

Submission  
No 55

## INQUIRY INTO OFF-PROTOCOL PRESCRIBING OF CHEMOTHERAPY IN NSW

**Organisation:** Medical Oncology Group of Australia

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Submission: New South Wales Legislative Council

Select Committee on Off-protocol Prescribing of Chemotherapy in New South Wales



MEDICAL ONCOLOGY GROUP OF AUSTRALIA INCORPORATED

A.B.N 94 601 175 669

Sunday 23 October 2016

**Submission to the**

**New South Wales Legislative Council**

**Select Committee on Off-protocol Prescribing of Chemotherapy in New South Wales**

**Inquiry into Off-protocol Prescribing of Chemotherapy in New South Wales**

**From the**

**Medical Oncology Group of Australia Incorporated (MOGA)**

**Associate Professor Chris Karapetis, Chairman**

## **Introduction**

I am making this submission in my capacity as Chairman of the Medical Oncology Group of Australia Incorporated (MOGA) on behalf of the Association's Executive and membership. The Association is the peak professional organization for medical oncologists and the medical oncology profession in Australia; and a specialty society of the Royal Australian College of Physicians. At the time of making this submission the Association has 485 consultant members and 163 trainee members working across Australia. The Association's current membership includes medical oncologists working in both the public and private sectors, representing the majority of the Australian medical oncology workforce.

Ongoing media reportage concerning chemotherapy dosing issues that have arisen in South Australia and New South Wales over the last 6 months and the recently released Inquiry under section 122 of the Health Services Act 1997, **Off-protocol prescribing of chemotherapy for head and neck cancers, Final report, 31 July 2016**, the announcements on August 2 of a **Five Year Review of NSW Public Cancer Patients** and this **Inquiry into Off-protocol Prescribing of Chemotherapy in New South Wales** on 11 August, have raised a spectrum of professional issues that are of serious concern to Australian medical oncologists and their patients.

The Association welcomed the announcement that the NSW Government planned to initiate a **Review of Cancer Services** and plans to allocate \$6 million over three years to roll out new software to ensure chemotherapy prescribed in electronic prescribing systems is delivering evidence-based treatment to allow clinical practice to be monitored, with particular emphasis on any changes in chemotherapy dosing. We believe the planned Review to be extremely important above all in assisting in maintaining public confidence and trust in our health system, oncology clinical practice and patient care to reduce patient and clinician distress.

The Association has a place on the Review's Working Group and is actively participating in the Review process. We believe that senior advice from the Australian medical oncology and related

**23 October 2016**

**Submission: New South Wales Legislative Council**

**Select Committee on Off-protocol Prescribing of Chemotherapy in New South Wales**

oncology professions will assist in achieving the best outcomes. The Association has also engaged in discussions with members of the eviQ Executive Committee and will be assisting with the clarification of the use of the eviQ protocols by members of the Australian medical oncology and related professions.

The Association would welcome the opportunity to address the members of the Select Committee at any public hearing/s and/or answer any questions the members may have concerning medical oncology clinical practice in Australia and overseas, that may arise in the course of the Inquiry.

The Association looks forward to working collaboratively with the Select Committee, the NSW Health Department and Professor David Currow, the NSW Chief Cancer Officer, in the interest of ensuring the highest standards of clinical care to all Australian cancer patients are delivered and maintained by members of our profession.

### **Terms of reference**

*“That a select committee be established to inquire into and report on off-protocol prescribing of chemotherapy in NSW including at St Vincent’s Hospital, St George Hospital, Sutherland Hospital, Macquarie University Hospital and clinics at Orange and Bathurst, and in particular:”*

The Association is of the view that this Term of Reference;

- Focuses narrowly on one area of the treatment of cancer, specifically off-protocol prescribing of chemotherapy in NSW without clarifying the parameters of the prescribing issues to be considered and the sectors covered by the Inquiry. Outcomes (e.g. survival or morbidity) are not to be considered by the Inquiry despite the fact that Australia, including New South Wales, has some of the best cancer outcomes and one of the most highly skilled and well trained medical oncology workforces in the world, including global leaders in cancer research, discovery and clinical practice.
- Demonstrates a lack of understanding of the clinical role and place of off-protocol prescribing in medical oncology and medical practice.
- The issues of incorrect diagnosis, delayed diagnosis or inadequate follow-up do not fall within the scope of the Inquiry. However, Inquiry submissions will present issues around these matters. Patients and their families often put all of these issues into the category of ‘cancer treatment’. Submissions will need to be carefully reviewed and monitored by expert reviewers to cull cases that fall out of the intended scope of the Inquiry.
- Submissions to the Inquiry can also be subject to misuse and misinformation, with the risk of personality conflict or communication breakdown leading to inaccurate, vexatious and litigious submissions. Submissions will need to be carefully reviewed and monitored by expert reviewers to ensure accurate information is considered and made available in the public domain.
- Regrettably names specific NSW hospital facilities and publicly calls into question the standard and quality of medical oncology clinicians, services and care at these facilities. The Association and our members are extremely concerned that the Inquiry reflects

**23 October 2016**

**Submission: New South Wales Legislative Council**

**Select Committee on Off-protocol Prescribing of Chemotherapy in New South Wales**

poorly on the State public health system and the members of our profession who practice in that system. Indeed the announcement, information and advertising of the Inquiry has been extremely concerning and resulted in exacerbating public concerns and generating negative media reports, contributing to an extremely difficult time for cancer patients and their clinicians.

- The Inquiry website regrettably and without recourse to due process specifically names two Australian medical oncologists and calls for their patients to make submissions. This has caused the clinicians concerned, their families and patients as well the members of the Australian medical oncology profession great distress and concern. This is not consistent with fair and equitable natural justice nor current human resource management practices.

