

**THE COMMONWEALTH GOVERNMENT
RESPONSE TO THE REPORT OF THE
JOINT EXPERT TECHNICAL ADVISORY
COMMITTEE ON ANTIBIOTIC RESISTANCE
(JETACAR)**

August 2000

**Commonwealth Department of Health and Aged Care
Commonwealth Department of Agriculture, Fisheries and Forestry - Australia**

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SUMMARY

The Commonwealth Government acknowledges the threat from antibiotic resistant organisms to the health and economic prosperity of the Australian population, and it strongly supports the intent of the recommendations from the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR). To implement its response, the Government will establish:

- An Expert Advisory Group on Antibiotics (EAGA), under the auspices of the National Health and Medical Research Council (NHMRC), to provide continuing advice on antibiotic resistance and related matters; and
- An Interdepartmental JETACAR Implementation Group to oversight and coordinate the continuing Government response to the JETACAR, to respond to the policy advice received from the EAGA, and to seek funding for implementation purposes.

INTRODUCTION

This document constitutes the Commonwealth Government response to the report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) *The use of antibiotics in food-producing animals: antibiotic-resistant bacteria in animals and humans*.

There has been increasing public concern about the threat posed by antibiotic-resistant bacteria to human health and the selective effect of agricultural use and medical over-use of antibiotics in increasing the prevalence of resistant bacteria.

In December 1997 the Minister for Health and Family Services and the then Minister for Primary Industries and Energy established the JETACAR. In broad terms, the committee was asked to assess the scientific evidence for the link between the use of antibiotics in food producing animals and the emergence of antibiotic-resistant bacteria and their spread to humans, and to develop recommendations for appropriate future management of antibiotic use.

Stakeholder consultation was a two stage process. Initially, the JETACAR consulted 52 key stakeholders and received 23 submissions. A draft report was released to key stakeholders in March 1999 and a further 35 submissions were received and considered by the committee.

The Ministers released the final report of the JETACAR in October 1999. A steering committee was then established to develop a Commonwealth Government response. After careful consideration the Government now puts forward its response to the 22 recommendations of the JETACAR. The Government believes this response to be a balanced approach that considers the impact of issues and recommendations on industry, agriculture, consumers, health professions and the health system, and other key stakeholders.

Further consultations are in progress to establish and justify the full costs of implementing the JETACAR recommendations. Although the costs would be considerable, a more strategic approach to the control of antibiotic resistance would not only be of benefit to human health, but also strengthen Australia's capacity to compete on the world food market, with quality products.

1. GENERAL COMMENTS

The Government congratulates the JETACAR on completion of a very difficult task, and thanks the various stakeholders for their valuable input into the processes that led to the JETACAR report and to this Government response. The Government will now work with stakeholders to refine, further develop or implement the recommendations contained in this document – *The Commonwealth Government response to the report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR)*.

For the purpose of this response the Government is of the view that “antibiotics” should be defined as antibacterial agents (including ionophores) but not including antiprotozoals, antifungals, antiseptics, disinfectants, antineoplastic agents, antivirals, immunologicals, direct-fed microbials or enzyme substances. Notwithstanding the use of this definition with respect to the recommendations of the JETACAR, the Government notes that similar considerations about resistance may be applied appropriately to other antimicrobial agents.

With respect to the scientific evidence-base, the Government acknowledges the comment by the JETACAR that the levels of evidence were variable for the various bacteria and antibiotic combinations. It also notes that new evidence has continued to emerge since the literature review was completed in late 1998 and that these data generally reinforce the case that antibiotic use in animal production can affect human health. However, the Government is also cognisant of the comment by the JETACAR that the use and overuse of antibiotics in human medicine is the major factor contributing to the development of antibiotic resistance.

In this context, the Government acknowledges the expert assessment of the JETACAR in reaching its overall conclusions and accepts that recent scientific literature continues to support the findings of the committee. The Government therefore accepts the advice from the JETACAR that, after considering the whole area of the occurrence of antibiotic resistance and its importance in human and veterinary medicine, that there was evidence for:

- the emergence of resistant bacteria in humans and animals following antibiotic use;
- the spread of resistant animal bacteria to humans;
- the transfer of antibiotic-resistance genes from animal bacteria to human pathogens; and
- resistant strains of animal bacteria causing human disease.

The JETACAR agreed that it was important to report these matters to Government and make a series of recommendations about the use of antibiotics in human and veterinary medicine because remedial action taken now can reduce future adverse effects. The Government notes that a number of other countries are taking action on the same basis.

The JETACAR identified four factors that influence emergence and spread of antibiotic-resistant bacteria: antibiotic load; antibiotic regimen; bacterial load; and prevalence of resistant bacteria. Based on these factors and the scientific findings the JETACAR proposes an antibiotic resistance management program that focuses on both animal and human use of antibiotics in Australia.

The Government supports the fundamental thrust of the five key elements of the proposed program and undertakes to promote their application in both human and animal medicine, and in other areas of antibiotic use:

- Regulatory controls (recommendations 1-9);
- Monitoring and surveillance (recommendations 10 – 11);
- Infection prevention strategies (recommendations 12-14);
- Education (recommendations 15-17); and
- Research (recommendation 18).

