AIDE MEMOIRE FOR GDP INSPECTION OF WHOLESALERS
COMPLIANCE WITH COMMISSION DELEGATED REGULATION (EU) 2016/161 FOR SAFETY FEATURES
22 January 2020

Area of operations / items	**Questions/Show me**	**References (where applicable)**
General	Are there medicinal products in the portfolio of the wholesaler required to bear safety features? Are any products exempted under Annex I? Are any OTC products required to bear safety features under Annex II? How are the different requirements for the different products controlled/managed? Are the requirements built into to the product master data on the inventory/stock control system? Are there products with different requirements in different EU Member States (e.g. prescription in certain MS & OTC in another)? If so, how is this handled? Is there a procedure or authorised listings available specifying which products are within the scope of the DR and specific requirements in the different Member States (if applicable)? Is the wholesaler a 'designated wholesaler'? For what companies and products? If yes, show me the written contract, where the wholesaler is named as "designated wholesaler" by the MAH. Does the contract cover at a minimum, responsibilities for the following: ➢ Verification and decommissioning of safety features; ➢ Notification, reporting and investigation of suspected falsified medicinal products; ➢ Handling and processing of returns; ➢ Handling medicinal products destined for export; ➢ Record keeping Have you confirmed that information about you being a 'designated wholesaler' is correctly entered by the MAH into the system? Are there products bearing safety features which are required to be verified by the wholesaler (i.e. it is not the designated wholesaler nor does it receive product from the designated wholesaler)?	GDP Guidelines, Chapter 1, Paragraph 1.3 Article 20, Article 36 (g) DR

	How are the different scenarios handled/controlled at the site? For each of the products it distributes, does the wholesaler have access to the lists of wholesalers who are designated by the marketing authorisation holder to store and distribute its products, for the purposes of determining whether it has to verify the unique identifier of a given medicinal product? Show us how you find out who the designated wholesaler is for particular products? Are individual unique identifiers (UIs) scanned / are aggregated codes scanned allowing the simultaneous verification of multiple UIs? At what point is the verification conducted, e.g. at the point of receipt, at the point of supply etc.? Is this reflected in a procedure?	
Connection to Repository System	Is the wholesaler connected to the national repository system?	Article 11 DR
Registration with the NMVOs	Has the wholesaler registered with all relevant NMVOs? Show me the registration documentation.	
Quality System	Was serialisation for EU implemented at the site under change control? Did this change control process include identification of Quality System documentation which required update to incorporate safety features? {e.g. procedures for goods receipt, dispatch/distribution, returns, recalls, falsified medicinal products, destruction (*could be one procedure taking into account all the listed points*); record keeping; technical/quality agreements etc.} Was new equipment installed and was it qualified? Is the number of scanners etc. appropriate? Have personnel received training? Review the change control(s), qualification documentation etc. Is aggregation implemented for certain product lines? Explain how (e.g. from individual pack to shipper to pallet; or UI's in 1 data-file, what happens with the	GDP Guidelines, Chapter 1, Paragraph 1.2; Chapter 3, Paragraphs 3.3.1, 3.3.2

	data-file, how is this protected/transferred in a secure way)? How is the integrity of an entire aggregated shipper/pallet verified?	
Verification of the safety features	When verifying the safety features, are the following verified: (a) the authenticity of the unique identifier (UI); (b) the integrity of the anti-tampering device (ATD). Request to see records of the verification checks completed; e.g. electronic records for UI, manual records for ATD. Has the procedure/form been updated to document the ATD check? Does the wholesaler verify the UI of medicines returned by customers? (Note: In the event that these are already decommissioned, how does the wholesaler handle this situation?) Does the wholesaler verify the UI of medicines supplied by other wholesalers (except the ones coming from a manufacturer, MAH, designated wholesaler, distributed by wholesalers located in the same premises, or another warehouse of the same wholesaler)?	Article 10, Article 20, Article 21 DR
Records	Are records kept for any transaction in medicinal products received and supplied (i.e. purchase/sales invoices, delivery slips, or on computer or any other form)? Do these records include at least the following information: ➢ date; ➢ name of the medicinal product; ➢ quantity received or supplied; ➢ name and address of the supplier, customer, or consignee, as appropriate; ➢ batch number at least for medicinal product bearing the safety features	GDP Guidelines, Chapter 4, Paragraphs 4.2, 5.8
Returns	Has the Returns procedure been updated to capture requirements related to safety features? Does it include the following: ➢ Verification of safety features for all returned packs? ➢ Are records maintained?	Article 20 (a) DR GDP Guidelines, Chapter 6, Paragraph 6.3 (v)

