Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 21

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Fenthion review
Proof Hansard page: 45

Senator BACK asked:

Senator BACK: Just for clarification, the writer of the data that is going to be presented to you now communicated with us to say that Ms Schipp of the APVMA had in fact been offered access to this data during the public submission period of the Fenthion review, but it was rejected on the grounds that the data was not collected in a controlled situation and therefore not scientifically accurate. I just wonder if you could give us advice, not now but on notice, as to what the circumstances are, or what your requirements are, during a public submission process because clearly the information is now to be handed to you. My concern is that in fact there may have been some miscommunication or whatever. But that could, indeed, have been provided to you during the public submission process.
Mrs Bennet-Jenkins: We are happy to provide that on notice, yes.

Answer:

Australian Pesticides and Veterinary Medicines Authority (APVMA) requirements are that results from controlled field trials are required for the setting of a new Maximum Residue Limit (MRL). The APVMA officer conveyed that requirement to the person enquiring.

Information, such as individual spray records, individual residue testing information, and results of random quality assurance testing programs is not normally offered to the APVMA, as it is information confidential to individual growers. Such information cannot be disclosed or made public. In addition, many jurisdictions do not require growers to keep such information. In most cases, such information is incomplete and insufficient to enable the APVMA to adjust proposed restrictions to be applied during a suspension period or a final review outcome.

In the case of fenthion, further discussions with growers and an assessment of existing information revealed that this was not the case. The APVMA therefore agreed to assess the documented history of use at lower than label rates, with confirmatory QA testing and individual grower residue testing information. The APVMA found it had sufficient information, together with a commitment to generate further controlled residue field trial data within the next 12 months, to enable it to develop alternative use instructions for the suspension period. The requirement to provide results from controlled field trials, current use and for confirming a new MRL remains.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 22

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: antimicrobial resistance
Proof Hansard page: 50

Senator DI NATALE asked:

Dr Bryce: The APVMA has taken on the job of collecting information on the sales of antibiotics for veterinary use. This is a different question, though, than the question you are asking about surveillance of antimicrobial resistance.
Senator DI NATALE: So you do not play any role in collecting and analysing the results of testing for residues or, for example, the emergence of antimicrobial resistance amongst bacteria and so on?
Dr Bryce: That is correct.
Senator DI NATALE: Who does that?
Mr Koval: Dr Bryce mentioned that there was a survey done in 2003-04, I think. I am not aware of a survey done since then, but I am happy to take that on notice and have a look at that. In terms of testing the residues of products, we do that through our residue survey which looks at antibiotics. I am not quite sure, and I will have to go and talk to the development people in our food division or our animal biosecurity division, about whether or not that then is looked at from the point of view of resistance. As Dr Bennet-Jenkins mentioned, it is a whole-of-government thing and is done across portfolios and, when a new antibiotic is considered for use in animals, the Department of Health and Ageing look at it. They do an antimicrobial risk assessment. The Department of Health and Ageing are very, very conscious of the impact on human health and in their advice to APVMA I am sure that that is considered. But I will have to take that on notice for you in terms of how detailed our analysis is within the department.
Senator DI NATALE: Okay, I look forward to that. Let me ask about a few other things, for example, off-label use where a drug is prescribed in a way that is outside the guidelines for that substance. For example, I understand that in veterinary practice it is not illegal to prescribe a drug that might be registered for one class of animals—cattle—for another class, such as other food-producing animals—pigs, sheep et cetera. Is that correct?

Answer:

National monitoring of antimicrobial residues in livestock products is the responsibility of the industry-funded Australian Government National Residue Survey. Recent antimicrobial resistance surveillance included the Department of Agriculture, Fisheries and Forestry ‘Pilot Surveillance Program for Antimicrobial Resistance (AMR) in Bacteria of Animal Origin’ in 2007. Surveys, research and other input into animal origin AMR have also been recently undertaken by some state and territory governments and universities.

Question: 22 (continued)

In June 2012, SAFEMEAT (a partnership between the red meat and livestock industry with Australian Government and state and territory governments) committed to conduct new research to quantify the prevalence of antimicrobial resistant bacteria in the cattle meat supply chain. The report from this work is expected to be submitted in early 2014.

Yes, it is legal to do this, to varying degrees, under state and territory laws.

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Agriculture, Fisheries and Forestry

Question: 24

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Technical report to a work order
Proof Hansard page: 52

Senator COLBECK asked:

Mr Matthew: There is a current arrangement with the successor agency to SEWPaC.
Senator COLBECK: I want to go to clause 3B.5 which says:
The Agency's obligations to provide the Final Technical Report in relation to a Work Order allows for three working days after the day on which the Work Order is due to be finalised and dispatched by the Agency to the APVMA.
To me that is saying, 'We set a date when we want the stuff done, but you can give it to us three days after that if you like.' Am I interpreting that correctly?
Mr Matthew: I am sorry, I do not actually have a copy of the SLAs with me. I will have to take on notice how that provision is being interpreted.
Senator COLBECK: Well how does it work in practice if you set a date? It says:
The Agency's obligations to provide the Final Technical Report in relation to a Work Order allows for three working days after the day on which the Work Order is due to be finalised and dispatched by the Agency to the APVMA.
Why would there be a clause like that in the service agreement? Why do you not just set a date for when you want the work completed?
Mrs Bennet-Jenkins: Senator Colbeck, we might have to go back and look at the whole service level agreement and answer that more fully on notice.

Answer:

The three working days is an allowance for the transmission of data as hardcopy to the agencies that need to conduct assessments, and for the return of technical assessment reports and any associated data. The material invariably contains valuable commercially confidential information, and the dossiers can be too large to be able to be processed through the secure Commonwealth email system (Fedlink).

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 25

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Service agreement
Proof Hansard page: 52

Senator COLBECK asked:

Senator COLBECK: Gee whiz! The service agreement also requires that the APVMA be advised by SEWPaC if it is experiencing difficulties or expects to experience difficulties with staff numbers or in providing expertise. How many times have you had representations from SEWPaC in relation to those issues since 2008?
Mr Matthew: I am sorry, Senator, I will have to take that on notice. We do have quarterly meetings where issues about work throughput and planning are discussed, but if you want a specific number I had best take the question on notice.

Answer:

None.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 26

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: New service level agreements
Proof Hansard page: 53

Senator COLBECK asked:

Mr Matthew: I suppose I would answer that by saying that we certainly are aware of the problems that we have had, and that we have already commenced the negotiations for new service level arrangements to support the revised legislation for financial year 2013-14 onwards. We are hoping that will address a number of those sorts of issues with the advising agencies at that time.
Senator COLBECK: 'In the case of deficiencies continuing for more than 44 days, there is provision to consider the work order and whether those obligations can be performed by alternative means'—can you give me an example of the alternative means, how often this situation has arisen in the course of the agreement and the circumstances?
Mrs Bennet-Jenkins: Again, could we could take the actual numbers on notice please? There are situations where we may use other external expertise in that area to provide us with advice.
Senator COLBECK: So is your obligation to go to SEWPaC first?
Mrs Bennet-Jenkins: Generally speaking, for our routine day-to-day work

Answer:

What might constitute ‘alternative means’ is not constrained under the agreement and could include agreeing on a suitable third party to undertake or complete a work order where a continuing deficiency has been noted. To date it has not been necessary to complete any work orders by ‘alternative means’.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 67

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: R & D expenditure
Proof Hansard page: 121

Senator BACK asked:

Senator BACK: One of the points not made earlier today was that the notation that expenditure on R&D as a percentage of total turnover in Australian industry has declined from between nine and 10 per cent in 2006 to 7.7 per cent in 2011. From your observations and experience, would you regard that as an inaccurate comment or do you think that that too ought to be the subject of further scrutiny?
Mr Koval: I will have to have a look at the report. I do not recall that comment about expenditure. This is a percentage of expenditure of the total animal health product market, the portion of research as the total animal health market, which is down to only six per cent or seven per cent now. I do not know whether Mr Parnell would have any comments to make.
Mr Parnell: No, I do not have anything to add.
Mr Koval: I will have to have a look at that on notice and get back to you, if I can.