In addition, the JETACAR makes four other recommendations. Of these, 19 and 20 deal with communicating the issues surrounding antibiotic resistance to stakeholders and the general public while 21 and 22 refer to coordination and implementation of the various components of the program. The Government's view is that a successor to the Working Party on Antibiotics (WPA), to be named the Expert Advisory Group on

Antibiotics (EAGA), should provide advice to Government on each element of the antibiotic resistance management program. By virtue of its expert advisory role this group will assist in facilitating effective cross-portfolio action and inform policy initiatives inclusive of appropriate stakeholder input.

While the Government may propose slightly different mechanisms or alternative approaches in this response than suggested by the JETACAR, the overall intent to improve communication and provide strategic direction for reducing the impact of antibiotic overuse or misuse is supported.

The Government recognises that antibiotic resistance is a problem of increasing global significance. This message is conveyed clearly through the scientific literature and a number of major reviews similar to the JETACAR Report, as well as at international conferences. The World Health Organisation (WHO) hosted major meetings in Berlin in 1997 and Geneva in 1998. Currently, considerable debate is focussed on the development of a WHO Global Strategy for the Containment of Antimicrobial Resistance. A draft WHO document, *Recommendations for the prudent use of antimicrobials in food producing animals*, is under discussion. As well as WHO activity, discussions are under way between the Food and Agriculture Organisation (FAO) and the Office International des Epizooties (OIE), the animal health equivalent of WHO. The OIE is producing a major document outlining the issues and approach that should be taken when OIE member countries consider antimicrobial use in animals and the antimicrobial resistance issue.

It is clear that governments and international animal and human health agencies are very concerned with the trends in antimicrobial resistance and are taking steps to review and analyse the issues with a view to instituting appropriate measures. In recognition of this, Australia needs to respond to this problem with strategies that are consistent with and complementary to global initiatives. The Government finds that, fundamentally, the JETACAR's recommendations aim to meet this objective.

The JETACAR covered extensive ground within its terms of reference. However, the Government notes some issues that fall outside the scope

of the JETACAR and this Government response, and is mindful that these issues may contribute to or influence the overall problem of antibiotic resistance. For these gaps to be addressed by governments and stakeholders, national as well as international strategies may be required. The need for more comprehensive data on antibiotic resistant genes and bacteria, and particularly nosocomial infections, is dealt with specifically in the following pages of this report. Linked to this is a need to examine the impact and costs of resistant infections on health services including pathology and out-of-hospital care, and consequential national productivity, quality of life, morbidity and mortality in Australia. On another level, the use of antibiotics in horticulture (eg. crop spraying) or aquaculture and the influence these may have on the overall selection pressures leading to further emergence of antibiotic resistance remain areas for further consideration. The effect of these and other uses of antibiotics on human defined daily dose (ddd) and the relationship of this to the emergence of antibiotic resistance is also an area requiring further clarification.

Detailed studies of the costs and benefits to the Australian community of implementing various strategies to reduce antibiotic resistance are also required.

With all of the above points in mind, the Government provides the following responses to specific recommendations of the JETACAR report.

2. REGULATORY CONTROLS (Recommendations 1-9)

Recommendation 1

That Australia adopt a conservative approach to minimise the use of antibiotics in humans and animals and, to further this policy, that infeed antibiotics used in food-producing animals for growth promotant purposes, or other routine uses where duration and dose level are the same, or very similar, should not be used unless they:

- **are of demonstrable efficacy in livestock production under Australian farming conditions; and**
- **are rarely or never used as systemic therapeutic agents in humans or animals, or are not considered critical therapy for human use; and**
- **are not likely to impair the efficacy of any other prescribed therapeutic antibiotic or antibiotics for animal or human infections through the development of resistant strains of organisms.**

Response

In light of the overall conclusions of the JETACAR, and recognising the importance of antibiotic resistance in human and veterinary medicine, the Government accepts Recommendation 1.

The Government is of the view that its following response to the JETACAR recommendations gives practical expression to the discharge of the general principles expressed by this recommendation.

Recommendation 2

That the National Registration Authority (NRA) reviews the use of antibiotic growth promotants currently registered in Australia that do not appear to fulfil the criteria listed in Recommendation 1 in terms of their impact on human and animal health, using a risk analysis approach, including a cost-benefit analysis. The priority determined should be consistent with recent international reviews and use the conditions outlined in Recommendations 1 and 4.

It is recommended that the priority of the review at this stage be:

- 1. glycopeptides (avoparcin is currently under review by NRA)**
- 2. streptogramins (virginiamycin)**
- 3. macrolides (tylosin, kitasamycin, oleandomycin)**

This review is to be completed and outcomes acted upon within three years. Growth promotant claims of such antibiotics that do not pass the review process should be phased out of use within one year subject to consultation with relevant stakeholders.

