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MEPs approve laws to curb counterfeit drugs

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The European Parliament approved on Wednesday (16 February) laws to curb sales of counterfeit medicines, which are increasing around 15% a year in Europe and rampant on the Internet.

Background

The problem of counterfeit medicines has grown steadily over the past decade – fuelled in part by the Internet – posing a major public health hazard and becoming a headache for customs authorities.

The volume of fake medicines seized by European authorities has risen but counterfeits continue to find their way into the supply chain. Research has found falsified medicines have been unwittingly sold over-the-counter by retail pharmacies in addition to booming online sales.

Over the past decade, there has been a significant increase in amount of counterfeit medicines reaching consumers across Europe through illicit sources, including the Internet.

Seizures at EU borders have increased from just over half a million articles in 2005 to over four million in 2007. More recently, 34 million fake tablets were seized on European boarders in just two months.

The trade in counterfeit medicine sales has exploded and it is now estimated that global counterfeit drug sales will reach €60 billion this year. In Europe alone, the fake drugs market is estimated to be worth more than €10.5bn every year.

Within three years after the directive takes effect, pharmaceutical companies will be required to stamp each package with a serial number that can be tracked across the European Union from the manufacturing plant to the pharmacy.

The new steps, in addition to current safety seals and holograms, are aimed at counterfeiters who spend little money on the ingredients in fake medicines but a lot on identical packaging.

"Falsified medicines are silent killers, either because they are devoid of effect or because they contain toxic substances that may harm, or even kill, those who take them. The absence of a legal framework encourages counterfeiting, an organized crime," said Marisa Matias, a Portuguese MEP from the European United Left, who led discussions in the Parliament.

The resolution was adopted with 569 votes in favour, 12 against and seven abstentions. Research suggests that one in five Europeans is putting themselves at risk and admit purchasing prescription-only medicines without a prescription – that's over 77 million people.

The problem affects poor populations just as much as it hits wealthy nations. The World Health Organisation (WHO) estimates that counterfeit drugs constitute up to 25% of the total medicine supply in less developed countries.

According to a report by the International Policy Network (IPN), a detailed study of medicines in Africa and South East Asia revealed that between 30% and 60% of medicines were "substandard". The largest producers of fake medicines are India and China, according to the IPN.

Criminal penalties to tackle growing health threat

The array of counterfeit medicines has burgeoned beyond lifestyle drugs for sexual performance and weight loss, and now includes drugs for a number of serious ailments including high cholesterol and heart conditions (non-prescription drugs are not covered by the rules).

There were more than 11 million counterfeit medicines seized at EU borders in 2009, a spike of more than 400% in just three years, according to a report on EU customs enforcement.

The directive calls for criminal penalties involving fake drugs to be as harsh as those for illegal acts involving narcotics. The European Commission is expected to issue guidelines.

More than half of medicines purchased over the websites of illegal pharmacies are fake, according to the WHO. And when members of the European consumer advocates association (BEUC) tested Internet sales of medicines, they were able to order prescriptions without a doctor's order, received pills with the wrong dose, and even got pills wrapped in sheets of newspaper.

"The key is consumer awareness, especially when they buy online," said Ophelie Spanneut, a policy analyst for BEUC in Brussels.

Increased safety and higher costs

Currently, six EU members allow patients to buy prescriptions online: Denmark, Germany, the Netherlands, Portugal, Sweden, and the United Kingdom. Under the new laws, pharmacies that comply with the rules will have an EU logo on their websites, she said.

Under the rules, the chief pharmacist must be identified on the websites for all mail-order pharmacies, and the doctor's original prescription must be obtained before mailing out the medicine.

Increased safety measures, however, could mean higher prices for consumers. The Commission estimated the cost would be between €6 billion and €11 billion, the bulk of which would hit the industry. The pharmaceutical industry estimates the new serial numbers will add less than half a cent to the price of a package of pills.