Answer:

The methodology used in the 2011 International Federation for Animal Health benchmarking survey is not transparent, and therefore the figures on R&D expenditure may be inaccurate and should be considered further.

Reforms proposed in the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, among other things, improve the regulation of agricultural and veterinary chemicals by: improving the consistency, efficiency and transparency of chemicals assessments and reconsiderations; aligning regulatory effort with chemical risk; and removing disincentives while providing greater incentives for companies to invest in innovation. Together, these measures are aimed at encouraging the development of newer, safer chemicals, which will in turn support investment in research.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 197

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Service agreements cost recovery
Proof Hansard page: Written

Senator BACK asked:

1. Is the Price Waterhouse Coopers review of the APVMA finalised?
2. How has the APVMA responded to the PwC observation that cost recovery is significantly lower than the level of reimbursement required under the current cost recovery arrangements?
3. The PwC review in 2008 also found that cost recovery guidelines were not being met and that there was an "intention to amend as appropriate the various fees to better align with the cost recovery arrangements however, due to events beyond the control of the APVMA, no such alignment occurred". What were these events and has this situation been rectified?
4. Data presented in the PwC draft report shows that corporate services cost nearly as much as the registration process. What consideration has been given to removing costs from corporate services (public affairs, principal scientist, human resources, finance and corporate)?
5. Has any interagency or inter-organisational benchmarking of cost ratio between service delivery (eg registration of chemicals) and corporate overheads (eg corporate services) been undertaken?
6. If not, why not?
7. If so, what did it find?

Answer:

1. PriceWaterhouse Coopers (PwC) completed an activity based costing study, rather than a full review of cost recovery, in 2010-11. PwC is currently updating the study to reflect 2011-12 costs.

2. This observation related to application fees which, due to Consumer Price Index (CPI) increases over a number of years, have fallen below the Government's target of 40 per cent recovery via fees. The Australian Pesticides and Veterinary Medicine Australia (APVMA) has sought approval to return application fees to 40 per cent through the next Cost Recovery Impact Statement (CRIS).

3. The event referred to was the decision to vary the 2005 CRIS to increase fees by 10 per cent from 1 July 2010, rather than implement a new CRIS. The situation is proposed to be rectified through a phased adjustment of fees over three years to align with the current 40 per cent target and further consideration in a first principles review of the APVMA's cost recovery arrangements being conducted by the Department of Agriculture, Fisheries and Forestry.

Question: 197 (continued)

4. All costs are continually reviewed to ensure the agency is operating efficiently. The APVMA is participating in two separate external interagency benchmarking studies on corporate services costs. The studies have not yet been completed. The PwC report discusses 'corporate overheads' and their allocation. It is noteworthy these costs include a variety of expenses that are not typically allocated to corporate services such as the Executive, the Principal Scientists, expenses related to Freedom of Information (FOI) requests, as well as property related costs for the entire agency (rent, light & power, water, security etc) and depreciation.

5. Please the response to question 4.

6. Not applicable.

7. No findings have been reported from the two separate external interagency benchmarking studies on corporate services costs as they are not yet been completed.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 198

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Charge out rates
Proof Hansard page: Written

Senator COLBECK asked:

The hourly rates charged by SEWPaC for services have increased from $126 in 2008 to $141 in 2011. Over the same period were the charge out rates to industry for the services provided to the APVMA by SEWPaC?

The hourly rate charged by DoHA in the 2010/2016 agreement is $159. Over the same period were the charge out rates to industry for the services provided to the APVMA by DoHA?

What were the charge out rates for services provided by the APVMA since 2010?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) does not charge industry an hourly rate for the services provided by staff from the Department of Sustainability, Environment, Water, Population and Communities (SEWPaC), the Department of Health and Ageing (DoHA) or the APVMA.

The APVMA charges one of the following three fees depending on the complexity of the environmental assessment. These fees are:

	July 2005 -June 2010	July 2010 - Current Day
Environment—Level 1	11 460	12 605
Environment—Level 2	2960	3255
Environment—Level 3	565	620

The APVMA charges one of the following fees depending on nature and complexity of the work performed by DoHA:

	July 2005 -June 2010	July 2010 - Current Day
Toxicology—Level 1	17 720	19 490
Toxicology—Level 2	13 290	14 620
Toxicology—Level 3	2635	2900
Toxicology—Scheduling	3380	3720
OH&S—Level 1	3920	4310
OH&S—Level 2	2635	2900
OH&S—Level 3	1305	1435

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 201

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Draft ag and vet chemical legislation
Proof Hansard page: Written

Senator COLBECK asked:

1. What was the result of the cost benefit analysis of the sun setting / mandatory review process?

2. What were the key points on the cost side and on the benefit side?

3. Who undertook the analysis?

Answer:

1. No cost-benefit analysis was undertaken for any sun setting / mandatory review. These items are not being progressed by the government.

2. Not required to answer, see answer to part 1 of the question, above.

3. Not required to answer, see answer to part 1 of the question, above

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 227

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Permit system for veterinary pharmaceuticals
Proof Hansard page: Written

Senator BACK asked:

1. Is the purpose of the permit system to make pharmaceuticals that are uneconomic to register due to small indication available to veterinarians?
2. Is it specifically stated that the product should not be under regulatory review?
3. Did the APVMA repeatedly over a number of years renew a permit for the use of Pentosan Gold when the product was under review for registration?
4. If so, why did the APVMA renew permits for Pentosan Gold (PG) via intra-venous (IV) route when it had concluded the IV use was unsafe and its registration via this route had been rejected by the APVMA?
5. Was the APVMA aware that the permit holder of PG continued to widely advertise the administration of this product by the IV route over an extended period in Australia at conferences and over the internet where claims of efficacy were made when used via the intravenous route?
6. If so, what action did the APVMA take to require the permit holder to refrain from this action, if the APVMA had determined its use by the IV route was unsafe and that registration was not permitted for this use?
7. Was the APVMA aware that this product with the Australian permit number was marketed internationally?
8. Is the APVMA aware of fatalities in horses after administration of PG with instructions for IV after APVMA approval was only granted for the safer intramuscular (IM) or subcutaneous (SC) injection routes?
9. Did the APVMA withdraw the permit for intravenous use after it registered the PG via the IM and SC route?
10. What action has the APVMA taken against the company for this abuse of process?
11. Can the APVMA assure the public that it investigates compliance issues in relation to proper procedures for the use of permit products, such as individual records for their use?
12. Can the APVMA assure that they do not issue permits to untested and dangerous drugs.

Answer:

1. Yes, that is one of its purposes.

2. No.

3. No. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has never issued a minor use permit for a product called Pentosan Gold to be used alone.

