Additional guidance on 'Article 23 providers', 'Healthcare Institutions' and 'Article 26 exemption'

This is designed to be an iterative document which provides additional information for stakeholders considering whether an organisation is covered under Article 23, needs to fulfil decommissioning obligations as a healthcare institution or a community pharmacy, or meets the requirements for exemption under Article 26. Please note this is a guidance document only, and is not legally binding. This document is subject to the MHRA consultation.

'Article 23 providers'

The EU Delegated Regulation 2016/61 lays down the detailed rules on 'safety features' under the Falsified Medicines Directive (FMD). Article 23 provides Member States with legal flexibility regarding their respective supply chains about where the decommissioning process should take place for persons or organisations captured under Article 23. These are 'Article 23 providers', who supply medicines to the public but do not operate within a pharmacy or a healthcare institution.

Where there is an agreement to supply medicines:

While the legal responsibility to decommission as necessary for Article 23 providers ultimately rests with wholesalers, we would expect Article 23 providers to work with their wholesalers to ensure that both sides are clear on their obligations so that all medicines are correctly decommissioned. It's important to note that a wholesaler can choose not to supply medicines, so there must be agreement on the use of Article 23.

Where Article 23 applies but the provider is not explicitly listed, the provider has the responsibility to ensure the decision is in line with the Regulation. In this scenario, as with those explicitly listed under Article 23, the wholesaler must decommission. As above, a wholesaler can choose not to supply medicines, so there must be agreement on the use of Article 23. Again, we would expect Article 23 providers to work with their wholesalers to ensure that both sides are clear on their obligations so that all medicines are correctly decommissioned.

Whilst Article 23 provided a catch-all for any person or organisation not part of a healthcare institution or pharmacy, there were a number of specific sectors that were explicitly named – this list is not subject to change at this time and is taken directly from the Delegated Regulation. This guidance is designed to support organisations in how they approach Article 23. However, we do not have any legal flexibility to extend the type of organisation covered under Article 23 beyond what is allowed under the Delegated regulation:

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 who 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;	*NHS Employed Paramedics and emergency medical practitioners working for NHS ambulance trust/service receive their medicines supply via their employing organisation acting as a healthcare institution. This will be via a managed supply process through an ambulance station or remote holding facility acting as a collection and supply point direct to paramedics. The NHS Ambulance trust/service is a healthcare institution and will be required to verify and decommission its medicines as required under the FMD regulations. When individual paramedics or emergency medical practitioners are not providing services directly for an NHS ambulance trust/service their medicines supplier is able to decommission medicines for these practitioners.*
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 i.e. a university hospital or GP surgery.*
h) prisons;	*All prisons and other custodial 'secure environments', for example - immigration removal centre, secure training centres and secure children's homes. However, a pharmacy operating in a prison or other 'secure environments' 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.*

There may also be scenarios where an organisation's activity as a pharmacy or healthcare institution takes priority because they a legally operating as another organisation despite physically being in an 'Article 23' organisation. For example, a registered community pharmacy operating within a prison setting that dispenses named patient stock. Here, given it is acting as a licensed community pharmacy we would expect that pharmacy to decommission medicines, despite being based within a prison. However, all other bulk stock (i.e. not on a named patient basis) being supplied directly to the prison by wholesalers, bypassing the registered pharmacy in the prison, should be decommissioned under Article 23 before being supplied to the prison pharmacy.

Medicines for the Purposes of Research

There is also some limited flexibility in terms of supply for the purpose of research to Article 23 providers provided by the EU. This is picked up in a specific example in the EU Commission's Q&A document – available on the EU Falsified Medicines page: https://ec.europa.eu/health/human-use/falsified_medicines_en

Question: Do wholesalers have the obligation to decommission the unique identifier of a medicinal product when they sell the product "business-to-business" to a company which buys it for the purpose of research?
Answer: Article 23(g) allows the decommissioning by wholesalers of medicinal products supplied for the purpose of research, except when supplied to healthcare institutions. Although the Article does not explicitly mention that it applies to the supply of products for the purpose of research to companies which are not universities or other higher education establishments, it is desirable to include such a case in the scope of this Article (provided that those companies are not healthcare institutions) in order to guarantee the decommissioning of the unique identifiers on those products.

This question is helpful both for understanding the Commission's flexibility in terms of supply to Article 23 provides but it also reaffirms the EU position that healthcare institutions must decommission products themselves. Any organisation who is not explicitly covered under Article 23 should firstly consider if they are a healthcare institution or pharmacy, as the Article 23 exemption cannot be used if this is the case. Article 23 only automatically applies if you are explicitly listed, otherwise **there needs to be agreement between the provider and wholesaler over the use of Article 23** based on Delegated Regulation. In these cases, the provider bears the responsibility that Article 23 is being be used correctly in line with the Delegated Regulation and that medicines are being decommissioned correctly.

'Healthcare Institutions'

In Article 3(f) the Delegated Regulation defines a 'healthcare institution' as - 'a hospital, in-or outpatient clinic or health centre'.

While there are regulators of health services such as the Care Quality Commission (CQC) in England, being regulated by such an organisation does not determine whether or not Article 23 applies to you. Article 23 explicitly excludes listed providers that are similarly regulated, and on the other hand some health clinics may also be considered as healthcare institutions but are not regulated in such a way.

Therefore, organisations should consider the nature of their activity and where and how the dispensing of medicines is carried out. Below are some areas to consider:

- **Is my organisation a hospital, in-or outpatient clinic or health centre? If so will I need to decommission medicines within my organisation and cannot rely on others to do this on my behalf?**

  If 'Yes', I will need to decommission medicines.