	➢ Is there provision for products which have left the premises of the wholesaler to only be returned to saleable stock if there is reasonable evidence that the product was supplied to that customer (via copies of the original delivery note or by referencing invoice numbers, etc.) and the batch number for products bearing the safety features is known, and that there is no reason to believe that the product has been falsified.	
Suspected falsified medicinal products	Is there a procedure in place for handling of suspected falsified medicinal products? Does it include the following: ➢ The requirement to immediately inform the competent authority and the marketing authorisation holder of any medicinal products identified as falsified or suspect to be falsified? ➢ The requirement to record all the original details and to investigate and for records to be maintained? ➢ The requirement to physically segregate the suspect stock and to store it in a dedicated area away from all other medicinal products? Does the wholesaler have in its premises medicines with a decommissioned UI or a UI that raised an alert, without it being segregated from saleable stock? (conduct some simple random checks) Does the wholesaler have in its premises medicines with a broken ATD, without it being segregated from saleable stock? (conduct simple random checks) Have the suspected falsified situations been communicated to the NCA?	GDP Guidelines, Chapter 6, Paragraph 6.4 Article 12, Article 24 DR
Decommissioning of unique identifiers	Are UIs verified and decommissioned at the site of the wholesaler, who has the medicinal product in his physical possession, for the following: (a) products which he intends to distribute outside of the Union; (b) products which have been returned to him by persons authorised or entitled to supply medicinal products to the public or another wholesaler and cannot be returned to saleable stock; (c) products which are intended for destruction; (d) products which, while in his physical possession, are requested as a sample by NCAs; (e) products which he intends to distribute to the persons or institutions referred to in Article 23, where	Articles 22, 23 DR

	required by national legislation in accordance with the same Article. Are the above requirements included in a procedure? Are stock management/distribution systems configured to meet these requirements for the Article 23 entities? Has the process been qualified?	
Reversing the status of a decommissioned unique identifier	Under what circumstances is the reversal of the status of a decommissioned unique identifier to an active status permitted? Is this covered by a procedure? Does the procedure provide for the following: (a) the person performing the reverting operation is covered by the same authorisation or entitlement and operates in the same premises as the person that decommissioned the unique identifier; (b) the reverting of the status takes place not more than 10 days after the unique identifier was decommissioned; (c) the pack of medicinal product has not expired; (d) the pack of medicinal product has not been registered in the repositories system as recalled, withdrawn, intended for destruction or stolen and the person performing the reverting operation does not have knowledge that the pack is stolen; (e) the medicinal product has not been supplied to the public.	Article 13 DR
Provisions to accommodate specific characteristics of Member States' supply chains	Is the wholesaler engaged in decommissioning of safety features under Article 23 of the DR? Does the wholesaler carry this out according to the national law at the place distributed, which implements Article 23?	Article 23 DR
Training	Have personnel received training in the relevant SOPs and activities related to the implementation of safety features? Have personnel received training in the handling of technical alerts and how to deal with them? Are records available?	

Outsourced Activities	If the wholesaler has subcontracted to a logistics provider, review the technical agreement/contract with respect to responsibilities related to the FMD, for example: ➢ Verification and decommissioning of safety features; ➢ Notification, reporting and investigation of suspected falsified medicinal products; ➢ Handling and processing of returns; ➢ Handling medicinal products destined for export; ➢ Record keeping Has the subcontractor been audited?	GDP Guidelines, Chapter 1, Paragraph 1.3