THE UNIVERSITY OF QUEENSLAND
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CRICOS PROVIDER NUMBER 00025B

Standing Committee on Finance and Public Administration
Ref: Inquiry into implementation of the 1999 JETACAR Recommendations
PO Box 6100, Parliament House
Canberra ACT 2600

17 February 2013

Dear Standing Committee,

The remit of JETACAR covered Multi-Drug Resistant (MDR) bacteria, or superbugs, and the use of antibiotics for 'growth promotion' (prophylactic) and veterinary use (treatment of sick animal).

Unfortunately responsibilities for prioritisation and implementation of the 22 JETACAR recommendations concerned dozens of departments and governmental agencies. This meant that no one agency, or minister was responsible or accountable. Competing interests from the pharmaceutical, agricultural and medical sectors necessitate a high degree of ministerial oversight to ensure that vested interests do not block reform.

Given the severity of the threat to ***human*** health, priority should be given to the Dept. Health and Aging to manage the process and hold other agencies and departments accountable (to the Prime Minister) in order to ensure recommendations are implemented and enacted into law. In 2011, the WHO termed superbugs "the greatest threat to human health we face today". Australia needs to start taking this threat seriously.

We need to:

1. Inaugurate **a mandatory national reporting system for the incidence of MDR bacteria in food-chain animals, hospitals and healthcare clinics.** This system should be visible to the public and updated quarterly. Whilst local and state-based systems exist (e.g. AGAR, CHRISP), these to not cover national trends, nor report on a timely basis, and are difficult to access and understand for the general public.

2. **Give the public better, contemporary information on the incidence, and the fiscal, societal and human cost of superbugs**. We could consider linking hospital CEO bonuses and other performance incentives to antibiotic-incidence rates. This strategy was used in the UK, and resulted in a year-on-year reduction in MRSA incidence rates from the late-2000's onwards. Figures reporting the number of deaths, extended hospital stays, etc. for the USA and EU are easy available and easily accessible and understood. The government should fund a national study to allow calculation of the full economic cost of superbug infections to better prioritise actions and allocate relevant funding if required.

3. Implement a national, **standardized hand-washing and antibiotic stewardship programs** in hospitals, GP clinics and other healthcare centers.

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4. **Review drug pricing for antibiotics to encourage further R&D** from the private sector and **increase NHMRC funding for antibiotic and superbug research** (currently not a national priority area for research funding from either the ARC nor NHRMC). Based on the EU and US figures available using a pro-rata population approach the full economic cost for superbug infections to Australian society is in excess of $750m, however <2% of the NHMRC budget was allocated to research in this area.

5. Review (again) **alternatives to antibiotic use in animals** (JETACAR Chpt 11). There has been considerable progress in implementation of zero antibiotic, or minimal antibiotic-use farming in the US and EU since 1999, and these alternatives merit re-examination. A visible, accessible list of antibiotics allowed and banned for use in animals (for treatment and for prophylaxis) should be published. The medical implications of registration and use of animal antimicrobials needs to be taken into account as part of product registration and review. There is no justification for use of 3rd generation cephalosporins or carbapenems in livestock or pets. "Off label" veterinary practices need to be reviewed again.

Yours sincerely,

Professor Matthew Cooper
NHMRC Australia Fellow

Appendix 1 – Cost of ESKAPE pathogens

Antimicrobial resistance is an escalating problem of global significance. Well documented throughout the world with an increasing impetus on government and industry to take action, the problem continues to grow costing millions of lives and billions in medical and societal costs. Policy makers have been slow to react and without informed leadership and the necessary commitment to invest in R&D infrastructure, the future of infection control is heading for the dark ages.

Leading government and industry bodies have focused their efforts to highlight and communicate this growing problem. The World Health Organization has declared antimicrobial resistance to be one of the greatest threats to human health. On World Health Day 2011, themed "combating antimicrobial resistance", WHO issued an international call for concerted action to halt the spread of antimicrobial resistance launching a six-point policy package, recommended for governments, which sets out the measures governments and their national partners need to combat drug resistance.

