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European Commission
DG SANTE
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REGULATION (EU) 2019/6 ON VETERINARY MEDICINAL PRODUCTS – COMMENTS ON EMA ADVICES ON IMPLEMENTING MEASURES REGARDING GDP

Dear Ms Zamora Escribano,

First of all, we wish to thank you again for your prompt reply to our letter of 22 July 2020.

Today, we contact you in relation to the EMA's recommendations on implementing measures under Regulation (EU) 2019/6 on veterinary medicinal products regarding Good distribution practice (GDP), i.e.

- *EMA/87754/2020 Advice on implementing measures under Article 95 (8) of Regulation (EU) 2019/6 – GDP for active substances used as starting materials in veterinary medicinal products*
- *EMA/567192/2019 Advice on implementing measures under Article 99 (6) of Regulation (EU) 2019/6 – GDP for veterinary medicinal products.*

We would like to take this opportunity to share with you some brief comments on the provisions on physical and/or electronical segregation of products/active substances in these documents:

Need for Alignment of GDP Guidelines for the Veterinary Sector with those for the Human Sector

The above specified documents emphasise on page 3 (under the heading "Recommendations") that they follow the principles of the respective GDP Guidelines for medicinal products for human use, taking into account the specificities in the veterinary field. We agree with the Agency's approach to align the GDP guidelines for medicinal products for veterinary use (and the active substances used therein) as far as possible with the corresponding guidelines for medicinal products for human use (and the active substances used therein) as

- a significant number of active substances are used as starting materials both in medicinal products for human and for veterinary use;
- GDP inspections for both types of medicine will often be carried out by the same inspectors;
- the same wholesalers may distribute both veterinary and human medicinal products (or active substances for both types of products).

Consequently, EMA stresses in both documents (on page 3): "*Therefore, it is essential that the future Implementing Act does not introduce any requirements more stringent than the corresponding GDP guidance for the human sector*."

Divergence Regarding Method of Separation of Medicinal Products/Active Substances and Proposal for Amendment

However, regarding the method of separating (also referred to as “segregating”) medicinal products/active substances in specific circumstances both EMA documents stipulate more stringent requirements than the corresponding GDP guidance for medicinal products for human use: Whereas the latter mostly foresee the possibility to replace the physical separation of medicinal products/active substances by using an equivalent electronic system, the EMA recommendations require in some corresponding sections that the veterinary medicinal products/active substances should be separated physically and electronically, if an electronic system is available. An overview of the provisions concerned is attached to this letter.

For the reasons mentioned above, requirements diverging from the GDP guidance for the human sector need to be avoided. In particular as far as the separation/segregation of veterinary medicinal products/active substances is concerned, we do not see a need for stricter requirements: Validated electronic segregation systems are widely used to replace physical segregation and recognised as safe. If medicinal products/active substances are quarantined or electronically blocked in a validated electronic system, they cannot be scheduled in any sales order. Goods that are electronically blocked cannot be moved in the system. The electronic separation is therefore as reliable as the physical separation. No additional safety can be gained through the obligation to combine a validated, equivalent electronic segregation with an additional physical segregation.

To avoid an additional burden for distributors without gaining additional safety for the patient, the GDP guidances for the veterinary sector should be aligned with the GDP guidances for the human sector also in respect to the possibility to replace the physical separation of medicinal products/active substances by using an equivalent electronic system.

The provisions recommended by EMA on obligatory physical segregation lead to an unnecessary increase in complexity insofar as they deviate from GDP guidances for the human sector. Consequently, these provisions are not in line with the European Commission’s ambition to promote administrative simplification and strengthen European production and competitiveness as outlined in the Roadmap for a Pharmaceutical Strategy (Ref. Ares (2020)2842126).

Our concrete proposals for some adjustments of the provisions concerned are provided in the overview on the next pages. We remain at your disposal for any questions or comments on this matter and thank you in advance for your attention to our comments.