It is also recommended that the NRA should review the prophylactic use of avoparcin and virginiamycin in animals and the possible public health impact of this use using the parameters outlined in Recommendation 4. In order that the reviews are performed in a timely manner, it is further recommended that the federal ministers of health and agriculture ensure an adequate allocation of resources to the NRA to facilitate the rapid completion of the task and implementation of changes.

Response

The Government accepts that these reviews should be progressed in a timely way, and has asked the NRA to indicate appropriate timeframes. The NRA has advised that:

- the avoparcin review, which was nearing completion, is suspended as both of the registrants withdrew the product from the market. Registration and approval ceased on 30 June 2000;

- a review of Virginiamycin will commence during the second half of 2000, and be completed by December 2001; and
- a review of the macrolides will commence in the first half of 2002, and be completed by June 2003.

The NRA has indicated that the reviews will be in accordance with the criteria in Recommendations 1 and 4.

The NRA has informed the Government that it intends to fully satisfy this recommendation and will consider reviews of other antibiotics at a future time.

Recommendation 3

That an appropriate government authority or authorities license, or otherwise control, all importers of antibiotics (for any purpose other than individual human patient use). Licensed importers must provide import returns and distribution, and information based on amounts of active ingredient of agents intended for animal use, to the National Registration Authority, and to the Therapeutic Goods Administration for agents intended for human use.

It is also recommended that a much stronger audit trail for antibiotics from the importer to the end-user be implemented, particularly in the veterinary field, and that the aggregated information on import quantities are made available for scrutiny by relevant authorities and the results are made public.

Response

The Government accepts the recommendation that there should be a much stronger audit trail for antibiotics from the importer to the end-user, particularly in the veterinary field, but is not convinced that the licensing of importers would provide all of the required information about end-use. The Government notes that information from the distribution chain may help identify illicit products or diversion, but it is end-use information

which will guide the regulators to risk areas for resistance development and transfer.

Accordingly, the Government proposes that the Working Party on Antibiotics (WPA) or its successor, the National Registration Authority and the Therapeutic Goods Administration (TGA) work cooperatively and ask medical and veterinary professional groups and user industry groups to draw up proposals for a scheme for the reporting and audit of the end use of antibiotics in humans and in animals. A reliable and transparent scheme conducted by the user industries and professions might avoid the need for the licensing of importers and elaborate distribution tracking.

Recommendation 4

That the National Registration Authority (NRA) evaluate all new applications, major extensions of use and any reviews of currently registered antibiotics for use in animals by applying the recently redrafted Special Data Requirements (Part 10 of the *Vet Requirements Series: Guidelines for Registering Veterinary Chemicals*, NRA 1998), which includes a risk analysis of microbial resistance safety.

Response

The Government supports this recommendation.

The NRA has advised that the redrafted Special Data Requirements for submissions to the Working Party on Antibiotics (Part 10) guideline was issued in June 2000. The redraft is based on risk assessment principles and on Appendix 4 of the JETACAR report and was issued after consultation with both the WPA and members of the veterinary pharmaceutical industry.

The NRA is also involved in a VICH (International Cooperation on the Harmonisation of Technical Requirements for the Registration of Veterinary Medicinal Products) working group preparing a guideline on pre-approval studies related to the potential transfer of antibiotic

resistance to humans, and expects in due course to adopt the international guideline.

Recommendation 5

That a recognised expert authority (the Working Party on Antibiotics or its successor) defines threshold (or trigger) rates of resistance for antibiotics registered for use in animals and circumstances where usage should be investigated and mitigation proceedings instigated where appropriate. In addition, resistance prevalence data should be included in the product information and this information should be updated on a five-yearly basis.

Response

The Government agrees with the basic intent of the recommendation, which is to monitor and limit transfer of antibiotic-resistance genes and bacteria from animals to humans. The recommendation has qualified support.

The recommendation is in two parts. As to the first part, the Government accepts that the WPA or its successor review the results of surveillance of antibiotic resistance associated with antibiotic use in animals and identify cases where increases in resistance may indicate increased risk of transfer of resistance to humans. The prime focus of such surveillance would be on bacteria and antibiotic resistance genes with the potential to contribute to human health risk. The outcome of this work would initially be advice to appropriate regulatory bodies (eg. the NRA) to initiate a special review of the relevant antibiotic.

The second part of the recommendation relates to the inclusion of resistance prevalence data in product information, updated five yearly. The NRA queries the usefulness of such data on human pathogens for users of veterinary antibiotics, and suggests instead that the antibiotic resistance data associated with antibiotic use in animals be reported at least five yearly to the NRA and the WPA or its successor for monitoring

and action as outlined in the first part of the recommendation. The Government accepts this approach.

Recommendations 6, 7 and 8

Response to 6,7, 8

The Government accepts and supports the intent of Recommendations 6, 7 and 8. Specific responses to these three recommendations are also given below.

Recommendation 6

That all antibiotics for use in humans and animals (including fish) be classified as S4 (prescription only).

Response

The Government accepts the concept that all antibiotics for use in humans and animals (including fish) be classified as S4 (prescription only). However the Government is of the view that certain antibiotic products might be exempted from this scheduling class where the relevant regulatory authorities (NRA and TGA) and the National Drugs and Poisons Schedule Committee (NDPSC) assess the antibiotic products as having a low and acceptable risk of promoting antibiotic resistance. Further, the Government notes that a review of the NDPSC is currently being completed, and scheduling of veterinary antibiotics may be affected by outcomes of that review.

