FAKE DRUGS: ARE EUROPEAN CONSUMERS SAFE?

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Counterfeiting of medicines is a criminal activity that puts consumers' health at serious risk. To date, European consumers have been relatively well protected but counterfeit medicines are beginning to appear in Europe and there are signs of a growing hazard.

BEUC therefore welcomes the European Commission proposals to combat falsified medicines as a necessary step to respond to this rising health threat and to better ensure patients safety. We believe that the proposed measures will ensure more control and transparency of the supply chain and a better protection of consumers against the risks of counterfeit.

Counterfeit medicines exist but it is not clear from the official figures where and in which proportions. To ensure that the new measures are effective and proportionate it is vital to have more precise figures and a realistic idea about the risks to which European consumers are exposed.

The proposal refers to the costs implications of the new measures for industry, wholesalers' distributors and manufactures of active pharmaceuticals ingredients (API), but not for consumers and health care systems. It is essential to ensure that consumers do not bear all the costs of the new safety measures and that the costs are spread along the supply chain. Any policy change should be based on a sound impact assessment on its economic implications for private and public budgets. So far they have not been fully assessed with regard to this proposal.

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

Illegal internet pharmacies operate internationally and sell unapproved or counterfeit products that have an unknown origin1.
BEUC members in different countries tested sales of medicines on the internet to verify the safety and reliability of this supply channel. They also made laboratory analyses to assess the quality of the products they purchased.

The results are worrying:

- in most cases they managed to buy prescription-only medicines without prescription;
- the laboratory tests revealed major quality problems , in addition to concerns regarding the storage and shipping of the products. A recent survey2 published in October 2009 by the Dutch consumer association Consumentenbond, found that out of the 47 orders received, in 16 cases the dosage of active ingredient exceeded the standard dosage by more than 10% or fell short of it by more than 10%. In many cases the medicines contained the wrong substance or contamination of other substances;
- they received pills wrapped in newspaper sheets or loose bags;
- they didn't find any safety information on the web sites;

[1] Illegal y arriesgada, OCU n.75, January 2008.
[2] Consumentenbond, October 2009.

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- the medicines were not accompanied by the patient leaflet or the leaflet was an inaccurate translation;
- the web sites didn't disclose the origin of the products and declined any responsibility;
- many of the web sites they used no longer existed two months afterwards.

The proposal addresses only the traditional supply chain while evidence shows that it is urgent to take measures against illegal internet sales of medicines. We understand that from a legal point of view the Directive cannot directly address internet pharmacies and illegal sales but we believe that some concrete measures could be taken within the existing legal framework, namely:

1. Special initiatives could be launched to make consumers aware of the risks they run when purchasing on line medicines from unknown sources

The national competent authorities should launch ad hoc campaigns to warn consumers against the risk of buying medicines online from illegal sources as it has been done, just to give an example, in the Netherlands and in Portugal
and in Belgium.

Consumers' organizations also have a role to play in informing the public. Consumers should also be informed about how and to whom they can report suspected unlawful sale of medical products on the internet (for example to the competent health authorities or to their pharmacists). In the US the Food and Drug Administration (FDA) has a dedicated toll-free information line for these cases.

2. a ban on sponsored advertising of illegal pharmacies on line

A US study conducted by research firms LegitScript.com and KnujOn.com.has found that over 80% of on-line advertisements for Internet pharmacies accepted by different search engines were fake or illegal Internet pharmacies and in violation of US federal and state laws. The researchers were also able to purchase prescription drugs without a prescription and were sent counterfeit medications.

The liability of search engines that provide sponsored advertising needs to be carefully assessed in line with the existing Community legislation taking into account that, as pointed out by the Advocate General of the European Court of Justice, sponsored advertising services provided for by Information Service Providers (ISPs) are not a neutral information vehicle as opposed to the natural results presented by search engines.

Companies that provide sponsored advertising services should be responsible and accountable for ensuring that the links they sponsor comply with the legislation and should not advertise illegal web sites selling medications.

3. the creation of certification systems for authorised pharmacies on line in those countries where on line sales are legal

The on line sale of prescription medicines is legal only in some member states (e.g. UK, Netherlands and Germany) while in other member states the on line sale is authorised only for non-prescription medicines (e.g. Belgium, Ireland) or in the form of mail order when the web site is linked to a "bricks and mortar pharmacy" (e.g. Denmark, Portugal).In those countries where on line sales of medicines are authorised consumers should be provided with appropriate tools to identify legal

sources such as a public register of legal internet pharmacies and a specific logo as it is already done in some member states. In Germany for example the German Institute of Medical Documentation and Information administers a registry of mail order pharmacies, on behalf of the Federal Ministry of health. Consumers can easily verify if the mail order pharmacy is registered by clicking on the safety logo on the website of the mail order pharmacy. If the pharmacy is registered, a window opens that contains the essential data for this pharmacy, e.g. address and contact data. The internet address given then links (back) to the pharmacy website. Consumers who decide to buy medicines on line from legal sources should be informed about the fact that it is always essential to seek information from their doctor and/or pharmacist especially regarding safety aspects and possible interactions with other medications.

The safety features and the authentification system will have high costs and it is true that some medicines present more risks than others. But it is also true that all products (from car batteries to medical devices) can be counterfeit as long as they ensure (in terms of price or volume) a profit for counterfeiters. For this reason all medicines (including non-prescription and generic medicines) should be subject to the same level of assessment and therefore fall within the scope of the Directive. We thus suggest reconsidering the risk-based approach in order to ensure its effectiveness and to maintain consistency with the rationale and the overarching principles of the proposal.

The new track and trace technologies and product authentication technologies will 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;
- safeguards consumer privacy;
- doesn't hinder competition;
- has no major impact on the final price of medicines.

Of all possible technologies, we do not currently support the use of RFID (radio frequency identification technology) because of the numerous privacy and security concerns it raises as well as the lack of information on the effects on health. Other technologies, with lower safety, data protection and privacy implications should be exploited. For instance, as reported in the Bridge report, the pharmaceuticals industry is supporting 2D barcode instead of RFID as the preferred identification technology3.

With the new measures the pharmacists will scan the safety features and check them against the manufacturer electronic database. We are concerned that the collection of such sensitive information might raise significant privacy issues and potential abuses for commercial interests. First of all, consumers (e.g. those who use an electronic social security card when they buy a medicine) must be reassured that their personal data cannot be held within the system without their prior and expressed permission (opt-in). Second, the data regarding the number and the types of medicines sold by a single pharmacy should not be made available to the manufacturers who could use them to analyse prescribing trends in specific

[3] Bridge report, February 2007.

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geographical areas and better target promotional activities towards health care professionals. At the moment pharmaceutical companies can purchase this information in the form of statistics but do not have detailed data for each pharmacy.

Last but not least, the issue of counterfeit should not be mixed with intellectual property rights arguments. These arguments are based exclusively on commercial considerations and not on public health concerns.

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