



02 February 2018

FMD Safety Features - Newsletter 09

Implementation Advisory Board – 23rd January 2018

MHRA welcomed stakeholders from across public sector bodies and industry associations for the latest Implementation Advisory Board. The Board provides advice and guidance to support the UK's implementation of the safety features aspects of FMD.

MHRA and DHSC updated the group on implementation work and news since the last meeting in September 2017 including:

- Publication of guidance in different sectors. [FAQs for secondary care](#) published in November and Community Pharmacy (see below);
- A reaffirmed commitment to issue the public consultation as soon as possible. The consultation will focus solely on flexibilities, sanctions and enforcement where the UK has legal scope to make changes. It will not include other issues which must be implemented according to the Regulation;
- Working collaboratively with SecurMed UK to address challenges in its delivery of the UK national verification organisation; and
- Our work at a European level harmonising implementation.

There was also a wide ranging discussion on implementation throughout the supply chain which covered some of the important work being done and the issues facing different sectors. We do not underestimate the challenge of delivering implementation on time and to the right standard. We also remain committed to continuing to work constructively to deliver the benefits of the safety features aspects of FMD.

Article 23 Flexibility

The Board also heard reports from three of the groups potentially impacted by the Article 23 Flexibility. Under Article 23 the UK can require wholesalers to decommission for others supplying to the public as long as they are not operating in a healthcare institution or pharmacy. Our positions on the flexibilities are subject to change during the public consultation.

Provisional discussions have included:

- **Health and Justice & Hospices:** A mixed model with bulk stock decommissioned at wholesaler level under the Article 23 flexibility, and named patient medicines decommissioned by community or hospital pharmacies.
- **Homecare:** As registered pharmacies they will be expected to meet the obligations of supplying medicines to the public rather than coming under the Article 23 flexibility.

If there are issues you would like to raise either to do with these groups or others covered under Article 23, please email our mailbox - FMD.safetyfeatures@mhra.gov.uk with the subject field 'Article 23'.

New guidance in community pharmacy

New guidance for community pharmacy owners has been issued by the UK FMD Working Group for Community Pharmacy (for further details on the group please see their website). The guidance is intended to build understanding of the options open to pharmacy contractors as the 12-month milestone for implementation approaches.

The Way Forward for FMD in community pharmacy covers key assumptions about FMD, high level processes for incorporating authentication in to existing dispensing workflows, handling stock transition, what IT systems will need to deliver and implications for patient safety.

The guidance has been published on **FMD Source** (www.fmdsource.co.uk) and will be updated by the Working Group as new information becomes available.

SecurMed UK Information

We understand that during Q1 2018 SecurMed UK will publish the UK Funding Model, setting out the fee structure and contracting model for Marketing Authorisation Holders. SecurMed UK request all manufacturers and parallel distributors pre-register with SecurMed UK. Please refer to the SecurMed UK website at www.securmed.org.uk for more details on pre-registration information required, the FMD implementation and how to register for the IT System Solution Provider toolkit.

For questions to SecurMed please email info@securmed.org.uk Questions relating to FMD process or compliance should be addressed to FMD.safetyfeatures@mhra.gov.uk

Mailbox

MHRA will continue to answer your questions about FMD through our dedicated mailbox, FMD.safetyfeatures@mhra.gov.uk Please send queries to this mailbox rather than other MHRA email addresses.

Best regards,

MHRA Safety Features team