

**Rural and Regional Affairs and Transport Legislation Committee**

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2015

**Agriculture**

**Question:** 71

**Division/Agency:** Australian Pesticides and Veterinary Medicines Authority

**Topic:** Classifications and qualifications of staff

**Proof Hansard page:** 122 (25.5.2015)

**Senator CAMERON asked:**

**Ms Arthy:** To give you an idea, we have about 70 specialist regulatory scientists. These are the people who do the evaluation of the applications that come in. They are also the chemists, the people who specialise in residues, the people who do the reviews. They are over various classifications from EL2 down to APS5. We also have up to 12 specialist compliance people. We have seven legal specialists. The rest are made up of our big-case management unit, which manages all the admin around the 3½ thousand applications we hold. Then there are the normal corporate functions we have as well as the manufacturing-licensing scheme. I do not have those numbers at hand, but I can provide them to you on notice, if you wish.

**Senator CAMERON:** That would be helpful, thank you. Everyone is important but, in terms of specialist skills, would the regulatory scientists and chemists have the key skills?

**Answer:**

In addition to the CEO a breakdown of current APVMA staffing by functional area and classification is as follows:

<b>Regulatory Scientists</b> (staff with scientific expertise in chemistry, toxicology, residues and environmental, agricultural and veterinary science)	<b>Number of staff</b>
SES Band 1	2
Principal Scientists	2
Executive Level 2	11
Executive Level 1	26
APS Level 6	28
APS Level 5	3
<b>Total</b>	<b>72</b>

**Question: 71 (continued)**

<b>Legal</b>	<b>Number of staff</b>
SES Band 1	1
Executive Level 2	3
Executive Level 1	2
APS Level 6	1
<b>Total</b>	<b>7</b>
<b>Compliance</b>	<b>Number of staff</b>
Executive Level 2	1
Executive Level 1	4
APS Level 6	5
APS Level 5	1
APS Level 4	1
<b>Total</b>	<b>12</b>
<b>Manufacturing Quality and Licensing</b>	<b>Number of staff</b>
Executive Level 2	1
Executive Level 1	1
APS Level 6	3
APS Level 4	1
<b>Total</b>	<b>6</b>

**Question: 71 (continued)**

<b>Case Management and Administration</b>	<b>Number of staff</b>
Executive Level 2	1
Executive Level 1	2
APS Level 6	3
APS Level 5	6
APS Level 4	9
APS Level 3	8
<b>Total</b>	<b>29</b>
<b>Corporate and Support Functions (including Human Resources, Information Technology and Communications)</b>	<b>Number of staff</b>
SES Band 1	1
Executive Level 2	8
Executive Level 1	17
APS Level 6	10
APS Level 5	8
APS Level 4	1
<b>Total</b>	<b>45</b>

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ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2015

**Agriculture**

**Question:** 72

**Division/Agency:** Australian Pesticides and Veterinary Medicines Authority

**Topic:** Generic Products

**Proof Hansard page:** Written

**Senator BULLOCK asked:**

In coming to the view that s 162 (1) of the Agvet Code requires you to reject applications for a generic product that relied on the CCI of a reference product what consideration, if any, was given to the decision in *Smithkline Beecham (Australia) Pty Limited v Minister of Family Services and Alphapharm Pty Limited [1993] FCA 523*?

**Answer:**

The Government does not generally disclose the content of legal advice received by the Government or its agencies. It is important for any government to be able to make fully informed decisions based on comprehensive and confidential legal advice.

**Rural and Regional Affairs and Transport Legislation Committee**

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2015

**Agriculture**

**Question:** 73

**Division/Agency:** Australian Pesticides and Veterinary Medicines Authority

**Topic:** Generic Products

**Proof Hansard page:** Written

**Senator BULLOCK asked:**

How many generic products have been registered since 1 January 2015?

**Answer:**

The Australian Pesticides and Veterinary Medicines Authority does not specifically monitor or record 'generic' agricultural and veterinary chemical product registrations. There were however, for the period 1 January to 10 June 2015, 273 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).

**Rural and Regional Affairs and Transport Legislation Committee**

ANSWERS TO QUESTIONS ON NOTICE

Budget Estimates May 2015

**Agriculture**

**Question:** 74

**Division/Agency:** Australian Pesticides and Veterinary Medicines Authority

**Topic:** Labelling for worker health and safety

**Proof Hansard page:** Written

**Senator LEYONHJELM asked:**

On what dates has the APVMA been engaged in consultation with Safe Work Australia regarding the adequacy of APVMA labelling for worker health and safety? In these consultations, has APVMA expressed concerns or opposition to the requirement for additional labelling by 2017 for worker health and safety? If so, what is the nature of these concerns/opposition?

**Answer:**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) engaged extensively with Safe Work Australia between 2006 and 2011 regarding the impact of reforms to the National Code of Practice for the Labelling of Workplace Hazardous Substances on the APVMA's regulation of agricultural and veterinary (agvet) chemicals. The APVMA provided a submission to Work Safe Australia which can be found at submission number 1238 at: <http://www.safeworkaustralia.gov.au/sites/swa/model-whs-laws/public-comment/pages/publicsubmissions>

In summary, two main concerns were outlined in the submission:

- The APVMA considers that hazards identified from specific ingredients in agvet product formulations are fully accounted for by the hazard identification and risk assessment processes that occur prior to an agvet chemical being authorised for use.
- The APVMA is concerned that the duplication of this information on agvet labels may not have the desired effect of improving worker safety outcomes for agvet chemical users.