

Rural and Regional Affairs and Transport Legislation Committee

ANSWERS TO QUESTIONS ON NOTICE

Additional Estimates February 2016

Agriculture and Water Resources

Question: 56

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Approval of pesticide applications

Proof Hansard page: 73

Senator BULLOCK asked:

Senator BULLOCK: For the 2014-15 financial year, how many applications for registration of veterinary chemical products were received?

Ms Arthy: Is this just for generics or total?

Senator BULLOCK: Total.

Mr Norden: From the annual report: for pesticide applications, in 2014-15 we received 1 388 applications; and for veterinary medicines we received 653 applications. Applications finalised for the financial year for pesticides—

Senator BULLOCK: Does 'finalised' mean approved or finally dealt with either by approval or rejection? What does 'finalised' mean?

Mr Norden: I am sorry; the figures I have at the moment do not include refused applications, just finalised applications. So we would have to take that on notice.

Senator BULLOCK: What does 'finalised' mean?

Mr Norden: It would include both approvals and refusals and withdrawals, as well.

Senator BULLOCK: I would like to know how many were approved.

Mr Norden: We would have to take that on notice.

Answer:

For the 2014-15 financial year the total number of applications for pesticide and veterinary chemical products approved by the APVMA was 1 876. This included 1 299 approved applications for pesticide products and 647 approved applications for veterinary medicine products.

Question: 56 (Continued)

	Number of Approved Applications for 2014-15
Pesticides	1 229
Veterinary Medicines	647
Total	1 876

Source: APVMA

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Agriculture and Water Resources

Question: 57

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Number of Approval of pesticide applications that required detailed assessment

Proof Hansard page: 73

Senator BULLOCK asked:

Senator BULLOCK: You have been doing it pretty well on notice, yes. I am pessimistic as to the next question because, if you do not know that one, you are probably not going to know this one. How many of those that were approved required actual assessment as opposed to being label changes, changes of registrant or other simple changes that did not require any scientific assessment? A lot of applications are the same product by the same people in a different size or whatever; they do not require a thorough assessment of their contents.

Ms Arthy: We will have to take that on notice. We do not have the 2014-15 figures with us. But we can certainly get them for you.

Answer:

For the 2014-15 financial year, the number of approved applications for pesticide and veterinary chemical products that required major assessments is 1 260. Major assessments have assessment periods more than three months, require one or more technical assessments and include applications under item numbers 1, 2, 3, 4, 5, 6, 10, 11 and 14 as set out in the table of fees and assessment periods under schedule 6 of the Agvet Code Regulations 1995.

This figure is broken down in terms of pesticides and veterinary medicines applications in the table below.

	Pesticides	Veterinary Medicines	Total
Major assessment items	709	551	1 260

Source: APVMA

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Agriculture and Water Resources

Question: 58

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Which applications have been refused?

Proof Hansard page: 73

Senator BULLOCK asked:

Senator BULLOCK: The rules as you implemented them limit the ability to approve applications based on CCI. I am not asking you to compromise yourself with regard to any case which is currently on foot, nor am I asking you to identify any products. But you should be able to tell me which of the applications you have refused because you refused to use rather than a use which would have disclosed the CCI. That is not a matter which I can see would bear on any current or pending possible legal dispute.

Ms Arthy: Without getting into the technicalities of the difference between 'use' and 'disclosure' in terms of what we can pull out of our records, we can certainly take on notice to see what we can pull out to provide you that might be useful.

Senator BULLOCK: Do your best.

Ms Arthy: Yes, we will.

Answer:

The APVMA does not currently collect records of applications for veterinary and agricultural chemical products requiring the use or disclosure of confidential commercial information (CCI) and the provision of this information would entail a substantial diversion of resources.

Product applications that are most likely to require the use or disclosure of CCI are generally for registration of closely similar products which are submitted as item 6 or item 7 applications. The number of finalised item 6 and item 7 applications in 2014-15 are listed in the table below.

During this period seven veterinary medicines and 41 pesticide applications assessed under item 6 and item 7 were refused registration. We have examined the reasons for each of these refusals and can advise that thirteen of these refusals involved consent not being provided by the registrant for a nominated reference product, noting three were veterinary medicine products and 10 were pesticide products.

Question: 58 (continued)

Item 6 and 7 applications, 2014-15

	Item 6 and Item 7	
	Registered	Refused
Veterinary	32	7
Pesticides	218	41
Total	250	48

Source APVMA

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Agriculture and Water Resources

Question: 59

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Costs associated with court case

Proof Hansard page: 74

Senator BULLOCK asked:

Senator BULLOCK: With regard to all of these matters, what has been the total cost to you of implementing the new interpretation of the CCI issue within APVMA, including legal advice, court costs, computer programming for the online portal to enable you to apply this new approach to CCI? Can you look at your books and determine what it has cost you?