But that has still raised concerns among makers of generic drugs, which operate on razor-thin margins. These companies argue the cost should be spread in proportion to the price, because expensive medicines are more often targeted by crooks, according to the European Generic Medicines Association.

It is also unclear how much the laws will raise costs for re-sellers who buy cheap medicines in countries like Greece and repackage them for sale in higher-priced markets such as the UK.

"It will add to the cost of packaging materials, they have to be more secure, and that's something that affects us," said Heinz Kobelt, secretary-general for the European Association of Euro-Pharmaceutical Companies, which represents re-sellers. These companies will be required to install equivalent safety measures, which could result in "unintended haggling about what is equivalent," he said.

The Commission will assess the costs and benefits of the safety measures.

In addition to potentially higher prices, consumer advocates are also concerned about data privacy. With serial tracking numbers, a lot of sensitive health information will be stored in pharmacy databases and shared across national borders.

Positions

Brian Ager, director-general of the **European Federation of Pharmaceutical Industries and Associations**, said "implementation of the directive will require the involvement of all key stakeholders - manufacturers, pharmacists and wholesalers but also patients – to ensure success. With their involvement in the design, implementation and running of systems, we can deliver the highest possible level of patient safety, the fastest roll-out in member states at the optimal possible cost."

The **European Generic Medicines Association** supports the directive but called on the Commission to ensure that the "white list" approach to all prescription medicines and the risk assessment criteria used for assessing risk status and adopting provisions related to safety features do not put an unnecessary burden on low-risk products, such as generic medicines.

The **Association of the European Self-Medication Industry** applauded the fact that over-the-counter medicines were not included. "A good compromise has been found in the spirit of smart regulation," said **Director-General Hubertus Cranz**.

"The new law takes into account the particularities of non-prescription medicines which normally will not need to bear specific safety features [...] A systematic inclusion of non-prescription medicines would have meant considerable additional costs to be paid at the end by the European citizens without any gain from a public health perspective," Cranz said.

The **Pharmaceutical Group of the European Union (PGEU)** supported the directive, but cautioned that "many of the details of electronic verification are left to be determined by the European Commission, including the type of unique identifier to be attached to medicine packs, the organisation of databases which will support the verification system, and even which medicines are to be covered by the verification process".

"PGEU believes that the application of the risk assessment used to determine which medicines are verified by pharmacists should begin from a strong presumption that all prescription medicines are at risk of falsification," it said.

The **Standing Committee of European Doctors (CPME)** welcomed the decision.

"Patient safety is paramount" underlined **Dr. Konstanty Radziwill**, President of the CPME. "The draft directive is a huge step ahead in fighting falsified medicines and also illegal internet sales. The challenges are best accommodated at EU level since a directive is the right instrument to also address the increasing number of cross border supply chains and internet sales. We as physicians are pleased to see European politicians taking appropriate action to increase patient safety."

French MEP Françoise Grossetête (European People's Party) said "fake Viagra, fake painkiller, or even fake cancer drugs, fakes that contain little or no active ingredients, don't cure people. But too often, there are deaths because the illegal medicine contains aluminum or arsenic. This is why reinforcing European inspections of manufacturers of active ingredients is most important".

"To achieve that environment, a traceability scheme that goes as far as possible is being established. All prescription medicines will be in tamper-evident packaging in combination with a unique code (storing product identification number, batch number, expiry date, and a unique serial code)," said **German MEP Dagmar Roth-Behrendt, Socialists & Democrats group** vice-president and shadow rapporteur.

"By checking this code, the product can be traced at all stages from the producer to the distributor, and this way the pharmacist will be able to see if the product looks suspicious," Roth-Behrendt said.

The **European Association of Euro-Pharmaceutical Companies**, which represents resellers, said it "will now carefully prepare for the implementation of the proposal through the 'delegated acts', ensuring that the measures which will be adopted to determine the technical specifications related to safety features won't be abused for commercial purposes, and eventually work in the interest of European patients".

Next Steps

- **Early 2011:** Council to adopt the directive.