

Jonathan Mogford
Director of Policy
Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road
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25th April 2012

Dear Jonathan,

As the MHRA considers its response to the European Commission consultation on the delegated acts of the Falsified Medicines Directive (2011/62), the following organisations representing the breadth of the medicines supply chain within the UK wish to set out our support for the policy position expressed jointly by our own respective European Associations (EAEPC, EFPIA, GIRP and PGEU). We will forward a copy of the joint statement which is being submitted to the European Commission in the very near future.

The Falsified Medicines Directive, and the proposed system set out by the pan-European industry associations, present an opportunity to improve the lives and safety of patients through serialisation and authentication of medicine packs, and by modernising procedures to prevent recalled medicines being dispensed.

In summary, we believe that:

- The 2D (data matrix) barcode has technical and economic advantages and should be adopted as the data carrier
- A track-and-trace system is costly and disproportionate to the objectives of the Directive and offers no additional patient safety benefits to a point of dispensing verification system
- A stakeholder governance model should be fully developed by the stakeholder partners, as the best means of achieving a timely, secure and efficient system of product authentication which also delivers value for money and improves patient service
- All prescription medicines and all points at which patients receive these medicines should be within scope of a mandatory system and thus be subject to the same level of security
- The benefits of being included in a system that offers protection for UK citizens on a par with what is experienced in the rest of the Europe Union are considerable

We trust that this provides a useful overview of the positions of UK stakeholders, and that these elements will be incorporated into the Government's thinking on this issue.

On behalf of the following organisations:

Association of the British Pharmaceutical Industry
British Association of European Pharmaceutical Distributors
British Association of Pharmaceutical Wholesalers
National Pharmacy Association
Pharmaceutical Society of Northern Ireland
Royal Pharmaceutical Society

cc:

John Dalli, Commissioner for Health and Consumer Policy, European Commission
Susan Grieve, Department of Health
Keith Ridge, Department of Health