
From: Weiss, Guy [mailto:guy.weiss@hp.com]
Sent: Monday, April 28, 2008 11:25 AM
To: ATZOR Sabine (ENTR)
Subject: Contribution to public consultation in preparation of a legal proposal to combat counterfeit medicines for human use

Dear Ms. Atzor,

Within the framework of the **PUBLIC CONSULTATION IN PREPARATION OF A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE**, Hewlett-Packard intend to make their contribution.

HP is among the world's largest IT companies, with revenue totaling \$107.7 billion for the four fiscal quarters ended Jan. 31, 2008. HP's 2007 Fortune 500 ranking: No. 14.

HP serves more than one billion customers in more than 170 countries on six continents and has approximately 172,000 employees worldwide.

HP dedicates \$3.6 billion (U.S.) annually to its research and development of products, solutions and new technologies.

HP is looking for being instrumental at every level in the supply chain traceability initiatives. The solution developed by HP is comprehensive and provides a multi layered security approach. It is holistic and encompasses authentication, real time track & trace (EPCIS) and program management through Quality Assurance Plan with 3rd party auditors.

The part of the solution depicted hereby can be seen at *hp* premises or in operational situations with customer's agreement.

Contribution proposed by Guy Weiss, responsible for promoting traceability solutions in various industries.

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Problem statement

Improving product integrity through a unique seal from the manufacturer to the retailer or wholesaler, supported by a ban on repackaging:

Admittedly, certain shortcomings in product integrity intervene when packs are opened for repackaging and changed for relabelling purposes.

In order to make it more difficult for counterfeit medicinal products to infiltrate the legal supply chain, it is crucial to maintain the integrity of the outer packaging with the medicinal product contained in it.

This integrity should be secured by an obligatory product sealing. The right to open the seal would be restricted to the market authorization holder and the end user (hospital, health care professional, or patient)

It must also be taken in account that there is a potential for misuse of original packs, especially when discarded after repackaging. Counterfeit products could be packaged into an outer packaging bearing safety features.

Our solution

It is clear that only a concert of various measures designed to protect the outer package from being opened can help to minimize the risk of counterfeit medicines entering the legal supply chain. We herein present multiple levels of protection and functionality simultaneously.

Tampering prevention: The medallion (seal) attached to the outer package must be broken for opening the package.

Serialization Authentication: Variable data (i.e. Serial number) affixed on the medallion would be unreadable when the seal is broken.

Image-based authentication: A variable color tile, on the medallion, provides overt/semi-forensic protection.

Evidence that the Solution Works

Our solution is made of two parts:

- l The tamper evident seal, also called medallion, which satisfies many customizable anti tampering requirements (wet strength, breaking strength, load resistance, life span...).
- The digital printing function. Digital printers are capable to affix variable data on the medallion (seal). That data can represent variable unique numbers and the output is checked by a centrally managed service, or it can be a specific marketing data.

The affixing of variable data is agnostic of every carrier. It can be printed in readable or non-readable format on the medallion (i.e. SGTIN indicator is written on a 2D matrix and printed on the medallion or even RFID technology can be used).

Moreover, an additional security layer can be considered; the color tile. This technology simultaneously provides covert and forensic protection.

The color tile provides an “innate moving target” for the would-be counterfeiter.

The color tile can also be associated with microtext. Microtext is miniature text in which the characters can only be printed using Indigo digital printer + software. Astronomically large numbers of microtext font families can be defined by allowing multiple representations on each character.

For common alphanumeric and punctuation characters, there are greater than googol (10^{100}) font families, allowing every printed item to have a “forever unique” microtext font. In addition, the microtext can be positioned differently in each tile, and can be independently sequenced in comparison to the sequence of tiles. This combination of possibilities lends a powerful “forensic” deterrence in as much as the odds of randomly guessing a correct combination of color sequences, microtext fonts, and their combination is essentially 0.

It is worth noting that the medallion along with the printing function could be completely outsourced to *HP*. The manufacturer packaging line would be provided with pre adapted seals ready to be glued on the outer package. This situation would make the purchasing of a printer unnecessary.

Depending on the foreseen granularity of the serialization, a parent-child association may also be considered between the outer packaging serial number and the inside saleable unit (i.e. bottle, blister...).

Best regards.

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