ASOCIACION ESPAÑOLA
DE FARMACEUTICOS DE LA INDUSTRIA

AEFI COMMENTS TO DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION

Ref. Sanco.ddg1.d.3(2011)1342823

April 27, 2012

Topic 1

1/2

We consider that harmonization through regulation is the best option. It would be advisable that the stakeholder would use similar code, equipments and controls.

2.1

The serialization number would have to contain manufacture product code, pack number, batch number, and expiry date. Similar technical characteristics should be used in all the steps and counties, in order to make easier and to speed up the circulation of the products.

Regarding the national reimbursement number, it's possible that its inclusion would be desirable, but the unification of criteria is complicated. We wouldn't include it in the serialisation number. It has another function.

2.1

The carrier 2D Datamatrix and RFID codes would be the most versatile and quite affordable proposal, but EFPIA / Health Authorities decisions are needed.

Topic 2

We propose the option 2/2, the verification at the dispensing point, but with random verifications at the level of the wholesale distributors. A systematic verification would be too expensive.

Topic 3

Proposed option: 3/3 National Governance. The cost of the EU governance would be too high.

Topic 4

The application of the proposed classification criteria seems to be the most adequate; it includes the risk of falsification and the severity of the conditions intended to be treated.

Topic 5

No remarks.