Government believes that in implementing controls of in-feed and drinking water use of antibiotics for animals (including fish) full account should be taken of established industry codes that are implemented through third party audited quality assurance programs incorporating veterinary authorisation.

Recommendation 7

That the Agricultural Resource Management Council of Australia and New Zealand (ARMCANZ) implement a harmonised approach by all States and Territories in Australia (including clarification of responsibilities) to the control of use of veterinary chemicals, including antibiotics.

Response

The Government will utilise the ARMCANZ process to facilitate harmonisation of State and Territory control of antibiotic use in food animal species. This process has begun.

Recommendation 8

That, following the implementation of Recommendation 7, the relevant State and Territory health agriculture/primary industries legislation is amended to make it an offence to prescribe and/or use a veterinary chemical product contrary to a National Registration Authority (NRA) label restraint, unless authorised to do so by an NRA permit.

Response

The Government supports the recommendation. When recommendation 7 (harmonisation of control of use of veterinary chemicals) is in place, Governments should undertake the necessary legislative reform to ensure uniform and enforceable Australia-wide control of antibiotic use.

Recommendation 9

Similar to recommendations made in veterinary medicine, it is recommended that the Therapeutic Goods Administration (TGA) implement the following:

- inclusion of microbial resistance safety data, including the propensity for promoting resistance and cross-resistance, as a basic requirement of the assessment of all new antibiotics by the TGA, with adoption of similar data requirements to those required in the registration of veterinary antibiotics (Recommendation 4);
- definition by a recognised expert authority (Working Party on Antibiotics or its successor) of the threshold rates of resistance to registered human antibiotics and circumstances where usage should be investigated and mitigation procedures instigated where appropriate; and
- inclusion of national human antibiotic-resistance prevalence data in the product information and updating on a five-yearly basis.

Response

The Government accepts the recommendation. The TGA will consult with relevant stakeholders and prepare advice for the Minister of Health and Aged Care on the implementation of this recommendation, including any changes to legislation.

3. MONITORING AND SURVEILLANCE (Recommendations 10-11)

Recommendation 10

That a comprehensive surveillance system be established incorporating passive and active components measuring incidence and prevalence of antibiotic-resistant bacteria and resistance genes, covering all areas of antibiotic use. To achieve this aim, it is further recommended that a multidisciplinary taskforce of relevant experts be formed by the federal ministers of health and agriculture to design, cost and recommend funding mechanisms and management systems for reporting and analysis of antibiotic resistance data in Australia.

The overall surveillance system should include medical (including nosocomial), food-producing animal and veterinary areas, with particular emphasis on the establishment of food-chain (including imported food) and environmental connections, and include molecular studies of resistance genes. The efforts of the taskforce should be directed at adopting a uniform, systematic and synergistic approach across all areas by utilising, enhancing and extending currently available systems and organisational structures.

Response

The Government supports the overall concept of improving the surveillance of antibiotic-resistant bacteria and resistance genes across the food chain and in human medicine, but emphasises the importance of further investigations to determine the most appropriate and cost-effective option for national integration of animal and human surveillance data.

The Government proposes that a feasibility study be commissioned to determine the way forward. The Departments of Agriculture, Fisheries and Forestry (AFFA) – Australia and Health and Aged Care will be jointly

responsible for scoping, commissioning and managing the study, by whatever mechanisms they deem suitable. The scoping should define the parameters necessary to address the overall antibiotic resistance issue. The feasibility study should include options for the design, costing, funding and management systems for the reporting and analysis of data, and should include a cost-benefit analysis and appropriate options for a pilot study to trial the system. The two Departments will consult with the WPA or its successor, other expert organisations and industry to develop a system that makes best use of existing surveillance systems and provides uniform and useful data. The study is to be completed within twelve months of the release of this Government response.

The scoping and feasibility study will be funded and resourced jointly by the two Departments.

Recommendation 11

That a comprehensive monitoring and audit system for antibiotic usage be established that covers all areas of antibiotic use. To achieve this aim, it is recommended that the federal ministers of health and agriculture form a multidisciplinary taskforce of medical, veterinary, industry and regulatory experts (including Customs, Therapeutic Goods Administration, Department of Health and Aged Care, National Registration Authority and Department of Agriculture, Fisheries and Forestry - Australia) to refine the current antibiotic import data collection and audit process, and make recommendations to relevant authorities for developing methods of monitoring and auditing usage.

Response

The Government supports the principles of accountability and audit trail inherent in this recommendation, but notes that it overlaps with Recommendation 3. If the proposals under the response to

Recommendation 3 are successful, the Government considers that Recommendation 11 will be, for the most part, addressed.

