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3rd February 2013

We wish to make a submission on behalf of the Australian Society for Antimicrobials (ASA) to:

The Senate inquiry to investigate progress in the implementation of the recommendations of the 1999 Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR).

The Australian Society for Antimicrobials is a professional association whose membership is drawn from multiple disciplines, and includes Infectious Diseases Physicians, Microbiologists, Scientists, Pharmacists, Epidemiologists, Public Health Physicians and Veterinarians; members who professionally have committed their careers to furthering the acquisition and dissemination of knowledge in the field of antimicrobials.

The Society's stated aims include public demonstration of the need for an educated and considered approach to the use of antimicrobials; support for original Australian research in the study of antimicrobials and provision of advice to administrative, scientific, governmental and other bodies on matters concerning antimicrobials. Hence we feel our Society and membership, by bringing together such diverse participation, can provide a unique contribution to a national debate on the many pressing issues related to the community's use of antimicrobials and the resultant spread of antimicrobial resistance.

ASA also provides financial and organisational support for AGAR (the Australian Group on Antimicrobial Resistance), which, since 1985, has provided the only national longitudinal surveillance for resistance in staphylococci, enterococci, and Enterobacteriaceae.

Together with the Australasian Society for Infectious diseases (ASID), ASA convened the Antimicrobial Resistance Summit in Sydney in February 2011. The aim of the Summit was to update the work generated in the first JETACAR report, and with discussion and consensus, to help determine future strategies for control. The meeting was organised out of both Societies' concerns that the important recommendations of JETACAR had failed to be implemented and by the recognition of increasing antimicrobial use and spread of antimicrobial resistance worldwide and in Australia, affecting the medical, veterinary and agricultural sectors. The Society recognised that there was a lack of constituted bodies in Australia (unlike Europe and the United States) with a

capacity to bring together key groups in these sectors and to co-ordinate necessary surveillance, educational and regulatory activities.

The proceedings, and a cohesive call to action were published in the Medical Journal of Australia in 2011 (Gottlieb T, Nimmo G. Med J Austr. 2011; 194 (6): 281-283). The recommendations were based on the pillars that had been formulated in the original 1999 JETACAR report. As this document enunciates many of the points to be made related to issues of antimicrobial resistance, we have drawn on the conclusions of the proceedings in answering a number of the questions in the terms of reference for the Senate enquiry.

The 2011 Summit was effective in that it (voluntarily) drew together broad participation from key stakeholder groups, including veterinary sectors and consumer organisations, each independently recognising the serious implication of continuing antimicrobial resistance for their membership and activities, and if not addressed urgently, for Australia. We believe that the Summit was a stimulus to the formation in 2012 of the Antimicrobial Resistance Standing Committee (AMRSC) of the Australian Health Protection Principal Committee.

To quote from the Summit:

"*The problem of antibiotic resistance worldwide, including Australia, is one of the foremost issues that we face in the coming decades. We strongly believe that there is an urgent requirement for a debate within Australia on how to comprehensively address the problems of antimicrobial resistance, with the goal to implement a coordinated national approach.*"

The issues that drive antimicrobial resistance are multi-factorial. These issues are part of a mosaic that (simplistically) affects medical, veterinary and agricultural concerns, and until recently these have been addressed independently of each other and in a fragmented manner at best. To date there has been a failure to bring these concerns together and to provide a means for a common dialogue across these sectors, despite this being a key feature underlying the JETACAR recommendations. Perhaps because of such 'sectarian' concerns, there has also been a lack of willingness to see a common purpose, which may have been part of the reason for the lack of implementation of the recommendations stemming from JETACAR.

Recently, the World Health Organization (WHO) has identified antimicrobial resistance as one of the three greatest threats to human health, jeopardising patient safety and public health worldwide. ASA believes that to address the problem or crisis of antimicrobial resistance, which we see as one of the major public health challenges facing our community, we need to ensure that all these groups are working together around the same table.

Indeed our Society's broad representation goes some way to address this void. We also strongly believe the formation of the AMRSC, on which ASA has representation, and which has representation from across the sectors, including representation from medical and veterinary regulatory bodies, finally provides a great opportunity to bring together the many segments of this mosaic and to co-ordinate a plan for action and a co-ordinated national response. The Australian Commission on Safety and Quality in Health Care ACSQHC has been instrumental in facilitating the formation of AMRSC.