The European Centre for Disease control has been involved in coordinating the Antibiotic Awareness Day, an EU-wide initiative to promote more prudent antibiotic use, since 2008; and for the past decade the Infectious Disease Society of America has been highlighting its concerns on the threat of multi drug resistant bacteria and the lean pipeline for development of new antibiotics. Via a 2004 policy report, Bad Bugs, No Drugs: As Antibiotic R&D Stagnates, a Public Health Crisis Brews," and a recently issued a "call to action" to provide an update on the scope of the problem and the proposed solutions, the IDSA aims to lobby government to establish greater financial parity between the antimicrobial development and the development of other drugs.

The antibiotic resistant bacteria, of most significance, are: *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumanii, Pseudomonas aeruginosa*, and Enterobacter species. Rice[1] recently reported these as the "ESKAPE" pathogens to emphasize that they currently cause the majority of US hospital infections and effectively "escape" the effects of antibacterial drugs.

Antimicrobial resistant infections can be categorized to either community based (acquired) or hospital acquired infections. There is little data on community based infections however HAI's or Nosocomial infections are classified and recorded in many hospitals throughout the western world. In the US, UK and Europe there are mandatory requirements for hospitals to monitor and record HAI's. The US data is coordinated via the Centre for Disease Controls National Nosocomial Infections Surveillance system (NNIS). In 2002 the CDC estimated the number of HAIs in the US was approximately 1.7million, estimated deaths with HAI's in US hospitals were almost 99,000.[2] US HAI's result in up to 4.5 billion in additional healthcare expenses annually.[3]

In depth studies have been undertaken in specific hospitals and or groups of hospitals internationally. In England a study of 4000 patients estimates HAI's cost the hospital sector £930.62 million per year,[3] and over 5000 people died of infectious or parasitic disease in England & Wales in 2010.[4] In Argentina a study of 142 patients with central line associated BSI infections cost on average an extra $4888.42 over the mean extra 11.9 days stay. The excess mortality was 24.6%.

Despite the many red flags highlighting the problem, no significant changes or initiatives have been implemented. To date, best practice within hospital and clinical environments

focuses on prevention and control. This incorporates hospital approved guidelines & management practices to prevent spread of infection, contact precautions, screening efforts to identify high or "at risk" patients, effective antimicrobial stewardship and in some countries, surveillance and monitoring / point-prevalence surveys for HAIs. Hospitals that have implemented such management plans have seen a decline in the incidence of HAI's, however the problem of infection remains and is exacerbated where there are cases of highly transmissible strains. Where infections develop that are antimicrobial resistant, not only does the hospital incur the high costs of its infection control program, but the added financial burden of ineffective treatment, prolonged stay or even death of the patient. In third world countries where clinical practices are inconsistent, overburdened and underfunded the problem of infection is significantly larger. A three year study in four Mexican public hospitals ICU's revealed device associated nosocomial infection rates of 24.4%.

References

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6. Ramirez Barba EJ, Rosenthal VD, Higuera F, Oropeza MS, Hernández HT, López MS, Lona EL, Duarte P, Ruiz J, Hernandez RR. Device-associated nosocomial infection rates in intensive care units in four Mexican public hospitals. Am J Infect Control. 2006;34:244–7.

Appendix 2 – Antibiotic use in animals

When a bank is looking to give you a loan or credit card they carry out a risk analysis; basically trying to work out how you manage your income and where you sit on a sliding scale between a prudent saver who pays off the credit card each month, and a credit junky who sees no limit to the possibilities of future funds coming 'just in time'. The juxtaposition of views in Monday's Medical Journal of Australia also deals with attitudes to risk and economics, but with the added gravitas of a life-or-death outcome added to the consideration. The two articles[1] discuss the use of antibiotics in humans and animals. Antibiotics are one of the most important discoveries of the 20th century and have saved hundreds of millions of lives. Unlike money, which we seem to be able to print limitless amounts of currently, there are no new antibiotics coming down the pipeline.