The Therapeutic Goods Administration currently issues permits and collects end-use data to monitor the antibiotics imported into Australia. The Government is supportive of this existing scheme and will establish an interdepartmental working group consisting of representative of the TGA, Customs, NRA, and AFFA to refine the existing systems for recording the use and distribution of antibiotics by importers. This group will seek advice from the WPA or its successor and stakeholders in order to develop options for end-use schemes for auditing and improving import data collection, and report its findings to Government within 12 months.

The Government currently collects data on prescribing (not usage) of antibiotics for human use through the Pharmaceutical Benefits Scheme (PBS). In the 2000/2001 budget Government committed additional resources for strategies to improve this data set. The Government recognises that monitoring antibiotic usage in humans is both costly and difficult, and that additional benefits will flow through public education and best practice in prescribing. See also the responses to Recommendations 15-17 and 19-20.

4. INFECTION PREVENTION STRATEGIES AND HYGIENIC MEASURES (Recommendations 12-14)

Recommendation 12

That ‘hazard analysis critical control points’ (HACCP)-based food safety procedures be implemented as a means of reducing the contamination of food products with foodborne organisms, including antibiotic-resistant organisms, and that these programs also address on-farm infection control.

Response

The Government supports this recommendation. The Government supports the role of industry based codes of practice which may include HACCP elements, as appropriate, in addressing identified risk factors in food animal production systems. It recognises the benefits of these activities: improvements to public health and reduction of food borne illness through lower levels of pathogens in food, including bacterial contamination; reduction of overall bacterial load in humans; and improved control over the spread of antibiotic resistant bacteria.

The Australia and New Zealand Food Authority (ANZFA) and AFFA are already progressing strategies and policies in this area. AFFA has been at the forefront of HACCP development internationally through the implementation of industry based HACCP programs for the slaughter of animals in abattoirs. These programs focus on improving food safety by reducing microbiological contamination of carcasses. ANZFA has been working with State and Territory Health Departments since 1995 to develop new food safety standards under the Foods Standard Code of Australia and New Zealand. A draft *Food Safety Program Standard* based on HACCP principles has been developed and the necessary infrastructure is established to support implementation of the draft standard in a consistent fashion.

ANZFA has recommended to the Australia New Zealand Foods Standard Council (ANZFSC) that the food safety programs be introduced over a six year period based on risk, beginning with high risk businesses. At each stage of implementation adequate consultation and evaluation will occur. The Government will review its position after considering the outcomes of costs and efficacy studies being undertaken on food safety programs by the Department of Health and Aged Care. The Government is working with the States and Territories, ANZFA, industry, public health and consumer groups in undertaking these studies.

There are already highly developed mechanisms, material and infrastructure to facilitate implementation of the recommended control strategy. Implementation of the recommendation post the farm gate will involve ANZFSC, ANZFA, State and Territory Health Departments, Commonwealth and State and Territory Cabinets, local Government, industry associations, and food businesses.

Recommendation 13

That where the intensive animal industries (such as meat chicken, pig, feedlot cattle and aquaculture) currently depend on the use of antibiotics to improve feed conversion and prevent and treat disease, cost-effective nonantibiotic methods to increase productivity and prevent disease should be developed by these industries. In relation to this, it is further recommended that the federal ministers of health and agriculture explore additional funding alternatives for this work, taking into account the current efforts of the animal industry research and development organisations.

Response

The Government encourages research and development activities through established R&D Corporations to develop cost effective and safe food animal production systems and will encourage further research efforts to help decrease food animal industry dependence on antibiotic use.

The Government acknowledges the independence of the animal industry in determining research priorities, and their efforts to date to reduce industry dependence on antimicrobials through, for example, housing and disease control research. The Government will, however, be taking steps to ensure that all animal industry R&D funding organisations are fully aware of the concern with which the Government views the issue of antimicrobial resistance.

Further comments on funding for research are included under Recommendation 18.

Recommendation 14

That the Department of Health and Aged Care examine current surveillance activities for hospital-acquired (nosocomial) infections, particularly for antibiotic-resistant strains; and that the department work with stakeholders (including the States and Territories) to further develop a comprehensive and standardised national system for monitoring nosocomial infections that will facilitate:

- **earlier recognition of a public health problem;**
- **improvements in infection control and hygiene measures; and**
- **the timely development of national standards, guidelines and practices for both surveillance and infection control in the health care setting.**

Response

The Government supports and is already taking action in response to this recommendation. The Government has initiated a national scoping study to examine existing surveillance of nosocomial infections in Australia. The study is funded and managed through the National Centre for Disease Control (NCDC) and will provide vital information for future national planning of nosocomial surveillance. Findings from the scoping study will be referred to the Departments of Health and Aged Care and Agriculture, Fisheries and Forestry - Australia and to the WPA or its successor for

consideration in the overall planning process for the coordinated resistance management plan for human antibiotics (refer to Recommendations 21 and 22). The Government will consult with the States and Territories and other stakeholders to develop an affordable and useful national system for monitoring nosocomial infections, building on existing systems and harnessing current expertise.

A review of the national infection control guidelines pertaining to the health care setting is also well under way by the NCDC. The Government will review national infection control guidelines on a regular basis under the auspices of the Communicable Diseases Network Australia and New Zealand (CDNANZ) and the NHMRC.

