

COMMENTS BY PHILIP MORRIS INTERNATIONAL

on the

Public Consultation Paper in preparation of a legal proposal to combat counterfeit medicines for human use

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PMI Comments

Philip Morris International (“PMI”) welcomes the opportunity to provide its expertise and know-how in the areas of product tracking & tracing and product authentication to assist the European Commission in its efforts to combat counterfeit medicines.

EU Commissioner McGreevy recently stated that *“The “misappropriation” of intellectual property rights costs about 150 billion euros (\$235 billion) a year, according to the Organization for Economic Cooperation and Development. The EU last year reported a 50 percent increase in the number of counterfeit items that threaten human health, such as fake cigarettes, Viagra and food being removed from sale. All products and industries that could generate a profit are affected and production is happening on an industrial scale¹”*.

PMI is the world’s leading tobacco manufacturer. Illicit trade, both in the form of counterfeited goods as well as contraband products diverted from the legitimate trade channels, is a major issue for governments, consumers and businesses. To better cooperate in the fight against illicit trade, PMI signed in 2004 a Cooperation Agreement with the European Community, represented by the EU Commission, and to date 26 Member States (the “Participating Member States”). This Agreement includes measures to develop, adopt and maintain the necessary tracking & tracing tools.

In this paper, we would like to share the PMI best practice in implementing effective tracking and tracing and product authentication solutions. We believe that tracking and tracing and product authentication solutions and methodologies can be applied across industries.

¹ Bloomberg, April 28, 2008, reporting about the World Intellectual Property Day

Article 4.1.4 Centrally accessible record to facilitate traceability of batches throughout the distribution chain

For the last several years, PMI has been working closely with law-enforcement agencies and representatives of many governments on developing and implementing cigarette marking regimes. As part of those efforts, PMI has devoted substantial time and resources to research, development and testing in this area. As a result, and in cooperation with the Participating Member States as well as the European Commission and the European Anti-Fraud Office (“OLAF”), PMI has deployed a state-of-the-art worldwide product tracking and tracing system for its products. This system, which utilizes a series of interconnecting product marking technologies, currently consolidates data from more than 500 separate tracking systems and, to date, has enabled PMI and the participating governments to track and trace tens of billions of cigarettes in 43 countries.

According to the EC², the partnership with PMI that has created and implemented this comprehensive product marking regime has “proven in practice to be a highly effective means of combating cigarette smuggling,” and “should therefore serve as a model for other cigarette companies.”

The expertise we built through our partnership with the European Commission leads us to believe that many times, there is confusion on what an effective tracking and tracing system should do. We will outline the key challenges a tracking and tracing system must master in order to be effective.

PMI’s experience shows that an effective cigarette tracking and tracing system can follow the movement of bulk quantities of genuine product through the supply chain such that, upon a seizure of contraband product, law-enforcement officials can readily determine (1) where the seized product came from; (2) where it was supposed to go; and (3) who actually received it along the distribution chain. Tracking and tracing information is a key part of the fight against illegal cigarettes because it:

- assists manufacturers and law-enforcement officials in identifying the point at which diverted genuine product entered into illegal distribution channels;
- serves as key evidence in any legal proceedings brought in connection with the diversion of product; and
- allows manufacturers, law enforcement, and other parties to take appropriate corrective action to disrupt the flow of contraband cigarettes.

Further, the system must also allow for the identification of the following information about contraband cigarettes that are contained in detained or seized master cases (“Essential Tracking & Tracing Data”):

² EC Press Release No. IP/06/735 (June 6, 2006)

- the date of manufacture of the seized cigarettes;
- the place of manufacture of the seized cigarettes, including the manufacturing facility and the machine of manufacture;
- the intended market of retail sale;
- the date and location of shipment to the First Purchaser; and
- the identity and location of the First Purchaser.

Further, we believe that a central database is a key element in the tracking and tracing architecture. Without a central database, the collection and query of tracking and tracing information is impossible. PMI stores the information regarding the movement of cigarettes through the distribution chain electronically in a central database so that it can be quickly and easily accessed later by PMI or law-enforcement officials – for example, following a seizure of contraband product. PMI keeps computerized records of relevant information on all shipments through the use of machine readable codes and overt markings linked to a tracking and tracing system, and stored in a single standard format.

Article 4.1.5 Mass serialization for pack-tracing and authenticity checks on a case-by-case basis.

As part of the overall objective to fight the trade in illicit cigarettes, PMI has developed an effective solution - CODENTIFY™ - for cigarette pack serialization which we believe could be an interesting precedent for the European Commission pack-tracking objective for medicines. The CODENTIFY™ system is an adaptable technology for automated fiscal marking and product authentication at pack level and can enable tracking & tracing at carton level. The key element of the CODENTIFY™ technology is that it prints a unique 12 digit code (datamatrix/2D barcode) directly onto the pack and/or carton during the manufacturing process. These 12-digit codes are generated using a “double key algorithm” that achieves a high level of security. While seemingly random, the codes contain information concerning the product’s date, time, and place of manufacture and also allow for quick and costless authentication of the product as genuine or counterfeit by wholesalers, retailers, consumers, and law enforcement.

Secure. Unlike holograms and other security inks, which are vulnerable to replication, no two codes are identical, and there is no commercially feasible method of deciphering how to generate genuine codes by analysis of coded product.

Accessible. Unlike graphical security devices, these codes consist of an alphanumeric, human-readable series of digits that do not require the use of scanners or other sophisticated devices. There is also no subjective element to the authentication process; customers and others seeking verification need only provide the code to service centers maintained by the Company, which can quickly authenticate the product. Codes can be transmitted and verified using the types of common communications technologies widely available to the public: telephone, text-message, e-mail and Web sites. These

alphanumeric codes also appear on cigarette cartons in barcode format, so they can be scanned to allow for easy point-of-sale or large-volume authentication of product.

Cost-effective. Because data is stored in the carton and pack code itself and then elicited through the use of an algorithm, there is no need to maintain an enormous database of stored codes. The application of the codes to product packaging also has a minimal impact on the manufacturing process, which is very important in a high-volume business such as cigarettes or any other consumer goods. PMI estimates that the application of these product codes costs as little as US\$0.0001 per mark.

Adaptable. PMI's code system can be integrated with preexisting product security architecture, and serves as a foundation for the layering of additional technologies as innovation permits.

Tested. Since March 2007 CODENTIFY™ is printed on MARLBORO and L&M packs and bundles in Germany. Consumers and retailers can call a toll-free hotline printed on each pack in order to verify the code and authenticate their pack. If the code cannot be verified or if consumers/retailers are doubtful of the quality, the product can be sent to Philip Morris GmbH for examination.

Conclusion

PMI's product marking system demonstrates that the objectives for such a regime discussed above are achievable with existing technologies in a cost-effective manner.

The adoption of this system as part of PMI's cooperation with the Participating Member States, the EC and OLAF, and the confidence that those entities have expressed in the PMI system, demonstrate why this system could be used as a model for an effective medicine marking system.

For further information, please contact Kristof Doms at

PMI EU Office
Rond Point Schuman 11
B – 1040 Brussels
+32-2-237.01.12