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European Commission
Enterprise & Industry Directorate General

Addressed to:
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Dear Sir/Madam

Better Protection of Patients from the Risk of Counterfeit Medicines
Public Consultation

I am writing on behalf of the International Authentication Association (IAA) for which I am the General Secretary. The IAA is a practice based, non-profit organization made up of 22 member companies who are users or suppliers of authentication or tracking technologies used in the fight against global counterfeiting. IAA members either use or provide of authentication and/or tracking services in critical product categories including pharmaceuticals, computer software, electronics and apparel in their constant battle against counterfeiting and piracy.

IAA Member Companies include:

3M Company	Johnson & Johnson Health Care Systems
Advanced Coding Systems	Label Systems Authentication
American Bank Note Holographics	NanoInk
ARmark Authentication Technologies	Payne Security
Authentix	Richemont
BP Labels	Schreiner ProSecure
DuPont Authentication	Securikett
Hologram Company Rako	SICPA
Hologram Industries	Solos Identificazione Protezione
Honeywell	Tesa Scribos GmbH
Ingenia Technology	TUV Rheinland Group
JDSU	

On behalf of our members, I am writing in response to your request for comments in regards to the preparation of a legal proposal to combat counterfeit medicines for human use.

As you see from the introduction to the IAA above, our members have a great deal of experience with counterfeiting and its effects and are committed to working together to fight it. We believe that one of the most effective tools for fighting counterfeits is the development and implementation of systems for the authentication of genuine products (which methods to establish a product secure trail), and its corollary, the detection and seizure of counterfeit

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products. Authentication technologies and systems are performing this important role every day, world-wide.

In furtherance of a better understanding and implementation of authentication as part of an anti-counterfeiting strategy, the IAA is working with the European Standards Committee (CEN) to devise a “Protocol for the Detection of Counterfeits”. I, representing the IAA and in regular consultation with members, chair the CEN Workshop that is devising this proposed standard. Through our Chairman, David Howard of Johnson & Johnson, we are also involved with GSI Healthcare in the development and introduction of standards for medical products supply- and distribution-chain monitoring.

As these standards are completed and adopted, they will, we believe, benefit the work that the EC is now embarked upon.

Tracking & Authentication

The digital tracking of products by recording their presence at several locations along their distribution chain, undoubtedly improves their security but is not a complete solution for several reasons:

- a. The product pedigree is only as good as the information recorded;
- b. The databases created are critical but potentially vulnerable to unauthorized access;
- c. Relatively few people in the supply chain will have access to the pedigree data because they don't have access to the required reader/scanner, or a networked computer or mobile phone with appropriate coverage;
- d. Sole reliance on electronic data can mislead, because it is likely that in due course a serious and well-funded counterfeiting operation would establish a website and infrastructure that would simulate the official system, so that a patient buying medicines would be misled into believing the medicine is genuine by a positive reading from a false system.

The ability to establish a secure trail by tracking product through the distribution chain contributes to demonstrating the provenance of the product, and this in turn contributes to determining that a given product is authentic. But medicines (as well as other products) are not all distributed through the formally-sanctioned distribution chain, and sub-standard and counterfeit medicines in particular are sold through unofficial channels and unofficial retailers. If such channels don't go as far as suggested in (d) above to create false tracking systems, they may well have the means to print or otherwise add to the product pack, codes or patterns that look genuine. Without the electronic tools to test these codes, dispensing or retailing “pharmacists” and customers - ie patients – will not be able to determine that these codes are false.

Having to use an electronic tool to examine the product limits the number of people able to carry out such examinations. The use of *sensory authenticators*, conversely, allows many more people to conduct examinations. Sensory authenticators are overt and covert technologies which are

detectable for examination by one or more human senses and which do not require access to databases. Such authenticators are exemplified by holograms, optically variable inks, taggants, invisible inks etc.

It is our strong belief that the more responsible people there are who are able to carry out some kind of a check or inspection on the product, the more likely the patient is to be protected from unsuitable medication.

This range of “examiners” includes:

- Company personnel
- The public
- Distribution chain partners such as distributors and retailers
- Enforcement and investigative personnel including customs, police and private investigators.
- The judiciary, including attorneys, judges and juries.

This last group is critical to achieve successful prosecutions. When it becomes necessary to prove, in a court of law, that a product is counterfeit, it is much easier in court to compare and contrast, say, a genuine hologram with a counterfeit version than to point to a spurious digital record or lack of it.

Yet each of these groups will have different levels of awareness, training and motivation relative to authentication. The reality is, that in operating an authentication programme, the following cannot be controlled:

- Who will need to authenticate the medicine;
- When and where they will need to authenticate;
- What level of training they will have;
- What tools they may have access to.

Given that these factors are outside the control of even the most regulated and controlled supply chain, it is logical to ensure that the authenticators on the product can be examined as easily as possible, as frequently as possible, by as many people as possible. Not all such examinations can be, or need to be, an interrogation of all levels of the authenticators, but each examination is nonetheless a check on the item. If any examination raises cause to suspect the authenticity of the product then complementary levels of authentication can be examined by more expert examiners with more specific tools.

