Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2015

Agriculture

Question: 14

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Generic Products

Proof Hansard page: Written

Senator BULLOCK asked:

Prior to your decision in July 2014 to apply a new interpretation of s 162 (1) of the Agvet Code so as to reject applications for a generic product that relied on the CCI of a reference product:

- On how many occasions did the owner of the CCI initiate, threaten or otherwise indicate that they may take legal action against the Authority or any of the persons specified in s162 (1) of the Code for any action involved in the processing of an application for a generic product that relied on the CCI of a reference product?
- On how many occasions did any law enforcement authority question or otherwise take any action in regard to any alleged breach of s 162(1) of the Code for any action involved in the processing of an application for a generic product that relied on the CCI of a reference product?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has no record of legal action being initiated in respect of potential breaches of s162 (1) of the Agvet Code. The APVMA has administrative processes in place to manage any concerns regarding confidential commercial information (CCI). This is done on a case-by-case basis with the relevant applicant or product registrant, which includes notifying all affected parties of their obligations in respect of any such information.

There has been no enforcement action taken under section 162 (1) of the Agvet Code by a law enforcement agency.

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Question: 15

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Generic Products

Proof Hansard page: Written

Senator BULLOCK asked:

Who first suggested to you that s162 (1) of the Code prohibited the Authority from using CCI for a reference product in the processing of an application for a generic product?

Answer:

The changes to the way the Australian Pesticides and Veterinary Medicines Authority (APVMA) assesses applications to ensure the integrity of confidential commercial information (CCI) was undertaken after a review of APVMA processes, rather than in response to a specific suggestion.

The APVMA provided briefing to industry peak bodies, and all affected current applicants received letters advising them of the next steps required to progress their applications after implementing the revised processes.

The APVMA sought external legal advice from the Australian Government Solicitor and DLA Piper.

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Agriculture

Question: 16

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Generic Products

Proof Hansard page: Written

Senator BULLOCK asked:

Apart from seeking legal advice who else did you consult with on this matter prior to implementing a change of practice?

Answer:

Please refer to the answer to QoN 15, (Australian Pesticides and Veterinary Medicines Authority) from the Additional Estimates hearing in February 2015.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture

Question: 17

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Generic Products

Proof Hansard page: Written

Senator BULLOCK asked:

From whom did you seek legal advice on this matter?

Answer:

Please refer to the answer to QoN15, (Australian Pesticides and Veterinary Medicines Authority) from the Additional Estimates hearing in February 2015.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2015

Agriculture

Question: 18

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Generic Products

Proof Hansard page: Written

Senator BULLOCK asked:

On 20 November 2014 you stated that as of 14 November:

> *there were 164 affected agricultural applications on hand. In 48 of those we were waiting on a response from the applicant; 76 had responded and we were assessing that response; and in 40 the applicant had provided additional data or consent to access the CCI and the application was proceeding. That is for agricultural chemicals. For veterinary chemicals, as at 7 November we had 76 affected veterinary applications. In 31 we were waiting on the response from the applicant; in 14 we were assessing the response; and in 31 the applicant had provided additional data or consent to access CCI and the application was proceeding.*

Could you provide us with an update on those figures now three months on?

Answer:

As at 17 February 2015 there were approximately 160 agricultural applications affected by this issue, as follows:

- The Australian Pesticides and Veterinary Medicines Authority (APVMA) is awaiting a response from the applicant for 28 applications
- There have been 20 applications refused due to no response being provided from the applicant
- There have been ten applications withdrawn voluntarily by the applicant
- The applicant has provided additional data/information or consent to access the confidential commercial information (CCI) and the application is proceeding or has been finalised for the remaining 102 applications.

Question: 18 (continued)

As at 17 February 2015 there were approximately 31 veterinary medicines applications affected by this issue, as follows:

- The APVMA is awaiting a response from the applicant for ten applications
- The APVMA is assessing a response from the applicant for 12 applications
- The applicant has provided additional data/information or consent to access CCI and the application is proceeding for the remaining nine applications.

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2015

Agriculture

Question: 19

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Generic Products

Proof Hansard page: Written

Senator BULLOCK asked:

How many generic products were registered in each of the four six month periods from January 2013-December 2014 (i.e Jan-Jun 2013; Jul-Dec 2013; Jan-Jun 2014; Jul-Dec 2014)?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) does not specifically monitor or record 'generic' agricultural and veterinary chemical product registrations. The figures below represent new registrations seeking to mirror existing registered products that either do not require any, or require only limited supporting data (i.e. chemistry or bioequivalence):

- Jan-Jun 2013: 511
- July-Dec 2013: 486
- Jan-Jun 2014: 350
- July-Dec 2014: 200