Question: 227 (continued)

4. The APVMA had not concluded that the product NV Pentosan Gold Injection for Horses when administered via the intravenous route was unsafe.

5. Yes. Advertising as described was not a breach of agvet legislation.

6. Please see the responses to questions 4 and 5.

7. Yes.

8. Yes.

9. No.

10. There was no abuse of process. See answers to questions 4, 5 and 9.

11. Yes. The APVMA may conduct compliance audits to verify that permit holders comply with the conditions as specified in a particular permit. Accusations of non-compliance with the legislation are taken very seriously by the regulator.

12. Products supplied to the market under permits are tested and assessed as safe. However, research permits regulate research and development of registered or unregistered agvet products or for other genuine scientific purposes. Therefore, some permits are issued for products in early stages of development so they can undergo testing under appropriate controls, usually in research facilities.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 228

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Registration of untested drugs
Proof Hansard page: Written

Senator BACK asked:

1. Did the APVMA inform the applicants that their application for registration of PG via the IV route would be refused?
2. Did the APVMA subsequently register PG via the IM and SC route?
3. Did the APVMA register PG without undertaking or considering safety studies in the horse by either the IV or IM route?
4. Did the APVMA register Nature Vet PG without clinical studies demonstrating efficacy via the IM and SC route?
5. Did the APVMA register Nature Vet PG, which is a combination of drugs, without demonstration of any benefit of such a combination compared to one component alone?
6. Did the APVMA publish details of its PG registration which described the registration details for the dog?
7. Did the APVMA accept the safety data on subcutaneous administration in the dog as adequate for registration for IM use in the horse?
8. Did the APVMA accept data on a component of PG N-acetyl glucosamine which was a different route, different species and different structural and pharmacological characteristics as evidence of efficacy?
9. Was the APVMA aware that the company seeking registration of Nature Vet PG was sold to the French multi-national pharmaceutical company CEVA?
10. Was it not evident that the registration of PG the companies (Nature Vet) leading product would affect the sale and its terms?
11. Did parties representing Nature Vet make application to the APVMA in relation to this unusual registration process?
12. If so, what was the outcome? Who in APVMA made the decision to register this pharmaceutical under these conditions of registration?
13. Does the APVMA agree that Australia's reputation as a source of proven effective safe and properly tested drugs for veterinary use can potentially be damaged if untested drugs are registered and found subsequently to be ineffective, unsafe or dangerous for use?

Answer:

1. Not applicable. The applicant did not apply for registration of Pentosan Gold (PG), to be administered intravenously.

2. No.

3. No.

Question: 228 (continued)

4. Yes. Clinical trials are not required for all applications. A combination of published data and *in vitro* data was assessed to support efficacy for the intramuscular route of administration.

5. Yes. There is no legislative requirement for the Australian Pesticides and Veterinary Medicines Authority (APVMA) to consider the benefits of a combination of active constituents compared to a product containing only a single active constituent, unless the market claim for the combination product exceeds that of the product containing only one active constituent.

6. Yes, this was mistakenly published. The error was rectified and the correct advice summary was published on 23 April 2012.

7. No. Safety data for intramuscular use in the horse was provided, assessed and found to support safe use in the horse.

8. Yes. It is common for data packages to include background information such as publicly available data on the use of active constituents in other dose forms, in other species and for other uses as well as studies which used the formulation, in the intended species, via the intended route.

9. Yes.

10. This is not a relevant consideration for the APVMA.

11. The usual registration process was followed. This involves company representatives or their agents interacting with the APVMA.

12. See the response to question 11. The product was registered on 6 March 2012.

13. Yes. Untested drugs are not able to be registered.

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ANSWERS TO QUESTIONS ON NOTICE

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Agriculture, Fisheries and Forestry

Question: 229

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Registration of ineffective drugs
Proof Hansard page: Written

Senator BACK asked:

1. Does the APVMA require controlled clinical studies demonstrating clinical efficacy in the species and via the route applied for in a registration?
2. Does the APVMA accept data on different compounds with different activities and different routes of administration and different species as evidence for efficacy and mode of activity for a IV product in horses?
3. Does the recent registration of IV Glucosamine fit this description?
4. Does the APVMA accept the opinion of outside consultants without question?
5. What steps are taken to assure the outside consultants have not a conflict of interest?

Answer:

1. No. Not all categories of registration application require controlled clinical studies. For some applications, data other than clinical trials, such as bioequivalence or pharmaceutical equivalence data, may demonstrate efficacy.

2. Yes. Ultimately, the Australian Pesticides and Veterinary Medicines Authority must have received sufficient data to be satisfied that the product is efficacious in the species for which it is intended via the route specified on the proposed label, in order to register a product.

3. Yes.

4. No.

5. Outside consultants undergo a stringent process of selection and are bound to declare any potential conflicts of interest. An example of the conflict of interest declaration is available from www.apvma.gov.au/about/foi/operational/core/docs/KP25E_F16.pdf.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 231

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Use of gloricide
Proof Hansard page: Written

Senator HEFFERNAN asked:

1. What are APVMA's regulations in regard to the use of gloricide?
2. With regard to Gloricide and the use of banned herbicides in aquatic areas, can you advise has the UNEP investigated whether Article III of the Rotterdam Convention has been breached by mixing 2,4,5-T precursor products with Nitriles, Chlorines and changing their "PH", temperature and pressure?
3. Environmental poisonings are occurring on a day to day basis by QLD Council Contractors, they are using either a Metulfuron methyl or 2,4-D formula or another insidious unregistered agricultural product called Gloricide, a mix of 2,4-D Metsulfuron methyl and wetting agent, have you had any reports of misuse of gloricide, if so, please provide a list of places and dates?
4. Are you aware that the Sunshine Coast Regional Council has been using gloricide without a lawful Permit by the APVMA and with no testing? If not, do you intend to investigate?
5. If you are aware, what were the penalties?
6. Can you confirm that the majority of all Bush Regeneration work in Australia is under an APVMA Minor Use Permit. – what is a Minor Use permit.
7. My understanding is that APVMA has not expressed permission to mix certain products together in a 'Minor Use Permit ' as they have done for the control of a single species i.e. Lippia, because the risks of doing so greatly increase the expected exposure - can you explain why APVMA allows the mass unrestricted use and mixing of Endocrine Blocking carcinogens, in a total oblivion to the risks and expected mass loss of life and breaches of our various International Contracts.
8. I understand APVMA allows Unregistered Chemical Products to be used without a registration or Permit, especially in and around Aquatic Areas and Endangered Species of Amphibians. It would appear as though with the APVMA warnings of keeping a 20 m buffer from waterways with Glyphosate 450, the APVMA has allowed not only 2,4-D and metsulfuron methyl to be used up to the edge and over waterways on mass, but APVMA has allowed Gloricide to be used as well in those areas. Is this true or false, please provide details

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) understands that the name 'Gloricide' is used for a tank mix of two herbicides metsulfuron-methyl and 2,4-D. The APVMA has issued a permit for the use of a range of herbicides for the control of environmental weeds in non-agricultural areas in Queensland (Permit 11463) that includes these two herbicides.

Question: 231 (continued)

2. The United Nations Environment Program is not responsible for investigating the use of chemicals listed in Annex III of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

3. No. The APVMA has conducted a compliance audit and found no breach of the *Agricultural and Veterinary Code Act 1994* by the permit holder. However, control-of-use rests with the relevant state authority, in this case the Queensland Department of Agriculture, Fisheries and Forestry (QDAFF).

