MEDICINE

Status of equine stem cell-based veterinary medicine in the UK

THE Veterinary Medicines Directorate (VMD) would like to highlight to vets the stem cell-based veterinary medicines available in the UK for horses.

Earlier this year, two stem cell-based veterinary medicines – Arti Cell Forte (Boehringer Ingelheim) and HorStem (EquiCord) – were the first to be granted EU-wide marketing authorisation. Arti Cell Forte is authorised for the reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation in horses. HorStem is authorised for the reduction of lameness associated with mild to moderate degenerative joint disease (osteoarthritis) in horses. Both medicines are composed of allogeneic stem cells. As authorised medicines, they have undergone rigorous scientific assessment to ensure they are safe, effective and meet specified quality standards. Table 1 gives the classification of stem cell-based veterinary medical products.

Allogeneic and xenogeneic stem cell-based medicines require marketing authorisation before they can be placed on the UK market.

Historically, stem cell-based veterinary medicines have been available in the UK from stem cell centres that have been granted equine stem cell centre authorisation (ESCCA) by the VMD; these veterinary medicines remain available. These are autologous medicines and are exclusively for use in non-food-producing horses. Allogeneic and xenogeneic stem cell-based products are not permitted under an ESCCA.

An ESCCA provides assurances that:

- the stem cell centre meets satisfactory manufacturing standards and uses an appropriate production process;
- the welfare of animals will be respected during the collection of stem cells;
- the stem cells will be collected under the responsibility of a vet; and
- the stem cell centre is under the supervision of a vet or a person the VMD considers to be suitably qualified.

Table 1: Classification of stem cell-based veterinary medical products according to the relationship between donor and recipient

Autologous	Stem cells are derived from the patient's own tissues
Allogeneic	Stem cells are derived from the tissues of a donor of the same species as the recipient(s)
Xenogeneic	Stem cells are derived from the tissues of a donor animal of a different species from the recipient(s)

However, products produced by an ESCCA holder:

- are not authorised medicines, since the final product has not been assessed by the VMD for its quality, safety and efficacy;
- can only be administered by a vet under their direct responsibility;
- have the same regulatory status as extemporaneous preparations;
- cannot be advertised, although ESCCA holders may promote their stem cell services directly to vets, provided they do not make any medicinal claims or references to specific diseases.

The Veterinary Medicines Regulations prohibit the administration of unauthorised veterinary medicines (ie, those that do not have a marketing authorisation) unless their use is justified under the prescribing cascade.

In instances where there is no clinically suitable veterinary medicine authorised in the UK for a specific condition, the prescribing cascade permits vets to use their clinical judgement when treating the animals under their care. The cascade is, therefore, a framework for the prescribing of unauthorised products – in particular, to avoid unacceptable suffering. When considering whether to use a product produced by an ESCCA holder, the prescribing vet should first consider the clinical suitability of available authorised stem cell-based products and other authorised veterinary medicines.

Guidance on ESCCAs is available on the VMD's website: www.gov.uk/government/organisations/veterinary-medicines-directorate

Two stem cell-based veterinary medicines become first to be granted EU-wide marketing authorisation

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doi: 10.1136/vr.l6272