- **Does my organisation dispense medicines on a named patient basis against a prescription issued by a prescriber?**

  Full packs supplied under a WDA to another healthcare institution cannot be decommissioned as Article 23 does not apply. However, if the product is being dispensed against a prescription on a named patient basis– that would be considered the point of supply and should be decommissioned. This could be considered in the context of out of hours supply.

- **Is my organisation exempt from the general rules on selling, supplying and/or administering medicines?**

  The Human Medicines Regulations 2012 sets out the legal requirements over the sale and supply of medicines and alongside this due consideration should also be given to location. Generally, prescription only medicines can only be sold or supplied at a registered pharmacy premises or under the supervision of a pharmacist but there are exceptions including paramedics or through patient group directions (PGDs). Article 23, may or may not apply. Decommissioning doesn't have to happen in a pharmacy but Article 23 is more likely to apply where there isn't a pharmacy. For example, a clinic being run in the premises of hospital, the clinic could be providing specialist advice but the service and supply of medicines is being provided for the host hospital, who should therefore decommission. Equally, a service could be physically happening in a space owned by 'healthcare institution' but that doesn't shift responsibility from who is supplying the product, for example satellite renal services being carried out in a room in another hospital. Pre-packs may be supplied in a secure location that cannot be considered as a healthcare institution and in which decommissioning is not practical. For example, where a medicine is supplied in the course of a drug treatment service that is not being dispensed to the patient in a healthcare institution or pharmacy setting.

When considering FMD requirements against UK law, it's important to note that the Delegated Regulation takes precedence. That said, current definitions in regulations can be helpful in interpreting the EU definition of a healthcare institution:

Human Medicines Regulations 2012 - “hospital” includes a clinic, nursing home or similar institution”.
NHS Act 2006 - “hospital” means— • (a) any institution for the reception and treatment of persons suffering from illness, • (b) any maternity home, and • (c) any institution for the reception and treatment of persons during convalescence or persons requiring medical rehabilitation, and includes clinics, dispensaries and out-patient departments maintained in connection with any such home or institution, and “hospital accommodation” must be construed accordingly.

There may be instances where an organisation that is defined as a Healthcare Institution also falls under one of the categories of Article 23. This could occur due to the open-natured definition of a Healthcare Institution used by the Delegated Regulation, prompting the use of further definitions (in the UK provided by the Human Medicines Regulations 2012 and NHS Act 2006). In cases such as this, the Delegated Regulation is clear that **being on the Article 23 list takes priority over being considered a Healthcare Institution** provided they are part of the same legal entity. These organisations would therefore be exempt from the responsibility of decommissioning, as stated under Article 23 of the Regulation.

Further Guidance to GPs and Dispensing Doctors

The UK has classed General Practitioners (GPs) as health centres and therefore healthcare institutions – that includes both dispensing and non-dispensing GPs. We have recently reviewed this alongside the consultation and can confirm this position stands, GPs are not exempt under Article 23 and must decommission medicines. In fulfilling their obligations on decommissioning, because of the nature of their activity Dispensing Doctors should seek to remain equitable to what pharmacies do where appropriate. This needs to fit with the nature of the business, for example out of hours care decommissioning could happen when medicines are prepared and sealed in drugs bags, effectively as close to the point of supply as is reasonably possible.

Other Considerations

Split packs

The EU Delegated Regulation also allows for split packs, whether you are operating in a hospital or pharmacy this product should be decommissioned as soon as the pack is split and part of the product is first administered to a patient. This is set out in the EU Q&A document:

Question: Many hospitals and other healthcare institutions supply the contents of packages of a medicinal product to more than one patient. Where only part of a pack of a medicinal product is supplied, when should the decommissioning of the unique identifier be performed?
Answer: The unique identifier should be decommissioned when the packaging is opened for the first time, as required by Article 28 of Commission Delegated Regulation (EU) 2016/161.

‘Article 26 exemption’

Further to the outcome of the public consultation, the Government plans to allow this exemption. Article 25 provides further detail on the obligations on those who supply to the public, Article 26 provides additional flexibility alongside this. Article 26 will allow some healthcare intuitions (e.g. hospitals) who have a Wholesale Distribution Authorisation (WDA) additional flexibility, especially if they have different and geographically separate facilities or sites. The Delegated Regulation allows the UK powers to turn the flexibility in Article 26 on or off, but we do not have any powers to amend its scope. Article 26(3) exempts a person authorised or entitled to supply medicinal products to the public operating within a healthcare institution from the obligations of verification and decommissioning, provided that **all** of the following conditions are met:

(a) the person authorised or entitled to supply medicinal products to the public is operating within a healthcare institution;

(b) the person authorised or entitled to supply medicinal products to the public obtains the medicinal product bearing the unique identifier through a wholesaler belonging to the same legal entity as the healthcare institution;

(c) the verification and decommissioning of the unique identifier is performed by the wholesaler that supplies the product to the healthcare institution;

(d) no sale of the medicinal product takes place between the wholesaler supplying the product and that healthcare institution;

(e) the medicinal product is supplied to the public within that healthcare institution.

Dispensing Doctors practices with a WDA, with or without a community pharmacy contract, will have to decommission. Practices who are acting as a dispensing practice and a pharmacy for all of their patients, where stock doesn’t physically move and there is no sale, can decommission in one process.

Under condition of Article 26(3a) the wholesaler must belong to the same legal entity as the healthcare institution. This means that the exemption only applies to a healthcare institution holding a Wholesale Dealers Licence. This does <u>not</u> mean that the healthcare institution must decommission from under their Wholesale Dealers License, only that the option to do so is there.

This exemption does <u>not</u> allow a hospital to decommission for another hospital which is a separate legal entity.