4. No. Control-of-use rests with the relevant state authority.

5. Please see the response to Question 4.

6. No. Minor use permits are defined through Regulation 3 and 57, Agricultural and Veterinary Chemicals Code Regulations 1995. Minor use means a use "that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration ... of the product for that use".

7. The mixing of registered products is generally permitted under state control-of -use legislation, unless the APVMA-approved product label contains a statement expressly prohibiting mixing.

8. The APVMA does not allow unregistered products to be supplied or used without a registration or permit. Tank mixes of registered products (i.e. where separate registered products are mixed before application) are widely used and are not considered to be unregistered products (see Question 7). Permit 11463 specifically states "only those specific products which have label approvals currently in place for aquatic use, may be used in or near aquatic areas". Labels for products containing metsulfuron-methyl and products containing 2,4-D do not specify any buffer zone to be observed when using near aquatic areas. Product labels, however, contain a warning "DO NOT contaminate streams, rivers or waterways with the chemical or containers". Responsibility for control-of-use rests with the relevant state authority, QDAFF.

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ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 238

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Dimethoate
Proof Hansard page: Written

Senator NASH asked:

1. Has the APVMA been in discussions with the NZ Ministry of Primary Industries in accepting tomatoes that have a lower level of Dimethoate for export into New Zealand?
2. Food Standards Australia New Zealand media release from 26th September 2012 "Call for submission on application to irradiate tomatoes and capsicums" is APVMA aware that FSANZ is calling for submissions to irradiate tomatoes and capsicums?
3. Would APVMA be likely to approve this method of treatment against Fruit fly when DAFF Biosecurity and NZ Ministry of Primary Industry have both sent letters to FSANZ approving this method of treatment?
4. While the method of irridation is in the process of trying to get approval, what has the APVMA done in when the current phytosanitary methods such as the use of Dimethoate have been restricted because of Australia's regulations of healthy levels of consumption is a lot lower to what NZ government expects when receiving tomatoes from Australia?

5. I refer to the WTO as it states on its website;
   [1]*On the assumption that they are technically and economically feasible and provide the same level of food safety or animal and plant health - governments should select those which are not more trade restrictive than required to meet their health objective. Furthermore, if another country can show measures it applied provide that same level of health protection; these should be accepted as equivalent. This helps ensure that protection is maintained while providing the greatest quality and variety of safe foodstuffs for consumers, the best availability of safe inputs for producers and healthy economic competition.*

   WTO, *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures,* http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm

   Wouldn't the Australia Government be going against the WTO i.e. *governments should select those which are not more trade restrictive than required to meet their health objective. Furthermore, if another country can show measures it applied provide that same level of health protection; these should be accepted as equivalent.* If the NZ Government has showed evidence that increased levels of Dimethoate is acceptable to NZ safety on human consumption levels, is it not correct that Australia is being as the WTO states *trade restrictive?*

Question: 238 (continued)

Answer:

1. No. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has no role in the regulation of food in New Zealand.

2. No. The APVMA has no role in the regulation of food irradiation.

3. Please refer to the answer to question 2.

4. The APVMA has no role in determining phytosanitary requirements. However, the APVMA has issued a number of permits for chemical alternatives to dimethoate and fenthion.

5. Under the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), WTO members have the sovereign right to set their appropriate level of protection (ALOP). The measures that Australia has taken in relation to dimethoate are consistent with the ALOP determined by Australia.

   New Zealand's measures in relation to dimethoate reflect New Zealand's ALOP and are without prejudice to Australia's right to establish its own measures for this chemical consistent with Australia's ALOP.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 240

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Regulations
Proof Hansard page: Written

Senator NASH asked:

1. AVPMA currently uses a risk analysis as the basis for its decision making, will this continue under the proposed regulations?
2. What affect do overseas decision making processes have on the proposed regulations?
3. Are new chemistry products currently meeting the target deadlines for registration?
   (a) if not, how much are they missing the target deadlines by?
4. In appendix 2 of the details of proposed regulations (page 16) an example is given in a timeline for the re-consideration period taking 54 months. How does this compare with current practice?

Answer:

1. Yes.

2. A new section of the Agvet Code (s47A) provides for the Regulations to prescribe the overseas regulatory agencies for which decisions may trigger a re-registration process for a particular chemical.

3. No.
   (a) In the financial year 2011-12 where the target date for a new chemistry product registration was exceeded, the additional time taken varied between 48 and 463 days.

4. In terms of current timeframes, a review can take anywhere between two years to more than 12 years to complete. Where reviews take a longer time to complete, the time taken often involves a period in which new data is being generated (by registrants and/or user groups) and then assessed. The new provisions propose to introduce a limit on the additional time for data to be generated that can be considered by the review.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 249

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Joint Expert Technical Advisory Committee on Antibiotic Resistance Progress report
Proof Hansard page: Written

Senator DI NATALE asked:

According to the 2003 Joint Expert Technical Advisory Committee on Antibiotic Resistance Progress report by the Commonwealth Interdepartmental JETACAR Implementation Group (CIJIG) the Australian Pesticides and Veterinary Medicines Authority began a review of selected macrolide antibiotics December 2001 because of concerns over the potential risk to human health. The review was to provide the Authority with information to enable it to determine whether the existing uses of these macrolide antibiotics should continue in Australia.

Please provide a full copy of the final Report of this review. If such a Report does not exist, why does it not exist and what happened to the review? What were the findings of the review? Were those findings published or otherwise made publicly available? Was the review completed or aborted before completion? If the review was not completed why not?

Answer:

No report is available as the reconsideration (i.e. review) of the macrolide antibiotics (kitasamycin, oleandomycin and tylosin) is still in progress. Finalisation of this reconsideration has been delayed to allow further consideration of new developments, including the outcome of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) reconsideration of a related antibiotic, virginiamycin.

The APVMA's reconsideration of virginiamycin was finalised in April 2012. The APVMA's original decision was to limit the continued use of virginiamycin. This was based on the advice of the Australian Government Department of Health and Ageing, which drew on the Joint Expert Advisory Committee on Antibiotic Resistance report. However, that decision was modified following an Administrative Appeals Tribunal ruling, to allow continued use of products containing virginiamycin, provided they bear a mandatory prudent-use statement.

See www.apvma.gov.au/products/review/completed/virginiamycin.php for a copy of the virginiamycin report.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 250

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Risk assessment in relation to off-label use of antibiotics in veterinary practice
Proof Hansard page: Written

Senator DI NATALE asked:

What is the Authority's risk assessment in relation to off-label use of antibiotics in veterinary practice? On what basis has the Authority made this assessment? What actions have been taken as a result of this assessment?

Answer:

The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates veterinary and agricultural chemical products up to and including the point of sale. State and territory legislation controls the use of these products after retail sale. Off-label use falls under state/territory jurisdiction that allows veterinarians to use products off-label. They must exercise professional judgement and comply with all relevant legislation.

