Public Health England

Protecting and improving the nation's health

Guidance for recipients of PHE supplied vaccines and other medicines under the EU Falsified Medicines Directive 2011/62/EU (FMD) and Delegated Regulation ((EU) 2016/161)

July 2019

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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Purpose of this document

The EU Falsified Medicines Directive 2011/62/EU (FMD) and Delegated Regulation ((EU) 2016/161) (The Delegated Regulation) impose legal obligations on the EU medicines supply chain to prevent entry of falsified medicinal products into the legal supply chain. The Regulation came into force on 9 February 2019.

This document has been produced by Public Health England (PHE) to set out and clarify roles and responsibilities in the application of FMD and the Delegated Regulation to vaccines and other medicines centrally supplied by PHE to the NHS and other customers.

The intended audience of this guidance is any person or organisation that orders vaccines and other medicines from PHE via ImmForm and/or that are supplied by Movianto UK on behalf of PHE.

Please note this is a guidance document only and is not legally binding.

Introduction to Commission Delegated Regulation (EU) 2016/161 of the Falsified Medicines Directive (FMD)

The Delegated Regulation was implemented in all EU Member States on 9 February 2019. This legislation introduced new requirements for the majority of prescription only medicines (POM) to carry safety features including a unique identifier (contained in a 2D barcode) and an anti-tampering device (a seal). It also introduced legal obligations on the UK medicines supply chain to 'verify' the authenticity of the products that it applies to, and 'decommission' those products before they are given to patients.

A central EU database (the European Medicines Verification System; the EMVS database) has been established by manufacturers and marketing authorisation (MA) holders, to which product data will be uploaded, enabling products to be scanned and verified throughout the supply chain.

The Delegated Regulation requires a decommissioning process, which is a "check out" from the EMVS database. This should be conducted as close to the point of supply (or in the case of vaccines at the point of administration) as possible.

This legislation applies to all organisations that manufacture and supply POM, and all those who supply medicines to patients. Organisations that are not considered to be a healthcare institution or a pharmacy, but who still supply medicines to the public are exempt from decommissioning vaccines and other medicines under Article 23 of the Delegated Regulation (Article 23).

Article 23 allows wholesalers to decommission on behalf of these organisations. A table which details the scope of Article 23 is included on pages 11 and 12, and additional guidance has been published by the Medicines and Healthcare products Regulatory Agency (MHRA) on Article 23, which can be found here.

Impact of FMD on vaccines and other medicines supplied by PHE to the NHS and other customers

The requirements of FMD affect organisations across the UK who access centrally supplied vaccines from PHE for the routine national immunisation programme, and/or other products for use in urgent treatment (such as various immunoglobulins, anti-toxins, and anti-venoms).

Not all the medicines supplied by PHE are licensed and so not all will be supplied with the safety features. Products without an EU or UK licence are exempt. Products with an EU licence but without a UK licence will be decommissioned prior to import into the UK.

PHE's contracted chilled storage and distribution service provider (currently Movianto UK, as referred to throughout this document), receives vaccines and other medicines directly from manufacturers and their designated wholesalers. Movianto UK stores and distributes these products on behalf of PHE to ordering bodies across the UK.

Verification of a medicine must take place whenever a medicine changes hands, except where it is received directly from the manufacturer or a designated wholesaler (as designated by the manufacturer of that product), or it is transferred between members of the same legal entity.

Movianto UK will only decommission stock prior to supplying onwards when supplying organisations defined in Article 23 of the Regulation, or where a product is being exported (see pages 11 and 12).

We would encourage all of our ImmForm customers to review pages 11 and 12 of this guidance document and the MHRA guidance on the use of Article 23 to determine if the exemption applies to your organisation with respect to vaccines or other medicines ordered via ImmForm (the online ordering portal for PHE supplied vaccines). If you believe that Article 23 applies to your organisation, you will need to contact helpdesk@immform.org.uk quoting your ImmForm vaccine ordering account number, so that PHE can agree your assessment and ensure your account is set up correctly.

A table setting out the responsibilities with respect to verification and decommissioning across the PHE supply chain is included as Annex A.

It should be noted that although the Regulation came into force on 9 February 2019, PHE will continue to issue some products to customers that are not subject to the

requirements of FMD throughout 2019 and into 2020. This is because PHE held large stockpiles of vaccines which were manufactured and delivered to PHE prior to 9 February. PHE will be issuing a mixture of FMD compliant and non-compliant products, some with safety features and some without until all of the older packs without safety features are used. It is still permissible to supply or administer these products to patients, provided they have not expired.

The latest information on which of the products supplied by PHE are now subject to the requirements of the Regulation will be available to PHE customers via the ImmForm news item until all product lines being issued are compliant.
Further information and a wide range of guidance related to FMD and the safety features is available here.

Scope of products affected

The legislation applies to all licensed prescription only medicines (POM), which includes the majority of vaccines[1] ordered through ImmForm.