Why is this important? The World Health Organization has declared antimicrobial resistance, or 'superbugs', to be one of the greatest threats to human health today. In the US, UK and parts of Europe there are mandatory requirements for hospitals to monitor and record hospital-acquired infections on a national database. Remarkably there is no national database or policy in Australia. The US Centre for Disease Control estimated[2] that in 2002, 1.7 million people in the US were infected by hospital-acquired infections (where you go to hospital infection free, and pick up a superbug during your stay). This leads to $4.5 billion in additional healthcare expenses[3] each year, and leads **directly** to 99,000 deaths.

Director of the Infectious Disease Unit at Canberra Hospital and a Veterinary Clinical Pharmacologist at a the Advanced Veterinary Therapeutics Company in Sydney, present point and counterpoint on whether the use of antibiotics in farmed animals poses a risk to human health. (the medic) and (the vet) disagree on a key point: whether the use of identical or near-identical antibiotics in our food chain is one of several contributing factors to the problem of antimicrobial resistance in humans.

Here it is important to separate the use of antibiotics for treating sick animals (veterinary use), and the daily application of antibiotics as 'growth promoters'. argues that only 39 antibiotics are approved for use in animals, of which 6 are from classes with no human counterpart (this of course means that 33 are used in both humans and animal). Australia imports approximately 700 tonnes of antibiotics annually; of this, 550 tonnes are used for either veterinary therapy (sick animals) or growth promotion (higher yields of growth of farmed animals). Of the 33 classes of antibiotics used in animal and humans, one third of these are classified as of 'high/medium importance in human therapy.[4]

The Australian Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETCAR), which was disbanded in 2002, found that antibiotic resistance could spread by consumption of animal products contaminated with a resistant bacterial strain, or via close contact with animals. When we have the foresight to ban a class of antibiotics in animals, as

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[1] Med J Aust 2012; 196 (5): 302. doi:10.5694/mja12.10329 & Med J Aust 2012; 196 (5): 303. doi: 10.5694/mja12.10364

2 Klevens, RM, Edwards JR, Richards CL, Horan T, Gaynes R, Pollock D, Cardo D. "Estimating healthcare-associated infections in U.S. hospitals," 2002. Public Health Rep 2007;122:160-166.

3 Reed, D, Kemmerly SA. "Infection Control and Prevention: A Review of Hospital-Acquired Infections and the Economic Implications," 2009. The Ochsner Journal 9:27–31.

[4] "Quantity of antimicrobial products sold for veterinary use in Australia 1999/2000 – 2001/2002", APVMA March 2005.

was the case with fluoroquinolones, there are very few superbugs resistant to that antibiotic found in humans. and both note that industry should be applauded for self-regulation here; the Australian Poultry Industry decided not to use a third-generation drug called cephalosporin in chickens. As a result, the level of drug resistance in human infections is 3% in Australia, compared to more than 50% in countries that use the drugs (cephalosporin is infected into the chicken; fluoroquinolones are given in the drinking water). adds that in Denmark, which has one of the most highly regulated policies for antibiotic use in the world, superbugs in animals are still a problem. Does this mean that such policies are ineffectual or that we decided to ban antibiotic use too late?

Bacteria	Human drug	Animal drug	Resistance
Escherichia coli	Synercid	Virginiamycin	17-87%
Pseudomonas aeruginosa	Cephalosporins	Cephalosporins	65%
Staphylococcus aureus	Methicillin	Methicillin	57%
Campylobacter	Ampicillin	Ampicillin	55%
Campylobacter	Sulfisoxazole	Sulfisoxazole	46%
Campylobacter	Ciprofloxacin (fluoroquinalones)	**Banned in Australia**	**3-5%**

The Australian Dept. of Health and Ageing notes that "Australia's food supply is one of the safest and cleanest in the world"[5]. We are lucky in Australia in that we enjoy access to a high standard of healthcare. Whilst it is inhumane to withhold antibiotics for veterinary care of sick animals, Australia needs to think carefully about our attitude to risk and antibiotic use. With superbugs appearing more often in hospitals and causing more deaths, what risks are we prepared to take with human health if we continue to use antibiotics as growth promoters in animals?