Ms Arthy: I can certainly have a look and see what we can provide you. It is probably limited to cost of legal advice, because I am not aware of any—

Senator BULLOCK: I know that a legal bill is likely to go up by the day, Ms Arthy. You can only do your best.

Ms Arthy: We will look at it and we will be excluding of course the cost of the court case but looking at specifically that decision we can certainly provide you with what we have spent in terms of legal. I do not think there would be any other costs associated with it, but we will have a look at it.

Senator BULLOCK: You took legal advice.

Ms Arthy: Yes. That is what I am saying. Apart from legal advice I am not sure that there would be any other significant cost involved.

Senator BULLOCK: You had to defend your position in court. That is a cost.

Ms Arthy: As I said, at this point I will be not be including any cost related to the current court case.

Senator BULLOCK asked: I am asking you to. Why wouldn't you include costs associated with the court case?

Ms Arthy: It is a matter that is on foot. Whatever we provide you—

Senator BULLOCK: It does not go to whether or not you did the right thing; it is just a question of what it cost. That is all I am asking.

Ms Arthy: I will take that one on notice, talk to my counsel about what we can realistically provide you.

Question: 59 (continued)

Answer:

The cost to the APVMA of implementing the change in interpretation of confidential commercial information (CCI) is largely limited to the cost of legal advice sought as part of this process. As no new internal infrastructure or major changes to existing APVMA systems were required, the other costs of implementation were minimal.

The legal costs to the APVMA associated with the change in interpretation of CCI are outlined in the table below. All figures are for costs invoiced until 1 February 2016. Costs of in-house legal staff are not included in this table as these figures are not broken down in APVMA records and to do so would entail a substantial diversion of agency resources.

Item	Detail	Cost
Abbey Laboratories v APVMA Federal Court matter: NSD402/2015	Part of the costs associated with legal proceedings commenced by Abbey Laboratories in the Federal Court on 15 April 2015 related to the APVMA's interpretation of its obligations in relation to CCI. This matter was resolved on different grounds on 17 June 2015. It is not possible to separate out the costs associated with CCI from other issues. The figure is for the total legal cost, including settlement and the cost of counsel for this matter.	\$36 655 (GST incl.)
Abbey Laboratories v APVMA Federal Court matter: NSD1404/2015	This matter was commenced on 13 November 2015 by Abbey Laboratories. The APVMA is not able to fully report on these costs as the matter is still before the Federal Court.	\$28 775 (GST incl.)
Administrative Appeals Tribunal (AAT) proceedings	AAT proceedings relating to the use and disclosure of third party CCI.	\$13 107 (GST incl.)
General legal advice	DLA Piper	\$44 821 (GST incl.)
General legal advice	Australian Government Solicitor	\$12 021 (GST incl.)
Total		\$135 379 (GST incl.)

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Question: 60

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Budget impact

Proof Hansard page: 79

Senator SIEWERT asked:

Senator SIEWERT: This may be a question for the department, but what is the budget impact of the abolition?

Ms Arthy: That one is ours. From memory, the board cost us just over \$100 000 a year. I will just confirm that. I will come back to you with the exact number, but it is between \$100 000 and \$150 000.

Answer:

Based on 2015 costs, the annual cost to the Australian Pesticides and Veterinary Medicines Authority (APVMA) of its former Advisory Board is estimated to be \$103 517.

This includes \$70 237 for a total of four meetings and an annual salary for the Advisory Board Chair of \$33 280, as determined by the Remuneration Tribunal.

However, the actual cost to the APVMA for the Advisory Board in 2015 was \$99 140. The variation is due to a pro rata payment to the Advisory Board chair of \$28 903 following the cessation of the Advisory Board prior to the end of 2015.

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Agriculture and Water Resources

Question: 61

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nano material 1

Proof Hansard page: 80

Senator SIEWERT asked:

Senator SIEWERT: Thank you; that answered my question. Have you had contact from any companies that want to look at agricultural products and/or veterinary products that contain nano material?

Mr Norden: Yes, we have. I would have to take that on notice in terms of how many, but we have had discussions, yes.

Answer:

The Australian Pesticides and Veterinary Medicines Authority is aware of contact from three companies and organisations regarding agricultural and/or veterinary chemical products that contain nano materials.