Yours sincerely,

Dr. Oliver Sude
Deputy Secretary General

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EMA Advice on implementing measures under Article 95(8) of Regulation (EU) 2019/6 on veterinary medicinal products – Good distribution practices (GDP) for active substances used as starting materials in veterinary medicinal products			
	Guidelines of 19 March 2015 on GDP of active substances for medicinal products for human use *(emphasis added)*	**EMA Advice on GDP for active substances used as starting materials in veterinary medicinal products** *(emphasis added)*	**Proposal for amendments of EMA Advice on GDP for active substances in veterinary medicinal products** *(emphasis added, proposed amendments ~~deleted~~ and inserted in red)*
Chapter 6 – Operations, Sections on Receipt	Section 6.3: "Active substances with broken seals, damaged packaging, or suspected of possible contamination should be **quarantined either physically or using an equivalent electronic system** and the cause of the issue investigated."	Section 6.2, sub para 2: "Active substances used as starting materials in veterinary medicinal products with broken seals, damaged packaging, or suspected of possible contamination should be **separated physically and electronically**, if an electronic system is available and the cause of the issue investigated."	Section 6.2, sub para 2: Active substances used as starting materials in veterinary medicinal products with broken seals, damaged packaging, or suspected of possible contamination should be **separated either physically ~~and~~ or through an equivalent electronically ~~system~~**, if an electronic system is available and the cause of the issue investigated.
	Section 6.5: "Where the distributor suspects that an active substance procured or imported by him is falsified, he should **segregate it either physically or using an equivalent electronic system** and inform the national competent authority of the country in which he is registered."	Section 6.2, sub para 4: "Where the distributor suspects that an active substance used as starting materials in veterinary medicinal products procured or imported by him is falsified, he should **segregate it physically and electronically,** if an electronic system is available and inform the national competent authority of the country in which he is registered."	Section 6.2, sub para 4: Where the distributor suspects that an active substance used as starting materials in veterinary medicinal products procured or imported by him is falsified, he should **segregate it either physically ~~and~~ or through an equivalent electronically ~~system~~**, if an electronic system is available and inform the national competent authority of the country in which he is registered.
Chapter 6 – Operations, Sections on Storage	Section 6.11: "Active substances beyond their expiry date should be separated, **either physically or using an equivalent electronic system**, from approved stock and not be supplied."	Section 6.3, sub para 5: "Active substances used as starting materials in veterinary medicinal products beyond their expiry date should be **separated physically and electronically,** if an electronic system is available, from approved stock and not be supplied."	Section 6.3, sub para 5: Active substances used as starting materials in veterinary medicinal products beyond their expiry date should be **separated, either physically ~~and~~ or through an equivalent electronically ~~system~~**, if an electronic system is available, from approved stock and not be supplied.

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EMA Advice on implementing measures under Article 99(6) of Regulation (EU) 2019/6 on veterinary medicinal products – Good distribution practices (GDP) for veterinary medicinal products			
	Guidelines of 05.11.2013 on GDP of medicinal products for human use *(emphasis added)*	**EMA Advice on GDP for veterinary medicinal products** *(emphasis added)*	**Proposal for amendments of EMA Advice on GDP for veterinary medicinal products** *(emphasis added, proposed amendments ~~deleted~~ and inserted in red)*
Section 3.2 Premises	Section 3.2, sub para. 3: "Medicinal products should be stored in segregated areas which are clearly marked and have access restricted to authorised personnel. **Any system replacing physical segregation, such as electronic segregation** based on a computerised system, **should provide equivalent security and should be validated."**	Section 3.2, sub para. 3: "Veterinary medicinal products should be stored in segregated areas which are clearly marked and have access restricted to authorised personnel. **Any system replacing physical segregation, such as electronic segregation** based on a computerised system, **should provide equivalent security and should be validated."**	*No proposal as provisions are identical.*
	Section 3.2, sub para. 4: "Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated **either physically or through an equivalent electronic system**. This includes, for example, any product suspected of falsification and returned products. Medicinal products received from a third country but not intended for the Union market should also be physically segregated. Any falsified medicinal products, expired products, recalled products and rejected products found in the supply chain should be immediately physically segregated and stored in a dedicated area away from all other medicinal products. The	Section 3.2, sub para. 4: "Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated **physically and electronically**, if an electronic system is available. This includes, for example returned products. Veterinary medicinal products received from a third country but not intended for the Union market should also be physically segregated. Any product suspected of falsification and falsified veterinary medicinal products found in the supply chain, expired products, recalled products and rejected products should be immediately physically and electronically separated, if an electronic system is available and stored in a	Section 3.2, sub para. 4: Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated **either physically ~~and~~ or through an equivalent electronic~~ally~~ system**, if an electronic system is available. This includes, for example any product suspected of falsification returned products. Veterinary medicinal products received from a third country but not intended for the Union market should also be physically segregated. Any ~~product suspected of falsification and~~ falsified veterinary medicinal products found in the supply chain, expired products, recalled products and rejected products should be immediately

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	appropriate degree of security should be applied in these areas to ensure that such items remain separate from saleable stock. These areas should be clearly identified."	dedicated area away from all other veterinary medicinal products. The appropriate degree of security should be applied in these areas to ensure that such items remain separate from saleable stock. These areas should be clearly identified."	physically and electronically separated, if an electronic system is available and stored in a dedicated area away from all other veterinary medicinal products. The appropriate degree of security should be applied in these areas to ensure that such items remain separate from saleable stock. These areas should be clearly identified.
Section 5.5 Storage	Section 5.5: "Medicinal products that are nearing their expiry date/shelf life should be withdrawn immediately from saleable stock **either physically or through other equivalent electronic segregation.**"	Section 5.5: "Veterinary medicinal products that are nearing their expiry date/shelf life should be separated immediately from saleable stock **physically and electronically**, if an electronic system is available."	Section 5.5: Veterinary medicinal products that are nearing their expiry date/shelf life should be separated immediately from saleable stock **either physically ~~and~~ or through an equivalent electronic~~ally~~ system,** if an electronic system is available.
Section 5.6 Destruction of obsolete Goods	Section 5.6: "Medicinal products intended for destruction should be appropriately identified, **held separately** and handled in accordance with a written procedure."	Section 5.6: "Veterinary medicinal products intended for destruction should be appropriately identified, **held physically and electronically separated**, if an electronic system is available and handled in accordance with a written procedure."	Section 5.6: Veterinary medicinal products intended for destruction should be appropriately identified, held **either physically ~~and~~ or through an equivalent electronic~~ally~~ system separated**, if an electronic system is available and handled in accordance with a written procedure.

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