



Consultation launched on implementing the Falsified Medicines Directive in the UK

The Falsified Medicines Directive and associated Delegated Regulation introduces measures which aim to prevent the entry of falsified medicines into the legal pharmaceutical supply chain. It requires the placing of safety features consisting of a unique identifier and an anti-tampering device on the packaging of certain medicinal products for human use, for the purposes of enabling their identification and authentication.

This Regulation also sets out obligations on pharmaceutical manufacturers and supply chain stakeholders to establish a pan European system where the identification and the authentication of medicinal products is guaranteed by the end-to-end verification of all medicinal products bearing the safety features.

BGMA, along with the other principle representative stakeholder associations; ABPI (Research-based pharmaceutical industry representatives), BAEPD (Parallel Distributor representatives), NPA and CCA (Dispensing Entity representatives) and HDA (Wholesaler representatives)) have created an informal alliance (UK ESM FMD Partners) to drive the UK implementation.

This notice launches a 4-week consultation on the proposed User Requirement Specifications (URS) for the UK Medicines Verification System (UKMVS) as required by the Delegated Regulation (EU) 2016/161 of 2 October 2015. This consultation also introduces a Framework Memorandum of Understanding (MoU) developed and agreed between the UK pharmaceutical supply chain stakeholders who will take on the responsibility for its management under the supervision of the UK competent authority.

We would welcome your organisation's feedback and would ask that you share this notice with interested colleagues.

The closing date for the consultation is 13 July 2016.

The on-line consultation response document is available at <https://app.citizenspace.com/ukmvo/consultation-on-the-ukmvs-urs>

Alternatively completed response forms can also be sent electronically by e-mail to esm-fmd-consultations@abpi.org.uk