



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



# TRADE ADVICE NOTICE

on the Product SILIRUM VACCINE

APVMA Product Number 59642

**FEBRUARY 2014**

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This publication is available from the APVMA website: [www.apvma.gov.au](http://www.apvma.gov.au).

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## PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies including Department of Agriculture and Animal Health Committee

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices where there may be trade implications.

Comment is sought from industry groups and stakeholders on the information contained within this document.

## Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to register the new product SILIRUM VACCINE should be granted. Submissions should relate only to matters that the APVMA is required, by legislation, to take into account in deciding whether to grant the application. These matters relate to the **implications for export trade** of the use of the product. Comments received outside these matters cannot be considered by the APVMA. Submissions should state the grounds on which they are based.

Submissions must be received by the APVMA by close of business on **Thursday, 6 March 2014** and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post. Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email address or postal address (if available)
- the date you made the submission.

All personal and **confidential commercial information (CCI)**<sup>1</sup> material contained in submissions will be treated confidentially.

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<sup>1</sup> A full definition of "confidential commercial information" is contained in the Agvet Code.

Written submissions on the APVMA's proposal to grant the application to register the new product SILIRUM VACCINE that relate to the **trade implications for registration** should be emailed to the email address provided below:

Hardcopy submissions (or files on digital media) can be sent to:

Contact Officer  
Veterinary Medicines Program  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
Kingston ACT 2604

**Phone:** +612 6210 4736

**Fax:** +612 6210 4741

**Email:** [vetmedicines@apvma.gov.au](mailto:vetmedicines@apvma.gov.au)

## Further information

Further information on trade advice notices can be found on the APVMA website: [www.apvma.gov.au](http://www.apvma.gov.au).

## 1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Zoetis Australia Pty Ltd, to register the new product SILIRUM VACCINE as an aid in control of Bovine Johne's disease (BJD).

Johne's disease or paratuberculosis is a chronic debilitating enteritis of ruminants caused by *Mycobacterium avium* subsp. *paratuberculosis*.

SILIRUM VACCINE for cattle is an inactivated and oil adjuvanted vaccine, indicated for the active immunisation of cattle against *Mycobacterium avium* subsp. *paratuberculosis*, as an aid in the control of Bovine Johne's Disease (BJD). It contains 2.5 mg/ml of dried *Mycobacterium avium* subsp. *paratuberculosis* (Map) Strain 316 F.

All major live cattle export countries require individual testing and/or property freedom status for a set time for BJD.

Data provided by Zoetis has indicated that cattle administered with SILIRUM VACCINE are likely to test positive when screened for tuberculosis (caudal fold test) or Johne's disease (blood antibody test) which might have serious implications on the Australian exports of live cattle.

## 2 TRADE CONSIDERATIONS

Exported live cattle which have been vaccinated with SILIRUM VACCINE may pose a risk to Australia trade in situations where negative screening test results are required by the importing countries for tuberculosis (caudal fold test) or Johne's disease (blood antibody test). All the major live cattle export countries like Indonesia, Malaysia, Vietnam, China, Japan, Philippines and Russia require individual testing and/or property freedom status for a set time for of Bovine Johne's disease (BJD).

Although some countries accept the tuberculosis free status of Australia, some countries like Japan still require the screening test.

The Animal Health Committee (AHC) has considered the implications of the registration of SILIRUM VACCINE on Australia's live export trade and made the following main recommendations.

1. vaccinated animals are excluded from export markets that are sensitive to Johne's Disease or bovine tuberculosis unless there is an agreement on the eligibility for export of vaccinated animals with the importing country and
2. the vaccinates are positively identified with a unique identifier such as NLIS-style button.

The APVMA has proposed to include the following two label restraint statements to address the trade concerns:

1. DO NOT vaccinate cattle intended for live export to countries requiring tuberculosis testing. Cattle administered with this killed vaccine are likely to test positive when screened for tuberculosis (caudal fold test) due to cross reactivity between the vaccine and the test.
2. DO NOT vaccinate cattle intended for live export to countries requiring JD negative antibody testing. Cattle administered with this killed vaccine may test positive when screened for Johne's Disease (JD-ELISA - blood antibody test) due to immunity developed to the vaccine.

### 2.1 Proposed Australian use pattern

Live cattle

### 2.2 Destination and value of exports

The total exports of Australian Live cattle are valued at approximately \$340 million. The 5 largest export markets for Australian live cattle by value are shown below (Australian Commodity Statistics 2013).

Live cattle exports in 2012-2013 (Source: ABARE 2013)

Table 1: Five largest export markets by value for live cattle in 2013.

| RANK<br>(BY \$<br>VALUE) | IMPORTING<br>COUNTRY | QUANTITY<br>(‘000 OF ANIMALS) | VALUE<br>(\$AUS MILLION) |
|--------------------------|----------------------|-------------------------------|--------------------------|
| 1                        | Indonesia            | 266.1                         | 164.5                    |
| 2                        | Israel               | 63.8                          | 45.1                     |
| 3                        | Turkey               | 35.6                          | 23.7                     |
| 4                        | Malaysia             | 36.9                          | 23.1                     |
| 5                        | Philippines          | 35.3                          | 21.5                     |
| Total                    |                      | 513.1                         | 338.6                    |

### 3 CONCLUSIONS

The APVMA has considered whether the use of SILIRUM VACCINE for cattle in accordance with the proposed label instructions could “unduly prejudice trade or commerce between Australia and places outside Australia”, as per Section 14(3)(e)(iv) of the Agvet Code.

The risk to Australia's live cattle export trade could be mitigated when the following proposed label restraint statements are observed:

1. DO NOT vaccinate cattle intended for live export to countries requiring tuberculosis testing. Cattle administered with this killed vaccine are likely to test positive when screened for tuberculosis (caudal fold test) due to cross reactivity between the vaccine and the test.
2. DO NOT vaccinate cattle intended for live export to countries requiring JD negative antibody testing. Cattle administered with this killed vaccine may test positive when screened for Johne's Disease (JD-ELISA - blood antibody test) due to immunity developed to the vaccine

The APVMA is seeking comment from relevant industry groups and stakeholders in relation to the perceived level of risk to Australia's live cattle export trade.