(a) examination of steps taken, their timeliness and effectiveness;

The JETACAR report led to the establishment of committees for its implementation, including the Commonwealth JETACAR Implementation Group (CIJIG) and the Expert Advisory Group on

Antimicrobial Resistance (EAGAR), the latter within the National Health and Medical research Council.

Through the combined efforts of these two committees, the following initiatives, based on JETACAR recommendations, were taken:

- At the time of the release of JETACAR's report, the APVMA predecessor (the National registration Authority – NRA) implemented a formal requirement that antimicrobial resistance be considered as part of risk assessment (a so-called part 10 assessment) for new and extended indications of veterinary and agricultural antimicrobials.
- All antimicrobials in the human, veterinary and agricultural sectors were reviewed by the National Drugs and Poisons Scheduling Committee. With the exception of one class, the ionophores which have no direct equivalent in human medicine, all antimicrobials remained or were converted to prescription only (S4) by a medical practitioner or veterinarian.
- A review of avoparcin use in the food animal sector was undertaken by the NRA, but the agent was withdrawn world-wide before the review was completed
- A number of food animal peak bodies undertook reviews of practice standards for antimicrobial use, and made recommendations for prudent use in their respective sectors.
- The Department of Health and Aging, in conjunction with the NHMRC, developed and produced national Infection Control Standards.

Subsequently, the Australian Commission on Safety and Quality in Health Care (ACSQHC) commenced programs related to human health and specifically in hospital care, with projects related to hospital infection control, mandating the presence of effective antimicrobial stewardship programs in all hospitals, and in selected aspects of antimicrobial resistance (eg. guiding approaches to Gram negative resistance).

The Australian Commonwealth Government (DoHA) has supported AGAR surveillance studies since 2004 and the National Antibimicrobial Utilisation Surveillance Program which monitors antimicrobial usage in contributing Australian hospitals

As ACSQHC, AGAR, and NAUSP surveillance are involved in human health, this leaves gaps in data related to surveillance of antimicrobial use and resistance in food-producing animals, and in related studies of antibiotic resistant organisms in humans and animals and data on antibiotic use outside of large hospitals.

(b) where and why failures have occurred;

The JETACAR report, though tabled in 1999, and endorsed by the Commonwealth Government in 2000, was a blueprint for tackling antibiotic resistance which is still relevant and even more cogent today. It was in line with the recommendations of the World Health Organisation, and programs in other developed countries in Europe and North America.
A number of JETACAR recommendations were only partially or not addressed:

- An initiative to have formal resistance risk assessment as part of the registration of new antimicrobials and extension of their indication, similar to the process introduced by the APVMA, was *commenced* by the Therapeutic Goods Administration, but never completed In

the absence of a central co-ordinating authority, the reasons for this have not been made clear.

- A review of streptogramin (virginiamycin) use in the food animal sector was completed and recommendations were made for restricted use. The proposals were then the subject of appeal by the sponsor. The Administrative Appeals Tribunal heard the appeal, but set aside its decision. The agent remains on the market under its pre-JETACAR license.
- A third food animal antimicrobial group recommended by JETACAR for review, the macrolides, had their reviews postponed pending the outcome of the virginiamycin appeal. Those reviews have not commenced.
- Attempts were made to harmonise veterinary prescribing legislation across states by the Primary Industries Standing Committee, but met with only partial success. The recommendation to make it an offence to prescribe and/or use a veterinary chemical product contrary to a label constraint was not implemented
- The EAGAR developed a proposal for comprehensive antimicrobial resistance and usage surveillance across all sectors, but this was never released.
- There was no implementation of co-ordinated policies to minimise the use of antibiotics in humans and animals, and no licensing and monitoring process for antimicrobial importers
- Thresholds of resistance for co-ordinated action were not developed by the APVMA or TGA
- The requirement for TGA to provide resistance rate data in the human product label was not followed up, largely due to the lack of comprehensive national resistance surveillance
- Medical Colleges were approached but failed to respond to the call or develop educational strategies for their members
- An attempt to establish a targeted antimicrobial resistance management research agenda by the NHMRC was unsuccessful.

