International Authentication Association (IAA)

Response to Consultation on concept paper

Delegated Act on the detailed rules for a unique identifier for medical products for human use, and its verification

We would like to thank the European Commission for consulting on the above and are very pleased to submit our response.

The IAA

The IAA is a leading global authority on counterfeit detection and product authentication. More specifically, the IAA works on behalf of its members and stakeholders in order to accelerate and improve the detection of counterfeits; the authentication of genuine products and the provision of evidence for successful prosecutions, through the use of appropriate business practices and technologies.

The IAA commissions relevant research papers and studies into the process of authentication, its value, costs and benefits. It communicates and cooperates with, and supports others in the industry. This includes anti-counterfeiting associations and law enforcement bodies, creating a wide reaching forum, thus enabling a comprehensive understanding and a holistic approach to counterfeit detection and authentication.

IAA members are brands and other companies that can contribute to the association's aims. The IAA is a forum for all brand protection professionals who have an interest and expertise in counterfeit detection and product authentication.

The IAA is an international association which contributes to national and international discussions by providing a genuinely global perspective on the use of appropriate business practices and technologies for counterfeit detection and product authentication.

The IAA and its members have a great wealth of expertise in the field of anti-counterfeiting, counterfeit detection and product authentication and our response to this consultation has therefore been focused on those areas where the IAA and its members can provide insight, as well as a unique depth and breadth of expertise.

A. CONSULTATION TOPIC N° 1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

As experts in the field of authentication the IAA must draw attention to the introduction of this section and in particular the following paragraphs:

'12. The only way to uniquely identify a pack is to give it a number (serialisation number). In order to act as an effective authentication tool, the number has to be randomised. A carrier (bar code or other) affixed on the outer packaging 'holds' the serialisation number.

13. The serialisation number on the pack is checked against its entry in a repositories system (see consultation topic n° 3), thus verifying its authenticity (see consultation topic n°2).'

The IAA must point out that a serialisation number will never provide authentication of a product. There is a fundamental difference between features such as numbers (randomised or otherwise) and authentication features. Serialisation can increase the level of security around the product packaging by enabling increased transparency throughout the supply chain. It can be used as a tool with which counterfeit packaging may be detected. However, it cannot act as an authentication feature for genuine products. For this a multi-layered authentication system must be employed.

Serialised numbers are a visible feature and therefore may be altered, distorted or deleted by the fraudsters. In order to provide authentication of a product or package it is therefore essential to include covert and forensic authentication features as part of the defence mechanism.

The International ISO Standard 12931: 2011 states clearly that "Performance Criteria for Authentication Solutions in the Field of Material Goods track & trace systems are explicitly excluded from authentication systems, nor does this International Standard apply to technologies or systems designed for the tracking and tracing of material goods. Track and trace on its own is not an authentication solution and is therefore outside the scope of this International Standard."

It should always be remembered that, in the pharmaceutical industry in particular, a product will only be authenticated as absolutely genuine once product analysis has been carried out in a laboratory. The deployment of different features should therefore be seen as a gradually increasing level of protection, starting with serialisation at the lowest level, continuing with authentication features and finally ending with individual product analysis.

It is also very important to acknowledge the fact that any protection of the outer packaging of pharmaceutical products will not guarantee the authenticity of the product inside. Re-packaging operations across the EU will create a multitude of opportunities for the fraudsters to infiltrate the genuine supply chain with counterfeit pharmaceutical products which may end up in correctly serialised packaging.

Claiming that serialisation is equivalent to authentication could mislead stakeholders and patients and may create a false sense of security which could ultimately lead to accusations of false claims and hence expose the industry to potential liability.

Consultation item no 1: Please comment on points 1 and 2 (policy options no 1/1 and no 1/2). Where do you see the benefits and disadvantages of each policy option?

It is vital to maintain competition in this industry and to allow rights holders the freedom to select from a range of suppliers. Competition will not only maintain cost effectiveness of solutions but will also allow for choice which will encourage further product innovation and creativity. It is also important to state that many rights holders have long established supply agreements and relationships which they would prefer to preserve.

It is also important to note that the variety of new features introduced to the market is a result of the numerous development projects funded by a wide range of companies. Such diversity of features and innovations makes it more difficult for the counterfeiters to respond.

Consultation item no 5: Please comment on the three concepts described under point 2.2. Where do you see the benefits and disadvantages of each of the three concepts. What are the costs for each concept? Please quantify your reply, wherever possible, by listing for example:

- costs for reading devices for the different carriers;
- costs for adapting packaging lines of medicines packaged for the EU market.

The IAA does not have a specific preference for any particular serialisation option. However, we would like to make some general comments:

It is vital to remember that serialisation in whatever form cannot provide authentication of the product. Serialisation does increase the transparency of the supply chain and, as such, is a useful tool for improving the security of the product to some degree. However, the overall security of the product and its packaging has to be proportionate to the risk that it is exposed to. Whereas a bar code serialisation may be sufficient for some low risk pharmaceutical products, a complete authentication solution combining numbering and overt, cover and forensic authentication features on product and packaging may be required for the higher risk products. The IAA therefore believes that the choice of serialisation system should be based on cost considerations, supply chain efficiencies and the degree of information required by the rights holder, as well as other side benefits of serialisation, such as interactive communication with the consumer.

The consultation already highlights the two main benefits for use of linear and 2D bar codes – that of infrastructure availability for linear bar codes and the potential for linking to the consumer for 2D bar codes. A bar code solution can easily and cost effectively be combined with other authentication features and would therefore be the most sensible option. It should also be remembered that serialisation can not only be achieved by those methods cited in the consultation document.

D. CONSULTATION TOPIC N° 4 – LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES WHICH, IN THE CASE OF PRESCRIPTION MEDICINES SHALL NOT BEAR THE SAFETY FEATURES, AND IN THE CASE OF NON-PRESCRIPTION MEDICINES SHALL BEAR THE SAFETY FEATURES

Consultation item no 11: Which approach seems the most plausible from your view? Can you think of arguments other than those set out above? Can you think of other identification criteria to be considered?

It is important to understand the counterfeiters' operation. They will attack those areas that provide the most lucrative and most easily accessible supply chain. They are agile and can change their product selection within days. They range from small home businesses to global organised crime rings. They will not wait for two years for a change in the lists but will target those pharmaceuticals not on the list, if that represents the most efficient and safe option for them. It is therefore essential for these lists to have the flexibility to quickly adjust to counterfeiters' behaviour. We therefore see the proposal of producing a new list only every two years as dangerous. Some degree of flexibility and the ability to amend the lists within this two-year term is essential in order to combat counterfeiting. We therefore see the fixing of lists for a two year term without such flexibility as a major flaw in this directive.

In addition, it may also be confusing for everyone inside the genuine supply chain to know instantly which drug is on the list and which one is not. It is therefore vital that these lists should be easily accessible by all concerned. However, it may be even more cost effective to number all pharmaceuticals across the board thus not providing unnecessary opportunities for the fraudsters and having clarity of purpose throughout the system. Further security could then be provided by additional authentication features which could then be applied in an appropriate risk setting.

E. CONSULTATION TOPIC N° 5 – OTHER ISSUES

Consultation item no 13: Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

We reiterate our comments under section **A. CONSULTATION TOPIC N° 1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER**

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