*“The efficacy of electronic prescribing systems, and their capacity to stop or limit off-protocol prescribing of chemotherapy.”*

The Association is of the view that electronic prescribing systems are fundamental to improving cancer patient care by contributing to the safe and effective prescribing and dispensing of oncology drugs and treatments including chemotherapy in Australia. Such systems can assist in reducing errors during the dispensing process and serve as a recording system for monitoring the prescription records of cancer patients as well as other areas of patients’ medical histories. However, such systems need to be integrated into a comprehensive electronic patient health record system and supported by appropriate management infrastructure. This requires extensive resourcing and staffing support

*“The value of a potential new patient information sheet on dose adjustment for patients and caregivers information.”*

The Association is of the view that a patient information sheet on dose adjustment for patients and caregivers would provide supplementary assistance to cancer patients to understand the oncology drugs and treatments that they have consented to undertake in consultation with their treating medical oncologists. At present, written information sheets that detail the complex and highly specialised area of chemotherapy dose adjustment are not considered a requirement in oncology practice in any part of the world.

*“The process and systems around informed consent for all medical interventions, including chemotherapy. “*

The Association is of the view that:

- Informed consent for chemotherapy administration is a standard component of Australian medical oncology practice. Consent to treatment is an important part of the delivery of quality cancer care nationally. International best practice dictates that consent conversations should be well documented and this area has been widely considered by the global medical oncology profession. Eg., The American Society for Clinical Oncology has designed a modifiable template consent form for patients receiving chemotherapy supported by a user's guide. Ethically, consent conversations allow medical oncologists to fulfill their obligations to assist cancer patients to make independent choices about their medical care. Accordingly, informed consent is not

23 October 2016

Submission: New South Wales Legislative Council

Select Committee on Off-protocol Prescribing of Chemotherapy in New South Wales

limited to a single discussion or a form; rather, it is an ongoing communication process that is central to the medical oncologist-cancer patient relationship. Consent conversations can be documented through a written consent form that is reviewed with the cancer patient, signed, and stored in their medical record. Making a detailed note in a patient's medical record to document that all of the required elements of a consent conversation took place is equally appropriate because written consent forms are not always required by law or facility policies. At this time international practice in medical oncology is that either a note in the patient's medical record or the use of a consent form are taken as an indication that a consent conversation took place.

- Consent forms cannot replace direct communication between a medical oncologist and their cancer patient. However they can enhance the consent process and the quality of the patient experience. Consent forms can serve as a guide for medical oncologists during consent conversations to ensure all required elements are covered, and provide a reference for patients about their treatment plan. In addition, a signed consent form can serve as instant, standardized documentation that can be helpful if litigation arises. A signed consent form can be considered strong evidence that the medical oncologist engaged the cancer patient in an appropriate discussion and create a presumption that the patient was adequately informed.

*“The capacity of the NSW Health system to have all notifiable cancer patients in New South Wales overseen by a Multidisciplinary Cancer Care Teams, and if this may prevent off-protocol prescribing.”*

The Association is of the view that:

- the Australian Public Health system, including NSW Health should have the capacity for all cancer patients to be overseen by a Multidisciplinary Care Team (MDT) or Multidisciplinary Cancer Care Team (MCCT);
- MDT and MCCT oversight can assist in ensuring that patients receive best practice care and enhance the quality of a cancer patient's treatment and experience, as well as facilitate the contribution of each of the team members, including addressing the need for and any medical issues that may arise in relation to off-protocol prescribing, such as adverse effects.
- Off-protocol prescribing is a viable treatment option in medical oncology and others oncology specialties. It is a recognized clinical practice internationally, especially in cases where there is no extant protocol. The boundaries of cancer care and medical oncology clinical practice need to take into account personalization of management. Treatment outside of approved guidelines is common. Indeed, population level research often reveals compliance or management concordance with treatment guidelines for certain cancers is poor. Determining what is an “unacceptable dose variation in cases” and “reasonable norms” in medical oncology clinical practice is extremely complex and not readily addressed by a standardized approach. Where no protocol is extant, treatment is empirically based and clinical judgement comes into play. This is a point of major criticism that the Inquiry needs to address up front in defining its parameters.

23 October 2016

Submission: New South Wales Legislative Council

Select Committee on Off-protocol Prescribing of Chemotherapy in New South Wales

- Currently in Australia all cancer patients do not participate in a documented MDT of MCCT nor is this international standard practice. The funding, resources and facilities required to make this a reality in Australia mean that this is one of a number of recommended goals that could form part of an extensive quality improvement initiative for NSW Health in the future.

*“St Vincent’s Hospital capability to comply with relevant NSW Health Policy Directives and Guidelines, particularly Open Disclosure Policy (PD2014\_028) and Incident Management Policy (PD2014\_004).*

*“The NSW Health Code of Conduct and specific programmes within NSW Health and St Vincent’s Hospital, in relation to staff raising concerns about the practice of clinicians, and other breaches of the Code of Conduct.”*

The Association is of the view that the two terms of reference noted above should be dealt with through internal facility and departmental systems and any additional matters of this nature should be addressed by the NSW Health Department, the CEOs and the Directors of Cancer Services at the facilities concerned and, the Medical Board of Australia as the relevant professional body responsible for regulating Australian medical practitioners.

*Inquiry Timeline*

Given the scope, complexities and specialized medical issues to be considered by the Inquiry and the need for extensive consultation and research we recommend that the reporting timeline of March 2017 be extended by a further 6 months and then subject to additional review.

Yours Sincerely,

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