FMD does not apply to unlicensed medicines. Some products routinely supplied by PHE are not licensed medicines in the UK and are therefore not subject to FMD. Products that have an EU licence but no UK licence will be decommissioned prior to import into the UK. A list of products supplied by PHE that are not subject to the requirements of FMD can be found at Annex B.

Any products that were manufactured and supplied to PHE before the safety features became a legal requirement are out of scope of FMD and remain exempt from the verification and decommissioning process after 9 February 2019. It is still permissible to supply or administer these products to patients, provided they have not expired.

PHE will begin distributing fully compliant packs which both carry the safety features and are registered on EMVS at different times (throughout 2019 and into 2020) for individual product lines. This is due to the large volume of non-FMD compliant stock already held by PHE prior to 9 February 2019.

Products that were manufactured before the 9th February 2019, but that carry the safety features and have been registered onto the EMVS database are able to be verified and decommissioned.

Vaccines supplied for clinical trials need to be decommissioned. When a licensed medicine is intended to be used as an investigational medicinal product it must be decommissioned before it leaves the supply chain and becomes part of the trial medication stock.

[1] Including diluents which accompany some vaccines.

Decommissioning and verification

Verification can take place at any time during the movement of the medicine through the supply chain. Verification checks the Unique Identifier (UI) of the product against the EMVS database to confirm that the product is authentic.

Verification must take place whenever a commissioned medicine changes hands. The only exceptions are where it is received directly from a designated wholesaler for that product, or it is transferred between members of the same legal entity.

Decommissioning happens only once (unless a product's status is reverted – see below) and takes place at the end of the supply chain when the product is supplied to the patient or otherwise leaves control of an organisation (for example where it is supplied onwards under Article 23 of the regulation). Where products are supplied onwards but within the same legal entity, if no sale is taking place then decommissioning can happen at any point within the organisation.

Decommissioning 'checks out' the product from the EMVS database but does not prevent scanning the code for other reasons, for example, recording batch and expiry dates or checking for any recall.

Organisations receiving products that require verification may wish to verify upon receipt. However, when a product is supplied or administered to a patient (or otherwise leaves the control of a pharmacy or healthcare institution) it must be decommissioned; which verifies a product by default.

The Regulation allows for the decommissioning of products within a healthcare institution to take place at any point whilst the product is in the physical possession of the institution, provided that no sale takes place between the receipt of the product and the point of supply (or administration). It is for the healthcare institution to consider, given the operational procedures within its organisation, when and where would be best for products to be decommissioned so that is has the minimum impact on the business processes, and minimal deviation from required storage conditions. Decommissioning as close as possible to dispensing or administering will ensure that checks are current.

Where the safety features are applied to the outer packaging of a pack containing more than one dose of the product (eg Bexsero® or Prevenar13®), decommissioning should be carried out the first time the pack is opened. Once a multipack has been opened and the unique identifier has been decommissioned it is not possible to check the data back into the EMVS database system for part packs.

Manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public may revert the status of a decommissioned product if the following conditions are fulfilled:

- the person reverting the status is covered by the same authorisation or entitlement, in the same premises as the person that decommissioned the UI
- it takes place no more than 10 days after the product was decommissioned
- the product has not expired
- the product has not been registered in the EMVS database as recalled, withdrawn, intended for destruction, or stolen, or the person performing the operation does believe the product is stolen
- the product has not been supplied to the public

If your organisation is exempt under Article 23 of the Regulation and you have arranged with PHE to be supplied on that basis, then products will be decommissioned by Movianto UK before being delivered. Movianto UK are unable to decommission on behalf of organisations that fall outside of the scope of Article 23. Organisations that are not exempt under Article 23 are responsible for decommissioning the products that they supply or administer to patients.

The status of products that have not been decommissioned will remain active on the EMVS database until the expiry date.

Aggregated codes would allow decommissioning of multiple UIs from a specific shipment via an additional barcode, and are allowed under the Regulation. However, aggregation through the FMD verification system as it is currently configured is not yet available, and stakeholders estimate it will take several years to develop fully. The UK has fed into the development of EU guidance on short-term aggregation solutions adopted while a fully-integrated system is developed. The document adopted by the EU expert group on safety features has now been published here.

Article 23

The types of organisation that are covered under Article 23 of the Regulation are set out in the table below:

Article 23	UK Guidance
a) persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;	This is a catch all for organisations that may not be explicitly listed. Critically it is clear that they are neither a healthcare institution nor pharmacy.
b) veterinarians and retailers of veterinary medicinal products;	For all products leaving the human medicines supply chain.
c) dental practitioners;	All dental practices.
d) optometrists and opticians;	All optometrists and opticians.
e) paramedics and emergency medical practitioners;	Paramedics and emergency medical practitioners. Ambulance trusts will need to consider how they manage their medicines supply – if this is in house, for example through an ambulance holding facility, is that just a collection and supply point or is the supply coming direct from the healthcare institution (eg hospital). If it is the latter, the hospital will need to decommission as the wholesaler cannot decommission for a healthcare institution.
f) armed forces, police and other governmental institutions maintaining stocks of medicinal products for the purposes of civil protection and disaster control;	All MOD sites.
g) universities and other higher education establishments using medicinal products for the purposes of research and education, with the exceptions of healthcare institutions;	All universities and other higher education establishments but limited to medicinal products for the purposes of research and education. As set out in the Delegated Regulation it does not apply to healthcare institutions such as a university hospital or GP surgery.
h) prisons;	All prisons and custody suites and other ‘secure environments’, for example - immigration removal centres and secure children’s homes. However, a pharmacy operating in a prison or a prison hospital would need to decommission themselves.
i) schools;	Education establishments.

j) Hospices; and	Institutions whose primary function is the provision of palliative care.
k) nursing homes	Nursing and care home providing residential care.