[5] "Australia's food supply gets clean bill of health" [press release], Department of Health and Ageing. 28 Feb 2003. http://www.health.gov.au/internet/main/publishing.nsf/Content/health-mediarel-yr2003-tw-tw03044.htm

Appendix 3 – Fix the antibiotic pipeline

Most experts who have examined the subject agree that our antibiotic development pipeline is not sufficient by a long shot. The days when there was always a new antibiotic just around the corner that would allow treatment of the latest superbug are long gone.

Fixing the antibiotic pipeline is not rocket science. The main difficulty lies in finding molecules that enter the bacterial cell, stay there and inhibit growth of the bug without being toxic to us. One thing that prevents us from overcoming this difficulty is that the number of people working on the problem has shrunk to historically low levels.

The continuing consolidation (mergers and acquisitions) within large pharmaceutical companies, plus the outright abandonment of antibiotic research by these companies has severely impacted our ability to come up with new ideas, new approaches and new molecules. In addition, the lack of experience and training of well-meaning academics in the science of drug discovery undermines current efforts in the public sector.

So how can we fix this? We can't make scientific discovery any easier. But there are three areas over which we have some control.

First and foremost we need regulatory reform. One of the reasons industry has abandoned the area has been the increasing regulatory stringency, which translates into larger clinical trials and greater development expense, and the accompanying regulatory uncertainty for antibiotics. Regulators are working on the use of small, streamlined trials to get antibiotics specifically targeting specific resistant bacteria to the market quickly to help those patients who truly need these life-saving drugs. Of course this approach may increase the safety risk to patients. Europe has been leading the way in this effort with a transparent process. The US is making great strides but this is still al behind closed doors. This leads to continued uncertainty within the industry. Finally – Asia and emerging markets have not really focused on this problem yet from a regulatory perspective.

Secondly, we need to attack the economic factors that have led industry to leave antibiotic R&D. Push incentives such as funding to support expensive stages of research and development are important. A good example is BARDA in the US and the Wellcome Trust in the UK.

The other economic factor we can control is drug pricing. We are happy to pay tens of thousands of dollars for oncology drugs that prolong life maybe a few months, while we expect to pay only a few dollars for antibiotics that can be incredibly effective in curing disease, but that are only taken for days. As a global society, we must value new antibiotics appropriately. This means that for those new drugs developed to serve a small population of patients with highly resistant infections for whom other effective options do not exist, we have to be willing to allow industry to recoup its costs and to make a small profit. Prices for such drugs could range from $2000 to $30,000 for a course of therapy.

One area we do not think we need to fix is the market itself. There has been discussion of "pull" incentives where government would provide a guaranteed market for antibiotics active against key drug-resistant superbugs. Given the evolving dominance of emerging economies in the global antibiotic market and the high incidence of superbugs in many of these countries, we think that the market will provide enough incentive in this regard.

Finally, we need to train our academic researchers in the science of drug discovery. We support using government funds to provide such training within industry in exchange programs. Academics should be allowed, even encouraged to spend time with partner pharmaceutical companies and 'learn by doing'.

So a **five point plan to fix the antibiotic pipeline** –

1) **regulatory reform**
2) **streamlined clinical trials for antibiotics against resistant superbugs**
3) **better antibiotic pricing policies**
4) **getting needed and appropriately valued new antibiotics to emerging economies**
5) **training for academic researchers**

Appendix 4 - Economic models to revive antibiotic development

The framework for antibiotic discovery, development and approval is broken. Only four new chemical classes of antibiotics have been launched in the past 40 years; linezolid (2000) and daptomycin (2003) for systemic infections, mupirocin (1985) and retapamulin (2007) for topical infections. Today the World Health Organisation announces a policy package to combat the spread of antimicrobial resistance, forecasting an impending disaster due to its rapid, unchecked increase, combined with decreasing investment in antibiotic R&D.

Antibiotic resistance cannot be eliminated by stewardship alone. There needs to be a sustained effort from government and industry to develop new drugs quickly.

