REPORTING SUSPECTED ADVERSE EVENTS

The first point of contact should be your vet! Your vet can help manage suspected adverse events and also report (or help you report) to Zoetis and/or your country's regulator. If you wish to report yourself/too, please see below.

Reporting suspected adverse events—which include lack of effectiveness—will help medicines regulators detect potential emerging risks/safety signals and update the product information accordingly.

TIPS

- Contact information is on the next page
  - Forms that say "download" (UK, NZ, and US) will, after clicking the hyperlink, automatically download (and should be in the downloads folder of your device)
- Regardless of how you submit (by phone, form/email, or online portal), you may want to draft, review, and save your work to avoid inadvertent omission of important details
- Basic elements (patient, drug, event, reporter) are usually the minimum required to capture an adverse event, but the more information you have, the better
- If your dog had a serious and unexpected adverse event, say so, because it should expedite handling of your report
  - For example, in the US, per the FDA's Post-approval Animal Drug Reporting Requirements, Zoetis must submit reports of serious and unexpected adverse drug experiences (defined in 21CFR514.3) within 15 working days.
  - Definitions for "serious" and "unexpected" can vary by country/region; if you have any question, you should ask your regulator
- If/when you or your vet report to Zoetis, you can ask for your case number which you can then later confirm and/or supplement with your country's regulator
- You may consider keeping a diary to chronicle your dog's experience over time, logging photographs, videos, real-time medical records, invoices, etc.
- You can and should update Zoetis and/or your country's regulator with your dog's progress
  - For example, in the US, Zoetis must submit followup reports of serious and unexpected adverse drug experiences to comply with 21CFR518.40(b)(2)(ii)

CONTACT INFORMATION

Region	Zoetis	Medicine Regulator
UK	Zoetis UK Email: customersupportuk@zoetis.com Phone: 0345 300 8034	VMD Online Adverse Reaction Reporting VMD Adverse Event Reporting Form download Email: adverse.events@vmd.gov.uk Phone: 01932 336911
EU	(Scroll down to) Zoetis' Choose Your Region tool or look to the end of the product information	HMA National Contacts Drop-Down List
AUS	Zoetis Australia Email: productsupport.au@zoetis.com Phone: 1800 814 883	APVMA Adverse Experience Reporting Program APVMA Adverse Experience Reporting Form Email: enquiries@apvma.gov.au Phone: 61 2 6770 2300
NZ	Zoetis New Zealand Email: nzcontactus@zoetis.com Phone: 0800 ZOETIS (963 847)	NZ Adverse Event Reporting Programme NZ Adverse Event Report Form download Email: ACVM-AdverseEvents@mpi.govt.nz Phone: 04 894 2550
CA	Zoetis Canada Zoetis Canada Online Adverse Event Form Email: productsupport@zoetis.com Phone: 800-461-0917	Heath Canada Online Adverse Reaction Reporting Health Canada Adverse Event Reporting Form Email: pv-vet@hc-sc.gc.ca Phone: 1-877-838-7322
US	Zoetis US Zoetis US VMIPS Online Report Email: supportUS@zoetis.com Phone: 1-888-963-8471 Option 2	US FDA CVM—How to Report… ▪ FDA Form 1932a—Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report Form download, complete as much as possible, save, and send to CVM1932a@fda.hhs.gov Email: AskCVM@fda.hhs.gov Phone: 1-888-FDA-VETS (1-888-332-8387)
Other	(Scroll down to) Zoetis' Choose Your Region tool	