In addition, the Government will work with the WPA or its successor, the Public Health Laboratory Network (PHLN), the CDNANZ and health professions to develop national consistency with case definitions for nosocomial infections including antibiotic-resistant bacteria, uniform laboratory testing standards, and national policies on monitoring of individuals who are at high risk or susceptible to colonisation with antibiotic-resistant bacteria.

The NCDC will also work closely with the States and Territories through the CDNANZ to improve early recognition and reporting of nosocomial infections of public health significance, including vancomycin resistant enterococci (VRE).

The level of funding required to develop a national system of surveillance will be determined through the scoping study and the feasibility study described in the response to Recommendation 10. The Government will develop new policy proposals to seek necessary funds which cannot be met from existing resources.

5. EDUCATION (Recommendations 15-17)

Recommendation 15

That prudent use codes of practice for antibiotics be developed and regularly updated by medical and veterinary peak bodies, including learned societies, professional organisations, producer organisations, pharmaceutical companies and State/Territory medical and veterinary registration boards, and promulgated to their members. These codes of practice should be based on the principles articulated in this report.

Recommendation 16

That regularly updated ‘antibiotic use guidelines’, both human and veterinary, supported and endorsed by the appropriate professional organisations, the pharmaceutical industry and the federal and State and Territory departments of health and agriculture, are widely disseminated and adopted as a ‘standard of care’ by training institutions, and established as the benchmark for undergraduate and postgraduate teaching. The effectiveness of the ‘antibiotic use guidelines’ in ensuring prudent prescribing of antibiotics needs to be evaluated every five years.

Recommendation 17

That, as a priority, learned (medical and veterinary) and professional societies develop continuing educational programs on the issue of antibiotic resistance, including a focus on the prudent use principles, antibiotic use guidelines and alternatives to antibiotic usage.

Response to 15, 16 and 17

The Government supports the proposals in Recommendations 15 to 17.

The proposals are consistent with the National Medicines Policy and the Quality Use of Medicines (QUM) program. The community use of antibiotics in Australia is declining in absolute terms from a peak in 1994. This could indicate increasing professional and consumer awareness of the benefits of appropriate use. The experience gained from various approaches to effecting behavioural and attitudinal change in prescribing may well inform similar initiatives suggested by the JETACAR. The Department of Health and Aged Care will continue activities that focus on the need for further improvement in antibiotic use. The recommendations on the prudent use principles for antibiotics will be disseminated to a broad range of stakeholders, advisory and regulatory groups involved in the Pharmaceutical Benefits Scheme, including the Australian Pharmaceutical Advisory Committee, the Pharmaceutical and Rational Use of Medicines Committee, the Pharmaceutical Benefits Advisory Committee and the National Prescribing Service. These bodies will be asked to provide input on this issue, review existing antibiotic use guidelines for consistency with the prudent use principles and, if appropriate, publically endorse the principles and existing guidelines.

In addition, the JETACAR recommendations will be disseminated with a specific request to promote the quality use of antibiotics. Particular attention will be given to those organisations involved in evidence-based guideline development and in influencing clinical behaviour. It is widely agreed that dissemination of guidelines needs further support. The National Prescribing Service will be asked to highlight antibiotic prescribing in the new national therapeutics curriculum for undergraduates, in computer systems to provide decision support to health professionals, and in other activities.

Recent initiatives relating to PBS eligibility and the introduction of information technology have the potential to improve the monitoring of antibiotic use. Formal links will be established between those involved in antibiotic use surveillance and the PBS drug utilisation sub-committee.

Through AFFA and the Standing Committee on Agriculture Resource Management (SCARM) and ARMCANZ mechanisms the Government will

encourage stakeholders with an interest in the area of animal health to develop a coordinated and ongoing approach to implementing Recommendations 15 to 17. Non-government and Government bodies can contribute to various aspects of education on prudent antibiotic use within their respective communities. These include Avcare representing agricultural and veterinary chemical manufacturers, the NRA, the Australian Veterinary Association, the Council of Australian Veterinary Boards and State Veterinary Boards, the Post Graduate Foundation in Veterinary Science, Australian Veterinary Schools, State Departments of Agriculture, and peak industry bodies such as the Australian Lot Feeders Association and the Australian Cattle Council, the Australian Poultry Industry Association and the Australian Pork Producers Association.

6. FURTHER RESEARCH (Recommendation 18)

Recommendation 18

That all relevant research funding agencies be asked to give priority to research into antibiotic resistance, including:

- **alternatives to antibiotics for growth promotion;**
- **alternatives to antibiotics for prevention and treatment of infections (including vaccines);**
- **molecular epidemiology and mechanisms of gene transfer;**
- **population dynamics of antibiotic resistance;**
- **resistance epidemiology;**
- **pharmacoepidemiology;**
- **efficacy of interventions to reduce antibiotic prescribing and use;**
- **clinical efficacy studies; and**
- **rapid diagnostic tests.**

Response

The Government acknowledges that research into these areas plays an important and necessary role in controlling the emergence and impact of antibiotic resistance. The Government also acknowledges that antibiotic resistance is a global problem and that a large amount of research is generated overseas. Australia has access to much of this research and should continue to use this information to help guide our own research priorities and assist us in making evidence-based policy decisions.