Nevertheless, although much of the effort, and goodwill to address the problem in all areas of antibiotic use (human, veterinary, agricultural) was lost with the disbanding of the JETACAR related committees, we strongly believe that it is still possible to address the problems comprehensively and effectively, provided that we develop a properly co-ordinated national approach, involving all the key stakeholders and using the framework of the JETACAR report.

(c) implications of antimicrobial resistance on public health and the environment;

Australia is facing ever increasing problems with multi-resistant bacteria in both the community and our hospitals. Examples include methicillin-resistant *Staphylococcus aureus* (MRSA), multiresistant *Streptococcus pneumoniae*, vancomycin-resistant enterococci (VRE) and multiresistant *Escherichia coli.* Resistant "golden staph" (MRSA) is now a growing problem in the community, especially in indigenous Australians, resulting in a significant increase in burden of disease. This is seen in both general practice and hospital emergency departments and results in increased admissions and surgical procedures. Some strains possess a toxin that can cause serious disease and even death. We have witnessed the increase of multi-resistant (ESBL) strains of *E. coli* from other countries where they are more prevalent but also locally acquired especially in nursing homes, causing increasing numbers of urinary tract infections particularly in the community, sometimes resulting in life-threatening sepsis. In our hospitals and nursing homes, MRSA continues to be a problem that will only partly be reduced by hand hygiene programs, and we see rising

numbers of vancomycin-resistant enterococci (VRE) and multi-resistant Gram-negative bacteria. Most recently we have witnessed the arrival of an antibiotic-resistant strain of *Clostridium difficile* that has caused large outbreaks of life-threatening and fatal infection in North America and Europe. The reservoirs of these resistant organisms are diverse, and they exist due to both the human and non-human use of antibiotics (as recognised at the time of JETACAR). Many resistant organisms cannot now be treated by oral antibiotics, putting increasing demands on our hospitals. For many bacterial pathogens, resistance to last-line antibiotics, such as carbapenems, fluoroquinolones, glycopeptides and third-generation cephalosporins, is now commonly found in Australian hospitals and, to an increasing extent, in the community. The era of untreatable bacterial infections has returned.

What does a world without antibiotics mean? The implications of such a future are grim. Transplant surgery will become virtually impossible. Current advances in haematology, and with this, the potential to cure many patients with cancer will be set back. Removing a burst appendix will become a dangerous operation. Antibiotic prophylaxis for a prostate biopsy, a prosthetic joint replacement or cardio-vascular surgery, for example, will have a substantial risk of failure resulting in severe post operative infection. Peri-partum infections and incurable tuberculosis will again become a reality. Pneumonia, urinary tract infections and other simple community-onset infections will be difficult to manage, and often will require hospitalisation, due to lack of available oral antibiotics. Empiric antibiotic choices in sepsis and for other infections will become complex and precarious. The safety of much medical care that we now take for granted, will become compromised. As this threatens to compromise all aspects of medical care, it is an issue that needs to be discussed and understood amongst the whole medical profession. Antimicrobial resistance and antimicrobial stewardship should become mandatory items on the curricula on all health-care trainees.

The growing ineffectiveness of once-reliable drugs has seen health care professionals increasingly turning to alternatives that are more toxic, more expensive and less likely to be orally available, putting increased pressure on a strained hospital system. In addition, compared with susceptible bacteria, antibiotic-resistant strains are associated with increased patient morbidity and mortality and increased costs of health care.

There are too few new antibiotics coming onto the market to deal with these bacteria and a dwindling pipeline of new antimicrobial agents. Hence we cannot rely on newer antibiotics filling the void. Of note, of 15 companies with previous antibiotic discovery programs, only 5 maintain current active research and development capacity in antibiotics , and few new compounds are in development.

(d) implications for ensuring transparency, accountability and effectiveness in future management of antimicrobial resistance;

In the Summit report (MJA 2011) our Societies indicated what we concluded were key initiatives to ensure effectiveness and accountability in the future management of antimicrobial resistance. As these have not largely changed, we have again listed these.

1. Antimicrobial resistance and antibiotic usage surveillance

- A comprehensive national surveillance system encompassing both passive and targeted components should be developed to monitor how much resistance is present, in which bacteria and where. This should include medical (hospital and community) and veterinary areas, as well as agriculture (including imported food).