There is no general APVMA risk assessment covering off-label use of antibiotics in veterinary practice, as it is seldom possible to foresee all off-label uses. The APVMA may decide, following its risk assessment for an individual antibiotic product or a specific active constituent, to impose conditions of use that may include controls on off-label use. Conditions of use specified on a product label by the APVMA form part of the state/territory control-of use regime. When the APVMA determines that off-label use of a product should be restricted, specific label instructions are included under a "RESTRAINT" heading, for example: "RESTRAINT: Not for use in food producing animals". Restraints are enforceable under state/territory control-of-use legislation.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 251

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Advice by NHMRC on cephalosporins
Proof Hansard page: Written

Senator DI NATALE asked:

What advice has the former National Health and Medical Research Council's Expert Advisory Group on Antimicrobial Resistance given to the Authority on cephalosporins? Please provide full copies of this advice.

Answer:

The National Health and Medical Research Council (NHMRC) policy on cephalosporins was stated in Table 6.1 of the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) report. This policy was established by the Working Party on Antibiotics which was convened by National Health and Medical Research Council (NHMRC). The report is available at www.health.gov.au/internet/main/publishing.nsf/content/2A8435C711929352CA256F180057901E/$File/jetacar.pdf.

More recently, NHMRC has provided advice to APVMA on critically important antibiotics for human medicine on two occasions. Copies of the two letters are attached (Attachments A and B), as is a copy (Attachment C) of the document titled *Importance Rating and Summary of Antibiotic Use in Humans in Australia*, which is referred to in both letters.

Australian Government
National Health and Medical Research Council

NHMRC

WORKING TO BUILD A HEALTHY AUSTRALIA
www.nhmrc.gov.au

Dr Eva Bennet-Jenkins
Chief Executive Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Dear Dr Bennet-Jenkins

Thank you for your letter of 25 March 2008, seeking advice from the National Health and Medical Research Council (NHMRC) on the on the use of all 'critically important' antibiotics in animals and the registration of 4th generation cephalosporins. I apologise for the delay in our response.

Specifically, you sought expert advice on a) whether the NHMRC, as a general principle, advises the APVMA whether it should or should not register any animal uses for 'critically important' antibiotics and b) what factors the NHMRC advises the APVMA to be aware of when considering whether to grant applications for registration of 4th generation cephalosporins for use in horses (and other companion animals) and also food-producing species of animals.

The NHMRC consulted experts in antimicrobial resistance in developing this response. In line with previous advice, the NHMRC is of the view that no 'critically important' antibiotics should be registered for use in any animals, due to strong concerns about the potential of introducing or amplifying antimicrobial resistance in humans. All antibiotics considered of high importance by the NHMRC are provided as outlined in Attachment A. This list will be updated in the near future.

In your letter you have indicated that the APVMA intends to use the general principles provided by the NHMRC as overarching principles when assessing whether to grant applications for registration of a particular antibiotic for use in food-producing animals and/or companion animals and will not routinely seek advice from the NHMRC on individual applications for registration. The NHMRC is aware that in assessing antimicrobial products the APVMA must be satisfied of the quality, safety and efficacy of the product, and that through your processes these considerations are properly addressed. I would welcome an opportunity to meet with you again to discuss this in more detail.

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During the second half of 2008, the NHMRC intends to conduct a review of the published data on the risk that the use of antibiotics in food producing animals poses to human health. It is anticipated that the review will assist the NHMRC in providing future advice to the APVMA.

Should you require further information or would like to arrange a meeting, please do not hesitate to contact Dr David Abbott, Director, Emerging Issues on (02) 6217 9330 or email david.abbott@nhmrc.gov.au.

Yours sincerely

Dr Clive Morris
Chief Knowledge and Development Officer

10 June 2008

Australian Government
National Health and Medical Research Council
N H M R C

Dr Allen Bryce
Program Manager, Veterinary Medicines
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Dear Dr Bryce

Thank you for contacting me late last year to discuss the provision of National Health and Medical Research Council (NHMRC) advice on the use of 'critically important' antibiotics in animals and the registration of 4th generation cephalosporins.

The Office of NHMRC's position remains unchanged from that outlined in a letter to your predecessor, Mr Martin Homes, in October 2008. To reiterate, the focus of NHMRC's advice is the importance of antibiotics or classes of antibiotics in human medicine. NHMRC advice is guided by its reference document, *NHMRC Importance Rating and Summary of Antibiotic uses in Humans in Australia* (2006) (Attachment A). While this document is not directly applicable to veterinary use, it provides an indication of the importance to human clinical treatment and current restrictions on use, which may assist the APVMA in making regulatory decisions. NHMRC understands that it is at APVMA's discretion as to if, and how, such advice is used.

Consistent with Attachment A and previous advice, NHMRC has concerns about the use of antibiotics which are 'highly important' to human health, such as 4th generation cephalosporins. The development of resistance to these antibiotics would severely limit the ability to treat serious bacterial infections in humans, as there are very limited or in some cases no alternatives available.

If APVMA provided support, NHMRC may consider conducting a review of the published data on the risks that the use of antibiotics in food producing and companion animals poses to human health. Such a review would cover scientific and technical developments since the publication of the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) report in 1999 and would assist NHMRC in providing future advice to the APVMA.

Should you require further information please do not hesitate to contact me on 6217 9330 or email david.abbott@nhmrc.gov.au.

Yours sincerely

David Abbott (PhD)
Director, Emerging Issues Section

12 April 2010

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Attachment A.

Australian Government
National Health and Medical Research Council

NHMRC Importance Ratings and Summary of Antibiotic Uses in Humans in Australia

Background

The following table is intended to provide guidance to clinicians and the pharmaceutical industry (human and animal) about the importance of the various antibacterial agents available for human use in Australia. If an antibiotic is classified as 'High', it implies that if resistance develops there will be very limited or in some cases no alternatives available to treat serious bacterial infections. It is based on a table published originally in the 1999 JETACAR report (Joint Expert Technical Advisory Committee on Antibiotic Resistance).

Details are also given on the current ways in which all antibiotics are used in humans. This list is for guidance only, and does not include every use of the agent or class. All agents with significant antibacterial activity are included in the table, even if their primary use is for other than treatment of bacterial infections (e.g. pyrimethamine, a dihydrofolate reductase inhibitor whose main role is treatment of malaria and toxoplasmosis, but with the same antibacterial activity as trimethoprim).

The NHMRC uses this information as a guide in providing advice to regulatory agencies and government committees including the APVMA (Australian Pesticides and Veterinary Medicines Authority), TGA (Therapeutic Goods Administration), NDPSC (National drugs and Poisons Schedule Committee) and the PBAC (Pharmaceutical Benefits Authority Committee), as a method of assessing the risk to human health after exposure of susceptible humans to either an antibiotic or antibiotic-resistant bacteria. In risk assessment terms, this table is relevant to the 'severity of impact' which is an important element to overall risk characterisation. As an example, if an antibiotic is rated as 'High', the NHMRC would consider that the severity of impact caused by bacteria resistant to that antibiotic is high, as there are few or no alternatives to many infections. Ratings in this table do not affect other parts of risk assessment including hazard, exposure, impact or probability of disease as a result of exposure.

The NHMRC ratings will change over time as resistance levels change, new drugs are introduced, and optimum drug choices alter because of new medical evidence. Consequently, the table will be updated at regular intervals.

