SecurMed
The UK Medicines Verification Organisation

SecurMed UK Position Statement – In the event of a no-deal Brexit

Proposed Short holding Statement until Position finalised

"*The SecurMed Board is aware of the potential implications of a No-Deal Brexit and is considering how best to mitigate negative impacts in the light of legal advice*."

Background

Following a No-Deal Brexit, the UK becomes a third country in relation to the EU. As a consequence, UK supply chain stakeholders would no longer be able to consistently comply with the established Union-wide rules and requirement to verify and authenticate all relevant medicines under Commission Delegated Regulation 2016/161. For example, the unique identifier in a 2D data matrix code on packs of medicines released on the UK market post a No-Deal Brexit may be inactive (or missing) as the EU regulation only applies to countries within the EU, whilst the European Commission has confirmed that, under EU law, packs imported from the EU are required to have been decommissioned (made inactive) on export from the EU (under Article 22(a) of Commission Delegated Regulation 2016/161).

Reflecting that UK stakeholders cannot be expected to follow regulatory obligations that cannot be consistently fulfilled, the UK Government released a Statutory Instrument (SI) The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 No. 775, outlining the changes to be made to regulations around the use of medicines in the UK, in the event of a No-Deal UK Exit.

Its related Explanatory Memorandum (Article 7.14) makes clear that the requirements placed on all actors in the UK supply chain from 9 February 2019, by virtue of the Human Medicines (Amendment) Regulations 2019/62, regarding the safety features aspects of the Falsified Medicines Directive, will be removed.

This removes the obligations on the UK supply chain to affix the safety features, upload unique identifier data, fund the repositories system or to scan packs of medicines. Packs already affixed with FMD safety features will continue to be accepted in the UK, provided that they are in line with other UK packaging requirements. In the interests of public safety, the UK Government will evaluate the options for a future UK falsified medicines and pack serialisation framework, taking into account the investment already made by stakeholders.

The consequences of European Commission rules and UK legislative changes due to a No-Deal Brexit will impact the purpose and activities of SecurMed UK – the UK medicines verification organisation - and may impact on the functionality and integrity of the European Medicines Verification System (EMVS).
SecurMed formally submitted a change request to the European Medicines Verification Organisation (EMVO) to consider the impact of a No Deal Brexit in May 2019 and adopt changes to cope with that impact.

Issues

SecurMed have been advised by the EMVO that issues with the removal of a National Medicines Verification System (such as SecurMed UK) are complex and significant.

SecurMed further understands that, at the time of developing and building the EMVS, it was not imagined that countries would fall-out of scope of the EU legislation, and therefore arrangements for cleanly removing or disconnecting national systems are not in place.

Despite not being advised of the actual technical complexity of disconnection, SecurMed understands that, to avoid Inter-Market Transaction and Multi-Market Pack synchronisation issues with the remaining EMVS, and the generation of inappropriate system errors and alerts, it may be appropriate to retain a level of UK connectivity to the EMVS (specifically to access pack data status in the UK repository), so that any impact on other National and EU Hub repositories is minimised.

SecurMed understands that these issues are primarily in relation to legacy pack data upload (released on UK market prior to the No-Deal Brexit date), as upload of UK pack data to EMVS and data flow to UKMVS post-No-Deal Brexit can be curtailed and any post-No-Deal Brexit import of EU packs to the UK will require unique identifiers to be decommissioned from the EMVS.

SecurMed also recognises that post-Brexit decommissioning of legacy or exported Multi-Market Packs (involving the UK) may compromise their ability to be dispensed in EU countries (Malta, Ireland, Cyprus), e.g. alert generation due to authentication failure, if packs have been previously decommissioned as 'exported'. SecurMed encourages EMVO to issue guidance and introduce systems, if possible, to ensure that any changes made to Master Data Upload or decommissioning of legacy packs (e.g. by parallel importers or wholesalers) is specific to the UK market, and does not impact on Master Data relating to other countries.

SecurMed is sympathetic to these technical issues and wishes to minimise any risk to the integrity and operation of the EMVS, however, SecurMed is required to function within, and prioritise, its own legal and fiduciary responsibilities.

During previous discussions with EMVO, a number of options and approaches have been tabled for further consideration. These have included;

1. Immediate UKMVS disconnection, shutdown SecurMed
2. Retain short term SecurMed connection to EMVS, enabling further planning (SecurMed/EMVO)
3. Medium term UKMVS (dormant) connection to EMVS, mid-2020, prepare an EMVS change
4. Long term UKMVS (dormant) connection to EMVS, allowing legacy packs to reach expiry date and/ or the transfer "novation" of UK MVS contracts, all requirements and liabilities to EMVO. This would minimize need for changes to EMVS by, in effect, maintaining EMVS access to UK pack data for synchronisation purposes .

SecurMed has now taken the opportunity to review these options and has taken wide ranging legal advice including;

- Public and private law considerations
- Directors duties and insolvency, including termination rights
- Data and Data-Ownership
- No-deal Brexit

SecurMed Considerations

SecurMed is sympathetic to the impact of no-deal Brexit on the function and integrity of the EMVS.

SecurMed is informed by the European Commission's advice on the application of EU law and the consequent UK Government intention to revoke EU FMD Safety Features legislation.

SecurMed is required to function within and prioritise its own legal and fiduciary responsibilities.

The financial envelope available to SecurMed is determined by the date of No-Deal Brexit and SecurMed's ability to invoice MAHs in relation to their regulatory obligations.

SecurMed's financial liabilities vary significantly depending on date of notification of contracts/agreement termination.

The concept of novation (transfer of the rights and responsibilities) of SecurMed's contracts to EMVO is fraught with legal complexity and uncertainties, to the extent that our legal advice is that it is practically not possible

This is in part because the transfer of rights and responsibilities would be reliant upon the agreement of the affected counterparties, particularly with respect to the Arvato Agreement and the EMVO Agreement. The potential assignment to EMVO of some or all of the agreements between SecurMed and MAHs would itself mean that all of the relevant counterparties would need to enter into a novation agreement recording the arrangements. This would involve individual novation agreements for each arrangement.

The MHRA has informed SecurMed –

> In a no-deal scenario the Safety Features Regulation will be revoked in the UK. As such, there will be no requirement to maintain the repository or retain the data that has been uploaded.
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> Any information that SecurMed holds will remain subject to general UK data protection law as well as any contractual obligations that SecurMed has with the companies that uploaded the information. SecurMed will need to continue to seek and rely on its own legal advice to ensure that it continues to comply with those obligations.

SecurMed Position Statement

Following a No-Deal Brexit, SecurMed proposes to retain connectivity to the EMVS in the short-term (with EMVO and Arvato contracts expected to be retained until the end of December 2019), whilst making preparations for the winding down of the UKMVS. These preparations include the termination of associated contracts and agreements, disconnection of end-users and the purging of retained end-user data.

SecurMed is committed to work with EMVO during the wind-down period to ensure any impact on wider EMVS is minimised and to ensure appropriate and necessary data transfers (e.g. legacy pack data) are enabled and supported, prior to contract termination with EMVO and Arvato.

Further discussion is required before finalising SecurMed's view on the retention of legacy transaction data.

Dr Rick Greville
Chair of SecurMed UK Board