- Priority should be given to staphylococci and *E. coli*, which have the greatest impact on human health (emerging resistance in *E. coli* and other Gram-negative bacteria poses a major new threat).

- Methods used in resistance testing should be standardised wherever possible to enable comparison and pooling of data.

- A comprehensive national monitoring and audit system covering all areas of antibiotic usage should be established. This should include comprehensive surveillance of hospital usage (eg, by expanding the National Antimicrobial Utilisation Surveillance Program), representative sampling of community prescribing, and collating distribution data from agricultural antibiotic suppliers.

- Data on the appropriateness of usage should also be evaluated (using point-prevalence surveys comparing diagnosis with prescription).

- Voluntary identification of hospitals in surveillance programs is recommended to encourage benchmarking and transparency.

2. Education and stewardship: key recommendations

- Educational initiatives need to define antimicrobial resistance as an urgent public health issue. The skills of social marketers and behavioural change experts should be utilised to drive a national campaign targeting both the public and prescribers.

- The NPS (National Prescribing Service) antibiotic educational campaign should also be reinstituted.
  (This has been effected in 2012, following the Summit, but needs to continue long-term)

- A uniform national medical curriculum should be implemented that acknowledges over-usage of antibiotics and embraces better stewardship, building on the National Prescribing Curriculum.

- Stewardship, based on national antibiotic guidelines and local epidemiology, must be mandated in all hospitals within a quality framework based on audit and feedback. (A new national stewardship standard has been mandated for hospitals beginning 2013)

- Effective stewardship requires a team-based approach including infection-prevention units, microbiologists, pharmacists and clinicians. It must be strongly supported by senior hospital management and underpinned by effective use of information technology.

- Stewardship should also be extended beyond health care institutions to community care, long-term care facilities and non-medical antibiotic use. A well resourced national body

should be created to provide effective national coordination of educational activities and antibiotic stewardship.

- Recognising that antibiotic resistance does not respect international borders, Australia has an obligation to contribute to international programs to control antibiotic use / resistance.

3. Infection prevention and control strategies: key recommendations

- Improved training on strategies for infection prevention and control should be provided to health care workers.
- All major hospitals should have the capacity to identify and investigate outbreaks of multiresistant organisms, and to monitor and respond to changing patterns of pathogens.
- National evidence-based standards for multi-resistant organism control in aged-care facilities should be developed, implemented and robustly enforced and monitored.
- A national coordinating centre for the control of antimicrobial resistance is needed, with the authority and capacity to collect and analyse data on multiresistant organisms from all jurisdictions. This will facilitate timely, consistent and effective control of multiresistant organisms.

4. Future research agenda: key recommendation

- A new NHMRC funding call (similar to that for pandemic influenza in 2009) is needed for research on antimicrobial resistance and usage in Australia and its near neighbours. The key areas of focus should be:

  - epidemiology (in both human and animal settings)
  - effective interventions for the public sectors, focusing on education and behavioural change

5. Regulation: key recommendations

- Resistance risk assessments should be part of the regulatory process for bringing new antibiotics to market for both humans and animals.
- The Pharmaceutical Benefits Advisory Committee should consider resistance in the criteria for inclusion or restriction of antibiotics on the Pharmaceutical Benefits Scheme.
- Strategies should be implemented to enable “fast-tracking” of important new antimicrobials through the regulatory approval system.
- Strategies should be implemented to enable the registration of “orphan” non-commercial drugs that have the potential to improve patient outcomes and reduce disease burden.
- Adopting an antibiotic importance rating system as regulatory policy should be considered.

At present, the extent of antimicrobial resistance in Australia remains poorly defined. The current systems of data collection and collation vary between states and territories and there is limited coordination at a national level. Surveillance for antimicrobial resistance in Australia is currently

restricted to planned surveillance studies (active or targeted surveillance) of a narrow range of organisms conducted by groups such as the Australian Group on Antimicrobial Resistance, and the National Gonococcal Surveillance Programme. The AMRSC has commissioned a review of surveillance options best suited to Australia, and this may result in new opportunities in surveillance, data collection and interpretation

AGAR has in 2013 moved from collecting sequential isolates from multiple sources to collecting data from bacteraemia for key organisms - *Staphylococcus aureus, Enterococcus* species and the Enterobacteriaceae. This approach should result in data that are more interpretable and will allow Australia to compare itself with surveillance programs such as the EARS-NET program in Europe.

