News story: Animal medicines improvement notice: Bio-Tech Solutions Ltd

This notice was issued to Bio-Tech Solutions Ltd, following a pharmacovigilance (PhV) inspection which highlighted Bio-tech Solutions Ltd had contravened the Veterinary Medicines Regulation 2013:

- Schedule 1, paragraph 55 (Qualified persons responsible for pharmacovigilance)
- Schedule 1, paragraph 56 (Duties relating to the qualified person)
- Schedule 1, paragraph 57 (Adverse reactions to a veterinary medicinal product administered in the United Kingdom)
- Schedule 1, paragraph 59 (Periodic safety update reports)

The improvements required are:

- Implement a back-up procedure covering all aspects of PhV
- Implement an appropriate training plan and training records for the Qualified Person for Pharmacovigilance (QPPV) and deputy
- Implement PhV agreements with all named distributors
- Establish a database to ensure all suspected adverse reactions are collated and accessible
- Migrate historical adverse events into the database once established
- Register with EVVET
- Ensure internal procedures are adequate to ensure reporting deadlines are not missed
- Ensure internal procedures are sufficient to ensure all PSURs contain all required information and are submitted on time
- PSURs with data lock point of 31/12/17 should be submitted to the VMD no later than 60 days after data lock point