Antibiotic	NHMRC Importance Rating[1]	Uses P, T, R	Comments
Narrow-spectrum penicillins			
Benzylpenicillin (pen G) and phenoxymethylpenicillin (pen V)	Low	P2, T3, R1	Primary agents in pneumococcal and streptococcal infection
Procaine penicillin	Low	P2, T3, R1	Intramuscular – occasional substitute for benzylpenicillin
Benzathine penicillin	Low	P3, T3, R1	Intramuscular – syphilis treatment and rheumatic fever prophylaxis
Moderate-spectrum penicillins			
Amoxycillin and ampicillin	Low	P2, T3, R1	Principal role in respiratory tract infections; widespread IV hospital use in combination for a range of moderate and serious infections. Surgical and endocarditis prophylaxis
Antipseudomonal penicillins			
Piperacillin	High	P1, T3, R3	Primary agent for *Pseudomonas aeruginosa*
Antistaphylococcal penicillins			
Cloxacillin, dicloxacillin and flucloxacillin (methicillin)	Medium	P3, T3, R1	Standard treatment for *Staphylococcus aureus* infections (not MRSA). Surgical prophylaxis, especially orthopaedics
ß-lactamase inhibitor combinations			
Amoxycillin-clavulanate	Medium	P1, T3, R1	Second line agent for respiratory tract infections; role in certain types of skin/soft tissue infections and mixed staphylococcal/Gram-negative infections and aerobic/anaerobic infections.
Ticarcillin-clavulanate and Piperacillin-tazobactam	High	P1, T2, R2	Valuable agents for a range of severe mixed aerobic-anaerobic infections including intra-abdominal infections, aspiration pneumonia, skin/soft tissue infections. Neutropenic sepsis.
1st Generation Cephalosporins			
Cephalexin, cephalothin and cephazolin	Medium	P3, T3, R1	Treatment of minor and staphylococcal infections in penicillin allergic patients. Prophylaxis in orthopaedic and other surgery
2nd Generation Cephalosporins			
Cefaclor and cefuroxime-axetil	Medium	P0, T2, R1	Treatment of respiratory infections in penicillin-allergic patients
Cephamycins			
Cefoxitin a	Medium	P3, T1, R2	Useful anti-anaerobic activity, major role in surgical prophylaxis
3rd Generation Cephalosporins			
Ceftriaxone	High	P2, T3, R2	Major agent in severe pneumonia and meningitis. Used in selected cases for treatment of gonorrhoea and alternative for prophylaxis of meningococcal infection
Cefotaxime	High	P0, T3, R2	Major agent in severe pneumonia and meningitis
4th Generation Cephalosporins (and anti pseudomonal)			
Ceftazidime, cefpirome and cefepime	High	P1, T3, R3	Restricted role in pseudomonal infection and neutropenic sepsis
Carbapenems			
Imipenem, meropenem and ertapenem	High	P0, T3, R4	Very broad-spectrum reserve agents for serious Gram-negative infections
Monobactams			
Aztreonam	High	P0, T3, R4	Reserve agents for resistant Gram-negative infections or patients with severe ß-lactam allergy
Tetracyclines			
Doxycycline, minocycline, and tetracycline (demeciccycline)	Low	P2, T3, R1	Major agents for minor respiratory tract infections and acne. Supportive role in pneumonia for treating *Mycoplasma* and *Chlamydia pneumoniae*. Malaria prophylaxis (doxycycline)

1 The importance of the drug class to the treatment of infections in humans, and the seriousness of the consequences of emergence of resistance.

Antibiotic	NHMRC Importance Rating	Uses P, T, R	Comments
Clycylcyclines			
Tigecycline	High	P0, T1, R4	Reserve agent for multi-resistant gram-positives and some multi-resistant gram-negatives
Glycopeptides			
Vancomycin	High	P2, T3, R2	Drug of choice for serious methicillin-resistant staphylococcal infections. Reserve agent for enterococcal infection when there is resistance or penicillin allergy
Teicoplanin	High	P1, T1, R4	Substitute for vancomycin if intolerance or outpatient IV therapy
Aminoglycosides			
Neomycin (including framycetin)	Low	P1, T2, R1	Topical agent for skin infection and gut suppression
Gentamicin and tobramycin	Medium	P2, T3, R1	Standard agents in combination for serious and pseudomonal infection. Gentamicin used in combination for endocarditis
Netilmicin, amikacin	High	P0, T2, R4	Reserve agents for Gram-negatives resistant to gentamicin and tobramycin
Spectinomycin	Medium	P0, T2, R1	Spectinomycin only used for gonorrhoea (infrequently)
Streptomycin	Low	P0, T1, R4	Rare use in treatment of TB and enterococcal endocarditis
Capreomycin	Low	P0, T1, R4	Rare use in TB
Paromomycin	Low	P0, T1, R4	Rare use for *Cryptosporidium* infection
Sulfonamides and DHFR inhibitors			
Sulfadiazine	Low	P0, T3, R4	Treatment of acute toxoplasmosis
Trimethoprim	Low	P2, T3, R1	Treatment and prophylaxis of UTI
Trimethoprim-sulfamethoxazole (co-trimoxazole)	Medium	P2, T3, R1	Minor infections, especially treatment and prophylaxis of UTI. Standard for treatment and prophylaxis of *Pneumocystis carinii* infection and nocardiasis. Important for community-acquired MRSA infections
Sulfadoxine-pyrimethamine	Low	P1, T1, R3	Treatment and prophylaxis of malaria
Proguanil	Low	P2, T1, R3	Malaria prophylaxis
Oxazolidinones			
Linezolid	High	P0, T1, R4	Treatment of multi-resistant Gram-positive infections, especially MRSA and VRE
Macrolides			
Azithromycin	Low	P3, T3, R2	Treatment of *Chlamydia trachomatis* infections. Major agent for treatment and suppression of atypical mycobacterial infection
Clarithromycin	Low	P2, T2, R1	Treatment of minor Gram-positive infections. Major agent for treatment and suppression of atypical mycobacterial infection
Erythromycin and roxithromycin	Low	P1, T3, R1	Treatment of minor Gram-positive, *Chlamydia* and *Mycoplasma* infections
Lincosamides			
Clindamycin and lincomycin	Medium	P1, T3, R2	Reserved for Gram-positive and anaerobic infections in penicillin-allergic patients. Clindamycin topical used for acne
Nitroimidazoles			
Metronidazole and tinidazole	Medium	P2, T3, R1	Major agents for the treatment and prevention of anaerobic infections in hospitals. Principal agents for the treatment of giardiasis and trichomoniasis
Quinolones			
Nalidixic acid	Medium	P1, T2, R1	Use confined to treatment and prophylaxis of UTI
Fluoroquinolones			
Norfloxacin	High	P1, T3, R2	Treatment and prevention of complicated UTI
Ciprofloxacin	High	P2, T3, R3	Major oral agent for the treatment of Gram-negative infections resistant to other agents. Minor role in meningococcal prophylaxis
Moxifloxacin	High	P0, T3, R4	Restricted role in the management of serious respiratory infections, especially pneumonia in patients with severe penicillin allergy
Ofloxacin	High	P0, T2, R3	Topical treatment of severe eye infections