In addition to measuring antimicrobial resistance, it is important to understand antibiotic usage. Surveillance for antimicrobial use is patchy; data are available from a sample of large hospitals in the National Antibiotic Utilisation Surveillance Project. Currently, the NAUSP program is the only nationwide systematic surveillance of antibiotic usage, but it is based on voluntary and imperfect data submitted from major hospitals, representing about 50% of Australian tertiary referral beds. Community utilisation data are very limited.

Research has demonstrated that the education campaigns and guidelines are ineffective unless they are combined with sustained interventions such as audit and feedback methods and/or a system where proactive steps are taken to assist prescribing and interventions are made to address poor performance. Further initiatives are required in the community, where the majority of human antibiotics are prescribed. Despite funding by the NHMRC and other bodies for basic science research on microbiology, many essential aspects, such as research into educational interventions required to combat antibiotic resistance do not find a ready place in existing project grant structures.

There is no overarching body that is responsible for antimicrobial resistance in Australia. The WHO provides a framework for recommended steps that need to be taken, and two examples of successful implementation are provided by Sweden and the United States, although many more exist.

The 2001 World Health Organisation's Global Strategy for Containment of Antimicrobial Resistance includes, inter alia,

- The creation of an intersectorial task force to raise awareness about antimicrobial resistance, organize data collection and oversee local task forces.
- Allocation of resources to promote the implementation of measures to contain resistance
- Development of indicators to monitor and evaluate the impact of a resistance containment strategy
- The introduction of legal requirements for manufacturers to collect and report data on antimicrobial distribution
- The creation of economic incentives for the appropriate use of antimicrobials.
- Establishing surveillance for resistance, antimicrobial use in hospitals and the community, and linking these to infectious diseases surveillance

The Swedish Strategic Programme against Antibiotic Resistance (STRAMA) is an example of a whole-of-system approach to the problem of antimicrobial resistance. This body advises the Swedish Institute for Infectious Diseases Control in

1. matters regarding antibiotic use and containment of antibiotic resistance
2. facilitating an interdisciplinary and locally approved working model, ensuring involvement by concerned authorities, counties, municipalities and non-profit organizations.

STRAMA compiles and publishes reports on resistance and antibiotic use in humans and animals, undertakes studies to better understand antibiotic resistance and interventions that decrease use, and collaborates with other organisations in producing clinical practice guidelines.

In the United States, the US Interagency Task Force on Antimicrobial Resistance was created in 1999 and includes representatives of the Food and Drug Administration, the Centers for Disease Control (CDC), the National Institutes of Health. Other agencies represented include Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), the Department of Agriculture (USDA), the Department of Defense, the Department of Veterans Affairs, the Environmental Protection Agency and the U.S. Agency for International Development.

The elements of US 2001 Public Health Action Plan to Combat Antimicrobial Resistance, included surveillance, prevention and control, research and product development. This task force has established systems for monitoring of resistance in food-borne bacteria, published prudent use guidelines for the use of antimicrobials in veterinary medicine, and provided guidance to industry on regulatory requirements for antimicrobials.

The Infectious Diseases Society of America (IDSA) published a policy document summarising the IDSA's recommendations for dealing with threat of antibiotic resistance and waning approvals of new antibiotics in a document as a supplement to Clinical Infectious Diseases journal in 2011, [Volume 52, Issue suppl 5, Pp. S397-S428.]. This was titled "Combating Antimicrobial Resistance: Policy Recommendations to Save Lives". The IDSA attempted to represent the best interests of patients and health care professionals by recommending public policy strategies and research activities that would reverse antibiotics' decline and save lives. The document also includes specific recommendations for the United States Congress to embrace as related to legislative action and funding needs.

