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Citizen's Summary

Legal proposal on measures preventing the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source

1. WHAT IS THE ISSUE?

Medicines contribute considerably to the health of EU citizens. However, there is a significant increase of false medicinal products which are detected within the legal supply chain of the Member States. These false representations of medicines can be unsafe, inefficient, or of low-quality thus posing a risk to human health.

2. WHAT IS THE BACKGROUND TO THE PROBLEM? WHY SHOULD THE EU BE INVOLVED?

Counterfeiting high-price medicines is a growing illegal business and a threat to public health worldwide. The number of false representations is increasing and the risk profile of counterfeited medicines is changing to cover not just life-style products, but more and more innovative and life-saving medicines. Moreover, these products are channelled increasingly through the legal supply chain.

The legal supply chain of pharmaceuticals within the EU often covers actors in different Member States. The risk of distributing counterfeited medicines has therefore a significant cross-border aspect which calls for harmonised action at EU level.

3. WHAT ARE THE PROPOSED ACTIONS?

The European Commission is proposing a number of measures to provide the highest possible level of assurance that only high-quality medicines are sold within the legal supply chain:

- Identify more easily false representations of medicinal products in particular through safety features ensuring full traceability of each individual package of high-risk products.
- Improving the control at the EU external borders through which false medicinal products could enter; and
- Ensure that the active pharmaceutical ingredients is of high quality standard and not falsified.

4. WHY ARE THESE ACTIONS USEFUL FOR EUROPEAN CITIZENS?

These actions ensure a safe supply of authentic, thus high-quality medicines to EU citizens.

5. WHAT ARE THE NEXT STEPS?

The legal proposal will now be debated in the European Parliament¹, representing citizens, and in the Council, representing Member States².

¹ <http://www.europarl.europa.eu/>
² <http://www.consilium.europa.eu/>