Improvements to surveillance and monitoring as proposed in Recommendations 3, 10, 11 and 14 will provide information on antibiotic use and the emergence and extent of antibiotic resistance in Australia, and support more rapid policy responses.

In 2000/2001 the NHMRC will provide \$221.6 million for health and medical research. The Research Committee of NHMRC, which allocates the highest proportion of funds, does not routinely set aside funding for specific areas of research. The majority of funding is directed towards health and medical research applications that are investigator initiated and funding decisions are made on the basis of the scientific excellence as judged by peer review. Through this, the Research Committee seeks to maintain a strong research endeavour in all areas.

The NHMRC Strategic Research Development Committee (SRDC) has a role in developing strategic research capability in areas of identified importance to health care in Australia where the research effort is currently underdeveloped. In 1998/1999 the SRDC conducted a series of consultations with researchers, Government representatives, health care providers and consumers to assist in assessing and evaluating possible strategic research priorities for the new triennium. The issue of antibiotic resistance, and particularly antibiotic overuse in humans, was raised during this consultation with suggestions for a more targeted research effort in the new triennium. The JETACAR recommendations will be tabled for consideration at the first meeting of the new SRDC. The Government will pursue this matter with the NHMRC, and work with stakeholders to identify the priorities for research funding.

The Government will also support the WPA or its successor in taking a more pro-active role in identifying research priorities and informing the NHMRC and other Research and Development Corporations on directions for priority research. The Government encourages the WPA or its successor, professional bodies, industry and Governments to investigate ancillary options for research funding such as the establishment of cooperative research centres (CRCs), joint funded pilots of national significance, and investment by non-government organisations.

The issue of animal industry research has been considered under Recommendation 13.

7. COMMUNICATION (Recommendations 19-20)

The Government notes that Recommendation 19 and 20 overlap with Recommendations 15 to 17, and should form part of an overall education and communication strategy. In relation to each of these recommendations the Government suggests a strong advisory role for the WPA or its successor in developing appropriate communication and education strategies with the two Departments. Specific responses to Recommendations 19 and 20 are also given below.

Recommendation 19

That an ongoing funded education strategy be developed by the relevant federal/State/Territory departments with input from stakeholders to provide appropriately targeted information about infection, the role and benefits of prudent antibiotic use and the risks of overuse to the public, relevant professional bodies and stakeholders.

Response

The Government supports the development of further education campaigns to ensure that health professionals, industry and the community are well informed about the quality use of antibiotics and the risks and dangers of antibiotic overuse. It believes that further change in the prevailing views about appropriate use of these medicines is required to achieve improved health outcomes and a reduced number of adverse effects. The National Prescribing Service and the Quality Use of Medicines stakeholder communities will be involved in any new communication and education campaigns.

Recommendation 20

That a recognised expert authority (the Working Party on Antibiotics or its successor) assume responsibility for ensuring and coordinating the communication of data on antibiotic usage and prevalence of resistant bacteria to the public and other relevant stakeholders on a regular basis, taking into account the sensitivities of trade and other international implications.

Response

The Government agrees that there should be better coordination and communication of data to relevant stakeholders. The Departments of Agriculture, Fisheries and Forestry – Australia and Health and Aged Care should assume joint responsibility for the development of a communications strategy, inclusive of a publicly accessible WEB site and implementation of appropriate clearance mechanisms for data. The communications strategy should link into the education measures described in Recommendation 19, as well as proposals at Recommendations 15 to 17. The two Departments shall work with the WPA and stakeholders to identify and target information.

8. COORDINATION OF THE RESISTANCE MANAGEMENT PROGRAM

(Recommendations 21-22)

Recommendation 21

It is recommended to the Ministers of health and agriculture that:

- the current functions and membership of the Working Party on Antibiotics (WPA) be expanded to carry out the antibiotic risk management program outlined in earlier recommendations;**
- the administrative and reporting arrangements of the WPA (or its successor) be clarified so it can maintain its independent position and advise the Therapeutic Goods Administration (TGA) and the National Registration Authority (NRA) and other agencies/statutory bodies as required;**
- the coordination of the antibiotic risk management program across government portfolios and industry be provided with secure recurrent funding for the additional tasks outlined in Recommendations 1 to 20;**
- the WPA or its successor keep the regulatory framework for the use of antibiotics in human and veterinary medicine and food-producing animals under review and make appropriate recommendations to the regulatory authorities to review the uses of particular antibiotics, taking account of**
 - the importance of the drug or class of drug in human and veterinary medicine, and**
 - the potential for human exposure to antibiotic-resistant bacteria acquired from food-producing animals that are human pathogens or that can transfer their antibiotic resistance genes to human pathogens;**

- the WPA or its successor, the National Registration Authority and the Therapeutic Goods Administration develop appropriate procedures to ensure accountability and transparency of its activities, including established time-frames for reviews;
- the WPA (or its successor) develop a five-year strategic plan and an annual budget for its activities; and
- the operations of the WPA (or its successor) be subject to a five year independent review program.