The recommendations were outlined within the following chapters

- Adoption of Economic Incentives and Support for Other Collaborative Mechanisms to Address the Market Failure of Antibiotics
- New Regulatory Approaches to Facilitate Antimicrobial Development and Approval
- Greater Coordination of Relevant Federal Agencies' Efforts
- Enhancement of Antimicrobial Resistance Surveillance Systems
- Strengthening Activities to Prevent and Control Antimicrobial Resistance
- Significant Investments in Antimicrobial Focused Research
- Greater Investment in Rapid Diagnostics R&D and Integration into Clinical Practice
- Eliminating Non-Judicious Antibiotic Use in Animals, Plants, and Marine Environments

This is a detailed document, and provides analysis that is too substantial for us to provide within this response to the Senate enquiry. However, the Australian Society for Antimicrobials endorses the policy suggestions recommended within the IDSA document, and commends it to the Senate enquiry for review.

The IDSA concluded:

"Society worldwide is facing a public health crisis due to stagnation in the antibiotic drug pipeline combined with rapidly spreading, deadly antibiotic-resistant pathogens. The lack of effective antibiotics already is resulting in deaths and maiming of patients and the problem will only continue to worsen until Congress and the Administration act. The time for debate about the problem has passed. Immediate action is critically needed now."

The Australian Society for Antimicrobials concurs with this summary.

(e) any other related matter.

The WHO, USA and European Union governments have recognised antimicrobial resistance as an epidemic problem and a major public health challenge. The USA and Europe have established a formal taskforce (TATFAR – Transatlantic Task Force on Antimicrobial Resistance) to address the growing problem. In Australia, while some steps have been taken, a comprehensive and coordinated approach has been lacking. We need an urgent and vigorous national approach to control resistance in the community, in healthcare settings and in companion and food animals and in agriculture, along the lines suggested in the JETACAR report. To reiterate, these should focus on:

- Resistance Surveillance (targeted and passive antimicrobial resistance surveillance)
- Antimicrobial Utilisation Surveillance
- Antimicrobial Stewardship and Education (hospital and community programs)
- Infection Prevention Strategies, Infection Control and Guidelines
- Regulatory Controls overseeing access to antimicrobials in human health and with links with agriculture and animal health regulatory organisations
- Research into (eg.) drivers for resistance, effects of resistance and outcomes of interventions to guide best-practice, and control and prevention interventions with links to the research capabilities of NHMRC

Co-ordinated public policy or regulatory control has been shown to be effective in Australia in relation to restricted fluoroquinolone use in animals and in human health. As a result, Australia has maintained low fluoroquinolone resistance rates in comparison to the rest of world. This has successfully preserved this valuable class of antibiotics for continued use for serious infections and highlights the effectiveness of regulatory controls where education and guidelines may fail. (Cheng A. Emerg Infect Dis 2012. 18:1453-60.)

We need to find and implement other strategies to what we see as an urgent public health problem, one requiring an integrated national response. Although Australia is currently lagging behind in efforts to control antimicrobial resistance, we believe we can implement steps to reverse the problem with a co-ordinated response to this public health crisis. We previously have proposed the establishment of a national authority similar to the Swedish model, the Swedish Strategic Programme against Antibiotic Resistance (STRAMA), with a role to develop and implement control strategies for antibiotic resistance and with involvement of both the health and non-human sectors. Any such authority should extend beyond an advisory role to governments, and instead would formally co-ordinate and fund the multiple strategies required to control antibiotic resistance in both the health and non-human sectors and help develop public policy and enable information sharing. It is vital that both human and non-human health sectors are included as there is increasing evidence of the relatedness of bacteria from human and animal sources. For example, a recent study from the Netherlands found a substantial overlap in the genetic composition of resistant *E.coli* from chicken meat, human carriers, and blood cultures indicating that chicken meat (and antimicrobial use in the livestock industry) is a source for resistant *E. coli* in humans and suggesting increasing need for surveillance in food-producing animals. [Kluytmans J. CID 2013 56:478-487. http://cid.oxfordjournals.org/content/56/4/478.abstract.html?etoc]

The establishment of the AMRSC must provide the impetus and guidance for a co-ordinated approach to address antimicrobial resistance in humans and animals. The establishment of the AMRSC is an early, but very positive step. We need it to continue to fulfil its promise by being provided with sufficient ongoing funding and authority. Australia needs this to be complemented by the establishment of an Antibiotic Resistance Management Authority as outlined above.

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