From: McGroarty, Feargal (IMS) [fmcgroarty@stjames.ie]
Sent: mardi 6 mai 2008 15:36
To: ENTR PHARMACEUTICALS COUNTERFEIT
Cc:
Subject: RE: Public Consultation on combating 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:
The National Centre for Hereditary Coagulation Disorders (NCHCD) is based at St. James's Hospital, Dublin, Ireland and manages patients with acquired and inherited bleeding disorders. The treatment for people with these conditions involves replacement of the missing clotting factor that causes the bleeding. This medication is called Coagulation Factor Concentrate (CFC). During the 1980's CFC became contaminated with HIV. However, because there was no standardised barcoding on the medication a real-time recall was impossible. This lead to infected medication remaining in the supply chain after a recall was initiated.
Following a national Tribunal of enquiry (The Lindsey enquiry) the NCHCD developed and implemented an electronic real-time system to track and trace all CFC in Ireland based on unique serialized bar coding at pack level (using GS1 global standards). NCHCD is now capable of performing a real-time medication recall, identifying the location of every pack of CFC in the supply chain (including the patient home or the hospital) within 10 minutes.
This project has highlighted the strengths and weaknesses of bar code technology in the twin goals of the fight against medication counterfeiting and improving patient safety, and NCHCD sees its self as a key stakeholder in this area.

Submission:
1. We agree that mass serialisation at pack level (4.1.5) would help improve traceability through the supply chain, but only if it is combined with the recommendation to implement the e- pedigree (4.1.4.) This is because, unlike Radio Frequency ID (RFID) tags, replicating or copying a barcode is simple. Therefore if a counterfeit pack is scanned and it contains a valid (copied) barcode, it may pass unnoticed. However, a system that allows information on the barcode to be compared to a centrally assessable pedigree database would facilitate the quicker identification of possible counterfeit medication. The possible additional step of implementing the transmission of an electronic Advance Shipping Note (ASN) between trading partners in the supply chain would provide an additional layer of security as any unexpected stock would then immediately be identified.

2. As mentioned in 4.1.5., industry is moving towards agreeing a standard for medication identification based on the datamatrix barcode. However, the discussions centre on the structure and content of the bar code and, as indicated above, the application of a barcode alone will not make the packs tamper proof.

3. Although a datamatrix barcode has been endorsed by the European Federation of Pharmaceutical Industries and Associations (efpia) we feel that delays in adoption of this standard may lead to manufacturers and member states unilaterally adopting their own variations in structure and content.

This, in turn, may lead to difficulties in implementing a European wide pedigree solution if barcode data content and structure of medications between countries is not standardised. We would therefore urge the Directorate-General for Enterprise and Industry to use its influence in the adoption of a Europe wide datamatrix standard for medication identification.

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