Article 23(a), 'persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy' is a catch-all for organisations that are not explicitly listed.

Where Article 23 applies but a provider is not explicitly listed, the provider has the responsibility to ensure that the decision on whether they are an Article 23 organisation is in line with the Regulation. More detailed guidance on this is available here.

Movianto UK, as PHE's contracted distribution agent, will decommission products that PHE agrees to supply to organisations which are exempt from decommissioning under Article 23. It is important that our customers work with us to ensure that products are correctly decommissioned.

We would encourage our customers to review the Article 23 guidance to determine whether the exemption applies to your organisation with respect to products ordered from PHE via ImmForm. If you believe that Article 23 applies, you will need to contact helpdesk@immform.org.uk quoting your ImmForm vaccine ordering account number so that PHE can agree your assessment and ensure your ImmForm account is set up correctly.

FMD compliant products supplied to GPs, pharmacies and other healthcare institutions by PHE will not be decommissioned prior to delivery.

PHE (and hence Movianto UK) are unable to decommission on behalf of any organisation that falls outside of the exemption provided by Article 23, except where a product is being exported.

The European medicines verification system (EMVS) database and I.T. provisions

The EMVS holds information on the authenticity of the medicine. No patient related data will be held or reported on the system. Local systems may be designed in a way that uses the product data within the UI to link products to patients; however, this is outside the scope of FMD.

Data from verification and decommissioning of medicines is relayed to/from EMVS via the UK medicines verification system (UK MVS), which has been established by SecurMed UK.

Organisations are required to register their functions (GP, wholesaler, pharmacist etc.) and locations (where verification and/or decommissioning activity will take place) with SecurMed UK, in order to be able to verify/decommission medicines using their chosen IT system.

SecurMed registration is of functional locations, rather than of individuals performing these functions.

IT software changes required to support automated systems are being developed by the relevant system suppliers, who offer a range of both integrated and standalone systems to enable access to the UK MVS via SecurMed. A list of these suppliers and links to their respective websites can be found on the SecurMed website.

We recommend that our customers speak to the persons within their organisation who are responsible for medicines/pharmaceutical compliance, in conjunction with your IT team(s), to ensure the supply chain for your area of business is considered as FMD is rolled out throughout your organisation.

Annex A – Summary of FMD responsibilities across the PHE supply chain

Responsibilities	Applicable to
Requirement to verify products before supplying onwards, except where they are received directly from the manufacturer or a designated wholesaler (as designated by the manufacturer of that product). If supplying to an Article 23 organisation, then there is also a responsibility for decommissioning before onward supply.	• NHS Trust Hospital Pharmacies • NHS Community Pharmacies • Wholesalers • Vaccine holding centres (Scotland) or Health Boards (Wales) or Health and Social Care Trusts (Northern Ireland)
Requirement to decommission products prior to dispensing/administering to a patient.	• General Practice (including in Crown Dependencies) • Hospitals (acute care, A&E, pharmacy) (including in Crown Dependencies) • NHS Community Pharmacies • School age immunisation providers who operate as part of a healthcare institution • Private Healthcare Institutions • Community interest companies/social enterprises operating as healthcare institutions • Occupational Health (operating as part of healthcare institution) • GUM/HIV clinics (operating as part of healthcare institution)

No verification or decommissioning requirements other than checking the anti-tamper device (seal).	• Organisations who fall within Article 23, including but not limited to:
	  ○ Universities using vaccine for research purposes.
	  ○ Ministry of Defence bases.
	• UK overseas territories
	• Occupational Health (operating outside of healthcare institution)

Annex B – Products currently supplied by PHE that are not subject o the requirements of FMD in the UK

Please note, the products listed below are subject to change. The most up to date information on individual products can be found on ImmForm

Products that are in the scope of the Regulation but which are unlicensed in the UK will be decommissioned prior to import into the UK. These products include:

- Tuberculin Purified Protein Derivative (Mantoux test) – this product will be issued in non-barcoded packs in the UK
- Diphtheria Antitoxin*

Products that are unlicensed in the EU and UK are outside the scope of the Regulation, and will not require decommissioning. These products include:

- European viper antivenom (ViperaTab®)
- Botulinum antitoxin*
- all antivenoms*

*These products are not available on ImmForm and can only be ordered from PHE by exception.