Antibiotic	NHMRC Importance Rating	Uses P, T, R	Comments
Streptogramins			
Quinupristin with dalfopristin	High	P0, T1, R4	Reserve agent for multi-resistant Gram-positive infections (MRSA and vancomycin-resistant *Enterococcus faecium*)
Antimycobacterials			
Isoniazid	High	P2, T3, R4	Primary agent for treatment and prevention of tuberculosis
Ethambutol and pyrazinamide	High	P1, T3, R4	Primary agent for treatment of TB
Cycloserine, p-aminosalicylic acid, and prothionamide	High	P0, T1, R4	Reserve agents for complicated or resistant TB
Antileprotics			
Clofazimine and dapsone	High	P0, T3, R4	Usage predominantly for treatment of leprosy
Ansamycins (Rifamycins)			
Rifampicin (Rifampin)	High	P3, T3, R2	Meningococcal and *H. influenzae* type b prophylaxis; Standard part of TB regimens; Important oral agent in combination for MRSA infections
Rifabutin	High	P3, T2, R4	Treatment and prophylaxis of *Mycobacterium avium* complex infections
Polypeptides			
Bacitracin, gramicidin	Low	P0, T2, R1	Topical agents with Gram-positive activity
Polymyxin B	Low	P0, T2, R1	Topical agent with Gram-negative activity
Colistin	High	P0, T1, R2	Reserve agent for very multi-resistant gram-negative infection (both inhaled and intravenous)
Amphenicols			
Chloramphenicol	Low	P0, T2, R1	Usage largely as topical eye preparation. Occasional need for the treatment of bacterial meningitis
Nitrofurans			
Nitrofurantoin	Low	P2, T2, R1	Treatment and prophylaxis of urinary tract infections only
Fusidanes			
Sodium fusidate	High	P0, T3, R2	Used in combination therapy with rifampicin for MRSA
t-RNA synthesis inhibitors			
Mupirocin	Medium	P1, T3, R1	Topical treatment of skin infections and clearance of *S. aureus* nasal carriage (including MRSA)

Antibacterial drug classes which are not used in humans and with no cross-resistance known to classes of antibacterials used in humans include arsenicals, bambermycins (flavophospholipol), ionophores, orthosomycins, quinoxalines and nisin. Pleuromutulins for human use are undergoing development.

Abbreviations:

UTI = urinary tract infections
TB = tuberculosis
MRSA = methicillin-resistant *Staphylococcus aureus*
VRE = vancomycin resistant *Enterococcus* species

LEGEND for TABLE

NHMRC Importance Rating

High
These are essential antibiotics for treatment of human infections where there are few or no alternatives for many infections. Also have been called "critical", "last-resort" or "last line" antibiotics. The use of these antibiotics should be preserved, as loss of efficacy of these drugs due to emergence of antimicrobial resistance, would have an adverse impact on human health.

Medium
There are other alternatives available but less than for those classified as Low.

Low
There are a reasonable number of alternative agents in different classes are available to treat most infections even if antibiotic resistance develops.

Human Uses
These reflect the current use of these antibiotics in Australia in human medicine. It does not necessarily reflect what the NHMRC believes should be the uses of these agents or what restrictions should apply to their use..

P: prophylactic use
- 0 = not recommended for prophylactic use
- 1 = rarely used
- 2 = moderate
- 3 = frequent or major use

T: therapeutic use
- 1 = infrequently used for listed indications
- 2 = moderate use for listed indications
- 3 = used frequently for listed indications

R = Restriction on use (Pharmaceutical Benefits Scheme or hospitals)
- 1 = readily available
- 2 = some extra rules on use e.g. 'Restricted benefit' in the Pharmaceutical Benefits Scheme (PBS) or not listed on the PBS and therefore not subsidised
- 3 = higher level of restriction e.g. needs an 'Authority required' prescription on the PBS or not listed on the PBS and therefore not subsidised; often restricted use in hospitals
- 4 = use severely restricted (e.g. not available for prescription under PBS, available in major hospitals but only with permission from microbiologist or infectious diseases consultant, or in a special clinic).

Reference

Therapeutic Guidelines – Antibiotic. Version 13, 2006. Therapeutic Guidelines Limited, Melbourne (www.tg.com.au)

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 252

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Growth promotants and prophylactic use of antimicrobials
Proof Hansard page: Written

Senator DI NATALE asked:

In Supplementary Estimates, the Authority asserted that "there is a grey area between growth promotants and prophylactic use" of antimicrobials. Given that some countries such as Sweden have banned antibiotic use as a growth promotant, how have they done this if the definition is not clear? How does the Department inform itself of international policies on antimicrobial resistance?

Answer:

This statement was made in the context of categorising antibiotics by this type of use from the available reporting, not in relation to defining use per se. The latter can be done on a case by case basis. The Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Department attend international conferences to keep informed of international developments in regard to antimicrobial resistance – most recently the Chief Veterinary Officer (CVO) attended a regional workshop on 'Antimicrobial Use and Resistance in Livestock Production in the Asia-Pacific Region' where the regional situation was reviewed, and the APVMA's Program Manager, Veterinary Medicines attended an 'International Conference on Responsible Use of Antibiotics in Animals' in the Netherlands, and gave a presentation on Regulation of Veterinary Antibiotics in Australia.

Also, the Department of Agriculture, Fisheries and Forestry is a member of relevant international organisations and networks, and has an active environmental scanning network which monitors, among other topics, international developments in antimicrobial resistance, including in the European Union and the United States of America.

Australia is a member of the World Organisation for Animal Health (OIE) that works with the Food and Agriculture Organization and World Health Organization to provide guidelines and information to assist countries manage antimicrobial resistance. OIE disseminates information about international developments to the CVO and his office.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 253

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Antibiotic use in aquaculture
Proof Hansard page: Written

Senator DI NATALE asked:

What antibiotics are used in aquaculture? In what geographic areas does use occur and in what quantities? Are you aware of off-label antibiotic use in aquaculture? How does the Authority inform itself of this? Does the Authority perform independent studies or research on this issue? How does the Authority ensure that information on use and resistance flows from states and territories?

The Authority asserted in Supplementary Estimates that "before we allow any use of antibiotics in aquaculture—if we issue a permit for large-scale use—we do an environmental risk assessment". How many such permits have been issued, over what time periods? What is "large-scale use"? Are these assessments publicly available?

Answer:

Oxytetracyline, florfenicol, tylosin and trimethoprim are known to be prescribed since 2009. There has been the occasional use of chlortetracycline.

The salmon industry of Tasmania uses the bulk of antibiotic that is supplied to aquaculture in Australia. Leases in Tasmania are located in the D'Entrecasteaux Channel, Huon River, Port Esperance, Tasman Peninsula and Tamar estuary.

The table below lists usage of oxytetracycline, trimethoprim and total antibiotics as reported by Mcleod & Eriksen (2009) for the period 2003-2008. The Australian Pesticides and Veterinary Medicines Authority (APVMA) compiled additional data for 2009-2012 from reports received from permit holders, lease holders, veterinarians servicing the industry, and the Tasmanian Salmonid Growers Association Ltd.

Question: 253 (continued)

Antimicrobial usage in salmonid production in Tasmania, 2003-12

Year	Oxytetracycline Usage (kg)	Trimethoprim Usage (kg)	Total Antimicrobial Usage** (kg)
2003	-	32	285
2004	790	64	996
2005	845	21	878
2006	4453	44	4536
2007	8665	78	9295
2008	3381	165	4007
2009	2946	24	3281
2010	N/A	N/A	N/A
2011	139.75	127.49	267.24
2012*	42.5	57.04	138.54

* Data for January to June 2012
**Includes amoxycillin, chlortetracycline and oxolinic acid for 2003-2008; and tylosin, florfenicol and chlortetracycline for 2009-2012
N/A: Not Available.

