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European Parliament targets online fake medicines

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The EU executive's decision not to legislate against online pharmacies is a major flaw in its proposal to fight counterfeit medicines, according to leading politicians responsible for pushing the new law through the European Parliament.

Background:

The EU 'pharma package' of legislation, unveiled in Brussels, focuses on three priority policy areas ([EurActiv 11/12/08](#)):

- Protecting the European market from counterfeit medicines;
- Improving pharmacovigilance to reduce the adverse effects of medicines, and;
- Improving information for patients on prescription medicines.

The counterfeit medicines proposal has not been as politically sensitive as the directive on providing information to patients, which critics say is "advertising in disguise".

However, finding a foolproof way of tracking medicines through the distribution chain from manufacturer to patient has proven technically challenging, not least because the EU executive wants to allow parallel traders to repackage medicines for distribution in Europe's internal market.

Speaking at a meeting of industry groups in the European Parliament, MEP Jorgo Chatzimarkakis said the online trade in fake medicines is a growing illegal business and its omission from the European Commission's proposed directive is a "weakness".

80% of counterfeit medicines come from the Internet and this poses a significant health risk, he said, pointing to a World Health Organisation study which shows half of all medicines bought online are fake.

"I'm not happy that the Internet is not mentioned at all by the Commission – they leave it to the member states to stop Internet sales," he said.

Chatzimarkakis, a German Liberal, also warned fake drugs are increasingly being channelled through the legal supply chain. He said that countries allowing Internet drug sales should produce a list of reliable online pharmacies to help consumers avoid illegal medicines.

Leftist Portuguese MEP Marisa Matias, who is responsible for drafting a report on counterfeit medicines for the European Parliament's environment committee, said ignoring Web sales is "a major gap" in the directive.

She said parallel trade represents a large part of the medicines market and will be included in the regulatory framework. She said she would examine the practicalities of allowing parallel traders to repackage medicines for resale in other European countries.

Traceability key to beating bootleggers

Introducing new traceability measures is a central part of plans to fight counterfeit medicines, but there are some concerns over cost and data protection issues.

Pharmacists fear that commercially sensitive data on their prescribing practices collected by new computer systems could be exploited by drug makers. They are also worried that new scanning systems will add to their cost-base without bringing major benefits.

SMEs in the pharma sector are also concerned by the cost of adding traceability features to medicines. Claudia Glasow from Ursapharm, a German pharmaceutical SME, estimated new equipment and software could cost between €80,000 and €120,000 for every production line.

"We have 15 packaging lines so it could cost up to €1.8 million in order to comply with the technical requirements arising from the serialisation guidelines," she said.

There is also debate among industry groups as to which form of barcode would be most practical. Some argue for a radio frequency identification system, but problems with accuracy and the potential for radio waves to change the properties of medicines could make this impractical. Manufacturers and wholesalers prefer 2-D barcodes which are easily scanned and can be encrypted with detailed information.

Positions:

Domenico Di Giorgio from the **Italian Medicines Agency** said the market for counterfeit drugs used to focus on "lifestyle" medicines such as Viagra and weight loss pills, but there is now a booming trade in anti-cholesterol medication and anticoagulants such as heparin.

He said Italy has put in place an effective "track and trace" system which has put a major dent in the illegal drugs trade.

"It's not impossible to get illegal medicines into the system but it's very expensive," he said.

John Chave of the **Pharmaceutical Group of the European Union (PGEU)** said pharmacists accept that swift action is needed to shore up the medicines supply chain.

However, he cautioned against focusing exclusively on so-called "high risk" medicines, arguing that bootleggers will simply move on to counterfeiting other drugs. According to Chave, the cost of implementing new traceability systems must be proportionate and pharmacists have concerns about data protection.

Personal information from customers must be safeguarded, he said, but so too should sensitive commercial data on what medicines pharmacists dispense.

"Transactional data is normally the property of pharmacists and should not be available for commercial exploitation by third parties," he said. On Internet trade, Chave said the most effective measures against Web sales is prohibition, which is used in the United States.

Hugo Carradinha of the **European Generic Medicines Association** said less than 1% of Europe's medicines are counterfeit and urged politicians to be proportionate when amending legislation.

