October 2017

Recent feedback received by our dedicated mailbox has revealed the need to clarify two areas, exemptions of prescription medicines and a potential National Reimbursement Number.

Prescription medicines exemptions

The safety features **should only be applied** on the packaging of the following medical products for human use:

1. medicinal products subject to a prescription which are not set out in Annex I of the delegated regulation. Annex I provides a list of prescription products exempted from safety features; where relevant, ATC codes (Anatomical Therapeutic Chemical Classification System) have been provided to identify products.
2. medicinal products not subject to a prescription in Annex II of the delegated regulation. Annex II provides a list of products not subject to a prescription which must bear the safety features.

The Annexes can be found at the end of the delegation regulation - https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf. Guidance from the EU Commission is that there will be no change to the products listed in the Annexes before the delegated regulation is applied.

Within the Commission's delegated regulation there is flexibility in some specific areas to consider different implementation options for the UK supply chain. One of these flexibilities is to extend the scope of safety features to other products, beyond those in the list above. We are minded not to extend the scope of the unique identifier to any other products. However, we remain minded to continue to allow tamper evident features to be added to any product, at the discretion of the manufacturer. Both of these positions are subject to views gathered through the formal public consultation.

National Reimbursement Number

Another area of flexibility for the UK to determine is the addition of a National Reimbursement Number, or other national number which can be a requirement for products being placed on our national market. Our preference, to reduce burden, has been to map products to UK NHS identifiers through the information already available under the FMD requirements. Working with SecurMed UK, we believe we have found a solution which will allow this to happen and therefore we are minded **not** to require a reimbursement or national number. As above, this position is subject to views gathered through the formal public consultation.

Secondary Care Guidance

To support secondary care in implementing the safety feature element of FMD a FAQ document is being produced by NHS Improvement linking to the NHS Digital (Domain E – Digital Medicines) - Pharmacy Supply Chain & Secondary Uses of Data work. Once published, we see this as an iterative document and will welcome your feedback for future versions. We plan to publish this document next month, details will be circulated through the FMD newsletter.

Communications Update

SecurMed facilitated a positive FMD Communications Strategy workshop on 4th October at the Walgreens-Boots-Alliance offices in Weybridge with participation from DH, MHRA and the main industry associations (ABPI, BGMA, CCA, NPA, HDA). Following this workshop, it has been agreed MHRA will, in the near future, re-start the FMD Communications Group under the Implementation Advisory Board to manage overall communications for the FMD safety-features rollout.

In addition to this, we will also be looking to engage with groups of specific stakeholders on areas which are of particular interest to them.

SecurMed UK Update

SecurMed are holding a further IT System Solution Provider web-cast workshop on Friday 3rd November from 13.00-15.30. To register for this workshop please contact info@securmed.org.uk

For further information on SecurMed, the FMD implementation and how to register for the IT System Solution Provider toolkit please visit www.securmed.org.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.

The mailbox is monitored daily and you can expect to receive a response within 5 working days. If you don't currently receive a copy of the newsletter and would like to, please email by return with the following – your name, your organisation (if applicable) and your title (if applicable).

Best regards,

MHRA Safety Features team