Phase III registration trials for an antibiotic for use in a single disease indication cost around $70 million. The problem for biotech and academia is that their funding sources (venture capital or government grants) cannot realistically cover this critical step to commercialisation of a drug that will be sold mainly for short duration courses. Following the financial crisis, public markets in the US and Europe have continued to struggle, with successful biotech IPOs still rare. The concomitant exit of many large pharma from antibiotic R&D has left few parties able to register and market new compounds.

Several solutions have been debated over the past decade, yet no concrete action has been taken, and the trend on both sides of the Atlantic has been continuing antibiotic misuse and a distressing lack of new antibiotic launches. It is time for the US and EU to take a far more proactive role and recognise the health and economic benefits that antibiotics bring to society. The US government and EU need to pick a solution from those we outline below now, enact this in legislation and set a clear mandate for change. This must all be done by year's end to stop the 100,000's of people dying each year from resistant infections turning into millions in the near future.

One solution was suggested in a report[6] from the London School of Economics. It proposed a 'push-pull' mechanism to provide a global incentive for more investment in antibiotic R&D. This incentive would be limited to potential drugs that meet stringent criteria for medical need and probability of successful registration. The push, in our view, would involve governments funding the otherwise prohibitively expensive pivotal Phase III trials for at least one indication. Push incentives lower R&D costs, barriers to entry, and are particularly useful for attracting small and medium enterprises with limited funds.[7] However, developers subsidised in this way alone may lack the motivation, and critical expertise, to successfully manage Phase III trials. Hence a 'pull' is required to engage larger companies that have extensive clinical trial expertise and global marketing reach.

One such 'pull' would prescribe a guaranteed market for an antibiotic via government purchase of a defined supply for national stockpile and biodefense purposes; as has been the case in risk management of pandemic influenza and anthrax. Henry Waxman, Chair of the House of Energy and Commerce Committee, has proposed another 'pull' in his bill "Generating Antibiotic Incentives". This would give certain antibiotics five extra years of patent protection from generic competition to improve the business case for R&D. The bill would also empower congress to enforce review of critical new antibiotics by the FDA. In addition, the FDA could consider designation of life saving antibiotics as a special regulatory

[6] "Policies and incentives for promoting innovation in antibiotic research", LSE Health, London School of Economics & Political Science, Sept. 2009.

[7] BMJ 2010; 340: c2115

class (similar to orphan drugs). “There is a market failure,” Waxman has said, “we need to look at ways to spur development of this market.”[8]

Such a system would make the licensing of biotech and academic candidate antibiotics much more attractive to pharma. The promise of both immediate (stockpile) and more sustained (patent lifetime) revenues, plus subsidised de-risking of Phase III development would allow small companies to go to the public markets more easily. The approach would also encourage the formation of new biotech ventures, providing a healthier climate for fundamental academic research.

Governments would get a significant economic return on investment — making savings, for example, on reductions in the estimated 2 million patients in the EU who catch hospital-acquired infections every year (of which 175,000 die). The US-based Alliance for the Prudent use of Antibiotics has estimated the cost of antibiotic resistance in US hospitals at greater than $20 billion annually, adding one to two weeks extra stay in hospital per patient. Directly subsidizing drug companies may be unpopular in many quarters, but it is necessary to bridge the gap between the high value of new antibiotics to society and the low returns they provide to drug companies

“Pull-only” incentives, such as that proposed by Waxman, return financial rewards only after a drug has been developed. However, there is normally a decade or more between the decision to engage in antibiotic R&D and commercial returns, so the developer bears all the risk. The LSE push-pull incentive, with addition of Waxman’s five year patent extension for antibiotics with a novel mode of action seems to us a clear front-runner.

Looking beyond the US and EU, incomes in India, China, and Brazil, are rising and access to antibiotics is growing along with the incidence of resistance. The FDA is seen as the global gold standard regulatory agency, yet Waxman’s bill requires cultural and structural change at the FDA. Unless we see leadership from the US soon, antibiotic developers (especially those in smaller companies) may simply chose to ignore the FDA. A company could obtain approval in Europe under the European Medicines Agency (EMA), and then use that to drive approvals in other countries. For example, doripenem from Johnson & Johnson is approved for the treatment of nosocomial pneumonia in virtually every country except the US. Of course, this will only work if the EMA continues to allow affordable, timely trial designs for key antibiotic indications, in contrast to the FDA’s lurch in the opposite direction of more costly, larger cohort studies to prove drug superiority over an existing antibiotic.