Thus:

- A patient/consumer will use their own senses but is unlikely to have any training or examination tools;

- A pharmacist may have training and equipment to examine covert authenticators or to access a tracking database;
- Company personnel or law enforcement agencies (DRAs, Customs) may have equipment to detect and decode covert coded marks or taggants, and/or to access a tracking database;
- A forensic laboratory can examine the molecular composition of the product and the authenticators.

In summary, a system to establish that a product is genuine needs to work to:

- a. detect fakes introduced in to the legitimate supply and distribution chains;
- b. detect fakes in illicit, un-regulated parallel supply and distribution chains, including those sophisticated enough to mimic the serialisation systems of the legitimate chains.

The IAA Recommendations

Clearly, we firmly believe that cooperation and development of common standards and practices for the authentication of products must be a fundamental part of any system that seeks to develop an effective response to counterfeit products.

Our overall recommendation, for the reasons given above, is that *any system to reduce the impact of counterfeit pharmaceuticals on patients should combine methods for:*

- the tracking of products through the distribution chain;
- the authentication of products using methods that do not require network connection to a database, ie sensory authenticators.

The combination of tracking and authentication is demonstrably the most effective in detecting counterfeits and in then aiding investigation and prosecution. Prosecution of counterfeiters, with appropriate penalties for the guilty, is the most effective deterrent, therefore the anti-counterfeiting system must take in to account the need to detect the counterfeits and then successfully prosecute the perpetrators.

Within this overall recommendation, in response to specific EC Enterprise and Industry Directorate-General proposals, we recommend that the following language, or the concepts contained within it, be a part of any legislation.

4.1.1 We strongly support the notion that all actors involved in the distribution chain of pharmaceutical products, whether they touch the product or not, should be held accountable if the products from which they profit financially are counterfeit or substandard in a way likely to endanger the health of the end user. Qualified auditors should be identified or trained to ensure compliance with GMP and/or GDP.

- 4.1.2 Strengthen the provision for the inspection of facilities used for storage, warehousing or distribution of pharmaceutical products within the EU. Where the origin of products lies outside the EU, procedures similar to, or harmonized with, USTR Special 301 process should be considered, placing more accountability on the countries of origin.

The US Trade Representative already monitors developing countries for intellectual property violations and has a system of sanctions already in place. This system could serve as a model for EU *modus operandi* specifically in the area of pharmaceutical infringements.

- 4.1.3 The repackaging of product at some point during the distribution represents a major threat to the integrity of the product and the intention to create a product pedigree. Such repackaging should be discouraged and, if feasible, banned so that primary and secondary packaging accompanies the product from the manufacturer to the consumer. The IAA strongly supports any measure to encourage the use of a packaging seal, which should be defined as:

a tamper-evidencing closure or seal with product authentication components, which cannot be copied, removed or altered once affixed by the manufacturer.

- 4.1.4 The IAA recognizes the potential value of a central, and generally accessible, database recording the so called ‘pedigree’ of each pharmaceutical product but is also aware of the logistical difficulty of maintaining the database current (input) and of creating records which are simultaneously useful and non-sensitive (output). Indeed the two aspects are probably mutually exclusive and accessibility to all players in the distribution chain unrealistic.

Our recommendation would be for a closed loop system accessible only to the participants of the distribution of individual products and the monitoring inspectors of GDP. It is likely that a central database which is accessible to all is too controversial to be practical. Our recommendation is that those parts relating to a particular product should be accessible only to those directly involved in the distribution of that product.

- 4.1.5 The IAA supports the idea of mass serialization at the unit pack level but only if combined with a layered approach to pack authentication through the use of sensory authenticators. Sensory authenticators are overt and covert technologies which are detectable for examination by one or more human senses and which do not require access to databases. Such authenticators are exemplified by holograms, optically variable inks, taggants, invisible inks etc.
- 4.1.6 The IAA wishes to point out that the issue of GDP certificates following each inspection of wholesalers is desirable but these also need to contain means to demonstrate their authenticity such that they be protected against fraudulent issue or manipulation.



While we support the development of standards for procedures and processes for authentication, we do not favour the mandating or recommendation of specific technologies or types of technology, because this would make it easier for the counterfeiters by providing a common target for them to aim at. It is also unlikely that there is one technology that will best suit all products and distribution patterns. There are many credible and effective options for authenticating products in use today and to limit this range would also be anti-competitive.

In conclusion, from our combined experience of implementing product authentication programmes at the national and international level we urge strong consideration be given to the aspect of training and public awareness for any security initiatives. The success of any programme depends on the extent to which it can proactively detect and correct threats to patient safety. The most well intentioned programme has failed if it acts only after the damage has been done. For this reason, we encourage the use of packaging elements that can trigger suspicion in all who handle the pack, not just authorized inspectors.

By using agreed definitions and procedures, more effective use can be made by all parties concerned in combating counterfeit goods through the improved detection of fakes and prosecution of counterfeiters.

Yours sincerely

Ian Lancaster
General Secretary