ANIMAL MEDICINES TRAINING REGULATORY AUTHORITY

PHARMACOVIGILANCE REPORTING INFORMATION GATHERING TEMPLATE

The following is a questionnaire/form that can be used to obtain the necessary relevant information.

The elements highlighted with * are the minimum requirement. If you have the minimum pieces of information, you have a case to report, but the more information you can obtain, the better. If you or the reporter do not have every detail, don't worry, just report with what you do have to the VMD via their reporting tool (www.gov.uk/report-veterinary-medicine-problem) or the Marketing Authorisation Holder/manufacturer.

Please do not report these to AMTRA as we have no pharmacovigilance remit.

Reporter Details

Make sure you obtain their name and at least one way of corresponding with the reporter should the need arise.

Report all pharmacovigilance events to the VMD via their reporting tool (www.gov.uk/report-veterinary-medicine-problem) or the Manufacturer. Keep a record of the reporting reference after you have reported the event. The elements highlighted with * are the minimum requirement.

It is important to encourage the farmer or pet owner to seek veterinary advice where there is any potential impact on animal welfare.

Name*:

Surname*:

Phone number:

Email address:

Physical Address (including Postcode):

Product

Product Name*	Batch Number	Expiry Date	Formulation e.g tablet/solution	Product strength e.g. mg/ml % or mg/tablet:	Dose administered	Dates administered	Route of administration e.g by mouth, topical, injectable etc.

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Patient Details

Species*:

Age:

Breed:

Weight :

Gender/neuter status/ reproductive status/lactation:

Herd/flock/litter numbers:
(Include numbers exposed and numbers reacting…

e.g. a herd of 100 dairy cows had product X. 10 of those cows had milk drop. Or 6 puppies had product Y and 2 have reacted).

Adverse Event Details

Include specific signs such as weak, inappetant, lethargic, lame etc. The animal 'wasn't right' or it's 'not well' is not specific enough.

If a lack of efficacy is suspected, the details around this including any investigations that may have been done. Product didn't work is a lack of efficacy but the 'why' is important e.g. lambs still scouring, worms seen in dung or high FWEC post dosing.

If a human has been exposed to a veterinary medicine, e.g. accidentally swallowed a pets tablet, spilled product on skin or pricked their finger with a needle while administering a product, these must be reported, even if no sign is noted. In this instance make a note 'no sign' or 'asymptomatic'. **We strongly recommend the person seeks medical advice in all cases of human exposure.**

Clinical signs*	Date noted	Any treatment given for the signs

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Notes: Always include any other relevant details

It is important to encourage the farmer or pet owner to seek veterinary advice where there is any potential impact on animal welfare.
Include any other clinically relevant information or details that may be relevant.