From:
Sent: 07 December 2012 09:36
To: SANCO INTRODUCTION FALSIFIED

Subject: Consultation Paper feedback

Dear Sir/Madam,

Please find below our comments regarding the Consultation Paper ‘Public consultation on the delegated act on the criteria to be considered and the verifications to be made when assessing the potential falsified character of medicinal products introduced in the Union but not intended to be placed on the market’

We are the Responsible Person Office for the Central Procurement and Supplies Unit (CPSU) working for the Ministry of Health the Elderly & Community Care (MHEC), Malta (Europe).

Paragraphs 15, 16 and 17

We are of the opinion that it will be difficult to implement these checks and verifications. The number of products produced worldwide which can be falsified is enormous and to identify these products by comparing packaging, labelling and documentation to the supposed appearance of the original product is difficult. We are of the opinion that this can only be done by having a worldwide database to which every Member State can compare with and refer to. Regarding paragraph 16 in particular, information regarding manufacturer and country of manufacture can be captured and stored in the database.

Paragraphs 20 and 21

We agree in principal that different Member States can have different authorities who perform these checks and verifications. However, it is important that information is relayed to the Member State Medicines Authority (in our case, the Malta Medicines Authority) as a central hub of information and for ease of communication and sharing of information between Member States.

Thanks and regards