Finally, the recently formed Trans-Atlantic Task Force on Antimicrobial Resistance (TATFAR) held a face-to-face meeting on March 23 to finalise a draft proposal to the EU and US that will define areas of future cooperation and policy alignment between industry, governmental agencies, the FDA and EMA. This long awaited proposal[9] and the push-pull model singled out above require urgent translation into policy. The impending health crisis of antibiotic resistance is a global one and requires global action before we lose in the 21st century one of the most valuable discoveries of the 20th century.

[8] New York Times Nov 6 2010

[9] http://www.ecdc.europa.eu/en/activities/diseaseprogrammes/TATFAR/Pages/Documents.aspx

Appendix 5 – Antibiotics approved for use in animals (as 2012)

Category	Active constituent
Aminoglycosides	Apramycin
	Dihydrostreptomycin
	Framycetin Sulphate
	Gentamicin Sulphate
	Neomycin Sulfate
	Spectinomycin AS
Amphenicols	Chloramphenicol
	Florfenicol
Antiprotozoans	**3,5-Dinitro-O-Toluamide**
	Amprolium
	Nicarbazine
	Robenidine
Cephalosporins	Cefadroxil
	Ceftiofur
	Cefuroxime NA
	Cephalexin
Glycophospholopids	Flavophospholipol
Lincosamide	Clindamycin AS
Lincosamide	Lincomycin
Macrolides	Erythromycin
	Kitasamycin
	Oleandomycin AS
	tilmicosin
	Tylosin Tartrate
Miscellaneous	Novobiocin Sodium
Miscellaneous	Tiamulin Furarate
Nitrofurans	Nitrofurazone
Nitroimidazole	Dimetridazole
Nitroimidazole	Metronidazole
Olaquindoxalines	Olaquindox
Oligosaccharide	Avilamycin
Penicillins & Beta Lactamase	Procaine Penicillin
	Amoxycillin Trihydrate
	Ampicillin
	Benzyl Penicillin
	Clavulanic Acid As
	Cloxacillin
	Penethamate Hydriodide
	Potassium Clavulanate
	Polymixin
	(Cont next page)

Category	Active constituent
Polyethers/Ionophores	Lasalocid Sodium
	Maduramicin
	Monensin Sodium
	Narasin
	Salinomycin Sodium
	Semduramycin Sodium
Polypeptides	Bacitracin Zinc
	Polymyxin B Sulfate
Quinolones (only used in non-fod animals)	Enrofloxacin
	Marbofloxacin
	Orbifloxacin
	Difloracin
Streptogramins	Virginiamycin
Sulphonamides Triomethoprim	Phthalylsulfathiazole
	Silver Sulphadiazine
	Sulfacetamide Sodium
	Sulfadiazine
	Sulfadimidine)
	Sulfadoxine
	Sulfamerazine
	Trimethoprim
Tetracyclines	Chlortetracycline Hydrochloride
	Doxyxycline HC
	Oxytetracycline Hcl

Appendix 6 – Response to specific questions in preparation for this submission

The Government released the JETACAR report on 22 October 1999. The 22 JETACAR recommendations fall into five main categories:

- regulatory controls aimed at ensuring responsible use of antibiotics in humans and food-producing animals;
- monitoring and surveillance of the use of antibiotics and changes in antibiotic resistance patterns;
- infection prevention strategies and hygienic measures to reduce the need for antibiotics;
- education, including prudent-use codes of practice; and
- further research into antibiotic use and alternatives to antibiotics.

