

Use of serialisation for veterinary medicinal products

Issue

The Animal Health Industry is not in favour of the serialisation of veterinary medicinal products.

Background

In several countries regulators tend to request a serialisation* of veterinary medicinal products because of identical requirements implemented in the human pharmaceutical sector. It would however be a disproportionate measure for the animal health sector, using an unaffordable approach to tackle close to non-existent problems in the animal health sector.

Position

The Animal Health Industry stands aligned that the two-dimensional (2D) Datamatrix veterinary products identification is the global standard as the method of traceability of veterinary medicinal products, but does not recommend serialisation.

Mandatory serialisation is an inappropriate approach for the animal health sector to tackle close to non-existing problems:

- Fighting counterfeiting cannot be addressed by serialisation unless there is a single global data synchronisation network, allowing veterinarians (or any authorised user of animal health products) to check the integrity of the origin of a product, ensuring data is current and kept up to date.
- Serialisation as a means to secure the reimbursement is unnecessary for a sector – veterinary medicine - that does not operate on the basis of public fund.
- Within the animal health sector there is a huge mix of different stakeholders (manufacturers, tollers, wholesalers, vet clinics, pet shops, industrial partners, regional distributors, purchasing cooperatives, etc.) in different business relationships (Business to Business or Business to Consumer).
- The end user would need a hand held scanner connected to the above mentioned, currently non-existent global database, which is not feasible in most regions of the world.
- The cost and the complexity of implementing serialisation would have a negative impact on the global availability of veterinary medicines.

* Serialisation is the assignment and placement of a unique serial number to each sales unit to enable the identification and tracking from the packaging line to the final user.