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European Federation of Pharmaceutical Industries and Associations

Press release

Pharma industry leaders call for strong EU measures to combat counterfeit medicines, including a ban on medicine repackaging

Penalties for counterfeiting medicines are inadequate, says Jean-François Dehecq, EFPIA's anti-counterfeits champion

Paris, 19 June 2008 – Leaders of the research-based pharmaceutical industry meeting in Paris today have called for strong EU measures to tackle the growing threat of counterfeit medicines, including a ban on medicine repackaging, a harmonised EU-system of identification of medicines, and heavier penalties for trafficking in counterfeit medicines.

"It is time for Europe to act as the driving force in the fight against this deadly crime", said EFPIA Vice-President and Chairman of sanofi-aventis, Jean-François Dehecq. "Organised crime gangs operating on an international scale and playing with human lives in the name of profit must be dismantled through determined action, systematic prosecution and appropriate sanctions (civil and penal). Penalties in place in Member States today are inadequate. Administrative and operational tools and resources are required for effective law enforcement".

EU statistics released on 19 May 2008 show that a total of 4.081 million medicinal products (articles) were seized at EU customs borders in 2007. While Internet-based sales are the main source of counterfeit medicines, these products are also appearing in the traditional supply chain.

Counterfeit medicines have been found to contain toxic substances, no active ingredient, or the wrong amount of it. Life-saving medicines are increasingly targeted, including medicines to treat cancer and heart disease, psychiatric disorders, and infections.

Proposals for tougher EU legislation are expected before the end of the year, as part of the new 'pharmaceutical package'. Options outlined by the European Commission in its public consultation document (March) include obligatory product sealing and a ban on medicine repackaging.

EFPIA's recommendations

- An EU ban on medicine repackaging

  One essential component of any effective anti-counterfeiting strategy is the development of security features on medicine packaging. These security features include unique identification codes enabling the pharmacist to verify the origin of a medicine before dispensing it to the patient.

  But under current EU rules, medicines can be re-boxed or re-labelled after they have left the production site. Tablets can be removed from their blisters and reconditioned. This means that efforts to put in place security features on medicine packaging are wasted.

  The original package should remain untouched throughout the entire supply chain, from the time the product leaves the original manufacturer to the point that it reaches the patient. A ban on all forms of medicine repackaging is a prerequisite for an effective anti-counterfeiting strategy.

- A harmonized EU-wide identification system for medicines

  10 different systems coexist in Europe today (with different types of barcode and with or without unique pack identification). This fragmentation increases the difficulty to track and trace medicines effectively at a European level and constitutes a substantial cost for the pharmaceutical industry. EFPIA recommends the implementation of a standardized and unique coding system for medicines in Europe.

- Liabilities should be more clearly defined for all involved in the distribution chain, including brokers, traders and agents.

- Heavy penalties should be enforced for trafficking in counterfeits. Sanctions should be particularly severe when counterfeiting threatens public health. Medicines are not goods like others – fakes can kill instead of treating. The penalties should be at least as strong as for trafficking in narcotics (same criminal gangs switch from one business to the other).

- Internet pharmacies are still the main source of counterfeit medicines; better consumer education is necessary as to the importance of purchasing medicines exclusively from the legitimate supply chain.

In addition to the development of security features on medicine packaging, individual companies are assisting authorities in different ways, for example by training officials to recognize fakes and by assisting with international police investigations.

EFPIA is making plans to launch a pilot scheme of a unique bar code system, which will enable the pharmacist to verify each medicine pack before dispensing it to the patient. This pilot will be launched before the end of 2008. The technology used – the 2 dimensional data matrix – is considered the best option today and could be used as an EU standard.

Useful links

Video 'The Genuine Danger of Counterfeit Medicines'

EFPIA response to the European Commission's public consultation (9 May 2008)

European Commission Public Consultation in preparation of a legal proposal to combat counterfeit medicines for human (March 2008)

European Commission Report on Community customs activities on counterfeit and piracy (May 2008)

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Contact:

Chantal Porges
EFPIA Director
Communication & Partnerships
Tel: +32 (0)2 626 2571
e-mail: chantalporges@efpia.org

Tel: (+32) 2 626 25 71

About EFPIA

EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 32 national associations and 43 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,200 companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.