"The safety features some people are proposing could cost between €6.8 billion and €12 billion – which I'm not sure is proportional. There's no point trying to kill a mouse with a tank," he said.

Carradinha added that safety measures such as holograms and tamper-proof seals can be replicated by criminals within six to 12 months. To date, he said, there have been no reported cases of generic medicines being counterfeited in Europe.

He called for a harmonisation of criminal penalties across the European Union for anyone found guilty of counterfeiting drugs. Some countries, Carradinha said, impose prison sentences but others are too lenient.

Monika Derecque-Pois, who represents pharmaceutical wholesalers, said 2-D barcodes "are the only way forward," although she acknowledged that radio frequency identification (RFID) could become useful in future. The problem with RFID, she said, is that it is not accurate when the frequency is too low, and it can boil some medicines if the frequency is too high.

Derecque-Pois called for all participants in the medicines supply chain to be fully licensed and for the licensing system to be more transparent.

Claudia Glasow from **Ursapharm**, a German pharmaceutical SME, said the costs for small producers of adding traceability features can be high. She said manufacturers would have to spend at least €40,000 on cameras and scanners for each production line. In addition, specialist software would be required, at a cost of between €80,000 and €120,000.

Glasow highlighted the technical challenges of adding barcodes to small boxes of eye drops while also complying with labelling guidelines. She agreed that Internet trade remains a primary source of low quality counterfeit medicines and that this must be addressed.

John Ricketts of drugmaker **Lilly Europe** said counterfeit medicines producers use very crude manufacturing facilities, but "the one thing they invest in is packaging," making it very difficult to differentiate between real and fake medicines.

He said a combination of robust measures is needed to stamp out illegal trade. The simplest way would be to ban repackaging, he said, but the Commission has avoided this for fear of putting parallel traders out of business.

If parallel traders are allowed to stay in business, said Ricketts, they should be forced to apply equivalent safety features to those required of pharmaceutical companies. He said the research-based pharmaceutical sector is in favour of 2-D barcodes to aid traceability, and companies are also using nanotechnology "deep holograms" to help tell real packages from fake ones.

"If it is going to take until 2013 to implement this directive, we would like to see interim measures introduced between the time an agreement is reached and its implementation," Ricketts said.

The secretary-general of the **Belgian Pharmacists' Association**, **Dirk Broeckx**, said Belgium has introduced a system whereby every type of pharmaceutical product is examined.

Using a unique barcode system, pharmacists are instantly informed if they try to dispense illegal or unsafe medicines. Product recalls can be done with great efficiency, Broeckx said, adding that Belgian pharmacists have benefited from adopting the system.

"We have been proactive and as first movers, we have had the opportunity to steer the system as it develops," he said. He said there are costs for manufacturers and pharmacists but these are largely compensated for by the added value of having a safer, more efficient system, which reduces pharmacists' liability arising from selling dangerous products.

Gary Noon, CEO of **Aegate**, the company that provides the system used by Belgian pharmacists, said authorities and industry must make it uneconomical for criminals to continue manufacturing counterfeit drugs.

He said the system had been rolled out in Belgium, Greece and Italy and had been highly successful. Noon said his view is that the transactional data collected by the system belongs to pharmacists and it is not shared with third parties.

Steven Simoens of the Centre for Pharma-economics at the **Katholieke Universiteit Leuven** has studied the Aegate system and said there are significant benefits in identifying substandard drugs. It helps avoid litigation cases against pharmacists and avoids labelling errors. Simeons said his analysis shows that the cost-effectiveness of the system depends on the volume of counterfeit medicines present in an individual country.

He said it is technically cost-efficient in Belgium but not in Greece, because Belgium had a higher number of cases of substandard drugs.

EFPIA, which represents innovative pharmaceutical companies, said a ban on repackaging would be the "simplest and most effective route to preventing counterfeits entering the legitimate supply chain".

"In the absence of a ban, mass serialisation offers a partial solution. However to be effective it needs to be standardised and inter-operable between countries. If it is not, then it cannot be effective," said a spokesman.

EFPIA is trialling a 2-D barcode system which will be launched later this month.