From: Jim Bracken [jim.bracken@gs1ie.org]

Sent: samedi 3 mai 2008 13:21

To: ENTR PHARMACEUTICALS COUNTERFEIT

Cc:

Subject: Public Consultation on combatting counterfeit medicines for human use

To whom it concerns:

I refer to the European Commission consultation document issued on 11th March 2008 and would like to submit the following contribution.

Background:

For some 6 years now GS1 Ireland has been very involved in efforts to improve patient safety both at a National and European level.
In particular through promoting the benefits of using the GS1 System of Standards as a basis of ensuring that medication and other key healthcare processes are supported by AIDC (automatic identification and data capture) solutions in order to facilitate effective and efficient track & trace solutions. Our work included significant involvement with GS1 in Europe's European Healthcare Initiative and this included participation in the Council of Europe's consultative process on Counterfeit Medicines both in Strasbourg 2005 and Moscow 2006.

On a local basis we have supported the NCHCD's (National Centre for Hereditary Coagulation Disorders) "world class solution" for the safe tracking and tracing of medication used in the treatment of haemophilia patients in Ireland. This solution which was the brainchild of Dr.Barry White Director of the NCHCD uses patient pack serialization in order to provide certainty of identification of all products used for treatment of patients with haemophilia.

Submission:

Firstly I would like to commend the Commission for the quality of the consultation document and I would offer the following particular comments on its contents.

1.Experience of patient pack serialization with the NCHCD solution has demonstrated the potential for securing the pharmaceutical supply chain against the threat of counterfeit products. Indeed the EFPIA solution for the protection of pharmaceuticals contains the same data content and structure as that in use by the NCHCD for the past 4 years. Accordingly we would urge the Commission to adopt their proposal for mass serialization for pack-tracing and authenticity checks on a case-by-case basis as set out in S.4.1.5

2. S. 4.1.3 proposes the deployment of unique seals on patient packs in order to ensure integrity of the product throughout its journey in the supply chain to market authorization holder. As a former Security Printing Industry expert I would respectively suggest that from my experience that counterfeiters have shown an incredible capacity to replicate printed security features to a level at least good enough to ensure that the consumer (healthcare professional or patient) does not notice the difference and so trusts that the pack is authentic. A futher point would be that as patient packs generally have two openings it might necessitate two labels and therefore increase the cost significantly.

For GS1 Ireland,

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