



ACVM Alert Notification 16-002

ACTIVE SUBSTANCE IDENTITY AND CONFORMITY ADVISORY

Zhejiang Hisun Pharmaceutical Co. Ltd. 46 Waisha Road Jiaojiang District. Taizhou City, Zhejiang, 318000, China

The ACVM Group has been advised by the European Medicines Authority (EMA) that active substances from Zhejiang Hisun Pharmaceutical Co. Ltd, China may present a risk when used in the manufacture of finished product. This advice follows an audit of the facilities by the national competent authority in Spain which identified significant issues with the Waisha manufacturing site.

Actives of concern include but are not limited to:

**FIPRONIL
CLORSULON
PRAZIQUANTEL**

New Zealand Manufacturers of products containing actives sourced from Zhejiang Hisun Pharmaceutical Co. Ltd, Waisha Campus, Yantou Campus and East Factory Campus are advised to:

- 1) Seek alternative supply; and
- 2) Implement increased inspection measures prior to release.

Where sourcing from an alternative site is not possible full analytical testing in accordance with your GMP programme should be conducted, including impurities, residual solvents and microbiological burden (where applicable).

Contact details

Ministry for Primary Industries (MPI)
Regulation and Assurance Branch
Agricultural Compounds and Veterinary Medicines
PO Box 2526
Wellington 6140
Email: acvm-recallsandcompliance@mpi.govt.nz

ISSUED BY:

Glen Bradbury
Manager Agricultural Compounds and Veterinary Medicines
System Audit, Assurance and Monitoring Directorate

19 OCTOBER 2016