1. *Do you know when the antimicrobials that are deemed significant to humans where scheduled to S4, and who developed /enacted this law or policy?*

It stemmed from the above report. This recommendation was implemented by the Commonwealth Depart Of Health through The National Drug and Poison Scheduling Committee (NDPSC) if you want more information about it I will suggest

2. *Focusing only on the antibiotics that are approved for use as a food additive / growth promotant in animals; who would have data (DAFF or APVAP or other) on the usage levels (%) or prevalence for each of the major meat industries – Beef, Pork, Poultry.*

The APVMA last published such information in 2003/04 see the link below
http://www.apvma.gov.au/publications/reports/docs/antimicrobials_1999-2002.pdf

We are collating information for 2005-2010. This will be published in the first quarter of 2012.

I don't know what info major meat organisations hold. DAFF will rely on APVMA for info.

3. *Are there any laws/policies/regulations or controls regarding the use of these approved antibiotics other than labeling requirements?*

Control of use
The APVMA is responsible for the evaluation and registration process and for regulation of antibiotics up to and including the point of sale. While the scope of the APVMA does not extend to controlling product use, the conditions of use specified by APVMA during product registration form part of the state and territory control-of use regimes. State/Territory health, agriculture and primary industries departments provide further controls over the supply and use of the products, through relevant legislation:

- health legislation - enables registered veterinarians to prescribe PARs, licenses sellers of PARs and regulates conditions of supply of PARs, including scheduling classifications;
- health, agriculture/ primary industries legislation - allows registered veterinarians to practise through registration by veterinary surgeons boards under veterinary

surgeons legislation, which regulates professional standards and behaviour, including the responsible use of drugs.

- agriculture/primary industries legislation - enables control of the use of registered products, off-label use, trace-back and regulatory action associated with violation of permitted residue levels.

Veterinarians are allowed by law to 'off-label'. Off label is prescribing, using or authorising a client to use a registered drug or veterinary chemical in a manner outside the range of uses permitted by the approved label directions - including species of animal, dosage, treatment interval etc. (but not contrary to a specific label restraint). Veterinarians are permitted to exercise professional judgement in the 'off-label' use or supply of most drugs or other veterinary medicines.

This gives veterinarians access to beneficial drugs which may be registered for human use or which have limited registration for veterinary use. A number of legal limits have been placed on the 'off label' prescribing of drugs by veterinarians under national control-of-use principles adopted by most states and territories. These primarily relate to treatments for defined food-producing species (excluding horses), and are less stringent for companion animals. In most jurisdictions use of any product for companion animals is permitted, but supply for their treatment is usually restricted to human pharmaceuticals or products compounded by the veterinarian or on the veterinarian's prescription. These limits generally include:

- a ban on the use of unregistered products, to treat food-producing animals, with the exception of single animals
- a limitation on 'off-label' use, prescribing or authorising for food-producing animals of drugs and other veterinary chemicals unless they are already registered in at least one major food producing species
- a ban on use (or prescription/authorisation) contrary to any instructions under a "Restraint(s)" heading on a product label
- a requirement to ensure all treated animals are adequately identified, sufficient to last until the expiry of any relevant withholding period; ƒ A ban on formulating, dispensing or using a veterinary chemical, registered for oral or external use, as an injection.

There are a number of programs administered by various authorities that monitor the use and effectiveness of antimicrobial control strategies. Veterinarians, as the prescribing professionals, play a key role in ensuring prudent use of antimicrobials consistent with species specific judicious and prudent use guidelines developed by the Australian Veterinary Association (AVA). In all cases it advocates that when a decision is reached to use antimicrobials for therapy, veterinarians should strive to optimise therapeutic efficacy and minimise resistance to antimicrobials to protect public and animal health. The AVA also has in place a Code of Practice for the use of antimicrobial drugs in food animal veterinary practice. The Code aims to raise awareness among veterinarians of antimicrobial resistance and minimise the development of resistance through the responsible use of antimicrobial agents, particularly antibiotics.

Farmers participate in various on-farm programs that require them to declare the veterinary treatments their livestock have received. Food safety issues are monitored by various commercial bodies plus State and Commonwealth Government agencies through the application and monitoring of maximum residue limits. The APVMA also administers the Adverse Experience Reporting Program that allows the APVMA to monitor the performance of veterinary medicines including antibiotics