Under State and territory legislation, veterinarians may prescribe antibiotics off-label. Prior to APVMA permits, all previous antibiotic use in aquaculture was off-label . Currently, trimethoprim is prescribed off-label.

The APVMA informs itself of off-label use through reports from state and territory agriculture departments and discussions with user groups and/or their representative bodies, such as the Tasmanian Salmonid Growers Association Ltd, antibiotic registrants and veterinarians practicing in the industry.

The APVMA has no capacity to conduct independent studies or research, but can commission independent literature reviews. This was done as part of the re-considerations of the approvals of the macrolides and of virginiamycin.

For permitted uses of antibiotics, there are provisions that require permit holders and the prescribing veterinarians to report usage and monitoring information to the APVMA and State Coordinators. Veterinary scripts are to be made available to the APVMA on request.

Individual minor use permits for florfenicol (PER9644), oxytetracycline (PER9665 and PER9675) and tylosin (PER11829) were issued between December 2007 and December 2010. An environmental assessment was conducted for each of these permits.

Question: 253 (continued)

Large scale use refers to access of the antibiotic by several leases in all states through a minor use permit. This is in contrast to other APVMA permits, such as research permits or other minor use permits (e.g. PER11829), which impose limitations on matters such as the location where the permitted product(s) may be used, the number of treatments, the number of animals to be treated or the persons authorised to use the permitted product(s).

None of the environmental assessments is published.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 254

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Drug reclassificiation and risk analysis of microbial resistance safety
Proof Hansard page: Written

Senator DI NATALE asked:

What happens when the World Health Organisation reviews the status of a drug and reclassifies the drug as of higher importance to human medicine than had previously been the case (as has happened with polypeptides) and that drug is being routinely used on animals? Does the reclassification by WHO mean that there is automatically a risk analysis of microbial resistance safety and a review of its use in animals?

Answer:

Under s31 of the *Agricultural and Veterinary Chemicals Code Act 1994*, the Australian Pesticides and Veterinary Medicine Authority may at any time reconsider the approval of an active constituent or the registration of a chemical product, or the approval of a label for a chemical product. A reconsideration may be initiated when new research or evidence, such as the World Health Organisation reviewing the status of a drug and reclassifying it a higher level of importance to human medicine, has raised concerns about the safety of a particular chemical or product.

Such reclassification of an antibiotic's status does not automatically trigger a risk analysis of microbial resistance safety or a review of its use in animals in Australia.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 265

Division/Agency: Agricultural Productivity Division/Australian Pesticides and Veterinary Medicines Authority
Topic: Agricultural chemicals – spray drift
Proof Hansard page: Written

Senator EDWARDS asked:

With reference to answers given to Written Questions on Notice 125 and 126 (Additional February Estimates 2012), where the APVMA stated that there have been talks around harmonising regulation of chemicals use as a part of the CoAG reforms.

1. What has APVMA's involvement been in the process of harmonising state regulations?
2. What was APVMA's advice to CoAG?
3. Which other agencies are involved?
4. What are the developments around harmonising regulation of chemical use?
5. How likely are national regulations?
6. How long will they take to develop?
7. Has industry been consulted?
8. If so, who has been consulted?

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has not had any specific role in harmonising state and territory regulations as part of the Council of Australian Governments (CoAG) agricultural chemicals and veterinary medicines (agvet) reforms. The reform process has been managed by the Department.

2. The APVMA has not provided any advice to CoAG.

3. Other Australian Government agencies that have been involved in harmonising regulations are the Departments of: Attorney General and Justice; Education, Employment and Workplace Relations; Finance and Deregulation; Foreign Affairs and Trade; Health and Ageing; Industry, Innovation, Science, Research and Tertiary Education; Prime Minister and Cabinet; Regional Australia, Local Government, Arts and Sport; and Sustainability, Environment, Water, Population and Communities.

4. A regulatory model, funding model and intergovernmental agreement have been prepared for CoAG's endorsement. It is expected that a new single national framework for agvet chemical reforms will be agreed this year.

5. Following a CoAG agreement, it would be expected that jurisdictions would move promptly to amend the necessary regulations.

6. It is anticipated that implementation will take at least 18 months.

Question: 265 (continued)

7. Yes

8. Industry stakeholders were given the opportunity to provide input throughout the reform process including a Consultation Regulation Impact Statement for the CoAG agvet chemical reforms, where stakeholders provided 70 formal submissions. The National Agvet Systems Policy Taskforce, which includes Commonwealth and State and Territory representatives, also held a workshop on the CoAG agvet chemical reforms in September 2012, which was attended by 29 key stakeholder representatives.

Rural and Regional Affairs and Transport Committee

ANSWERS TO QUESTIONS ON NOTICE

Supplementary Budget Estimates October 2012

Agriculture, Fisheries and Forestry

Question: 295

Division/Agency: Agricultural Productivity Division/Australian Pesticide and Veterinary Medicine Australia
Topic: Usage levels of Diuron
Proof Hansard page: Written

Senator WATERS asked:

1. Please provide an update on the process and evidence base leading to the recent decision to change the authorised usage levels of Diuron.
2. Please outline the effect of the change for landholders using Diuron.
3. Please outline any research or knowledge APVMA has about alternatives to Diuron.

Answer:

1. The Australian Pesticides and Veterinary Medicines Authority (APVMA) has published three environmental risk assessment reports related to diuron (2005, 2011, 2012). Suspension action was taken in 2011 and continued in 2012, which modified the way in which diuron could be used while the review is being completed.

   The 2012 report, prepared by the Department of Sustainability, Environment, Water, Populations and Communities (SEWPaC), took into consideration the information provided in submissions to the APVMA (more than 100) when the 2011 environmental assessment report was published. These submissions included newly available environmental monitoring data from the reef monitoring program and scientific studies not previously considered.

   The new information and assessment approach undertaken in the 2012 assessment has allowed the APVMA to make crop-specific recommendations. The more refined crop-specific assessment approach has found runoff risk to be acceptable for some crops, compared to the previous worst case scenario approach used in the report published in 2011. Full details are available at the following link:
   www.apvma.gov.au/products/review/current/diuron.php

   A final decision on the authorised use levels of diuron is expected to be made before the end of November 2012.

2. The proposed changes to the use of diuron as outlined by the APVMA in September 2012, if implemented, will impact materially on those industries and situations where the continued use of diuron can no longer be supported (*apples & pears, citrus, bananas (high rates), citrus, coffee, driveways, paths, lanes, duboisia, factory sites, lucerne, non-crop areas, ornamentals, paw paws, peas, perennial grass seed crops, phalaris, pineapple (high rates), right of way, tea, vineyards*). Alternative herbicides are approved for use in these situations although they provide a shorter period of weed control in comparison to diuron.

Question: 295 (continued)

The APVMA is proposing to vary labels to retain only those current uses that are supported on environmental grounds *(asparagus, bananas (low rates), bore drains, cotton, irrigation channels, lupins, pulses, faba beans, sugarcane, pineapples, summer fallows, wheat, barley, oats, triticale, cereal rye).*

For uses that can continue, additional instructions, designed to reduce the potential for runoff, will be included on labels.

3. Information on registered herbicides and their approved uses can be found in the APVMA's public database of registered products (PUBCRIS). Other herbicide products are registered for the control of weeds in those crops for which diuron is currently used. See also the response to Question 2 above.