Recommendation 22

That the Department of Health and Aged Care convene a working group to develop a fully coordinated resistance management plan for human antibiotics, incorporating the elements included in Recommendations 9, 10, 11, 14, 15, 16, 17, 18, 19 and 20. The plan so developed should be incorporated into the recommended functions of the Working Party on Antibiotics or its successor (see Recommendation 21).

Response to 21 and 22

The Government supports the general concepts and intent of these two recommendations.

The Government proposes that the WPA be reconstituted as an Expert Advisory Group on Antibiotics (EAGA) under the auspices of the NHMRC, with a balanced and technically expert membership reflecting human and veterinary antibiotic use patterns. The proposed terms of reference and operational procedures for such a group are at Appendix A to this report.

In addition, the Departments of Agriculture, Fisheries and Forestry – Australia and Health and Aged Care will establish an Interdepartmental JETACAR Implementation Group to facilitate and monitor implementation of the JETACAR recommendations, as modified in this Government response. The Implementation Group will facilitate the planning, coordination and implementation of the antibiotic resistance risk

management program proposed by the JETACAR, including those components identified in Recommendation 22. The plan should embrace current initiatives by governments, industry, medical establishments and professions, and other key stakeholders, and expand on these activities in the most cost effective and timely manner. The plan should also include processes for stakeholder consultation and participation and information sharing. The EAGA would have a strong advisory role in these activities.

The Government proposes that the EAGA be funded for three years in the first instance, with ongoing funding subject to the outcome of a review to be conducted two years into its term. Through the Implementation Group the Department of Health and Aged Care and the NHMRC, in collaboration with NRA and AFFA, will examine funding options to support an ongoing EAGA secretariat and to facilitate development and implementation of the comprehensive antibiotic resistance management program put forward by the JETACAR.

APPENDIX A

WORKING PARTY ON ANTIBIOTICS

Background

The Working Party on Antibiotics (WPA), currently a non-statutory committee administered by the Therapeutic Goods Administration (TGA), provides advice on antibiotic resistance to government authorities, including TGA, PBAC (Pharmaceutical Benefits Advisory Committee) and the National Registration Authority (NRA). In its response to Recommendation 21 of the JETACAR report, the Joint Steering Committee proposes that the WPA be reconstituted as an advisory panel under the NHMRC Health Advisory Committee with the working name “Expert Advisory Group on Antibiotics” (EAGA), as described below:

Expert advisory group on antibiotics

Draft Terms of Reference

1. The Expert Advisory Group on Antibiotics (EAGA) shall provide expert advice to Commonwealth, State and Territory governments and Commonwealth Statutory organisations on:
 - measures to reduce the risks of antibiotic resistance;
 - assessment of the risk of developing resistance to new and marketed antibiotics
 - public health implications of antibiotic resistance;
 - the monitoring of antibiotic use;
 - surveillance and monitoring of antibiotic resistance;
 - antibiotic use in medical and veterinary practice and food production;
 - relevant research and evaluation needs;
 - educational strategies; and
 - other matters relating to the control of antibiotic resistance in Australia.

2. The advice of the EAGA shall be based on an ongoing review of the relevant scientific literature, other available relevant scientific data, surveillance information and measures already adopted to minimise the risks of antibiotic resistance.

Membership

There will be 12 to 14 members, all with appropriate expertise in one or more of the areas of public health, microbiology, molecular biology, infection control, biochemistry/chemistry, medicine, and veterinary science. Other relevant expertise may be required and will be called on as necessary.

Membership will include:

- one member drawn from the NHMRC Health Advisory Committee;
- relevant nominees from the Commonwealth Department of Health and Aged Care (including TGA and Population Health Division), State and Territory Governments, the National Registration Authority, and the Commonwealth Department of Agriculture, Fisheries and Forestry - Australia; and
- recognised experts from the scientific community, including previous members of the Working Party on Antibiotics.

Operation and Budget

- The Expert Advisory Group is expected to meet up to four times a year.
- Agenda items will be raised by members of the group, with work plans approved by Council.
- An initial agenda item would be the consideration of advice on implementation of relevant recommendations from the JETACAR report, as outlined in the Commonwealth Government Response to the JETACAR Report.
- Provision of *ad hoc* advice to be minuted for Council information.
- Guidelines and other publications to be tabled for adoption by Council.
- Secretariat support will be provided from within the Office of NHMRC, and an annual operating budget will be provided by the Government to enable the EAGA to operate effectively.

- Membership and Terms of Reference should be reviewed on a regular basis. It is proposed that this occur two years into its first term, and at the end of each triennium if the EAGA is deemed to continue.
- Planning and outcome reporting should occur on an annual basis, in line with NHMRC and Department of Health and Aged Care reporting requirements.

Interim Arrangements

The current WPA should continue until EAGA has been constituted and membership finalised.

Coordinating Committee

An Interdepartmental JETACAR Implementation Group will facilitate and monitor implementation of the recommendations of the JETACAR report, working closely with the EAGA in its expert advisory capacity.