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Agriculture and Water Resources

Question: 62

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nano material 2

Proof Hansard page: 80-81

Senator SIEWERT asked:

Senator SIEWERT: If you could take on notice how many companies have contacted you about that, or that you have had discussions with, and whether you able to provide us with information on what advice you provided to the companies. Are you aware of whether those companies are proceeding to lodge an application? Have any been told that they do not need to lodge an application? Does all that make sense?

Mr Norden: Yes, it does. Again, I would have to take that on notice as well.

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has had discussions with three organisations and provided advice to two organisations about agricultural and/or veterinary chemical products that contain nano material. The APVMA is aware of three organisations intending to lodge applications for the registration of such products. The APVMA has not identified any instance where any company or organisation has been advised that it does not need to lodge an application for registration of products containing nano material.

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Agriculture and Water Resources

Question: 63

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Nano material 3

Proof Hansard page: Written

Senator SIEWERT asked:

1. Has the APVMA surveyed agricultural chemical companies – manufacturers, wholesalers and distributors - in the period 2014 to the present to determine if any agricultural and veterinary chemicals containing nanomaterials are being sold commercially?
2. Has the APVMA undertaken any testing of agricultural chemicals to ascertain whether agricultural and veterinary chemicals containing nanomaterials are being sold here?
3. Given that the French Government's Register of nanomaterials indicates that the most common use of nanomaterials is in agriculture and that many of the manufacturers of agricultural and veterinary chemicals are transnational corporations, would the APVMA expect that the use of nanomaterials in agricultural and veterinary chemicals in France indicates that they are likely to be present in Australia?
4. Has the APVMA sought advice from the French Authorities regarding what nanomaterials are being used in agricultural and veterinary chemicals in France in order to determine the likelihood of their use here?

Answer:

1. No.
2. No.
3. No. The Australian Pesticides and Veterinary Medicines Authority has seen no evidence of nanomaterials present in agricultural and veterinary chemicals in Australia.
4. No.

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Agriculture and Water Resources

Question: 64

Division/Agency: Australian Pesticides and Veterinary Medicines Authority

Topic: Relocation

Proof Hansard page: Written

Senator STERLE asked:

1. What is the current state of play with the Minister seeking to move the APVMA out of Canberra?
2. Has the Minister responded to the staff survey relating to the relocation?
3. On average what are the staff turnover numbers for the APVMA?
4. How will relocating out of Canberra impact on the capability of the APVMA?
5. Is the APVMA aware of the global shortage of Duvaxyn Equine Herpes Virus Vaccine?
6. When did the APVMA become aware of the global shortage?
7. Has the Department or Minister's office requested a briefing on the global shortage? – Dept input
8. When did the Department or the Minister's office ask for the briefing? – Dept input
9. Detail process for emergency use permit
10. Table emergency use permit guidelines

Answer:

1. The Department of Agriculture and Water Resources is in the process of engaging an independent provider to conduct a cost benefit risk analysis for the potential relocation of the Australian Pesticides and Veterinary Medicines Authority (APVMA) to Armidale, New South Wales.
2. On 31 July 2015, Ms Kareena Arthy, Chief Executive Officer of the APVMA, wrote to Minister Joyce about the APVMA's potential relocation. This letter included information on the results of an APVMA staff survey. On 22 January 2016, Minister Joyce responded to Ms Arthy advising he will develop a fully costed business case, including an independent cost-benefit risk analysis of the potential relocation of the APVMA.

Question: 64 (continued)

3. Between the 2010-11 and 2014-15 financial years, the separation rate of ongoing staff at the APVMA averaged 9.1 per cent per year.
4. This will be considered as part of the independent cost-benefit analysis.
5. Yes.
6. The APVMA became aware of the global shortage on 4 February 2016.
7. The Minister's office requested a briefing from the Department of Agriculture and Water Resources to which the APVMA provided input.
8. The Minister's office has spoken to the department on a number of occasions relating to this issue and I am aware that the Minister's office has also discussed this with representatives for Zoetis in November 2015. The Minister's office requested a formal briefing from the Department of Agriculture and Water Resources on 4 February 2016, to which the APVMA provided input.
9. Any individual or a body corporate (holder) can apply for a permit through the APVMA. The process for applying for an emergency use permit from the APVMA is similar to that for a minor use application. Applications can be made through the APVMA website and should include detailed information demonstrating that the use is for a genuine emergency.

Submissions from the relevant state coordinator or government authority to the effect that there is a genuine emergency for which the use of a particular product or constituent is needed will be considered as strong evidence of that fact.

Permit applications for an emergency use are not subject to a fee, irrespective of the applicant.

10. More information about this process is in the APVMA *Guide for Determining Emergency Uses or Research Purposes* is published on the APVMA website at www.apvma.gov.au/node/10926 and is provided at Attachment A.