efpia
European Federation of Pharmaceutical Industries and Associations

# Press release

## PHARMACEUTICAL INDUSTRY BACKS 2-D BAR CODE TECHNOLOGY IN THE FIGHT AGAINST COUNTERFEITS

**Brussels, 30 May 2007 –** The European Federation of Pharmaceutical Industries and Associations (EFPIA) today announced its support for a pan-European and industry-wide solution to protect patient safety through a more transparent medicine supply chain, thereby attempting to tackle the rise in counterfeit medicines entering the European legitimate supply chain.

Championing 2D Data-Matrix Bar Coding, instead of the less reliable and more expensive RFID, EFPIA have taken the lead in the European healthcare sector on proposing a common Pan European technological solution to support its call for tighter regulation and better enforcement in the supply chain to protect patient safety.

Speaking at the Brussels meeting, Thomas Cueni, member of EFPIA Board and chair of the Economic and Social Policy Committee that oversees the proposal, spoke of the pressing need for a transparent and secure medicines supply chain that puts the patient first and where all stakeholders take responsibility for guaranteeing the integrity of medicines. “EFPIA proposes introducing unique bar-coding on every medicine pack in Europe before it leaves its manufacturer” said Cueni “Thereafter, at every stage of its distribution, up to the point at which it reaches the patient, the medicine can be authenticated to make sure it is genuine.”

The encrypted 2D Data Matrix Bar-Code can also carry a randomized number unique to the individual pack, making it even harder for counterfeiters to successfully copy and bring their fakes to market. By using a hand held bar-code reader common in most European pharmacies, the dispenser will be free to scan the encrypted 2-D data matrix code and check vital data including recall information and the details of every trader who has handled that pack in the supply chain.

2D Data Matrix

EFPIA’s recommendation for a unique coding standard throughout Europe

Brian Ager, Director-General of EFPIA, welcomed the proactive stance of the industry and urged all stakeholders to support EFPIA’s position. “It is the right of every patient in Europe to receive quality medicines. To achieve this, changes will be needed to current European regulations to preserve a medicine’s integrity and stop intermediaries tampering with them. We therefore strongly urge the European Commission to consider the benefits to all stakeholders of medicines traceability and authentication through its review of medicines distribution in Europe.”

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Background to
Safer European Medicines

**The problem**

Counterfeit medicines are entering Europe's legitimate supply chain in increasing numbers. More than 500,000 medicines were seized at Europe's borders in 2005, twice the rate of 2004.[1] According to the World Health Organisation, around one percent of medicines in Europe are now counterfeit.[2]

Medicines counterfeiting is highly sophisticated and it is almost impossible for patients and dispensing healthcare professionals to spot the fakes. There is also a lack of transparency in the legitimate medicines supply chain, which makes it vulnerable to infiltration by counterfeiters.

This puts lives at risk. Counterfeit medicines contain wrong ingredients, insufficient ingredients and sometimes no active ingredients at all. The consequences of taking counterfeit medicines include treatment failure, drug resistance and sometimes death.

**Who is responsible?**

From the manufacturer to the dispensing healthcare professional, the safe supply of medicines can only be achieved if each and every stage of the supply chain enforces safe practice. This is not currently the case. The existing system makes it almost impossible to establish the pedigree of a medicine dispensed to a patient. This is made worse by repackaging and re-labelling medicines within the supply chain, which contributes to uncertainty and is exploited by counterfeiters.

**The solutions**

The introduction of unique coding for each pack of medicine, together with authentication, track and trace systems and physical security in the form of tamper resistant packaging, would dramatically improve the safety of medicines supply. This involves the integration of four key elements.

**Tamper resistant packaging**

Medicines currently lack the type of tamper resistant devices now taken for granted in other sectors such as the food and drinks industry. All medicines should have special features to show whether the packaging has been opened. This includes bottles with external seals or tamper evident screw caps, and boxes with seals or perforated panels.

**2D Bar Codes**

2D data matrix bar codes printed on packaging during manufacture can provide each medicine with a unique identity before it enters the supply chain. Significant quantities of encrypted information can be stored this way to support pharmacists, regulators and government authorities in the authentication and tracing of individual medicines.

2D Data Matrix

EFPIA's recommendation for a unique coding standard throughout Europe

2D data matrix bar codes help prevent dispensing errors and make counterfeit medicines easily identifiable. Existing scanners found in most pharmacies can read the bar codes and no additional work is required by the pharmacist. Scanned information is transmitted to an independent electronic data hub and a verification message is quickly returned to the dispensing pharmacist.



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**Dispensing authentication and transparency**

No part of the supply chain should accept medicines without validation. With tamper resistant packaging and 2D data matrix bar codes in place, a unified system with agreed responsibilities across the European Union would allow each individual medicine pack to be traced. This would take the place of existing national coding systems, which currently follow different formats and do not allow the pedigree of medicines imported across national boundaries to be checked. A safe medicines supply is one in which every stakeholder is able to trace and authenticate the medicine back to the manufacturer.

**Integrity of manufacturers packaging**

Removing or interfering with manufacturers packaging can never be in the interests of patient safety. Parallel traders repackage and over-label medicines. These practices may have to be reviewed with the introduction of a new, safer medicines tracing and authentification system.

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**References**

1. 2005 Customs Seizures of Counterfeit Goods. European Commission. November 2006.
2. Counterfeit Medicines – a New Update on Estimates. Position statement by the International Medical Products Anti-Counterfeiting Taskforce (WHO). November 2006.





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