

# COUNTERFEIT MEDICINES

**BEUC response to the European Commission public  
consultation in preparation of a legal proposal to combat  
counterfeit medicines**

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## Summary

BEUC welcomes the European Commission preliminary proposals to combat counterfeit medicines as outlined in the consultation paper published on 11 March 2008.<sup>1</sup> We believe that the proposed measures will ensure more control and transparency of the supply chain and a better protection of consumers against the risk of counterfeit medicines.

We call for increased public information, mandatory reporting, education and involvement of consumers, specific measures for internet sales, stronger penalties for counterfeiters, enhanced international cooperation, safe trace technologies that do not incur additional costs for consumers.

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In view of the preparation of the final proposal we would like the European Commission to clarify the economic impact of the new provisions and the consequences on parallel trade.

The proposals focus on preventing counterfeit medicines to enter the supply chain, however, we would like to take this opportunity to reiterate<sup>2</sup> some issues which go beyond the scope of the Commission initiative but that we consider particularly important in relation to this serious public health threat:

- **Information and mandatory reporting**

Increased public information is essential for consumers and health care professionals who have the right to know if there are suspect goods on the market and who can also actively contribute to detecting counterfeits by reporting suspicious cases. Reporting to the competent authorities should be mandatory. This would also help to have more data and a better understanding of the phenomenon, including the health consequences for the patients. The competent authorities should have the legal duty to investigate, issue appropriate public warnings, and share information across the borders.

- **Educating consumers**

Consumers can play an important role in the detection and in the reporting of suspect cases. Educational programmes to increase consumer awareness about the existence of counterfeit products and the risk of buying drugs from unauthorised channels should be put in place. Consumers should be educated on how to recognise a counterfeited product and how and to whom they can report. They should be educated on how to recognise an authentication mechanism.

Consumers need more information about the risks associated with counterfeit medicines and illegal medicines but the argument of counterfeit medicines shouldn't be used against generics or to support any kind of direct to consumer advertisement of prescription drugs from the pharmaceutical companies.

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<sup>1</sup>[http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008\\_03/consult\\_counterfeit\\_20080307.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_03/consult_counterfeit_20080307.pdf)

<sup>2</sup> Put Health First, BEUC, October 2007.

In addition, the argument of counterfeit, which is a genuine health policy issue with major effects on the safety of medicines and of patients, shouldn't be mixed with the discussions about the competitiveness of the pharmaceutical industry.

- **Internet sales**

Internet-based sales of pharmaceuticals are a major source of counterfeit medicines, threatening those who seek cheaper, stigmatized or unauthorized treatments.

Illegal internet pharmacies sell medications without prescriptions and use unapproved or counterfeit products, operate internationally and sell products that have an unknown origin<sup>3</sup>. Special initiatives could be launched to make consumers aware of the risks they run when purchasing on line medicines from unknown sources.

- **Stronger penalties for counterfeiters**

EU Member States should adopt stronger measures to fight against medicines counterfeiting: the police and the customs authorities should be given more tools to arrest and prosecute counterfeiters and most of all, stronger criminal penalties are needed. Counterfeiting medicines is not a minor offence. It is an organised criminal activity which is not different from inflicting physical violence on people. Penalties for medicines counterfeiters should be consistent and proportionate to the potential harm they might cause.

- **Foster cooperation**

Although enforcement of medicines legislation is a competence of the Member States, coordination between various national and international bodies involved in fighting counterfeits is necessary. It's important to facilitate communication between enforcement and health authorities, improve international collaboration and develop appropriate mechanisms that will enable importing countries to trigger investigation and identification of the actual source of counterfeit medicines entering their markets.

- **Technology**

Track and trace technologies and product authentication technologies might help to identify counterfeit medicines on the market. Our main concern is that any technology used fully ensures consumer safety, is reliable and applicable, improves the tracing mechanisms allowing identification and safe recall, has no impact on the final price of the drugs and is pro-competitive. From all possible technologies, we do not support the use of RFID (radio frequency identification technology) because of the numerous privacy and security concerns it raises. Other technologies, with lower safety and data protection implications should be exploited.

Given the disparities between the level of technological access in industrialized and developing countries, it is essential to facilitate the transfer of technology across both developed and developing countries.

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<sup>3</sup> Illegal y arriesgada, OCU n.75, December 2007 – January 2008.