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EU launches public consultation on counterfeit drugs

The European Commission has launched a public consultation on the dangers of counterfeit drugs, and is asking all stakeholders and interested parties to submit key ideas for regulatory reform by May 9.

Counterfeit medicines have become an increasing threat for patients, healthcare professionals and the industry, and a concern for European Union and national policymakers, says the Commission. In particular, it notes the following “worrying” trends: a sharp increase in seized fake medicines at EU customs borders; the counterfeiting of life-saving drugs; targeting by counterfeiters of the “classical” supply chain; and a “blurred line” between counterfeit and substandard active substances in medicines.

This growing problem may have been facilitated by deficiencies in supply chain integrity, says the Commission, noting that there is “uncertainty as to whether certain participants in the distribution chain (eg, brokers, traders, business-to-business platforms) are subject to pharmaceutical legislation.’ It also cites: a lack of transparency as to whether wholesalers and others in the distribution chain comply with Good Distribution Practice (GDP); shortcomings in product integrity, especially when packs are opened for repackaging and changed for relabeling purposes; difficulties in conducting targeted recalls, especially for counterfeits; legal uncertainty and differing practices between EU member states concerning the application of legislation to “imports for the purpose of export;” and the fact that active substances may not be manufacturing in compliance with Good Manufacturing Practice (GMP) standards, at declared sites and in accordance with declared procedures.

In addition, member states are starting to consider taking unilateral actions to address these problems, and while the Commission acknowledges that these are motivated by justifiable concerns, it warns that they may create issues of compatibility with EU internal market rules. These varying approaches may also lead to different levels of protection for public health and safety, it adds, and cautions: “indirectly, this kind of way forward could encourage counterfeiters to target member states with lower levels of protection of the legal distribution chain.” Therefore, “the EU must act firmly.”

The EU’s plans to prioritise and speed up moves to tackle counterfeits were first announced in January, when Commission Vice President Guenter Verheugen told Parliament that the initial findings of a study into drug distribution had shown that parallel imports pose a “considerable” risk for patient safety for “numerous” reasons.

The consultation - to be conducted by the Commission’s Directorate-General (DG) Enterprise and Industry, which is headed by Commissioner Verheugen and has responsibility for the pharmaceutical industry - will focus on the manufacture and marketing of active substances and finished medicines, plus related inspections, and on the import, export and transshipment of drugs. Improvements to the regulatory framework in these areas could make a “real contribution” to protecting patients, it says.

As a result of the Commission’s concerns, there has been a major change to the DG’s work programme, and it plans to introduce legislative proposals after the summer break.

Positive response

The European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomed the consultation, pointing out that the Commission's findings corroborate its own evidence on prevalence of counterfeits, including the increasing penetration in the EU legitimate supply chain.

As long as repackaging and breaking of seals in the distribution chain is allowed, patient safety will be highly at risk, says the EFPIA, which is calling for: a ban on repackaging; clearly defined liabilities for all involved in the distribution chain (including brokers, traders and agents); stricter auditing rules and controls of the supply chain; and penalties for trafficking in counterfeits.

The industry is investing in anti-counterfeiting technologies to enhance product security, and the EFPIA plans to launch a pilot project in the area of mass serialization (2D bar-coding system) towards the end of this year, it adds.

DG Enterprise and Industry is calling for responses to the consultation to be sent by e-mail to entr-pharmaceuticals-counterfeit@ec.europa.eu by 9 May 2008

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