with the creation of a European list of authorised online pharmacies;