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DG Health and Consumers
4 Rue Breydel
1040 Brussels
Belgium

Dear Sirs,

Reference: SANCO/C8/AM/an D (2010) 380358. Commission guidelines on good distribution practice of medicinal products for human use

We would like to contribute the following comments regarding the consultation on proposed new guidelines that will replace the content of the guidelines on good distribution practice of medicinal products for human used published in 1994.

Aegate is a specialist pharmaceutical authentication company established in 2004 with authentication systems operating in pharmacies in three member states today, where unique serialisation is mandatory. We will confine our comments as part of this consultation to the areas where Aegate has expertise, namely Chapter 6 of this consultation.

Chapter 6; complaints, returns, suspected falsified medicinal products and medicinal product recalls.

Returned medicinal products:

6.9 medicinal products which have left the premises of the distributor should only be returned to saleable stock if

vi) the product has been verified to ensure its integrity i.e. that is has not been falsified, recalled or expired.

Suspected falsified medicinal products

6.13 There should be documentation in place that describes how the distributor increases their staff's awareness of the risks of falsified medicinal products entering the supply chain. *A sample inspection check should be performed on all deliveries to ensure the integrity of each batch delivered.*

Medicinal product recalls

6.2.1 Recalled medicinal products should be identified and stored separately in a secure area while awaiting a decision on their disposition.

To note that depending upon the decisions taken within the delegated acts on the detailed rules for a unique identifier for medicinal products for human use and its verification; should policy option Number 2/2 or 2/3 be decided upon, it will be possible for electronic verifications at the level of wholesale distributors, enabling recalled or falsified medicinal products to be identified. We have had one experience whereby a pharmacist using Aegate's authentication system identified a recalled pack and returned the stock to their wholesaler requesting replacement. The wholesaler subsequently reissued the same affected stock. This error would be prevented if wholesalers were to use the same verification system in the returned goods area to confirm recalled or falsified packs.

Chapter 10 Specific Provisions for Brokers

Documentation

10.4 In addition to the proposed procedures and instructions, *we would like to recommend that brokers are issued a certificate of compliance and that there are audit procedures in place to confirm they meet these guidelines for falsified medicines checking, recalls and returned goods handling.*

Yours faithfully

Alison Williams

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